Zachary M. Schrag

Institutional Review Blog

December 2006 – August 2012

This document contains all text appearing on the Institutional Review Blog, http://www.institutionalreviewblog.com/, from its launch on 12 December 2006 through the start of the fall semester at George Mason University, 28 August 2012. Except where noted, all entries were written by Zachary M. Schrag, of the George Mason University Department of History and Art History. This version was prepared for archiving at the Mason Archival Repository Service (MARS), mars.gmu.edu.

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From Blog to Book.

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Chapter 1

2006

1.1 December

1.1.1 Introduction (2006-12-12 13:33)

In 1974, Congress passed the National Research Act. This act required researchers in biomedical or behavioral fields who received federal funds and who conducted experiments on humans to submit their work to the oversight of "institutional review boards," or IRBs. These boards, established by universities, hospitals, and other institutions, were required to judge the ethics of a project before it could proceed. This step, Congress hoped, would prevent researchers from denying treatment to or otherwise harming the people who participated in their studies.

At some point (and I hope to learn more about this history), university IRBs around the nation began insisting that researchers in the humanities and social sciences also submit their projects for review. Ever since, many of those scholars have questioned the legality and wisdom of these demands. This blog is designed to inform the debate over IRBs by collecting breaking news, commentary, and background information on the subject.

I first became interested in this issue in July 2000. I had received a grant from the National Science Foundation to support my dissertation on the history of the Washington Metro. The grant required that if I involved human subjects in my research, I had to get approval from my university IRB. Since the definition of human subjects research seemed to include the oral-history interviews I was conducting, I accordingly gained approval for my research from Columbia University's Human Subjects Research Committee. I kept that approval active until I had completed my research, which has now been published as The Great Society Subway: A History of the Washington Metro (Johns Hopkins University Press). More recently, I gained the approval of George Mason University's Human Subjects Research Board for a series of interviews on the history of riot control.

At neither university did the review process do much to aid my research, and, on the whole, I consider the applications to have been a poor use of my time and that of the staff doing the review. Based on my own experience and that of other scholars, I am skeptical of the application of IRB oversight to non-experimental research. On the other hand, I do believe that historians and perhaps other scholars in the humanities and social sciences could learn from IRBs' practices of mandatory training, careful documentation, and the review of consent forms. I therefore hope to find ways in which scholars in the humanities and social sciences can learn from IRB practices without being subjected to standards and practices never meant for them.

Christopher Tassava (2007-01-16 12:40:00)

Zach -

I just found this blog (perhaps via the AHA's blog; I forget the provenance), and I'm enjoying it.

Though I'm not presently conducting any research which might necessitate IRB approval, I am serving on the IRB at Carleton College by dint of my administrative position here. The work is quite engrossing, but we have come across some situations

where the oral history/interview line is at least within sight, if not actually crossed.
This blog will be a useful way to stay informed. Thank you for starting and maintaining it.
Christopher Tassava

David Hunter (2007-08-01 04:02:00)
Zach I likewise just found this blog, and sitting on the other side of the fence (I sit on three research ethics committees which is what we call them in the UK) I'm finding it fascinating to read. I'm personally of the view that all research ought to have some ethics review, and the best form of that review is via a research ethics committee. I agree this will often be a waste of time for the researcher, since often, barring perhaps minor problems with the information sheet there is no real problems with their research. Nonetheless I have seen several social science research applications where the research would have been genuinely unethical if it had been carried out. I'm curious, how would you protect against this research being carried out?

Zachary M. Schrag (2007-08-01 13:10:00)
Thanks for your message.
A good alternative to IRB review is departmental review. This gives researchers the chance to have their projects judged by the ethical standards of their discipline, rather than those of some other social science or, worse, of medical research.
For elaboration of this point, please see my essay, "[1]Ethical Training for Oral Historians," as well as the following posts:
[2]In Search of Expertise
[3]Why IRBs Are Not Peer Review: A Reply to E. Taylor...
[4]My Problem with Anthropologists
You write, "I have seen several social science research applications where the research would have been genuinely unethical if it had been carried out." I would be very interested to learn more about these.
Best,
ZMS

1. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm
2. http://institutionalreviewblog.blogspot.com/2007/02/in-search-of-expertise.html
3. http://institutionalreviewblog.blogspot.com/2007/03/why-irbs-are-not-peer-review-reply-to-e.html
4. http://institutionalreviewblog.blogspot.com/2007/03/my-problem-with-anthropologists.html

David Hunter (2007-08-02 04:03:00)
I'd disagree on departmental review being best for two reasons.
1. While a committee which has some knowledge and expertise in the area of the project, too much expertise and it becomes too close to the subject matter. This can mean that it misses significant ethical issues because they are standard practice within a specific discipline. To give one example, psychologists often want to give part of their students grade (10 %) for being involved in their research. Most RECs I am involved in don't allow this practice because it is felt it is unduely coercive. I imagine if a REC/IRB was entirely composed of psychologists they may disagree.
2. It is important for a REC to be substantially independent from the researcher, but this doesn't happen in departmental review, instead the REC has an interest in the research being let to go ahead.
My university presently runs on a departmental review model, and while I can't name names I have personally seen examples of both of the above issues coming up.
I've written about these problems here:
Hunter, D. 'An alternative model for research ethics review at UK universities' Research Ethics Review. (2006) Vol 2, No 2, 47-51.
(Which unfortunately isn't available online)
and here: Hunter, D. '[1]Proportional Ethical Review and the Identification of Ethical Issues Journal of Medical Ethics. (2007);33:241-245.
I certainly agree with you that IRBs shouldn't be dominated by medics and medical concerns, they instead should have a wide range of representation. I'm inclined to think though that the baseline ethical issues are similar and while different rules may be appropriate for different disciplines they flow out of the same background.
In terms of examples here are a few, I can't be too specific with details for reasons of confidentiality.
1. Study of sexual attitudes in school children. Asked very probing questions as one might expect, but didn't intend to get parental consent to carry out the research a parallel can be found here: [2]India Research Ethics Scandal: Students made guinea

pigs in sex study
No consideration had been given to what might have been done if there was disclosure of harmful behaviour etc.
2. Historian was going to civil war stricken country to interview dissidents about the war, intended to publish identifying comments (without getting consent for this) which were likely to be highly critical of the current regime.
3. Social scientist wanted to understand children's attitudes towards a particular topic. As a blind so that the participant would not know the questions they wanted to answers to, they proposed to use the becks depression index. This contains questions about self harm, future worth and was potentially very distressing, not at all appropriate as a blind.
4. Student wished to conduct interviews with employees of a company on an issue that could significantly damage the companies profitability. No consideration was given to how to best report this information to minimise harm to the company.
I'm inclined to think that any sort of research involving humans can lead to harm whether that is physical, social, financial, psychological or so on. As such the benefits and the risks need to be balanced, and it needs to be considered how to minimise that harm. That I take it is the job of the researcher. However, having sat on RECs for a while it is a job that sometimes the researchers fail at spectacularly, then it becomes the job of the IRB/REC. The difficulty is how, without full review by a properly constituted REC, do you identify those applications that have serious ethical issues?

1. http://jme.bmj.com/cgi/content/abstract/33/4/241
2. http://philosophyandbioethics.blogspot.com/2007/08/india-research-ethics-scandal-students.html

Zachary M. Schrag (2007-08-02 21:57:00)
Thanks for these examples. I have replied to them in a new posting: [1]IRBs vs. Departmental Review.
Zach

1. http://institutionalreviewblog.blogspot.com/2007/08/irbs-vs-departmental-review.html

1.1.2 Carome, Cohen, and Normal Science (2006-12-18 22:47)

Dr. Jeffrey Cohen [1]reports the following:

> At the PRIM &R conference in Washington last week I moderated a panel with Michael Carome and Julie Kaneshiro from OHRP on "When is it Human Subjects Research?" In his presentation, Dr. Carome finally clarified OHRP's position on oral history. As many of you know, in 2003 Dr. Carome wrote a letter stating that OHRP concurred with the position that oral history activities in general do not involve research as defined by the HHS regulations. Many oral historians took that to say that oral history was excluded from IRB review, including the Oral History Association. In his presentation at PRIM &R Dr. Carome clarified that this was meant in the same sense that drawing blood "in general" was not research.

Two points worth noting:
1. Dr. Carome chose to announce his latest views on historical research not to a group of historians, but to a group called Public Responsibility in Medicine and Research, a body dominated by professionals involved in biomedical research.
2. To understand the ethics of historical research, he sought an analogy in medical research: drawing blood.
In both these actions, he shows his deep grounding in biomedical research and his discomfort and unfamiliarity with other fields.
Dr. Cohen himself continues:

> It is not the methodology that determines whether an activity is human subjects research, but whether it meets the regulatory definition of research - a systematic investigation designed to develop or contribute

> to generalizable knowledge. . . . The problem is that the regulations don't define "systematic investigation" or "generalizable knowledge" and they don't say who is to make that determination.

It is unfortunately true that the regulations, 45 CFR 46, fail to define "generalizable knowledge." But Cohen could have considered the two places where the regulations use the term, other than to define what is research. [2]Section 46.406 twice refers to "generalizable knowledge about the subjects' disorder or condition." In a medical setting this makes sense; it distinguishes between knowledge about an individual's prognosis and knowledge about the disease itself. But the distinction is meaningless when disease is not the issue.

Thomas Kuhn writes, "in science . . . novelty emerges only with difficulty, manifested by resistance, against a background provided by expectation." (The Structure of Scientific Revolutions, 2d edition, p. 64). Both Carome and Cohen expect to see research that fits into their expectations for medical research. Faced with cases that don't fit, they try to shoehorn them into their preconceived models, ignoring contrary evidence. We need a revolution.

1. http://hrpp.blogspot.com/2006/11/ohrp-and-oral-history.html
2. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.406

Jeffrey Cohen (2007-04-13 00:03:00)

I finally got around to reading this and I want to make a couple of comments. First of all, I want to take issue with your categorizing me as someone who "...expect[s] to see research that fits into their expectations for medical research." As you know, I am not a physician. I have a Ph.D. in Psychology and spent twenty years working with an IRB that primarily reviewed social and behavioral research. I certainly don't expect everything to fit the medical model. Second, you quickly dismiss Mike Carome's example of blood draws because it comes from the field of medicine. Can social scientists only understand examples from their own fields? The example of blood draws is very apt. Even in medical research, blood draws are "generally not human subjects research". As I said, it is not the fact that you are drawing blood from someone that makes it human subjects research, but the purpose for which you do it what is the deciding factor. People draw blood for many purposes, if it is part of a systematic investigation that is designed to contribute to generalizable knowledge, only then it is human subjects research. The analogy to oral history is obvious. If I have to spell it out for you, I will. People interview people for many reasons. If they are doing it in a systematic way to draw conclusions beyond the subjects being interviewed, then it may be human subjects research. Finally, your characterization of "generalizable knowledge" in the context of disease is not applicable to the way it is used in the regulations. Generalizable knowledge, in the context used in the regulations, is information that is gathered to draw general conclusions beyond the subjects from which the data is gathered. This has nothing to do with disease. Finally, even though PRIM &R's name refers to medicine, that is a carry over from it formation over 30 years ago. Since then PRIM &R has grown into an organization that includes all aspects of human subjects research, including the social sciences. In fact, Mike's talk was in the social/behavioral track of the conference. Critics love to throw around the term "biomedical" as if that somehow attack the validity of the argument. There are many of us who fully understand non-biomedical research, even qualitative research, and still believe that the regulations should apply to all human subjects research.

Zachary M. Schrag (2007-04-13 11:38:00)

I refer Dr. Cohen to the findings of the National Bioethics Advisory Commission in its 2001 report, [1]Ethical and Policy Issues in Research Involving Human Participants:

"Because the National Commission focused its attention on medicine, it used a framework of 'the individual versus the group.' The basic element of this distinction was that the practice of medicine referred to activities designed solely to enhance the well-being of the specific patient, while research, often using many individuals, was designed to develop or contribute to generalizable knowledge.

"Of great interest to the National Commission were ways in which to classify innovative therapies or practices (London and Klerman 1979; Robertson 1979; Sabiston 1979). It was widely recognized that a common practice in medicine involved physicians trying therapies or administering drugs in a manner that differed from generally accepted practice standards. Such innovative practices were considered not to be research because they are generally not carried out in a systematic fashion and they do not generate generalizable knowledge. In addition, there is no built-in conflict of interest between the physician and the patient, because it is presumed that the sole interest of the physician is to provide potential benefit to the patient. However, the National Commission recommended that innovative practices be studied under a research protocol as soon as it became

appropriate to study them systematically (National Commission 1979). NBAC agrees with the views and recommendations of the National Commission regarding the handling of innovative therapies.
"Missing from the National Commission's deliberations, however, were activities outside clinical or behavioral settings. For example, public health and certain types of research in the humanities and social sciences (e.g., oral history) were only minimally addressed in the National Commission's reports. Thus, a definition of research emerged that differentiated clinical practice from clinical research, but did little to help differentiate practice from research activities in other areas."
There is more work to be done on the history of the National Commission. But the available scholarship contradicts Cohen's assertion that "Generalizable knowledge . . . has nothing to do with disease."

1. http://www.georgetown.edu/research/nrcbl/nbac/human/overvol1.html

Jeffrey Cohen (2007-04-17 00:08:00)
Whether the National Commission adequately considered non-biomedical research in its deliberations is a matter of historical interest, but not directly relevant to understanding the regulations. The regulations were not written by the National Commission, but by individuals within the then Department of Health and Human Services. The regulations, as they are written, do not relate "generalizable knowledge" to disease. When those regulations were written, in the late 1970s, they were always intended to cover non-biomedical research. I was at the PRIM &R meeting in the fall of 1979 when officials from the Office for the Protection from Research Risks (OPRR, the predecessor to OHRP) discussed how the "new" regulations would apply to the social and behavioral sciences. At that meeting they discussed how they were building into the regulations adequate flexibility for IRBs to effecitively review social and behavioral research. The subsequent regulations had that flexibility built in and it works well. The interpretation of "generalizable knowledge" that I described in my comment works to help us differentiate between research that needs IRB review and that which does not.

Zachary M. Schrag (2008-01-01 21:00:00)
This discussion continues at [1]Jeffrey Cohen on Generalizable Knowledge

1. http://institutionalreviewblog.blogspot.com/2007/04/jeffrey-cohen-on-generalizable.html

1.1.3 A thousand cuts (2006-12-23 23:57)

Many complaints about the IRB regime, such as the [1]AAUP's recent report, focus on extreme cases where IRBs delayed or prohibited research. [2]10-Year-Plan, a graduate student's blog, describes a more typical problem, the loss of time even when an application is eventually approved or ruled exempt:

> I spent a good deal of time this semester working on an IRB application. My dissertation research includes a good deal of oral history. Some of these are taped and archived in libraries across the country. However, most of what I am interested in, (girls' lives, gender-related issues) cannot be found in traditional archives. So, in the best-case scenario, I will be conducting oral histories myself . . .
> The official word is that oral history is NOT regulated by the IRB–as long as events covered in interviews are confined to the past. However, there is some argument as to whether or non-regulated status is going to stay. In addition, the American Historical Association encourages all graduate students to clear their oral history projects just in case. In case of what, I am not certain. The chair of our department agrees and so, I embarked on the application process.
> The application is long and tedious. NO, I will not inject my subjects with any substances. I am doing no testing of DNA...
> Anyway, I found out today that they gave me the status of "not regulated" which means I don't have to change anything! And I don't have to re-apply next year! Happy Holidays, me.

Happy Holidays, LaKisha. The AHA was right to warn you; some IRBs would strip you of your degree if you did not follow their procedures. But your IRB has robbed you of valuable time. Had it published its criteria for what is and is

not regulated, you could have avoided the time-consuming application.

1. http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm
2. http://10-year.blogspot.com/2006/12/ethical-research.html

1.1.4 Carpenter and Hyman (2006-12-26 13:31)

The Northwestern Law Review is preparing a symposium issue about IRBs. At least two papers from the symposium have appeared on SSRN.
Dale Carpenter, in "[1]Institutional Review Boards, Regulatory Incentives, and Some Modest Proposals for Reform," writes that "IRBs understand well the physical risks to subjects that come from biomedical research. They are much less adept at identifying substantial nonphysical risks or the research methods in social science that can create them. Thus, in an abundance of caution, they 'make decisions on the basis of worst-case scenarios.' Fear of these worst-case scenarios leads them to over-regulate."
David Hyman, one of the authors of the recent [2]AAUP report on IRBs, is more aggressive in his piece, "[3]Institutional Review Boards: Is This the Least Worst We Can Do?" He notes that even in biomedical research, "there is no empirical evidence that IRBs have any benefit whatsoever," and that "it is hard to make the case that IRBs, with their obsession with paperwork and the tweaking of consent forms, actually promote the protection of human subjects." Both agree that the current system punishes IRB members for approving dangerous research but not for blocking legitimate research, thus encouraging boards to be over-cautious and censorious.
Both Carpenter and Hyman offer what they term "modest reforms." But many of their suggestions are anything but modest. In particular, excluding from review all interview-based research with legally competent adults (as advocated by the AAUP) seems to require either a rewriting of federal regulations (and corresponding state laws) or a willingness of institutions to risk the suspension of all research by the federal Office of Human Research Protections. I hope that legal scholars will do more to determine exactly how to change the current regulations or establish a saner and more consistent interpretation of them than the arbitrary pronouncements of the past few years.

1. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=948739
2. http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm
3. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=942862

1.1.5 The Miseducation of Jystar (2006-12-28 23:00)

Jystar, a PhD student in information and computer sciences at the University of California, Irvine, [1]writes:

> I was at the gym this morning, and on the large and annoyingly loud HD TV that I usually try to ignore was a news story, I believe it was on ABC, and badly behaved kids in a restaurant. I know, urgent breaking news, right? apparently, the station had hired two child actors to be obnoxiously loud and annoying children in a restaurant, as well as hiring an actor to play the father who ignored them and talked on his cell phone the whole time. they showed clips from hidden cameras in the restaurant in which the kids were banging on the plates and silverware, singing loudly, chasing around, diving under tables, etc. I think the purpose was to see how far they could go before someone would do something. a number of people tried to talk to the father, who just acted confused. "what do you mean my kids are out of control?" others tried to stop the kids, who either ignored them or got more annoying. when the restaurant manager came out, the kids hid under a table. why this is news is beyond me, but there's something even more troubling here.

> through what process did this station have to go to get this segment approved? clearly, there are specific legal processes through which one must go to show a recording of some random person on TV. did they do a "gotcha" thing where they came out and had everyone sign forms? even beyond the legal questions, these people's dinners were almost completely ruined. and for what? for our entertainment on the morning news? if I wanted to do a similar social-behavior experiment, I would have to get it approved by my university's Institutional Review Board (IRB).

Under the First Amendment, there are, in fact, no "specific legal processes through which one must go to show a recording of some random person on TV." It is true that under some circumstances television crews and other journalists can be found liable for various [2]privacy torts, but for the most part they enjoy great leeway to report the news, and they are not subject to prior restraint.

The IRB regime rejects the free-speech approach of relying on tort law to deter bad behavior, and replaces it with the idea that all is forbidden unless it is specifically approved. In doing so, it has robbed Jystar, and countless others, of their understanding of what it means to live in a free society.

1. http://numinoria.blogspot.com/2006/12/who-approved-kids-from-hell.html
2. http://www.cas.okstate.edu/jb/faculty/senat/jb3163/privacytorts.html

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Chapter 2

2007

2.1 January

2.1.1 Why not make IRB review voluntary? (2007-01-03 22:29)

One of the best arguments I have read in favor of IRB review of interview and survey research is Joan E. Sieber, "Privacy and Confidentiality: As Related to Human Research in Social and Behavioral Science," in National Bioethics Advisory Commission, [1]Ethical and Policy Issues in Research Involving Human Participants, volume II (The Commission, 2001).
Sieber, a psychologist who has studied the ethics of research since the early 1980s, provides some compelling examples of cases in which a researcher might have trouble deciding what levels of confidentiality are appropriate and how to achieve them. For example, she lists the complex networks of laws that might require the disclosure of research data. And she points out the technical difficulties of knowing what data–age, job title, and the like–might be harmless in one case but sufficient to identify individuals in others. While I do not agree with all of her judgments, were I planning research in some of the sensitive areas she describes, I would want to have her advice or that of someone like her.
Sieber concedes, however, that many or most IRBs are unable to provide such guidance:

> The regulations of human research, as currently written, give little hint of how finely the protocol and informed consent relationship must be crafted in response to the manifold aspects of privacy and confidentiality in social research. Worse, they do not allude to the background of concepts and plans that would underlie such an effective protocol and relationship. Remarkably, some IRBs function quite effectively despite these ambiguities, through wise interpretation by IRB members who are well schooled in ethical problem solving and whose scientific training has provided relevant research competencies. Such a fortunate confluence of education, competency, and effort is not the norm, however. Nor can such outstanding performance reasonably be expected of most IRBs, which are woefully overworked and under-budgeted.

She continues:

> There is now a literature of virtually hundreds of approaches to protecting privacy or assuring confidentiality. This literature is rarely sought out by IRBs, researchers, or teachers of research methods. Most are not even aware that it exists. . . .
> Many IRBs have little sense of the range of privacy issues they should consider or of the range of solutions that might be employed in the service of valid and ethical research. Many IRB chairs, members, and staff

> persons are not in a position to effectively guide or teach their clientele, or to gain the respect of their clientele.

In other words, many IRBs know less about research ethics than the researchers themselves, and are likely to do more harm than good when they intervene.

Sieber proposes to remedy this problem with a "web-based educational resource . . . that will guide the ethical problem solving in research. Itshould not be offered as an official regulation, or interpretation of regulations, but as a user-friendly educational resource that will challenge IRBs, researchers, teachers, and students to improve their ability to craft solutions to ethical and methodological problems." Instead of judging protocols by guesswork, IRBs could apply scholarly standards, backing up their recommendations with citations to empirical research. In this vein, Sieber now edits a new journal, the [2]Journal of Empirical Research on Human Research Ethics, which presumably seeks to provide the kind of knowledge she identified as crucial in 2001.

Unfortunately, Sieber fails to address the institutional barriers to her recommendations. As Carpenter and Hyman note, IRBs have little incentive to base their decisions on scholarly ethics, rather than regulations. If the federal government audits them, it will judge them on their compliance with procedures, not the soundness of their advice. And since the researchers at their institutions form a captive audience, they have no real reason to "gain the respect of their clientele," as Sieber puts it.

If Sieber really believes in the power of IRBs to educate researchers, she should advocate voluntary review. Good librarians do not need federal requirements to attract researchers; they need sticks to keep the researchers away. The same is true of other university offices that offer research assistance, such as writing centers and statistical or computer training departments. Why not make IRB review voluntary?

Skilled IRBs would lose nothing, since serious researchers would continue to seek their advice. Unskilled IRBs, in contrast, would have to shape up by educating themselves in the ways Sieber recommends. And neither researchers nor their subjects would lose anything as researchers quit consulting incompetent boards.

The system would not be perfect, but it would impose a quality control now lacking.

1. `http://www.georgetown.edu/research/nrcbl/nbac/pubs.html`
2. `http://www.ucpressjournals.com/journal.asp?jIssn=1556-2646`

John (2007-01-18 10:38:00)

"Sieber concedes, however, that many or most IRBs are unable to provide such guidance"

That doesn't keep them from trying, given that they have adopted a mandate to "find a problem," not "is there extraordinary risk"

The point re seeking out librarians is quite good, I have always thought researchers to be more aware of their limits than ethicists.

2.1.2 Nancy Janovicek offers a Canadian perspective (2007-01-07 00:44)

Historian Nancy Janovicek of the University of Calgary has written a thoughtful description of the problems faced by Canadian oral historians as they face ethical review by scholars "not well versed in historical methodologies." The article, "[1]Oral History and Ethical Practice: Toward Effective Policies and Procedures," is slated to appear in the Journal of Academic Ethics, but it has already been posted at the SpringerLink website.

In Canada, institutional review boards are known as "research ethics boards" (REBs), and the Canadian equivalent of the Common Rule is the Tri-Council Policy Statment: Ethical Conduct for Research Involving Humans. But though the names are different, the effects are the same. Janovicek's complaints will be familiar to anyone who has followed the American debate over IRB review of oral history, but her account is particularly eloquent on two points.

First, she notes ethics boards' obsession with confidentiality and anonymity, despite the wishes of both researchers and subjects. When Janovicek told one narrator of this poicy, "a lesbian activist who has struggled to maintain lesbian visibility in her communinity replied, 'I like my name.'" (This point would have resonated better had Janovicek named the activist in this article.)

Second, Janovicek complains of policies that seek to prevent the exploitation of Aboriginal communities by requiring reseachers to "acquire written approval from Band Councils in order to interview members of the community." But, she asks, "what happens when leaders act as gatekeepers for research about less powerful people in their communities?" Both of these arguments show how well-meaning policies crafted for medical research can strip power away from autonomous adults who are not only able to decide whether they want to speak to a historian, but are able to seize the opportunity to challenge existing power structures.

My one cavil concerns Janovicek's statements that "the American Historical Association has argued successfully that oral histories should not be subject to review by Institutional Review Boards" and that, in the United States, "oral history projects are exempt from IRB review." As [2]Robert B. Townsend and Mériam Belli[3] have noted, the AHA's 2003 declaration of victory was premature, and the debate continues on both sides of the border.

1. http://www.springerlink.com/content/w05959x263420364/
2. http://www.historians.org/Perspectives/Issues/2004/0412/0412new4.cfm
3. http://www.historians.org/Perspectives/Issues/2004/0412/0412new4.cfm

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2.1.3 "Generalizable" revisited (2007-01-10 23:50)

One persistent question about the need for IRB oversight of oral history is whether oral history interviews come under the jurisdiction of [1]45 CFR 46, which defines research as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Any project not "designed to develop or contribute to generalizable knowledge" is therefore excluded from the requirement for review.

In October 2003, Dr. Michael Carome, associate director of the Office of Human Research Protection, U.S. Department of Health and Human Services (OHRP), sought to answer that question in a discussion with representatives of the UCLA Office for Protection of Research Subjects. UCLA prepared an [2]outline of that discussion, and Carome subsequently confirmed it in [3]correspondence to Northern Illinois University. Carome offered descriptions of three hypothetical projects, explaining that one of them would be excluded from review, while the other two would require IRB approval. Because these were hypothetical, it was impossible to tease out the distinctions among them, so the guidance was unclear.

In 2004, however, OHRP offered a concrete example of non-generalizable oral history. OHRP staff, including director Bernard A. Schwetz, conducted a series of videotaped interviews with former members and staff of the the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Recordings and transcripts of those interviews, entitled the Belmont Oral History Project, are online at [4]http://www.hhs.gov/ohrp/belmontArchive.h tml.

I recently asked OHRP if the project had been reviewed by an IRB, and received the following reply:

Date: Wed, 10 Jan 2007 09:39:42 -0500
From: "OS OPHS OHRP (HHS/OPHS)"
Subject: RE: Belmont Report Oral History
Sender: "Nellis, Kevin (HHS/OPHS)"
To: "Zachary M. Schrag"
Cc: "ElHinnawy, Patricia C (HHS/OPHS)"

Dear Dr. Schrag,

OHRP determined that obtaining oral histories of members and staff of the National Commission did not represent research as defined at 45 CFR 46.102(d) because the activity was not a systematic investigation, nor was it intended to contribute to generalizable knowledge. This oral history activity was designed merely to preserve a set of individuals' recollections; therefore, this activity was not subject to IRB review.

The interviewers had no specific training related to this activity; and those interviewed did not sign a consent document.
I am delighted that you found the interviews informative and helpful. If you have any more questions regarding the protection of human subjects in research or need clarifications on this response, please do not hesitate to contact OHRP.
Best Regards,
Kevin L. Nellis, M.S., M.T. (A.S.C.P.)
Public Health Analyst
Division of Education and Development
Office of Human Research Protections

Zach comments:
Based on this project, then, recorded interviews do not represent research as defined at 45 CFR 46.102(d) even when:

- interviewers ask some standardized questions (several narrators are asked, for example, how much time they spent deliberating about social and behavioral, as opposed to biomedical, science).
- interviewers ask prepared questions tailored to the narrators' individual experiences.
- interviewers ask follow-up questions based on the narrators' replies to initial questions.
- interviewers ask narrators to draw conclusions about the lasting significance of their work.
- recordings and transcripts are posted on the Internet and labeled "Oral History Archive."
- portions of the interviews are used in an interpretive work of history (in this case a [5]video arguing that the 1970s "marked a turning point in how human research was controlled in the United States," and that the authors of the Belmont Report should be thanked "for their help in guiding our decisions far into the future").
- the interviews appear as part of a website that draws on history to inform present policy ("Today, the Belmont Report continues as an essential reference for institutional review boards (IRBs) that review HHS-conducted or -supported human subjects research proposals involving human subjects, in order to ensure that the research meets the ethical foundations of the regulations").

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102
2. http://www.oprs.ucla.edu/human/documents/pdf/oral-history-031209.pdf
3. http://www.nyu.edu/ucaihs/forms/oralhistory/email.php
4. http://www.hhs.gov/ohrp/belmontArchive.html
5. http://videocast.nih.gov/ram/belmont_tribute.ram

2.1.4 Menikoff, "Where's the Law?" (2007-01-16 20:48)

Another paper from the 2006 conference, "Censorship and Institutional Review Boards," has appeared on SSRN: Jerry Menikoff, "[1]Where's the Law? Uncovering the Truth About IRBs and Censorship."
Most of the article repeats claims made by Joan E. Sieber, Stuart Plattner, and Philip Rubin in their 2002 essay, "[2]How (Not) to Regulate Social and Behavioral Research," Professional Ethics Report (Spring 2002), 1-4. They argue that any abuses by IRBs are the fault of individual IRBs, not the regulations governing them. They conclude, therefore, that "IRBs and researchers can return to true interpretation of the Belmont Report under the Common Rule, if they make

use of the flexibility it offers for reasonable interpretation of its requirements." Similarly, Menikoff believes that "both the regulators, and the regulations they enforce, reflect a system that, properly understood and implemented, already imposes a fairly minimal burden on individual researchers in the area of social and behavioral research."
These arguments suggest that inflexible, inappropriate impositions by IRBs are anomalies in a fundamentally sound system. But for several years now, complaints have poured in from scholars in anthropology, communications, folklore, history, law, and sociology; from universities across the country; from researchers at the undergraduate, graduate, and faculty level. And these are just the most outrageous cases; the August 2005 issue of the Journal of Applied Communication Research, devoted entirely to the question of IRB review, suggests that many researchers suffer in silence. To blame all of these problems on individual IRBs strikes me as unfair; the pattern suggests a problem in the system itself.
How many examples must critics accumulate before Sieber, Menikoff, and others will ask if these problems are not the fault of individual IRBs, but of the application of rules designed for experimental research to non-experimental research?
Menikoff's second argument is that while IRB review of the social sciences may be bad policy, "individual researchers are not subject to a burden rising to the level of constitutional concern." Perhaps not, but since Menikoff cites no case law on what does constitute censorship, it's hard to understand how he reached this conclusion. How many questions must a board turn down before you can call it a ban?
A more complete discussion of this question can be found in Robert L. Kerr, "Unconstitutional Review Board? Considering a First Amendment Challenge to IRB Regulation of Journalistic Research Methods," Communication Law & Policy 11 (2006): 393–447. Kerr concedes that the courts have yet to offer clear guidance, but he notes that

> "In a variety of contexts" the Supreme Court has declared that "even though the governmental purpose be legitimate and substantial, that purpose cannot be pursued by means that broadly stifle fundamental personal liberties when the end can be more narrowly achieved." . . . In the interest of addressing concerns arising from abuse in biomedical research, the IRB regulations reach so far as to prevent scholars from utilizing journalistic research methods that are fully protected in other contexts. The breadth of the regulations means that scholars are not able to conduct interviews at the time that they may be most available or most fruitful, because they generally must wait at least a number of weeks before their request for IRB approval can be processed. If an interview subject is no longer available after the wait, the delay imposed by the IRB might as well be a ban. Even when permission is eventually granted, the interview sought may be lost for good during the waiting period.

Since the Northwestern conference was held in April 2006, it's likely that contributors had not had a chance to read Kerr's thoughtful paper. I hope that future legal scholarship on this issue will build on his work. I would also like to hear some explanations of why no IRB has, to my knowledge, dared assert authority to review university journalism programs.

1. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=951533
2. http://www.aaas.org/spp/sfrl/per/per29.htm

2.1.5 IRB demands destruction of tapes (2007-01-16 20:55)

Kathy Staley of Appalachian State University writes on [1]H-Oral:

> I'm currently doing an oral history project on my university's LGBT population and have run into some interesting challenges. Older people (50+ years) requiring pseudonyms. My IRB approval required

> several hoops to be jumped through (such as no 3rd party names are to be listed in the transcripts and my tapes are to be destroyed) to ensure strict confidentiality. I'm completely ill about this and although I disagree with IRBs being required for oral histories philosophically and my particular requirements, I want to graduate and my thesis adviser required me to do it too.

There is a case to be made for blanking out the names of third parties; I regard this as an ethical question yet to be sufficiently explored. The National Human Research Protections Advisory Committee's [2]"Clarification of the Status of Third Parties When Referenced by Human Subjects in Research" is not particularly helpful. It states that researchers don't need informed consent from third parties, but does not explain how they should regard those parties' privacy. The demand to destroy tapes, in contrast, is just wrong. Tapes can be sealed for decades; historians are patient folks. Here an IRB has forced a historian to violate her professional ethics.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=0701&week=c&msg=wYf3/Xdi0RnG0zoWlJ908Q
2. http://www.aera.net/aera.old/humansubjects/NHRPAC_Final_Third_Parties.pdf

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2.1.6 John Mueller (2007-01-18 23:05)

John Mueller of the University of Calgary kindly alerted me to his page on [1]Research Ethics, which offers a skeptical look at IRBs' utility.

1. http://mueller.educ.ucalgary.ca/research-ethics.html

2.1.7 Inside Higher Ed (2007-01-19 09:23)

This blog is five weeks old and already famous; see Paul D. Thacker, "[1]Reviewing the Reviewers," Inside Higher Ed, 19 January 2007.

1. http://insidehighered.com/news/2007/01/19/irb

2.1.8 Special Issues (2007-01-19 22:42)

One of my hopes for this blog is that it will bring together viewpoints from a variety of disciplines. To this end, I am grateful to have been alerted to two recent journal issues with multiple articles about IRB review:
[1]Journal of Social Distress and the Homeless, Volume 15, Number 1 (January 2006)
[2]American Ethnologist, Vol. 33, No. 4 (November 2006)
I plan to start reading and blogging these issues shortly.

1. http://psyckelogo.metapress.com/openurl.asp?genre=issue&issn=1053-0789&volume=15&issue=1
2. http://www.aesonline.org/ae/334

2.1.9 The Language of Exemption (2007-01-21 21:18)

In an earlier [1]posting, I asked

> How many examples must critics accumulate before Sieber, Menikoff, and others will ask if these problems are not the fault of individual IRBs, but of the application of rules designed for experimental research to non-experimental research?

A correspondent comments:

> I do not think 'experimental' versus 'non-experimental' gets at the problem you are trying to address. The rules are not really designed for experiments. For example, the 'Tuskegee Experiment', despite the name, was not an experiment.

I am not sure I am ready to concede this point, but the comment does highlight the need for language that precisely delineates the kind of research I and others would like to exempt from IRB review. I therefore present four proposals, made over the years, that would exempt qualitative interview research:

1. In 1979, the Department of Health, Education, and Welfare (HEW) announced planned revisions to 45 CFR 46 (the federal regulation requiring IRBs). Overall, the proposal would have greatly expanded the reach of IRBs, but one of the possibilities it considered would have exempted "survey activities involving solely product or marketing research, journalistic research, historical research, studies of organizations, public opinion polls, or management evaluations, in which the potential for invasion of privacy is absent or minimal." (Federal Register, 14 August 1979, [2]PDF)
2. The announcement provoked outcry from a variety of scholarly organizations. The American Association for the Advancement of Science "resolved that the Association urge that further government regulation designed to protect the human subjects of scientific inquiry not be made applicable to studies that involve no more than the free exchange of information between adult subjects, competent to make their own decisions, and the scientist."
(American Association for the Advancement of Science, "[3]AAAS Resolution: Protection of Human Subjects of Research," Center for the Study of Ethics in the Professions at IIT, 14 August 1979.
3. In 1980, several groups endorsed the American Council on Education's demand that the regulations include the proviso,

"These regulations do not apply to research using legally competent subjects that involves neither deceit nor intrusion upon the subject's person nor denial or withholding of accustomed or necessary resources."

[J. W. Peltason, "Comment on the Proposed Regulations from Higher Education and Professional Social Science Associations," IRB: Ethics and Human Research 2 (February 1980), 10, [4]JSTOR]
4. I haven't traced all the proposals since then, but in 2006, the American Association of University Professors recommended "that research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption." (AAUP, "[5]Research on Human Subjects: Academic Freedom and the Institutional Review Board," 2006)

Since any of these proposals would get historians off the hook, they all strike me as improvements over the status quo. But there are significant differences among them.

The HEW proposal is the most limited. By listing by name only a few disciplines to be exempted, it would have kept IRB review of disciplines, such as folklore, even further removed from the biomedical and behavioral research that was the target of the National Research Act of 1974. Far better to list methodologies, such as interviewing. Moreover, from the recent debate over the meanings of "generalizable" and "in general," we can now see that the proposal would have left unresolved the question of who gets to determine when "the potential for invasion of privacy is absent or

minimal."
The 1979 AAAS proposal and the 2006 AAUP proposal are quite similar to each other, in that they both stress the right to talk to competent adults. However, the AAAS is less precise in its language. Many researchers who have found themselves subject to IRB review do not consider ourselves "scientists." Moreover, the AAUP recognizes the need for self-exemption. If only IRBs (and their designees) can exempt researchers from IRB review, then researchers will remain subject to the caprice of the IRBs.
A comparison of the AAUP proposal to that of the ACE raises an interesting issue. Since the AAUP's exemption targets "methodology [that] consists entirely" of surveys, interviews, and observation, it would not encompass research that withheld resources, such as the penicillin denied the subjects of the Tuskegee study. But what about deception, which can be part of surveys and interviews? The AAUP's report is ambiguous on the issue. On the one hand, it raises the specter of Milgram's obedience experiments (which relied on deception) to suggest that "an across-the-board exemption for all social science research is arguably overbroad." On the other hand, it cites Keith Humphreys and Michelle L. Brandt to note that we have no empirical evidence that IRBs protect human subjects. Thus, even if we concede that research using deception raises significant ethical problems, that's no reason to assume that IRB review can identify or resolve those problems.
The AAUP's proposal still needs a bit of tweaking on this question, but it is very close to a plausible amendment to the current regulations.

1. http://institutionalreviewblog.blogspot.com/2007/01/menikoff-wheres-law.html
2. http://www.hhs.gov/ohrp/documents/19790814.pdf
3. http://ethics.iit.edu/codes/coe/amer.assoc.advancement.sci.c.html
4. http://links.jstor.org/sici?sici=0193-7758%28198002%292%3A2%3C10%3ACOTPRF%3E2.0.CO%3B2-6
5. http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm

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2.1.10 Still no evidence? (2007-01-26 08:53)

Twenty-six years ago today, on 26 January 1981, the Department of Health and Human Services published in the Federal Register its "Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects." ([1]PDF) The department rejected a proposal by several social-science organizations to "exempt all research utilizing legally competent subjects if that research involved neither deceit nor intrusion upon the subject's person, nor the denial or withholding of accustomed or necessary resources." It justified this decision in empirical terms, stating that "despite some general comments that the regulations would impede social research, the Department has been presented no evidence that social science research that may present risks to subjects has been unduly hampered by the requirement for IRB review and approval" (emphasis added).
What's striking is the department's suggestion that evidence of undue hampering might have changed its decision on the regulations. Twenty-six years later, it's a good deal easier to find such evidence. See, for example,

- Jennifer Howard, "[2]Oral History Under Review," Chronicle of Higher Education, 10 November 2006.
- AAUP, "[3]Research on Human Subjects: Academic Freedom and the Institutional Review Board," (2006)
- Robert L. Kerr, "Unconstitutional Review Board? Considering a First Amendment Challenge to IRB Regulation of Journalistic Research Methods," Communication Law & Policy 11 (2006): 393–447.
- American Ethnologist 33, No. 4 (November 2006)
- Journal of Applied Communication Research 33, No. 3, (August 2005).
- Patricia Loomis Marshall, "Human Subjects Protections, Institutional Review Boards, and Cultural Anthropological Research" Anthropological Quarterly 76 (Spring 2003): 269-285

Even scholars who have served on IRBs despair when confronted by all the stories of inappropriate review. Is it time for the federal government to revisit its decision?

1. http://www.hhs.gov/ohrp/documents/19810126.pdf
2. http://chronicle.com/free/v53/i12/12a01401.htm
3. http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm

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2.2 February

2.2.1 In Search of Expertise (2007-02-11 22:37)

When, in the 1960s, the federal government began requiring ethical review of proposals seeking funding for medical experiments, regulators expected that the review would be conducted by experts in the field. Thus, the U.S. Public Health Service's PPO #129, "Clinical Investigations Using Human Subjects" (8 February 1966), required "prior review of the judgment of the principal investigator or program director by a committee of his institutional associates," presumably other doctors or biomedical researchers. The 1974 version of 45 CFR 46 [[1]PDF] required that each IRB be composed of "not less than five persons with varying backgrounds to assure complete and adequate review of activities commonly conducted by the organization. The committee must be sufficiently qualified through the maturity, experience, and expertise of its members and diversity of its membership to insure respect for its advice and counsel for safeguarding the rights and welfare of human subjects."

In response to concerns that researchers could not be trusted to watch other researchers, in 1981 the Department of Health and Human Services added the requirement that "each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy." [[2]PDF] The language of the provision shows that the department did not imagine applying these rules to nonscientific researchers (such as lawyers, ethicists, or members of the clergy), but that's not the point here. The point is that the regulations' drafters expected IRBs to be dominated by experts "possessing the professional competence necessary to review specific research activities," with one or two lay members added to represent the conscience of the community.

Recently, some have called for a greater role for non-expert members. In 2001, for example, the [3]National Bioethics Advisory Commission recommended that "members who represent the perspectives of participants, members who are unaffiliated with the institution, and members whose primary concerns are in nonscientific areas . . . should collectively represent at least 25 percent of the Institutional Review Board membership," rather than the single member now required.

But a bigger problem may be not a lack of lay representation, but a lack of expertise. In their 2002 paper, "[4]The Crisis in Human Participants Research: Identifying the Problems and Proposing Solutions," Anne Wood, Christine Grady, and Ezekiel J. Emanuel described this problem in IRB review of clinical research:

> A single IRB often reviews research on a wide variety of scientific topics and research settings, some of which are not aligned with the scientific expertise of the board members. For instance, IRBs may need to review research studies using drugs or interventions that lie outside the expertise of any of the members. Similarly, IRBs may review research studies being conducted in a developing country when none of the IRB members have first hand experience much less professional expertise concerning the health care infrastructure or social and cultural practices of that country. Further, vital information about experimental drugs or interventions may not be published but only known by experts in the research area through conference presentations or word of mouth. To remedy these deficiencies in information, IRBs can consult experts or investigate external materials some of which may not even be published. This requires a commitment of IRBs limited resources and time, and therefore may not be readily done. Indeed, it is fair to say that IRBs are relatively passive, responding to the information provided rather than actively

> seeking information in addition to that submitted in the research protocol. Under these circumstances, IRBs can make poor decisions about the permissibility of a study that can sometimes result in avoidable harms to participants.

In non-clinical research, the problem may be greater. Even when non-biomedical research is reviewed by a board nominally specializing in "social and behavioral" research, those categories are too great to assure researchers that their projects will be reviewed by anyone in the same discipline. Many IRB horror stories arise from reviews by boards without expertise. For example, Jennifer Howard's Chronicle of Higher Education article, "[5]Oral History Under Review," mentioned the fact that "no historians currently sit on Purdue's social-sciences IRB, which is chaired by Richard D. Mattes, a professor of foods and nutrition." That background led Mattes to declare, bizarrely, that talking to someone is "not different from creating a database of DNA." Whatever Mattes's knowledge of nutrition, when it comes to history, he is clearly a layperson.

I have seen three types of proposals to remedy this problem.

First, some call for frustrated researchers to join their local IRBs, thus bringing their expertise to the board (see various comments on the article, "[6]Reviewing the Reviewers," at Inside Higher Ed). If the board is truly intransigent, this is obviously not going to help, since one member cannot sway a board. More likely, however, boards will delegate the task of review to the most expert member. This is what happened to anthropologist Rena Lederman when she joined Princeton's review board, as she reports in her essay, "[7]The Perils of Working at Home." She could not understand the ethics of the social psychologists who dominated the board, and they could not understand ethnography. Rather than hash out the differences, members avoided evaluating proposals in other disciplines:

> The potential for cross-disciplinary conflict latent in the panel's work was . . . systematically defused by an explicit etiquette—characteristic of the university, generally—of disciplinary autonomy. Those of us on the panel would, from time to time, remind ourselves that "we're not here to evaluate the research"; that is, technical evaluations of research design and significance were—within rather broad limits—understood to be the proper concern of disciplinary peers (e.g., departmental thesis advisors and external grant reviewers), not of the IRB. In this way, overt expressions of our respective disciplinary worldviews were muted.

In other words, each discipline left the others alone, which suggests that the whole concept of a board was abandoned. It sounds like a criminal waste of the time of eminent scholars.

A second suggestion is that ethical review of non-biomedical research be handled by departments. The National Science Foundation, in its "[8]Frequently Asked Questions and Vignettes," suggests that individual departments create human research committees to review classroom exercises, which are not covered by federal regulations. Likewise, the AAUP's 2006 report on "[9]Research on Human Subjects," while declining to "recommend alternatives to imposing the requirement of IRB approval on research that is not federally funded," nevertheless suggests that "schools might consider an alternative under which the approval required is limited to approval by the researcher's department or other appropriate academic unit."

Full devolution to departments would might work well in most cases, but it provides no clear paths for departments lacking the expertise to review potentially unethical proposals. For example, since most historians work primarily using documents alone, many history departments may have a single faculty member—or even none—who regularly conducts interviews. Or an anthropology department might lack an expert in conducting research in countries with authoritarian regimes and low rates of literacy. Should a graduate student present a research proposal for such work, such departments might not be able to give needed advice.

A third suggestion would replace the 4,000 – 6,000 local IRBs now in existence with some kind of centralized system more likely to match expert reviewers to particular proposals. This suggestion has come primarily from clinical researchers, such as Wood, Grady, and Emanuel, cited above. Another version, with references to several more, is Rita McWilliams, Carl W. Hebden, and Adele M. K. Gilpin, "[10]Concept Paper: A Virtual Centralized IRB System."

I won't comment on these proposals' fitness for biomedical research. For the humanities and the social sciences, I would say they seem extremely cumbersome and likely to result in needless paperwork for routine proposals.

On the other hand, a centralized system might prove very helpful in special cases beyond the competence of departmental reviewers. Were present regulations clarified or changed, centralization would not necessarily take the coercive forms envisioned by the clinical researchers. A history department ethics committee seeking outside expertise could, for instance, post a query on [11]H-Oralhist, which already serves as a way to tap the collective wisdom of oral historians on matters ethical, technical, and methodological. Or, just as scholarly journal editors maintain lists of experts ready to review manuscripts, professional associations could compile lists of researchers with experience in various difficult situations, who could be called upon to review proposals. Thus, combining proposals for devolution with proposals for centralization could yield a system of review that eased the path for routine research, while quickly matching hard cases to expert advisers.

Too many defenses of IRB review rely on the fallacy of the false dilemma, arguing that because some interview and survey projects present ethical challenges, all such projects require IRB review or formal exemption by an IRB delegate. Proposals for devolution to the departments, or centralization to national bodies, show that review by local IRBs is not the only way to get another set of eyes on a researcher's plans. Indeed, when it comes to finding reviewers who understand the proposals sent to them, it may be the worst way.

1. http://www.hhs.gov/ohrp/documents/19740530.pdf
2. http://www.hhs.gov/ohrp/documents/19810126.pdf
3. http://www.georgetown.edu/research/nrcbl/nbac/human/overvol1.html
4. http://bioethics.georgetown.edu/pcbe/background/emanuelpaper.html
5. http://chronicle.com/free/v53/i12/12a01401.htm
6. http://insidehighered.com/news/2007/01/19/irb
7. http://www.aesonline.org/ae/334
8. http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp#count
9. http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm
10. http://www.ingentaconnect.com/content/tandf/gacr/2006/00000013/00000001/art00003
11. http://www.h-net.org/%7Eoralhist/

2.2.2 The Australian (2007-02-21 10:24)

John Mueller kindly alerted me to an essay from Australia: Greg Bamber and Jennifer Sappey, [1]"Consenting Adults and the Path to Truth," The Australian, 21 February 2007.

Bamber and Sappey study management, and their most detailed complaint about human research ethics committees (HRECs, the Australian for IRBs) concerns workplace case studies. They note that such studies

> may challenge a unitary view of the workplace as essentially harmonious, which chief executives and their spin doctors seek to promote. This challenge is significant because it seems likely that under the new statement many HRECs will continue with their practice of requiring a researcher to obtain written consent from a chief executive or the equivalent before beginning a case study. A condition of granting consent may be the opportunity to veto output.
>
> How well does this correlate with the university principle that research is the pursuit of truth? In the case of workplace studies, it is reasonable to ask: whose truth - that of the chief executive, other managers, workers or customers? Chief executives' denial of access or their selective filtering of the information provided could deny the work force's (or customers') right to have their truth told.

Unfortunately, having asserted the duty of the researcher to pursue truth, Bamber and Sappey step back to a meeker position:

> In view of their health-research paradigm, there is a tendency for HRECs to err on the side of being risk-averse, overstating the importance of consent and of the welfare and privacy of participants, while giving too little weight to the benefits of research to society. In social science research the risks are invariably much lower than in health research.

That last sentence is unworthy of the rest of the essay. How can a study that challenges the power structure of a workplace be less risky than collecting undergraduates' spit? If Bamber and Sappey believe, as I do, that some researchers have the duty to pursue truth and justice, even if that means that a business executive is jailed for corruption or fraud, they should come out and say so. Let's not hide behind the idea that social science research doesn't hurt.

1. http://www.theaustralian.news.com.au/printpage/0,5942,21259575,00.html

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2.2.3 Schwetz Promises New Guidelines (New York Times) (2007-02-28 12:43)

Today's New York Times features a front-page story on IRBs by reporter Patricia Cohen: "[1]As Ethics Panels Expand Grip, No Field Is Off Limits."
Included in the story is some potentially very important news:

> Bernard A. Schwetz, director of the federal Office for Human Research Protections, which administers the regulations, acknowledges that the guidelines covering the boards' actions have not been clear enough and says he intends to make public new proposed guidelines before the end of the year.

Unless I am mistaken, these will be the first new guidelines since the broadening of [2]categories for expedited review in 1998. Researchers should not miss this once-in-a-decade opportunity for action.

1. http://www.nytimes.com/2007/02/28/arts/28board.html?ex=1330405200&en=c85e708083bf4c41&ei=5124&partner=permalink&exprod=permalink
2. http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm

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2.3 March

2.3.1 AHA Perspectives: Forum on IRBs (2007-03-11 17:56)

The March 2007 issue of the American Historical Association's newsletter, [1]Perspectives, features three essays on IRBs:

- Linda Shopes, "[2]Negotiating Institutional Review Boards"
- E. Taylor Atkins, "[3]Oral History and IRBs: An Update from the 2006 HRPP Conference"

and

- Zachary M. Schrag, "[4]Ethical Training for Oral Historians"

I plan to comment on the Atkins essay in a separate posting. For the Shopes piece, I offer a small factual correction: 45 CFR 46 was first promulgated in 1974, not 1981. See Final Rule, HEW, Protection of Human Subjects, Federal Register, May 30, 1974. [[5]PDF] I am working on a history of the regulation of the social sciences as "human subjects research" from 1966 to 1991, which I hope will clear up some of this chronology.

1. http://historians.org/Perspectives/issues/2007/0703/index.cfm
2. http://historians.org/Perspectives/issues/2007/0703/0703vie1.cfm
3. http://historians.org/Perspectives/issues/2007/0703/0703vie2.cfm
4. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm
5. http://www.hhs.gov/ohrp/documents/19740530.pdf

2.3.2 Savage Minds (2007-03-13 01:39)

Professor Rena Lederman is guest-blogging on [1]Savage Minds, an anthropologists' blog. She plans to provoke discussion on the "special problems ethnographers face in negotiating with IRBs, especially given the expansion and intensification of IRB scrutiny over the past several years."

1. http://savageminds.org/2007/03/09/please-welcome-guest-blogger-rena-lederman/

2.3.3 Why IRBs Are Not Peer Review: A Reply to E. Taylor Atkins (2007-03-13 10:09)

In his recent article on "[1]Oral History and IRBs," E. Taylor Atkins applauds the argument of J. Michael Oakes "that IRBs should be viewed as—and should behave as—peer review systems rather than as unaccountable 'leviathans' exercising authority from on high." But Oakes and Atkins overlook profound differences between IRB review and peer review. The two systems are not merely different; they are antithetical.

The most obvious difference between peer review and IRB review is that peer review means review by peers—fellow scholars in one's field. This was also the system envisioned in 1966 when the Public Health Service first mandated "prior review by [a researcher's] institutional associates" before that researcher could received PHS funds, and to some degree it is the way IRB review works in biomedical research, where teams of physicians and other biomedical researchers review protocols by others in their field. But fundamental to the complaints of oral historians and others in the humanities and social sciences is the fact that IRBs are never (to my knowledge) composed mostly of scholars who conduct qualitative interviews. Indeed, most IRBs probably lack a single such researcher.

Even when IRBs do include such scholars, they operate in a web of laws, regulations, and guidelines written by biomedical researchers and bioethicists without input from historians. Consider the involvement of historians in shaping the present system:

- Number of historians invited to testify before Congress as it was shaping the National Research Act: zero
- Number of historians on the [2]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, creator of the Belmont Report: zero
- Number of historians among the advisors and consultants to the [3]Institutional Review Board Guidebook : zero
- Number of historians on the board of [4]Public Responsibility in Medicine and Research (PRIM &R): zero
- Number of historians among the authors of the [5]CITI Program: zero
- Number of historians on the [6]Secretary's Advisory Committee on Human Research Protections : zero

Although historians have had no chance to shape the framework within which IRBs operate, by law and by their responsibility to their institutions, IRBs cannot ignore this framework. So it is not peer review at all that they impose, but values foreign to the historical profession.

One result of this peerless system is that IRBs are rarely able to offer the kind of expert advice we seek in good peer review. I have reviewed many manuscripts myself, but only when editors sought me out among a national or international pool of scholars. As a result, every manuscript I have read concerned some aspect of urban planning, infrastructure, or transportation—areas to which I have devoted years of research—or was designed as a textbook for use in the kinds of courses I regularly teach. Yet, as I note in my posting, "[7]In Search of Expertise," IRBs rely not on such a broad pool, but on whomever happens to be on campus and willing to serve on the local IRB.

Atkins also ignores the power of researchers to shape the peer review of their work. Certainly a university researcher who never submitted anything for peer review would be unlikely to win promotion, but Atkins forgets the choice researchers enjoy in deciding which peer-reviewed journal or press will receive their manuscripts, and which will be alternatives should the first choice reject the proposal. Comparable choosiness in ethical review is derided as "IRB shopping," and university IRBs retain their monopolies (See Jeffrey Brainard, "Federal Agency Decides Not to Regulate 'IRB Shopping,"' Chronicle of Higher Education, 18 January 2006). Moreover, scholars and editors are free to ignore the advice of peer reviewers in preparing a final publication; how fondly I recall my first editor's telling me not to worry about the difficult theory one reviewer wanted me to incorporate! Most importantly, scholars are always free to publish in non-peer-reviewed forums, such as this blog. In contrast, IRBs insist on the power to decide when a project requires their review.

Atkins recently attended a PRIM &R conference and "was astounded by the persistent ignorance among IRB administrators and board members in attendance about the special needs of SBER and oral history." He responded by blaming the victim: "If we refuse to teach IRBs, how can they learn what we need them to know?" What he refuses to acknowledge is that IRBs' power frees them of any incentive to learn. A publisher whose peer-reviewers offered consistently bad advice would soon lack for material. An IRB can mistreat researchers yet suffer no loss of power; its decisions are final.

While peer review is a persuasive effort by volunteers, IRB review is a coercive practice by agents of the state. Leviathans or not, IRBs do little but exercise authority from on high, empowered by [8]federal regulations stating that "an IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by [federal] policy," and that no university official can overturn such decisions. Institutions that disobey this mandate risk losing millions of dollars in funds; individual researchers risk denial of degrees, promotion, or even the right to continue any research.

Take away this coercive power, and perhaps historians will learn to respect IRBs. Until then, expect them to resist.

1. http://historians.org/Perspectives/issues/2007/0703/0703vie2.cfm
2. http://ohsr.od.nih.gov/guidelines/belmont.html
3. http://www2.blogger.com/%3C%20http://www.hhs.gov/ohrp/irb/irb_acknowledgments.htm
4. http://www.primr.org/about/bod.html
5. http://www.citiprogram.org/
6. http://www.hhs.gov/ohrp/sachrp/
7. http://institutionalreviewblog.blogspot.com/2007/02/in-search-of-expertise.html
8. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.109

2.3.4 My Problem with Anthropologists (2007-03-18 16:28)

(In honor of the discussion going on at [1]Savage Minds, I present some thoughts on the role of anthropologists in the IRB debates.)

In terms of methods, anthropology and oral history seem to have a lot in common. Researchers in both disciplines enjoy learning about other people's lives by talking to those people, often with a recording device. But the two fields have different ethical approaches, and I sometimes fear this makes anthropologists unreliable allies in the struggle for

the freedom of research.
The problem starts with the [2]code of ethics of the American Anthropological Association, which states that

> anthropological researchers have primary ethical obligations to the people, species, and materials they study and to the people with whom they work. These obligations can supersede the goal of seeking new knowledge, and can lead to decisions not to undertake or to discontinue a research project when the primary obligation conflicts with other responsibilities, such as those owed to sponsors or clients. These ethical obligations include to avoid harm or wrong, understanding that the development of knowledge can lead to change which may be positive or negative for the people or animals worked with or studied.

Maybe I am missing something, but I don't see anything in the American Sociological Association's [3]code of ethics, the [4]Principles and Standards of the Oral History Association or the American Historical Association's [5]Statement on Standards of Professional Conduct that obliges members of those organizations to avoid harm or to abandon the pursuit of knowledge lest someone be hurt. In seeking a balance between truth and inoffensiveness, the anthropologists have gone much further toward physicians' Hippocratic standard of doing no harm than have their fellow social scientists. This decision may explain some troubling behavior:

1. Knee-Jerk Anonymity

My favorite anthropologist is Kathryn Marie Dudley, author of Debt and Dispossession and The End of the Line. Both books show how Americans struggle to reconcile their faith in the free market with their often conflicting belief that hard work should be rewarded regardless of market demand. That tension is central to many of today's cultural and political debates, and Dudley did a magnificent job getting Midwestern farmers, teachers, and automobile workers to talk about their beliefs.
My complaint is that having done so, she fabricated names for her narrators, and barely felt the need to explain that decision. (Each book has a two-sentence note declaring that she wished to protect the privacy or confidentiality of the narrators, not why she thought this necessary.)
This has terrible consequences. First, it prevents other researchers from learning more about the lives of the people she studies, the way Dudley's advisor, Katherine Newman, did by following up on the lives of her informants from a previous book. (Or at least it is supposed to. When I assigned Debt and Dispossession, one of my undergraduates did a quick search of newspaper databases and identified Dudley's pseudonymous "Star Prairie" and some of its inhabitants.) And second, it suggests that the people who are the subjects of her books are not real, important people the way that other figures in the books—Lee Iacocca and Jesse Jackson—are. Unlike Iacocca and Jackson, their backgrounds need not be explored, and their words need not have consequences.
Most significantly for this discussion, the assumption that anonymity should be the norm contributes to the idea that interviewing is a dirty, dangerous activity. Of course some narrators wish their names to be disguised, and under some circumstances that is appropriate. But to see what happens when anonymity is the exception, not the rule, compare Dudley's books to historian Leon Fink's Maya of Morganton, another wonderful study of work in contemporary America. Fink offered anonymity to all his subjects, but the only ones who chose it were powerful executives and lawyers, not ordinary workers. In his book, interviews are opportunities to be heard, not sources of shame.

2. Disciplinary Imperialism

A voice of moderation in the IRB debates it that of Kristine L. Fitch, Professor of Communication Studies at the University of Iowa. (Since she defines herself as an ethnographer, I am including her in this rant about anthropologists. Perhaps that is unfair, but keep reading before you decide.) Fitch has been through IRB fights on both sides. In the 1990s, she writes, "I saw firsthand the aspects of human subjects review that so frustrate social science researchers, particularly those in the qualitative/ethnographic domain: applications full of questions aimed at biomedical research, requirements to obtain written consent despite cultural barriers to doing so, board members who said, in so many words, that their goal was to put a stop to as much research as they could." ("Ethical and Regulatory Issues," noted below.)

Fitch joined the University of Iowa's social and behavioral IRB as chair and developed training materials that focused on the challenges faced by social scientists, in contrast to the medically-oriented materials mandated by most IRBs. At Iowa, researchers have their choice between "a two-hour workshop [focused on social and behavioral research], or completion of the National Institutes of Health (NIH) web-based certification course." (See Fitch, "Difficult Interactions between IRBs and Investigators: Applications and Solutions," Journal of Applied Communication Research 33 [August 2005]: 269–276. Apparently social-science ethics require live teachers, while medical ethics can be done in multiple-choice.) To help researchers and IRBs beyond Iowa, Fitch helped develop a CD and online training course called "[6]Ethical and Regulatory Issues in Ethnographic Human Subjects Research."

It is encouraging to see some training materials built from the ground up for social scientists. Rather than clubbing researchers over the head with more stories of Tuskegee, the CD focuses specifically on challenges in social-science research, such as how to protect privacy when studying sensitive topics, like eating disorders and illegal drug use.

But the CD goes wrong when it lumps in other disciplines with anthropology:

> An issue that frequently creates tension between ethnographic researchers and IRBs has to do with translation of the ethical principles outlined in the Belmont Report into interpretations of federal regulations governing human subjects research. Some disciplines, such as the American Anthropological Association, the Oral History Association, and others have established systems of ethical principles specific to the kinds of research most characteristic of their areas. Those ethical principles arise from particular disciplinary histories and have been crafted by respected members of those professions. As such, they are often defended as more relevant, appropriate, and in fact more stringent than the necessarily more distant philosophy of the Belmont Report. Part of the disputable territory between researchers and IRBs that becomes contentious, then, is the distinction between abstract ethical principles and the regulations that spell out particular definitions, distinctions and prohibitions. Although researchers and IRBs would probably agree on ethical principles interaction between them is usually limited to the application of regulations to particular procedures, wording of consent documents, and so forth.

Did you catch the sleight of hand? Because anthropologists "and IRBs would probably agree on ethical principles," Fitch assumes that "researchers and IRBs would probably agree on ethical principles." I, for one, do not, and I see nothing in the guidelines of the Oral History Association that conforms to the Belmont Report's demands for beneficence or what it calls justice. (See [7]"Ethical Training for Oral Historians.")

Beyond this misperception, I think Fitch is simply naïve about the operations of IRBs. "Ethical and Regulatory Issues," for example, states that "IRB chairs and board members often have seen firsthand the negative consequences of . . . unanticipated problems." Talk to researchers, talk to IRB members, read the postings on [8]IRB Forum, and I think you'll see that IRBs generally make decisions based on guesswork and what other IRBs are doing (in Fitch's terms "long and thoughtful discussion among several reasonable people"), not firsthand or scholarly knowledge of the consequences of poor protocol design. If IRBs were required to support each decision with real-life examples of comparable projects gone bad, we would have many fewer restrictions on research, and essentially none on oral history.

And then there's her claim in "Difficult Interactions" that "university administrators have a stake in human subjects oversight being carried out effectively and should be open to addressing problems within their IRB system. If they are not, the Office of Human Research Protection (OHRP) can be notified of hypervigilant regulation on the part of a local IRB. They can sanction IRBs for over-interpretation or misapplication of regulations when there is evidence that such is the case." If OHRP has ever sanctioned an IRB for hypervigilance, I would love to hear about it.

3. Submission to the IRB Regime

What really concerns me are anthropologists in government, and here I am thinking of Stuart Plattner. Plattner served for thirteen years as the human subjects specialist for the National Science Foundation, and he worked to moderate some of the claims of IRBs. For example, the NSF's website, "[9]Frequently Asked Questions and Vignettes: Interpreting the Common Rule for the Protection of Human Subjects Behavioral and Social Science Research," created under his watch, includes the clearest statement by a federal agency that the Common Rule does not apply to classroom

projects.

But Plattner is too ready to apply anthropology's delicate ethics to other fields. In his 2003 Anthropological Quarterly article, "Human Subjects Protection and Cultural Anthropology," he complains of "biomedical hegemony," that is, the imposition of biomedical ethics on other disciplines. Yet in the same article he promotes a sort of anthropological hegemony when he writes, "no one should ever be hurt just because they were involved in a research project, if at all possible." That's consistent with anthropologists' ethical statements, but other disciplines are happy to bring malefactors to account.

Where Plattner really gets scary is in his more recent "Comment on IRB Regulation of Ethnographic Research" (American Ethnologist 33 [2006]: 525–528). There he writes,

> The journalist has a mandate from society to document contemporary reality. It is expected that this may involve an exposure of wrongdoing. A reporter's reason for getting information from a person is to establish what happened. Those who speak to reporters accept the potential for harm that publicity may bring. Social scientists have no such mandate; we document reality to explain it. Our audience is professional, and society gives us no protection in the First Amendment. Our reason for getting information from individuals is to help us explain general processes. A normal condition for an ethnographic encounter or interview is that the information will never be used to harm the respondent.

The line that "our audience is professional" is simply defeatist; my undergraduates enjoyed Dudley's books, and I hope plenty of readers outside the academy have found them as well. The bit about seeking to "explain general processes" is at odds with historians' study of contingency, and I hope that other social scientists would reject that notion as well. But for the issue at hand, the key statement is that "society gives us no protection in the First Amendment."

As a matter of jurisprudence, this is simply false. First Amendment liberties are common to all Americans, and if anything scholars enjoy heightened protection. In the 1967 case Keyishian v. Board of Regents of the University of the State of New York ([10]385 U.S. 589) the Supreme Court held that "our Nation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us, and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment, which does not tolerate laws that cast a pall of orthodoxy over the classroom." It's shocking that Plattner, who served so long as perhaps the most senior social scientist involved in shaping federal human subjects policy, has such little understanding of the law and such little concern for academic freedom.

Of course many anthropologists have written critically of IRB interference with their research. In the same journal that features Plattner's dismissal of academic freedom, Richard Schweder eloquently argues that "a great university will do things that are upsetting," citing Socrates, rather than Hippocrates, as the best Greek model for social science. ("Protecting Human Subjects and Preserving Academic Freedom: Prospects at the University of Chicago," American Ethnologist 33 [2006]: 507–518). Yet who best represents the discipline: Schweder or Plattner? How far a leap is it from the American Anthropological Association's subordination of the search for knowledge to Plattner's suggestion that the First Amendment does not apply to scholarly research? Can anthropologists fight for academic freedom while holding that research shouldn't hurt?

1. http://savageminds.org/2007/03/09/please-welcome-guest-blogger-rena-lederman/
2. http://www.aaanet.org/committees/ethics/ethcode.htm
3. http://www.asanet.org/galleries/default-file/Code%20of%20Ethics.pdf
4. http://omega.dickinson.edu/organizations/oha/pub_eg.html
5. http://www.historians.org/pubs/Free/ProfessionalStandards.cfm
6. http://research.uiowa.edu/hso/resources/ethnographic/
7. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm
8. http://www.irbforum.org/
9. http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp
10. http://www.law.cornell.edu/supct/html/historics/USSC_CR_0385_0589_ZS.html

Anonymous (2007-03-25 00:14:00)

Given that you state that historians have no ethical demands to "to avoid harm or to abandon the pursuit of knowledge lest someone be hurt" , could you elaborate on what kind of harm you, or oral historians in general, are comfortable with in terms of causing harm or hurt as a result of your rearch to human subjects?

Or are you pointing out that the kind of research oral historians or social scientists do has no potential to cause real harm so why worry about the consequences?

Zachary M. Schrag (2007-03-25 21:38:00)

Thanks for your question. The type of harm historians should accept is harm to reputation.

Let me give you an example. In the early 1970s, Harry Weese, the chief architect of the Washington Metro, opposed the addition of elevators to Metro stations, something demanded by people who used wheelchairs and their advocates. In his 1991 interview for the [1]Chicago Architects Oral History Project (an absolutely superb project, by the way), Weese explained,

"what we don't like is the government being a fall guy for the handicapped. The handicapped got very tough in Washington, slowed us down for two or three years and that added a huge amount of cost to upgrading the building. They wanted all kinds of fancy gadgets."

(Harry Mohr Weese, interview by Betty J. Blum, Chicago Architects Oral History Project, 1991)

The first question is whether this statement "could reasonably . . . be damaging to [Weese's] financial standing, employability, or reputation," the criterion for review under 45 CFR §46.101(b)(2)(ii). The first two seem unlikely, and there may be many people out there who applaud Weese's willingness to stand up to the handicapped. But the callousness of this statement certainly diminished my own admiration for Weese, and every time I have talked to audiences about the elevator debate, they side with the advocates for the handicapped. So let's stipulate that by printing this statement, Blum damaged Weese's reputation.

Good for her. Her job as a historian was to seek and report the truth, not to edit out any unpleasantness. Saying only nice things about other people makes for good manners but bad history.

1. http://www.artic.edu/aic/libraries/caohp/

Jeffrey Cohen (2007-04-19 11:15:00)

This discussion about harm is based on a misunderstanding of the principle of beneficence in the Belmont Report and in the regulations. The principle is not limited to "do no harm", but, rather, requires that the risks of the research be balanced by the benefits to come from the research. As the regulations state [45 CFr 46.111(a)(2)]: "Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result." Neither the Belmont Report nor the regulations require that research not harm subjects, only that any risks are justified by the potential benefits to come from the research. I can't imagine that any reputable scholar in any field would be willing to harm individuals for no good reason. Presumably, the benefits to be derived from Blum's work justifies the damage to the respondant's reputation. If the respondent had inadvertantly admitted during the interview that he beat his wife, would Blum have published that? I would guess not, because there would be no benefit to publishing that (although she might have felt compelled to report it to the appropriate officials to protect the wife). IRBs that impose an absolute "do no harm" requirement are misapplying both the Belmont Principles and the regulations.

Zachary M. Schrag (2007-04-19 13:50:00)

An oral historian following the

[1]Principles and Standards of the Oral History Association would not publish an inadvertent comment by Weese, whether it involved beating his wife or winning the Brunner Prize. The procedures specified by the standards are designed to make all comments as advertent as possible. This tracks the Belmont Report's call for respect for autonomy.

But this has nothing to do with beneficence, since it leaves narrators free to record comments that are damaging to themselves yet useless to society.

Dr. Cohen writes, "I can't imagine that any reputable scholar in any field would be willing to harm individuals for no good reason." If the search for truth alone is enough of a reason to justify harm to a narrator's reputation, then all oral history projects are justified, and we do not need IRBs to test for beneficence.

I challenge Dr. Cohen to provide examples of IRBs that have engaged in what the Belmont Report calls a "Systematic Assessment of Risks and Benefits" of oral history projects and come up with a meaningful result that reflects the ethics of oral history.

1. http://omega.dickinson.edu/organizations/oha/pub_eg.html#Principles%20and%20Standards

2.3.5 PRIM&R Plans SBER Conference (2007-03-19 15:13)

Public Responsibility in Medicine and Research (PRIM &R), the professional organization for human subjects enforcers, has scheduled the "[1]2007 Social, Behavioral, Educational Research (SBER) Conference: Sharing Tools and Joining Forces: Ethical and Regulatory Balance in SBER." The conference will be held in Broomfield, Colorado, on May 9 and 10.

The conference is notable because its planning committee includes two scholars who have written quite critically of IRB review of non-biomedical research: C. Kristina Gunsalus and Joan E. Sieber. (An earlier announcement also listed Felice J. Levine, but her name does not appear on the website.)

The conference program includes two sessions that promise to wrestle with the murky questions of definitions and exemptions:

> A4. Developing Guidance on the Definition of Human Subjects Research (IRB Tool Kit I Track) [Please note that this is a double session and will end at 1:15 PM. This session has been designed with the dual purpose of discussing strategies and contributing to a written document that will provide guidance, definitions, and examples. This document will be electronically distributed to all Conference attendees following the meeting.]
>
> A5. Developing Guidance on Applying the Exemptions
>
> (IRB Tool Kit II Track) [Please note that this is a double session and will end at 1:15 PM. This session has been designed with the dual purpose of discussing strategies and contributing to a written document that will provide guidance, definitions, and examples. This document will be electronically distributed to all Conference attendees following the meeting.]

Potentially these documents could provide IRBs the guidance and cover they need to exempt survey, interview, and observation research with autonomous adults. While I am sorry I will not be able to attend the conference, I am very interested to see what it produces.

1. http://www.primr.org/education/2007_SBER/overview_SBER_07.html

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2.4 April

2.4.1 Anthropologist Patricia Marshall Appointed to SACHRP (2007-04-05 10:35)

The Department of Health and Human Services has [1]announced the appointment of a new chair and three new members to the Secretary's Advisory Committee on Human Research Protections. Among the three new members is Professor [2]Patricia A. Marshall of Case Western University. Like Lorna Rhodes who left the committee in 2006, Marshall is a medical anthropologist, making me wonder if the department has unofficially reserved a seat for such a scholar, who is then supposed to represent all social scientists.

Marshall brings a somewhat critical perspective, having complained about her own treatment by an IRB. In the early 1990s, she wanted to interview patients in a waiting room, and—in a classic example of IRB formalism–her IRB insisted that because she was doing research in a medical setting, she had to warn her interview subjects that "emergency medical treatment for physical injuries resulting from participation would be provided." (Patricia A. Marshall, "Research Ethics in Applied Anthropology," IRB: Ethics and Human Research 14 [Nov. - Dec., 1992]: 1-5).

Perhaps as a result of this experience, she has maintained some skepticism about IRB review of anthropology, as

expressed in her essay, "Human Subjects Protections, Institutional Review Boards, and Cultural Anthropological Research," Anthropological Quarterly 76 (Spring 2003): 269-285. That essay shows Marshall's familiarity with much of the critical literature on IRBs, and she repeats some of that criticism herself:

- "IRBs may be overly zealous in their interpretation and application of federal guidelines, exacerbating the challenges faced by anthropologists and other professionals in seeking approval for studies." (270)
- "Although committees must include representatives from diverse scientific fields and the community, IRBs have a strong orientation to biomedical and experimental research. In fact, a significant flaw in the development of the federal guidelines for ethical research is that social scientists were not included in the process. The result is a conflation of two related problems for anthropologists: first, the Common Rule emphasizes concerns for biomedical researchers; and second, most IRBs do not have members with expertise in anthropological methods." (272)
- "Misapplications of the Common Rule and inappropriate requests for revisions from IRBs can have a paralyzing effect on anthropological research. Moreover, it reinforces a cynical view of institutional requirements for protection of human subjects, and it uses scarce resources that would be better spent on studies involving greater risks for participants." (273)

Given her understanding of these problems, one might expect her to advocate, or at least consider, the exclusion of anthropological research from IRB review. Instead, she concludes, "regulatory oversight by IRBs is a fact of life for scientific researchers. Anthropologists are not and should not be exempt." (280)
Huh?
This conclusion is so contrary to the rest of the essay that I can only guess at how it got in there. Perhaps it represents a resigned surrender after years of failed efforts to exclude some review. Perhaps it is a failure of imagination. Perhaps Marshall believes that only by embracing IRB review will anthropologists be taken seriously by the biomedical researchers she works with.
Or perhaps the key issue is that Marshall fits the pattern I mentioned earlier of some [3]anthropologists' embrace of the Belmont Report principles. In "Research Ethics in Applied Anthropology," Marshall cites not the Code of Ethics of the American Anthropological Association, but the comparable [4]Ethical Guidelines of the National Association for the Practice of Anthropology, which state that "Our primary responsibility is to respect and consider the welfare and human rights of all categories of people affected by decisions, programs or research in which we take part."
I have no complaint with applying those guidelines to their intended subject: "a professionally trained anthropologist who is employed or retained to apply his or her specialized knowledge problem solving related to human welfare and human activities." But they are inappropriate restrictions for scholars whose primary role is academic inquiry, not problem solving.
Thus, like Stuart Plattner, Marshall uncritically assumes that one field's ethics can be imposed on another. She writes, "ethical principles governing applied anthropological research are not unique to this discipline. Respect for persons, beneficence, and justice are fundamental concerns for any scientist." ("Research Ethics in Applied Anthropology," 4) While that sounds lovely, the latter two terms, as defined by the Belmont Report, are foreign to the ethical codes of most academic research. Until she recognizes the distinction between problem-solvers whose primary goal is to do no harm and researchers whose primary goal is to seek the truth, she will be a poor advocate for most scholars in the social sciences and humanities.
Yet in previous work, Marshall herself has argued against the idea that humans share a single set of ethics, recognizing instead that "ethics and values cannot be separated from social, cultural, and historical determinants that regulate both the definition and resolution of moral quandaries." ("Anthropology and Bioethics," Medical Anthropology Quarterly, New Series, 6 [Mar., 1992]: 62) If she brings that insight to the committee, perhaps she will recognize the basic wrongness of forcing Belmont's biomedical ethics on non-biomedical fields.

1. http://www.hhs.gov/news/press/2007pres/20070329.html
2. http://www.case.edu/med/bioethics/pam20.htm
3. http://institutionalreviewblog.blogspot.com/2007/03/my-problem-with-anthropologists.html
4. http://www.practicinganthropology.org/inside/?section=resources_ethical_guidelines

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2.4.2 What is PRIM&R? (2007-04-13 20:49)

In a comment on an earlier [1]posting, Dr. Jeffrey Cohen takes issue with my referring to Public Responsibility in Medicine and Research (PRIM &R) as "a body dominated by professionals involved in biomedical research."
[2]Cohen writes,
"even though PRIM &R's name refers to medicine, that is a carry over from it formation over 30 years ago. Since then PRIM &R has grown into an organization that includes all aspects of human subjects research, including the social sciences."
PRIM &R indeed seeks to control many kinds of research, but it fails to include all types of researchers. Its [3]board of directors includes 22 active members. Nineteen of them (86 percent) are by training or affiliation clearly in the biomedical camp. Of the remaining three, Charles McCarthy is a former senior official at the National Institutes of Health. That leaves two university IRB officials—Keane and Selwitz—as the sole directors whose affiliation is not primarily biomedical. No social or economic researchers sit on the board. That's what I call domination.
Even when PRIM &R ponders what it calls "social, behavioral, and economic research," it ignores social and economic researchers. The [4]faculty list for the upcoming "SBER" conference lists twenty people. Some of them are psychologists, known in IRB terms as behavioral scientists. But how many are researchers in economics, the social sciences, or the humanities? Well, if we count law, there's one.
So let me amend my comment: PRIM &R is a body dominated by professionals involved in biomedical research who like to impose medical ethics on other fields.

1. http://institutionalreviewblog.blogspot.com/2006/12/carome-cohen-and-normal-science.html
2. http://institutionalreviewblog.blogspot.com/2006/12/carome-cohen-and-normal-science.html#comment-2859376995421987906
3. http://primr.org/about/bod.html
4. http://primr.org/education/2007_SBER/Faculty%20List.pdf

Jeffrey Cohen (2007-04-17 08:25:00)

First of all, PRIM &R does not "control" research and does not "like to impose medical ethics on other fields". PRIM &R is solely an educational and professional organization. It conducts educational programs, such as conferences, and professional development activities for its members. It does not regulate research or IRBs, nor does it set policy on human subjects research.

I will concede your point about the membership being dominated by biomedical people and I have passed along your concern to the PRIM &R officers.

Given that, however, PRIM &R has always addressed social and behavioral science issues in its conference. I have been atending and participating in almost all of the PRIM &R human subjects conferences since 1979 (probably when you were in grade school) and they have always included sessions on these issues. Many distinguished social and behavioral scientists, including historians & economists, have been on the faculty and have participated in workshops and panels. Last year we invited Linda Shopes to the conferenc. She participated on a panel on oral history and IRBs (with me) and moderated several workshops. We would be happy to include more historians in this year's conference. In fact, if you would like to participate in the conference, we'd be happy to work you in to the program (provided you have something constructive to say). Conversely, how many IRB people have been invited to professional meetings in your discipline? I would be happy to come to any meeting of historians and defend IRBs.

With regard to the upcoming PRIM &R SBER Conference in May, what you posted was a early, preliminary list of the faculty.

The final list will have more social scientists. We also tried to get more social science researcher to participate, but many that we contacted could not make the conference. I am Co-Chair of the conference (along with Tina Gunsalus) and the conference is dedicated, among other things, to educating IRBs on how to use the flexibility in the regulations to review SBER research without unduly burdening or interfering with the research process.

Zachary M. Schrag (2007-04-18 00:05:00)
I am deeply frustrated by disclaimers of responsibility like the one that begins Dr. Cohen's comment. IRB members attend PRIM &R conferences and purchase PRIM &R training materials. For Cohen to claim that PRIM &R does not control research is like Wal-Mart claiming that it has no responsibility for the sweatshop conditions in its suppliers' factories. In theory, the IRBs and the factories are independent, but in practice, they follow guidance from above.
PRIM &R does have a good record of inviting critics, going back to Pattullo and Pool in 1979. But I question the parameters under which they participate. If the purpose of the upcoming conference is to educate "IRBs on how to use the flexibility in the regulations to review SBER research," that already assumes that IRBs will regulate SBER research, and that SBER research is a meaningful category. It seems that PRIM &R's answer to complaints from social scientists always takes the form of expedited review, rather than consideration of excluding whole categories of research.
I appreciate the invitation to Colorado and regret that family responsibilities will keep me from traveling in May. Should I find myself on a program committee or panel dealing with these issues, I will keep in mind Dr. Cohen's kind offer to participate.

2.4.3 Jeffrey Cohen on Generalizable Knowledge (2007-04-17 23:40)

Dr. Jeffrey Cohen, an important figure in the IRB world, has offered further comments on a [1]post I wrote in December. I appreciate his attention to my writing, and lest his critique be lost in the comments section of such an old post, I present it here as well:
Cohen writes:

> Whether the National Commission adequately considered non-biomedical research in its deliberations is a matter of historical interest, but not directly relevant to understanding the regulations. The regulations were not written by the National Commission, but by individuals within the then Department of Health and Human Services. The regulations, as they are written, do not relate "generalizable knowledge" to disease. When those regulations were written, in the late 1970s, they were always intended to cover non-biomedical research. I was at the PRIM &R meeting in the fall of 1979 when officials from the Office for the Protection from Research Risks (OPRR, the predecessor to OHRP) discussed how the "new" regulations would apply to the social and behavioral sciences. At that meeting they discussed how they were building into the regulations adequate flexibility for IRBs to effectively review social and behavioral research. The subsequent regulations had that flexibility built in and it works well. The interpretation of "generalizable knowledge" that I described in my comment works to help us differentiate between research that needs IRB review and that which does not.

Let me respond step by step:
1. Cohen writes: "Whether the National Commission adequately considered non-biomedical research in its deliberations is a matter of historical interest, but not directly relevant to understanding the regulations. The regulations were not written by the National Commission, but by individuals within the then Department of Health and Human Services."
Schrag responds: When the regulations were revised in 1979, the [2]Federal Register reported: "The Department of Health, Education, and Welfare (HEW or Department) is proposing regulations amending HEW policy for the protection of human research subjects and responding to the recommendations of the National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research (Commission) concerning institutional review boards (IRBs or Boards). These proposed rules adopt, for the most part, the recommendations of the Commission . . ." Since the stated goal of the revision was to follow the National Commission, I would expect serious interpretation to include attention to that Commission. I also note that the term we are debating, "generalizable," was introduced into the regulations as a result of its appearance in the Commission's [3]Belmont Report.
2. Cohen: "The regulations, as they are written, do not relate 'generalizable knowledge' to disease."
Schrag: I repeat, [4]Section 46.406 twice refers to "generalizable knowledge about the subjects' disorder or condition."
3. Cohen: "When those regulations were written, in the late 1970s, they were always intended to cover non-biomedical research. I was at the PRIM &R meeting in the fall of 1979 when officials from the Office for the Protection from Research Risks (OPRR, the predecessor to OHRP) discussed how the 'new' regulations would apply to the social and behavioral sciences. At that meeting they discussed how they were building into the regulations adequate flexibility for IRBs to effectively review social and behavioral research."
Schrag: At the same PRIM &R meeting, psychologist E. L. Pattullo lamented, "what began as fifteen years ago as an afterthought about legitimate concern for the protection of biomedical subjects has become, at present, a classic example of counterproductive over-regulation." Political scientist Ithiel de Sola Pool called the regulations "grossly improper and unconstitutional." ([5]PRIM &R Through the Years, pp. 37 and 42) In other words, for nearly three decades, federal officials have been trying to impose medical ethics on the social sciences, and social scientists have resisted. That some (not all) of the regulations' authors intended this imposition does not make it proper.
4. Cohen: "The subsequent regulations had that flexibility built in and it works well. The interpretation of 'generalizable knowledge' that I described in my comment works to help us differentiate between research that needs IRB review and that which does not."
Schrag: These are empirical claims that demand evidence. One of the purposes of this blog is to document cases where the current regulations do not work well, and I invite readers to read past posts and follow the links and references to choose their own examples. February's [6]New York Times story and November's [7]Chronicle of Higher Education story make a fine introduction.
On his blog, [8]Dr. Cohen offered his own interpretation of the term "generalizable," and here he claims that it "works to help us differentiate between research that needs IRB review and that which does not." Who is "us"? What institutions have taken Cohen's advice, and do the historians there feel they have been treated fairly?

1. http://institutionalreviewblog.blogspot.com/2006/12/carome-cohen-and-normal-science.html
2. http://www.hhs.gov/ohrp/documents/19790814.pdf
3. http://ohsr.od.nih.gov/guidelines/belmont.html
4. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.406
5. http://www.primr.org/resources/through_the_years.html
6. http://www.nytimes.com/2007/02/28/arts/28board.html
7. http://chronicle.com/free/v53/i12/12a01401.htm
8. http://hrpp.blogspot.com/2006/11/ohrp-and-oral-history.html

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2.4.4 Yale historians vs. Yale IRBs (2007-04-19 17:27)

Kanya Balakrishna, "[1]Humanities research may see more rules," Yale Daily News, 17 April 2007.
At Yale, Human Subjects Committee chair Susan Bouregy believes everyone is happy: "Humanities research at Yale is reviewed by an IRB which reviews exclusively social science, behavioral, educational and humanities research so there is a degree of familiarity with the techniques and practices of these disciplines as well as where the regulations allow flexibility to meet the needs of these types of projects."
But the reporter also talked to three Yale historians, all of whom thought IRB review was inappropriate. For a dissenting voice, she had to go to [2]Taylor Atkins, perhaps the only historian to go on record in favor of IRB review.

1. http://www.yaledailynews.com/articles/view/20774
2. http://institutionalreviewblog.blogspot.com/2007/03/why-irbs-are-not-peer-review-reply-to-e.html

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2.4.5 The Canard of Interview Trauma (2007-04-24 10:12)

In his essay, "[1]Oral History and IRBs," historian Taylor Atkins justifies IRB review of oral history in large part based on the alleged risk that interviewers will traumatize their narrators. He writes:

> As unimpeachable as the OHA's own Professional Guidelines may be, I think it is arrogant to assume that oral historians have nothing to learn from other disciplines with regard to the ethical treatment of human subjects. If nothing else, they can become more sensitized to the possibilities for psychological or social harm that may result from oral history interviewing. Whenever our IRB reviews a protocol from the psychology department that involves questions about childhood abuse or some other trauma, we make sure that the investigator is either qualified to directly provide appropriate counseling or intervention, or provides a list of appropriate support services. How many oral historians have the expertise or qualifications to handle a situation in which an informant with PTSD experiences distress during an interview? How many would have a list of counseling services at hand in case it was necessary? How many even imagine such a scenario when they venture out with their tape recorders?

I would like to suggest that historians don't imagine such a scenario because it doesn't happen.
When I asked Atkins what made him think interviews could traumatize narrators, he replied,

> when I was at the 2004 OHA meeting, I attended a panel on the Veterans' Oral History Project, at which the presenters very casually remarked that several veterans, being interviewed by small groups of fourth-graders, broke down into tears when talking about their battlefield experiences. My first thought was, "so how did a bunch of fourth-graders respond to that?" Breaking down crying is not always indicative of PTSD, but you surely understand that the possibility is there.

As Atkins concedes, crying is not trauma requiring "counseling or intervention" by a licensed therapist. Basic decencies—a pause in the recording and some words of sympathy—are enough. And while the possibility of real trauma exists, so does the possibility that a narrator will fall down the stairs trying to answer the interviewer's knock at the door. The question is whether the risk is great enough to justify the hassle of IRB review, and Atkins presents no evidence that it is. Historians have recorded oral history interviews for half a century, and he cannot point to one that has traumatized the narrator.
Having imagined a harm, Atkins also imagines a remedy: "a list of appropriate support services" to be tucked into the interviewer's bag, next to spare batteries for the recorder. Unsurprisingly, he has no evidence that such a list has ever helped anyone.
For researchers in parts of the world where such support services are common, carrying such a list isn't much of a burden. But the paperwork and training it takes to get to the point where the IRB will approve one's project is a real burden. And the requirement of a list could disrupt research in parts of the world where those services don't exist, or even for a researcher who travels around the United States to collect stories, and would have to carry lists for each area she visits.
Atkins is not alone in making such claims. Comparable fears appear in Lynn Amowitz, et al., "Prevalence of War-Related Sexual Violence and Other Human Rights Abuses among Internally Displaced Persons in Sierra Leone," JAMA 287 (2002), 513-521, and Pam Bell, "The Ethics of Conducting Psychiatric Research in War-Torn Contexts,"

in Marie Smyth and Gillian Robinson, Researching Violently Divided Societies (Tokyo: United Nations University Press, 2001). But neither Amowitz nor Bell cites any evidence to suggest that interview research traumatizes narrators. (If anything, Bell's piece indicates that narrators know how to protect themselves, for example, by choosing to be interviewed as a group rather than one-on-one.)

In contrast, the existing empirical evidence suggests that, if anything, conversation is therapeutic. In her essay, "Negotiating Institutional Review Boards," Linda Shopes cites three articles to make this point:

- Kari Dyregrov, Atle Dyregov, and Magne Raundalen, "Refugee Families' Experience of Research Participation," Journal of Traumatic Stress 12:3 (2000), 413–26.
- Elana Newman, Edward A. Walker, and Anne Gefland, "Assessing the Ethical Costs and Benefits of Trauma-Focused Research," General Hospital Psychiatry 21 (1999), 187–196.
- Edward A. Walker, Elana Newman, Mary Koss, and David Bernstein, "Does the Study of Victimization Revictimize the Victims?" General Hospital Psychiatry 19 (1997), pp. 403–10.

To these I would add Elisabeth Jean Wood, "The Ethical Challenges of Field Research in Conflict Zones," Qualitative Sociology 29 (2006): 373-386. Wood writes:

> While the discussion of this consent protocol initially caused some interviewees some confusion, once the idea had been conveyed that they could exercise control over the content of the interview and my use of it, participants demonstrated a clear understanding of its terms. In particular, many residents of my case study areas took skillful advantage of the different levels of confidentiality offered in the oral consent procedure. This probably reflected the fact that during the war residents of contested areas of the Salvadoran countryside daily weighed the potential consequences of everyday activities (whether or not to go to the field, to gather firewood, to attempt to go to the nearest market) and what to tell to whom. Moreover, I had an abiding impression that many of them deeply appreciated what they interpreted as a practice that recognized and respected their experience and expertise. Although for many telling their histories involved telling of violence suffered and grief endured, I did not observe significant re-traumatization as a result, as have researchers in some conflict settings (Bell, 2001). I believe the terms of the consent protocol may have helped prevent re-traumatization as it passed a degree of control and responsibility over interview content to the interviewee.

(It's worth repeating that Bell's article presents no observations of re-traumatization.)

Though I have not interviewed trauma survivors myself–at least, not about their trauma–I have no doubt that it is a tricky business. If anyone can show me that interviews can aggravate real trauma, I welcome correction. I would also welcome more scholarship on how interviewers can maximize the catharsis described by Wood.

Unfortunately, the arbitrary power enjoyed by IRBs relieves them of the responsibility or incentive to seek out such real solutions to real problems. Atkins and his colleagues can dream up phantom menaces and require burdensome, useless conditions based only on guesswork. Only the removal of their power is likely to force them to support their arguments with evidence.

Note: I thank Amelia Hoover for pointing me to the Wood and Amowitz articles.

1. http://historians.org/Perspectives/issues/2007/0703/0703vie2.cfm

2.4.6 Alternative IRB Models Conference Ignores Behavioral and Social Research (2007-04-27 21:27)

The Association of American Medical Colleges has posted the report of the November 2006 [1]"National Conference on Alternative IRB Models." The 53-page report's findings concerning social and behavioral research consist of a single sentence: "Finally, participants observed that social and behavioral research has not been widely discussed during this conference and deserves further exploration."

This is probably not much of a loss, since the various alternatives studied at the conference appear irrelevant to social and behavioral research. But the comment does continue a long tradition of promises that the methods, ethics, and needs of social scientists will get the attention they deserve . . . someday.

1. http://www.aamc.org/research/irbreview/2006/start.htm

2.5 May

2.5.1 PRIM&R Finds Another Social Researcher (2007-05-07 17:13)

On [1]April 13, I noted that the preliminary faculty list for this week's "Social, Behavioral, Educational Research Conference" included only one social researcher among twenty faculty. One of the conference's organizers, Jeffrey Cohen, replied that "the final list will have more social scientists." Well, the [2]final list includes one more researcher: Steven Pennell, Survey Director, University of Michigan. Since the total list has been expanded to 33 faculty, this brings the representation of social researchers from five percent up to six percent. Many of the panels will feature no such representation at all.

The conference [3]announcement asks, "Why is it often so difficult for IRBs and investigators to work together effectively when reviewing sophisticated, socially sensitive social/behavioral/educational research?" One answer might be PRIM &R's apparent belief that IRB administrators can learn to regulate research without hearing from researchers.

1. http://institutionalreviewblog.blogspot.com/2007/04/what-is-prim.html
2. http://primr.org/education/2007_SBER/Faculty%20List.pdf
3. http://primr.org/education/2007_SBER/program_SBER_07.html

Jeffrey Cohen (2007-05-14 08:49:00)

I don't understand why you continue to criticize a program designed to explain and encourage the use of the flexibility available in the regulation and to promote communication and collaboration between IRBs and investigators to facilitate research. If you were to talk to any of the over 400 people who attended the conference you would hear that this message came through loud and clear, including from the ORHP representatives that were there. I can only conclude that you have no interest in making IRB review work better for researchers, but only in eliminating IRB review for your research.

With regard to the faculty, there were 12 researchers out of 33 on the faculty, including psychologists, sociologists, social workers and epidemiologists (who are social scientists). Most of the rest of the faculty were IRB administrators from institutions that primarily review social and behavioral research. Admittedly, we didn't have faculty from all areas of the social and behavioral research and no one from oral history (although I did ask you to come). We were limited by the dates of the conference and those researchers who were available. The members of the planning committee contacted many more researchers to participate, but most were not able to make it. If you have any suggestions for faculty for the fall PRIM &R meeting, we'd be happy to consider them.

The concerns of oral historians and other researchers received considerable airing and discussion at the conference, including from Tina Gunsalus, the conference co-chair.

Zachary M. Schrag (2007-05-16 23:36:00)
Thanks for these comments.
I am glad the conference went well, and I will look forward to reports from researchers at hundreds of institutions that their IRBs are offering greater flexibility.
While I am waiting, I have responded to your comments at greater length in a new post: [1]PRIM &R's Public Responsibilities.

1. http://institutionalreviewblog.blogspot.com/2007/05/prim-public-responsibilities.html

2.5.2 Boise State University's IRB Makes a Poor First Impression (2007-05-10 11:39)

I received an anonymous comment expressing alarm about the new website of Boise State University's [1]Office of Research Administration.
The site presents the following information about the requirement of IRB review:

> Federal, state and university regulations require all research (including surveys and questionnaires) involving human subjects or data collected, directly or through records (i.e. medical records, specimens, educational test results, or legal documents) to be reviewed by an Institutional Review Board (IRB) . . .
> If you are a faculty or staff member, or student at Boise State University, and your research involves the use of human subjects (either directly or through records or other data such as specimens or autopsy materials), your research requires human subjects review.
> "Research" is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge." 45 CFR 46.102(d). Research includes surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration and service programs and clinical trials. In addition, FDA includes under the definition of reviewable research, any use of a FDA regulated product except for use of a marketed product in the practice of medicine.
> Note: Any administrative, departmental or course assignments involving surveys, questionnaires and interviews designed for internal use and operations of the University do not constitute "research" within the meaning of this policy if the information or conclusion of this data is not intended for scholarly publication or for dissemination to persons outside the administrative organization of the University.

That's it. No explanation of what federal and state regulations apply. No hint of the exceptions specified in [2]45 CFR 46.101, nor an easy way to learn more about the requirements.
The site does offer a link to the university's "[3]Human Research Protection Policy - BSU 6325 B," but that link, as well as others on the site, is broken. (Yesterday I wrote to the e-mail address on the site, pointing out these broken links, but I have not received a reply). There's also a link to an "[4]IRB Guideline Summary," which in turn offers a link to a Word document called "[5]TYPES OF IRB REVIEW AND APPROVAL," which finally lists the exceptions. Since neither of these link titles mention exceptions, a visitor who knows enough to find this document probably knows about the exceptions already.
All told, my correspondent can be forgiven for fearing (I hope mistakenly) that Boise State "seems to require submission to IRB for analysis of any record of human behavior."
Boise State's Office of Research Administration shows how to antagonize researchers before even meeting them. I would like to remind all such offices that researchers are trained to read critically. Offer them complete and accurate information, and cite your sources.
Update: The links were fixed on May 15.

1. http://ora.boisestate.edu/human_intro.html
2. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101

3. http://policy.boisestate.edu/index.asp?section=6&policynum=6325
4. http://ora.boisestate.edu/IRB_GUIDELINES_SUMMARY.html
5. http://ora.boisestate.edu/Forms/III.%20Types%20of%20IRB%20Review%20and%20Approval.doc

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2.5.3 PRIM&R's Public Responsibilities (2007-05-16 22:54)

[1]Jeffrey Cohen writes, "I don't understand why you continue to criticize a program designed to explain and encourage the use of the flexibility available in the regulation and to promote communication and collaboration between IRBs and investigators to facilitate research." His comment shows that I have not made clear my concern with PRIM &R's constitution and operation. Let me suggest, therefore, that PRIM &R is a semi-official body that fails to conduct itself in a manner commensurate to its power and responsibility.
We first need to understand PRIM &R's special status as a chosen instrument of the federal government. Unlike scholarly associations, whose [2]letters to OHRP get brushed off, PRIM &R has long functioned as an arm of OHRP and its predecessor, OPRR. For example,

- OHRP [3]promotes and distributes PRIM &R's "Investigator 101" CD-ROM. Similarly, PRIM &R prepared the first edition of the Department of Health and Human Services' [4]IRB Guidebook.
- Former OPRR head Charles McCarthy serves on the PRIM &R board; Cohen, a former OHRP official, co-organized the last conference; and current OHRP officials participate as PRIM &R conference faculty.
- OHRP exhibits at PRIM &R conferences, and OHRP officials, particularly Michael Carome, use PRIM &R conferences to offer [5]guidance that then gets broadcast by IRB consultants, such as Dr. Cohen.

Given these connections, an IRB member or staffer could reasonably assume that following PRIM &R's guidance is a good way to avoid sanctions by OHRP. (Indeed, she would be foolish to assume otherwise.) Since it these staffers who then return to their institutions and impose conditions on research there, PRIM &R is a key link in the chain between federal power and the daily work of researchers.
PRIM &R itself recognizes this function. For example, the recent conference provided attendees with documents offering [6]guidance on the regulatory definition of human subjects research and the proper application of the exemptions. Since providing just such guidance is one of the responsibilities of OHRP, the conference organizers must feel pretty confident that they have OHRP's blessing to take over this important role. (Note that unlike real OHRP guidance, PRIM &R's documents are not made public.)
If this is so, what must PRIM &R do to use its power wisely and justly?

1. Identify its constituents

[7]PRIM &R's website states that "since 1974, PRIM &R has served the full array of individuals and organizations involved in biomedical and social science/behavioral/educational research." But what constitutes that full array? Is "social science/behavioral/educational research" one category or three? If the latter, what disciplines come under which category? And are there varieties of research (such as folklore, nonfiction writing, and law) that fit none of those categories, yet that face IRB review?
I would like to see PRIM &R list all the disciplines that come under review by IRBs whose members it trains. Then it could try to make some distinctions, for example, between disciplines that offer therapy or advocacy and those that do not; disciplines that study the body and those that do not, disciplines that use formal scientific protocols and those that do not; and the like. This would lead to a second task:

2. Include a range of disciplinary perspectives

As I mentioned earlier, [8]PRIM &R's board of directors is dominated by researchers and administrators from hospitals and medical schools. They cannot be expected to be expert in the ethics and methodologies of the full range of disciplines in the behavioral sciences, social sciences, humanities, and professions, nor could any group of scholars drawn from any one field. If PRIM &R wants to offer sound guidance to researchers in all fields subject to IRB review, it should include them on every level, from conference panels to editorial boards to the board of directors itself. The goal should be that each field has the chance to shape any guidance that affects that field, so PRIM &R does not again, for example, offer a conference panel on oral history with no historians present.

Since the vast bulk of IRB review does concern biomedical research, I would not expect equal numbers for researchers in other fields. But I do think that folklorists should have as much power to shape PRIM &R's advice on folklore as physicians have to shape PRIM &R's advice on medical research. If this requires a complex committee structure, so be it.

3. Include a range of viewpoints

Prior to the recent conference, [9]Dr. Cohen wrote me, "if you would like to participate in the conference, we'd be happy to work you in to the program (provided you have something constructive to say)." Now he writes, "I can only conclude that you have no interest in making IRB review work better for researchers, but only in eliminating IRB review for your research."

Does that mean that someone who believes in wider exemptions from review has nothing constructive to say, and therefore no place in PRIM &R? This would contradict Cohen's earlier pride in having invited Linda Shopes, who has advocated an oral-history exemption far longer and more effectively than I. And it would contradict the above-mentioned panels at the last conference, which seem to assume that the proper scope of exemptions has yet to be determined.

I suggest that PRIM &R invite participants based on their knowledge, experience, and ability to represent their discipline, not their adherence to a party line, and that it make public its criteria for choosing participants in all of its endeavors. Perhaps I am not the right person to represent my field at PRIM &R conferences, but [10]Taylor Atkins sure as heck isn't either.

4. Ease participation in conferences

Now I get to Dr. Cohen's specific invitation for suggestions for future conferences. I have three:

a. Don't schedule the conference during exam week. Dr. Cohen informs me that many researchers declined his invitation to participate in the conference. My guess would be that a big part of their refusal resulted from the fact that the second week of May is exam week around the nation–not a problem for federal officials, administrators, and consultants, but a big one for active teaching faculty. As it is, I am surprised he got three researchers from the University of Minnesota; it was exam week there too. October and November are pretty busy with conferences as well for many scholars. I suggest February or March might be more fruitful.

b. Announce the conference. I'm not sure how I found out about the 2007 SBER conference, but I know it was only a few weeks before the conference, and that I did not hear about it through any of my usual reading as a historian, such as [11]H-ORALHIST, the list for oral historians. An open call for participants, months in advance, sent to scholarly newsletters and e-mail lists might boost participation.

c. Pay the costs of researchers. Maybe PRIM &R already pays the travel costs of conference faculty, but if not, it should. Most university professors are lucky to get funding to travel to one or two conferences a year, and they want to use this to attend conferences within their own disciplines. With PRIM &R charging hundreds of IRB staffers up to $950 to attend, it should be able to subsidize a few dozen researchers.

These last three suggestions might bring a few more researchers to the next PRIM &R conference, but I think the real problem is far deeper than participation at conferences. If, as Cohen suggests, PRIM &R truly seeks "to promote communication and collaboration between IRBs and investigators to facilitate research," it will have to work much harder to include the many investigators it has so long neglected.

1. http://institutionalreviewblog.blogspot.com/2007/05/prim-finds-another-social-researcher.html
2. http://www.historians.org/perspectives/issues/2006/0602/0602aha1.cfm
3. http://www.hhs.gov/ohrp/education/index.html#materials
4. http://www.hhs.gov/ohrp/irb/irb_foreward.htm
5. http://hrpp.blogspot.com/2006/11/ohrp-and-oral-history.html
6. http://institutionalreviewblog.blogspot.com/2007/03/prim-plans-sber-conference.html
7. http://primr.org/about/overview.html
8. http://institutionalreviewblog.blogspot.com/2007/04/what-is-prim.html
9. http://institutionalreviewblog.blogspot.com/2007/04/what-is-prim.html
10. http://institutionalreviewblog.blogspot.com/2007/03/why-irbs-are-not-peer-review-reply-to-e.html
11. http://www.h-net.org/%7Eoralhist/

2.5.4 A Trimmer PRIM&R (2007-05-19 18:42)

In my [1]previous posting, I detailed the ways that the composition of PRIM &R's board and the operations of its conferences fail to match its stated mission, and I suggested what it would take for PRIM &R to live up to its claim to serve "[2]the full array of individuals and organizations involved in biomedical and social science/behavioral/educational research." The other option, of course, would be for it to scale back its ambitions to serving merely "the full array of individuals and organizations involved in biomedical research," a noble task and one that its biomedical membership is far better equipped to handle.

PRIM &R's adopting this approach would mean recognizing that current regulations were written with biomedical research in mind and have never suited social science. It should therefore use its prestige to advocate broader exemptions from federal regulation for non-biomedical research. Such exemptions might exclude from IRB review:

> * Research involving survey or interview procedures, where the subjects are legally competent, and where the investigator identifies himself/herself, and states that he/she is conducting a research survey or interview
> Research involving the observation (including observation by participants) of public behavior in places where there is no recognized expectation of privacy.
> and
> Research involving the observation (including observation by participants) of public behavior in places where there is a recognized expectation of privacy, except where all of the following conditions exist:
> (i) Observation are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,
> (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and
> (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

I fear that Dr. Cohen will reject such proposed exemptions, taking them as evidence that I have "[3]no interest in making IRB review work better for researchers, but only in eliminating IRB review for [my] research." Before he does so, let me point out that these exemptions are not my creations, but those of a joint subcommittee of the American Association of University Professors' Committee A on Academic Freedom and Tenure and Committee R on Government Relations. They were published as a report on Regulations Governing Research on Human Subjects, Academe, December 1981, 358-370.

A member of the subcommittee, and a signatory to the recommendations, was Sanford Chodosh, MD, the founder of PRIM &R.

1. http://institutionalreviewblog.blogspot.com/2007/05/prim-public-responsibilities.html
2. http://primr.org/about/overview.html
3. http://institutionalreviewblog.blogspot.com/2007/05/prim-finds-another-social-researcher.html

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2.5.5 Zywicki, "Institutional Review Boards as Academic Bureaucracies" (2007-05-21 23:04)

My colleague Todd J. Zywicki, of Mason's law school, has posted on SSRN his contribution to the forthcoming Northwestern Law Review issue on IRBs: "Institutional Review Boards as Academic Bureaucracies: An Economic and Experiential Analysis," [1]http://ssrn.com/abstract _id=983649
As stated in the abstract, the article "argues that the problem is that IRBs are fundamentally bureaucracies, and that this bureaucratic structure explains much of their frequent suboptimal decision-making. The poor performance of IRBs is thus not a consequence of those individuals who comprise it, but rather a reflection of their bureaucratic nature. The bureaucratic nature of IRBs appears to do nothing to improve the decisions that they make, while being the source of many of their problems."
Zywicki is right to note that people who gain money, power, and prestige from controlling other people's work have an incentive to define their duties broadly, even as they fret about researchers' conflicts of interest. Ironically, he seems only dimly aware of the extent to which administrators have seized power from researchers. He writes, "IRBs are fundamentally bureaucracies," not understanding that IRBs themselves are committees of researchers, and that the true bureaucracies are the university compliance offices. He notes, "there is reported to be a growing IRB conference circuit," suggesting his unfamiliarity with PRIM &R and its administrator-dominated conferences. And he makes no mention of the creation, in 1999, of the "[2]Certified IRB Professional" as a new kind of administrator, someone who has staked a great deal on the maintenance, if not expansion, of IRBs' reach.
But buried in the essay is another explanation of the IRBs' expansion:

> With respect to university bureaucracies such as IRBs, at least some of the growth in their internal administrative burden has been spurred by governmental regulations. In addition, the preoccupation of IRBs with paperwork and forms has been promoted by a regime of "fear" of governmental oversight, "[f]ear by the institution that it will be 'out of compliance' with one or more aspects of the paperwork, and so subject to penalty upon audit (be that by the NIH, the Office for Human Research Protection, the US Department of Agriculture, or whatever other organization is involved)."

How much of the growth of IRB staffs is due to the internal dynamic Zywicki stresses compared to the growing external threat of federal penalty? One way to find out would be to compare the growth of compliance regimes to major OHRP enforcement actions. If as Zywicki notes, the Northwestern University Office for the Protection of Research subjects "grew from two full-time professionals in the late 1990s to 25 professionals and an administrative staff of 20 last year," I'd like to know how much of that growth took place as a response to the suspension of sponsored research at Hopkins, Virginia Commonwealth, and other universities.
Without far more research on the actual workings of IRBs and compliance offices around the country, we can't test hypotheses such as Zywicki's.

1. http://ssrn.com/abstract_id=983649
2. http://www.primr.org/certification/about.html

2.5.6 Jeffrey Cohen: More Argument Without Evidence (2007-05-23 21:38)

In a new posting on his blog, [1]Jeffrey Cohen writes,

> One of the major propositions that the critics of IRB review of social research put forth is that minimal risk social research with competent adults should be completely exempt from IRB review. On the surface, this makes some sense. We're talking about research that is unlikely to harm anyone and where adults can decide for themselves whether to participate. Why do we need to review such research? Based on my experience personally reviewing thousands of research protocols in the social sciences, there is one basic problem with this - researchers are human beings. Human beings are not perfect - they overlook things, make mistakes and and can't be totally objective about their own work. If researchers were perfect, if they always took all of the ethical issues into account when planning and conducting their research, then we wouldn't need IRB review. But they are not perfect - none of us are perfect. So, every research activity needs an independent, objective review.

Characteristically, Cohen offers not a single example of a social research project whose ethical content was improved by his or any IRB review, much less one that could only be improved thanks to the broad definitions and coercive rules now used by IRBs. (And no, [2]forcing interviewers to carry lists of mental-health centers doesn't count.) If he has such examples, he should offer them. If not, a vague reference to "thousands of research protocols" is unlikely to persuade a community of scholars trained to think critically and to weigh evidence.

1. http://hrpp.blogspot.com/2007/05/why-not-exempt-social-research.html
2. http://institutionalreviewblog.blogspot.com/2007/04/canard-of-interview-trauma.html

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2.5.7 Even the Best IRB Can Antagonize Researchers (2007-05-24 12:45)

Judging from Samuel P. Jacobs's story, "[1]Stern Lessons For Terrorism Expert," Harvard Crimson, March 23, 2007, the Harvard IRB is pretty darn good when it comes to non-biomedical research. Policy researcher Jessica E. Stern learned from the IRB to "not learn the names of many of the people she is interviewing—preferring to use pseudonyms—thus protecting the privacy of her interviewees and making her notes less valuable to federal investigators." She states, "Harvard's IRB is the only one I know of to approve the kind of research I do. They've bent over backwards to make what I do possible, which is better than any other IRB." Law professor Elizabeth Warren has "never encountered an IRB as helpful as Harvard's."

Yet another researcher finds "the process is so cryptic and idiosyncratic" that "his students often can't anticipate the reasons why the institutional review board will reject a proposal." And Stern herself, who got valuable help from the IRB, complains that "Before I came to Harvard, I had pretty remarkable interviews with terrorists . . . There are a lot of reasons that those kind of interviews would be hard today. One of them is the post-September 11 environment, but the other is the IRB strictures." One project, to interview radical black Muslims, died entirely because of the delay in approval. (Note: this is just what [2]Robert Kerr warned us about.)

How can we have the best of both worlds—helpful advice without arbitrary rejections and delays? [3]Voluntary review.

1. http://www.thecrimson.com/article.aspx?ref=517924
2. http://institutionalreviewblog.blogspot.com/2007/01/menikoff-wheres-law.html
3. http://institutionalreviewblog.blogspot.com/2007/01/why-not-make-irb-review-voluntary.html

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2.5.8 Scott Atran, "Research Police – How a University IRB Thwarts Understanding of Terrorism" (2007-05-28 12:10)

> Blogger's note: In March the [1]Harvard Crimson mentioned an unpublished essay by ethnographer Scott Atran of the University of Michigan, detailing his complaints about the IRB process. With Dr. Atran's kind permission, I present the complete essay here. ZMS

Scott Atran, research director in anthropology at the National Center for Scientific Research in Paris, visiting professor of Psychology and Public Policy at the University of Michigan, and presidential scholar in sociology at the John Jay College of Criminal Justice in New York City.*

Many bemoan the academic community's lack of input and influence in shaping society's understanding and actions regarding one of the most pressing issues of our time – terrorism.

On one side, those close to the "war on terrorism" often argue that academics are stuck in a post-Vietnam syndrome, basically out to lunch on the "hard" issues of helping their own society defend against aggressors or build enduring peace, or even acknowledging that there may be fundamental clashes between different cultural values that underlie and sustain conflict. In an article in The National Interest, "Thinking Outside the Tank," senior Rand analyst Steve Simon and counter-terrorism expert Jonathan Stevenson surmised that "scholars are now farther than ever from furnishing creative analytical support to policymakers," and recommended that academics should be left to their irrelevance.

On the other side, many in academia fear that their intellectual interests, integrity and independence could again be corrupted, as in the McCarthy and Vietnam years, and as in societies where governments have dictated what those interests should be, such as Nazi Germany, Soviet Russia, Saddam's Iraq, or many of our current allies in the Muslim world. Often they believe that the U.S. administration's motives in "the war against terrorism" are dishonest and that its effects disastrously corrode civil society and international relationships. They believe that academics should stay above the fray, but remain critically-minded.

Both sides have valid points, but also tend to exaggerate the naivété or malevolence of the other side. That's not unique to these groups; it's pretty much a character of adversarial groups anywhere, anytime. Research by Stanford social psychologist Lee Ross and others shows that individuals tend to misperceive differences between groups as more extreme than they really are, and also that individuals believe that their own group sees the world more objectively than other groups.

But a strong impediment to academic involvement in the great social issue of where terrorism comes from and what to do about it may not be from any lack of will or interest, but from the narrow vision of a relatively young but increasingly powerful bureaucratic institution that rigidly rules university research – the Institutional Review Board (IRB).

The roots of the IRB go back to the Nuremberg trials, where recognition of the need for guidelines dealing with human subjects in research emerged following disclosure of medical experimentation abuses by Nazi doctors. But the three guiding principles for IRBs were only formally codified in the 1979 "Belmont Report" by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by Public Law 93-348): Beneficence (to maximize benefits for science, humanity, and research participants and to avoid or minimize risk or harm), Respect (to protect the autonomy and privacy rights of participants), Justice (To ensure the fair distribution among persons and groups of the costs and benefits of research). At one of my home institutions, the University of Michigan, you can't even submit research for IRB approval until you take a test showing that you've memorized these principles.

Despite these good intentions, almost anyone who has tried to do research with human subjects outside of standard contexts has horror stories to tell about IRB demands to fit research that explores unfamiliar settings into a structurally familiar mode, no matter how arbitrary or uncomfortable the fit for subjects or researchers. What's a standard context? In non-clinical psychology, for example, well over 90 percent of studies are done within a few miles of major research universities, typically with undergraduates, and then usually generalized to Homo sapiens without a blink.

Many complaints, my own included, often have more to do with conflicts over procedures and protocols than over the nature and value of the research itself. For example, it's standard procedure to have subjects sign statements of informed consent acknowledging that the researcher has told them clearly and understandably what the study is about,

making provisions to safeguard subjects from physical or psychological harm or discomfort, clarifying issues of how data will be accessed and used, spelling out costs and payments, and so on. IRBs do genuinely care about protecting the people who are being studied from being exploited or coming to harm. And so do I; I've used my research to help set up a forest reserve for the last Lowland Maya of northern Guatemala and to provide backdoor channels for Middle East truce negotiations. But it took me months to convince the University of Michigan IRB that Maya who can't read or write can't sign consent forms, that if they could they wouldn't (these Maya once put their "X" on a piece of paper they couldn't read, signing away most of their land), and that collective payment to subjects in the form of supplies for the community's forest reserve was a better idea than individual payments that would cause jealousies.

On terrorism, though, my row with IRB is different. There are very, very few scholars who directly talk to terrorists or those who inspire and care for them, although there's no end to elaborate theories and voluminous books on the subject. But I'm an anthropologist who believes in the principle, first spelled out by Isaac Newton in a letter to Nathaniel Hawes, that: "If, instead of sending the observations of able seamen to able mathematicians on land, the land would send able mathematicians to sea, it would signify much more to the improvement of navigation and the safety of men's lives and estates on that element."

On the basis of this principle, joined to solid research proposals, the National Science Foundation and Department of Defense independently granted a considerable sum of the U.S. taxpayer money to our cross-disciplinary, multi-university, international team (including researchers from Michigan, MIT, Harvard, Northwestern, Germany, France, Israel, Palestine and Indonesia) to interview jihadis in different settings, and run experiments with them on a range of theoretically interesting issues, including how group dynamics can trump individual personality in motivating suicide bombers, and how sacred values can limit rational choice with cultural taboos that block tradeoffs and kill attempts at compromise and negotiation. For example, our society considers that selling children or selling out one's country is immoral and sociopathic; many Native Americans believe that uninhabited burial grounds ought not be violated no matter what the majority voters decide or what material compensation is offered. But what's sacred and non-negotiable for jihadis, and what policy implications follow?

To date, UM's's arguments are these: You can't interview failed suicide bombers or their sponsors who are prisoners, because prisoners cannot, in principle, freely give informed consent. Thus, the IRB stipulated that parole boards must be kept abreast of everything and lawyers had to come along into the jail cells of the Bali bombers to verify that questions weren't potentially prejudicial to the prisoners. But it's nigh impossible to do serious anthropology or psychology with a lawyer present, and there are no parole boards in Indonesian military prisons. Nor is there any reasonable likelihood of that this sort of research will worsen the condition of convicted mass killers. Even if the IRBs conditions could be met, UM's told me that it considers research with prisoners like these to be "in principle" incompatible with the rights of human subjects and therefore "never" likely to be approved. This, despite the fact that the prisoners and the organizations that originally sponsored their actions are more than willing to give their consent and eager to get their ideas out.

So what about interviewing freely operating jihadis and would-be suicide bombers. Initially, the IRB decided that federal funds could not be used, despite well-accepted guarantees of complete anonymity (no recording of names, physical characteristics, places, settings, etc), because subjects might inadvertently reveal operational plans that could put them in jeopardy. Although any statement of consent would expressly inform subjects not to talk about operations, IRB's argument was that government intelligence services, or others, might find out about the interviews to identify and use against subjects. I do believe it is reasonable for the IRB to require a researcher not to ask about current or future operations because such information could put the interviewer in an impossible ethical bind with respect to whether to inform authorities so that victims lives might be spared. But it seems unreasonable to prevent research wherever avoidance of ethical dilemmas cannot be foolproof.

As it turns out, in August 2005 I did inadvertently find out about the formation of a rogue Jemaah Islamiyah suicide squad, thoifah moqatilah (fighting group), and vague plans to attack western targets, possibly tourist spots in Bali again. And I did report this to the U.S. Senate Foreign Affairs staff at a briefing on my research in September 2005, shortly before the October Bali bombing. But my receiving this information, and the moral obligation to report it, did not seriously compromise the health or welfare of the suicide bombers who carried out the attack or those who sponsored them. And if it had? If the suicide bombers had been stopped because of the information I inadvertently obtained, then by UM's's moral logic I would have been ethically remiss by disrespectfully violating the bombers' wishes in helping

to save their lives and the lives of their intended victims.

Other IRBs, it is true, might have balanced this ostensible ethical lapse on Respect with the values of Beneficence and Justice. But I also apparently failed to make a sufficient case of the "costs and benefits" to the university and society of the research, though I pointed out that my interviews with radical Islamist leaders resulted in fruitful contacts during a crucial Middle East ceasefire negotiation and that any lives saved should count as a net benefit of the research. More generally, helping to understand why someone would want to blow up Manhattan, London, Tel Aviv or Jakarta could help to stop Manhattan, London, Tel Aviv or Jakarta from getting blown up and that, too, would be a pretty good benefit. But that argument was not, it appears, strong or clear enough.

After many months, the IRB decided to release emergency funds that were specifically awarded by the National Science Foundation for "high risk research" to do pilot interviews with freely operating jihadis, but with two caveats: no group identifications should be registered (this forbids comparing, say, Jemaah Islamiyah to Hamas, or to any other group in the world, which puts a serious constraint on a project aimed at comparative understanding of jihadi groups); and no personal details should be collected (this rules out asking what personally may have motivated someone to join jihad, which puts a serious constraint on understanding what motivates individual jihadis). In a penultimate round of discussions, the IRB seemed to have accepted the argument that labels like "Group A" versus "Group B" were permissible and that general descriptions of motivations without any details that could identify persons, places or events were allowed.

In the end, UM's IRB decided that the permission it had given me to carry out the truncated emergency research could not be pursued further, even on matters that had been previously approved, and against which no new objections had been raised. Although initial research results were tentative, as in almost any research project, the research itself could not reasonably have been judged shoddy or trivial: preliminary results of the research were published in reputable scientific and public outlets, including articles in Science and Nature magazines, The Washington Quarterly and Foreign Policy, and The New York Times and Wall Street Journal.

Because the IRB has dictatorial powers, with no right of representation by those being judged and no right of appeal to any higher authority in the university – or for that matter, in the land – it seemed the research was dead. It turns out, however, that after intense lobbying by several faculty and university administrators, the IRB did ultimately give temporary dry approval (approval to plan research only, with no involvement of human subjects) for one of the research projects, although the IRB declined to do so for the identical design on another project. But dry approval only means that money may be spent for travel and meetings with colleagues to discuss the results of previous research and to plan for future research, but not to have students or anyone else undertake research, or even to analyze or do any work with the results of previous research. For those who may think that sounds crazy, the IRB has a stunning reply: because the implications of previously collected data or previous findings related to human subjects may have implications for those subjects, or other humans, that may be different from the implications originally foreseen, then any proposal for the analysis of secondary data that does not directly involve human subjects must be treated as a new proposal involving human subjects. This is a chilling constraint that has the potential to stop a research program dead in its tracks, in the face of any politically correct wind, no matter how advanced that research or how distant from any living or dead human subjects.

My own view is that most of this is nuts: how is anybody in academia ever going have as much as possible to offer in this whole mess – though people in academia keep complaining that the government doesn't pay attention to serious scholars – if no one can even talk to the people most involved? Now, it's getting next to impossible to even talk to people who are dying to kill in order to better understand why they die to kill, or just why they want what they want. And, of course, IRB expressly forbids even thinking about trying to stop them from actually doing what they want because that could interfere with their rights. "Don't ask, don't tell" isn't enough – IRB wants guarantees that the opportunity for discovery can never arise.

Ask any anthropologist, political mediator, or hostage negotiator worth their salt and they'll tell you that you need to show empathy and respect towards the other party to learn anything of true or lasting value. If that's what the IRB required it would be good and right. But that isn't what IRB asks for: IRB rules say nothing about promoting empathy for subjects, only about following to the letter rules that are tailored to respect subjects' individual rights to their own privacy and property as if the research were in an American university classroom or laboratory.

I'd like to be clear that I don't simply blame the members of UM's IRB. I think the major fault lies with the IRB

as an institution and the rules it is required to implement, rather than the people enforcing the rules. Perhaps one remedy is that certain kinds of IRB approvals should be taken at the national rather than the university level, though institutionally protected from the political riptides of the electoral cycle. The advantage of a national board is that their sponsors could be government agencies whose interests focus more on their mission (such as national security) than on protection of undergraduate students. A national board (or boards) could then use guidelines that would differ from those designed to protect interests of typical subjects. There are various ways to define the domain of a national board, such as "prisoner's and those hiding from the law." Alternatively, it could be defined as using subjects who are relevant to national security (under a very narrow formulation). One would have to decide whether, for example, studies of urban gangs in the USA should be covered or not by a national board.

There are, to be sure, also serious disadvantages to a national IRB, including the potential for pressure from the sponsors to say "anything goes." So, another remedy might be to change the guidelines used by university IRB's that would apply to special circumstances, such as working with violent militants, where even requiring respect may be tricky. Perhaps most important, all the boards should understand and evaluate the facts to some definable standard and apply the same values, unless there were defensible differences in community standards. Lack of inter-board reliability is a guarantee of lack of validity in judgment of facts and in judgment of values.

Over three years ago, in testimony before the House Science Committee, Dr. M.R.C. Greenwood, Chancellor of the University of California, Santa Cruz, argued that "the traditions and structure of research in the U.S. today depends on replication and refutation, which means… sufficient data and methods," and that "balancing the perceived risks of open access with the risks to the health and vitality of the research community is exactly the kind of issue that calls for a new partnership between the research community and the government." That partnership is woefully lacking when it comes to dealing with terrorism, in part because universities and the government have chained themselves to an institution that not only never fathomed dealing with suicide bombers – true not just for IRBs – but which lacks the flexibility and imagination to face the problem. Yet suicide bombers are here; they've burst upon the world and, along with their sponsors and supporters, are changing how societies seek security and interact. This needs to be looked at up close. So IRBs, let the scholars go out to sea.

I wish to thank Robert and Amy Axelrod, Richard Nisbett, Douglas Medin, Steven Pinker, Baruch Fischhoff and Charles Strozier for suggestions on an earlier draft. They bear no responsibility for any arguments presented here.

1. http://www.thecrimson.com/article.aspx?ref=517924

2.6 June

2.6.1 The History of 45 CFR 46 (2007-06-14 09:46)

I am working on an article on the development of federal regulation of social science research from 1966 to 1981, and perhaps to 1991, when the current 45 CFR 46 was promulgated. I will present portions of this work at two upcoming conferences: the [1]Oral History Association meeting in Oakland, California, October 24-28, 2007, and the [2]Organization of American Historians meeting in New York City, March 28-31, 2008.

While I cannot offer IRB advocates a place on my panels, if anyone wishes to attend and comment, I will ask my panel chair to recognize that person.

1. http://omega.dickinson.edu/organizations/oha/org_am_oakland.html
2. http://oah.org/meetings/2008/index.html

2.7 July

2.7.1 White, "Institutional Review Board Mission Creep" (2007-07-26 10:51)

Ronald F. White, a professor of philosophy at the College of Mount St. Joseph, is fed up with IRB review of the social sciences: "[1]Institutional Review Board Mission Creep: The Common Rule, Social Science, and the Nanny State," Independent Review 11 (Spring 2007): 547-564.
Much of the piece will be familiar to those who have followed recent IRB debates, but I did enjoy White's first-hand account:

> My IRB experience with graduate student projects on leadership was eye opening. A colleague and I taught the course. We spent hours checking student IRB forms, and half the semester was consumed in getting their protocols past the committee chair. All of these projects involved harmless interviews and questionnaires to be done in the workplace. The overwhelming majority of the students' employers not only supported their research, but in many instances were paying for them to attend graduate school. All of my students found the IRB debacle to be nitpicking nonsense. Many of them ultimately received an "incomplete" for the course. It would be convenient simply to blame our IRB chair for this debacle. However, that person was not only a highly competent and cooperative IRB chair and an established social scientist, but also an extraordinarily cooperative friend of mine. In short, the IRB fiasco is not about persons, but about a system.
> After that initial experience, the program redefined the project so that all students could get IRB approval by providing the same answers on the form. This adaptation made IRB compliance less onerous, but it severely limited the student's choice of topics and deprived them of the opportunity to do real science. Since then, the course has introduced a whole new kind of research option for students that avoids IRB involvement. I surmise that in most educational settings, the demands of IRB compliance have led to requiring topics and projects that are easier to get past boards.

There are a couple of points here. First, as [2]Robert Kerr has noted, research delay may be research denied, so we should not take at face value IRB claims about the low percentage of projects that are rejected outright. Second, boilerplate approval processes may lead to boilerplate research–the chilling effect that IRB critics have noted for decades. What intrigues me most is how a philosopher got snared in this mess, and I hope to learn more about the course and the research White's students were pursuing.

1. http://independent.org/publications/tir/article.asp?issueID=49&articleID=630
2. http://institutionalreviewblog.blogspot.com/2007/01/menikoff-wheres-law.html

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2.7.2 OHRP Reprimand Puts Forms Over Substance (2007-07-31 09:35)

The federal Office for Human Research Protections (OHRP) has [1]reprimanded the University of California at Berkeley's Committee for Protection of Human Subjects (CPHS) for what it considers misconduct in approving several projects. For a blog on the humanities and social sciences, the most relevant project was an economic study of Kenyan women, who were asked to record their sexual encounters, finances, and family events so researchers could understand their decision to engage in risky commercial sex.
Here's what OHRP had to say about the project:

OHRP finds that the informed consent documents reviewed and approved by the CPHS for study Sex Work as a Response to Risk in Kenya (Study 2005-5-2) failed to include and adequately address the following elements required by HHS regulations at 45 CFR 46.116(a):
(a) Section 46.116(a)(2): A description of any reasonably foreseeable risks and discomforts (i.e., risks and discomforts not described).
(b) Section 46.116(a)(3): A description of any benefits to the subject or others that may reasonably be expected from the research.
(c) Section 46.116(a)(7): An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights (should include someone other than the investigator), and whom to contact in the event of a research-related injury to the subject. OHRP notes that CPHS approved an informed consent document that referenced a separate document containing the required contact information in lieu of requiring the informed consent document to contain such information.
Please note that HHS regulations at 45 CFR 46.116(d) require that an IRB find and document four specific criteria when approving waiver or alteration of some or all of the required elements of informed consent. OHRP finds no evidence demonstrating that CPHS found and documented such criteria prior to approving the informed consent document for this study, which did not include two elements of informed consent, i.e., 46.116(a)(2) and (a)(3), and which altered one element of informed consent, i.e., 46.116(a)(7).

Charge (c) strikes me as simple nitpicking. 45 CFR 46.116(a)(7) requires only that "in seeking informed consent the following information shall be provided to each subject: . . . An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject." It does not state that the information must be on the "informed consent document" rather than a separate document.
Charge (b) is also doubtful. According to a paper derived from the study, Jonathan Robinson and Ethan Yeh, "[2]Sex Work as a Response to Risk in Western Kenya," "Respondents in Round 1 (October - December, 2005) were compensated 1,000 Kenyan shillings (US $14), and respondents in Round 2 (July - October, 2006) were compensated 1,500 Kenyan shillings (US $21) for participating in the study." Does OHRP suppose that the respondents were not told in advance that they would be paid?
And then there's charge (a), complaining of a lack of a "description of any reasonably foreseeable risks and discomforts." Just what are the reasonably foreseeable risks and discomforts to a woman keeping "a daily diary (or logbook) in which she self-reported the shocks she encountered (own illness or injury, illness or injury of another household member, death of a friend or family member, menstruation, and incidence of a sexually transmitted infection), her sexual behavior with up to 3 partners each day, her income, and her expenditures [and] additional information on client characteristics and unprotected vaginal and anal sex, separately"? Or, more precisely, who is best able to describe those risks: the IRB, the investigator, or the women who are keeping the diaries and would have to live with the consequences of their somehow getting into the wrong hands? I'd say it's the women, so a list of risks provided by a couple of American economists would be useless.
As Bradford Gray wrote in 1978, there is a "distinction between informed consent and consent forms." (American Sociologist, August 1978, 163). Joan E. Sieber and Robert J. Levine expand on this distinction in "[3]Informed Consent and Consent Forms for Research Participants," Observer, April 2004).
OHRP also complains that

CPHS conditionally approved the above-referenced study even though CPHS noted that the protocol contained little information regarding:
(i) Ensuring that risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (namely, sample size);
(ii) Equitable selection of subjects (namely, subject recruitment and enrollment procedure); and
(iii) Informed consent (how sought and documented).

It is not clear how the sample size would affect the ethical validity of the study. The other issues are nicely addressed in the Robinson and Yeh paper, though I can only guess what materials they submitted to CPHS in 2005. But notice that OHRP complains only that paper is missing, not that the project was ill-designed, or the participants ill-used. A true audit of the CPHS's effectiveness in this case would require going to Kenya and asking the participants in the study whether they understood the study and felt they had been treated fairly. Lacking the will or resources to do so, OHRP frets over Berkeley's failure to shoehorn a social science project into requirements devised for medical experimentation. The lesson for IRBs is that they will be judged not by the ethical content of the projects they approve, but by the adherence of consent forms to standard templates.
Berkeley's IRB is being scolded for cutting its researchers some slack, and now, I fear, other IRBs will react by becoming even stricter with social research. So much for flexibility.

1. http://www.hhs.gov/ohrp/detrm_letrs/YR07/jun07c.pdf
2. http://www.saga.cornell.edu/saga/aercconf/yeh.pdf
3. http://www.psychologicalscience.org/observer/getArticle.cfm?id=1556

2.7.3 Schwetz Retires (2007-07-31 09:40)

Dr. Bernard Schwetz has announced his [1]retirement as director of the Office for Human Research Protections (OHRP). Schwetz has led the office since February 2003. During that time, it has agreed to broad exemptions from IRB review for oral history, reneged on that agreement by publishing nonsensical guidance, then refused to discuss the matter with historians. Most recently, in February Schwetz told the New York Times that he intended to issue new guidelines by the end of 2007, a promise that now seems unlikely to be kept.

1. http://www.thompson.com/public/newsbrief.jsp?cat=FOODDRUG&id=1605

2.7.4 A Biomedical Scientist Speaks Out (2007-07-31 14:31)

Adil E. Shamoo, a professor of biochemistry and molecular biology at the University of Maryland School of Medicine and editor in chief of the journal Accountability in Research, complains that human subjects regulations "have handicapped researchers whose work poses no threat to humans." ("[1]Deregulating Low-Risk Research," Chronicle of Higher Education, 3 August 2007; thanks to John Mueller for the heads-up.)
Shamoo cites with approval the 2006 AAUP report, "[2]Research on Human Subjects: Academic Freedom and the Institutional Review Board." The report, he notes,

> does not recommend an exemption from IRB approval for all social and behavioral studies. But it does suggest exempting low-risk research, which it defines as "research whose methodology consists entirely of collecting data by surveys, conducting interviews, or observing behavior in public places." The report distinguishes such research from studies that could reveal personal information, like genetic abnormalities or risky behavior, and recommends IRB approval for them.
> In 2002, while I was a member of the National Human Research Protections Advisory Committee, I expressed concern about requiring IRB reviews for such low-risk research, studies of public data, and class projects involving observational studies conducted by undergraduates, which usually must be done on such a short timetable as to make IRB approval impossible. I argued then that low-risk research should be exempt from federal regulation unless the studies could result in a breach of subjects' privacy or disclosures that could pose unreasonable risks to subjects.

> In the rare instances when low-risk research could cause harm, other mechanisms, such as improved education and training for investigators, would be more sensible than overly restrictive regulations. Currently most new researchers are required to take just one online course lasting a few hours. Only a few universities require as much as 30 hours of training in the responsible conduct of research or research ethics. That amount of preparation should be mandatory for all investigators.

For the most part I agree with Shamoo's argument, including his call for training in research ethics. (See "[3]Ethical Training for Oral Historians.")

But Shamoo mischaracterizes the AAUP report, which recommends that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption." No provisos means that researchers would, in fact, be free to interview consenting adults about their genetic abnormalities or risky behavior. (Ask me about my 33d tooth!)

Nor does Shamoo explore just what he means by "low-risk research," a term not used in the AAUP report. Does he propose exempting only research that bears little risk of harm? Or research that bears little risk of ethical wrong?

Research can be both ethical and risky, even harmful. Investigative journalism is the clearest example; earlier this year, the Washington Post's investigation of conditions at Walter Reed hospital rightfully destroyed the careers of some prominent Army officers and civilian officials. We need a system that allows researchers in the social sciences and humanities to work within the limits of their disciplines' ethical codes, and the laws that govern all people–not the medical ethics encoded in the Belmont Report.

The last word goes to E. L. Pattullo, who explained all of this in 1979 [Robert J. Levine, et al., panelists, "The Political, Legal, and Moral Limits to Institutional Review Board (IRB) Oversight of Behavioral and Social Science Research," in Paula Knudson, ed., PRIM &R through the Years: Three Decades of Protecting Human Subjects, 1974-2005 (Boston: PRIM &R, 2006), 39-40.]:

> The fact that a considerable number of social studies have resulted in subjects experiencing boredom, humiliation, self-doubt, and outrage I do not question. Further, it would be surprising if there were not others in which breaches of confidentiality, especially, have led to more dire consequences—though I am not aware of any such cases. Nevertheless, there remains a world of difference between a lost leg and a lost job. Neither is desirable, but few would find the choice hard—and the difference has great significance, given our traditional belief in the undesirability of trying to prevent social injury by imposing prior restraint on speech. . . The possible harm that inheres in most social research is of a kind that we decided long ago we must risk as the necessary price for a free society. . .
>
> As subjects, we could be entrapped, exposed, and embarrassed, with only the laws of slander, libel, privacy, and contract to protect us. But we are thus exposed already to friends, enemies, journalists, acquaintances, and strangers. Rather than accept regulation that begins to erode freedom of speech, would it not be wiser to return scientists to the ranks occupied by our friends and enemies?

1. http://chronicle.com/weekly/v53/i48/48b01601.htm
2. http://www.aaup.org/AAUP/About/committees/committee+repts/CommA/ResearchonHumanSubjects.htm
3. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm

2.8 August

2.8.1 IRBs vs. Departmental Review (2007-08-02 21:47)

In comments on this blog's [1]introduction, bioethicist David Hunter of the University of Ulster asked me about my preferred alternative to IRB review, and I mentioned my hopes for departmental review (hopes shared by the AAUP). Lest our conversation get lost in the comments, I am moving it to this new posting:
DAVID HUNTER:
I'd disagree on departmental review being best for two reasons.
1. While a committee which has some knowledge and expertise in the area of the project, too much expertise and it becomes too close to the subject matter. This can mean that it misses significant ethical issues because they are standard practice within a specific discipline. To give one example, psychologists often want to give part of their students grade (10 %) for being involved in their research. Most RECs I am involved in don't allow this practice because it is felt it is unduly coercive. I imagine if a REC/IRB was entirely composed of psychologists they may disagree.
2. It is important for a REC to be substantially independent from the researcher, but this doesn't happen in departmental review, instead the REC has an interest in the research being let to go ahead.
My university presently runs on a departmental review model, and while I can't name names I have personally seen examples of both of the above issues coming up.
I've written about these problems here:
Hunter, D. 'An alternative model for research ethics review at UK universities' Research Ethics Review. (2006) Vol 2, No 2, 47-51.
(Which unfortunately isn't available online)
and here: Hunter, D. '[2]Proportional Ethical Review and the Identification of Ethical Issues Journal of Medical Ethics. (2007);33:241-245.
I certainly agree with you that IRBs shouldn't be dominated by medics and medical concerns, they instead should have a wide range of representation. I'm inclined to think though that the baseline ethical issues are similar and while different rules may be appropriate for different disciplines they flow out of the same background.
In terms of examples here are a few, I can't be too specific with details for reasons of confidentiality.
1. Study of sexual attitudes in school children. Asked very probing questions as one might expect, but didn't intend to get parental consent to carry out the research a parallel can be found here: [3]India Research Ethics Scandal: Students made guinea pigs in sex study
No consideration had been given to what might have been done if there was disclosure of harmful behaviour etc.
2. Historian was going to civil war stricken country to interview dissidents about the war, intended to publish identifying comments (without getting consent for this) which were likely to be highly critical of the current regime.
3. Social scientist wanted to understand children's attitudes towards a particular topic. As a blind so that the participant would not know the questions they wanted to answers to, they proposed to use the becks depression index. This contains questions about self harm, future worth and was potentially very distressing, not at all appropriate as a blind.
4. Student wished to conduct interviews with employees of a company on an issue that could significantly damage the companies profitability. No consideration was given to how to best report this information to minimise harm to the company.
I'm inclined to think that any sort of research involving humans can lead to harm whether that is physical, social, financial, psychological or so on. As such the benefits and the risks need to be balanced, and it needs to be considered how to minimise that harm. That I take it is the job of the researcher. However, having sat on RECs for a while it is a job that sometimes the researchers fail at spectacularly, then it becomes the job of the IRB/REC. The difficulty is how, without full review by a properly constituted REC, do you identify those applications that have serious ethical issues?
ZACHARY SCHRAG:
Thanks for these examples.
First, let me state that I am primarily interested in projects that fit Pattullo's proposal of 1979: "There should be no requirement for prior review of research utilizing legally competent subjects if that research involves neither deceit, nor intrusion upon the subject's person, nor denial or withholding of accustomed or necessary resources." Under this

formula, the projects invovling children (who are not legally competent) and the project involving undergraduates (whose course credit is an accustomed or necessary resource) would still be subject to review.

That said, I have little confidence that IRBs are the right tool to review such research. As for child research, under U.S. regulations, and, I believe, the rules of most universities, the studies could be approved by three IRB members wholly lacking in expertise on child development. (The regulations encourage but do not require the inclusion of one or more experts when vulnerable populations are involved.) Were I the parent of a child involved in such studies (and I'm proud to say that both my children have furthered the cause of science by participating in language studies), I would greatly prefer that the protocols be reviewed not by a human subjects committee, but by a child subjects committee composed mostly or entirely of people expert in child research.

For the psychology course and the history project, the real question is whether a departmental committee can be trusted to enforce its own discipline's ethical code. The code of the [4]British Psychological Society forbids pressuring students to participate in an experiment. And the ethical guidelines of the the [5]Oral History Society require interviewers "to inform the interviewee of the arrangements to be made for the custody and preservation of the interview and accompanying material, both immediately and in the future, and to indicate any use to which the interview is likely to be put (for example research, education use, transcription, publication, broadcasting)." So yes, those sound like unethical projects.

Perhaps some departments would fail to correct these mistakes, just as some IRBs and RECs get them wrong. At some level this is an empirical question that cannot be answered due to the uniform imposition of IRB review. In the U.S., at least one university (the University of Illinois) had a system of departmental review in psychology that worked without complaint until it was crushed by federal regulation in 1981. With the federal government imposing the same rules nationwide, we can only guess about how well alternatives would work.

Moreover, departmental review would allow committees to bring in considerations unknown to more general ethics committees. For example, the British and American oral history codes require attention to preservation and access to recordings, something that and IRB/REC is unlikely to ask about.

I would also add that something close to departmental review is typical of the standard IRB, i.e., one in a hospital or medical school. It's true that the U.S. regulations require "at least one member whose primary concerns are in nonscientific areas" and "at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." But the rest of the members can be biomedical researchers of one stripe or another. If that's good enough for the doctors, how about letting each social science discipline form an IRB of its members, with a community member and a non-researcher thrown in?

Still, if IRBs/RECs limited themselves to holding researchers up to the standards of the researchers' own academic discipline, I wouldn't be complaining.

Where we really disagree, then, is on project 4. You write, a "Student wished to conduct interviews with employees of a company on an issue that could significantly damage the company's profitability. No consideration was given to how to best report this information to minimise harm to the company."

That sounds a lot like this case:

> Kobi Alexander's stellar business career began to unravel in early March with a call from a reporter asking why his stock options had often been granted at the bottom of sharp dips in the stock price of the telecom company he headed, Comverse Technology Inc.
>
> According to an affidavit by a Federal Bureau of Investigation agent, unsealed in Brooklyn, N.Y., the call to a Comverse director set off a furious chain of events inside the company that culminated yesterday in criminal charges against Mr. Alexander and two other former executives. Federal authorities alleged the trio were key players in a decade-long fraudulent scheme to manipulate the company's stock options to enrich themselves and other employees.
>
> After the March 3 phone call from a Wall Street Journal reporter, the FBI affidavit said, Mr. Alexander and the other two executives, former chief financial officer David Kreinberg and former senior general counsel William F. Sorin, attempted to hide the scheme. Their actions allegedly included lying to a company lawyer, misleading auditors and attempting to alter computer records to hide a secret options-

> related slush fund, originally nicknamed "I.M. Fanton." It wasn't until a dramatic series of confessions later in March, the affidavit said, that the executives admitted having backdated options. The trio resigned in May.

That's an excerpt from Charles Forelle and James Bandler, "Dating Game – Stock-Options Criminal Charge: Slush Fund and Fake Employees," Wall Street Journal, 10 August 2006. As far as I can tell, Forelle and Bandler made no effort to minimize the harms to the companies they studied or the executives they interviewed. Their "[6]Perfect Payday" series won the 2007 Pulitzer Prize for public service.

Your insistence that an interviewer minimize harm is a good example of an effort to impose medical ethics on non-medical research, and a good reason to get RECs away from social science.

1. http://institutionalreviewblog.blogspot.com/2006/12/introduction.html
2. http://jme.bmj.com/cgi/content/abstract/33/4/241
3. http://philosophyandbioethics.blogspot.com/2007/08/india-research-ethics-scandal-students.html
4. http://www.bps.org.uk/the-society/ethics-rules-charter-code-of-conduct/code-of-conduct/ethical-principles-for-conducting-research-with-human-participants.cfm
5. http://www.ohs.org.uk/ethics/index.php
6. http://online.wsj.com/public/page/perfectpayday.html

David Hunter (2007-08-03 14:34:00)

Thanks for bringing this to the front Zachary. There is plenty to respond to here, and I'm sure you understand that it may take a bit of time for me to formulate a complete response - as pleasant as discussing issues on a blog are, there are of course other time pressures in academia.

I should have said by the way, I don't see myself as necessarily championing the IRB system as it presently stands in the US, instead I'm more generally in favour of the view that all research ought to be reviewed by a substantially independent committee made up of a mix of members from different areas and outside academia as well. I don't think the US system necessarily does a good job of meeting that requirement at the moment, nor the British one for that matter. I do agree, that IRBs/RECs are often too heavily weighted towards medical research at the moment, and a broader membership would be good.

From what you have said in regards to IRB's I share your concern. (By the way thank you for your description of the system in the US, very helpful to someone like me, interested generally in research ethics & research ethics systems but with no experience of it in the States)

That 3 members would be all that was needed to sign off on research involving a vulnerable group such as children is astounding. I would have thought that a full committee ought to be required for this. Of course in the UK even less scrutiny may be required, depending largely on which university you work at. I will describe the present UK research ethics system over at philosophy and bioethics later on, so you have a point of comparison.

I think one of the further weaknesses of the American system is that the IRB's are institutionally associated, I am more keen on the system for the review of medical research over in the UK where the committees are not associated with institutions and can receive applications from researchers anywhere in the country. This reduces the possibility for conflicts of interest.

In regards to whether IRBs or departmental committees will make more mistakes, you do make a fair point, this is an empirical question, and in part because there is already existing legislation it is difficult to test. Perhaps cross country comparisons might help? In any case the data is difficult to assess because I suspect there would be substantial under-reporting of errors which were made, and it is difficult to assess whether a departmental review board or an IRB made a bad decision, we would need an accurate higher authority to test this.

Let me just check your view, is it that projects meeting this criteria: "research utilizing legally competent subjects if that research involves neither deceit, nor intrusion upon the subject's person, nor denial or withholding of accustomed or necessary resources." Ought to receive no independent scrutiny, or just independent scrutiny by a departmental review board?

I'll respond to the rest over the next few days.

Cheers

David

Zachary M. Schrag (2007-08-03 19:48:00)

You ask whether I think research involving consenting adults "ought to receive no independent scrutiny, or just independent scrutiny by a departmental review board?"

I would answer that this would depend on the discipline. For oral history, prior review of any kind often makes little sense, because the process is so unpredictable. Rather than project-by-project review, I would want departments to establish standardized ethical and methodological curricula and consent forms. If a researcher, student or faculty, had completed the training and was using a pre-approved consent form, I see no need for review of her particular project. I know that many anthropologists make the same case for their fieldwork. There may be other kinds of research that fit the exemption but whose protocols are more predictable, and therefore more amenable to prior review. But I don't want to write beyond my expertise.

I do think that cross-national comparisons might be helpful, and I would like to learn more about practices in the U.K. But I am dismayed by the findings of Mark Israel and Iain Hay, in *Research Ethics for Social Scientists* (2006). They found "angry and frustrated" social scientists in the U.S., Canada, the U.K., New Zealand, and Australia (p. 1), and note that regulations in all of those countries were established "with minimal consultation with social scientists and little recognition that social science is not the same as biomedical research." (143)

ZMS

PS. I should correct my earlier statement about three non-experts being sufficient to approve a project with children. Under U.S. regulations, and IRB need have only five members, and a majority (three) makes a quorum. Approval takes only "a majority of those members present at the meeting," so, in fact, "full committee" review can mean that only two IRB members approve the project. See [1]45 CFR 46.108

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.108

David Hunter (2007-08-04 03:01:00)

Okay so it is a discipline specific thing then. Education might be another example, particularly if the teacher is engaging in "action research" because this involves continuous small changes to your teaching practice depending on what you think is working. Under some (I think overly stringent) forms of review arguably every time they changed what they did, they would need to submit an amendment to the IRB/REC...

You are right, predictability makes it harder to pre-review well. What we typically do with interviews is ask for a broad interview schedule, to determine whether the topics that the researcher is interested in are likely to cause distress or potentially be harmful to interviewee. However we don't expect the researcher to only use the sample questions they have given us in a rigid fashion, they are just indicators. I can't see why oral history wouldn't fit within this model?

Standardised consent forms would help, but RECs at least are often more interested in the content of the participant information sheet which is harder to standardise except in the broadest sense.

The difficulty with having no review unless the research meets criteria x, y or z is that the researcher has to assess that, and they have some interest in avoiding review, usually. I would think it would be possible to at least be deceptive in oral history (misdescribing your project to get people to consent to it for example) and while I can't imagine it being an intrusion upon the subject's person... I think that there are other ways to harm people that could come up in oral history.

So while I will accept that pre-review may be difficult, and that perhaps oral history ought to be treated differently in certain respects (ie revealing the participants identity, presuming they consent to this) I don't think this indicates a need for no review, instead it seems to indicate a need to modify the current IRB system, both by increasing the number and range of people on IRB's and by giving them discipline specific training on ethical norms.

In regards to the practices of research ethics in the UK I have now summarised these here: [1]Research Ethics in the UK: The present "system"

I'm not surprised that research shows social scientists are unhappy with research ethics review, both because it is reasonably new for many of their disciplines, and because most models in most countries were originally set up for biomedical research and are only now changing to encompass more research. But I'm not sure how worried we should be by their unhappiness, many biomedical scientists appear to be unhappy with the ethical review of their work as well. What it seems to show to me is a need to make the system more broad and suited to the needs of different disciplines. The new electronic form used by the NHS RECs in the UK is a step in this direction, since what questions you are asked change depending on filter questions at the beginning, making it more appropriate for different types of research. I'm surprised that IRB's can be so small, NHS RECs have a quorum of 7 I believe, and 12-18 members if I recall my standard operating procedures correctly.

I'll take up the broader question of harm in a later comment since that seems to be the turning point here.

1. http://philosophyandbioethics.blogspot.com/2007/08/research-ethics-in-uk-present-system.html

Zachary M. Schrag (2007-08-04 13:39:00)

Yes, the question of harm is key. If you accept that a legally competent adult should be permitted to incriminate himself in a public statement–with or without the aid of a researcher–then I see no reason to demand topics in advance.

I'd be interested to learn why you think participant information sheets for oral history would be hard to standardize. While I am frustrated that oral historians have not done a better job of this, I don't think it would be that hard. For example, what do you think of [1]Indiana's standardized oral history consent form?

(Note that in the U.S., regulations require that the project information is included with the consent form, rather than a separate information sheet. I suspect that the British system is easier to understand.)

Finally, I am dismayed by your comment that "I think that there are other ways to harm people that could come up in oral history." Why not identify an existing problem and then come up with a solution, rather than dreaming up hypothetical wrongs?

Zach

1. http://www.indiana.edu/~cshm/informed.html

David Hunter (2007-08-06 03:36:00)

Alright then,

"Yes, the question of harm is key. If you accept that a legally competent adult should be permitted to incriminate himself in a public statement–with or without the aid of a researcher–then I see no reason to demand topics in advance."

Well there is a difference between being involved in research and making a public statement. Namely the researcher is involved, and they may have moral obligations towards their research participants outside of the normal obligations we have to each other.

I'd still be inclined to ask for broad topics beforehand for at least three reasons:

1. In some locations (Northern Ireland for example) if illegal activity is disclosed, then the researcher is legally obliged to inform the police. Where it is felt this may happen, we usually require something on the information sheet to the effect that this might happen. Regardless of the legal requirements, you may still feel that there are moral requirements in terms of public interest that sometimes require informing the appropriate authorities. However as a researcher your primary duty is to your participant, so it is important they are aware you may report them.

2. It could be that revealing their identity or words will lead to considerable harm to them. Even if they are consenting to that harm, it still may not be morally permissible to bring it about.

3. Their history may be considerably distressing for them to relive, in these cases the researcher has a moral obligation to provide support services, or at least contact details for support services, these are usually on the information sheet.

Sorry I wasn't perhaps clear (And you are right btw, in the UK as a standard rule information sheets & Consent forms are separated) I don't think oral history participant information sheets are specifically hard to standardise, I think participant information sheets more generally are hard to standardise. This is because what is required to be on them is to some degree project specific.

Having had a look at the example you give, I think it is all right but not great. I'd like to separate it out into two documents, a consent form and an information sheet for the sake of clarity but fair enough I can't do that in the States. I would also think an invitation paragraph would be in order, along with a description of the project and what it is aiming to achieve. (Perhaps that standardly gets added?) Hard to give informed consent when you know nothing about the project.

It is written in highly legal language that I wouldn't have thought was appropriate with the general public take this for example: "I can withdraw from the project without prejudice prior to the execution and delivery of a deed of gift, a form of which is attached hereto." So obviously it may need adjusting to make it audience appropriate.

Dependent on the nature of the project, and whether it could be distressing for the participants, I would also add details of appropriate support services (ie counselling, the Good Samaritans and so on.)

In regards to your final query, I'm a moral philosopher, my job is to dream up hypothetical possible harms... But seriously, I was just meaning that while the statement you quoted was pointed (one presumes) at physical harms, there is no reason to think that the sorts of non-physical harms possible in research don't warrant scrutiny over research which has the potential for non-physical harms.

Part of the overall discussion depends on what duties we think researchers generally have towards their research subjects. I'm inclined to think one of those duties is to minimise harm. I don't think this is a hold over from the biomedical model, since it is a standard feature of moral philosophy. Nor do I think that this is an over-riding duty, instead it is a prima facie duty, which can be outweighed by other considerations. These can be for example the public interest, consent to the harm or perhaps the value of

the research. Nonetheless, whether there are genuine over-riding benefits of the research is a judgement I am more comfortable having a properly constituted ethics committee (which I will concede may not describe an IRB) decide.

Zachary M. Schrag (2007-08-06 21:04:00)
Thanks for your reply.
Your first reason for demanding topics in advance is that a researcher may be legally obliged to report criminal activities. That is a good reason to require promises of confidentiality to be tempered by the disclaimer that the researcher may be legally obliged to report criminal activities. But why not just tell researchers that they must include such a disclaimer if their work might reasonably lead a respondent to report a crime? Why demand questions that they have yet to form, for a project they are just starting?
Your third reason is that narrators' "history may be considerably distressing for them to relive, in these cases the researcher has a moral obligation to provide support services, or at least contact details for support services." I addressed this argument in my April posting, "[1]The Canard of Interview Trauma," Do you know of any systematic studies of the likelihood that interviews will be "considerably distressing," and that a list of "contact details" is helpful in such cases? And do you see any irony in restricting distressing questions while co-authoring [2]a blog named for Socrates?
But it's your second reason that most concerns me. You suggest that when an interviewer and a legally competent narrator have agreed to the publication of the narrator's self-incriminating statement, an IRB/REC can overrule their moral judgment. It can block publication, and perhaps even the conversation, on the grounds that it is not "morally permissible." That is not ethical review. That is censorship.
You concede that the general duty not to hurt other people must be balanced against other values. I would say that freedom–freedom of speech, freedom of the press, academic freedom–is one of those values, and an important one at that.
William Blackstone advocated far fewer guarantees of press freedom than those enjoyed today by Americans (and, I believe, Britons). Yet even he saw prior restraint as a particularly noxious means of discouraging abuses. As he wrote in his 1769 [3]Commentaries,
"The liberty of the press is indeed essential to the nature of a free state: but this consists in laying no previous restraints upon publications, and not in freedom from censure for criminal matter when published. Every free man has an undoubted right to lay what sentiments he pleases before the public: to forbid this, is to destroy the freedom of the press: but if he publishes what is improper, mischievous, or illegal, he must take the consequence of his own temerity. To subject the press to the restrictive power of a licenser, as was formerly done, both before and since the revolution, is to subject all freedom of sentiment to the prejudices of one man, and make him the arbitrary and infallible judge of all controverted points in learning, religion, and government."
Your argument is that a right enjoyed by "every free man" disappears when that man joins a university, or talks to a university researcher. I don't see why this should be the case.
Finally, you concede that an IRB may not, in practice, be a "properly constituted ethics committee." That's the whole question, and the reason why this thread is entitled "IRBs vs. Departmental Review."
The composition of a review committee determines its legitimacy. Democratically elected legislatures and democratically appointed courts may legitimately set limits on the freedom of a citizen. Members of a profession may legitimately police the conduct of other members. But an IRB, appointed by a single institutional official, lacking a majority of members from the discipline whose work is being judged, lacks any such legitimacy. Having one man as "the arbitrary and infallible judge of all controverted points" is grim. Having a panel of bioethicists in that role is not much of an improvement.

1. http://institutionalreviewblog.blogspot.com/2007/04/canard-of-interview-trauma.html
2. http://insocrateswake.blogspot.com/
3. http://1stam.umn.edu/main/historic/Blackstone.htm

David Hunter (2007-08-07 12:58:00)
Hi Zach
You might be interested in this:
[1]An inside-outsider's view of Human Research Ethics Review
In regards to 1 you ask:
"But why not just tell researchers that they must include such a disclaimer if their work might reasonably lead a respondent to report a crime?"
We do. It is in the published guidance, I highlight it in the ethics courses I teach our students. Nonetheless, we still commonly have to request this is added to information sheets. The problem, as far as I see it, isn't that there isn't good quality guidance available, the problem is that either researchers don't always find it and/or they certainly don't always follow it, even if they have good intentions.

"Why demand questions that they have yet to form, for a project they are just starting?"
If this is the case, they shouldn't be in front of a REC/IRB, since it looks like they don't know what their project is yet. But surely this is a mischaracterisation of researchers in oral history, you must have some, maybe broad, ideas of why you are asking a particular person questions. It is true that research can go in new or unanticipated directions, and I can certainly imagine this happening in the context of history, but some things and topics are reasonably predictable.
In regards to 3. I don't know of any systematic studies, although many experienced researchers have given me some anecdotal evidence for this. I'd welcome a full study of it, might be an interesting project actually I will have to look into it. In the absence of evidence, I tend to take a precautionary approach though.
In regards to 2. I think I haven't explained the position very well. Let me try again. It is not that the individual cannot publicly incriminate themselves or say things that might harm themselves. They are welcome to, outside the context of the research. So I am not suggesting that anyone's free speech ought to be restrained. What I am suggesting is that sometimes, (emphasis on the sometimes) researchers ought not be allowed to lead someone into harming themselves, or providing circumstances in which they may harm themselves. In other words researchers are being restrained from causing harm, not research participants being restrained from speaking freely.
In regards to your final point, yes IRB's don't sound ideal, they still may be better than nothing (though that is another, tricky question).
I'm still not sure about this:
"The composition of a review committee determines its legitimacy. Democratically elected legislatures and democratically appointed courts may legitimately set limits on the freedom of a citizen. Members of a profession may legitimately police the conduct of other members."
There is good reason to be worried about closed shop self regulation, namely it often fails. This is why in some jurisdictions, professions are regulated at least in part, and sometimes in whole by outside bodies. I think the profession should be allowed to regulate itself of course, however, it may still also require outside regulation as well.
"But an IRB, appointed by a single institutional official, lacking a majority of members from the discipline whose work is being judged, lacks any such legitimacy. Having one man as "the arbitrary and infallible judge of all controverted points" is grim. Having a panel of bioethicists in that role is not much of an improvement."
Agreed. Particularly in regards to a panel of bioethicists alone, a worse prospect I can hardly imagine. But that isn't what I'm promoting, I'm keen instead on an IRB/REC which has a wide variety of members from an array of different disciplinary areas across the spectrum along with lay people and an ethicist or two.
I'm unkeen on this:
"lacking a majority of members from the discipline whose work is being judged"
I think IRBs/RECs are better if they are independent from any specific discipline. So I am inclined to think you should have wide, balanced representation. Not a member of every discipline, because that will make an unfeasibly large IRB/REC, more than 20 members gets absurd fast. I think it is important to have members who are familiar with a wide variety of research methodologies and paradigms, and sympathetic to the issues faced in research in different contexts.

1. http://culturematters.wordpress.com/2007/08/07/an-inside-outsiders-view-of-human-research-ethics-re

Zachary M. Schrag (2007-08-08 20:49:00)
On your methodological question, you write, "you must have some, maybe broad, ideas of why you are asking a particular person questions." Not at the start of a project, I don't. When I started my work on Metro, I hadn't heard of almost any of the people I ended up interviewing. And since I didn't know whom I would interview, I hadn't written questions for them. Being asked for sample questions is like being asked to list all the books one plans to read for the next four years, and what one expects to learn from them.
This is why standardized consent forms are more appropriate than efforts by IRBs to pry into the details of a project, details unknown to the investigator herself. If you want to say that any consent form promising confidentiality also includes a disclaimer about subpoenas, fine. But that's no reason to demand information a researcher doesn't have.
(By the way, if researchers are ignoring their training and the published guidance you give them, what makes you think they are sticking to their committee-approved protocols?)
But the big question here is not about informed consent, but about the risk-benefit calculus that underlies medical research and is so corrosive of social research. (In Britain's [1]Research Ethics Framework," it appears as the blanket statement that "Harm to research participants must be avoided.") And it comes down to the burden of proof.
You seem to believe that no research should be permitted until it is proven harmless. And I'll accept that for medical experimentation, for I have no *a priori* right to cut open my neighbor, irradiate him, or insert foreign substances, devices, or other matter into his body.

But I do think (with Blackstone) that I have the right to ask him the story of his life, and that it is up to the would-be regulators to explain why I should not be allowed to do so. You have yet to do that. Instead, you hint at "some anecdotal evidence" of traumatic interviews, that "sometimes, (emphasis on the sometimes) researchers ought not be allowed to lead someone into harming themselves," and that "closed shop self regulation . . . often fails." Anecdotal? Sometimes? Often? Frankly, this is all so vague that I don't know what you are talking about. Yet it is on this vagueness that you propose significant restrictions on the freedom of speech.
Historians have been interviewing people for 2500 years. I would really like to learn of some projects you think went badly, and why you think IRB review would have helped them.

1. http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/opportunities/research_ethics_framework/

David Hunter (2007-08-10 10:46:00)
"On your methodological question, you write, "you must have some, maybe broad, ideas of why you are asking a particular person questions." Not at the start of a project, I don't. When I started my work on Metro, I hadn't heard of almost any of the people I ended up interviewing. And since I didn't know whom I would interview, I hadn't written questions for them. Being asked for sample questions is like being asked to list all the books one plans to read for the next four years, and what one expects to learn from them."
I think you have misunderstood me. I was suggesting you would have a broad idea of the questions you might ask and the sorts of people you might talk to, and why you might talk to them. I don't think you should provide the individual questions you would ask each person who might be involved in your interview, but I still think a broad overview is possible. Is even this not the case?
"By the way, if researchers are ignoring their training and the published guidance you give them, what makes you think they are sticking to their committee-approved protocols?"
Tough question. For the most part the researchers appear to take on board the committee's recommendations, quite well, it isn't a case of neglect, but rather that ethics can be a complicated business. So I think most of them will stick to what they have agreed to do. However this is not always going to be the case. There seem to be two main reactions to this. The first is to provide further oversight and regulation, such as the reporting of researchers to research ethics committees, and random audits. This provides some assurances that the researchers are following what they have said, which broadly was the result of a recent voluntary audit at my own university. The other option is to react to any revealed breaches of ethics with punitive measures, which does happen from time to time. But of course neither measures guarantee that researchers will behave ethically, they just make it more likely.
"But the big question here is not about informed consent, but about the risk-benefit calculus that underlies medical research and is so corrosive of social research."
Well it is a bit more complicated than this. risk-benefit is one factor, other factors are informed consent, justice and other ethical norms that may be violated in the course of research.
"In Britain's Research Ethics Framework," it appears as the blanket statement that "Harm to research participants must be avoided.""
I should note that that is not Britain's research ethics framework, but instead one framework by the Economic and Social Research Council. Written specifically for the social sciences I might add and endorsed by the Arts and Humanities Council which I presume fund much of the historical research not funded by the ESRC in the UK. It has been highly influential on the structure of research ethics committees and their operation in universities in the UK, almost by default. I'll also agree, like many policy documents, it seems rather more aspirational than realistic in parts, and the quote you have highlighted is a good example of that.
"You seem to believe that no research should be permitted until it is proven harmless."
No, this is not either what I believe or I have stated above. I believe that no research should be permitted if it is significantly unethical.
There are two key points there:
1. I think mildly unethical research may be permitted to proceed in some cases.
2. Ethics doesn't merely reduce to avoiding harm, there are other important considerations such as autonomy and justice among others. Even if research is harmful there maybe reasons to let it proceed.
"But I do think (with Blackstone) that I have the right to ask him the story of his life, and that it is up to the would-be regulators

to explain why I should not be allowed to do so. You have yet to do that."
Alright, I will give the argument in a straightforward fashion:
Step 1, the general argument:
1. Being a researcher is a profession.
2. Professions carry with them certain ethos and duties dependent on their roles and clients.
3. The specific duties of researchers entail a high level of concern and care for their research participants, since these individuals are for the large part taking the risks involved in research.
Conclusion: Researchers have a professional obligation towards their research participants.
But this doesn't get us to independent review, that takes another argument.
Several arguments for independent ethical review:
A. Past harms
1. Researchers have a professional obligation towards their research participants.
2. In the past researchers have failed, sometimes spectacularly to uphold that obligation.
3. One way to minimise this is to have independent review of their research.
Conclusion: research should be independently reviewed.
B: Complexity
1. Ethical issues are complex and sometimes difficult to identify, especially if you are close to the subject matter.
2. An independent multidisciplinary group is going to be better at identifying these issues than an individual.
3. Researchers presumably want to avoid being unethical, thus they should seek independent review.
Conclusion: Research should be reviewed by independent committees.
C: Potential Unethical Behaviour
1. Research inherently involves the unknown, and entails potentially unethical behaviour, in regards to respect for autonomy, risk, justice and so on.
2. Since these can be significantly harmful for the research participant or others we ought to aim to minimise these.
3. One means of minimising these is by seeking independent review.
4. Therefore there should be individual ethical review.
Each of those rough arguments seems sound to me, and provides reasons why we might want independent ethical review for all research, I see no need or good reason to make special exception for oral history. As you have pointed out it is difficult to anticipate some aspects of the research, this is not unique by any means to oral history. Likewise the harms likely to be entailed by oral history research are liable to be lower than biomedical research, nonetheless possible harms are still there.
There are two more pragmatic arguments:
Harms to research
1. If unethical research is carried out then this may become publicly recognised.
2. If this is public then this is likely to make people less keen to be involved in any research.
3 Therefore we should welcome independent review.to try and minimise this.
Harms to university
1. If unethical research is carried out then this may become publicly recognised.
2. If this is public then this is likely to make people less keen to be involved in supporting our university.
3 Therefore we should welcome independent review.to try and minimise this.
"Yet it is on this vagueness that you propose significant restrictions on the freedom of speech."
As I said in the previous posts, I am suggesting no limitations on the freedom of speech. I am proposing limitations on the freedom of researchers but that is a different thing than freedom of speech.
"Historians have been interviewing people for 2500 years. I would really like to learn of some projects you think went badly, and why you think IRB review would have helped them."
I know of none, but then I am not a historian, so I am not sure why you should think that I would be aware of these case. And it is unlikely that we have records of how all of that research was conducted or any ethical issues that were raised in that history. Do you honestly think that every history project ever carried out in the last 2500 years has been ethically excellent? I'd be stunned that history performed that much better than other research areas. As for IRB's helping, no doubt in some cases they wouldn't have, but in others I am sure they would have.
Let me put back the question to you:

Do you think history research can be unethical?

If the answer is yes, then why would you oppose independent review as a means of reducing unethical research?

Zachary M. Schrag (2007-08-10 21:54:00)

Hunter: I think you have misunderstood me. I was suggesting you would have a broad idea of the questions you might ask and the sorts of people you might talk to, and why you might talk to them. I don't think you should provide the individual questions you would ask each person who might be involved in your interview, but I still think a broad overview is possible. Is even this not the case?

Schrag: Not in the work I've done. Right now I'm in the early stages of a book on the history of riot control. I'm still in the nineteenth century, but in 2005 I went through IRB approval so I could interview my brother about his National Guard service during Hurricane Katrina relief operations. At some point I may find some other people to talk to, but that's all I know.

Try this exercise: Get a copy of Studs Terkel's Hard Times or Christian Appy's Patriots. Then list all the topics mentioned in the book, and try to reconstruct all the questions the interviewer asked to get the responses. Then answer these questions:

1. How long did it take you to list all the topics?
2. Could the interviewer have anticipated the topics at the start of his project?
3. Of what use to an IRB would the list of topics be?

Hunter: "By the way, if researchers are ignoring their training and the published guidance you give them, what makes you think they are sticking to their committee-approved protocols?"

Tough question. For the most part the researchers appear to take on board the committee's recommendations, quite well, it isn't a case of neglect, but rather that ethics can be a complicated business. So I think most of them will stick to what they have agreed to do. However this is not always going to be the case. There seem to be two main reactions to this. The first is to provide further oversight and regulation, such as the reporting of researchers to research ethics committees, and random audits. This provides some assurances that the researchers are following what they have said, which broadly was the result of a recent voluntary audit at my own university. The other option is to react to any revealed breaches of ethics with punitive measures, which does happen from time to time. But of course neither measures guarantee that researchers will behave ethically, they just make it more likely.

Schrag: Audits and punitive measures can proceed without IRB review, so long as the standards are defined. That's how we police plagiarism, for example.

Hunter: "But the big question here is not about informed consent, but about the risk-benefit calculus that underlies medical research and is so corrosive of social research."

Well it is a bit more complicated than this. risk-benefit is one factor, other factors are informed consent, justice and other ethical norms that may be violated in the course of research. "In Britain's Research Ethics Framework," it appears as the blanket statement that "Harm to research participants must be avoided.""

I should note that that is not Britain's research ethics framework, but instead one framework by the Economic and Social Research Council. Written specifically for the social sciences I might add and endorsed by the Arts and Humanities Council which I presume fund much of the historical research not funded by the ESRC in the UK. It has been highly influential on the structure of research ethics committees and their operation in universities in the UK, almost by default. I'll also agree, like many policy documents, it seems rather more aspirational than realistic in parts, and the quote you have highlighted is a good example of that.

Schrag: I'd be very interested to learn who exactly had power in the drafting of the framework. I'm working on the history of recommendations and regulations in the United States; perhaps someone in the U.K. can take up the story there.

It's quite possible that historians and journalists were excluded from the drafting process. Notable is section 2.17:

"Some research that poses risks to research subjects in a way that is legitimate in context of the research and its outcomes.This might arise for two reasons. First, as is recognised elsewhere (see Tri-Council of Canada, 2002) research may be 'deliberately and legitimately opposed to the interests of the research subjects' in cases where the objectives of the research are to reveal and critique fundamental economic, political or cultural disadvantage or exploitation. Much social science research has a critical role to play in exploring and questioning social, cultural and economic structures and processes (for example relating to patterns of power and social inequality), and institutional dynamics and regimes that disadvantage some social groups over others, intentionally or not,. Such research results may have a negative impact on some of the research subjects. Principles of justice should, however, mean that researchers would seek to minimise any personal harm to such people. Secondly, researchers should also consider how to balance the potential of immediate or short-term risks to research subjects against longer-term gains to future beneficiaries. It is the responsibility of the research proposers to make such a case in detail to an REC."

In other words, you can harm a social group, but must minimize harm to an individual. This sounds like something written by a sociologist, intent on carving out some space for his discipline alone.

Hunter: "You seem to believe that no research should be permitted until it is proven harmless."

No, this is not either what I believe or I have stated above. I believe that no research should be permitted if it is significantly

unethical.
There are two key points there:
1. I think mildly unethical research may be permitted to proceed in some cases.
2. Ethics doesn't merely reduce to avoiding harm, there are other important considerations such as autonomy and justice among others. Even if research is harmful there maybe reasons to let it proceed.
Schrag: As you know, I am concerned about the protection of autonomy. I don't know what "justice" means in this context, since the above-quoted passage from the Research Ethics Framework is the only use of the term, and it equates justice with minimizing harm.
Hunter: "But I do think (with Blackstone) that I have the right to ask him the story of his life, and that it is up to the would-be regulators to explain why I should not be allowed to do so. You have yet to do that."
Alright, I will give the argument in a straightforward fashion:
Step 1, the general argument:
1. Being a researcher is a profession.
2. Professions carry with them certain ethos and duties dependent on their roles and clients.
3. The specific duties of researchers entail a high level of concern and care for their research participants, since these individuals are for the large part taking the risks involved in research.
Conclusion: Researchers have a professional obligation towards their research participants.
Schrag: I'm with you so far.
Hunter: But this doesn't get us to independent review, that takes another argument.
Several arguments for independent ethical review:
A. Past harms
1. Researchers have a professional obligation towards their research participants.
2. In the past researchers have failed, sometimes spectacularly to uphold that obligation.
Schrag: I dispute this premise, at least in regard to oral history.
I've been investigating this topic for about three years, and the only case I know of when a historian seriously failed his narrators is that of William Sheridan Allen's The Nazi Seizure of Powe: The Experience of a Single German Town, 1930-1935, first published in 1965. Allen interviewed residents of the town of Northeim, Germany, about their lives during Hitler's rise to power. He promised to keep secret the names of his informants and of the town itself, using pseudonyms in the published work. But soon after the book was translated into German, a German magazine disclosed the real name of the town and many of Allen's narrators.
This was clearly a failure, though I don't know enough about the case to pronounce it a "spectacular" failure. But one failure is a rather thin record of abuses. Nor is it clear that IRB review would have prevented this failure. And the victims were, after all, genuine Nazis.
(Where oral historians regularly fail is in their obligation to serve other researchers by archiving their interviews. I still owe George Washington University copies of some of my Metro interviews, more than a year since my book was published. The solution to this problem is more funding for oral history.)
I must leave other disciplines to defend their own records, but I will say this: I wish ethicists would give The Tearoom Trade a rest. However troubling you find Humphreys's methods, they were sufficiently exceptional that they should not be the basis of generalized rule-making.
Hunter: 3. One way to minimise this is to have independent review of their research.
Schrag: I dispute this premise as well. I see no evidence that independent review improves the likelihood that researchers will honor their ethical obligations, and a far amount of evidence that it reduces that likelihood. For example, in January I noted [1]an IRB's demand that a historian destroy the recording of interview tapes. In March I described the ways that [2]IRB-mandated training distorts the ethics of my profession. And I just noted William Burman's finding that [3]IRBs make consent forms harder to read. While I hope to do more systematic research on this issue, there are enough horror stories around to suggest that independent review is as or more likely to do harm as good. I hope you will take the time to read through my half-year of blogging on this subject.
Hunter: Conclusion: research should be independently reviewed.
Schrag. Even if I granted premises 2 and 3, this conclusion would not follow, any more than the conclusion that research should be banned outright. You would need to show that independent review minimizes ethical breaches without unduly harming other interests, such as the researcher's and the narrator's rights to free inquiry and expression. American jurisprudence holds that "even though the governmental purpose be legitimate and substantial, that purpose cannot be pursued by means that broadly stifle fundamental personal liberties when the end can be more narrowly achieved. The breadth of legislative abridgment must be viewed in the light of less drastic means for achieving the same basic purpose." (Shelton v. Tucker, [4]364 U.S. 479). I consider this declaration not merely a legal ruling, but a moral one, in that it upholds human dignity and freedom.
I will skip the remaining syllogisms because my objections are the same. I don't see evidence that IRB review reliably improves

the ethical content of research, but it does reliably delay and distort legitimate inquiry.

Hunter: I am suggesting no limitations on the freedom of speech. I am proposing limitations on the freedom of researchers but that is a different thing than freedom of speech.
Schrag: You want me to get permission before I talk to other people. How is that anything other than a limitation on the freedom of speech? Hunter: Let me put back the question to you:
Do you think history research can be unethical?
If the answer is yes, then why would you oppose independent review as a means of reducing unethical research?
Schrag: Historians occasionally break all sorts of ethical norms. They plagiarize. They falsify data. They steal books from the library, though not, perhaps, with the [5]rapacity of ethicists. But these breaches are rare enough that the profession handles them as they arise, by shaming or firing the offenders as they are caught. We have not imposed prior review on every publication and every trip to the library. Oral historians deserve the same freedom.

1. http://institutionalreviewblog.blogspot.com/2007/01/irb-demands-destruction-of-tapes.html
2. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm
3. http://institutionalreviewblog.blogspot.com/2007/08/study-finds-irbs-make-consent-forms.html
4. http://www.law.cornell.edu/supct/html/historics/USSC_CR_0364_0479_ZO.html
5. http://www.faculty.ucr.edu/%7Eeschwitz/SchwitzPapers/EthicsBooks070801.htm

David Hunter (2007-08-14 03:42:00)
Bolding, excellent idea. I'll use it too for quotes. I should also say I am going to go silent for a bit after this post, I am off to a conference tomorrow and won't be back until next week.
Schrag: Not in the work I've done. Right now I'm in the early stages of a book on the history of riot control. I'm still in the nineteenth century, but in 2005 I went through IRB approval so I could interview my brother about his National Guard service during Hurricane Katrina relief operations. At some point I may find some other people to talk to, but that's all I know.
Sounds like a fascinating book. Okay clearly you aren't at the point of going to an IRB yet. One thing you could do, (you certainly can in the British system) is apply with a broad set of questions around your topic, and then apply for a substantial amendment when you want to add new topics and/or people.
You don't need specific questions, and of course RECs/IRBs shouldn't ask you to provide the impossible. But some idea of general themes or anticipated areas of interest is helpful for the REC. That way they can anticipate whether there are likely to be more ethical issues, so suppose you were interested in the history of sexual deviancy for example, there are likely to be a few more issues raised there, than the history of tea cosys. (A British woollen cover for a tea pot. Yes the Brits are mad.)
Schrag: I'd be very interested to learn who exactly had power in the drafting of the framework. I'm working on the history of recommendations and regulations in the United States; perhaps someone in the U.K. can take up the story there.
The framework was developed in a two year consultation process from what I have read about it. The main players were of course the Economic & Social Research Council. I expect sociologists did dominate, although the consultation was reasonably wide, and I believe it wasn't just social scientists drafting it. However I am not sure how much input went into it from a history perspective simply because I am not sure who funds much of the history research. I would guess some of their funding would come from the ESRC, but the bulk would come from the Arts and Humanities Research Council, which rather than creating it's own research ethics framework has endorsed the ESRC REF.
Schrag: As you know, I am concerned about the protection of autonomy. I don't know what "justice" means in this context, since the above-quoted passage from the Research Ethics Framework is the only use of the term, and it equates justice with minimizing harm.
Right sorry should have explained myself more, most research ethics frameworks buy into something like the four principles approach. On this approach, there are four prima facie moral principles:
1. Respect for Autonomy
2. Respect for Beneficence
3. Respect for Non-maleficence
4. Respect for Justice
None of these principles is pre-eminent, what the outcome ought to be in each situation depends on the situation, and often balancing between these principles. This view is gained widespread acceptance in regards to bioethics and public policy (Even if many of us philosophers have our theoretical doubts about the model) in part because it provides a set of claims that people with wildly different ethical preconceptions can nonetheless agree upon. In this context justice is primarily about the distribution

of research and it's results. So it isn't about harm or benefit directly, it is about the distribution of that harm or benefit. It is somewhat neglected in research ethics (I think because justice issues tend to point to systemic concerns), but you can see cases of it in complaints about trials of drugs that would be unaffordable in the third world, being carried out in the third world (since the research participants gain no long term benefit from the treatment). You can also see it in concerns about over-researched populations, there the concern is that the burden of research is not being evenly spread.
Schrag: I dispute this premise, at least in regard to oral history.

Right, but I was making a more general argument about research, rather than oral history research.
I see no evidence that independent review improves the likelihood that researchers will honor their ethical obligations

There are some obvious explanations for this lack of evidence. The first is that often the outcomes of ethics committee meetings are considered confidential. The second of which is that measuring this is very difficult. However, while I will happily agree that ethics committees get it wrong some of the time, as per your examples, they get it right a lot more often. While the evidence may not be easily available, each time a consent form was improved by a REC that was a benefit, each time a potential harm was averted, that was a benefit... And so on. Is there evidence for this, perhaps not publicly available evidence (another interesting research project, thanks!) but there is a vast amount of anecdotal evidence.
And some evidence can be given to show that committees are more reliable decision makers than individuals, (I've recently written on this here: [1][View PDF] in the Journal of Medical Ethics.
Schrag: You want me to get permission before I talk to other people. How is that anything other than a limitation on the freedom of speech?

It is a limit to the right to research... which is not the same thing as speech even if it happens to involve speaking.
I guess I still am not convinced that there is a significant difference between oral history research and other sorts of research. It is the potential for serious ethics breaches that most bothers me.
Basically your points in favour of getting no or only departmental review are:
1. It is difficult to predict the content of the research beforehand.
2. The harms involved are lower than in other areas, especially biomedical sciences.
3. There is little evidence that IRBs/RECs are the best/most proportionate means of minimising ethical breaches.
My responses are:
1. Some rough outline of topic or area must be available even if the specifics are not. So I think the REC can still make some decision.
2. While the direct physical risk to the participants are infinitely lower (It is hard to see how an interview can directly kill you) the indirect physical risks and social risks are still present and potentially quite high. While sometimes it may be justified to let the participants choose to run those risks, I'm not convinced that a researcher with the obvious conflict of interest that they want to conduct the research is the best person to make that decision. Furthermore harms are only one part of the ethical equation, autonomy is also important. While you are right that a common consent form can help this, the devil is in the details, and without those details being scrutinised history research could still be done in a deceptive fashion for example.
3. I agree there is little overt evidence, but I think there is some reasonably obvious reasons for this as I argued above. I'm inclined to think that despite it being difficult to measure, if you want to argue that ethics committees have made some research ethical worse that they have made some research ethically better. It would take a stunning level of incompetence to do this. Indeed, it would be amazing that individual researchers can be ethically perfect, but get a bunch of them together into a committee, and suddenly they can only make things worse.
I'm all for reform of the current system, and it's moving away from a system designed by and staffed by for the most part medics. I just don't see the need to throw the whole thing away, I'm inclined to tweak it instead.

1. `http://jme.bmj.com/preprint/elliott.pdf`

Zachary M. Schrag (2007-08-15 21:47:00)

It seems that no lack of evidence will dissuade you from conjuring hosts of deceptive historians, and no amount of evidence will persuade you that ethics committees attain "a stunning level of incompetence" frequently enough to keep this blog in business.

The paper on "The experiences of Ethics Committee Members" shows only that the more people who review a project, the more likely they are to demand modifications. It does not show that these are modifications for the better. Too many cooks spoil the broth, and too many inexpert ethical reviewers leads to the kind of absurdity I document.

ZMS

2.8.2 Study Finds IRBs Make Consent Forms Harder to Read (2007-08-03 12:12)

In "[1]Human-Subjects Research: Trial and Error," (Nature, 2 August 2007), Heidi Ledford writes:

> When [physician William] Burman, of the University of Colorado in Denver, joined in two studies run by the Tuberculosis Trials Consortium, he knew that the consent forms needed to cater to people with an eighth-grade reading level (comprehensible to an educated 13-year-old). The trials involved multiple institutions, and the forms were sent to 39 institutional review boards (IRBs) — committees designed to determine whether a proposed experiment is ethically sound. The final approvals came in 346 days later, but what the IRBs sent back, Burman found disturbing.
> "The consent forms were longer. The language was more complex," Burman says. "And errors were inserted at a surprising frequency." In one case, a potential negative side effect of the treatment had been accidentally edited out. Burman responded to the problem as any researcher would: he studied it. He had an independent panel review the changes. The reviewers found that 85 % of the changes did not affect the meaning of the consent forms, but that the average reading level had jumped from that of an eighth grader to that of a twelfth grader (around 17 years old)1. His results confirmed something he'd suspected for some time. "I started to think about what was happening and it just seemed like the system was flawed." It was time to change the system.

Though the article (and the accompanying editorial, "[2]Board Games," does not mention non-biomedical research, it does highlight the problem of relying on local IRBs, which are essentially committees of amateurs, to handle specialized tasks like drafting consent forms and determining procedures for confidentiality. See [3]In Search of Expertise.

1. http://www.nature.com/news/2007/070730/full/448530a.html
2. http://www.nature.com/news/2007/070730/full/448511b.html
3. http://institutionalreviewblog.blogspot.com/2007/02/in-search-of-expertise.html

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2.8.3 To the Historian All Men Are Dead (2007-08-08 22:25)

> Blogger's note: Since I find myself in dialogue with a bioethicist working in the United Kingdom (see [1]IRBs vs. Departmental Review and its many [2]comments), now seems like a good time to present the views of Sir John Kaye, a British historian of the nineteenth century who used correspondence and interviews, as well as documents, in his work. I first read this passage as an impressionable college freshman, and it shaped my views of what historians do and why.
> ZMS

Sir John Kaye, "Preface," 1870.
From *Kaye's and Malleson's History of the Indian Mutiny of 1857-8* (1897-1898; reprint, Westport, Connecticut: Greenwood, 1971), vol. 2, xi-xiii.

Dealing with the large mass of facts, which are reproduced in the chapters now published, and in those which, though written, I have been compelled to reserve for future publication, I have consulted and collated vast piles of contemporary correspondence, and entered largely into communication, by personal intercourse or by letter, with men who have been individually connected with the events described. For every page published in this volume some ten pages have been written and compiled in aid of the narrative; and if I have failed in the one great object of my ambition, to

tell the truth, without exaggeration on the one hand or reservation on the other, it has not been for want of earnest and laborious inquiry or of conscientious endeavour to lay before the public and honest exposition of the historical facts as they have been unfolded before me.

Still it is probable that the accuracy of some of the details in this volume, especially those of personal incident, may be questioned, perhaps contradicted, notwithstanding, I was about to say, all the care I have taken to investigate them, but I believe that I should rather say "by reason of that very care." Such questionings or contradictions should not be too readily accepted; for although the authority of the questioner may be good, there may be still better authority on the other side. I have often had to choose between very conflicting statements; and I have sometimes found my informants to be wrong, though apparently with the best opportunities of being right, and have been compelled to reject, as convincing proof, even the overwhelming assertion, "But, I was there." Men who are personally engaged in stirring events are often too much occupied to know what is going on beyond the little spot of ground which holds them at the time, and often from this restricted stand-point they see through a glass darkly. It is hard to disbelieve a man of honour when he tells you what he himself did; but every writer, long engaged in historical inquiry, has had before him instances in which men, after even a brief lapse of time, have confounded in their minds the thought of doing, or the intent to do, a certain thing, with the fact of having actually done it. Indeed, in the commonest affairs of daily life, we often find the intent mistaken for the act, in the retrospect.

The case of Captain Rosser's alleged offer to take a Squadron of Dragoons and a troop of Horse Artillery to Dehli on the night of the 10th of May . . . may be regarded as an instance of this confusion. I could cite other instances. One will suffice:–a military officer of high rank, of stainless honour, with a great historical reputation, invited me some years ago to meet him, for the express purpose of making to me a most important statement, with reference to one of the most interesting episodes of the Sipáhi War. The statement was a very striking one; and I was referred, in confirmation of it, to another officer, who has since become illustrious in our national history. Immediately on leaving my informant, I wrote down as nearly as possible his very words. It was not until after his death that I was able orally to consult the friend to whom he had referred me, as being personally cognisant of the alleged fact–the only witness, indeed, of the scene described. The answer was that he had heard the story before, but that nothing of the kind had ever happened. The asserted incident was one, as I ventured to tell the man who had described it to me at the time, that did not cast additional lustre on his reputation; and it would have been obvious, even if he had rejoiced in a less unblemished reputation, that it was not for self-glorification, but in obedience to an irrepressible desire to declare the truth, that he told me what afterwards appeared to be not an accomplished fact, but an intention unfulfilled. Experiences of this kind render the historical inquirer very sceptical even of information supposed to be "on the best possible authority." Truly, it is very disheartening to find that the nearer one approaches the fountain-head of truth, the further off we may find ourselves from it.

But, notwithstanding such discouraging instances of the difficulty of extracting the truth, even from the testimony of truthful men, who have been actors in the scenes to be described, I cannot but admit the general value of such testimony to the writer of contemporary history. And, indeed, there need be some advantages in writing of events still fresh in the memory of men to compensate for its manifest disadvantages. These disadvantages, however, ought always to be felt by the writer rather than by the reader. It has been often said to me, in reply to my inquiries, "Yes, it is perfectly true. But these men are still living, and the truth cannot be told." To this my answer has been: "To the historian all men are dead." If a writer of contemporary history is not prepared to treat the living and the dead alike–to speak as freely and as truthfully of the former as of the latter, with no more reservation in the one case than in the other–he has altogether mistaken his vocation, and should look for a subject in prehistoric times. There are some actors in the scenes here described of whom I do not know whether they be living or whether they be dead. Some have passed away from the sphere of worldly exploits whilst this volume has been slowly taking shape beneath my pen. But if this has in any way influenced the character of my writing, it has only been by imparting increased tenderness to my judgment of men who can no longer defend themselves or explain their conduct to the world. Even this offence, if it be one against historical truth, I am not conscious of having actually committed.

1. http://institutionalreviewblog.blogspot.com/2007/08/irbs-vs-departmental-review.html
2. http://www.blogger.com/comment.g?blogID=52577829256554519&postID=7221933300006691539

2.8.4 Insider-Outsider-Down Under (2007-08-10 14:15)

[1]David Hunter kindly alerted me to "[2]An inside-outsider's view of Human Research Ethics Review," posted on [3]Culture Matters, a blog hosted by the Department of Anthropology at Macquarie University, Sydney, Australia. The posting is anonymous, but the author describes himself "as a sitting member of Macquarie University's review board for human research," which I think identifies him as [4]Greg Downey. Alas, another failed attempt at keeping an informant anonymous.

Downey's [?] essay is a rebuttal to Jack Katz, "[5]Ethical Escape Routes for Underground Ethnographers," American Ethnologist 33 (2006): 499-506. In that essay, Katz argues that protocol-review, the basic tool of ethics committees, is inappropriate for ethnographic fieldwork because fieldwork is so unpredictable. As Katz puts it

> when researchers participate in naturally occurring social life and write field notes on what they observe, they often encounter people and behavior they cannot anticipate. Indeed, one of the strongest reasons for conducting participant-observation research is the view that the current state of knowledge, as shaped by fixed-design research that prespecifies the kind of people to be studied and the ways to study them (sampling designs, formalized questions and protocols, and time- and space-delimited situations in which to observe), is artificial, a product not of the subjects' social lives but of prejudice.

He also notes that some ethnographers draw from past experiences and observations of everyday life, neither of which can be reviewed by an ethics committee. He then suggests ways that researchers and universities might escape the regulatory boundaries that seem to require prior review of research.

Downey [?] seeks to rebut this argument by insisting that prior review can improve the ethical content of anthropological research. He writes,

> The ethics review process should not be avoided, escaped, or 'exempted' away. Rather, ethics review boards can be educated about ethnographic research methods and encouraged to produce clear standards for our research. I worry that too many anthropologists inadvertently suggest that 'ethics' is a bureaucratic hoop, that the 'politics of representation' is a far more worthy consideration than the nuts and bolts of evaluating risk, minimizing dangers to participants (including researchers), balancing public interest against risks that can't be eliminated, and thinking hard about our relationships to our subjects, our collaborators, the field, the public at large, our home institutions, and those who support our work.

This is unresponsive to Katz's critique. If anthropologists lack "clear standards for our research," by all means they should develop them, with or without the help of scholars in other fields. But I don't see how ethics committees can contribute to this effort by demanding from researchers that they get "preauthorization for observations and interviews," as Katz puts it. That's just a demand for information that doesn't exist.

Downey [?] also writes,

> Katz's suggestion that decisions be made public—for many reasons—seems to me an excellent one, but that can happen on the departmental level even without university boards being involved. That is, each student need not invent the application anew every time. The goal is not vacuous or self-righteous 'boilerplate language' for ethics applications, as one recent anthropology blogger suggested, but a legitimate attempt by the anthropology community to think about effective techniques for recurring issues such

as oral informed consent, naturalistic observation in heavily trafficked settings, the use of photographs, the protection of populations under dangerous regimes, and the ethical requirements on those learning of illegal activity.

OK, so we have some movement toward compromise and consensus. I would like to suggest that if Downey [?] believes that departments are the appropriate organs to publicize ethics-committe success stories, the first department to do so should be the Department of Anthropology at Macquarie University. A listing of proposed ethnography projects and the improvements made to them by the Macquarie ethics committee could prove a model for researchers around the world.
Finally, I thank Downey [?] for drawing my attention to Australia's
[6]National Statement on Ethical Conduct in Human Research. This document is so shocking that I will save comments on it until I have more time.

1. http://www.blogger.com/profile/10511387997239132302
2. http://culturematters.wordpress.com/2007/08/07/an-inside-outsiders-view-of-human-research-ethics-review/
3. http://culturematters.wordpress.com/
4. http://www.anth.mq.edu.au/staff/staff_GDowney_profile.html
5. http://www.anthrosource.net/doi/abs/10.1525/ae.2006.33.4.499
6. http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Jovan (2007-08-12 07:36:00)
Zachary,
Greg's username appears on the post on the homepage of blog. I'm surprised that it doesn't appear anywhere on the permalink page – something I hadn't noticed before. Obviously a problem with our theme. We might have to change as we don't want to give the impression that we are posting anonymously.
Cheers,
Jovan Maud

Zachary M. Schrag (2007-08-12 12:01:00)
Thank you for the clarification.
ZMS

2.8.5 Symposium on Censorship and Institutional Review Boards (2007-08-10 22:09)

The long-awaited Northwestern University Law Review [1]Symposium on Censorship and Institutional Review Boards has hit the Web. I have read and blogged about some of these articles in their SSRN incarnations, but I look forward to reading the rest.

1. http://www.law.northwestern.edu/journals/lawreview/issues/101.2.html

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2.8.6 James Weinstein's Anti-Intellectualism (2007-08-11 14:08)

In his contribution to the Northwestern symposium, "[1]Institutional Review Boards and the Constitution," Professor James Weinstein defends the constitutionality of IRB review for both biomedical and non-biomedical research. Though he does not quite say that IRB review of journalism would be unconstitutional, he is clearly troubled by it, so

he needs to distinguish journalism from the social sciences. He does so by denigrating scholarly research as largely irrelevant to democracy:

> Although there is obviously a considerable area of overlap, social science research and journalism have distinct purposes and perform different societal functions. The primary purpose of research, at least at universities, is to discover knowledge both for its own sake and for the betterment of human kind, not to improve the practice of democracy by supplying the public with information to facilitate the "voting of wise decisions." While some of this knowledge will facilitate public as well as private decisionmaking, much will not. And while academic researchers occasionally engage in research with the specific purpose of producing information to persuade others on matters of public concern, such ideological advocacy is not the primary ethos of academic research and, indeed, can be in tension with the primary academic goal of discovering truth regardless of its political or social implication. In contrast, a primary purpose of journalism is to inform people about matters of public concern and to act as a "watchdog" against governmental abuse and official malfeasance. Similarly, the function of the editorial side of journalism is precisely to influence public opinion.
>
> This essential difference between social science research and journalism is reflected in the publications through which these two professions communicate with the public—scholarly journals and academic books versus newspapers and magazines. Scholarly publications are usually aimed at a narrow, specialized audience and address people in their professional capacity; journalistic media, in contrast, are typically aimed at a more general audience, often addressing people in their capacity as citizens (as well as consumers). Moreover, not only do general circulation newspapers and magazines usually contain an editorial page in which the publisher and editors try to persuade people on matters of public concern, these publications also often have an opinion page in which members of the public are invited to do the same. In contrast, while some scholarly publications publish editorials and even more commonly letters from scholars in response to an article or some academic issue, these publications do not generally solicit the views of the general public. Accordingly, although scholarly journals and books, on the one hand, and newspapers and magazines, on the other, both form part of the "structural skeleton that is necessary for public discourse to serve the constitutional value of democracy," it is the newspaper and magazines that form the "backbone" of this structure. Scholarly publications, in contrast, contribute less central support for the structure (a "shin bone" perhaps, to continue Post's orthopedic metaphor).
>
> The Court might therefore take a more refined approach to a law that imposed IRB regulations directly upon social scientists at research institutions than it would to similar restrictions imposed on journalists. Borrowing a page from its defamation jurisprudence, the Court might hold that to the extent the interviews related to matters of public concern such as attitudes towards homosexuality, abortion, or the war in Iraq, the regulations could not be applied. With respect to interviews on subjects not of public concern, such as the language used by waiters and waitresses or whether people can match dogs to their owners, the Court might well apply a lesser degree of scrutiny. This distinction would reflect the more important role played by the press in our democracy. It would also take account of the related fact that unlike the typical journalistic interview or survey, many social science interviews and surveys will not contribute to democratic self-governance.
>
> It is true that avoiding an overly-refined doctrine that is difficult to administer argues for deeming all interviewing techniques directed towards producing public information a unified medium warranting the same high level of First Amendment protection. Still, the lesser contribution that social science interviews generally make to the "constitutional value of democracy" suggests that regulations that burden these communications should trigger something less than the exacting scrutiny that would be applied if IRB regulations were applied to journalists' communication with their sources.

The idea that the "typical journalistic interview or survey" involves great questions of war and peace and commerce and culture, while the typical social-science interview or survey involves dog owners, is, I suppose, a testable hypoth-

esis, though not one that Weinstein tests by sampling news stories and journal articles. Absent such evidence, it is an anti-intellectual slur.
Weinstein concedes that "funding issues aside, it is possible that the Court would find IRB regulations unconstitutional as applied to research using only traditional interview techniques," especially if they were imposed on survey or interview research "on matters of public concern." His tolerance for IRBs must therefore rest on his belief that such research is so rare that it's OK if it is caught up in a system designed to protect human subjects from useless research.
I will let Dr. Woodrow Wilson reply:

> There is the statesmanship of thought and there is the statesmanship of action. The student of political science must furnish the first, out of his full store of truth, discovered by patient inquiry, dispassionate exposition, fearless analysis, and frank inference. He must spread a dragnet for all the facts, and must then look upon them steadily and look upon them whole. It is only thus that he can enrich the thinking and clarify the vision of the statesman of action, who has no time for patient inquiry, who must be found in his facts before he can apply them in law and policy, who must have the stuff of truth for his conscience and his resolution to rely on. . .
> The man who has the time, the discrimination, and the sagacity to collect and comprehend the principal facts and the man who must act upon them must draw near to one another and feel that they are engaged in a common enterprise. The student must look upon his studies more like a human being and a man of action, and the man of action must approach his conclusions more like a student.

[Woodrow Wilson, "[2]The Law and the Facts: Presidential Address, Seventh Annual Meeting of the American Political Science Association," The American Political Science Review 5 (February 1911), 8.]

1. http://www.law.northwestern.edu/journals/lawreview/v101/n2/493/LR101n2Weinstein.pdf
2. http://links.jstor.org/sici?sici=0003-0554%28191102%295%3A1%3C1%3ATLATFP%3E2.0.CO%3B2-P

Rebecca Tushnet (2007-08-11 17:59:00)
Another relevant question, it seems to me, is how many people read the newspaper every day v. how many attend college, where they learn things that are the result of social science research and that may shape their later political actions. Research results don't just sit in journals; the good ones get transmitted in other ways, not least through journalism. How else would the NYT Science section fill up?

Zachary M. Schrag (2007-08-11 19:19:00)
Or the [1]Washington Post Outlook section?

1. http://www.washingtonpost.com/wp-dyn/content/article/2006/05/05/AR2006050501768_pf.html

2.8.7 How Oral History Really Works (2007-08-12 13:25)

In "'[1]If I See Some of This in Writing, I'm Going to Shoot You': Reluctant Narrators, Taboo Topics, and the Ethical Dilemmas of the Oral Historian," Oral History Review 34 (2007): 71-93, Tracy E. K'Meyer and A. Glenn Crothers present some of the challenges faced by oral historians in determining how much deference to give to a narrator's wishes. They describe a series of interviews they conducted with Marguerite Davis Stewart, a World War II Red Cross veteran, who contacted the Oral History Center at the University of Louisville offering to tell her stories.
Over three months, the interviewers recorded 32 hours of conversation, and found themselves wrestling with a number of questions. For example, they had to decide how much they should credit Stewart's dubious claim that she didn't think about race, how hard to press her for details of important but sensitive topics like her divorce, and how seriously

to take Stewart's jests about not wanting some stories to be recorded. And since Stewart was blind and confined to a wheelchair, the interviewers had to decide how much time they could devote to helping her in daily life, and when to call in a qualified social worker.
Though the article does not mention IRB review, it suggests the futility of such review in solving the real questions that are likely to confront oral history interviewers. It shows that the hard questions were not present at the start of the process, but only emerged well after the point that an IRB would have approved, modified, or rejected a proposal. And that the tough questions were highly specific to the narrator. Thus, K'Meyer and Crothers write,

> Conflict arose when, over time, Stewart sought our commitment to write a book according to her vision and outline. By that point in the interview process it had become clear to us that there would not be sufficient documentary resources to supplement her oral history and support a book-length manuscript. More important, because of her resistance there were gaps in the story that could not be filled. In short, we explained to her on frequent occasions that we could not write her book. We did agree to fulfill the original goal, to help her record the story, and to put an edited form of the transcript into the library for public use, organized according to the themes and chapters she identified. In effect, we promised separate products: her story deposited in the library and our interpretations in our academic work.

Even the most aggressive IRBs have not–as far as I know–demanded to review oral histories one narrator at a time, so they could not police such idiosyncratic concerns.
Finally, the questions raised in this article do not have clear right or wrong answers. It would be dreadful if an IRB could forbid the research or punish the interviewers because its members did not like the choices the interviewers made.

1. http://caliber.ucpress.net/doi/abs/10.1525/ohr.2007.34.1.71

2.8.8 Evolving Research (2007-08-14 11:00)

Two recent blog postings raise the question of the awkward fit between IRBs' insistence on protocol review and research, such as ethnography and oral history, which begins with no set protocol.
University of Winnipeg professor of politics Christopher Leo poses and then answers positively the question, "[1]Does the Ethics Bureaucracy Pose a Threat to Critical Research?" This provocative essay raises so many key questions that I plan to return to it in future postings. For now, note Leo's description about the evolving nature of his work:

> Many researchers concerned with politics and policy stay in regular touch with politicians and public servants and, in the process, ask them questions the answers to which may well be used in future publications. That is an essential part of the research process because regular contact with well-informed people makes it possible for researchers to stay abreast of events and identify important issues as they arise.
> So when does a query become a research question and a conversation an interview that requires ethics review? The guidelines are little help in answering that question, but, if we take them literally, they would appear to have taken from university researchers a right that every ordinary citizen enjoys, namely that of picking up the phone and talking to a politician or public servant without applying for bureaucratic permission to do so.

Meanwhile, over at Savage Minds, Alex Golub, assistant professor of anthropology at the University of Hawai'i Manoa (aka Rex), touches on the same question in the posting, "[2]Using informed consent forms in fieldwork." He writes,

"In some cases I interviewed people I'd known for years. I'd have breakfast or lunch with them and then schedule the official 'interview' for later on in the week."
IRBs that rigidly follow a biomedical model for ethics may insist that research protocols be spelled out in advance– even demanding sample questions. Such demands are inappropriate for the kind of work described by Leo and Golub: keeping in touch with knowledgeable people over a period of time.
An alternative appears in the University of Pennsylvania's [3]Policy Regarding Human Subject Research in the Sociobehavioral Sciences. That policy accommodates such projects by freeing researchers from the requirement to submit "a fixed research protocol":

> Evolving Research
> Evolving research is a class of research in the sociobehavioral sciences in which the questions that are posed evolve in the course of investigation. An example is ethnography, where research questions may only be clarified after a period of observation and where current findings drive the next steps in the study. This class of research typically involves studying human behavior in non experimental settings, with or without active participation by the investigator; but it can also occur in more structured observational settings (e.g., oral histories, focus groups). In specific cases, such research does not pose more than minimal risk to human subjects and is considered to be "exempt from review," as stated below. An approved mechanism is necessary for presenting to the IRB a research protocol that will evolve in the course of investigation. This policy institutes such a mechanism via certification.
> 4a. Research involving only non-interventionist observation of behavior occurring in public (including domains of the Internet clearly intended to be publicly accessible), for which no identifying information is recorded, is exempt from review.
> 4b. Investigators are allowed to use their certification, as per policy item 1, as a reference for describing evolving research activities to the IRB in lieu of a fixed research protocol.
> This policy eliminates the need for investigators doing evolving research to spell out the details of a dynamic research protocol. The IRB can be assured that the research will be conducted in an ethically appropriate fashion, with full protection of human subjects, when certified investigators attest that their pre-registered research plan will be conducted within the ethical framework laid out in the training program for which they are certified.

In other words, if you have shown you know what you are doing, you don't have to get the IRB's approval for specific questions or topics.
I must note, however, that the Penn policy includes this disclaimer: "Note that different studies by the same investigator(s) must be submitted to the IRB as separate research protocols. These must not be viewed as a single study evolving from one investigation into another." I wonder what the Penn IRB would do with someone like Leo or Golub, who has the audacity to keep in touch with people for years.

1. http://blog.uwinnipeg.ca/ChristopherLeo/archives/2007/08/does_the_ethics.html#more
2. http://savageminds.org/2007/08/10/using-informed-consent-forms-in-fieldwork/
3. http://www.upenn.edu/almanac/volumes/v53/n06/or-hsresearch.html

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2.8.9 Another frustrated anthropologist (2007-08-14 13:30)

From
http://insidehighered.com/news/2007/08/14/soc

2.8.10 Incestuous Gay Monkey Sex (2007-08-14 22:16)

Scott Jaschik reports on the American Sociological Association annual meeting, "[1]Who's Afraid of Incestuous Gay Monkey Sex?," Inside Higher Ed, 14 August 2007:

> Mary L. Gray, an anthropologist at Indiana University at Bloomington, described her work in graduate school, which raised all kinds of red flags with her IRB at the time: She wanted to study the way gay, lesbian, bisexual and transgender youth develop their identities in the rural Southeast, and she wanted to base her research on interviews with such youth, under the age of 18, without their parents' knowledge. Her project, she said, "had every imaginable red flag."
>
> With some regrets, she won IRB support by appealing to prejudice many have of the rural South. Although she had no evidence to make this claim, she argued that the situation in the rural South is "so awful" for the young people she was studying that she couldn't possibly approach their parents for consent. (Actually Gray believes that the situation for gay youth is more subtle and less uniform than she suggested, but she guessed it would work with the IRB, and it did.)
>
> Because the IRB was — like most IRB's — oriented around medical research, not social science, the focus was on potential harm that Gray could cause her research subjects in person. Gray reported that she received relatively little questioning or guidance from her IRB on one of her major areas of research: what the young people she studied wrote about themselves online. Gray developed her own ethics rules (she wrote to the subjects to ask permission), but she was struck by what was and wasn't considered important by the IRB.
>
> To the IRB, "distance read as objectivity" and so was by definition "good," she said. Never mind that what her subjects shared about themselves online was as important as the thoughts they shared in person. This points to Gray's broader critique of the IRB process. Social scientists frequently complain about IRB's failing to understand their studies, but Gray suggested it was time to move beyond the idea of just adding more social scientists to the panel. Rather, she said it was time to question certain underlying assumptions of IRB's and whether they even make sense for social science. It's not that Gray doesn't think there are ethical issues researchers must consider, but whether the medical model can ever work for projects that don't follow the pattern of having a hypothesis designed to lead to the dispassionate creation of generalizable knowledge.
>
> Gray said that "IRB fatigue" is discouraging researchers — especially graduate students — from even trying to get projects approved.

I can't say that I'd want a graduate student in any field asking minors about their sex lives without some kind of supervision. But it sounds as though UC San Diego's IRB lacked the expertise to give Gray meaningful guidance. That lack of expertise is built into the system of local IRB review, and it can produce decisions that are too lax as well as those that are too strict.

1. http://insidehighered.com/news/2007/08/14/soc

2.8.11 Study Finds IRBs Impose Inappropriate Forms and Guidelines (2007-08-16 21:17)

I thank Brad Gray for alerting me to:
Sarah Flicker et al., "[1]Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards," Journal of Urban Health 84 (July 2007); 478-493.
I do not have access to the full article, but here's the abstract:

National and international codes of research conduct have been established in most industrialized nations to ensure greater adherence to ethical research practices. Despite these safeguards, however, traditional research approaches often continue to stigmatize marginalized and vulnerable communities. Community-based participatory research (CBPR) has evolved as an effective new research paradigm that attempts to make research a more inclusive and democratic process by fostering the development of partnerships between communities and academics to address community-relevant research priorities. As such, it attempts to redress ethical concerns that have emerged out of more traditional paradigms. Nevertheless, new and emerging ethical dilemmas are commonly associated with CBPR and are rarely addressed in traditional ethical reviews. We conducted a content analysis of forms and guidelines commonly used by institutional review boards (IRBs) in the USA and research ethics boards (REBs) in Canada. Our intent was to see if the forms used by boards reflected common CBPR experience. We drew our sample from affiliated members of the US-based Association of Schools of Public Health and from Canadian universities that offered graduate public health training. This convenience sample (n = 30) was garnered from programs where application forms were available online for download between July and August, 2004. Results show that ethical review forms and guidelines overwhelmingly operate within a biomedical framework that rarely takes into account common CBPR experience. They are primarily focused on the principle of assessing risk to individuals and not to communities and continue to perpetuate the notion that the domain of "knowledge production" is the sole right of academic researchers. Consequently, IRBs and REBs may be unintentionally placing communities at risk by continuing to use procedures inappropriate or unsuitable for CBPR. IRB/REB procedures require a new framework more suitable for CBPR, and we propose alternative questions and procedures that may be utilized when assessing the ethical appropriateness of CBPR.

1. http://www.springerlink.com/content/w1xw7343v362wh25/?p=4565f4e79c5d4ab995648c35a6bc8f34&pi=5

2.8.12 The Fine Line Between Social Science and Journalism (2007-08-19 21:01)

It's sometimes so fine you can't see it at all. The Washington Post and Stanford University are [1]cosponsoring a survey on political ads.

1. http://www.washingtonpost.com/wp-dyn/content/article/2006/09/19/AR2006091901180.html

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2.8.13 Guidance Creep (2007-08-20 09:11)

I am often frustrated by the argument that federal regulations provide, in Jeffrey Cohen's [1]words, "sufficient flexibility for the efficient and appropriate review of minimal risk research." While individual IRBs have much to answer for, federal regulators have, over the years, stripped them of a great deal of flexibility.
I recently came across a striking example of this. In 1983, Richard Louttit of the National Science Foundation, who had helped craft the list of exemptions encoded in 45 CFR 46.101, explained them as follows:

Much research of minimal risk was exempted from IRB review in order to reduce the IRB workload so that research involving ethical questions could get more than cursory review. But some institutions have decided that the IRB, or its chairperson, must review proposals to decide if they are exempt from review. If this seems contradictory, it is. And this was not envisioned by the staff group which worked out the exemptions.

> [Richard T. Louttit, "Government Regulations: Do They Facilitate or Hinder Social and Behavioral Research?," in Joan E. Sieber, ed., NIH Readings on the Protection of Human Subjects in Behavioral and Social Science Research: Conference Proceedings and Background Papers (Frederick, Md: University Publications of America, 1984), 179.]

Yet in 1995, the Office for Protection from Research Risks adopted just that contradictory position:

> Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. OPRR advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research. ([2]OPRR Reports, 95-02)

The regime in place today is far more intrusive than the one worked out in 1981. Changes in the regulations themselves are part of the problem, but so are radical reinterpretations like the one above.

1. http://hrpp.blogspot.com/2006/03/mission-creep.html
2. http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm

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Shirley Isbill (2007-08-22 22:52:00)
Office for Protection from Research Risks adopted the position: Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). It does not matter what the intent of the "proposing" group was; the deciding group adopted a policy which allowed institutions to give IRBs the authority to decide what research is exempt.

Zachary M. Schrag (2007-08-22 23:13:00)
Thank you for your comment. I have two replies.
First, OPRR did not "allow" institutions to grant more power to their IRBs. It *advised* them to do so. Such advice makes a farce of the idea of local autonomy.
Second, the 1981 regulations, including the exemptions, were promulgated after more than a year of public debate and comment following draft regulations in the Federal Register. They were accompanied by assurances from federal officials, like the one I cited, that social scientists had nothing to fear from the new rules. Perhaps it was legal for OPRR to gut the exemptions with a simple letter like this, but it was bad policy and dirty pool.

2.8.14 Northwestern IRB: Unsystematic Interviews Are Not Subject to Review (2007-08-21 10:47)

Today's New York Times features a story, "[1]Criticism of a Gender Theory, and a Scientist Under Siege," about the case of J. Michael Bailey, Professor of Psychology, Northwestern University. Bailey's controversial book about identity. The book provoked several complaints, including the charge by "four of the transgender women who spoke to Dr. Bailey during his reporting for the book . . . that they had been used as research subjects without having given, or been asked to sign, written consent."
As reported by the Times, the case was investigated by Alice Domurat Dreger, Associate Professor of Clinical Medical Humanities & Bioethics at Northwestern, who has posted a draft article on the subject, "The Controversy Surrounding The Man Who Would Be Queen: A Case History of the Politics of Science, Identity, and Sex in the Internet Age," [[2]PDF]

Dreger finds that Bailey did not commit serious ethical violations, nor did he violate the requirements for IRB review:

> the kind of research that is subject to IRB oversight is significantly more limited than the regulatory definition of "human subject" implies. What is critical to understand here is that, in the federal regulations regarding human subjects research, research is defined very specifically as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (United States Department of Health and Human Services, 2005, sect. 46.102, def. "b"). In other words, only research that is truly scientific in nature—that which is systematic and generalizable—is meant to be overseen by IRBs. Thus, a person might fit the U.S. federal definition of "human subject" in being a person from whom a researcher gains knowledge through interpersonal interaction, but if the way that the the knowledge she or he intends to gain is unlikely to be generalizable in the scientific sense, the research does not fall under the purview of the researcher's IRB.
>
> It is worth noting here, for purposes of illustration of what does and doesn't count as IRB-qualified work, that I consulted with the Northwestern IRB to confirm that the interviews I have conducted for this particular project do not fall under the purview of Northwestern's IRB. Although I have intentionally obtained data through interpersonal interaction, the interview work I have conducted for this historical project has been neither scientifically systematic nor generalizable. That is, I have not asked each subject a list of standardized questions—indeed, I typically enjoyed highly interactive conversations during interviews; I have not interviewed all of my subjects in the same way; I have negotiated with some of them to what extent I would protect their identities. This is a scholarly study, but not a systematic one in the scientific sense. Nor will the knowledge produced from this scholarly history be generalizable in the scientific sense. No one will be able to use this work to reasonably make any broad claims about transsexual women, sex researchers, or any other group.
>
> When I put my methodology to the Northwestern IRB, the IRB agreed with me that my work on this project is not IRB-qualified, i.e., that, although I have obtained data from living persons via interactions with them, what I am doing here is neither systematic nor generalizable in the scientific sense.

Clearly Bailey's work hurt the feelings of some people he wrote about, but, as Dreger notes, "scholarship (like journalism) would come to a screeching halt if scholars were only ever able to write about people exactly according to how they wish to be portrayed." Indeed, that's what social scientists have been arguing for three decades.

1. http://www.nytimes.com/2007/08/21/health/psychology/21gender.html
2. http://www.bioethics.northwestern.edu/faculty/work/dreger/controversy_tmwwbq.pdf

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2.8.15 Macquarie's Respect for Expertise (2007-08-24 16:05)

[1]A few weeks ago I critiqued "[2]An inside-outsider's view of Human Research Ethics Review," a blog post by Greg Downey of the Department of Anthropology at Macquarie University, Australia. Downey complained in a follow-up comment that I had "singled [him] out on [my] blog for derision," an unfair charge, given the effort I have put into deriding a wide assortment of scholars and public officials. But he took the bait, and in two follow-up posts, [3]Dr. Zachary Schrag on ethics, IRB & ethnography and [4]Some practical notes on ethics applications, he explains some of the ethics review process at Macquarie. Together with the "[5]Human Ethics" page of the Macquarie Research Office, these postings provide a glimpse at a system that cares more about research ethics than regulatory compliance.
Particularly striking is Downey's description of who reviews applications:

> A kind of departmental review does take place within the university-wide committee at Macquarie, as members of the committee are clustered so that color-coded sub-groups do the preliminary and most

> serious review of applications for which they have special expertise. If an application has to go to the whole committee (for example, research with children, medical procedures, Aboriginal Australian groups, or ethically challenging research tends to), we usually turn to the members of our committee who are best versed in the area of study. If we have a particularly difficult ones, we'll consult with a faculty member outside the committee who has special experience.

The key words here are "special expertise," "best versed in the area of study," and "special experience." Someone at Macquarie has decided that having a nutritionist review oral history, or an oral historian review nutrition experiments, is not in the best interest of researcher or subject, but that having knowledgeable people review applications might make everyone happy. I am particularly impressed that the experts do the preliminary review, which under the American regulatory framework (I'm not sure about Australia) would mean giving them the power to provide exemptions or expedited approval.

As I have noted in comments on his postings, Downey has yet to persuade me that even this level of expert review is necessary for projects by trained researchers that only involve survey, interview, and observation research, and I remain attracted to the University of Pennsylvania system, under which researchers are certified and then, largely, left alone. But I thank Downey for introducing me to a university that is thinking hard and creatively about ethical review.

1. http://institutionalreviewblog.blogspot.com/2007/08/insider-outsider-down-under.html
2. http://culturematters.wordpress.com/2007/08/07/an-inside-outsiders-view-of-human-research-ethics-review/
3. http://culturematters.wordpress.com/2007/08/20/dr-zachary-schrag-on-ethics-irb-ethnography/
4. http://culturematters.wordpress.com/2007/08/23/some-practical-notes-on-ethics-applications/
5. http://www.research.mq.edu.au/researchers/ethics/human_ethics

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2.9 September

2.9.1 Laud Humphreys Remembered (2007-09-14 11:43)

Scott McLemee's essay, "[1]Wide-Stance Sociology" (Inside Higher Ed, 12 September 2007) uses Senator Larry Craig's arrest as a news hook for a discussion of the life and career of sociologist Laud Humphreys. Humphreys's 1960s research on men who found male lovers in public restrooms is a touchstone for advocates of IRB review of observational research. But as McLemee and some of the comments make clear, the case was far more nuanced than the medical-research scandals that inspired the federal requirement for ethical review, nor was his use of deliberate deception in any way typical of the work of the social scientists who now find themselves constrained by IRBs.

1. http://insidehighered.com/views/2007/09/12/mclemee

2.9.2 Study Finds IRBs Exaggerate Risks of Survey Questions (2007-09-14 12:38)

Michael Fendrich, Adam M. Lippert, and Timothy P. Johnson, "[1]Respondent Reactions to Sensitive Questions," Journal of Empirical Research on Human Research Ethics 2 (September 2007): 31-37

Perhaps because they are punished for being too lax but never for being too strict, IRBs tend to err on the side of what they consider caution, exaggerating the risks of proposed research. It's easy to do so when, as these authors put it, "board members often rely on their 'gut' feeling in determining the potential for survey questions to effect adverse reactions."

To replace that gut feeling with some evidence, Fendrich, Lippert, and Johnson asked survey respondents who had

been asked about illegal drug use whether they had felt felt threatened or embarrassed by the questions. Not much: the average score was less than 2 on a 7-point scale. But when asked if other people would feel threatened by those questions, the numbers shot above 5. Thus, survey respondents are as bad as IRBs at guessing how other people will feel about being questioned.
The authors conclude:

> Consent documents often summarize potential adverse subject reactions to questions. For example, in the current study, the University of Illinois at Chicago's REC [research ethics committee] approved consent document contained the following two sentences under the heading: "What are the potential risks and discomforts?"
>
> > There is a risk that you may feel anxious, uncomfortable or embarrassed as a result of being asked abut drug use and drug testing experience. However, you are free not to answer any question, and you are free to withdraw from the study at any time.

If our findings can be generalized to other studies asking questions about drug use, the first sentence may inappropriately convey an exaggerated sense of a drug survey's risk. Even though voluntary participation is a non-contingent right, the second sentence seems to link the right of refusal and the voluntary nature of participation to this exaggerated risk.
The first author's experience as a member and Chair of a behavioral science REC leads him to conclude that paragraphs like those cited above are common in survey consent documents. Researchers may pair statements about rights with statements about risk in order to appease REC concerns about study interventions to address risk. In the absence of empirical data, RECs should be cautious about recommending and approving consent documents that include clauses suggesting that questions about drug use cause emotional discomfort. Furthermore, RECs should recommend that consent documents decouple important reminders about subject rights from statements about potential risk (whether or not those risks are valid). While it may be important to reinforce rights in a consent document, we believe it is contrary to best practice to even imply that voluntary participation (and the right to withdraw or refuse to answer questions) should be contingent on adverse reactions. The type of text described above, however, would be obviated if RECs adopted a more realistic view of subject perceptions regarding drug use surveys.

1. http://caliber.ucpress.net/doi/abs/10.1525/jer.2007.2.3.31

2.9.3 Bledsoe et al., Regulating Creativity (2007-09-21 13:24)

I am still working my way through the [1]Northwestern University Law Review symposium on IRBs. Today's comments focus on Caroline H. Bledsoe, Bruce Sherin, Adam G. Galinsky, Nathalia M. Headley, Carol A. Heimer, Erik Kjeldgaard, James T. Lindgren, Jon D. Miller, Michael E. Roloff & David H. Uttal, "[2]Regulating Creativity: Research and Survival in the IRB Iron Cage."
The article, based largely on events at Northwestern itself, is particularly effective at challenging three myths of IRBs and the social sciences:

Myth #1: Reports of IRB interference with research are overblown, since few projects are rejected and few researchers disciplined.

An example of this myth is [3]Jerry Menikoff's contribution to the same symposium, in which he claims, "social and behavioral scientists who maintain appropriate communication with their institution's IRBs need not be shaking in their boots, fearing some career-ending enforcement action is about to come down from Washington."

Unlike Menikoff, Bledsoe et al., talked to some researchers, asking their colleagues about experiences with Northwestern's IRB. They report,

> As a number of our colleagues have emphasized . . . both in person and in their responses to our email query, they alter their course not because of any real risk they perceive to their subjects but simply to pass IRB muster. Trying to reduce their own professional risk, they divert their work, choosing topics or populations selectively, or adapting methods that will entail less demanding IRB review and lessen the probability that they will have to make substantial changes before proceeding. IRB procedures, that is, can snuff out ambition even before the project begins.
> The disturbing point is that it is the mere anticipation of onerous IRB review that can result in some alteration of the proposed protocol. Because of the potential for delays and the IRB tendency to intrude into each step of the research process, many social science faculty report that they think twice about taking on research topics, methods, and populations that IRB frames in the mode of risk. One respondent described the impact thus:
> "The IRB has become a nightmare over the years that I have been a researcher. I'm sure most of this pressure is coming from the federal government, but the rigidity of the model (based on the medical sciences) and the number of hurdles/ forms, and the scrutiny (to the point of turning back projects for mispagination or other pithy errors, as has happened for some of my students) is just terrible. It is very discouraging, and I find myself thinking of EVERY new research project as it relates to the possibility of IRB approval."
> Two respondents indicated that faculty had moved toward non-field projects in large part because of IRB. One faculty member even pointed specifically to concerns about IRB in a decision to make a career shift away from field-project themes and methods that might jeopardize the researcher's career:
> "Since last year, my research became more theoretical in large part because of IRB requirements. I simply try not to do any research which would involve Panel E [the social science review panel at Northwestern]. . . . I no longer interview people during my trips abroad and try to limit the data gathering to passive observation or newspaper clippings."

An IRB that approves all social science projects submitted to it (and many, no doubt, do) may still crush research by making it so burdensome that researchers give up submitting proposals.

Myth #2: Medical IRBs are the problem, so an IRB devoted only to non-medical research is the solution.

This suggestion gets thrown out from time to time; for example, it appears as one of Dale Carpenter's admittedly "[4]modest proposals for reform" in his own Northwestern Law Review piece. But Bledsoe et al. report that Northwestern already has a separate non-medical panel, and it doesn't sound pretty:

> even a separate social science IRB enterprise suffers from internal tensions between the need for standardization, whether imposed by OHRP rules or by our own desires to ensure equity, and the need to allow the very stuff of novelty that studies are supposed to produce. We have observed that social scientists who confront their review assignments can be no less critical of their fellows' studies than a biomedical panel might be. Indeed, IRB staff have sometimes had to step in diplomatically to rescue a project from a zealous social science faculty panelist threatening to dismember it altogether. In this regard, we have observed a typical life cycle for social science panel members. The typical panel member begins his or her tenure by making it known that a great deal of harmless social science research is delayed without any reasonable cause, and that henceforth the reckless invasiveness of the IRB must be tempered. Yet this same panel member, when given projects to review, is often the most critical.
> This pattern reflects a broader impulse among social scientists. We think of ourselves first and foremost as academics. Our business is to read research proposals, journal articles, student papers, and to find fault. Turning to IRB protocols, we become fastidious reviewers. When we read consent forms, it is hard for us to refrain from editing them. When we read with an eye toward possible risk, whether large or small,

> our expertise itself will unmask it. As social science panel members, we will inevitably find problems with social science IRB submissions; we cannot help ourselves. Importing our own disciplines' ethical dilemmas, the concerns that we raise often go far beyond those imagined by the federal legislators. They also hand the IRB, seeing our plight, both our fears and our language of expressing them to incorporate into its already overburdened repertoire. Over time, such impulses are tempered, and we learn to see the big picture again. In the meantime, however, the damage to the research enterprise is done.
> In retrospect, giving the social sciences a separate review channel and letting them into the review process was helpful in that the social sciences gained mediators who could explain studies to their panel colleagues and attempt to buffer the power of the medical model. At the same time, our social science panel's own efforts to help both added to the layers of regulatory stratigraphy and intensified the regulatory flux. All this has undoubtedly provided further grounds for investigators to conclude that the IRB was capricious and inconsistent.

The authors are wrong, however, to suggest that Northwestern has a "social science" panel. According to "[5]Schools, Departments and Programs Served by Panel E of the Institutional Review Board, " Panel E has jurisdiction over "research projects involving human subjects that use social and behavioral science methodologies." The same document claims,

> Federal guidance defines social and behavioral science methodologies as those that include research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The range of methods included in this list means that far from letting ethnographers review ethnographers and experimental psychologists review experimental psychologists, Northwestern has locked all its non-medical researchers in a room and told them to fight it out. Such an arrangement makes no allowance for the wide variation of methods and ethics within non-medical research. (See "[6]My Problem with Anthropologists.")
Moreover, the claim that "federal guidance defines social and behavioral science methodologies" is incorrect. The list of methodologies is taken from OPRR's 1998 "[7]Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure." That document does just what its title suggests: it lists categories of research eligible for expedited review. It does not define social and behavioral science methodologies, nor, to my knowledge, has the federal human subjects apparatus ever defined social or behavioral science.
In reality, therefore, Northwestern's Panel E exists solely to provide full IRB review for projects that even the federal government admits do not require full IRB review. No wonder it doesn't work well.

Myth #3: If social scientists were to join IRBs and learn about their workings, they wouldn't complain so much.

Take this statement by J. Michael Oakes, "[8]Risks and Wrongs in Social Science Research: An Evaluator's Guide to the IRB," Evaluation Review 26 (October 2002) 443-479:
"Investigators well versed in the Belmont Report and more technical IRB procedures rarely need to dispute decisions, and when they do it concerns how known rules are interpreted or what is best for the subjects. It follows that a great deal of frustration may be eliminated by careful study of basic IRB regulations and issues. Education seems to modify frustration in the researcher-IRB-subject chain."
Nonsense. Bledsoe herself chaired a subcommittee of the Northwestern University IRB Advisory Committee, and several of her coauthors served on, chaired, or staffed IRBs at Northwestern or elsewhere, as well as having dealt with IRBs as applicants. They are about as educated and experienced in these issues as one could hope for, and they as frustrated as anyone by the current system.

Beyond busting myths, the article seeks to document the changes in IRB work since the 1990s. Based on their personal experience, Bledsoe and her co-authors describe the expansion of both OHRP and IRB jurisdiction:

> The university's Office for the Protection of Research Subjects spiraled from two professionals to what is now a staff of 26, of whom 21 support the IRB operation. Review panels went from one to six—four were created simultaneously in September 2000, with one for the social sciences created a year later, and another medical panel added subsequently— and appointing their membership became the duty of the university's vice president for research. The length of the basic protocol template for new projects went from two pages to its present length of twelve for the social sciences, and fifteen for biomedical research. In addition, the number of supplementary forms and documents required for each submission went from one or two to far more than that, depending on the nature of the study. Many protocols are now better measured in inches of thickness than in number of pages. The level of bureaucratic redundancy, inconvenience and aggravation increased dramatically: Unreturned phone calls, dropped correspondence, and administrative errors on forms became routine.

They also report some good news:

> For several years after the IRB ramp-up began, our IRB panel expected detailed interview protocols from everyone. Now, an ethnographer who intends to employ participant observation does not need to provide a detailed specification of what is to be said to participants, and is not asked for it. Without such collusion, ethnographic studies would not survive under the IRB system. As much as social scientists complain about the ill fit their projects pose in IRB review, their own protocols are now spared this level of scrutiny.

As I reported earlier, Northwestern has exempted oral history from review, though Bledsoe et al. do not explain when or why that happened.

The authors conclude that "one could scarcely imagine a better example of a bureaucracy of the kind that so fascinated and infuriated Weber than the contemporary IRB system." It is indeed crucial to look at the systematic pressures on members and administrators, for that can explain why the same IRB abuses show up in such diverse institutions spread around the country.

But while Weber can explain some long-term trends, analyzing bureaucracies, rather than people, obscures the role of individual decisions. In this lengthy account of events at Northwestern, the authors decline to blame, credit, or even name a single individual administrator, researcher, IRB member, consultant, or federal official. Typical is this passage:

> When the ratcheting up of the IRB bureaucracy at Northwestern was occurring, administrators were working in an environment in which suspension of federal funding to other institutions had produced considerable anxiety. It was no secret that the Northwestern IRB director was under pressure to bring the university into full compliance as quickly as possible.

Who was ratcheting? Who felt considerable anxiety and why? Who communicated with the federal government? Who was the Northwestern IRB director? Who pressured him or her? Who knew the secret? And, on the other end, who ruled that interviewers did not have to submit detailed protocols?

Because the authors decline to ask such questions, they can hold no one to account for sudden and important decisions. They instead conclude, "the odd history of IRB and its effects have been no one's fault; no one's intention. No convenient villains or victims emerge anywhere we look." But there is nothing to indicate that they looked terribly hard.

1. http://www.law.northwestern.edu/journals/lawreview/issues/101.2.html
2. http://www.law.northwestern.edu/journals/lawreview/v101/n2/593/LR101n2Bledsoe.pdf

3. http://www.law.northwestern.edu/journals/lawreview/v101/n2/791/LR101n2Menikoff.pdf
4. http://www.law.northwestern.edu/journals/lawreview/v101/n2/687/LR101n2Carpenter.pdf
5. http://www.northwestern.edu/research/OPRS/irb/training/docs/panelEReviews.doc
6. http://institutionalreviewblog.blogspot.com/2007/03/my-problem-with-anthropologists.html
7. http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm
8. http://erx.sagepub.com/cgi/content/abstract/26/5/443

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> As a number of our colleagues have emphasized . . . both in person and in their responses to our email query, they alter their course not because of any real risk they perceive to their subjects but simply to pass IRB muster. Trying to reduce their own professional risk, they divert their work, choosing topics or populations selectively, or adapting methods that will entail less demanding IRB review and lessen the probability that they will have to make substantial changes before proceeding. IRB procedures, that is, can snuff out ambition even before the project begins.
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"Investigators well versed in the Belmont Report and more technical IRB procedures rarely need to dispute decisions, and when they do it concerns how known rules are interpreted or what is best for the subjects. It follows that a great deal of frustration may be eliminated by careful study of basic IRB regulations and issues. Education seems to modify frustration in the researcher-IRB-subject chain."
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As I reported earlier, Northwestern has exempted oral history from review, though Bledsoe et al. do not explain when or why that happened.
The authors conclude that "one could scarcely imagine a better example of a bureaucracy of the kind that so fascinated and infuriated Weber than the contemporary IRB system." It is indeed crucial to look at the systematic pressures on members and administrators, for that can explain why the same IRB abuses show up in such diverse institutions spread around the country. But while Weber can explain some long-term trends, analyzing bureaucracies, rather than people, obscures the role of individual decisions. In this lengthy account of events at Northwestern, the authors decline to blame, credit, or even name a single individual administrator, researcher, IRB member, consultant, or federal official. Typical is this passage:
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Who was ratcheting? Who felt considerable anxiety and why? Who communicated with the federal government? Who was the Northwestern IRB director? Who pressured him or her? Who knew the secret? And, on the other end, who ruled that interviewers did not have to submit detailed protocols?
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2.9.5 Roberta S. Gold, "None of Anybody's Goddamned Business"? (2007-09-29 17:06)

> Blogger's note: On September 3, Christopher Leo posted a [1]query to the H-Urban list, asking about the effect of ethics review on urban research . Roberta Gold's response hinted that she had thought hard about the issue, so I asked her to share her thoughts on this blog. She has graciously agreed.

Roberta S. Gold, "'None of Anybody's Goddamned Business'?: Oral History and the Communist Past"

When I began my doctoral research on tenant activism in New York City, the powers-that-were at my university waived the extensive human subjects rigmarole after I filled out a short form attesting that my oral history interviews would pose minimal psychological risk. Not until years later, when I saw articles on the debate over Institutional Review Boards (IRBs), did I learn that this bit of common sense was so rare. I agree with the many oral historians who have criticized the application of medically-modeled human subjects review to oral history. Oral history can raise ethical quandaries. But these vary significantly from project to project, and generally call for more sensitive responses, grounded in the historical discipline, than those provided by the all-purpose IRB model.

Looking back at much of my research, I find the notion of a review board's responsibility to protect vulnerable subjects from my probing questions almost laughable. The subjects were veteran grassroots activists, many with decades of experience talking to the press. I was a rookie with a new tape recorder from Radio Shack. I was putty in their hands. When I posed questions they didn't like, they smiled and steered onto a different topic so deftly that I didn't realize what had happened until twenty minutes later. Or they told me why I was asking the wrong question. I recall a civil rights historian's remark that one does not so much interview SNCC veterans as get schooled by them; something like that could be said of talking to seasoned housing activists, too.

But once in awhile we did enter painful territory. The best preparation I had for these moments was a conversation with one of my faculty advisors, who warned, "Be very, very careful in asking anything about the Communist Party. You don't know how deep the scars from the McCarthy period run." This told me more than any IRB dictate could have done.

The second best preparation was not preparation at all, but experience. After I did some interviews, I got a better sense of the delicate organism of oral history, of the way one has to develop questions out of what's just been said, and of the need to build trust and rapport before broaching the harder topics. In a few cases, the process forged a connection that I know I cherished, and I think meant something to the "subjects" too. In the remaining space I'd like to recount the ways that Communist Party history, variation among individuals and my own learning process played out in my interviews with several people.

The first was Jane Benedict, a central figure in New York's tenant movement from the 1950s through the 1990s, whom I met in the summer of 2000. I was just starting my project then, and had barely begun the background reading, which meant that it was not an ideal time to conduct an interview. But, just as Marx predicted, economic determinism won out: Benedict and I were both on the West Coast – I at school and she having retired to Oakland – and I was about to head to New York for the year. I decided I'd better talk to her immediately so I would not have to cough up cross-country plane fare in a few months. As well, she was then 88 years old; one teacher told me, "Quick! Get her before she drops." We set a date for June.

I arrived in Oakland carrying a borrowed recorder (didn't invest in the Radio Shack model until I reached New York), a few pointers from teachers, and some guidelines from an oral history how-to book I'd found in the library. Ms.

Benedict (as I then thought of her, although she soon snapped, "Call me Jane!") met me in front of her house. Her warmth and magnetism calmed my nerves a little. At something like four feet, nine inches, she also made me fell tall (a rare experience for me at 5'2"). But my illusion of stature was fleeting.

It didn't take long before she led me to discard the few rules I'd learned. She announced that we would talk out back in the garden (Rule #1: conduct the interview indoors, where there's less background noise). She started telling me about her life before I'd even taken a seat (Rule #2: have tape recorder running before subject begins to talk). Within five minutes, and without any prompting, she disclosed that despite the Americanized "Benedict," she and her late husband were both Jewish; that they had both been trade union organizers (sometimes an indicator of leftism); that their daughter was gay; and that she (Jane) was looking forward to the birth of her first great-grandchild, who would be half black. I concluded that she had nothing to hide and oral history was a cinch (Rule #3: be careful asking about sensitive subjects). And she kept talking, with boundless verve, for about four hours (Rule #4: remember that old folks tire easily and keep the session short). Then she asked if I'd like to join her for dinner at the Thai place around the corner. This became the kernel of my yet-to-be-published theory that tenant activism leads to remarkable longevity and vitality in old age.

Breaking Rule #3 was the real blunder. Inspired by the "new" historiography of American Communism – studies from the 1980s and 1990s which looked at the grassroots experience of Party membership, challenged the top-down, Comintern-driven model, and sought to recover the creative, diverse, homegrown ways in which the U.S. Party had contributed to American justice movements – I was eager to explore the relations between New York's CP and its tenant groups (relations that my limited reading told me had probably existed). Of course, I also wanted to record the general biographies and reflections of tenant leaders, so I listened with interest for the first couple of hours as Jane reminisced fondly about her childhood, her husband Peter, her political awakening in the labor movement, her introduction to tenant issues in Yorkville in the 1950s – and less fondly about an array of officials (re Robert Moses: "Now he's a saint; I assure you he was a son of a bitch when I knew him"). Then I realized that we had not yet touched on an important topic. So, with a confidence born of breezy Jewish/union/lesbian/interracial disclosures, I asked how the Communist Party had fed New York's tenant movement. And suddenly the breezy talk stopped. She clammed up. Scars run deep indeed.

She did recover her poise pretty quickly, and managed to address the question in an oblique manner that took us rapidly in another direction. At least I had the sense to keep my mouth shut. And I think we stayed on a friendly footing (else why the invitation to Thai food?). But I felt I'd screwed up.

Sobered, I headed to New York, where one of my early interviews was with an even more experienced tenant leader named Frances Goldin. A head taller than I, clad in a bold "Free Mumia" t-shirt (she chairs his defense committee), possessed of a no-nonsense manner, she gave the distinct impression that she could knock me flat despite her seventy-odd years. I sat up straight and made a mental note to avoid impertinent questions. But it turned out I didn't have to. Ms. Goldin voluntarily told me all about the experiences that had led her into the Communist Party, what she had learned as a member, and how the organization had shaped her outlook and life. (All this came before the lesbian daughter discussion, although Goldin has two to Benedict's one, so you could say she comes out ahead on that score, too). Like Benedict, she spoke with great warmth about her father, and about the tenant community in which she'd settled (in this case, the Lower East Side). Unlike Benedict, she had once picked up a butcher knife to fight off a violent landlord and had nearly killed him.

Thoroughly mixed up, I proceeded through some more sessions with diverse veteran organizers. Each gave the interview its own flavor. All told moving stories of nefarious landlords, besieged tenants, solidarity and division, hard-won victories and painful defeats. One subject was Marie Runyon, a Morningside Heights resident since the 1940s, whom New York Times columnist Clyde Haberman wrote "still sounds as if she left her native North Carolina an hour and a half ago." She poured forth a stream of lively stories about her political adventures with the likes of Bayard Rustin, Moe Foner and Benjamin Spock. As a coda she noted a little sadly that she had never actually joined the Communist Party, then drawled, "But don't say that, because it's none of anybody's goddamned business."

By and by I came to interview Chelsea organizer Jane Wood, known as the other great Jane in New York tenant circles. At 93, she was the eldest of the bunch, and the most guarded. She said no to the tape recorder. She did tell me about her life in the tenant movement, in a terse, reserved manner. My hand notes make no mention of the CP, and frankly, I'm not sure now whether I asked and she stonewalled, or whether a grain of sense told me not to ask. But I have a

strong memory of her being hermetically sealed on that subject. (She did, however, offer clues when she spoke of her work with the American Labor Party and the CIO, both leftist groups. And when I asked how she met her husband, she said, "I don't remember." Right.)

Through all these sessions, I felt the tug of two ethical impulses. One was not to cause pain. I suppose that impulse, actually, had both ethical and self-serving dimensions. On the ethical side, I genuinely liked and admired these women. I appreciated their generosity (several had me into their homes and treated me with something of a grandmotherly air); who but a schmuck would pay them back by opening old wounds? On the self-serving side, I also didn't want to alienate them and thus make them unwilling to talk further.

The second impulse was a sense of responsibility to the historical record, and to the way future generations would understand the past. To me, revealing the richness of the American left's history was not just an interesting intellectual endeavor; it was an effort to do a little justice to people who had, for decades, been branded subverters of freedom, dupes of Moscow, unwavering Stalinists, and so forth. By now, others had documented the Party's contributions to the American labor and civil rights movements. I believed I was onto a story about the Party's – or Party veterans' – equally important contributions to struggles for tenants' rights and women's equality. I wanted to give the Party, and the activists, credit for those contributions. But I couldn't do that without asking some questions that made me sound like Joe McCarthy.

Let me stress, however, that these impulses, and the tension between them, did not neatly line up with the biomedical model of research that may harm human subjects but yield useful knowledge for "humanity." That is, I was not facing a simple conflict between the subjects' well-being and other people's historical knowledge. I believed that my project could do something positive for the subjects themselves, by treating with respect a chapter of their lives that many of them had felt compelled to keep hidden. And I believed that once-compelling reasons for secrecy – the blacklist, the legal prosecutions – were finally things of the past.

Amid all this I was also making my way through secondary and archival sources, which, especially when read alongside the oral histories, brought up new questions. So I contacted several subjects to request further interviews.

Marie Runyon had hardly been reserved on our first meeting, but she was even more voluble the second time around. Perhaps this was because we'd already established some rapport, perhaps because on the second visit I was more knowledgeable about the tenant movement and less green at oral history. Strangely, this second interview also benefited from a personal trait that I'd never considered especially scholarly (aspiring historians, take note! IRBs, try regulating this!): I have a way with cats. Ms. Runyon was by that time caring for an enormous, beautiful Maine Coon, which apparently shunned other visitors, but quickly befriended me. When the cat let me pet him, Ms. Runyon exclaimed; when he jumped up on my lap and settled there, kneading and purring, her jaw dropped. I got the sense that the cat's trust assuaged any remaining doubts the human might have harbored. Among the things she told me (unasked) was that Jane Benedict had been a Communist.

I did not seek a second interview with Jane Wood. This was partly because my ongoing research didn't raise anything I particularly needed to ask her. It was probably also because our first meeting, while friendly enough, didn't seem to offer many avenues for further discussion. She simply didn't want to talk much (unlike most of her peers, who were avid storytellers). I later learned more about her from her protégés, a generation younger and less fearful of political repercussions. Their reflections on Wood's ability to inspire and embolden immigrants, women and young organizers helped me, in my writing, to give her her rightful place in the tenant story.

The more I read and spoke to people in New York, the more I wanted to talk again with Jane Benedict, who for decades had directed the citywide tenant group, Metropolitan Council on Housing. Her failing hearing meant this could not happen over the phone. In the late fall of 2001 I flew back to California. Jane, now 90, seemed about the same as before, although her memory of details was starting to go. But I'd changed: I was less nervous and more informed than I'd been the first time we'd met, and I was on good terms with several of Jane's comrades back east. While I was not consciously trying to drop names, it probably helped that I introduced some questions with statements like, "Fran Goldin raised an interesting point . . . ."

We sat for a pleasant hour or so as I went through a list of questions that had emerged from my research over the last year and a half. Some were thematic (e.g., the connections between the civil rights and the tenant movements); others were aimed at filling in the blanks on specific people and events. She answered as well as her memory allowed.

Finally we reached the last questions, which of course had to do with that most fraught of subjects. By now I did

not need to hear Jane confess her Party membership; Marie Runyon and another person had already "outed" her (not maliciously; I think they didn't know she was still so secretive at this late date). But I did desperately want to ask questions that weren't far removed. There was a whole literature on the roots of the New Left in the Old Left, and I was very interested in Jane's thoughts on the ways in which the Party of the 1930s and 1940s had schooled people like her, who became legendary tenant organizers in subsequent years . Further, in background reading on the 1960s, I'd been struck by the sociological concept of "co-optable communications networks" among activists – that is, networks that develop in one social movement but can lay the groundwork for another. (Among the examples elaborated by political scientist Jo Freeman are the networks of civil rights, anti-war and radical youth groups, which she argues facilitated the explosive birth of second-wave feminism.) I wondered if such a phenomenon had tied the Party of the Popular Front and World War II periods to New York's resurgent tenant movement of the late 1950s. Several founders of Metropolitan Council on Housing, formed in 1958, had been Communists or fellow travelers who led anti-urban renewal tenant struggles in their neighborhoods. How exactly had they come together to form a citywide tenant alliance? Had they known one another through a "co-optable network"?

This time I did not just pop the question. I broached it, acknowledging its sensitive nature, stressing that I was coming to it in a sympathetic, not a prosecutorial, spirit (Jane said she could tell that). And I sketched out historians' sense of the ways that Party veterans had nurtured later social movements such as civil rights. Did something similar, I asked, happen in the tenant movement?

Jane's first answer was, "I don't know. My own history you know, was trade union. In Yorkville, where we lived, and where the kids were small, growing up . . . ." She started back on some Yorkville tenant stories I'd already heard.

With a knot in my stomach and as much gentleness as I could convey, I said, "Uh huh. And in your own history, may I ask, had you become part of the Party, ever?" Jane paused and said, "Well, if you don't mind, I'd rather not answer that." "That's fine," I said. She paused again. Maybe thinking that she was 90 and starting to decline? In any case, her next words were, "That's its own answer." She paused a third time; I nodded and we exchanged looks.

Now, not only did I know; she knew that I knew, and I knew that she knew I knew. Her "non-answer" possessed a gravity I could feel in my gut; I believe Jane felt it strongly too. And that silent exchange was the watershed.

Now she started to address my earlier question for real. "I suppose, I mean, I would say, that not only Met Council, but many organizations, benefited from the fact that people were rooted in the Party. And [pause] well, there was a need for A,B,C,D, whatever kind of organization …." I recounted part of my interview with Goldin, who had said that what she'd gained from the Party was a general education about economics and politics. Jane responded, "Well, I think that's true. I think it's also true that it puts people in a spirit, campaigns are fought better. What governs a person's life? I've known people who've been in various organizations and come and gone. Others plant their feet and say, 'This is what I want to do.' Or they don't say, 'This is what I want to do,' they just do.… [And] – it broadens one's point of view. I think if you say, 'Look, we only live once, I might as well do with my life what I want to do' and it broadens the point of view. It not only broadens the point of view, theoretically, but the more you have contact with people, the more you feel that you're down to earth. At least that's what it meant to me. And that's what it meant to Peter. And I think that's what it's meant to our children. In that that they are, that we all don't always agree, it's all right, people have a right to disagree, and certainly different generations. But there is something there, an integrity, that holds up."

She was leading the conversation again. She told me about her trips with Peter to the Soviet Union. She told me about the harrowing McCarthy years, when they'd had to instruct their children what to do if men in suits ever showed up at the door and took their parents away. She told it all without uttering the C-word.

That she poured all this out on her own, with just a word of response or sympathy from me here and there, makes me believe that she wanted to tell it, once she'd taken that fearful leap into this area of memory – a leap I'd undoubtedly pushed her to take. Had I induced her to do something frightening? Clearly. Had I harmed her? I don't think so.

But that just raises the question how we define and measure harm? And risk?

When I'd filled out my school's human subjects waiver form, I had checked the "minimal psychological risk" line in good faith (the human subjects worker who walked me through the form offered the example of questions about a subject's sexual history and health to illustrate psychologically risky ones, and I was pretty sure I would not be asking tenant organizers if they'd ever had gonorrhea). I did not understand until I actually got into the project, and the interviews themselves, how emotionally difficult topics might come up even in a study of people's activity in the public sphere. This was no doubt in part because I was a rookie at oral and CP history. But it also reflected a certain

unforseeability that is inherent in open-ended human conversation. Oral history is a venture into uncharted territory, not a controlled laboratory experiment.

Such unforseeability is equally inherent in the varied pasts and emotional structures that subjects bring to an interview. I recall that in the week before my college graduation, a classmate who'd been orphaned at a young age told me it pained her that acquaintances kept blithely asking, "When are your parents coming up for commencement?" Such a question would generally be considered polite small talk, but it hurt this woman because of her circumstances. Likewise, the same questions about party background went over very differently with Goldin and Benedict, both CP veterans of similar vintage, because they had coped differently with the Cold War witch-hunt. In short, there are limits to how well even an informed researcher can foresee "psychological risk" in a project that involves open-ended discussions with different people.

As for "harm," I am not persuaded that grappling with a discomfiting topic is always harmful. Sometimes it's satisfying. Sometimes it offers an opportunity to clarify one's thoughts, or to set the record "straight" (as one sees it). Which of these possibilities unfolds will depend not just on the subject's attributes, as indicated above, but on the researcher's. Although we don't often think of demeanor as a matter of ethics, it seems to me that in practice, the interviewer's manner – her tone, pace, responsiveness, courtesy and so forth – have at least as much effect as do her questions on how the interview "feels" to the subject.

Such subtleties aside, there's a difference between asking and badgering. One thing I believe I did right in my second meeting with Jane was to respect her initial decision not to answer the question about Party affiliation. And if she hadn't reconsidered that decision, I'd have had to live with the limits it would have set on the interview.

In short, I do believe there are ethical limits an oral history researcher should observe, and some of them ("Respect the subject's right to decline a question") can be spelled out. But the devils of the interview experience are in the details, details that often can't be foreseen or controlled by IRB-style rules.

Indeed, sometimes an ethical mode develops that could never have been planned ahead of time. The last question I raised with Jane pertained to the possibility of a "co-optable communications network" (I didn't use that phrase, but I introduced the concept) from the CP that might have accelerated the development of connections among later tenant organizers. She struggled with her memory. She confessed that she couldn't recall clearly how she'd met some of her fellow tenant leaders. But some, like Fran Goldin, she had known earlier, through – she paused again uncomfortably. "Prior activism?" I suggested. She relaxed and said yes. That code served as a meeting ground between her impulses and mine – in fact, between her own conflicting impulses (to keep a secret, on the one hand, and to contribute what she knew to the historical record, on the other).

Jane Benedict died in the summer of 2005. Her memorial service in New York was an uplifting event featuring many prominent activists and politicians who testified with great feeling to the ways Jane had inspired them, taught them and transformed their lives. (One, longtime CORE leader and Congressman Major Owens, an African American who is twice Jane's size, beamed from the podium as he declared, "I am a proud bearer of the philosophical DNA of Jane Benedict.") Her children spoke proudly of their parents' lives in the struggle, including their membership in the Communist Party – something they felt there was no longer any reason to hide. I noted very briefly that my dissertation, now completed, was starting to get some notice and thus publicize the story of Jane's life and work; this drew great applause. During the reception afterward I spoke with the family about that last interview in Oakland. As they thought back on the series of strokes Jane had suffered in her final years, they said I'd "caught" her at the last good moment. To this day I'm glad I did. I think Jane would be, too.

Frances Goldin and I have continued our interview over several sit-down sessions and phone conversations. Each time we've talked, the granite has worn down a little and the warmth has come through. A few months ago, Frances, now 83, had me down to her place for a soirée she threw to tell her comrades about her recent trip to Cuba (where she'd been promoting the newly-released Spanish translation of one of Mumia's books). As an uptown resident I was something of a foreigner among these Lower East Side nationalists. But Frances kissed me hello and had me introduce myself and my research project to the crowd; she told me afterwards how happy she was that they'd heard about the history I was writing.

Frances is not one for euphemisms or code-words, but she has directed that a very few of her frank statements (about episodes of discord within the movement) be kept off the record. I have not published those remarks. I hope she changes her mind someday, as I think that future generations can learn something useful from the dirty laundry of the

past. But it will be her call.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=h-urban&month=0709&week=a&msg=adH2vhHnfqjBRhDD/4rsTw&user=&pw=

2.10 October

2.10.1 The Dormant Right to Expertise (2007-10-07 13:34)

According to federal regulations ([1]45 CFR 46.107), scholars should be able to expect that their research will be reviewed by someone who understands it:

> each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

As [2]Jeffrey Cohen has recently noted, this means that "researchers have the right under the regulations to have their research reviewed with the appropriate expertise and it is the Institutional Official's responsibility to ensure that the review is appropriate to the research."
Unfortunately, as I have documented in this blog, researchers in the social sciences and humanities are routinely denied that right. A nice illustration of this problem appears in the recently released RAND Corporation working paper, "[3]Ethical Principles in Social-Behavioral Research on Terrorism: Probing the Parameters," September 2007. James R. Sayer of the University of Michigan's Behavioral Sciences Institutional Review Board describes the problem of reviewing research on terrorism. Presumably this includes the [4]research described on this blog by Scott Atran.
Here is how that case, or perhaps a similar case, appeared to Sayer, whose own expertise concerns "[5]the effects of hydrophobic and hydrophilic glass coatings, window tinting, and defrosters/defoggers on visual performance and driving behavior."

> We've struggled with expertise, or rather the lack of expertise. Two years ago we sought assistance from a number of academic and private institutions to get reviewers to assist us in the evaluation of one particular protocol. And we found nobody. Maybe that's because people really don't want to assume that risk themselves. Maybe it's because, from an academic standard perspective, I'm sure those of you who review IRB applications don't get many really big feathers in your cap for doing it. And you're certainly not going to get them for reviewing somebody outside of your institution. It's gotten to the point that at the University of Michigan we are seriously considering putting together another board. That board would deal exclusively with international research. There's enough of it going on that we could easily keep that board busy on a monthly basis. But we will still struggle with trying to find somebody that understands what the culture is like in rural provinces of China, in the Sudan. And as hard as we try, we can't always adhere to what is the intent of the federal regulations in having the necessary expertise.

This is a nicely humble statement, recognizing the limitations of not only Michigan's IRBs but also the entire IRB process. At the end, Sayer admits that his IRB fails to meet the very requirement Cohen identifies. Yet that humility did not stop the Michigan IRB from delaying and interfering with Atran's research.

The problem is that the right to expert review comes with no enforcement mechanism. Cohen suggests appeals should be directed to the institutional official, but in many cases that is the very person who failed to appoint appropriate experts to the IRB. One would be appealing the violation to the violator. Beyond that official lies only OHRP. And on the day OHRP reprimands an institution for constituting an IRB with insufficient expertise in the social sciences and humanities, I will buy Dr. Cohen an ice cream.

Whether Atran should have sued the university for violating the federal regulations is a question I'll leave to the lawyers.

See also, "[6]In Search of Expertise."

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107
2. http://hrpp.blogspot.com/2007/10/irb-expertise.html
3. http://www.rand.org/pubs/working_papers/WR490-4/
4. http://institutionalreviewblog.blogspot.com/2007/05/scott-atran-research-police-how.html
5. http://www.umtri.umich.edu/people.php?personID=38
6. http://institutionalreviewblog.blogspot.com/2007/02/in-search-of-expertise.html

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Anonymous (2007-10-07 14:12:00)

Regarding the alleged lack of expertise on IRBs reviewing social science IRBs: Perhaps social science researchers should make formal complaints to OHRP that the institution was not following regulations. Or is the goal not to have social science reviewed competently, but not to have it reviewed at all?

Zachary M. Schrag (2007-10-07 14:40:00)

Thanks for your comment (though I would have appreciated a name to go with it).

In regard to your question, I doubt that IRB critics agree on a single goal, and I myself am always interested in new models of ethical review. But it should be clear that many critics, such as the AAUP, would be much happier with some form of expert review than with the situation that exists now.

I have no reason to think that OHRP would be more responsive to complaints about violations of 45 CFR 46.107 than it has been to the complaints laid at its door by the American Historical Association and other critics. But perhaps it is worth a try.

Zachary M. Schrag (2007-10-07 22:13:00)

By the way, if anyone wants to try submitting a formal complaint to OHRP, instructions can be found at [1]http://www.hhs.gov/ohrp/compliance/.

1. http://www.hhs.gov/ohrp/compliance/

furedy@psych.utoronto.ca (2007-10-08 16:57:00)

If IRBs (or their Canadian equivalents, REBs—Research ETHICS Boards) accepted the basic distinction between epistemological and ethical matters, they would not be tempted to foolishly dvelve into epistemological issues that are the proper province of journal editors and grant allocating committees.

I have tried to make this distinction in http://www.psych.utoronto.ca/users/furedy/bioethic.htm, and, more specifically in such pieces as http://www.psych.utoronto.ca/users/furedy/Papers/be/tricsafs97.doc and http://www.psych.utoronto.ca/users/furedy/Papers/be/IRBsethics.doc, but, presumably because of the self interest of the North American Bioethics industry (that has little understanding of or concern with that part of philosophy that deals with ethics), my words have fallen largely on deaf ears.

All the best, John Furedy

Emeritus Professor of Psychology, University of Toronto

2.10.2 Brown U. IRB Chair: System is Broken (2007-10-22 01:36)

Ross Frazier of the Brown Daily Herald reports that Brown's "faculty are yet again pushing for change" in the human subjects review system there. ("[1]As IRB Debate Grows, Profs Push for Reform," 16 October 2007).
Frazier reports the views of Ron Seifer, professor of psychiatry:

> Seifer, the IRB chair, acknowledged the system is "fundamentally flawed and broken," adding that, "They are being asked to do something they were never intended to do."
> Seifer told the class that the IRBs around the country have expanded their reach because of federal bureaucrats and a community of university research administrators who have created a culture of avoiding risk. Those factors "all exist within very frightened university environments. They're afraid of lawsuits, and they are afraid of donors going away," Seifer said.

As reported by Frazier, senior Brown administrators seem unwilling either to defend the current system or to reform it, preferring instead to keep discussion of the issue off official agendas.

1. http://media.www.browndailyherald.com/media/storage/paper472/news/2007/10/16/CampusNews/As.Irb.Debate.Grows.Profs.Push.For.Reform-3034763.shtml

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2.10.3 Pentagon Says IRB Review Not Needed for War Zone Anthropology (2007-10-25 01:53)

As reported by [1]Inside Higher Ed, anthropologist [2]Thomas Strong has found that the U.S. Army's Human Terrain Systems (HTS) program, which employs anthropologists to work with combat units in Iraq and Afghanistan, has decided that it need not submit projects for IRB review.
Here is the relevant passage from Strong's post:

> [Col. Steve] Fondacaro . . . argues that HTS research is not subject to IRB oversight because of provision 32 CFR 219 sec. 101(b)(2), which states that research conducted through "the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior" is exempt.
> Thus, the HTS is understood by the program manager to be exempt from IRB regulation within the parameters specified by the common rule. However, as I wrote in a follow up to Fondacaro, "The exemption you cite, 32 CFR 219, sec. 101(b)(2), apparently applies to HTS-type research (that is, ethnographic research) that has already been reviewed. It apparently mandates that a review board at least look at the research in order to determine whether or not continuing oversight is necessary; I don't think this is typically understood as a determination the researcher him/herself or the research team itself makes. Further, as you know, the exemption stipulates stringent protocols regarding data recording in order to insure the anonymity of research subjects <32 CFR 219, sec. 101(b)(2)(i)>. I am therefore inclined to think the onus is on DoD to insure that those stipulations are being met through a review of the research protocol." I am waiting to hear from Fondacaro regarding this. It is important to add that Fondacaro says that HTS program managers are waiting for "final guidance" on the matter from US Army lawyers.

Strong is, I believe, confusing the regulation itself with the interpretations of the regulations set forward by OHRP and various IRBs.
First, he assumes that the regulation "apparently mandates that a review board at least look at the research in order to determine whether or not continuing oversight is necessary." But [3]as I noted in an earlier post, that mandate only

appeared in OPRR (OHRP's predecessor) guidance of 1995, sixteen years after the exemptions were drafted by the HEW Office of the General Counsel. At the time, that office explained,

> The regulations, as proposed, do not require any independent approval of a researcher's conclusion that his or her research is within one of the exceptions. In taking this approach for purposes of discussion, we have weighted the possibility of abuse against the administrative burdens that would be involved in introducing another element of review which might not be very different from the review that the exceptions are intended to eliminate.

["Applicability to Social and Educational Research," attached to Peter Hamilton, Deputy General Counsel, to Mary Berry et al., 27 March 1979, Res 3-1-B Proposed Policy Protections Human Subjects 1978-79, Record Group 443, National Archives]
As late as 1988, DHHS policy allowed institutions to choose who would decide whether an exception applied: the investigator, the IRB chair, or another official. The institutions could also decide, as a matter of institutional policy, that some or all of the exemptions were not valid.
[Robert E. Windom, Assistant Secretary for Health, to Charlotte Kitler, New Jersey Department of Health, 13 September 1988, RES-6-01 Human Subjects, OD Central Files, Office of the Director, NIH]
Thus, it is OPRR/OHRP, and not the Department of Defense, that has departed from the intention of the regulations.
Second, Strong claims that "the exemption stipulates stringent protocols regarding data recording in order to insure the anonymity of research subjects." No, the [4]regulation simply states that IRB review is required if

> (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
> (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

What this means is a matter of interpretation; there is nothing about "stringent protocols."
In any event, I must doubt that Strong would be any happier had he learned that the program had been approved by a three-person quorum of a five-person Department of Defense IRB, perhaps with no anthropologists as members. The ethical validity of the program should be debated not by a local IRB but by the anthropological profession itself. And I am glad to see that is [5]just what anthropologists are doing.

1. http://insidehighered.com/news/2007/10/22/anthro
2. http://savageminds.org/2007/10/18/human-terrain-and-the-irb-puzzle/
3. http://institutionalreviewblog.blogspot.com/2007/08/guidance-creep.html
4. http://a257.g.akamaitech.net/7/257/2422/03jul20071500/edocket.access.gpo.gov/cfr_2007/julqtr/32cfr219.101.htm
5. http://www.insidehighered.com/news/2006/09/01/anthro

2.11 November

2.11.1 OHRP Seeks Comment on Expedited Review (2007-11-03 14:40)

As stated in the Federal Register, "The Office for Human Research Protections (OHRP) is requesting written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board

(IRB) through an expedited review procedure, last published in the Federal Register on November 9, 1998 ([1]63 FR 60364)."
Comments are being taken until December 26, 2007. The full announcement can be found at [2]http://www.hhs.gov/ohrp/documents/20071026.htm
This announcement should be of particular interest to oral historians, because the 1998 guidance was, I believe, the first official document to suggest that oral history should even be subject to IRB review. Thus, this is a good opportunity for OHRP to reconsider its whole position on oral history.

1. http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm
2. http://www.hhs.gov/ohrp/documents/20071026.htm

2.11.2 Neuenschwander on IRBs and Oral History Legal Releases (2007-11-09 22:08)

The Fall 2007 issue of the Oral History Association newsletter features Professor John A. Neuenschwander's essay, "What's In Your Legal Release Agreement?" Neuenschwander collected "72 agreements from a wide variety of programs including major universities, libraries, government agencies, local historical societies, and independent oral historians," and offers various observations about what is and is not on them. He does not offer a model release, though we can hope that his research will inform the next edition of his indispensable work, Oral History and the Law. For purposes of this blog, the most interesting section of the essay is entitled "Institutional Review Board Modified Releases," in which Neuenschwander examines the nine forms of the 72 that had clearly been modified by IRBs to conform with the Common Rule. He presents a paragraph from a typically modified form:

> The interview will be conducted in the form of a guided conversation and will last approximately _ _ _ _ _ _ _ _. I will be free to decline any question that makes me uncomfortable. Moreover, I have the right to stop the tape recording at any time with no negative consequences. There are no foreseeable risks in doing this interview. The benefit of the interview is to the general public in the form of increased historical knowledge. I recognize that because the interview will be donated to the University of _ _ _ _ _ _ _ _ there is no assumption of confidentiality, unless I request it.

Neuenschwander approves of this language, stating "the gulf between the medical or scientific culture of the IRB and the social or humanistic one of the oral historian has been bridged successfully." But I fear he glosses over some potential problems in the IRB imposed language:
1. "The interview . . . will last approximately _ _ _ _ _ _ _ _." What is that statement doing there? While it is certainly courteous to ask a narrator to set aside a certain amount of time, interviews are quite unpredictable, and my sessions have ranged from 30 minutes to more than seven hours (with a break for lunch). Including an estimate of time in the release form elevates guesswork to an ethical duty, perhaps even a contractual obligation. This strikes me as a bad idea.
2. "There are no foreseeable risks in doing this interview." This statement is contradicted by Neuenschwander's finding that other forms asks narrators to indemnify the interviewer "from any and all claims or demands or lawsuits arising out of or in connection with the use of the interview, including but not limited to any claims for defamation, copyright violations, invasion of privacy or right of publicity." So someone is foreseeing risks from oral history interviews, and even that list doesn't consider the harms to reputation added to the Common Rule in 1991.
3. "There is no assumption of confidentiality, unless I request it." This is certainly an improvement over other IRB boilerplate that assumes confidentiality as the norm. But the statement does follow the OHA guidelines in allowing confidentiality in some circumstances. This raises questions of how far the interviewer must go to defend confidentiality against subpoenas, physical theft, ineptness by the depository, and so on. In another section, Neuenschwander notes that of the roughly 25 forms that promised confidentiality, only three qualified that promise with mention of

subpoena and the Freedom of Information Act. Thus, the IRB language is incomplete.
Oral historians need to work out language that can alert narrators to the real risks of speaking on the record without spooking them unnecessarily. If IRBs can help in this task, all power to them, but nothing in Neuenschwander's essay suggests that they can.

John Neuenschwander (2007-11-16 16:22:00)
While I am appreciative of your efforts to remove all oral history research from IRB oversight, I feel compelled to correct the record regarding some of the observations about my article that you made in your recent blog.
1. After presenting the IRB consent language that I offered in my article you quote me in such a way as to significantly change my meaning. My original statement was that the nine IRB modified releases "...suggest that perhaps on these campuses at least, the gulf between the medical or scientific culture of the IRB and the social or humanistic one of the oral historian has been bridged successfully." By ellipsing out my qualifying language you create the mistaken impression that I am an unabashed advocate of IRB control.
2. The assumptions you draw from your analysis in #2 & 3, both suffer from a common ailment. In the first one you indicate that because I discuss the idemnity clauses that seven of the agreements I reviewed contained, that this directly contradicts the "no foreseeable risk" assurance in the IRB modified agreement I quote from. But I provide no indication in the article that such language was found in this agreement or any of eight other IRB modified agreements I reviewed. Hence, this claim is without foundation and supporting evidence. The same problem appears in #3. There is no match presented by me between the three agreements that contain warnings about possible FOIA/subpoena and the nine IRB modified forms I examined. In each instance you seriously mischaracterize my scholarship.
I wish you well with your blogging efforts but can only hope that they is more factual accuracy in future endeavors.
Prof. Neuenschwander
History Dept.
Carthage College

Zachary M. Schrag (2007-11-16 16:27:00)
Thank you for your comments.
I am sorry if you feel I mischaracterized your specific findings, and I encourage my readers to read the original article. Unfortunately, it is not yet online. (It may eventually appear at http://alpha.dickinson.edu/oha/pub _nl.html.)
The question I posed about the article is whether IRBs can help oral historians improve their consent forms. The evidence in your article suggests only that IRBs and oral historians, working together, can turn a blind eye to the real risks of recorded interviews. For this reason, I see no successful bridging of gaps between IRBs and oral history.

2.12 December

2.12.1 Law & Society Review (2007-12-01 22:55)

John Mueller has kindly alerted me to the December 2007 issue of [1]Law & Society Review, which includes five items concerning IRBs. I will read and comment on them as time permits.
Readers interested in legal analysis of IRBs should also consult Philip Hamburger's "[2]'Ingenious Argument' or a Serious Constitutional Problem? A Comment on Professor Epstein's Paper," a follow-up to the Northwestern Law Review special issue.

1. http://www.blackwell-synergy.com/toc/lasr/41/4
2. http://colloquy.law.northwestern.edu/main/2007/10/ingenious-argum.html

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Zachary M. Schrag (2008-01-20 17:03:00)
I have posted my comments on these articles at [1]http://institutionalreviewblog.blogspot.com/2007/12/law-socie ty-review-continued.html.

1. http://institutionalreviewblog.blogspot.com/2007/12/law-society-review-continued.html

2.12.2 My Comments to OHRP (2007-12-21 17:00)

As I noted in November, [1]OHRP is soliciting comments on proposed changes to its 1998 guidance on expedited review. Below are the comments I submitted today. I thank Rob Townsend of the American Historical Association for his help in revision.

Comments on Proposed to Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review Procedure
To the Office of Human Research Protections:
The Federal Register of 26 October 2007 states that "OHRP is requesting comments on the entire expedited review list that was last published in the Federal Register on November 9, 1998 (63 FR 60364) to determine if other changes are needed." I would like to recommend that "oral history" be removed from this list, and that OHRP make an unambiguous statement that oral history does not constitute human subjects research as defined in 45 CFR 46.
I believe that other historians and the American Historical Association will submit comments describing the harm done to historical scholarship by well-meaning but inexpert IRBs. Since I have spent much of 2007 researching the history of IRB review of the social sciences, I think I can be most helpful by explaining the historical significance of the inclusion of oral history in the 1998 guidance. Put simply, the 1998 guidance unintentionally overturned half a century of oral history practice and a quarter century or more of federal policy toward oral history.
While I hope to learn more about the origins of the 1998 guidance, I have found nothing to suggest that its authors anticipated the results it has had. I hope that as it reconsiders this guidance, OHRP will do so with more information and deliberation. To this end, I offer the following brief account of the current regulations, and I would be happy to elaborate on any of these points if asked.
1. CONGRESS DID NOT INTEND TO REQUIRE IRB REVIEW OF ORAL HISTORY
Today's regulations for human subjects research draw their authority from two sets of congressional hearings. The first, the 1965 Special Inquiry on Invasion of Privacy, conducted by the House Committee on Government Operations, concerned itself with "a number of invasion-of-privacy matters" including "psychological testing of Federal employees and job applicants, electronic eavesdropping, mail covers, trash snooping, peepholes in Government buildings, the farm census questionnaire, and whether confidentiality is properly guarded in income-tax returns and Federal investigative and employment files." [1] The second, the Senate Subcommittee on Health's 1973 hearings on human experimentation, focused almost exclusively on medical research. [2] The only non-medical research the Senate investigated were behavioral experiments, such as B. F. Skinner's "research in to the modification of behavior by the use of positive and negative rewards and conditioning." [3] It was out of concern about this sort of behavior modification that that Congress included "behavioral research" in the National Research Act (93-348). [4]
At no point in either set of hearings, in subsequent reports, or in legislation did Congress concern itself with anything resembling oral history. Congress has never required IRB review of oral history research by its own staff or by the Library of Congress.
2. THE NATIONAL COMMISSION DID NOT INTEND TO REQUIRE IRB REVIEW OF ORAL HISTORY
As OHRP's website notes, the current regulations were intended to effect the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. But the National Commission never intended to require IRB review of oral history research. Oral history is not mentioned in any of its publications. In the course of my research I have spoken with the two leading authors of the commission's IRB report (Bradford Gray and Barbara Mishkin) and two of the leading authors of the Belmont Report (Tom Beauchamp and Albert Jon-

sen). All assured me that they had no intention of imposing IRB oversight on oral history.

3. THE AUTHORS OF 45 CFR 46 DID NOT INTEND TO REQUIRE IRB REVIEW OF ORAL HISTORY

In 1978 and 1979, officials at the Department of Health, Education, and Welfare (later the Department of Health and Human Services) worked to translate the commission's recommendations into a revised version of 45 CFR 46. Within the department, there was considerable debate between the Office of General Counsel, which did not believe that federal law provided for IRB oversight of any social science research, and officials of the health agencies, which sought broader coverage. But even the health agencies agreed to exempt "product and marketing research, historical research, journalistic research, studies on organizations, public opinion polls and management evaluations where the potential for invasion of privacy is absent or minimal." [5] In a careful review of NIH records of the period, I have found no document by any of the authors of the 1974 or 1981 regulations even hinting that oral history should be subject to review. Nor have I found any mention of oral history in the debates leading up to the 1991 revisions that produced the current regulations.

4. THE 1998 GUIDANCE WAS AN EFFORT TO RESTRAIN OVERZEALOUS IRBs

While all of this was going on, oral history had proceeded in federally supported institutions since at least 1948 and the founding of Columbia University's Oral History Research Office. Thus, over the course of thirty years, from the Public Health Service's first policies on extramural research in 1965, through the passage of the National Research Act in 1974, and through three versions of 45 CFR 46, oral historians had continued their work undisturbed by IRBs or OPRR, and without provoking any ethical scandals worthy of federal attention.

In the 1990s, however, some university IRBs began insisting on their jurisdiction over oral history. In 1995, for example, the University of Delaware threatened to reject a doctoral dissertation because its author had not sought IRB approval for oral history interviews. [6] Historians at the university had long conducted such interviews without IRB supervision.

In response to the interference by university IRBs, historians sought common ground with regulators and IRBs, based on their shared concern with ethical research. [7] As part of this effort, in 1998 the Oral History Association (with the endorsement of the American Studies Association and the American Historical Association) asked OPRR to make oral history projects eligible for expedited review procedures. [8] In the 1998 guidance now being reconsidered, OPRR agreed to this request, noting that "research on oral history has been included in response to approximately six comments," presumably including the Oral History Association comment. [9]

5. THE 1998 GUIDANCE HAD THE PERVERSE EFFECT OF RATIFYING THE BEHAVIOR IT SOUGHT TO RESTRAIN

Yet instead of improving relations between IRBs and historians, the inclusion of oral history in the 1998 guidance has disrupted oral history research throughout the United States, since IRBs have taken the list as evidence that OPRR wants oral history to be reviewed. For example, the CITI Program, a widely used training system for IRBs and researchers, claims erroneously that "the regulations specifically refer to interviews, oral history, focus groups, and other qualitative methods." [10] And Northwestern University's IRB claims that "Federal guidance defines social and behavioral science methodologies as those that include research on individual or group characteristics or behavior . . . or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies," using the language of the 1998 guidance. [11] My impression is that many IRBs have taken a similar position, interpreting the 1998 guidance as a list of activities that should be reviewed.

In response to such misinterpretation of the guidance, the Oral History Association and the American Historical Association have asked OHRP to return to the regulatory situation of the 1970s and 1980s, in which no one considered oral history to be subject to federal regulation. In 2003, in response to such requests, OHRP stated that "oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB)." [12]

As it stands, then, OHRP takes contradictory positions on the applicability of 45 CFR 46 to oral history interviewing. The 1998 guidance suggests that oral history can be subject to mandatory review, while the 2003 letter suggests that "in general" it is not. This contradictory guidance has contributed to the unhappiness of historians and IRB members across the country.

CONCLUSION: OHRP SHOULD REPLACE THE 1998 GUIDANCE WITH GUIDANCE CONSISTENT WITH

The 1998 guidance constituted a radical break with previous policy and a decision of lasting importance. Yet unlike the bulk of human subjects regulations and guidance, the current guidance concerning oral history is not based on the will of Congress or the findings of any federal commission. It was based on the request of historians' professional organizations, but since 2003 those same organizations have sought a very different policy.
The inclusion of oral history in the 1998 guidance was a well-intentioned effort, but it has proven harmful to ethical scholarship. With the reconsideration of the guidance, OHRP has a splendid opportunity to return to the original intent of Congress and the National Commission by unambiguously excluding oral history from review.
NOTES
[1] U.S. House of Representatives, Committee on Government Operations, Special Inquiry on Invasion of Privacy (89th Cong., 1st sess., 1965), 5.
[2] U.S. Senate, Quality of Health Care—Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, Part 3 (93d Cong., 1st sess., 1973).
[3] U.S. Senate, National Research Service Award Act (S. Report. 93-381, 93d Cong., 1st sess., 1973), 15.
[4] Sharland Trotter, "Strict Regulations Proposed for Human Experimentation," APA Monitor 5 (February 1974), 8.
[5] Gerald L. Klerman, Administrator, to Assistant Secretary for Health and Surgeon General, 30 March 1979, FRC box 78, Res 3-1-B Proposed Policy Protections Human Subjects 1978-79, RG 443, National Archives.
[6] Donald A. Ritchie, Doing Oral History: A Practical Guide (New York: Oxford University Press, 2003), 196.
[7] Linda Shopes, "Remarks before President's National Bioethics Advisory Commission," 6 April 2000, http://www.oah.org/pubs/nl/2000may/bioethics.html (20 December 2007).
[8] Linda Shopes, President, and Rebecca Sharpless, Executive Secretary, Oral History Association, to Office for Protection from Research Risks, 2 March 1998, copy in author's possession.
[9] Federal Register, November 9, 1998 (Volume 63, Number 216), pp. 60364-60367, http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm (18 December 2007).
[10] Lorna Hicks, "Defining Research with Human Subjects," CITI Program, https://www.citiprogram.org (30 October 2006).
[11] Northwestern University, "Schools, Departments and Programs Served by Panel E of the Institutional Review Board," http://www.northwestern.edu/research/OPRS/irb/training/docs/panelERe views.doc (18 December 2007).
[12] Michael Carome to Linda Shopes and Donald Ritchie, 22 September 2003, http://grants.nih.gov/grants/policy/hs/Oral _History.doc (20 December 2007).

1. http://institutionalreviewblog.blogspot.com/2007/11/ohrp-seeks-comment-on-expedited-review.html

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2.12.3 Law & Society Review (2007-12-24 15:15)

As I noted earlier, the December 2007 issue of Law & Society Review features five items concerning IRBs and the social sciences.

Malcolm M. Feeley, "Legality, Social Research, and the Challenge of Institutional Review Boards"

The section on IRBs begins with Malcolm M. Feeley's 2006 presidential address to the Law & Society Association. Feeley presents an impassioned critique of IRBs, complaining, "in the name of minimizing risks, IRBs subject researchers to petty tyranny. Graduate students and junior scholars are particularly likely to be caught in their web—and for them IRB tyranny is often more than petty. Senior scholars are generally more adept at avoidance, evasion, and adaptation, but they too are hardly exempt from this tyranny. A number of prominent social scientists, including some members of this Association, know all too well the harms of running afoul of campus IRBs. . . Entire research areas

and methodologies are in jeopardy, insofar as the difficulties of obtaining IRB approval affect research priorities for funding agencies and universities' willingness to support researchers."

Feeley then raises a number of specific problems, such as the ill fit between the beneficence encoded in regulation and the kind of social research that aspires to produce "tarnished reputations and forced resignations" of evil-doers.

To remedy this situation, Feely proposes three modes of action:

1. "Join [IRBs]; subvert them—or at least curtail them. Serve on them and do all you possibly can to facilitate the research of your colleagues rather than act as a censor."
2. Follow Richard Schweder's call to get your university to apply federal regulations only to federally funded research.
3. "Ask about estimates of how much actual harm to subjects in social science research has been prevented by IRB actions. And ask for documentation."

I am a bit skeptical about the first suggestion, for two reasons. First, few universities have IRBs strictly for the social sciences. This means that a sociologist, anthropologist, political scientist, or historian would spend most of her time on an IRB reviewing (or abstaining from reviewing) psychological experiments. That's an unfair price to pay to have some power over one's own research. Second, it assumes that IRBs are run by IRB members. As Caroline H. Bledsoe et al. report in "Regulating Creativity: Research and Survival in the IRB Iron Cage," the size of human protections staffs has ballooned in recent years. If the staff have the real power, IRB members will have little chance to facilitate research.

Laura Stark, "Victims in Our Own Minds? IRBs in Myth and Practice."

The first comment is Laura Stark's. It draws in part on Stark's 2006 Princeton dissertation, "Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation." I am glad to learn of this work, and I hope to comment on it in a later post.

Stark suggests trying to improve, rather than restrict, IRBs, because "ethics review in some form is here to stay because of institutional inertia, and [because of her] belief as a potential research subject that ethics review is not an entirely bad idea, even for social scientists." She advocates "changing local practices to suit the local research community, rather than refining federal regulations."

One intriguing example is the establishment of "IRB subcommittees, which can review lower-risk studies [and] have moved ethics review into academic departments. In so doing, these subcommittees of faculty members (who presumably understand the methods in question) have taken over the task of evaluating low-risk studies from board administrators." This sounds a lot like the departmental review that the AAUP suggested as an alternative to IRB control, and like the Macquarie model I described in August . I hope that Stark will publicize the name of the university that uses such subcommittees, so that it can better serve as an example to others. Stark does not explain why this model is appropriate only for low-risk studies. It seems to me the higher the risk, the more reason to have research reviewed by people who understand its methods.

Significantly, neither in her article nor in her dissertation does Stark take up Feeley's challenge to document cases in which IRBs have prevented actual harm to participants in social science research. Her research offers important insights about how IRBs reach decisions, but no evidence that those decisions do more good than harm, or that they are consistent with norms of academic freedom.

Finally, Stark claims, "the social science victim narrative—by which I mean the story that human subjects regulations were not meant to apply to us—is pervasive among academics, and it is particularly central to qualitative researchers as a justification for their criticisms of IRBs. Yet this victim narrative does not stand up to historical scrutiny, as I have shown." Yes and no. Stark's use of the passive voice (were not meant to apply) is telling; the question is who meant the regulations to apply to social scientists, and who did not. I am working on a full-scale history of the imposition of human subjects regulations on the social scientists, and I can tell Stark that more scrutiny will complicate her story.

Robert Dingwall, "Turn off the oxygen …"

The second comment is Robert Dingwall's "Turn off the oxygen …," the oxygen here referring to the legitimacy granted to IRBs by university faculty.

Dingwall is skeptical of legal challenges, given the cost, the possibility of failure, and the fact that the First Amendment only applies to the United States (Dingwall works in the UK.) He argues instead that "if we can show that ethical regulation does not actually contribute to a better society, but to a waste of public funds, serious information deficits for citizens, and long-term economic and, hence, political decline, then we may have identified a set of arguments that

might lead to a more skeptical approach to the self-serving claims of the philosopher kings who sustain that system." For example, we must continue to document ethical wrongs like the insistence by a British medical journal that two historians falsify the names of their oral history narrators, despite the wishes of most of the narrators to be named. [Smith, Graham, & Malcolm Nicolson (2007) "Re-expressing the Division of British Medicine under the NHS: The Importance of Locality in General Practitioners' Oral Histories," 64 Social Science & Medicine 938–48.] I hope Professor Dingwall has a chance to read Scott Atran's essay, "Research Police – How a University IRB Thwarts Understanding of Terrorism", http://institutionalreviewblog.blogspot.com/2007/05/scott-atran-rese arch-police-how.html, posted on this blog in May. It is an excellent example of the way that IRB interference can disrupt vitally important work.

Jack Katz, "Toward a Natural History of Ethical Censorship"

The third comment, by Jack Katz, is the most shocking, for it is the most thoroughly documented. (It even cites this blog, thanks.) Katz lists several cases, all recent, in which IRBs have derailed potentially important social research. Unlike the 2006 AAUP report, he gives names, universities, dates and citations for most of his horror stories. Among them:

"In Utah, Brigham Young University's IRB blocked an inquiry into the attitudes of homosexual Mormons on their church. When the same anonymous questionnaire study design was transferred to another researcher, the IRB at Idaho State University found the study unproblematic."

"A proposed study of university admissions practices [was] blocked by an IRB at a Cal State campus. The study had the potential to reveal illegal behavior, namely affirmative action, which was prohibited when Proposition 209 became California law."

"At UCLA, a labor institute developed a white paper lamenting the health benefits that Indian casinos offered their (largely Mexican and Filipino) workers. Despite the university's support for the labor institute when anti-union legislators at the state capitol have sought to eliminate its funding, publication was banned by the IRB after a complaint by an advocate for Indian tribes that the study had not gone through IRB review."

Stark would have us believe that "the local character of board review does not mean that IRB decisions are wrong so much as that they are idiosyncratic." But Katz shows that IRBs' idiosyncracies can be hard to distinguish from viewpoint-based censorship.

In contrast to these identifiable harms, Katz finds "no historical evidence that the social science and humanistic research now pre-reviewed by IRBs ever harmed subjects significantly, much less in ways that could not be redressed through post hoc remedies." I don't think I would go quite this far, given Carole Gaar Johnson's description of the harms caused to the residents of "Plainville" by the inept anonymization of their town ("Risks in the Publication of Fieldwork," in Joan E. Sieber, ed., The Ethics of Social Research: Fieldwork, Regulation, and Publication (New York: Springer, 1982). But the rarity of such cases means we should weigh IRB review against other methods of prevention, such as departmental review of projects or better certification of researchers.

Katz reiterates his call, previously set forth in the American Ethnologist, for a "culture of legality," in which IRBs would be forced to explain their decisions and "publicly disseminate proposed rules before they take the force of law." He believes that "were IRBs to recognize formally that they cannot properly demand the impossible, were they to invite public discussion of policy alternatives, and were they to open their files to public oversight, they would fundamentally alter the trajectory of institutional development by forcing confrontation with the central value choices currently ignored in the evolution of ethical research culture."

But what do we do when we confront those value choices? We get statements like Stuart Plattner's: "no one should ever be hurt just because they were involved in a research project, if at all possible," a position clearly at odds with Katz's applause for "the American tradition of critical social research." (Plattner, "Human Subjects Protection and Cultural Anthropology," Anthropological Quarterly, 2003) The problem with IRBs' value choices is not that they are hidden, but that they are often wrong. The Belmont Report is the most public and widely cited rule used by IRBs, and it is a terrible guide for the kind of critical research Feeley and Katz want done.

Feeley, "Response to Comments"

The most interesting part of Feeley's response comes at the very end. Noting that, with the AAUP's encouragement, some universities have ceased promising to review all human subjects research in favor of the regulatory minimum of federally funded research, he points out that we will soon know if the lack of IRB review of social science at those

universities yields a flood of unethical research. "If there are few reports of negative consequences . . . they might encourage national officials to rethink the need for such an expansive regulatory system . . . On the other hand, if opt-out results in increased problems, the findings might help convince Katz, Dingwall, me, and still others of the value of IRBs." This strikes me a very fair bet, and the experiment can't begin soon enough.

2.12.4 Law & Society Review, continued (2007-12-24 15:27)

As I noted earlier, the December 2007 issue of [1]Law & Society Review features five items concerning IRBs and the social sciences.

Malcolm M. Feeley, "Legality, Social Research, and the Challenge of Institutional Review Boards"

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Feeley then raises a number of specific problems, such as the ill fit between the beneficence encoded in regulation and the kind of social research that aspires to produce "tarnished reputations and forced resignations" of evil-doers.
To remedy this situation, Feely proposes three modes of action:
1. "Join [IRBs]; subvert them—or at least curtail them. Serve on them and do all you possibly can to facilitate the research of your colleagues rather than act as a censor."
2. Follow Richard Schweder's call to get your university to apply federal regulations only to federally funded research.
3. "Ask about estimates of how much actual harm to subjects in social science research has been prevented by IRB actions. And ask for documentation."
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Laura Stark, "Victims in Our Own Minds? IRBs in Myth and Practice."

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Stark suggests trying to improve, rather than restrict, IRBs, because "ethics review in some form is here to stay because of institutional inertia, and [because of her] belief as a potential research subject that ethics review is not an entirely bad idea, even for social scientists." She advocates "changing local practices to suit the local research community, rather than refining federal regulations."
One intriguing example is the establishment of "IRB subcommittees, which can review lower-risk studies [and] have moved ethics review into academic departments. In so doing, these subcommittees of faculty members (who presumably understand the methods in question) have taken over the task of evaluating low-risk studies from board administrators." This sounds a lot like the departmental review that the AAUP suggested as an alternative to IRB control, and

like the [3]Macquarie model I described in August. I hope that Stark will publicize the name of the university that uses such subcommittees, so that it can better serve as an example to others. Stark does not explain why this model is appropriate only for low-risk studies. It seems to me the higher the risk, the more reason to have research reviewed by people who understand its methods.

Significantly, neither in her article nor in her dissertation does Stark take up Feeley's challenge to document cases in which IRBs have prevented actual harm to participants in social science research. Her research offers important insights about how IRBs reach decisions, but no evidence that those decisions do more good than harm, or that they are consistent with norms of academic freedom.

Finally, Stark claims, "the social science victim narrative—by which I mean the story that human subjects regulations were not meant to apply to us—is pervasive among academics, and it is particularly central to qualitative researchers as a justification for their criticisms of IRBs. Yet this victim narrative does not stand up to historical scrutiny, as I have shown." Yes and no. Stark's use of the passive voice (were not meant to apply) is telling; the question is who meant the regulations to apply to social scientists, and who did not. I am working on a full-scale history of the imposition of human subjects regulations on the social scientists, and I can tell Stark that more scrutiny will complicate her story.

Robert Dingwall, "Turn off the oxygen …"

The second comment is Robert Dingwall's "Turn off the oxygen …," the oxygen here referring to the legitimacy granted to IRBs by university faculty.

Dingwall is skeptical of legal challenges, given the cost, the possibility of failure, and the fact that the First Amendment only applies to the United States (Dingwall works in the UK.) He argues instead that "if we can show that ethical regulation does not actually contribute to a better society, but to a waste of public funds, serious information deficits for citizens, and long-term economic and, hence, political decline, then we may have identified a set of arguments that might lead to a more skeptical approach to the self-serving claims of the philosopher kings who sustain that system." For example, we must continue to document ethical wrongs like the insistence by a British medical journal that two historians falsify the names of their oral history narrators, despite the wishes of most of the narrators to be named. [Graham Smith and Malcolm Nicolson, "Re-expressing the Division of British Medicine under the NHS: The Importance of Locality in General Practitioners' Oral Histories," Social Science & Medicine 64 (2007): 938–48.] I hope Professor Dingwall has a chance to read Scott Atran's essay, "[4]Research Police – How a University IRB Thwarts Understanding of Terrorism," posted on this blog in May. It is an excellent example of the way that IRB interference can disrupt vitally important work.

Jack Katz, "Toward a Natural History of Ethical Censorship"

The third comment, by Jack Katz, is the most shocking, for it is the most thoroughly documented. (It even cites this blog, thanks.) Katz lists several cases, all recent, in which IRBs have derailed potentially important social research. Unlike the 2006 AAUP report, he gives names, universities, dates and citations for most of his horror stories. Among them:

"In Utah, Brigham Young University's IRB blocked an inquiry into the attitudes of homosexual Mormons on their church. When the same anonymous questionnaire study design was transferred to another researcher, the IRB at Idaho State University found the study unproblematic."

"A proposed study of university admissions practices [was] blocked by an IRB at a Cal State campus. The study had the potential to reveal illegal behavior, namely affirmative action, which was prohibited when Proposition 209 became California law."

"At UCLA, a labor institute developed a white paper lamenting the health benefits that Indian casinos offered their (largely Mexican and Filipino) workers. Despite the university's support for the labor institute when anti-union legislators at the state capitol have sought to eliminate its funding, publication was banned by the IRB after a complaint by an advocate for Indian tribes that the study had not gone through IRB review."

Stark would have us believe that "the local character of board review does not mean that IRB decisions are wrong so much as that they are idiosyncratic." But Katz shows that IRBs' idiosyncracies can be hard to distinguish from

viewpoint-based censorship.

In contrast to these identifiable harms, Katz finds "no historical evidence that the social science and humanistic research now pre-reviewed by IRBs ever harmed subjects significantly, much less in ways that could not be redressed through post hoc remedies." I don't think I would go quite this far, given Carole Gaar Johnson's description of the harms caused to the residents of "Plainville" by the inept anonymization of their town ("Risks in the Publication of Fieldwork," in Joan E. Sieber, ed., The Ethics of Social Research: Fieldwork, Regulation, and Publication (New York: Springer, 1982). But the rarity of such cases means we should weigh IRB review against other methods of prevention, such as departmental review of projects or better certification of researchers.

Katz reiterates his call, previously set forth in the American Ethnologist, for a "culture of legality," in which IRBs would be forced to explain their decisions and "publicly disseminate proposed rules before they take the force of law." He believes that "were IRBs to recognize formally that they cannot properly demand the impossible, were they to invite public discussion of policy alternatives, and were they to open their files to public oversight, they would fundamentally alter the trajectory of institutional development by forcing confrontation with the central value choices currently ignored in the evolution of ethical research culture."

But what do we do when we confront those value choices? We get statements like Stuart Plattner's: "no one should ever be hurt just because they were involved in a research project, if at all possible," a position clearly at odds with Katz's applause for "the American tradition of critical social research." (Plattner, "Human Subjects Protection and Cultural Anthropology," Anthropological Quarterly, 2003) The problem with IRBs' value choices is not that they are hidden, but that they are often wrong. The Belmont Report is the most public and widely cited rule used by IRBs, and it is a terrible guide for the kind of critical research Feeley and Katz want done.

Feeley, "Response to Comments"

The most interesting part of Feeley's response comes at the very end. Noting that, with the AAUP's encouragement, some universities have ceased promising to review all human subjects research in favor of the regulatory minimum of federally funded research, he points out that we will soon know if the lack of IRB review of social science at those universities yields a flood of unethical research. "If there are few reports of negative consequences . . . they might encourage national officials to rethink the need for such an expansive regulatory system . . . On the other hand, if opt-out results in increased problems, the findings might help convince Katz, Dingwall, me, and still others of the value of IRBs." This strikes me a very fair bet, and the experiment can't begin soon enough.

1. http://www.blackwell-synergy.com/toc/lasr/41/4
2. http://www.law.northwestern.edu/journals/lawreview/v101/n2/593/LR101n2Bledsoe.pdf
3. http://institutionalreviewblog.blogspot.com/2007/08/macquaries-respect-for-expertise.html
4. http://institutionalreviewblog.blogspot.com/2007/05/scott-atran-research-police-how.html

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Robert Dingwall (2008-01-02 05:23:00)

In the UK, the introduction of IRB-type systems has been uneven and led by less research-intensive universities so that there are fewer documented cases of censorship akin to those described by Jack Katz. However, my attention has recently been drawn to a 2007 paper (R. Roberts et al., UK students and sex work:current knowledge and issues, Journal of Community and Applied Social Psychology, 17: 141-146) which resembles several of Katz's cases and suggests that even a 'voluntary' system of institutional review easily slides into censorship. In this case, the authors report on their efforts to investigate the claim that changes in government funding for English undergraduate students have led a significant number of young women to take up employment in the sex industry. Their own university approved the study only on the basis that they did not generate a sample from that institution's students and promised support from the National Union of Students did not materialize, apparently because of the close ties between the union and the political party responsible for the funding changes. This has similarities to both the Mormon case and the Indian casino workers case reported by Katz.

2.12.5 American Historical Association Asks for Oral History Exclusion (2007-12-28 12:32)

In its response to OHRP's solicitation of comments on its 1998 guidance, the American Historical Association asked that "'oral history' . . . be removed from category 7 and explicitly removed from IRB review." The AHA blog, [1]AHA Today, reports the request and posts the full text of the [2]association's letter to OHRP.

1. http://blog.historians.org/news/410/aha-asks-for-oral-history-exclusion
2. http://www.historians.org/press/OralHistoryExclusionLetter.pdf

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2.12.6 Columbia University Grants Oral History Exclusion (2007-12-28 12:35)

Mary Marshall Clark, director of Columbia University's Oral History Research Office, has announced on [1]H-Oralhist that the university yesterday approved a new policy on IRB review of oral history research. The policy notes that

> Oral history interviews, that only document specific historical events or the experiences of individuals or communities over different time periods would not constitute "human subjects research" as they would not support or lead to the development of a hypothesis in a manner that would have predictive value. The collection of such information, like journalism, is generally considered to be a biography, documentary, or a historical record of the individual's life or experience; or of historical events. Oral history interviews of individuals is not usually intended to be scientific or to produce generalizable information and hence is not usually considered 'research' in accordance with the federal regulations or CU policy. Therefore, such oral history activities should not be submitted to the CU IRB for review.

Still covered by IRB jurisdiction are psychological studies that borrow some oral history techniques to test hypotheses. An example might be Kim T. Buehlman, John M. Gottman, and Lynn Fainsilber Katz, "[2]How a Couple Views Their Past Predicts Their Future: Predicting Divorce from an Oral History Interview," Journal of Family Psychology 5 (March/June 1992): 295-318.
I hope Columbia will prove a model for other universities; [3]in lumine tuo videbimus lumen.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=0712&week=d&msg=CE4oApzK4yony5XWUFqswQ
2. http://www.gottman.com/research/abstracts/detail.php?id=14
3. http://www.columbia.edu/cu/pr/special/cuglance.html

Jeffrey Cohen (2007-12-29 10:57:00)
Zach,
This is what many of us have been saying all along. It is not the methodology that determines whether an activity meets the definition of human subjects research, it is how the information is intended to be used. Not all oral history is human subjects research just as not all medical interventions are human subjects research. The Columbia policy does a good job of this. The only comment I have is that "generalizable" does not just mean statistical generalizability, it also include drawing conclusions that can be generalized beyond the individuals interviewed. For example, an oral history of Iraq war veterans that is intended to determine the affect of using reserve soldiers to fight a war, would be human subjects research. An oral history of Iraq war veterans intended to preserve their experiences and describe a historical event would not.
You should know that Columbia is not the only university that has such a policy. Many universities have similar oral history policies. I have a similar policy that I provide to my clients and several have adopted it.
By the way, just to remind you, oral history that is human subjects research but that does not put subjects at risk generally is eligible for exemption. Institutions decide for themselves how exemption determination are made. ORHP recommends that

investigators not make those determinations, but it doesn't have to be the IRB. I have one client, whose program has been accredited by AAHRPP, that has those determinations made on the department level.
Jeff

Zachary M. Schrag (2007-12-29 19:00:00)
Thank you for this comment. I am glad that you approve of the Columbia policy.
I must take issue with your claim that "this is what many of us have been saying all along."
You addressed the question of oral history in your November 2006 posting, "[1]OHRP and Oral History," and made five recommendations.
You are right that Columbia has implemented one of your recommendations, that institutions "should provide guidance on how to determine if an oral history activity meets this definition. The guidance should include examples of oral history activities that meet the definition and those that don't. I would recommend that this guidance be developed in conjunction with the oral historians at the institution."
However, Columbia has departed from your advice in two highly significant ways:
1. You wrote, "it would be a mistake to allow investigators to make [the] determination [of what is generalizable research] on their own."
Columbia has wisely rejected that argument. It allows historians who use interviews to determine whether they are conducting IRB-regulated research, just as historians who use books can do so.
2. You recommended that universities state that "a 'systematic investigation' is an activity that involves a prospective research plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question. Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings."
Columbia has rejected this definition. Instead, a "systematic investigation" is one that would "support or lead to the development of a hypothesis in a manner that would have predictive value." This is very different; historical research, "like journalism," does not offer predictive value, but it often informs policy.
Since Columbia's new policy exempts pretty much anything a historian is likely to do, your remaining two recommendations, concerning how an IRB should approach non-exempt oral history research, is largely irrelevant.
You claim in your current comment that "Many universities have similar oral history policies. I have a similar policy that I provide to my clients and several have adopted it." As always, I find it hard to discuss these things with you when you make factual claims that cannot be verified. In 2006, the American Historical Association found that
"On almost 95 percent of the university web sites, the only guidance a faculty member or student will find is a passing mention of oral history among the research methods subject to 'expedited' review. This language comes from the insertion of 'oral history' into the federal regulations for review boards in 1998. Most university administrators see these regulations as inviolate law and refuse to accept the recent agreement with federal authorities as a valid interpretation of the rules. To make matters worse, the agreement was further undermined when staff at OHRP issued conflicting and contradictory statements about its meaning shortly after it was issued. The net result—stated explicitly by a few of the review boards—is that even if oral history is excluded from review, only the review boards can decide what is excluded on a case-by-case basis. As a consequence, it appears oral history is still subject to review on most campuses.
"Only eleven of the university web sites discuss the exclusion agreement with OHRP—nine mention the original agreement with the AHA, while seven of them mention the subsequent contradictory guidance from OHRP in fall 2003, and five mention the OHRP's reaffirmation of the exclusion in January 2004."
Robert B. Townsend, "[2]Oral History and Review Boards: Little Gain and More Pain," Perspectives, February 2006.
Are eleven universities "many"? Are any of them your clients?
I'm glad to hear that departmental review has passed AAHRPP scrutiny at "one client," but that client cannot serve as a model for others unless it makes known its policies. Columbia has acted in the scholarly tradition of sharing information freely. Will your client?
Zach

1. http://hrpp.blogspot.com/2006/11/ohrp-and-oral-history.html
2. http://www.historians.org/perspectives/issues/2006/0602/0602new1.cfm

Chapter 3

2008

3.1 January

3.1.1 Inside Higher Ed Reports on Comments to OHRP (2008-01-04 00:03)

Scott Jaschik's January 3 Inside Higher Ed story, "[1]Threat Seen to Oral History," reports on the comments submitted to OHRP by the AHA and by me. The story is a helpful summary of key issues, and the comments following it indicate the passion this issue arouses in scholars in a range of fields.

1. http://insidehighered.com/news/2008/01/03/history

3.1.2 How State IRB Laws Threaten the Social Sciences: A Comment on Shamoo and Schwartz (2008-01-06 14:50)

Dr. Adil E. Shamoo of the University of Maryland School of Medicine kindly sent me a copy of his new article, "[1]Universal and Uniform Protections of Human Subjects in Research," The American Journal of Bioethics 7 (December 2007): 7-9, co-authored with Jack Schwartz of the Maryland Attorney General's Office.

The article calls for a federal law "to require that all human subject research in the United States, regardless of funding source or relationship to FDA marketing approval, be undertaken only after IRB review and with the informed consent of subjects." Barring that, it applauds state laws to that effect, such as the one passed in Maryland in 2002, which states that "a person may not conduct research using a human subject unless the person conducts the research in accordance with the federal regulations on the protection of human subjects . . . notwithstanding any provision in the federal regulations on the protection of human subjects that limits the applicability of the federal regulations to certain research . . . ." (13 [2]Maryland Code §13-2002)

Having read the current New Yorker's story on "[3]Guinea-Pigging," which states that 70 percent of drug trials now take place in the private sector, I can see the reason to regulate biomedical research through the state's police power, rather than through funding restrictions. But aside from a quick mention that research sponsored by the National Endowment for the Humanities is not subject to the Common Rule, the article does not mention the law's effect on the humanities and social sciences. This is a bit surprising, given [4]Shamoo's earlier argument in the Chronicle of Higher Education that human subjects regulations "have handicapped researchers whose work poses no threat to humans." This being the case, why would he want to extend those same regulations to countless researchers not previously covered by them? And do the authors expect all journalists and oral historians in the state to be subject to IRB review, the way that many university-affiliated journalists and oral historians are now?

I wrote to both authors, and here is what I learned from them:
Shamoo does not believe that the law requires Maryland journalists to seek IRB approval of their work.
Schwartz does not believe that the law requires Maryland oral historians to seek IRB approval of their work, relying on a [5]22 November 2005 message from Michael Carome of OHRP.
According to Schwartz, "The Maryland law, like every bill passed by the Maryland Legislature, was reviewed for constitutionality. This overall review did not address whether some hypothetical application of the law, under a specific set of facts, might raise First Amendment or other constitutional concerns."
According to Schwartz, the Maryland attorney general's office has not brought any enforcement actions since the law's passage in 2002.
This last point is the key; a law that lies dormant for five years is unlikely to have any effect on anybody, so perhaps Shamoo and Schwartz have reason to think it will not handicap researchers more than they already are handicapped by existing federal regulation. Indeed, the legions of journalists, book authors, and market researchers who conduct interview and survey research outside of universities may have little to fear from a law that has not been enforced and might well fail constitutional scrutiny if it were.
But Shamoo and Schwartz ignore the potential effect of the law on social science and humanities researchers within universities, the very ones for whom Shamoo earlier expressed concern. These researchers have led a growing movement to get their universities to agree to review only research funded by the federal government. Such a move would free few, if any, university-affiliated biomedical researchers from oversight, since their expensive research is generally federally funded. Rather, it would free up the very kind of research that Shamoo considers too low-risk to merit review. But if the state imposes the same regulations regardless of the source of funding, university IRBs can close this door.
Thus, if the law has any effect at all, it will not be what Shamoo and Schwartz claim: "universal application of the ethical standards applicable to human subjects research." Instead, it will be the continued regulation of research by university-affiliated researchers while non-affiliated researchers conducting the same activities work in freedom. The result will not be uniformity, but entrenched disparity.
Shamoo's heart is in the right place. As he wrote in his Chronicle piece, "I have long advocated the creation of universal rules for all human-subject research, whether or not it receives federal funds. But an equally urgent reform is to exempt from present and future regulation any research that poses little or no risk to human subjects." Unfortunately, the state of Maryland has not treated exemption of social research as "equally urgent" to the universalization of rules. Thus, the effect of the law, if any, is to eliminate a path to the very type of exemption that Shamoo champions. Once again, regulators write rules in response to serious concerns about medical experimentation, with little or no attention to the social sciences and humanities.

1. http://www.informaworld.com/smpp/content~db=all~content=a788714428~tab=content
2. http://michie.lexisnexis.com/maryland/lpext.dll?f=templates&fn=main-h.htm&cp=mdcode
3. http://www.newyorker.com/reporting/2008/01/07/080107fa_fact_elliott
4. http://institutionalreviewblog.blogspot.com/2007/07/biomedical-scientist-speaks-out.html
5. http://www.utexas.edu/research/rsc/humanresearch/special_topics/documents/MichaelCaromeUpdated.pdf

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3.1.3 Johns Hopkins Dean: Generalizable Means "Hypothesis-Based" (2008-01-13 00:08)

In his comments on [1]Inside Higher Ed's recent story on oral history and IRBs, Eaton Lattman, Dean of Research at Johns Hopkins Krieger School of Arts and Sciences, writes that "many oral history projects probably do not meet the OHRP definition of research, and are therefore free from the need to go to an IRB for approval. They are not hypothesis-based projects and they do not produce generalizable results."
This interpretation of generalizability is consistent, as best I can tell, with the intent of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which first established generalizability as part of the definition of human subjects research. It also resembles [2]Columbia University's recent statement on oral history.

Dean Lattman's comment contrasts with definitions put forward by [3]Michael Carome of OHRP and consultant [4]Jeffrey Cohen, who maintain an oral history project is generalizable research if it lacks a hypothesis but draws conclusions, informs policy, or creates an archive for use by future researchers.
Thus, Hopkins joins Columbia and Northwestern in explicitly freeing oral history–as practiced by oral historians–from IRB review. While such advances are welcome, more welcome still would be a statement along the same lines from OHRP itself.

1. http://www.insidehighered.com/news/2008/01/03/history
2. http://institutionalreviewblog.blogspot.com/2007/12/columbia-university-grants-oral-history.html
3. http://www.oprs.ucla.edu/human/documents/pdf/oral-history-031209.pdf
4. http://hrpp.blogspot.com/2006_11_01_archive.html

3.1.4 How IRBs Decide–Badly: A Comment on Laura Stark's "Morality in Science" (2008-01-21 10:18)

Laura Stark's recent essay in [1]Law & Society Review led me to her 2006 Princeton University dissertation, "Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation." The heart of the dissertation is her description of the workings of three university IRBs–one in a medical school and two at universities without medical schools–based on recordings of their meetings and her direct observation of the IRBs at work. It makes for fascinating reading, and I applaud Stark for her achievement even as I disagree with her conclusions.
Stark claims to be neutral about IRBs' ability to perform their stated task: protecting the subjects of research. She writes, "My goal is not to judge the 'fairness' and 'effectiveness' of IRBs myself." (7) And she correctly notes that the ethical acceptability of an IRB-approved project is a "social truth," not an empirical one. (244) But her tone is generally sympathetic to the IRBs. For example, she writes that IRBs' "forms of evaluation provide directed, tangible ways for board members to carrying out their review process, given the practical difficulty of applying unmediated, abstract ethics principles," making the IRB members sound like heroes who have achieved a workable system against the odds. (186)
Indeed, in some cases she reports, IRBs seem to be doing some good. For example, a physiologist and a nurse had a fruitful debate about the need for a quick medical screening of subjects in an exercise study (197-200). That's an example of an IRB with multiple experts on a single type of research–something I hope is reasonably common in much biomedical research. But most of Stark's observations are distressing in ways I don't think she appreciates. Here, then, are some of the actions she observed, along with my reasons for finding in them an indictment of the IRB system as presently run.

NITPICKING

At all three IRBs she observed, Stark saw members judging proposals based on the proportion of spelling and typographical errors in the proposal. She calls such behavior "housekeeping" and excuses it on the grounds that it "was indispensable for IRBs because the apparent degree of care taken in submitting a tidy proposal served as a proxy for an investigator's ability, allowing board members to make judgments about people's reliability as researchers. In this way, ink and paper serve as character witnesses." (173)
Such behavior, I believe, represents what Sir James George Frazer called the practice of "homeopathic magic." As Frazer put it in the *[2]Golden Bough*, "the magician infers that he can produce any effect he desires merely by imitating it." In this case, the proposal serves as a magic charm, and a tidy proposal guarantees an ethical research project. That IRBs would resort to such practices is strong evidence that they lack the expertise to judge proposals on their merits.

KIBITZING

Stark calls a second kind of evaluation "scientific evaluation," which sounds nice. But her observations confirm the complaints of many researchers that IRB members demand changes in research they do not understand.

For example, when a social scientist sought permission to interview survivors of domestic violence who became community activists, a lay member considered insisting that the researcher also involve women who were not activists, or who remained in abusive relationships. Stark notes that "the investigator explained that she had not intended to do a comparative study and that the idea of constructing a control group and making her hypothesis explicit were antithetical to Grounded Theory," and that a statistician on the IRB rose the the researcher's defense (205). The statistician admirably stated his intention to remain silent when he lacks expertise, but it's clear that not everyone on the IRB possesses such self-restraint. In another case, a board demanded that an investigator justify decisions that, Stark notes, "did not bear directly on protection of human subjects." (179) The investgator became flustered, and almost agreed to changes that would have invalidated the findings, until another board member intervened and shut up his colleague, while the rest of the board laughed.

Stark reports such events gently, stating, "criticism of the quality of an investigator's science often came from expert members who did not belong to the same discipline as the [investigator]," leaving it up to the investigator's disciplinary colleagues to defend the proposal. (180) She writes, "license to evaluate the scientific merit of studies extended beyond what IRB members could justify in the name of research subjects. Science evaluation as a human subjects issue was at times self-consciously melded with criticisms made for the sake of better science." (181) But in her own examples, members' suggestions were at least as likely to degrade the science as improve it.

IGNORING EMPIRICAL EVIDENCE

Stark finds that IRB members who aim for "subject advocacy" rely on their imaginations, rather than empirical evidence about the effects of various types of research. She offers this story:

> "an IRB chair (at a board where I did not observe) described to me an episode involving a mental health worker who served as her board's community representative. An investigator had proposed a study on homeless people, which the community representative resisted because she felt that the population was too easily exploited. Her resistance to this research, according to the chair, was symptomatic of a broader problem in which the community representative would 'overly identify with patients and overestimate risks, and not really attend to data to balance her perspective.' In this instance, the community representative 'was not willing to hear the scientific data,' which indicated that interviewing homeless people did not harm them and that in fact interviewing them provided useful data that might aid the group. The community representative instead argued that 'the mere act of interviewing them was putting these folks as risk.' Thus, to this IRB chair, 'critical thinking and stepping back, taking a little distance from an issue, and trying to look at it in an objective fashion just wasn't something [the community representative] was willing to do…Since the committee doesn't function by consensus, we just moved ahead, and I'm certain she felt sidelined." (183)

It's nice to hear that this member was overruled, but I still pity the researchers who must present their proposals to her. Overall, Stark paints a particularly grim picture of the role of lay members on IRBs. It seems that they only get the attention of the researchers on the board once they've been so co-opted that their comments are indistinguishable from those of the "scientist" members.

SUBORNING DISHONESTY

Federal regulations (45 CFR 46.111) require IRBs to determine that "selection of subjects is equitable." While I don't think this is a wise criterion for judging research in the social sciences and the humanities, I can see its importance for medical research. Unfortunately, establishing an equitable selection of subjects is very difficult. In the case Stark observed, the IRB simply encouraged the researcher to lie about his intentions:

"The investigator indicated that it would be difficult in practice to use subjects from the [predominantly minority] location he had just mentioned because of the logistics of the study. Then, Reverend Quinn joined the discussion. Together, they clarified for the investigator what the board was looking for—and why:

> 'Reverend Quinn: Actually, even by adding the phrase after "efforts will be made to recruit from senior and community centers throughout the state," "including those that serve areas of minority populations." Just something like that, would simply make it clear you are being more proactive that otherwise people would think you were.
> 'Olin: And that would suggest, too, that we and you are being more vigilant.'" (185)

The language proposed by the IRB would indeed *suggest* that the researcher would be more vigilant, even when the researcher had little intention of recruiting minority subjects. A better strategy would have been to allow the researcher to honestly state his intentions and proceed with the research as planned, then seek the resources needed to do the difficult work of including minorities.

KILLING RESEARCH

Most of Stark's stories concern petty IRB interventions. There's some tinkering with a consent form (182), and squabbling over whether a phone call asking parents to participate in a follow-up study constitutes "invasion of privacy." (233) This sort of effort to avoid hurt feelings is far removed from the kinds of permanent harms against which federal regulations are meant to protect.

In one case Stark observed, an IRB intervened more seriously, perhaps killing a study. An investigator wanted to ask parents how they disciplined their children and was reluctant to report suspected child abuse to state authorities lest the prospect of such reporting lead parents to lie. An IRB member who knew a child who had been killed by abuse spoke up, and this led the board to refer the project to the university lawyers. So far so good; regardless of the personal experiences of the board members, an investigator in this position should know and follow the applicable laws about reporting child abuse. But, Stark continues, once the referral was made, "after several months with no decision, the investigator abandoned her research plan and withdrew the project from consideration." (211) She doesn't explain who delayed the project–the IRB or the university counsel–but the upshot is that rather than improve a potentially important research project, the process killed it. Moreover, because technically the proposal was withdrawn rather than rejected, the IRB can continue claiming a low rejection rate.

SINKING INTO A RUT

Stark acknowledges that when offered identical proposals to review, IRBs will respond with wild variation. She asked eighteen IRB chairs how they would react to a proposal to test job discrimination by sending black and white applicants to apply for the same job, then waiting to see who would get a call back. She reports that "the chairs diverged dramatically on both the problems that they identified and the modifications that they requested. Because of their distinctive local precedents, IRB chairs' had dissonant ideas about what risks the standard protocol entailed, to whom, and with what severity, which guided them towards distinctive decisions about whether consent could be waived, whether investigators could get consent without invalidating their data, and whether debriefing should be mandatory or prohibited as a source of harm in its own right." (231)

Stark defends such variation as evidence of "local precedents" that allow predictability within an institution (239). She compares such decision-making to the "pragmatic, not experimental, tradition that was developed in Anglo-American law and medicine during the late nineteenth century." (240) But the best doctors and lawyers of that century shared their knowledge broadly, and read broadly too. Stark offers no examples of an IRB member calling in an outside expert or doing some independent reading.

Stark argues that "the highest priority for IRBs is consistency–not with other IRBs, but with their own prior decisions." (4) She leaves this finding without further comment, neither praising nor condemning the IRBs. But she takes her

relativism too far. An IRB that bases its decisions on spelling errors is consistent, predictable, and irrelevant. An IRB that always requires oral historians to destroy their recordings is consistent, predictable–and wrong. And the highest priority of IRBs should be the protection of participants in research. If they are unwilling to shoulder that responsibility, they should disband.

Stark briefly hints at an awareness of this problem when she notes that "IRBs would make more similar judgments if local boards shared decision-making precedents at a national level. Given that IRBs make decisions based on cases, the challenge for a coordinated review system is not to craft more detailed federal regulations, but to train IRB members with a limited set of nationally-shared cases on which boards can base their decisions, as an alternative to local precedents." (243) That sounds like an interesting proposal, but it would require a massive overhaul of the current regime, from OHRP down to local boards. As it stands, Stark has given us a close look at a broken system.

1. http://institutionalreviewblog.blogspot.com/2007/12/law-society-review-continued.html
2. http://www.gutenberg.org/dirs/etext03/bough11.txt

3.1.5 Must Employees Consent? (2008-01-30 10:06)

Two recent items concerning IRBs and studies of job performance caught my eye.

The more prominent item was a December 30, 2007, New York Times op-ed, "[1]A Lifesaving Checklist" by Dr. Atul Gawande. Gawande describes efforts by the Johns Hopkins University and the Michigan Health and Hospital Association to offer five-step checklists to intensive-care providers, to help them remember to wash their hands and take other steps to avoid infection. OHRP shut the project down, even though it had been ruled exempt by the Hopkins IRB. (So much for local control.)

Although I try to keep this blog focused on issues concerning the humanities and social sciences, and to avoid issues concerning strictly medical research, I was struck by [2]OHRP's determination that "the subjects of the research were both the healthcare providers at the participating ICUs and their patients." Are healthcare providers really human subjects in a case like this?

A similar question arose in a non-medical setting a few weeks later. In her pseudonymous blog on Education Week, [3]eduwonkette complained that New York City teachers were being studied without their consent and without the approval of an IRB. Since eduwonkette herself concedes that "teachers did not need to consent in this case, as they are government employees and their employers can collect whatever data they want," I don't understand why she thought an IRB should be involved. But it does suggest that the question of studying employee effectiveness is not limited to medical contexts.

Poking around in my research notes, I find that at the July 1977 meeting of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Dr. Karen Lebacqz raised just this issue as a hypothetical:

> "Suppose you want to do a study that involves changing the delivery of services in a mental institution ward. The patients in the institution are the ones that you want to study in terms of what the impact is on their recovery rates and so on. The staff who work on that ward will also be very directly impacted by the research. Do they constitute subjects, even though the design and the purpose of the research is not set up to study the impact on them of what you are going to do?"

While Albert Jonsen initially suggested that the staff would constitute subjects, other commissioners disagreed:

> Lebacqz. "There is a very direct impact on the licensed staff.
> Ryan. "Then the administrator can force it on them as a condition of employment.
> Turtle. "Yes, I was going to say, that is the whole key, it is a condition of employment. Many things that, while I am a great libertarian here, lots of things I ask the people who work for me to do, I don't ask them for their informed consent."

[National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Transcript, Meeting #32, July 1977 (Bethesda: The Commission, 1977), 133-135.]

After this exchange, the commission moved onto another subject, suggesting a consensus that employees are not human subjects whose informed consent is required. In its recent determination letters on the checklist project, OHRP has ruled the opposite.

I don't expect the compliance officers at OHRP to be familiar with the commission's deliberations, and I fault the commission for not defining human subjects more carefully. But it's worth noting how far OHRP has strayed from the commission whose work nominally informs its decisions.

1. http://www.nytimes.com/2007/12/30/opinion/30gawande.html
2. http://www.hhs.gov/ohrp/detrm_letrs/YR07/nov07c.pdf
3. http://blogs.edweek.org/edweek/eduwonkette/2008/01/the_nyc_teacher_experiment_rev.html

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Anonymous (2011-10-27 11:07:56)

I disagree with your conclusion. Both the Belmont Report and the Common Rule are very clear that subjects of research must give informed consent in all but a very narrow range of circumstances. Being an employee is not an exception. OHRP is simply following the legal standard set out in the Common Rule. The problem is not its interpretation, but a massive flaw in the Common Rule itself. There are many kinds of research where informed consent should not be required, and it should not be mandated or even presumptively preferred in those cases. This is one of the obvious categories where the rule is wrong and needs to be changed.

Zachary M. Schrag (2011-10-27 11:13:01)

Thanks for this comment.

I cannot agree that the Belmont Report is "very clear" on this issue, particularly since it does not conform to the sentiments the commissioners expressed in their deliberation. And rather than specifying "a very narrow range of circumstances" in which consent is not needed, the Belmont Report confesses ignorance about a vast and undefined realm called "social experimentation."

Zachary M. Schrag (2011-10-27 11:35:51)

Also, please see Tom Beauchamp's comments on this matter:

Because the definition is so nonspecific, regulatory requirements that use the definition may judge that some activities that are questionably research involving human subjects nonetheless must be treated as such. Government requirements are today commonly applied even if 'human subjects' may not need to be protected by the rules of human-subjects research. A sweeping – that is, all-inclusive conception – of 'human-subjects research' can have immediate and unjustifiable practical impact on attempts to upgrade medical care . . ."

[1]Beauchamp Derides Federal Definition of Research

1. http://www.institutionalreviewblog.com/2011/04/beauchamp-derides-federal-definition-of.html

Anonymous (2011-11-02 10:34:39)

I won't disagree with you on the Belmont Report, though the document itself does not acknowledge the limitations you point out. The essential point I was trying to make is that the Common Rule is unambiguous that informed consent is required if there is more than minimal risk to the subjects. Hence, any research on employees that could lead to their firing is presumptively illegal under the rule. Given the almost unbounded scope of activities that count as "research" under the Common Rule, OHRP was essentially fulfilling its bureaucratic mission. The problems (plural) lie with the Rule, not with with some major misinterpretation by bureaucrats. One could certainly argue that in this case the employees weren't really the "subjects" of the research, or that it wasn't really "research" and I don't disagree with those arguments. But if the employees were research subjects, then voluntary informed consent was required. That is a crazy result, and one created by the text of the Rule.

Zachary M. Schrag (2011-11-02 10:55:41)

Thanks for this comment.

I should have said earlier that I agreed with you about the "massive flaw in the Common Rule itself," and only disagreed

about your reading of the Belmont Report. Both documents cause headaches, and those headaches are aggravated the National Commission's failure to reconcile the Belmont Report with its IRB recommendations, which formed the basis of the Common Rule.
The ANPRM represents an overdue acknowledgment of many of the flaws in the Common Rule, but it fails to ask about the Belmont Report. In my [1]personal comments on the ANPRM, I suggested that "the Belmont Report should be retired and replaced with a statement on research ethics that can be updated to reflect current thinking and experience."

1. http://www.institutionalreviewblog.com/2011/10/my-comments-on-anprm.html

3.2 February

3.2.1 Ethics Yes, IRBs No (2008-02-02 14:00)

The blog "Law and Letters" features a posting from "Belle Lettre" entitled [1]Venkatesh's Gang Leader For a Day and IRBs. The author asks whether the ethical problems raised by Sudhir Venkatesh's book form an argument for IRB review of ethnography.
As the [2]comments make clear, however, Lettre has uncritically equated IRB-approved research and ethical research. IRB critics do care about research ethics, but we question whether IRB review is either necessary or sufficient to ensure adherence to scholarly ethics and the law.

1. http://lawandletters.blogspot.com/2008/02/venkateshs-gang-leader-for-day-and-irbs.html
2. http://www.haloscan.com/comments/bellelettre/5363877854105761173/

3.2.2 Historians Flood OHRP With Comments (2008-02-02 14:18)

In response to the [1]October 2007 announcement in the Federal Register calling for comments about the existing guidance on expedited review, oral historians and their allies have flooded OHRP with complaints about IRB review of oral history and requests for an unambiguous exemption.
As the original announcement noted, comments sent in response to Federal Register notices are a public record. Mr. Glen Drew and Ms. Toni Goodwin of OHRP kindly sent me copies of all 65 comments on expedited review. Of these, 38 commented on oral history or folklore, with all but one of those seeking exclusion for such research.
The comments came from a wide range of scholars. University historians ranged in rank from graduate students to chaired professors. Non-university historians included those working for federal and state agencies and for private companies. Historians of science and medicine—among those most familiar with the medical research that led to the current regulatory scheme—were particularly vocal. The American Historical Association weighed in against IRB review—reversing its 1998 stance—as did the American Association for the History of Medicine, the American Folklore Society, and the Society of American Archivists. Scholars in sociology, English, psychology, medicine, and American studies also called for oral history's exclusion from IRB jurisdiction, as did one IRB chair.
These scholars' complaints about IRB review of oral history will be familiar to those who have followed this controversy. Many noted IRBs' demands that scholars submit questions to be approved in advance, a practice that outrages oral historians who pride themselves on their ability to improvise questions in response to their research and the stories they hear.
Of the 38 comments, only one did not condemn IRB jurisdiction over oral history. Yet even that comment, by Claytee White of the Oral History Research Center at UNLV, does not endorse IRB review as practiced at most universities. Rather, White notes that she spends only 15 minutes clearing each project, suggesting blanket approval for her work rather than the project-by-project review that is the focus of most complaints.
The comments acknowledge that "memory can be painful," but they also point out that "historians are professionally

obliged to ask our interview partners probing questions independent of the benefit or harm for the interviewee." Because they do not expect IRBs to understand this, historians—and the IRB chair—suggest that other oral historians would be better equipped to judge oral history projects than IRBs with few or no historians as members.
The scholars do not think IRB members mean-hearted, just hopelessly unfamiliar with the practice of oral history. "University IRBs do not have the necessary background to appreciate that oral history research is different from other research involving human subjects," wrote one. Nor do they expect this to change. A historian of medicine notes that "as long as IRB members are active, overworked faculty volunteering their time, they will be unable to track the nuances of a style of research they see very rarely."
For this reason, the historians do not seek modification of the current system, but an unambiguous removal of oral history from IRB jurisdiction. At least 14 comments, including the American Historical Association's, endorsed the [2]2006 recommendation of the American Association of University Professors "that research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."
As I noted in [3]my own comment, the present guidance was adopted in 1998 in response to six comments about oral history, one of which included the American Historical Association's endorsement of oral history's inclusion on the list of methods eligible for expedited review. Now that the AHA and 36 others have called for the wholesale exclusion of oral history from IRB review, I hope OHRP will be as responsive as its predecessor was a decade ago.
Here are excerpts from the [4]comments on oral history in PDF form.

1. http://institutionalreviewblog.blogspot.com/2007/11/ohrp-seeks-comment-on-expedited-review.html
2. http://www.blogger.com/%20http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm
3. http://institutionalreviewblog.blogspot.com/2007/12/my-comments-to-ohrp.html
4. http://schrag.info/irb/historians_comments_to_ohrp.pdf

3.2.3 AAHRPP Calls for Research on IRBs and Behavioral and Social Science (2008-02-12 11:15)

Rob Townsend kindly alerted me to the [1]Winter 2008 issue of AAHRPP Advance, published by the Association for the Accreditation of Human Research Protection Programs, which features the lead article, "IRBs and Behavioral and Social Science Research: Finding the Middle Ground." The article concedes that "many behavioral and social scientists feel constrained by a system that seems tilted toward biomedical research and, therefore, neither understands nor reflects their concerns." And it reports the interest of Drs. J. Michael Oakes, "an author and frequent lecturer on IRB review of behavioral and social science research," and Howard Silver, Executive Director of the Consortium of Social Science Associations, in addressing some of those concerns.
Oakes and Silver "encourage researchers to investigate scientifically IRB oversight of behavioral and social science research. Such research could determine whether IRBs are consistent in applying the federal regulations, whether IRBs are taking advantage of the flexibility that's built into the regulations, and whether relationships between IRBs and social scientists are less strained on campuses that have separate IRBs to review behavioral and social science research. The resulting data could shed light on ways to relieve tensions between these two groups."
That sounds good, but it's a bit disappointing that the article does not acknowledge the considerable research already completed on this topic, much of it already cited on this blog. Nor does it remark on the curiosity that IRB oversight has continued for four decades without anyone knowing if it does any good.
Moreover, the article states as fact some beliefs that should be investigated with just the sort of research it calls for. I hope Oakes, Silver, and AAHRPP will allow data to challenge some of their own presuppositions.
Here are some questions that could be answered by further research.

1. When did IRB review of social science go bad, and why?

AAHRPP thinks it already knows the answer to this one. The article claims that "Tensions began building in the late 1990s in response to increased government scrutiny of research involving human participants," and that "the regulations have not changed. What's new is their enforcement and, in many instances, that enforcement is overdue." I am at work on a history of IRB review of social science and humanities research, and I think more research can challenge this view.

The first part of the AAHRPP claim is doubtful; social scientists have protested IRB regulations since 1966, and tensions have waxed and waned since then. If we take this longer view, then the assertion about the immutability of the regulations is wrong; the regulations–first promulgated in 1974–changed twice, in 1981 and 1991. And the 1991 revisions greatly expanded the reach of IRBs. The 1981 regulations exempted survey, interview, and observational research unless it "deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or survey or interview procedures is use of alcohol" and if "the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability. The 1991 regulations, in contrast, eliminated the "sensitive aspects" clause and added potential harms to reputation to the list of triggers for IRB review. These changes were made over the objection of social scientists. And they set the stage for the conflict of the 1990s and today.

The claim that "what's new is [the regulations'] enforcement," is only half-true. Also new is the guidance issued by OPRR/OHRP since 1995 that reversed previous policies.

Finally, the article claims that "enforcement is overdue." Really? What errors did social scientists commit in the 1980s–a decade of relatively light regulation?

2. Why do IRBs sometimes delay or prohibit social science research?

Dr. Oakes states, "IRB members are not those folks who are looking to thwart your study. They are peer researchers who have a job to do." But clearly some IRB members are looking to thwart studies, or else studies wouldn't get thwarted as often as they do. The question is how many IRB members do this, and why.

One part of this question concerns membership. Oakes's claim that IRB members "are peer researchers" depends on an odd definition of peers. In the [2]NIH peer review process, for example, proposals are reviewed by study sections whose members are chosen for their expertise. The NIH's Center for Scientific Review requires, among other things, that

"* Expertise is the paramount consideration when developing/updating a study section roster.

"* Each scientific area reviewed by the study section needs appropriate expert representation."

IRBs theoretically must include experts on each type of research reviewed, but Oakes knows as well as I that this requirement is often ignored. Additional research might indicate how often a researcher faces an IRB with no expertise in the methods under review.

Then, of course, some IRB members are not researchers at all, but the "one member whose primary concerns are in nonscientific areas" required by the regulations. As [3]Laura Stark's dissertation suggests, these members can be particularly undisciplined in their meddling.

3. What types of research now fall subject to IRB review?

Like [4]PRIM &R, AAHRPP thinks that IRBs review only two kinds of scholarship: biomedical research, and something called "behavioral and social science research." The article states, "AAHRPP's Founding Members, Board of Directors, Council on Accreditation, and Supporting Members all include representatives of organizations engaged in behavioral and social science research."

This statement suggests the [5]fallacy of the undistributed middle term:

Ehnographers are represented by organizations engaged in behavioral and social science research.

Organizations engaged in behavioral and social science research have a voice in AAHRPP.

Therefore, ethnographers are represented by organizations that have a voice in AAHRPP.

The second premise is "undistributed," since it is not true that *all* organizations engaged in behavioral and social science research have a voice in AAHRPP.

Here's a counter example:
Countries in South America, Africa, and South Asia are not in North America or Europe.
Countries from parts of the world other than North America and Europe are permanent members of the UN security council and the G-8.
Therefore, countries in South America, Africa, and South Asia are permanent members of the UN Security Council and the G-8.
In committing this fallacy, AAHRPP lumps together a dozen or more scholarly disciplines–each with its own history, methods, and ethics–into a single category: "behavioral and social science research." The AAHRPP website does not list the disciplinary affiliations of members of its Board of Directors, Council on Accreditation, or list of site visitors, but if there's a journalist, historian, or folklorist in the lot, I'll be surprised.
To take the example I know best, oral historians do not expect psychologists, social workers, or education researchers to understand or represent their interests. AAHRPP (like PRIM &R) should find out how many disciplines are now subject to review, and include representatives from all of them.

4. What models of ethical review exist, and what models might we imagine?

The article asks "whether relationships between IRBs and social scientists are less strained on campuses that have separate IRBs to review behavioral and social science research." But that is only one of several alternative systems in place on various campuses. For example, [6]Macquarie University delegates ethical review to a number of subcommittees with special expertise in certain fields. And the [7]University of Pennsylvania allows researchers using some social science methods to forego "a fixed research protocol." And we can imagine even more models, some of which would require redrafting present regulations, others of which might not.
I appreciate AAHRPP's call for research, and I hope it agrees that research is most valuable when the answers are not predetermined.

1. http://www.aahrpp.org/Documents/D000156.PDF
2. http://cms.csr.nih.gov/PeerReviewMeetings/BestPractices/How+Scientists+Are+Selected+For+Study+Section+Service.htm
3. http://institutionalreviewblog.blogspot.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
4. http://institutionalreviewblog.blogspot.com/2007/05/prim-public-responsibilities.html
5. http://www.fallacyfiles.org/undismid.html
6. http://institutionalreviewblog.blogspot.com/2007/08/macquaries-respect-for-expertise.html
7. http://www.upenn.edu/almanac/volumes/v53/n06/or-hsresearch.html

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Anonymous (2008-02-15 16:30:00)
I just stumbled across your blog as I attempted to understand how and IRB board should review Oral History. Thank you for going to all of this effort.
First, I agree that rules designed for medical research are not appropriate for all other disciplines. However, I am still left with the idea that every effort must be put forth to protect human subjects. On my campus, the IRB is being pushed to exclude oral history from review. I can not believe that this is ultimately in the best interests of the people who participate.
It strikes me that the problem really is one of designing methodology that is more open to various modes of research. I would agree that this methodology would require research establishing validity and reliability.
Bill Hart, DEpt. of Health Sciences
Rogers State University

Zachary M. Schrag (2008-02-15 17:02:00)
Thanks for your comment, and for taking the time to learn more about these issues.
You state that you "can not believe that [IRB exclusion] is ultimately in the best interests of the people who participate." If you can explain the origins of your disbelief, we could begin to have a conversation. For example, can you list some cases in which

a participant in an oral history interview was wronged by the interviewer?

3.2.4 Peter Moskos on What to Tell Your IRB (2008-02-18 13:39)

Sociologist Peter Moskos is author of [1]Cop in the Hood, a book about police work he wrote based on his fieldwork as a Baltimore police cadet and police officer. He maintains a blog concerning the issues raised in the book (a splendid marriage of old media and new), and on February 12 he commented about the ethical issues raised by Sudhir Venkatesh's *Gang Leader for a Day*. In that posting, "[2]Outing the insiders," Moskos wrote,

> I've never been a fan of the I.R.B. Few professor are. I don't think that overt non-experimental academic researchers should need approval to observe and interact with most human subjects. We're not giving out experimental drugs. We're not running experiments. We're watching and talking and living. I don't even like the term "human subjects." It's dehumanizing. They're people, damnit! It's condescending to think that adults aren't smart enough to make their own decisions about what to say to whom. And if they're not, well, such is life.
> Nor am I convinced that research subjects who harm others deserve institutional protection. I believe academics should act under a code similar to journalists. But federal law disagrees with me. And the press has explicit constitutional protection that professors don't.

In a comment on his blog, I pressed him to elaborate on these points, and he graciously responded with a second posting, "[3]More on IRBs." I recommend reading the whole post, but here are some key points:
1. An IRB doesn't have to reject a proposal to stifle research. As Moskos notes, "the simple nuisance and fear of conflict with an IRB limit social-science research."
2. IRBs are set up to review protocols in advance, but that's not how ethnography works. Moskos is grateful to Harvard's IRB for requiring him, at the outset of his fieldwork, to announce to his academy classmates who he was and what he was doing. But as his work progressed, he found keeping his IRBs informed about every change to be so tedious that it wasn't worth the effort. And now that his book is out, he is still in touch with some friends from the department. When does oversight end?
As I noted in August, the University of Pennsylvania has addressed some of these concerns in its policy on [4]evolving research. I would like to learn how that policy is working.
3. IRBs apply the wrong ethical standards. They seek to ensure that no harm comes from research, when, in cases like Venkatesh's, the "risk of some harm from his research was so great as to be virtually inevitable." And IRBs "want a guarantee of confidentiality," which is not appropriate in all circumstances; Moskos did not witness any serious crimes, but he writes that "if, hypothetically, I witnessed a police officer rob and kill, or sexually abuse a 10-year-old child, or anally violate an innocent man with a plunger, I would feel little compunction legally and ethically to violate a vow of confidentiality."
This third argument is the one that most intrigues me, since it accepts the notion that good research can be harmful. Theoretically, IRBs can approve such research, so long as the benefits of the research are commensurate. But Venkatesh eloquently describes the ethnographer's uncertainty that his research will matter, either to the individuals studied or to society as a whole. Thus, it would be hard for most ethnographers to present the kind of cost-benefit analysis required by the Belmont Report.
Moskos' acceptance of harm seems fully consistent with the [5]ethics of the American Sociological Association, but not with the [6]code of the American Anthropological Association, which states that "anthropological researchers must do everything in their power to ensure that their research does not harm the safety, dignity, or privacy of the people with whom they work, conduct research, or perform other professional activities." Thus, Moskos's eloquent statement of his principles illustrates why folklorists, historians, sociologists, and others should reject being lumped together

with anthropologists as "social scientists," lest they find themselves subjected to ethical standards not their own.
At the end of his post, Moskos shares some of the language that he used to get IRB approval without compromising his ethical principles, and he encourages other researchers to use this language to avoid promising written consent forms or absolute confidentiality. Whether or not a researcher is subject to IRB oversight, such thoughtful statements about the ethics of research in specific contexts are valuable–far more so than the standardized ethical training mandated by most IRBs. I hope that other researchers will both read Moskos's statement and consider writing their own.

1. http://www.copinthehood.com/
2. http://www.copinthehood.com/2008/02/outing-insiders.html
3. http://www.copinthehood.com/2008/02/more-on-irbs.html
4. http://institutionalreviewblog.blogspot.com/2007/08/evolving-research.html
5. http://www.asanet.org/galleries/default-file/Code%20of%20Ethics.pdf
6. http://www.aaanet.org/committees/ethics/ethcode.htm

Anonymous (2008-02-19 11:04:00)
I am still sorting out some of my reactions to this post. But, I feel that this issue is important enough to try to comment now.
I am disturbed by the last part of his statement; "They're people, damnit! It's condescending to think that adults aren't smart enough to make their own decisions about what to say to whom. And if they're not, well, such is life."
I do agree that people are generally capable of interacting with other humans while maintaining a sense of self-protection. However, this seems to say to me, if they can't, oh well, so what. This implies that it is their fault for being stupid or naive or trusting?
My concern is that there is the implication in all of this that the researcher (or, whatever she.he would prefer as a label) is the only one capable of judging her/his own actions and intent. And, that outside interference is, in some fashion, bad.
I cannot help but feel that there is a certain level of hubris in this. To imply that the effort taken to ensure that people are protected from our nosiness into their lives is somehow constraining seems to me to miss the whole point. I don't 'enjoy' every law that is placed on the books but I try to obey them nonetheless because constraints are a price I pay for living with others. If everyone can chose to obey only those parts of the legal corpus that please them and ignore the rest, what kind of society do we end up with?
I don't wish to get into a flame war here. I am simply concerned that Dr Moskos seems to reject out of hand the need for oversight. I am firmly convinced that some oversight is needed even if, as currently structured, it needs to modified to accommodate other forms and methods.
Bill Hart
Rogers State University

Zachary M. Schrag (2008-02-20 16:37:00)
Thank you for your comment.
I still do not understand what problems in social research you think IRBs can solve. Here you suggest that people merit protection "from our nosiness," as if nosiness itself is a problem. But as an ethnographer, Moskos is paid to be nosy–just as he was as a cop.
You charge Moskos with "reject[ing] out of hand the need for oversight." But if you read his blog, you'll see that he began by cooperating with his IRB at Harvard. Only after years of fieldwork, and disappointing interactions with two university IRBs, did he come to his present position. That trajectory–of trying to work with IRBs before giving up on them–is shared by many social researchers, myself included.
By contrast, you seem to have come to these questions relatively recently, yet you are eager to proclaim what you "can not believe" and of what you are "firmly convinced." It is this putting of findings before research that worried me about the AAHRPP article. If we are to avoid hubris, wouldn't it be better to follow Moskos's example of drawing conclusions from experience?

Anonymous (2008-02-21 10:41:00)
Thank you for your reply. As I said at the beginning, my original thoughts were less digested than I would have preferred but contained the essence of what I meant.

I have been involved with IRBs for about 30 years, most recently as the chair of the brand-new IRB here at Rogers State. And, I too have had my own horror stories of unthinking, irrational and just plain silly requests. However, I still see the value of oversight into the process to protect the people with whom we work.
I used the terms 'I believe' and 'I am convinced' since that summed up my experience with IRBs both as a submitter and as a reviewer.
There is a burden to filling out the forms and keeping up with the required paperwork. The question is whether this burden is so onerous as to limit valid research.
There is always a tension between allowing research to process to hopefully answer substantive questions about important questions and the need to preclude harm. I would be the last person to say that the current system is optimal–by any measure. However, I have not seen any evidence presented that would compel the elimination of some system of safeguard.
Bill Hart
Rogers State Unversity

Zachary M. Schrag (2008-02-21 11:47:00)
Thanks for your reply. I have three responses.
First, I appreciate your distinction between the current system and your interest in "some system of safeguard." I don't know Moskos's position on this, but on this blog I have explored efforts to present alternatives to the IRB system defined in 45 CFR 46. The two most developed alternatives are what I'll call the peer review system and the certification system. In the peer review system, in place at [1]Macquarie University in Australia, projects are reviewed by specialists in the methods under review, so that ethnographers review ethnographers and survey researchers review survey researchers. In the certification system, in place at the [2]University of Pennsylvania, researchers who complete training relevant to their field may submit proof of such training "in lieu of a fixed research protocol." Would either regime satisfy you?
Second, you "have not seen any evidence presented that would compel the elimination of some system of safeguard." What evidence would suffice to convince you that the current system is fundamentally flawed? How many examples of poor decisions by IRBs are necessary? What kinds of abuses must they commit? What level of outrage must researchers attain?
Third, to turn the last question around, what evidence do you have that IRBs are helpful to survey, interview, and observation research? Earlier I asked you for examples of cases in which a participant in an oral history interview was wronged by the interviewer, but I have gotten none. In your 30 years of experience, how often was an IRB able to steer a social researcher away from unethical methods? I would like to suggest that in a free society, the burden of proof lies on those who would restrict speech between consenting adults, not the speakers.
Zach

1. http://institutionalreviewblog.blogspot.com/2007/08/macquaries-respect-for-expertise.html
2. http://institutionalreviewblog.blogspot.com/2007/08/evolving-research.html

Anonymous (2008-02-21 12:17:00)
Quick note; I am supposed to be attending meetings a t a conference.
I have not read it thoroughly but the Penn solution seems similar to ideas that we have tossed around here at RSU. I haven't have a chance to read it yet, I am basing this on your short descriptor. I look forward to reading both ideas and bouncing them off our faculty; both IRB members and faculty who have raised these issues with us.
Thanks,
Bill

PCM (2008-03-17 22:19:00)
Thank you Bill and Zachary for such interesting comments (even if I am a little late getting in this game).
Zach answers for me rather perfectly. I sense that Bill and I might actually be in agreement, by and large. I do think there should be some oversight (but not the current system). Part of my fear is that the language used by the IRB actually make things worse. Lofty abstract theory helps dehumanize the "subjects." The last thing we want is for researchers (I don't object to that term) thinking of people the same way the research scientists think of lab rats.
I am all for rational and non-cumbersome oversight (I think the best are talking to people to people in your field and talking to friends not in your field). Ultimately I don't trust the effectiveness of IRB oversight (for all the reasons Zach mentions in his comments).

Even worse, I'm afraid that the IRB makes it a game. The harder the game is, the more people will cheat to pass. Once people "pass" the IRB test, they may be less inclined to use their natural common sense and more inclined to hide things. The more things get pushed underground, the greater the potential for damage. Being open is key: with subjects, with colleagues, with friends.
I should mention that my "they're people!" line is a (perhaps obscure) reference to the 1973 movie Soylent Green. Too often I find myself substituted style for substance. The point I was trying to make comes before that: my objection to the term "human subjects" and "research subjects."
The first step to ethical research is treating those with whom you study and interact (I must say that even I am tempted to use "subjects" as convenient shorthand) as people.
I learned from and with my subjects in part because I didn't think of them as "subjects." They weren't simply objects I observed, clipboard in hand, as they ran through the maze of life.
All this being said, I am very happy that the IRB made me be overt about my research. Telling a class full of Baltimore police recruits on Day One of the police academy that you're from Harvard and you're doing researcher isn't the easiest or quickest way to be a "fly on the wall" (or make friends). But in my research, it was the best thing I ever did.
Being covert may have been the path of least resistance. I don't know what I would have done if I had a choice on being overt or covert. Had I gone in covert, how would I ever have outed myself without betraying friends? What if word got out and I denied it? What would people be saying not that my book is coming out? Being overt made my life and my research better. If that was solely because of the IRB's (and I honestly don't know), then I thank the IRB.

Anonymous (2008-03-26 11:45:00)
PCM, I really enjoyed your comments (and your comments to a later post). I do think that we are in agreement to at least some extent. I agree that far too often the IRB becomes one more political game rather than truly fostering a concern to respect and honor the people who help us in our research. I am perhaps overly influenced by a medical model but I recognise the short-comings of most committees in practice. As the first-ever head of our newly-formed IRB, I am determined to 'do it right' whatever that really means. I cannot get away from the issue of protection–which I think is really being respectful of the people with whom we work. Also, I am not sure that it is a 'good thing' to leave the whole decision of what constitutes adequate protection to the researcher alone. Independent oversight is valuable, as you noted in your work. Finally, even if we all decide that all IRB's should be scrapped, it is still someone else (President or VPAA usually) who is legally responsible for ensuring that we comply with all appropriate rules and regulations.
BTW, they do hire republicans in academia, they are all in the Business school.
Bill Hart
Rogers State University

David Hunter (2008-04-01 06:00:00)
Just on the use of "subject" to refer to research participants that PCM refers to, I agree this is potentially problematic it is at least better than it was. I've recently finished reading Maurice Pappworth's 1960s book about ethical abuses in scientific research where he points out that at the time research participants were referred to as "material".

3.3 March

3.3.1 Maureen Fitzgerald's Ethics Project (2008-03-05 14:13)

Anthropologist and George Mason University alumna Maureen Fitzgerald, now affiliated with the University of Sydney, is the director of "An Analysis of Research Ethics and the Ethical Review Process as Culture and Cultural Process," an ongoing investigation more succinctly named "[1]The Ethics Project."
Between 2001 and 2005 she and her associates observed the workings of 29 ethics committees in Australia, Canada, New Zealand, the United Kingdom, and the United States–not finding significant differences across national boundaries. They have published several papers based on this work, most of which are available on the [2]project's website.

Since the themes of many of these publications overlap, I will focus my comments on three articles that I found particularly helpful.

M. H. Fitzgerald, "Punctuated Equilibrium, Moral Panics and the Ethics Review Process," *Journal of Academic Ethics* 2 (2005)

[3]This article builds on Will C. van den Hoonaard, "Is Research-Ethics Review a Moral Panic?," *Canadian Review of Sociology and Anthropology* 38 (February 2001). In that article, van den Hoonaard deployed the concept of a "moral panic," introduced in 1972 by [4]Stanley Cohen. In van den Hoonaard's words, "a moral panic is indicated by hostility and sudden eruption of measured concern shared by a significant segment of the population, with disproportional claims about the potential harm moral deviants are able to wrought . . . Moral panics involve exaggeration of harm and risk, orchestration of the panic by elites or powerful special-interest groups, the construction of imaginary deviants, and reliance on diagnostic instruments." Van den Hoonaard went on to show how Canadian ethics committees' treatment of qualitative research fits that definition.
In her article, Fitzgerald stresses that the ethics review process is not in a constant state of moral panic, but rather expands in spurts that resemble the punctuated equilibrium of evolutionary biology. More significantly, the moral panic that van den Hoonaard identified on the national level can also take place within a single institution:

> local committees have their own folk devils and moral panics. These too sensitize committee members to consider 'worst case scenarios' in their discussions of applications so that a case of moral panic evokes further moral panic. Some committees referred to particular researchers who they saw as having been 'problems' in the past, commonly referred to in one meeting as "*that* researcher." Particularly long standing committees, especially those that have members who have been on the committee for significant periods of time, evoke memories of these in their deliberations. Sometimes this is done with a kind of code known only to local members. A particular name or phrase is used in the discussion of an application to remind members of previous cases, the problems associated with it, and how they were or were not addressed. Decisions related to the earlier case or cases are then use as historical precedent to make a ruling for a new case that may have, or at least appears to have, similar dimensions. In doing this, they deal with the moral panic evoked by the new case and try to prevent problems associated with the precedent from occurring again.

Moral panics, Fitzgerald continues, can take place even within a single meeting of a committee, which may stretch to seven hours:

> there are regular and predicable periods of heightened activity during a meeting and periods where members are more likely to engage in slow and deliberate scrutiny and debate in relation to the applications being reviewed. These periods are not generally related to the actual applications, although a particularly interesting or problematic case, at least in the minds of some committee members, can create periods of static in the process and, on rare occasions form a transition point in the level of activity or speed of review. In between the periods of heightened scrutiny there are short bursts of accelerated activity where applications are reviewed with great swiftness, often only a few minutes per application.

The review process is so uneven that

> applications that normally would not be subjected to in-depth scrutiny may be less likely to get through the process without questions to the applicant if it is reviewed at particular points in the review process or

> it is juxtapose against a critical case that evoked a kind of moral panic among committee members at that meeting or some time in the past. Thus it is not always the quality of the application or the issues it raises that are necessarily the most critical to the nature of or experience with the ethics review process.

M. H. Fitzgerald, P. A. Phillips, & E. Yule, "The Research Ethics Review Process and Ethics Review Narratives," *Ethics & Behavior*16 (2006): 377-395

[5]This article traces in somewhat more detail the evolution of a moral panic. The authors explain that ethics committee meetings consist of exchanges of narratives, some of which have little to do with the proposal under review. That is, it is not the researcher whose version of the project gets debated, but the primary reviewer. On its own, that sounds pretty benign, and not different from the work of a peer review committee or a job search committee looking for scholarly merit. But the authors hint that the process does not always work well:

> Sometimes the discussion gets off on tangents generated by the narrative, and sometimes people lose sight of how this does or does not relate to the actual application. Thus, at some point, as a result of this discussion, the committee came to think that an applicant had not addressed an issue when the applicant actually had, or that the applicant had said something he or she had not. In one meeting, a member said that the applicant had not addressed a point in the information sheet and that the applicant needed to do so before the person would approve the information sheet. Just as the person finished saying this, with the ethics officer writing it down, another member said, “But they did say that. It is right here on page x of y.” The committee had lost sight of what it was doing, not only because of a long and complicated information sheet (in this case an eight-page form), but because the discussion itself took the committee off on a tangent where they lost sight of what the applicant had actually provided. A common comment from researchers who have received letters that might fall into this category is, “Did anyone actually read the application?” If this committee member had not picked this up during the meeting and the ethics officer or chair had not checked it before the letter to the applicant was sent out, the applicant could reasonably wonder if anyone had read the application or information sheet.

The authors do not indicate how often committees flew off on such tangents, nor what types of proposals were more likley to receive such sloppy review.
Other types of narratives are more dangerous. There is the "what if" or "worst-case scenario" narrative, which leads committee members to compete to see who can dream up the most dreadful outcome:

> each potential version of the story builds on the one before it, and each version becomes more and more serious until it gets to the worst scenario they can come up with, one that may significantly overestimate the kind, potential for, probability of, or seriousness of the risk . . . In some cases, the discussion focused on the likelihood of that scenario, but more often the scenarios seemed to take on lives of their own. They can develop to the point where an uninformed listener might wonder if this research was worth the risk because as the versions of the hypothetical develop they become more and more believable and members with a moral conscience are placed in a position where they feel they have to raise questions about whether or not the project should be approved or approved as presented. Again, often this situation was resolved by sending the issue back to the researcher to address. Given the low probability of some of these worst case narratives actually happening, it is not surprising that researchers, not having heard the discussion,wonder where such ideas come from.

Related to these narratives are what Fitzgerald et al. call the "personal experience" narrative:

> a narrative based on the committee members' own experiences, particularly in relation to research, or a story of a known other's experience (friends, relatives, research participants). These narratives serve to contextualize, explain, or introduce a matter of some interest or concern in relation to the discussion. The narrative may or may not have direct relevance to the application being discussed, but becomes attached to it because of the context in which it is offered. These narratives are regularly related to the what if narratives to help support the possibility of such situations happening. In some cases they are, or take on the character of, urban myths or contemporary legends. They are told as true; they often cannot be attributed to any known person; there are often multiple versions, but in spite of the variations, they are told in such a way and with enough detail to be plausible.

The authors note that their "objective here is not to suggest whether or not such narratives should be a part of the process. Narratives are a natural part of verbal discourse and are always going to be a natural part of human gatherings such as ethics committee meetings. Our objective is to inform people that they are a part of the process and that they can, and do, affect the nature of the review process." That's too neutral for my taste. As a historian, I must agree that narratives are central to human life, but some narratives are better than others for certain tasks. Tellingly, the authors seem not to have observed the opposite of the personal-experience narrative: the scholarly narrative, in which a review member cites published evidence to suggest the ethical dangers of a proposal under review. For a process that is nominally part of an academic enterprise, is it too much to ask that ethics committees cite sources, rather than legends?
Thrown into this article is a comment that does not directly relate to narratives but that helps explain some committee decisions: "Few applications are approved as submitted. In some places, no applications are approved as submitted. There seems to be some need among committee members to make some comment or request some action."
This compulsive interference reminds me of George Orwell's *[6]Down and Out in Paris and London*:

> It is not a figure of speech, it is a mere statement of fact to say that a French cook will spit in the soup—that is, if he is not going to drink it himself. He is an artist, but his art is not cleanliness. To a certain extent he is even dirty because he is an artist, for food, to look smart, needs dirty treatment. When a steak, for instance, is brought up to the head cook's inspection, he does not handle it with a fork. He picks it up with his fingers and slaps it down, runs his thumb round the dish and licks it to taste the gravy, runs it round and licks again, then steps back and contemplates the piece of meat like an artist judging a picture, then presses it lovingly into place with his fat, pink fingers, every one of which he has licked a hunred times that morning. When he is satisfied, he takes a cloth and wipes his fingerprints from the dish, and hands it to the waiter. And the waiter, of course, dips *his* fingers into the gravy—his nasty, greasy fingers which he is for ever running through his brilliantined hair. Whenever one pays more than, say, ten francs for a dish of meat in Paris, one may be certain that it has been fingered in this manner. . . Roughly speaking, the more one pays for food, the more sweat and spittle one is obliged to eat with it.

Martin Tolich and Maureen H. Fitzgerald, "If Ethics Committees Were Designed For Ethnography," *Journal of Empirical Research on Human Research Ethics* 1 (2006): 71-78

Fitzgerald's investigations included hospital and general university ethics committees, with only three nonbiomedical committees among the 29 she observed, and most of her papers do not differentiate between the review of medical and non-medical research. [7]This article is the clearest exception.
The authors report that "In our own research projects, as well as Fitzgerald's extensive study of ethics committees in five countries (Australia, Canada, New Zealand, United Kingdom, and United States), we have yet to find an ethics committee that reflects qualitative epistemological assumptions."
They continue,

> Too often qualitative researchers report their experiences of the positivistic ethics review system as antagonistic and quantitative. For example, the typical form of communication between the researcher and the ethics committee underscores this disjuncture: the fill-in-the-boxes-oriented questionnaire does not correspond to qualitative researchers' opened-ended datagathering approach.

They cite numerous studies that document the frustration of ethnographers and other qualitative researchers faced with ignorant ethics committees. But the more interesting part of the article involves their proposed solution.
Ethics committees, they suggest, should ask qualitative researchers four open-ended questions:

> 1. What is the research project about?
> 2. What ethical issues does the researcher believe are raised by this project?
> 3. How does the researcher plan to address these ethical problems? . . .
> [4.] What contingencies are in place if the research project changes its focus after the research has been approved and has begun?

These questions, they explain, "examine the researcher's knowledge of ethics and her or his ability to predict possible changes and how they may be dealt with in the field." They avoid preconceptions drawn from medical experimentation, like the idea that every project requires written consent forms, or that every interaction with another person has a projected duration. I would like to suggest a fifth question: "What have you read about the ethical challenges posed by this kind of research?" If a committee were to accept a range of answers to this question, researchers would be relieved of the standardized, and often irrelevant, ethical training now imposed.
Tolich and Fitzgerald note that for ethnographic and other qualitative researchers, the best time to spot ethical hazards is usually not at the outset of an investigation, but near its end, just prior to publication. By this point, researchers no longer have to guess about whom they will meet and what questions they will ask, and they, along with ethical reviewers, can figure out what potentially harmful information has been collected. They call for manuscript reviewers and thesis examiners to engage in a kind of "ethical proofreading," to use Carole Gaar Johnson's term, to determine if a researcher has adequately identified and addressed the ethical concerns of the work.

Fitzgerald's Recommendations

Fitzgerald presents a grim assessment with the present state of affairs:

> With few exceptions, the people involved are truly concerned about the ethical conduct of research, the enhancement of knowledge that can affect the human condition, and protection of the people involved from risks greater than those of everyday life. Despite these shared concerns, the review process does not always adequately address them . . . Long meetings with far too many applications covering a range of topics by a group of people with good but limited expertise cannot address the concerns. ("Punctuated Equilibrium")

She and Tolich doubt whether current ethics committees are flexible enough to enact their recommendations for review of ethnography:

> Some committees already employ a procedure similar to what we describe. Some will move toward such a procedure. Some will not. Some will have purchased expensive online review software that will

> offer a challenge to any attempts to introduce an appropriate procedure for ethnographers and qualitative researchers. Second, the two-stage system would require ethics committees to address qualitative research by training both academic and lay members of an ethics committee. This requires strong leadership by persons who are knowledgeable about qualitative methods in general, and ethnography specifically. Unfortunately, it is easier to continue to use the positivist or medical model because it essentially fits the risk management exercise that ethics committees provide for institutions. When the risks to persons are known in advance, ethics review can be more structured and less ambiguous. Most people, including ethics committee members, have difficulty dealing with ambiguity. ("If Ethics Committees Were Designed")

They hint at review by units both smaller than university-wide ethics committees (i.e., academic departments) and larger ("websites might be developed based on the experiences of committees that do exemplary reviews of ethnographic research"). And in "Punctuated Equilibrium," Fitzgerald calls for "greater understanding of group processes that affect decisionmaking," as if a chair can eliminate irrationality by pointing it out.

Nowhere in these articles does Fitzgerald explain why, given all the many alternatives, university-wide ethics committees should be expected to play any positive role in the review of qualitative research. It is as if, having explained the difficulty of inserting a machine screw with a claw hammer, she expects the analysis alone to make the job easier. Wouldn't it be easier to replace the hammer with a screwdriver?

Though she shies away from saying so, Fitzgerald's arguments suggest that if ethics committees were designed for ethnography, they would not exist at all.

1. http://www.ethicsproject.com/
2. http://www.ethicsproject.com/
3. http://www.ethicsproject.com/FILES/Fitzgerald%20Punctuated%20equlibrium.pdf
4. http://www.amazon.com/Folk-Devils-Moral-Panics-Anniversary/dp/0415267129/ref=ed_oe_p
5. http://www.ethicsproject.com/FILES/Fitzgerald%20et%20al%20Research%20review%20process%20and%20narratives.pdf
6. http://www.amazon.com/Down-Paris-London-George-Orwell/dp/015626224X/ref=pd_rhf_p_t_3
7. http://www.ethicsproject.com/FILES/Tolich%20Fitzgerald%20If%20ethics%20committees%20were%20designed%20for%20ethnography.pdf

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PCM (2008-03-17 23:13:00)

That's very interesting. I'm glad to know there are some alternatives to an IRB. I wish them luck.

I have a three other thoughts which are hopefully relevant. Keep in mind that none of these thoughts was ever discussed with the IRB before my research began.

1) Sometimes it's hard to even say who your research subjects will be. My research was about police. My research wasn't really about those I policed, but of course at some level it is. I quote criminals and drug dealers and people I locked up (and normal good citizens, too). What was my duty to them? What about the harm I do to them? I'm actually arresting people in the course of my research.

How can a police officer with badge, handcuffs, and gun (and pen and paper) promise not to hurt somebody? I could have killed somebody. I don't think the IRB would be too cool with that. Or was everything I did automatically OK because I was, by definition, on the right side of the law? Was my research ethical as long as I was playing "good" cop? What about being a cop in the war on drugs? How is that ethical if you think drugs should be legalized? But then should arresting criminals ever be considered a harm?

2) Of course I'm favorably biased toward my style of research because it's what I did, but perhaps active-participant-observation research should be encouraged on ethical grounds. By actually being part of the police group I was studying, I was in a better position to judge the ethics of my research because I could apply it to myself (but this wouldn't apply to those I policed).

I would argue that the active-participant-observation research is by its nature both more ethical and harder to get past an IRB (because you can't describe events beforehand). There are many academic concerns about being active in the group you're studying. But here I'm just focusing on the IRB (for some discussion related to P.O. research and "objectivity," there's a bit more at [1]www.copinthehood.com).

3) There's the issue of researcher ethics conflicting with police officer ethics. Cops have their own moral obligations (professionally and socially, legally and informally). Had there ever been a time when I had to chose between my obligation to the police and my obligation to the IRB, I would have gone with the police (of course, in the real world such dilemmas are never

as clear as debating them in theory). I was paid to be a police officer, after all. To me, that trumped abstract theory about being a researcher.
Given that sentiment, how could an IRB ever approve a project where the researcher admits the committee is second to "other" concerns (even if these other concerns include an oath to defend the constitution)? I don't think any IRB proposal to become a cop would ever pass muster. I don't know of any.
I don't see how being a police officer can be reconciled with the IRB. And yet what was so wrong with my research that it should have been preventing on principle? Who is to say that police officers can't do ethical research? I sure hope not any university IRB. I hope nobody would advocate a blanket ban prohibiting police officers conducting academic research. What's wrong with being a cop?
Of course these questions were avoided entirely in my interaction with the IRB. Any good system of review should have had me discuss these issues. Not necessarily to provide answers, but at least to make me ask these questions.

1. http://www.copinthehood.com/

Zachary M. Schrag (2008-03-18 22:00:00)
Perhaps some anthropologist will weigh in, but it seems to me that your work does bear similarities to the military's Human Terrain System Project, in which anthropologists worked alongside American troops. For reasons like those you mention–power relationships, conflicts of interest, the possibility of doing harm–anthropologists' participation in that project was [1]condemned by the American Anthropological Association for just the reasons you mention. You should be glad you're a sociologist, not an anthropologist, I guess.
I quite agree that researchers, especially graduate students, should be encouraged to think through the ethical questions raised by their work, both in the planning stage and over the course of the research. Neither departments nor IRBs have shown themselves particularly good at this, which is why the search for alternative models is important.
Zach

1. http://www.aaanet.org/issues/policy-advocacy/Statement-on-HTS.cfm

PCM (2008-03-19 15:43:00)
This comment has been removed by the author.

PCM (2008-04-06 00:43:00)
I wonder if political biases influenced the objective decision making processes of the AAA. I just wonder if their position would be the same if an anthropologist wanted to conduct a study with, say, the Zapatista Front for National Liberation.
It makes me think of a story my father told me when his academic department was trying increase faculty diversity. He raised his hand and asked, "Why don't we hire a Republican?" They still haven't.
[Originally posted March 19, 2008, but later corrected for egregious typos.]

3.3.2 New URL (2008-03-22 11:15)

Perceptive readers may have noted a slight change in this blog. I have moved it to the custom domain, institutionalreviewblog.com. The old domain, institutionalreviewblog.blogspot.com, should still work as well.

3.3.3 Trauma-Based Research Is Less Risky Than Imagined (2008-03-23 14:15)

The March 2008 issue of the *[1]Journal of Empirical Research in Human Research Ethics* is out. As with previous issues of this journal, several articles present empirical evidence that challenges the assumptions used by many IRBs. The lead editoral, Joan E. Sieber's "Protecting the Vulnerable: Who Are They?" provides a good summation of some of the the findings:

> In this issue of JERHRE, five articles demonstrate the importance of applying an empirical approach to understanding vulnerability. Each article demonstrates a fallacy of using a simple subpopulation approach, and the importance of a more reasoned, nuanced and empirical evaluation of vulnerability.
> Luebbert, Tait, Chibnall, and Deshields show how the labels we apply to subpopulations can mislead. They found that ethics committee members view psychiatric subjects as having greater vulnerability to coercion and less decisional capacity than medical subjects, even when the medical illness is of a severity likely to engender serious psychiatric comorbidities.
> Three articles (DePrince and Chu; Chu, DePrince and Weinzierl; and Schwerdtfeger and Goff) evaluate the vulnerability of trauma victims, including children and young pregnant women, to research that focuses on their past traumas. Some have argued that such research "retraumatizes" the victims. However, all three studies found that trauma victims experience such research participation as distinctly beneficial.

In their article, "The Effects of Trauma-Focused Research on Pregnant Female Participants," Kami L. Schwerdtfeger and Briana S. Nelson Goff conclude from their review of the existing literature that

> although trauma-based research may produce intense emotions, it is not re-traumatizing nor does it cause harm to participants. Studies involving a variety of trauma survivors found that participation in the research was not overwhelming or distressing and was generally an experience that participants would be willing to repeat.

Their own study found this also to be true of pregnant women.
The possibility that interviewing may traumatize narrators has been used as a chief justification for IRB review of oral history. (See, for example, Taylor Atkins's comments in Kanya Balakrishna, "[2]Humanities Research May See More Rules," *Yale Daily News*, 17 April 2007.) But empirical research suggests that this possibility is rather small. It is therefore probable that by deterring interviews with trauma survivors, IRBs are significantly more likely to deny them a positive experience than to protect them from harm.

1. http://caliber.ucpress.net/toc/jer/3/1
2. http://www.yaledailynews.com/articles/view/20774

3.3.4 Trauma-Based Research Is Less Risky Than Imagined (2008-03-23 14:15)

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1. http://caliber.ucpress.net/toc/jer/3/1
2. http://www.yaledailynews.com/articles/view/20774

3.3.5 IRBs "Jerk Around" Education Research (2008-03-31 23:12)

Debra Viadero reports on the recent conference of the American Educational Research Association: "[1]Security Checks of U.S. Education Contractors to Change," *Education Week*, 2 April 2008.
She includes the following description of one session:

> Under federal human-protections laws, studies that involve human subjects—a category that includes most research in education—first have to be approved by institutional review boards, or IRBs, based at researchers' home universities or research organizations.
> But that process can sometimes be fraught with frustration and distrust . . . .
> "While I was behind the curtain, it seemed to me that our board was quite reasonable," said Frederick D. Erickson, a professor of anthropology in education at the University of California, Los Angeles. He has served on three institutional review boards over the course of his career. "Now, I've got a project of my own in expedited institutional review," he added, "and it's being jerked around in ways that make my blood boil."
> Some problems with the process, said Melissa S. Anderson, an associate professor of higher education at the University of Minnesota- Twin Cities who has studied IRBs, is that researchers often disagree with the boards' judgments or may be skeptical of their authority.
> "It's, 'What right do they have to tell me whether or not I can do research?' " she said. "The issue of peer review when peers aren't seen as peers is … a sticking point."
> "This can lead to IRB shopping," Ms. Anderson added, which is what occurs when researchers working

on a study involving multiple universities try to figure out which one's board is most likely to approve their project. "That's becoming increasingly common and problematic."
In a national survey of scientists that Ms. Anderson and her colleagues conducted last year, 5 percent of respondents admitted to having ignored or circumvented human-research requirements sometime in the previous three years. When medical researchers were removed from the sample, that percentage rose to 8 percent.

1. http://www.edweek.org/ew/articles/2008/04/02/31townhall.h27.html

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3.4 April

3.4.1 Researchers Honored for Harming Human Subjects (2008-04-10 00:01)

It's [1]Pulitzer Prize season, and once again my dear Columbia University has showered medals on reporters who placed the subjects of their stories at risk of criminal or civil liability or damaged their financial standing, employability, or reputation, all without IRB oversight. This year's board seems to have been particularly bloodthirsty, giving two prizes–rather than the usual one–for investigative reporting, as well as honoring muckraking work with prizes for public service, local reporting, and international reporting.
Since at least the 1970s, IRB critics have asked why such work is honored when a reporter does it but condemned–at least by IRBs–when a scholar is asking the questions. I have yet to find a clear answer from defenders of the system. Here's a typically fuzzy response–Dr. Jeffrey Cohen's statement before the October 2001 meeting of the [2]National Human Research Protections Advisory Committee:

> This is a very difficult issue and it borders on the whole issue of the distinction between journalism and research . . . And that is a really murky, murky area. As a matter of fact, it is one of the conversations I had at the Oral History Association because the oral historians are in that same sort of issue. I think that clearly there is a need for more guidance on distinguishing between journalism and research.
> I think the courts are doing that. I mean, the courts are addressing what constitutes journalism and the extent and scope of the First Amendment rights, especially in the context of the internet. Publishing something on the internet, does that make it journalism and so forth? And so I think that the human protections movement should look to the courts for guidance on some of that.
> There's also a distinction, though, between – in a sort of common sense way – between journalism and research. Journalism is done for the public knowledge and for the public good in the sense of providing information the public needs to know. Research has a sort of different context and that is, you know, further – the development and furthering of generalizable knowledge, which is a somewhat different thing than the public's right to know, although they're blurred.
> So I think that it is very clear in practice that the government, institutions and IRBs do have sort of a right or a responsibility particularly when it is focusing not on censorship but on protecting the rights and welfare of the subjects of research to review that, and I think the courts have upheld that. Particularly, I think, was the University of Minnesota case,* which wasn't particularly about human subjects but it was on research integrity. The courts upheld that right as opposed to journalism where infringing on that would be censorship. There is a murky area in between.
> There's also the sort of traditional knowledge that your right ends at the tip of my nose. And so that you can't yell fire in a crowded theater. And so there are things that even though we have constitutional rights, we also have the right to protect subjects and that there's a balancing there that needs to be done. It is not

that there's an easy answer to that.

The reason that the distinction remains a "really murky, murky area" is that the Department of Health and Human Services has failed, with all of its various commissions and advisory boards, ever to convene a group whose primary mission was to determine the rights and responsibilities of social scientists. (An exception might be the 1966 NIH conference at which social scientists asked to be left alone, but their recommendations were ignored.) Dr. Cohen's statement suggests that in lieu of such an investigation, the matter be turned over to the courts. That may yet happen, but I doubt it will be pretty. The courts can restrain the worst abuses of the present system, but a lawsuit is no substitute for sound policy-making, based on careful fact-finding.

Were regulators to take a serious look at the sort of journalism honored this week, they might find that different modes of inquiry involve different ethical practices, and different ethical goals. But once they concede that, their whole edifice starts to crumble.

See also, "[3]James Weinstein's Anti-Intellectualism."

Note: I don't know the nature or name of the "University of Minnesota case." I've sent a query to Dr. Cohen, and I hope to replace this footnote with his reply.

1. http://www.pulitzer.org/
2. http://www.hhs.gov/ohrp/nhrpac/mtg10-01/1030NHR.txt
3. http://www.institutionalreviewblog.com/2007/08/james-weinsteins-anti-intellectualism.html

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PCM (2008-04-13 01:51:00)

I don't understand the "common sense" distinction between journalism and research. "Blurred" is the key word. I would be hard-pressed to convince a good reporter than my work isn't journalism. And I don't see why I would want to.

3.4.2 Do UCLA Researchers Have Permission to Read This Blog? (2008-04-11 21:55)

In July 2007, the UCLA Office for Protection of Research Subjects (OPRS) issued a policy statement, "[1]Human Subjects Research Determinations," stating that:

> The UCLA OPRS/IRB has the sole authority to determine whether an activity conducted by UCLA faculty, staff, or students (or conducted on UCLA students) meets the regulatory definition of "human subjects research" and therefore requires IRB review and approval or certification of exemption from IRB review. UCLA faculty, staff, and students who intend to conduct activities that might represent "human subjects research" do not have the authority to make an independent determination that UCLA IRB review and approval or certification of exemption is not required.

As a result

> Investigators who intend to conduct activities that might represent "human subjects research" must submit a description of the proposed activities to the UCLA OPRS/IRB for a determination of whether UCLA IRB review and approval or certification of exemption is required prior to the UCLA investigator's involvement in the proposed activities.

Might represent to whom?
This policy can mean one of two things:
1. UCLA researchers should seek IRB permission before drinking a cup of coffee, reading the newspaper, talking with their spouses, or riding the bus. After all, any of these activities "might represent 'human subjects research,'" and the researcher can't be trusted to figure it out.
2. UCLA researchers should not seek IRB permission before drinking a cup of coffee, reading the newspaper, talking with their spouses, or riding the bus. Instead, they must ignore the literal meaning of the policy and instead make an independent determination that UCLA IRB review and approval or certification of exemption is not required.
The OPRS has just taken a step toward the first interpretation. As reported on a [2]UCLA library blog, the new [3]policy statement 42 gives university faculty, staff, and students blanket permission to use data from the U.S. Census and other publicly available datasets. If UCLA researchers must rely on such policy statements to read publicly available, public domain data on the friggin' internet, what can they possibly do without permission?
The 2007 policy statement ambiguously lists as references various state and federal documents, without directly claiming that any of them require or authorize the policy. As far as I can tell, they do neither. As reported on this blog, for example, [4]OHRP staff make independent determinations of what is and is not human subjects research. UCLA's OPRS is just making up powers for itself.

1. http://www.oprs.ucla.edu/human/documents/pdf/3.pdf
2. http://blogs.library.ucla.edu/ipmanagement/2008/04/10/update-to-irb-policy-makes-research-involving-public-use-data-files-easier/
3. http://oprs.ucla.edu/human/documents/pdf/42.pdf
4. http://www.institutionalreviewblog.com/2007/01/generalizable-revisited.html

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3.4.3 How Talking Became Human Subjects Research (2008-04-23 13:15)

The *Journal of Policy History* has accepted my article, "How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965-1991," drawn from my book-in-progress on the history of IRB review of the social sciences and humanities. The article is tentatively scheduled to be published in spring 2009, but in the meantime you can read a draft at SSRN: [1]http://ssrn.com/abstract=1124284. I welcome feedback.

1. http://ssrn.com/abstract=1124284

PCM (2008-05-02 14:35:00)
I think it's a great article! I was just able to give it very quick read, but at first glance I'd say it's a desperately needed historical record. And your analysis is great.
I'll read it again more slowly and try and offer some more specific thoughts and comments.

3.4.4 Michael Rowe on Situational Ethics (2008-04-25 16:23)

Bill Hart kindly referred me to Michael Rowe, "Tripping Over Molehills: Ethics and the Ethnography of Police Work," *International Journal of Social Research Methodology* 10 (February 2007): 37-48. Rowe, a criminologist at Victoria University, New Zealand, explains the ethical challenges he faced as a participant observer with British police in 2004. Rowe comes across as an unusually conscientious researcher. He writes, "while designing the project, and discussing it with academic colleagues and gatekeepers within the police service, I read many of the methodological texts on ethnography and accounts by previous researchers who had used similar methods with the police." (38) Some of this preparation was overkill, in that Rowe did not himself face some of the greatest challenges of previous researchers, like witnessing excessive force, false charges, or corruption. But it did sensitize him to some important issues about

police work, and the result seems to have been a careful study, respectful at once of the police, the citizens with whom they interacted, and the scholarly pursuit of truth.
Rowe concludes that generic ethical advice and rigid rules are poor guides to researchers doing fieldwork:

> It is the nature of ethnographic research that the principles contained in methodological textbooks or professional codes of conduct will be stretched and perhaps distorted as they are applied in dynamic situations. Since policing is unpredictable, the ethical dilemmas police researchers might face cannot be easily anticipated . . . If an absolute code of ethics is not feasible, researchers must be prepared to be reflexive in terms of ethical dilemmas and the methodological difficulties experienced in securing informed consent and meaningful access to research subjects. (48)

Though Rowe does not mention ethics committees in this article, it is striking how much his preparation diverged from the typical requirements of IRBs, at least in the United States. Rowe's experience points to the benefit of reading as specifically as possible in preparation for fieldwork. But the standardized training programs required by most IRBs, such as the CITI Program, present highly generic information about such topics as informed consent, and nothing about topics as specific as police ethnography. And while Rowe emphasizes the researcher's need to remain flexible, IRBs focus on protocol review. By making researchers pledge in advance what they will and will not do, protocol review reduces, rather than enhances, researchers' flexibility to adapt to unexpected situations. In other words, the IRB system is structured to hamper the kind of ethical preparation that Rowe recommends.
As I've mentioned before, the University of Pennsylvania's policy on [1]evolving research promises to relieve the second part of this problem, since some researchers, at least, are spared the need to file a "fixed research protocol."
But Penn still requires its researchers to "have documented discipline-appropriate education regarding human subject protection, in accordance with certification standards defined by the Vice Provost for Research." While Penn staff have refused me permission to see the approved training modules, from corresponding with people at Penn, I get the sense that they are pretty generic. Rowe's article suggests that such programs are not helpful, and what is really needed is for each researcher to prepare an ethical bibliography, based on problems faced by researchers who have conducted similar work. That way, each researcher would be equipped with the ethical guidance most relevant to her particular case. And in assembling the bibliography she would exercise the very independent judgment she will need in the field.
(Thanks to Rebecca Tushnet for discussing with me the idea of an ethical bibliography.)

1. `http://www.institutionalreviewblog.com/2007/08/evolving-research.html`

3.5 May

3.5.1 Participatory Research Meets the IRB (2008-05-17 11:14)

Participatory Research and Participatory Action Research are approaches that seek to include the people studied as participants in framing and answering questions. In Participatory Action Research, researchers also seek to work with participants to effect change, rather than merely identifying problems. For reasons unknown to me, many researchers who embrace these approaches are affiliated with the discipline of geography. In 2006, a number of American and British participatory researchers frustrated by ethics committees found themselves discussing the problem at meetings of the the Association of American Geographers and the Royal Geographical Society/Institute of British Geographers. The result was a special thematic issue (volume 6, number 3, 2007) of *[1]ACME: An International E-Journal for Critical Geographies*. The ten essays show that participatory researchers think hard about ethics, and as a result often find themselves struggling with ethics committees that do not.
In their introductory essay, "Participatory Ethics: Politics, Practices, Institutions," Caitlin Cahill, Farhana Sultana, and

Rachel Pain explain that

> As participatory researchers, we pursue research and other activities with communities (or traditional research 'subjects') as collaborating partners, with the primary goal of working towards positive changes on issues identified by the collective. We try to engage in all aspects of research - research questions, the choice and design of methods, the analysis of data, the presentation of findings, and the pursuit of follow up action - as collaborative projects which require negotiation between the different parties. So the complex challenge of negotiating 'ethics' – as multiple and contested, and whether in institutional or everyday spaces – is central to our research process and inquiry. (305)

Unfortunately, that kind of thoughtful approach to research ethics does not easily fit into the standardized, medical model of ethics committee in the United States and Britain. As the authors note, "researchers seem increasingly subject to a restrictive, inflexible and top-down view of what 'ethics' should be, via the codes of human subject panels which we are expected to adhere to." (307)
The remaining essays express frustrations that will be familiar to any social scientist who has followed the IRB debates. Deborah Martin complains that IRBs

> conceptualize research participants as "subjects" who face potential harm and exploitation in the research process . . . [Participatory research], however, seeks to redefine the researcher-subject model, conceptualizing research as a collaborative, negotiated process in which the direction and benefits of the research are as much a product of the participants' involvement as the researcher's. (322)

Sarah Elwood notes that "institutional ethics assume that ethical problems and risks can be identified before they occur, can be identified outside the context of the research situation, and that rules for ethical practices can be universal." (331) Kye Askins served on an ethics committee and was dismayed that the process emphasized forms and paperwork over training students to think ethically. (358) And Megan Blake complains that "the easy camaraderie born of friendship and underpinned by trust is undermined by [committee's] implicit assumption that the research may lead to harm, exploitation or suffering for those involved." (417)
Two essays present outrageous IRB behavior. Blake's experience at the University of Sheffield sounds more or less comical:

> I was required to get a [criminal background check] before I could research the food practices of my children and their friends, and had to have my friends sign confidentiality and copyright agreements as I served them a cup of tea and a biscuit in my home. If I followed strictly the guidelines on anonyminity, I would also be required to ignore the details that I know about my friends as individuals when I analyse their accounts. (417)

More seriously, Matt Bradley spent months meeting with IRB staff and the chair, only to have his project–a documentary film–rejected on the grounds that "there is risk that people in the community might be upset about the portrait that has been painted." (340) This is what lawyers call viewpoint discrimination; Bradley was free to tell a happy story, but barred from telling an angry one. Yet even as it guessed about this risk to a community, the IRB refused to compare it to any possible benefit to that community, as opposed to individual participants or to scholarly knowledge. He concludes that far from manifesting respect for persons,

> the IRB's insistence on anonymity in my case smacked of the paternalism and control . . . Evident in the communications I received from the committee is the notion that the people whom I was involving in my research are not smart enough to make decisions for themselves or to understand the implications and possible repercussions of their decisions. Even more problematic, however, is the notion that the committee is smart enough to make these decisions for the 'subjects' and will make choices both about what I can or cannot collect from them and how they can represent themselves. (347)

Other complaints are more specific to the authors' commitment to participatory research. Elwood enlisted non-scholars as "community map makers" in a participatory project. Though these map makers were, in effect, co-authors,her IRB wanted their names stripped from the maps. (333) Eventually, the authors agreed to remove the names from maps printed in academic publications. Thus, the IRB denied the map makers credit for their work. Caitlin Cahill dislikes the Belmont Report's admonition to "do no harm," on the grounds that for a participatory-action researcher, harmlessness alone is an abdication of responsibility. (366) Peter Hopkins complains that "the detached, disembodied and 'tick-box' approach adopted by many ethics committees often renders absent the positionalities of the researchers, downplaying the significance of researchers' life experiences, biographies and complex identities." (387) While he does not describe in detail his experience with committee approval, his article suggests that he was far better prepared by his own reading than by any guidance from a committee. (389)

The authors do find some benefits to the process. Elwood notes, "discussing how to address the IRB's concerns forced us to consider more specifically how the research process might affect participants whose experiences might differ dramatically from our own." (332) And rather than thrust an IRB-mandated consent form at her interviewees, she "begin[s] the process by trying to initiate discussion about the history and politics of informed consent in research, reasons why universities require researchers to follow certain protocols, or what the process recognizes and what it might leave out." (336) Thus, she concludes, "Institutional rules for ethical practice in research and systematic oversight of researchers, however partial and frustrating they may be, ensure that all university-based research has at least one forum where the ethics and human impacts of its activities must be considered." (337) Even Bradley, whose project was derailed ten years ago, claims that "the frustrations and different needs of qualitative and action researchers have been heard on many campuses," though for evidence he relies on an article noting positive developments on just two campuses. (347)

Despite the problems they have faced, the scholars represented in this issue appear remarkably hopeful, resilient, and determined to think seriously about research ethics, and they all seek to reform the ethics committee system rather than to escape from it. I hope the committees will prove worthy of their confidence.

1. `http://www.acme-journal.org/Volume6-3.htm`

3.6 June

3.6.1 Music Educator Finds IRBs Inconsistent, Restrictive, and Burdensome (2008-06-03 17:40)

Rhoda Bernard kindly alerted me to Linda C. Thornton, "The Role of IRBs in Music Education Research," in Linda K. Thompson and Mark Robin Campbell, eds., *Diverse Methodologies in the Study of Music Teaching and Learning* (Charlotte, North Carolina: Information Age, 2008), 201-214.

Thornton (along with co-author Martin Bergee) wanted to survey music education majors at the 26 top university programs to ask why they had chosen music education as a profession. She writes, "no personal information regarding race, habits, or preferences was being collected—only descriptive data such as each student's major instrument (saxophone, voice, etc.), age, and anticipated year of graduation." She dutifully submitted her proposal to her local IRB, and then the trouble began.

Thornton's own IRB forbade the researchers from surveying students at their own institutions, then imposed requirements suitable for a survey on sexuality or criminal activity. Most significantly, it required Thornton to seek permission

from the IRBs at the 24 universities remaining in her pool.

Nine of the 24 accepted the proposal as approved by Thornton's IRB, including one which noted it had a reciprocity agreement in place. Of the remaining 15, several imposed burdensome requirements, ranging from small changes in the informed consent letter (which then needed to re-approved by the original IRB), and the requirement that the instructor at the local institution, who was just going to distribute and collect questionnaires, be certified in human subjects research. Application forms ranged from two pages to eight; at least one IRB demanded to know the exact number of music education majors in every school to be surveyed. The result was that the researchers dropped many of the schools they hoped to study, cutting their sample from several thousand to 250.

This sad story touches on two points: inconsistency, and regulatory exemptions.

Since their creation in the 1960s, IRBs have been making decisions based on guesswork, with little attempt at developing a consistent system of best practices for research and for the review of research. As Jay Katz testified in 1973,

> The review committees work in isolation from one another, and no mechanisms have been established for disseminating whatever knowledge is gained from their individual experiences. Thus, each committee is condemned to repeat the process of finding its own answers. This is not only an overwhelming, unnecessary and unproductive assignment, but also one which most review committees are neither prepared nor willing to assume.
>
> [U.S. Senate, *Quality of Health Care—Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare*, Part 3 (93d Cong., 1st sess., 1973), 1050].

Katz's testimony helped inspire Congress to pass the National Research Act of 1974, requiring broader use of IRBs and establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to make further recommendations–recommendations that remain the basis of today's system in the United States and elsewhere. But neither the law nor the commission addressed the problem of disseminating knowledge. In 1982, Jerry Goldman and Martin D. Katz tested the system by submitting identical, flawed proposals for medical research to 32 IRBs. They found "substantial inconsistency in the application of ethical, methodological, and informed-consent standards for individual review boards." (Jerry Goldman and Martin D. Katz, "[1]Inconsistency and Institutional Review Boards," *Journal of the American Medical Association* 248, pages 197-202, 1982). Thornton did not set out to replicate the Goldman-Katz test (she wanted to learn about music students, not IRBs), but she did so by accident, and got similar results.

Perhaps no one will be surprised that Thornton's sample showed so much inconsistency. Indeed, even Laura Stark, something of a defender of the present system, encourages us to think of inconsistency as a feature, not a bug. "The local character of board review does not mean that IRB decisions are wrong so much as that they are idiosyncratic," she writes, suggesting that "the application of rules is always an act of interpretation and that sometimes this discretion can have positive, as well as negative, effects." (Laura Stark, "[2]Victims in Our Own Minds? IRBs in Myth and Practice," *Law & Society Review* 41 (December 2007), 782. Perhaps, but I suspect the negative effects are far more common. I doubt Stark would defend the treatment Thornton received.

I was more surprised by the one way the 24 IRBs *were* consistent in their response. Federal regulations offer exemptions for

> (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
> (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ([3]45 CFR 46.101)

Thornton's research clearly fits this exemption.
Universities may apply their own rules on top of federal regulations, and we know from a 1998 study that less than 40 percent of survey research eligible for exemption actually receives it. [James Bell, John Whiton and Sharon Connelly, *[4]Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects* (Arlington, Virginia: James Bell Associates, 1998), 29.] Still, I would have expected some IRBs to tell Thornton that her research required no review. No such luck. Thornton's own institution requires review of all research involving college students, and all or almost all of the other universities seem to have applied similar, non-federal rules.
Last year, Jerry Menikoff argued that social scientists had exaggerated the dangers of IRBs. He claimed that "most institutions assume that any study which falls within one of the exemption categories would automatically be in compliance with the Belmont Report criteria," and therefore "such studies, in a properly functioning IRB system, should receive relatively rapid and nonburdensome review." ("Where's the Law? Uncovering The Truth About IRBs and Censorship," *Northwestern University Law Review* 101 (2007), 794-795). Maybe they *should* receive such review, but Thorton's experience suggests they do not. If research universities that excel in music education are any indicator, overly restrictive IRBs are the rule and not (as Menikoff suggests) the exception.
The exemptions in 45 CFR 46 resemble the bill of rights in the old Soviet constitution. They may look good on paper, but don't count on them to protect the freedom of inquiry.

1. http://jama.ama-assn.org/cgi/content/abstract/248/2/197
2. http://www.blackwell-synergy.com/doi/abs/10.1111/j.1540-5893.2007.00323.x
3. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101
4. http://www.hhs.gov/ohrp/policy/hsp_final_rpt.pdf

3.6.2 IRB Disciplines and Punishes a Qualitative Researcher (2008-06-13 20:21)

Tara Star Johnson reports her experiences in "Qualitative Research in Question: A Narrative of Disciplinary Power With/in the IRB," *Qualitative Inquiry* 14 (March 2008): 212-232.
Johnson left teaching high school to pursue a PhD in Language Education at the University of Georgia. As she completed her preparatory work, she found "no qualitative studies investigating the phenomenon of sexual dynamics in the classroom." She decided, for her dissertation work, "to address this void in educational research through in-depth interviewing of teachers who have experienced desire for and/or from students to trace how these attractions happen and open the door for dialogue about embodiment, desire, and sexuality in education." Her professors were encouraging, and her advisor accompanied her to her appointment with the IRB.
After waiting an hour and a half beyond their scheduled appointment, Johnson and her advisor finally met with about twenty members of the IRB. The chair listed several restrictions, which Johnson found disappointing, but "not unreasonable or completely unexpected." Then the fun began.
One member found fault with Johnson's proposal to speak in depth with five high school teachers whom she already knew; wouldn't it be better to conduct an anonymous survey with ninety or so teachers? No, Johnson explained, it would not. "I'm looking for dialogue here, in-depth experiences of a few participants, not a bunch of Likert-scale responses."
Another member fretted, "Let's say, 10 years down the road, someone's having a party. One of your colleagues is there and happens to strike up a conversation with one of your research subjects. Your name comes up, and your subject says, 'Oh, I know her! I was in her dissertation study.' Your colleague would immediately be able to identify her." Well, yes. Participants in research are always free to identify themselves. Unless the IRB requires that they be shot.
Then the board rejected Johnson's plan to obtain an NIH certificate of confidentiality to protect the identities of any teachers who disclosed misdeeds, though such certificates are often trumpeted in IRB circles as the kind of thing a good board will suggest.
And, predictably, Johnson was asked "to come up with a list of counseling referrals in case my participants were traumatized by my research." (If anyone needed trauma counseling, it was the researcher whose work was reviewed before

Johnson. She fled the IRB meeting in tears.)

The meeting ended with the IRB chair's informing Johnson that she would send a list of required changes, and then the project would be considered at the next meeting, six weeks later. When the list arrived, Johnson was particularly distressed that she would not be allowed to record or transcribe the interviews that she hoped would be the basis of her dissertation. So Johnson dug in her heels, and kept recording and transcription in her revised proposal.

So here's the punch line: on the next round, the board voted to send the application off for expedited review, and approval itself came the next business day.

To some degree, the change in the board's position from the first round to the second reflects Johnson's abandonment of some of the most interesting parts of her study design. In particular, she had to reword her recruitment flyer to screen out any teachers who had actually had sex with their students. Apparently, there are some subjects that University of Georgia scholars may not study under any circumstances.

But many of the components that the board originally objected to remained in the final proposal. She would still interview a small number of teachers. She would still ask them about sexual feelings. And yes, they might still be allowed to attend parties ten years down the road. Does this make Johnson's research dangerous or not? If no, the board had no business, in its first meeting, bullying her about her plans. If yes, then its granting of expedited review (valid only for research involving "no more than minimal risk") was a violation of 45 CFR 46.110. In short, the IRB's behavior cannot be explained by an effort to protect participants in research while adhering to federal regulations.

What does explain such behavior?

Johnson suggests that "the real issue was not protecting participants so much as protecting the university from potential lawsuits and bad publicity." This is quite plausible; to see what can happen when reporters find out that a scholar is studying teacher-student sex, read Pat Sikes's essay, "At the Eye of the Storm: An Academic('s) Experience of Moral Panic," in the same issue of *Qualitative Inquiry*. If a university wants to keep researchers away from controversial topics, an IRB is a good tool.

But Johnson offers another explanation as well: quantitative researchers' contempt for qualitative work, like her interviewing. In this perspective, the IRB was not so much worried about protecting the university as they were in "disciplining my department in a Foucauldian sense for allowing its students to do research that was out of line," where "out of line" meant qualitative.

Both explanations recall Stefan Timmermans, "Cui Bono? Institutional Review Board Ethics and Ethnographic Research," *Studies in Symbolic Interaction* 19 (1995): 153-173. Like Johnson, Timmermans had his project approved, but only after being berated by an IRB in what he termed "a Goffmanian public degradation ceremony." Part of the problem was that the board members seemed to fear that his work would reflect badly on the hospital he was studying. And part was that they despised his ethnographic approach. A board member shouted at him, "The numbers should come through in the paper. This is not systematic. What about statistics! . . . If you write something, we should know HOW MANY PEOPLE said WHAT, there should be NUMBERS in here. There is NO DATA in this paper."

(At that point, Timmermans might have pointed out that if his work wasn't systematic, it wasn't subject to IRB review under the Common Rule. But I can see why he refrained.)

Johnson begs her readers to "read to the end before making any judgments about the people I portray." In her conclusion, she notes that individual members of IRBs face their own constraints. Outnumbered by scholars in other disciplines, the qualitative researchers most sympathetic to Johnson's work may have been unable to defend her too vocally, choosing instead to maneuver her subtly toward approval. That is an imaginative and generous supposition, but it still leaves us with an IRB that abuses its authority.

Scott Quarforth (2008-06-18 14:48:00)

I read this blog and then immediatly requested the article through our inter-library loan. It is a very well-written and intriguing personal account. I was very taken aback by the bluntness of the IRB board to clearly side with quantitative research. I agree with a lot of what Johnson said in regards to the trend of positivist thinking becoming more prevalent with national reports, NCLB's definition of research, and the What Works Clearinghouse.

Having just finishing up the first year of my PhD program, and feeling a personal pull towards qualitiative research, this article spoke to me about what I should pay attention to as I refine my disseration topic.

I feel this is an excellent article to bring into class discussions about ethics, IRB, and educational philosophies.

Zachary M. Schrag (2008-06-19 15:20:00)
Thanks for your comment. I hope that Johnson's experience won't shape your dissertation topic, but rather that you will define your research according to your own scholarly interests, and then fight any incompetent IRB that stands in your way.

3.6.3 The Psychologist Who Would Be Journalist (2008-06-29 16:42)

Back in [1]August 2007, I mentioned the controversy surrounding the book The Man Who Would be Queen (Washington: Joseph Henry Press, 2003) by J. Michael Bailey, Professor of Psychology, Northwestern University. At the time, Professor Alice Domurat Dreger, also of Northwestern, had just posted a draft article on the controversy. Now that article, along with twenty-three commentaries and a reply from Dreger, has appeared in the [2]June 2008 issue of the Archives of Sexual Behavior.
Dreger's article, the commentaries, and Dreger's response focus on big questions about the nature of transsexuality, the definitions of science, and the ground rules of scholarly debates. Only a handful take up the smaller question of whether—as a matter of law and as a matter of ethics–Bailey should have sought IRB approval prior to writing his book. But that's the question that falls within the scope of this blog.
The IRB question can be broken into three subsidiary questions.

Did Bailey's interactions with transsexaual women constitute human subjects research as defined by federal regulations?

Bailey's book is based, in part, on his knowledge of the life stories of several transsexual women. In July 2003, four of those women filed [3]formal complaints. They were Anjelica Kieltyka, a transsexual activist who had introduced Bailey to transsexual women seeking sex reassignment surgery, and three anonymous complainants. Also in July 2003, two prominent scholars, Deirdre McCloskey and Lynn Conway (both transsexuals) filed [4]their own complaint in support of Bailey's subjects.
In their complaints, the women note two sets of interactions with Bailey. First, Bailey had interviewed the three anonymous women prior to writing letters of support for their requests for sexual reassignment surgery. According to Dreger, the interviews allowed Bailey to write letters "reporting simply what he observed in terms of a pre-op transsexual woman's gender identity presentation, her apparent understanding of the surgery, and her likelihood of adjusting well after SRS." (372) It's not clear from any of the documents what questions he asked or what answers he got.
The second set of interactions came as a result of Bailey's invitation to Kieltyka and at least two other complainants to act as guest lecturers in his classes on human sexuality. As Dreger notes, these were "heavily attended," and "between 1994 and 2003, a total of several thousand Northwestern University students saw Kieltyka's annual appearances." (373) The complainants, including McCloskey and Conway, suggest that these lectures were themselves abusive. As McCloskey and Conway put it, "The women [who] have come forward . . . fear that the hundreds of Northwestern undergraduates before whom they were paraded in the on-going freak shows in Professor Bailey's classes might recognize them."
These latter are pretty weak charges. I don't know anyone who would argue that inviting someone to lecture to one's course constitutes human subjects research.
More plausible is the charge that the pre-surgery interviews should have triggered IRB review. While Bailey likely began writing reference letters in 1996, prior to beginning his work on the book in 1997, at least two interviews took place in 1998 and 2000. Chronologically, it's possible that he interviewed these women knowing he might use thier stories in his book, but not telling them.
But did he? The only evidence presented in the complaints is that on page 177, Bailey writes, "most of the homosexual transsexuals I have met, I met through Cher", his pseudonym for Kieltyka. But Dreger notes that Kieltyka also "encouraged Bailey to accompany her to the local bars frequented by pre- and post-op transsexual women and drag

queens where Kieltyka was familiar with many of the regulars." (372) And on page 181 of his book, Bailey makes it clear that these bars were the sites of his first encounters with at least some of the women on whom he based his writings–women whom he interviewed in IRB-approved, laboratory settings. Thus, the reference on page 177 could well be to Kieltyka's help in recruiting subjects for Bailey's IRB-approved studies. (Dreger, 377) There's no reason to think that Bailey used any information from the pre-surgery interviews in his writings, making it hard to label them as unauthorized research.

Dreger notes another set of interactions, not mentioned in the complaints:

> The information about individuals that Bailey gatheredfor the book from Kieltyka, Juanita, Braverman, and others he obtained haphazardly—without any developed plan of research—from their occasional presentations to his classes, from their joint social outings, and from one-on-one discussions that occurred on an irregular basis. Bailey did conduct a few fill-in-the-blank discussions with Kieltyka, Juanita, and others (Bailey to Dreger, p.e.c., August 22, 2006)—discussions during which, as I show below, they knew he was writing about them in his book, and with which they cooperated. But these fill-in-the-blank discussions can again hardly be called systematic or productive of generalizable knowledge. When I pressed him to consult or perhaps even turn over to me the notes he took from these conversations, Bailey admitted he had no organized notes that he had bothered to keep. Obviously, he never really thought of these discussions as research—systematic work meant to be productive of generalizable knowledge—any more than he ever imagined that the women who seemed eager to tell their stories and have him write about them might later charge him with abuse. Otherwise, he surely would have protected himself and his work by being significantly more organized.

Dreger agrees with Bailey that his work was neither systematic nor generalizable, and therefore not subject to IRB review.

Of the commentators in the journal who take on the human-subjects angle, most recognize the flimsiness of the human-subjects case against Bailey. Brian A. Gladue, of the University of North Texas Health Science Center's Office for the Protection of Human Subjects, writes:

> the Northwestern IRB would have determined that Bailey's book project did not need IRB review, and Bailey was correct, both ethically and by regulations, in not seeking or obtaining IRB review. Simply stated, he did not need it—any more than journalism students need IRB review for class projects, or history faculty need IRB review to ask people questions about growing up in their hometowns, or interviewing war veterans about their experiences, etc. Frankly, IRBs generally are busy enough and do not need the extra business and burden of evaluating minimal risk human interactions that are not in and of themselves scientific research.

He goes on to warn about the continued expansion of IRB jurisdiction.

(Gladue also claims that "it is hugely ironic that social activists and social scientists/life historians would even argue that Bailey should have obtained IRB review for his book. For years, these groups of scholars and academics have chafed under the regulatory burden of IRB reviews." (448) As Dreger notes in her response, two of Bailey's three main antagonists are not social scientists/life historians of any stripe. (507) Gladue has a better case against McCloskey, whom I doubt got IRB approval for her memoir–based in part on conversations with other people, and published by a university press.)

Elroi Windsor concurs with Dreger's conclusion that "as an unscientific work that lacked systematic inquiry, [Bailey's book] did not qualify as human subjects research and therefore Bailey did not violate research standards." (495) Likewise, Seth Roberts refers to the McCloskey-Conway effort as "an absurd human-subjects complaint." (485) He

elaborates (quoting his correspondence with McCloskey):

> Never before in the history of science had the subject of a story told to illustrate a point been thereby considered a research subject. Bailey's book is not a scientific monograph. It is not a piece of science. It is a trade book about science. When I or anyone else gives a lecture about a scientific subject, and tell a story from everyday life to make the conclusions come alive, do we need informed consent from everyone mentioned in the story? Of course not. No one has ever been required to do this. No one has ever done this. No one has ever even conceived of such a thing.

Of all the commentaries, only two argue that Bailey's work should have been subject to IRB review. Richard Green writes,

> I take exception to the Dreger article characterization of research as the systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge, and only then subject to protection of human subjects. A scholarly studymay differ from a scientific one welded to that definition but still impact its subjects. Stoller's (1973) epic "Splitting: A Case of Female Masculinity" was a 395 page case study of a woman convinced that she had a penis. It was seven years of interview transcripts. It was not generalizable. There was no hypothesis testing. But his subject required (and received) protection. (452)

While I don't know the details of Stoller's work, I do know that the current definition of human subjects research was adopted in 1981, so the treatment of a 1970s project is quite irrelevant to the interpretation of current rules. Green's essay may be an unintentional plea for a return to the pre-1981 regulations.
The other case for inclusion comes from sociologist John H. Gagnon:

> Bailey's usual scientific work has been with subjects in experiments or in surveys and in these studies he has (here I am supposing, I have not asked) submitted his research plans to his IRB on the main campus at Northwestern and provided consent forms to his (and his colleagues') subjects. His contacts with transgendered persons were (if I may infer), to his mind, more casual and less scientific than his other work. (447)

This passage shows that Gagnon did not read Dreger's article very carefully. Dreger makes clear (377) that Bailey did get IRB approval for his more systematic studies, and that those IRB-approved studies included transsexuals. Maybe Gagnon's claim of un-reviewed "field work" refers to the "fill-in-the-blank discussions" mentioned by Dreger. If so, he should have said so.
Gagnon writes that IRBs "are often (perhaps more often than not) excessively intrusive, legalistic, and ignorant of the methods and traditions of the disciplines which they review. However, they are part of the apparatus of managing ethical dilemmas in human science in the current political and economic atmosphere that surrounds the production of knowledge by academic researchers. The decision to define either Bailey's or Dreger's works as nonscience may be tactically useful in this case, but in my view, neither choice is the correct one." (447)
I don't know what Gagnon means by the "current political and economic atmosphere that surrounds the production of knowledge by academic researchers." Does he mean that we depend on federal money, so we'd better shut up? I do know that his essay makes no distinctions between what is and is not within IRB purview, and he offers no counterexamples of scholarly works that might not require review. As best I can tell, he thinks that any published writing by a

scholar who has talked with other people requires IRB review. That's a pretty extreme position.

Would IRB review have helped?

Significantly, Gagnon makes the case for IRB review on procedural grounds: "both {Bailey's book] and Dreger's comment are works which fall into recognizable genres of scientific writing and both are dressed in scientific costume. Both employ methods that bring them under the rules and regulations of the appropriate Institutional Review Boards about informing human subjects that they have become ''data.'" (447) He does not claim that IRB review would have prevented or resolved the conflict between Bailey and his critics. Would it?

Certainly, an IRB might have insisted on written consent from some of Dreger's sources, notably Kieltyka and the pseudonymous "Juanita," whose stories each take up several pages in the book. As Dreger notes in her article, both women seem to have been aware that Bailey was writing about them and gave oral consent, but later claimed that they had not known of the book. A paper trail would have been good for all concerned.

But it's clear from the complaints that Bailey's failure to secure written consent was hardly the issue that sparked real anger. The damage they allege is not to the individual participants, but to the transsexual community as a whole. They specifically complain that Bailey's students may get the wrong idea about transsexuals. This is a harm, but IRBs are not designed to protect communities against this kind of damage. As the National Commission put it in its Institutional Review Board; Report and Recommendations of National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

> In evaluating risks and benefits to subjects, an IRB should consider only those risks and benefits that may result from the conduct of the research. . . . The possible longrange effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy affecting a segment of the population) should not be considered as among those research risks falling within the purview of the IRB . . . .

Marta Meana's commentary faults McCloskey and Conway for trying to use Northwestern's IRB as a makeshift censorship board. She describes the ethical complaints as "completely off-topic and simply an attempt to inflict as much damage as possible." (471) Indeed, Bailey's critics accused him of everything from practicing clinical psychology without a license to [5]"plagiarism and identity theft." Roberts and Meana suspect (with reason) that McCloskey and Conway did not think through their human subjects complaint, but merely included it as part of a shotgun approach, using every means they could think of to discredit Bailey.

Bailey's critics think he wrote a stupid, offensive book that will poison readers' ideas about transsexuals. They may be right. Some of Bailey's informants suffered real harm as a result of his work. But IRBs cannot protect people from every kind of harm without stifling legitimate research, and universities accept that some of the ideas put forth by their researchers will hurt people.

Unfortunately, Northwestern University has not made this clear.

Should IRB investigations be secret?

Dreger notes her frustration with Northwestern University's refusal to release the results of its year-long investigation into the Bailey affair. (393) I share that frustration. The Bailey case confirms (as if confirmation were needed) that the federal definition of human subjects research fails to demarcate clear boundaries between the "behavioral research" that is subject to the National Research Act and the "casual journalism" that even McCloskey thinks should not require IRB review. (467) While I doubt that the Northwestern investigation resolved a problem that has festered for twenty-seven years, I would also be surprised if a year-long, high level investigation achieved no insight on the matter. Though the Northwestern report would not be binding on other universities and IRBs, if it was any good, it would provide helpful guidance. For example, when Emory University commissioned an investigation of alleged scholarly misconduct by

Professor Michael Bellesiles, it posted the [6]report on the Internet, making it a helpful resources for those interested in the rules of academic history. By keeping its report secret, Northwestern failed the academic community.
Moreover, Northwestern failed the four complainants. While I don't think these women's complaints were grounded in a good understanding of human subjects regulations, I do not think it was their responsibility to learn the nuances of those regulations. Rather, Northwestern owed them an explanation of why it did or did not act on their charges. If Northwestern punished Bailey, the women deserved that information as vindication of their position. If Northwestern concluded that the harms to the women were not the kinds of harms it was bound to police, the women deserved an explanation of the university's position that legitimate scholarship can hurt, or that some forms of hurt cannot be avoided.
Bailey's book and the resultant controversy could have provided a useful lesson in the regulation of research. But lessons require knowledge, and despite Dreger's impressive efforts, we still don't know what we need to about this case. Bailey failed us by not citing his sources. McCloskey and Conway failed us by drafting such vague complaints. And Northwestern failed us by keeping secret the result of its investigation. Without knowledge, we cannot attain wisdom.

Note: In related news, Psychologist Elizabeth Loftus has settled the lawsuit against her by Nicole Taus, who charged Loftus with invasion of privacy for interviewing Taus's former foster mother. Loftus characterizes the $7,500 payment to Taus by her insurance company as a "nuisance settlement." By contrast, Taus has been ordered to pay nearly $250,000 in attorney's fees and other costs to other defendants in the case.
The case is relevant here because Loftus was also the subject of a two-year investigation of charges that she had violated human subjects rules by conducting a small number of interviews. Though Loftus was eventually exonerated by her university, the IRB-inspired investigation delayed her work and included a seizure of her office files. Like Bailey's accusers, Taus found the IRB a convenient way of attacking a university scholar who was acting primarily as a journalist, and whose conclusions she did not like.
See Elizabeth F. Loftus, "[7]Perils of Provocative Scholarship," APS Observer, May 2008. Thanks to John Mueller for the reference.

1. http://www.institutionalreviewblog.com/2007/08/northwestern-irb-unsystematic.html
2. http://www.springerlink.com/content/t38u47730616/?p=3825629cc2c6475ab046b98170b1948d&pi=1
3. http://www.blogger.com/%E2%80%9D
4. http://www.blogger.com/%E2%80%9D
5. http://ai.eecs.umich.edu/people/conway/TS/Anjelica/Complaint.html#anchor601714
6. http://www.news.emory.edu/Releases/Final_Report.pdf
7. http://www.psychologicalscience.org/observer/getArticle.cfm?id=2339

3.6.4 Oral Historians Draw Conclusions, Inform Policy, and Generalize Findings (2008-06-29 21:09)

In the lead story of today's New York Times ("[1]Occupation Plan for Iraq Faulted in Army History"), Michael R. Gordon reports on a new 700-page official history of the early occupation of Iraq, produced by the Army's Combined Arms Center at Fort Leavenworth. As Gordon reports, "the study is based on 200 interviews conducted by military historians and includes long quotations from active or recently retired officers." He notes that "the study is an attempt by the Army to tell the story of one of the most contentious periods in its history to military experts — and to itself." It draws important conclusions with policy implications, finding, for example, that "the military means employed were sufficient to destroy the Saddam regime; they were not sufficient to replace it with the type of nation-state the United States wished to see in its place."
This sounds suspiciously like the kind of project comprising generalizable research as defined by OHRP's Michael Carome in his October 2003 discussion with the UCLA Office for Protection of Research Subjects (as [2]reported by

UCLA.) In that conversation, Carome noted that

> Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS regulations at 45 CFR 46.
> [Example]: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

Except for the fact that it's the wrong Gulf War, the Army study nicely fits Carome's example of research requiring review.

Fortunately for federal historians, no one else in the federal government seems to share Carome's view on this matter. I know of no federal agency, executive or legislative, that requires IRB review for oral histories conducted by its employees. As reported on this blog, even [3]OHRP officials did not submit to IRB review when conducting oral history research.

Maybe Dr. Carome will try to discipline the researchers at Fort Leavenworth. Him and what army?

1. http://www.nytimes.com/2008/06/29/washington/29army.html
2. http://www.oprs.ucla.edu/human/documents/pdf/oral-history-031209.pdf
3. http://www.institutionalreviewblog.com/2007/01/generalizable-revisited.html

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3.6.5 The Psychologist Who Would Be Journalist (2008-06-30 20:34)

Back in [1]August 2007, I mentioned the controversy surrounding the book The Man Who Would be Queen (Washington: Joseph Henry Press, 2003) by J. Michael Bailey, Professor of Psychology, Northwestern University. At the time, Professor Alice Domurat Dreger, also of Northwestern, had just posted a draft article on the controversy. Now that article, along with twenty-three commentaries and a reply from Dreger, has appeared in the [2]June 2008 issue of the Archives of Sexual Behavior.

Dreger's article, the commentaries, and Dreger's response focus on big questions about the nature of transsexuality, the definitions of science, power relationships in research, and the ground rules of scholarly debates. Only a handful take up the smaller question of whether—as a matter of law and as a matter of ethics–Bailey should have sought IRB approval prior to writing his book. But that's the question that falls within the scope of this blog.

Bailey's book is based, in part, on his knowledge of the life stories of several transsexual women. In July 2003, four of those women filed [3]formal complaints with Northwestern University's' Office of the Vice President for Research. They were Anjelica Kieltyka, a transsexual activist who had introduced Bailey to transsexual women seeking sex reassignment surgery, and three anonymous complainants who had sought Bailey's endorsement of the surgery. Also in July 2003, two prominent scholars, Deirdre McCloskey and Lynn Conway (both transsexuals) filed [4]their own complaint in support of the four women, alleging "misuse of human subjects" among other charges.

In their complaints, the women note two sets of interactions with Bailey. First, Bailey had interviewed the three anonymous women prior to writing letters of support for their requests for sexual reassignment surgery (SRS). According to Dreger, the interviews allowed Bailey to write letters "reporting simply what he observed in terms of a pre-op transsexual woman's gender identity presentation, her apparent understanding of the surgery, and her likelihood of adjusting well after SRS." (372) It's not clear from any of the documents what questions he asked or what answers he got, and the book itself does not mention the interviews.

The second set of interactions came as a result of Bailey's invitation to Kieltyka and at least two other complainants to act as guest lecturers in his classes on human sexuality. As Dreger notes, these were "heavily attended," and "between 1994 and 2003, a total of several thousand Northwestern University students saw Kieltyka's annual appearances."

(373) The complainants, including McCloskey and Conway, suggest that these lectures were themselves abusive. As McCloskey and Conway put it, "The women [who] have come forward . . . fear that the hundreds of Northwestern undergraduates before whom they were paraded in the on-going freak shows in Professor Bailey's classes might recognize them."

These latter are unusual charges for an IRB complaint. Does anyone familiar with IRB regulations argue that inviting someone to lecture to one's course constitutes human subjects research?

More plausible is the charge that the pre-surgery interviews should have triggered IRB review. While Bailey likely began writing reference letters in 1996, prior to beginning his work on the book in 1997, at least two interviews took place in 1998 and 2000. Chronologically, it's possible that he interviewed these women knowing he might use their stories in his book, but not telling them.

But did he? On page 177, Bailey writes, "most of the homosexual transsexuals I have met, I met through Cher", his pseudonym for Kieltyka. The complainants take this as a reference to them, and as evidence that he used material from the pre-surgery interviews in his book. But there is another explanation of that line. Dreger notes that Kieltyka also "encouraged Bailey to accompany her to the local bars frequented by pre- and post-op transsexual women and drag queens where Kieltyka was familiar with many of the regulars." (372) And on page 181 of his book, Bailey makes it clear that these bars were the sites of his first encounters with at least some of the women on whom he based his writings–women whom he interviewed in IRB-approved, laboratory settings. Thus, the reference on page 177 could well be to Kieltyka's help in recruiting subjects for Bailey's IRB-approved studies. (Dreger, 377) There's no reason to think that Bailey used any information from the pre-surgery interviews in his writings, making it hard to label them as unauthorized research.

Dreger notes another set of interactions, not mentioned in the complaints:

> The information about individuals that Bailey gathered for the book from Kieltyka, Juanita, Braverman, and others he obtained haphazardly—without any developed plan of research—from their occasional presentations to his classes, from their joint social outings, and from one-on-one discussions that occurred on an irregular basis. Bailey did conduct a few fill-in-the-blank discussions with Kieltyka, Juanita, and others (Bailey to Dreger, p.e.c., August 22, 2006)—discussions during which, as I show below, they knew he was writing about them in his book, and with which they cooperated. But these fill-in-the-blank discussions can again hardly be called systematic or productive of generalizable knowledge. When I pressed him to consult or perhaps even turn over to me the notes he took from these conversations, Bailey admitted he had no organized notes that he had bothered to keep. Obviously, he never really thought of these discussions as research—systematic work meant to be productive of generalizable knowledge—any more than he ever imagined that the women who seemed eager to tell their stories and have him write about them might later charge him with abuse. Otherwise, he surely would have protected himself and his work by being significantly more organized.

Dreger agrees with Bailey that his work was neither systematic nor generalizable, and therefore not subject to IRB review.

Of the commentators in the journal who take on the human-subjects angle, most recognize the flimsiness of the human-subjects case against Bailey. Brian A. Gladue, of the University of North Texas Health Science Center's Office for the Protection of Human Subjects, writes:

> the Northwestern IRB would have determined that Bailey's book project did not need IRB review, and Bailey was correct, both ethically and by regulations, in not seeking or obtaining IRB review. Simply stated, he did not need it—any more than journalism students need IRB review for class projects, or history faculty need IRB review to ask people questions about growing up in their hometowns, or interviewing war veterans about their experiences, etc. Frankly, IRBs generally are busy enough and do not need the

> extra business and burden of evaluating minimal risk human interactions that are not in and of themselves scientific research.

He goes on to warn about the continued expansion of IRB jurisdiction.
(Gladue also claims that "it is hugely ironic that social activists and social scientists/life historians would even argue that Bailey should have obtained IRB review for his book. For years, these groups of scholars and academics have chafed under the regulatory burden of IRB reviews." (448) As Dreger notes in her response, two of Bailey's three main antagonists are not social scientists/life historians of any stripe. (507) Gladue has a better case against McCloskey, whom I doubt got IRB approval for her memoir–based in part on conversations with other people, and published by a university press.)
Elroi Windsor concurs with Dreger's conclusion that "as an unscientific work that lacked systematic inquiry, [Bailey's book] did not qualify as human subjects research and therefore Bailey did not violate research standards." (495) Likewise, Seth Roberts refers to the McCloskey-Conway effort as "an absurd human-subjects complaint." (485) He elaborates (quoting his correspondence with McCloskey):

> Never before in the history of science had the subject of a story told to illustrate a point been thereby considered a research subject. Bailey's book is not a scientific monograph. It is not a piece of science. It is a trade book about science. When I or anyone else gives a lecture about a scientific subject, and tell a story from everyday life to make the conclusions come alive, do we need informed consent from everyone mentioned in the story? Of course not. No one has ever been required to do this. No one has ever done this. No one has ever even conceived of such a thing.

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Of all the commentaries, only two argue that Bailey's work should have been subject to IRB review. Richard Green writes,

> I take exception to the Dreger article characterization of research as the systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge, and only then subject to protection of human subjects. A scholarly studymay differ from a scientific one welded to that definition but still impact its subjects. Stoller's (1973) epic "Splitting: A Case of Female Masculinity" was a 395 page case study of a woman convinced that she had a penis. It was seven years of interview transcripts. It was not generalizable. There was no hypothesis testing. But his subject required (and received) protection. (452)

While I don't know the details of Stoller's work, I do know that the current definition of human subjects research was adopted in 1981, so the treatment of a 1970s project is quite irrelevant to the interpretation of current rules. Green's essay may be an unintentional plea for a return to the pre-1981 regulations.
The other case for inclusion comes from sociologist John H. Gagnon:

> Bailey's usual scientific work has been with subjects in experiments or in surveys and in these studies he has (here I am supposing, I have not asked) submitted his research plans to his IRB on the main campus at Northwestern and provided consent forms to his (and his colleagues') subjects. His contacts with

> transgendered persons were (if I may infer), to his mind, more casual and less scientific than his other work. (447)

This passage shows that Gagnon did not read Dreger's article very carefully. Dreger makes clear (377) that Bailey did get IRB approval for his more systematic studies, and that those IRB-approved studies included transsexuals. Maybe Gagnon's claim of un-reviewed "field work" refers to the "fill-in-the-blank discussions" mentioned by Dreger. But that's just a guess.

For good measure, Gagnon argues that Dreger herself should have faced IRB review for the interviews and correspondence she used in writing her article. Dreger did, in fact, consult the Northwestern University Office for the Protection of Research Subjects, which assured her that her work was "not IRB-qualified." (401) Gagnon tries to explain this away by claiming Dreger "was exempted from human subjects review by the IRB at Northwestern University's medical school despite the fact that she was interviewing people whom I would treat as 'human subjects.' I am not sure how the IRB on the main campus of Northwestern, which is far more familiar with social science research, would have dealt with Dreger's submission." (447) Again, Gagnon is a sloppy reader. Dreger consulted not with a medical-school IRB, but with Eileen Yates, an official with the university office that oversees both medical and non-medical research.

Gagnon writes that IRBs "are often (perhaps more often than not) excessively intrusive, legalistic, and ignorant of the methods and traditions of the disciplines which they review. However, they are part of the apparatus of managing ethical dilemmas in human science in the current political and economic atmosphere that surrounds the production of knowledge by academic researchers. The decision to define either Bailey's or Dreger's works as nonscience may be tactically useful in this case, but in my view, neither choice is the correct one." (447)

I don't know what Gagnon means by the "current political and economic atmosphere." Does he mean that we depend on federal money, so we'd better shut up? Is there a difference between a "political atmosphere" and federal law as enacted by Congress? In a different political and economic atmosphere, would Bailey's actions be ethical?

I do know that his essay makes no distinctions between what is and is not within IRB purview, and he offers no counterexamples of scholarly works that might not require review. As best I can tell, he thinks that any published writing by a scholar who has talked with other people requires IRB review. That's a pretty extreme position.

Significantly, Gagnon makes the case for IRB review only on procedural grounds: "both [Bailey's book] and Dreger's comment are works which fall into recognizable genres of scientific writing and both are dressed in scientific costume,." he writes. "Both employ methods that bring them under the rules and regulations of the appropriate Institutional Review Boards about informing human subjects that they have become ''data.'" (447) He does not claim that IRB review would have prevented or resolved the conflict between Bailey and his critics. Would it?

Certainly, an IRB might have insisted on written consent from some of Dreger's sources, notably Kieltyka and the pseudonymous "Juanita," whose stories each take up several pages in the book. As Dreger notes in her article, both women seem to have been aware that Bailey was writing about them and gave oral consent, but later claimed that they had not known of the book. A paper trail would have been good for all concerned.

But it's clear from the complaints that Bailey's failure to secure written consent was hardly the issue that sparked real anger. The damage they allege is not to the individual participants, but to the transsexual community as a whole. They specifically complain that Bailey's students may get the wrong idea about transsexuals. This is a harm, but IRBs are not designed to protect communities against this kind of damage. As the National Commission put it in its Institutional Review Board; Report and Recommendations of National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

> In evaluating risks and benefits to subjects, an IRB should consider only those risks and benefits that may result from the conduct of the research. . . . The possible longrange effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy affecting a segment of the population) should not be considered as among those research risks falling within the purview of the IRB . . . .

Bailey's critics, including some women whose experiences he drew on for his work, think he wrote a stupid, offensive book that will poison readers' ideas about transsexuals. They may be right. But IRBs cannot protect people from every kind of harm without stifling legitimate research, and universities accept that some of the ideas put forth by their researchers will hurt people.

1. http://www.institutionalreviewblog.com/2007/08/northwestern-irb-unsystematic.html
2. http://www.springerlink.com/content/t38u47730616/?p=3825629cc2c6475ab046b98170b1948d&pi=1
3. http://www.blogger.com/%E2%80%9D
4. http://www.blogger.com/%E2%80%9D
5. http://ai.eecs.umich.edu/people/conway/TS/Anjelica/Complaint.html#anchor601714

Alice Dreger (2008-07-26 18:17:00)
Just wanted to thank you for this very thoughtful review of the IRB issues at play here. I only wish this piece had been published as one of the commentaries on my article, though obviously that was impossible, since it also comments on some of the commentaries. Well done, and I look forward to your book. - Alice Dreger

3.7 July

3.7.1 Political Science Perspectives on IRBs (2008-07-01 14:29)

The July 2008 issue of PS, the journal of the American Political Science Association, offers a five-part symposium: "[1]Protecting Human Research Participants, IRBs, and Political Science Redux." Over the next few days I plan to comment on each article, but for now it's safe to say that while each author offers a different diagnosis and prescription, none thinks that the current system is working well.

1. http://www.apsanet.org/section_788.cfm

3.7.2 OHRP Seeks Comment on Training and Education Programs (2008-07-02 21:48)

Rob Townsend kindly alerted me to the July 1 announcement in the Federal Register that OHRP is seeking comments on its requirements for human subjects training for investigators and IRB members. The summary follows; the full text for the announcement is online at [1]http://edocket.access.gpo.gov/2008/E8-14917.htm. The deadline for comments is September 29.
[Federal Register: July 1, 2008 (Volume 73, Number 127)] [Notices] [Page 37460-37463] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr01jy08-43] —— —
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.
ACTION: Notice.
—— —
SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science is seeking information and comments from affected entities and individuals about (a) Whether OHRP should issue additional guidance recommending that institutions engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS) implement training and education programs for certain individuals involved in the

conduct, review, or oversight of human subjects research, or (b) whether HHS should develop a regulation requiring the implementation of such training and education programs. This request for information and comment stems from the 1998 report from the HHS Office of Inspector General (OIG) recommending that Federal requirements be enacted to help ensure that investigators and institutional review board (IRB) members be adequately educated about, and sensitized to, human subjects protections. More recently, the Secretary's Advisory Committee on Human Research Protections (SACHRP) recommended that OHRP require institutions to ensure that initial and continuing training is provided for IRB members and staff, investigators, and certain institutional officials. The implementation of such training and education programs might help to ensure that individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federalwide Assurances (FWAs) understand and meet their regulatory responsibilities for protecting human subjects.
DATES: Submit written or electronic comments by September 29, 2008.
ADDRESSES: You may submit comments by any of the following methods: E-mail: [2]humansubjectstraining@hhs.gov. Include "Human Subjects Protection Training and Education" in the subject line. Fax: 301-402-2071. Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments received within the public comment period, including any personal information, will be made available to the public upon request.
FOR FURTHER INFORMATION CONTACT: Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail [3]Michael.Carome@hhs.gov.

1. http://edocket.access.gpo.gov/2008/E8-14917.htm
2. mailto:humansubjectstraining@hhs.gov
3. mailto:Michael.Carome@hhs.gov

3.7.3 Research Restrictions Not Confined to IRBs (2008-07-03 11:01)

John Mueller alerts me to Douglas Todd's article, "[1]Academics Fight for B.C. Prof's Right to View Assisted Suicides," Vancouver Sun, 2 July 2008.
The article concerns the case of sociologist Russel Ogden, who studies assisted suicide. His employer, Kwantlen University College, has prohibited him from witnessing assisted suicides, according to the Canadian Association of University Teachers. The association wants scholars to have the opportunity to "understand politically unpopular behaviour."
The twist here is that the research ethics committee (the Canadian term for an IRB) is not to blame. They approved Ogden's research three years ago.

Update, July 7. Professor Mueller alerts me to further coverage by the [2]National Post and [3]Inside Higher Ed.

1. http://www.canada.com/vancouversun/news/story.html?id=b2fdd5af-adb3-422a-935f-5a753e3f064f
2. http://www.nationalpost.com/news/story.html?id=630214
3. http://www.insidehighered.com/news/2008/07/07/suicide

3.7.4 When Seligson is Non-Seligson (2008-07-04 16:11)

The first article in the July 2008 PS symposium is Mitchell A. Seligson's "[1]Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research." While it's great to have someone interested in the contradictions of IRB regulations, the absurdity of the present regime seems to have left Seligson hopelessly confused, and his incoherent essay calls for both expansion and contraction of IRB authority.

Rather than trying to outline his argument, let me just list some of the questions to which he poses contradictory answers.

1. Should social science and humanities research follow the Belmont Report?

Early in his essay, Seligson attacks the Belmont Report as irrelevant to social science research, especially survey research. He particularly dislikes its call for an assessment of risks and benefits, noting

> the problem of assessing risk is especially vexing for all of those who rely on large-N studies, typically in the field of survey research. Ironically, when only a handful of subjects are used in a campus laboratory-based experiment, the IRB is likely to approve the project with no objection. But survey research, which invariably relies on large-N studies, is viewed with suspicion by many IRBs simply because the risk, however small, is seen as being replicated 1,000 or more times, since most samples strive for confidence intervals of 63 % or better. Protocol analysts, who are used to seeing laboratory experiments and focus groups with samples of fewer than 100, are often taken aback when they confront the large sample sizes inherent in most survey research. And when they do, they question why such a large sample is needed. As a result, it is not at all uncommon to have IRB protocol analysts ask survey researchers to cut down their sample sizes. (479)

He also is skeptical of the Common Rule, especially its protections for pregnant women–irrelevant and damaging to survey research. And he quotes–seemingly with approval–the AAUP's 2006 recommendation "that research whose methodology consists entirely of collecting data by surveys, conducting interviews, or observing behavior in public places be exempt from the requirement of IRB review."
But then Seligson turns around, lamenting that "historians are not only exempt from IRB control, they have no requirement or even need to take human subjects protection training and pass tests on their knowledge of the principles and rules. Literature faculties often have no knowledge at all of human subjects protection." (480) He wants "faculty members in a broad range of institutions to familiarize themselves with the IRB regulations and to take the tests to demonstrate their knowledge of same," including "the Belmont principles." (482)
Why? Why should faculty members be required to familiarize themselves with guidelines that Seligson has told us are inapplicable to their work? Does he just want company in his misery?

2. Can researchers be trusted?

Seligson thinks that IRB regulations did not help survey research, because

> Long before human subjects regulations and the invention of IRBs, survey researchers in all fields instinctually knew that by guaranteeing anonymity they would encourage frankness on the part of respondents. . . . Political scientists who carry out surveys have been aware for decades of the importance of guaranteeing anonymity to their subjects. (480)

If this track record weren't enough, he notes that governments and universities trust political scientists to behave ethically in other aspects of their work.

> Even though political scientists conducting educational tests and surveys are exempt from federal regulation, they are not, after all, exempt because the federal government believes we cannot be trusted. What

> is so strange here is that in countless other important ways, we are trusted by that same federal government. When we grade tests taken by our students, we are not allowed to discriminate on the basis of race, creed, national origin, sexual preference, etc. Yet we are not asked to sign a statement saying that we will not discriminate before or indeed after! we grade each exam or before we determine final grades. We hold office hours, but are not asked to submit an application prior to each office hour, not even prior to the start of each term, to the affirmative action offices on our campuses that we will not sexually harass students. We submit articles to conferences but are not asked to submit signed statements saying that we did not plagiarize the material. (481)

Since political scientists have proven more or less trustworthy in these areas, Seligson wants IRBs "to stop assuming, . . . that we are all guilty of violations of human subjects rights unless we can prove otherwise." (482)
That's all very nice, but he's unwilling to extend the trust to researchers in other fields. He writes,

> some humanists may be naive about the risks involved in disclosing names of subjects. One can imagine many kinds of risk to respondents. One such risk is dismissal of employment from an employer who either might not like the views expressed in the oral history or testimonio or deems them harmful to the company's welfare. Potential employers might look at the oral history information and deny a position based on the statements contained therein. Another risk could be ostracism at work or in one's neighborhood for expressing politically unpopular views. One can even imagine law enforcement officials using oral histories to prosecute individuals for revelations that suggest criminal behavior. (480)

In other words, Seligson does not trust interview researchers to have the same instinctual knowledge of ethics he ascribes to survey researchers, he ignores oral historians' sixty-year record in favor of hypothetical abuses, and he assumes historians are guilty of violations of human subjects rights unless we can prove otherwise. Perhaps he wants us to get approval before grading tests as well.

3. Can IRBs be trusted?

Overall, Seligson takes a dim view of those in charge of human subjects regulations, whom he terms "overzealous bureaucrats, both federal and on campuses," and wants retrained. (482) He even relays the follwoing anecdote:

> A very senior IRB official at one university, in order to impress upon a political science faculty member his omnipotence, asked, "Do you ever use the library to read books about President Bush?" When the response was affirmative, he said, "Unless you file for IRB approval before opening those books, you will be held in violation, since Bush is a human, is living, and the books almost certainly contain personal information." (480)

I'm willing to believe a lot of bad things about IRBs, but even I can't swallow a story like this without names and dates attached.
Yet while portraying IRB officials as power-mad bureaucrats, Seligson wants to expand their jurisdiction "to cover all studies of any kind that obtain data on living humans." (482) Wouldn't that include a book about President Bush?
Seligson concludes that "the roadmap to the future should be clear." Maybe it should be, but this article isn't helping. Fortunately, the other essays in the symposium are better researched and reasoned.

1. http://www.apsanet.org/imgtest/PSJuly08Seligson.pdf

Anonymous (2008-07-06 17:32:00)
Lest your readers come away confused by your comments, let me clarify. 1. I attempted to point out in my essay that the protection of human subjects is important and therefore I worry about the loophole created by those who claim that they are not doing research (as defined by the regulations) and as a result presumably do not need to worry about human subjects protection. So, your comment that I state that human subjects protection is "inapplicable" to what historians (and other humanists) do is not consistent with my argument. In fact, it is precisely the opposite of what I argue in my essay.
2. I also do not argue that non-social scientists should not be trusted, as you claim I do. Rather, I argue that since many humanists either explicitly or implicitly claim that they are not covered by the regulations (since they do not do "research" as formally defined in those regulations), they may be unfamiliar with them. I believe that they should be.
3. I do not state that survey researchers have "instinctual knowledge of ethics," as you claim. Rather, the practice of survey research since its early formation has been to make survey responses anonymous. Oral historians, however, have a different tradition, and at times do indeed publish the real names of living humans they interview and the real names of others referred to in those oral histories. Therefore, it seems to me that there is a risk of harm to human subjects in calling this form of scholarship "non-research." Personally I think it is research.

Zachary M. Schrag (2008-07-06 20:37:00)
The previous comment was left anonymously; I assume from the context that the author is Professor Seligson. If so, I thank him for writing.
I will leave my readers to judge the persuasiveness of his essay and his intended clarifications.
ZMS

3.7.5 Human Subject of Biomedical Research Angry! (2008-07-05 16:25)

Peter Klein at [1]Organizations and Markets notes a brief dialogue concerning medical research ethics in The Incredible Hulk. Interestingly, the scientist involved suggests not the weighing of autonomy, beneficence, and justice demanded by the Belmont Report, but rather a prioritization of autonomy, allowing the subject, rather than an ethics committee, to decide whether the potential benefits justify the risks. Some ethicists of the 1970s proposed such a prioritization, but the National Commission rejected it.
The only movie I can think of off the top of my head, in which a comparable scene depicts an ethical debate in the social sciences and humanities, is Songcatcher. I haven't seen the movie, but even in the [2]trailer they're arguing about when research becomes exploitation. Maybe I should watch the whole thing.

1. http://organizationsandmarkets.com/2008/07/04/irb-in-the-movies/
2. http://www.imdb.com/title/tt0210299/trailers-screenplay-vi1335034137

3.7.6 Ideas on Fieldwork Are Oldies but Goodies (2008-07-07 11:02)

The second article in the PS symposium on IRBs is Dvora Yanow and Peregrine Schwartz-Shea, "[1]Reforming Institutional Review Board Policy: Issues in Implementation and Field Research."
The authors argue that "the character of its implicit research design model, embedded in its historical development, . . . renders IRB policy problematic for ethnographic and other field researchers." (483) Specifically, they contend that ethnographers are likley to have trouble meeting IRB demands that their protocols spell out procedures for selecting subjects, obtaining informed consent, disgusing the identity of participants, balancing risks and benefits, and protecting the data they collect. (489)
Fieldwork, they argue, is just too unpredictable to be planned out so thoroughly in advance. They note,

> Field researchers must enter others' worlds, and are expected to do so with care and respect, and these worlds can be complex, unbounded, and in flux. Instead of rigidly delimited, predesigned protocols laying out research steps that are invariable with respect to persons and time, which subjects can be handed as they step into the world of the medical researcher, field research often requires flexing the research design to accommodate unanticipated persons and personalities and unforeseen conditions.

And, they find,

> extending [the Belmont] principles to other, non-experimental research settings without making the underlying mode of science and its methodology explicit and without exploring their suitability to non-experimental scientific modes and methodologies has resulted in a hodgepodge of ethical guidance that is confused and confusing. Those guidelines do not give the many serious ethical problems of field research design and methodologies the sustained attention they deserve. (491)

All of this sounds perfectly sensible. What suprises me a bit is the authors' belief that they are the first to make these arguments:

> The proposals that we have seen to date for reforming IRB policy (e.g., Carpenter 2007) all tinker with the existing system. None of them, to the best of our knowledge, has yet identified and engaged the underlying methodological frame—experimental research design—shaping that policy and its implementation. Policy reforms that address resource, organizational, and other features of the existing policy leave that framing and its prosecution in place. The impact of these policies on field research is, however, serious, extending IRB policy to these other forms of research in the absence of systematic evidence of their having harmed research participants. If we are to have policies to ensure the protection of human participants in all areas of research, those policies need to be suited to other than just experimental research designs in ways that are commensurate with their own potential for harms. It is vital that recognition of the misfit between existing experimentally based policy and field research design and methodologies also be on the table in discussions of IRB policy reform. (491)

In fact, ethnographers have been complaining about the imposition of experimental research ethics on non-experimental research for thirty or forty years. Anthropologist Murray Wax, in particular, eloquently distinguished experimental research from fieldwork in just the way that Yanow and Schwartz-Shea do. See, for example, his essay, "On Fieldworkers and Those Exposed to Fieldwork: Federal Regulations and Moral Issues," Human Organization 36 (Fall 1977): 321-28. Indeed, despite a long bibliography, Yanow and Schwartz-Shea cite none of the many IRB critiques written in 1978-1980, when the IRB regulations were being overhauled.

I don't fault Yanow and Schwartz-Shea too much for not knowing this history. It is one of the tasks of the historian to save others from having to reinvent the wheel, and I hope my book, when finished, will make such a contribution.

Yanow and Schwartz-Shea end their article with "A Call for Action," most of which is fairly vague. IRB critics are split between those who seek to "tinker with the existing system," and those who seek to exclude large categories of research from any IRB jurisdiction. Yet it's not even clear on which side of this divide these authors fall. For example, they want APSA to "Issue a statement calling for reform of IRB policy in a substantive way that protects the interests of APSA members." (492) Lovely, but what should such a statement say? They demand reform without defining it.

More promising is their call for more research. They note,

> There is much that we do not know about the kind(s) of field research political scientists are doing today . . . We need more systematic, policy-oriented research about members' field research practices, and we call on APSA to take the lead in conducting or facilitating it . . . (491)

They mention the possibility of an APSA handbook on ethical issues and current regulations.
This sounds a bit like the effort undertaken by the American Psychological Association in the preparation of its 1973 Ethical Principles in the Conduct of Research with Human Participants. As described in the first chapter of that book, rather than sit together and lay down some rules, the drafting committee surveyed the APA membership and assembled thousands of descriptions of real research projects that had raised ethical issues. The descriptions became the basis for an ethical guide directly relevant to the needs and values of the APA's members.
Around the same time, APSA itself undertook a similar effort, on a smaller scale, by conducting a study of actual cases in which researchers faced problems with confidentiality. Unfortunately, the full study seems not to have been published. A brief summary was published as James D. Carroll and Charles R. Knerr, "The APSA Confidentiality in Social Science Research Project: A Final Report," PS 9 (Autumn 1976): 416-419.
Whether or not a detailed ethical study would help ethnographic political scientists with their IRBs, it would be a great resource for scholars who want to do right by the people they study. I hope APSA–and other scholarly societies–will consider such a project.

1. http://www.apsanet.org/imgtest/PSJuly08YanowSchwartz-Shea.pdf

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3.7.7 The Biomedical Ethics Juggernaut (2008-07-11 10:54)

The third contribution to the PS symposium is Tony Porter, "[1]Research Ethics Governance and Political Science in Canada."
Porter laments that "the history of research ethics governance in Canada reveals recurrent concerns expressed by political scientists and other SSH [social sciences and humanities] researchers that indicate the inappropriateness of the [ethics] regime for SSH research, and that also create the impression that the regime is a juggernaut that continues on its trajectory, relatively impervious to criticism." (495)
Porter then offers a helpful capsule history of the debates leading up to Canada's present policy statements. From an American perspective, they look pretty good. In contrast to the Belmont Report, which calls for informed consent and harms-benefit assessment without specifying the types of research to which it applies, Canada's Tri-Council Policy Statement declares:

> certain types of research— particularly biographies, artistic criticism or public policy research—may legitimately have a negative effect on organizations or on public figures in, for example, politics, the arts or business. Such research does not require the consent of the subject, and the research should not be blocked merely on the grounds of harms-benefits analysis because of the potentially negative nature of the findings. (496)

Unfortunately, Porter finds that in practice, research ethics boards ignore such guidance. For his own article, he was asked to specify questions in advance, destroy data, and write long explanations of his research plans. And he warns of even stricter regulation ahead.
Porter attributes the imposition of biomedical ethics and regulation on non-biomedical research to the clout that biomedical researchers have in government and universities. There are more of them, they have more money, and they care more about ethics–since they face more serious ethical challenges. As a result, "the growth of a biomedically oriented but unified research ethics regime has appeared as a seemingly unstoppable trend in Canada." (498) Rather dismally, Porter suggests that the only thing that will stop that trend is its own ability to alienate researchers until "opposition on the part of SSH researchers will increase and the legitimacy of the arrangements will be damaged, as will the ability of the regime to elicit the degree of voluntarism and acceptance that is needed to sustain it." (498)
Perhaps for lack of space, Porter does not consider another possibility: that the social sciences will internalize the medical ethics implicit in the "unified research ethics regime." The American Anthropological Association took a big

step in this direction in 1998, with the adoption of a code of ethics that comes close to rejecting the idea that research "may legitimately have a negative effect on organizations or on public figures." If the ethics regime grows stronger in Canada and elsewhere, and more social scientists follow the AAA's line, it may be that young people interested in "critical research," as Porter puts it (496), will seek careers in journalism, rather than in university scholarship. To use a Canadian example, if [2]Russel Ogden were writing for a newspaper, no one would be blocking his research.

1. http://www.apsanet.org/imgtest/PSJuly08Porter.pdf
2. http://www.institutionalreviewblog.com/2008/07/research-restrictions-not-confined-to.html

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3.7.8 Can We Patch This Flat Tire? (2008-07-14 15:19)

The fourth article in the PS symposium is Felice J. Levine and Paula R. Skedsvold, "[1]Where the Rubber Meets the Road: Aligning IRBs and Research Practice." Both authors been involved in IRB debates for several years, and this article reflects their sophisticated understanding of some of the issues involved. But for an article published in a political science journal, it is disappointingly insensitive to the power dynamics that govern IRB-researcher relationships.
Unlike symposium participants [2]Tony Porter, [3]Dvora Yanow and Peregrine Schwartz-Shea, Levine and Skedsvold do not question the premise that IRBs help promote ethical research. Instead, they assert that there is no fundamental conflict between IRBs and social science researchers: "federal regulations, professional ethics codes, and research practice may have shared goals but tend to speak with different languages—creating frustration and skepticism in a system that could potentially work quite well if transformations are made." (502) Based on that assertion, they suggest four such transformations, ranging from the bold to the timid.

Decentralizing the IRB

The first suggestion is the boldest: establishing IRBs at the level of the individual department or research unit. These departmental IRBs would still meet the requirements of 45 CFR 46, but they would include–and presumably be led by–researchers familiar with the methods under review. As I've written before, for those projects that can benefit from prospective review, I do like the idea of putting the responsibility for review in the hands of [4]scholars who know something about the proposals they encounter.
But Levine and Skedsvold seem naive when they suggest that "the regulations still provide latitude for institutions interested in developing new models for a local human research protection system to do so." (502) Reading the regulations in the absence of OHRP actions and policy statements doesn't tell you much about the real requirements for IRBs. For example, the regulations do not require that a quorum be documented for every IRB action item, but OHRP does. [Norman Fost and Robert J. Levine, "The Dysregulation of Human Subjects Research," JAMA 298 (14 November 2007), 2196.] That kind of picky demand can only be met by expert staff, which tends to move power away from IRB members and toward the administrators who have the time to keep up with all the rules. It also makes it harder to establish multiple IRBs.
Particularly painful is the article's pseudo-historical claim that "in contrast to when IRBs were first established, colleges and universities today are larger and more complex organizations with many more human subjects protocols to review," and therefore decentralization is more needed today than in the past. (503) Nonsense. When the Department of Health, Education, and Welfare first imposed IRB requirements for a wide range of research in the early 1970s, the fields of anthropology, political science, psychology, sociology, and the like were as varied as they are today, with differing ethical codes and methodological practices. To accommodate this diversity, some universities sought just the kind of department-level review that Levine and Skedsvold now propose. But OPRR (OHRP's predecessor) crushed that effort, insisting that all these fields be lumped into a single "behavioral" category. As Donald Chalkley, OPRR's director, put it in 1976,

> There were several questions with regard to the use of sub-committees by Institutional Review Boards. We have encouraged it, we have discouraged it. We have discouraged it when the tendency was to put a

> sub-committee in every department. We beat Ohio State out in that. And we have encouraged it when it was obvious to us that a board that had begun primarily as a medical board, was not capable of dealing with behavioral research and things of this sort. In fact, our current listing in general assurances distinguishes between those institutions which are capable of dealing with medical subjects, and those that are capable of dealing only with the behavioral. [National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Transcript, Meeting #24, November 1976, 175].

Would today's OHRP act differently? Here's hoping.

Simplifying and Expediting Expedited Review

The second suggestion is modest, but still important. Levine and Skedsvold suggest that IRBs be required to report on their efficiency at handling expedited reviews:

> Through the FWA, institutions could describe the expected timeframe for completing expedited review and provide an annual report regarding, for example, the number of applications submitted and approved for expedited review, the number that were ultimately taken to full review, and the time span between filing for expedited review and action by the expedited review official. (503)

While it seems a pity to add another layer of paperwork to the IRB process, quantifying IRB performance might be a start toward IRB accountability. As [5]Atul Gawande has advised, "if you count something interesting to you, I tell you: you will find something interesting."
It's important, however, to find ways to keep IRBs from gaming the statistics. IRBs have killed a lot of projects–by delaying approval until the researcher gives up, or forcing the researcher to modify the proposal beyond recognition–without outright rejecting them. I suggest, then, that the statistics proposed here are only the beginning. Indeed, if we are serious about IRB accountability, we need several measures of effectiveness. To date, we don't have one.

Limiting Review of Public Use Data Files

The third suggestion is that IRBs stop reviewing studies that use "public use data files," which contain "only data collected in anonymous form or that has been stripped of direct and indirect identifiers." The authors suggest a certification scheme so that "local IRBs would no longer need to determine that the use of the file by an investigator meets the criteria for exemption from IRB review." (503)
This sounds sensible enough, though I'd like to get more details about what kinds of files would need such certification. As I reported earlier, UCLA believes that its researchers need [6]IRB permission to read blogs (UCLA's [7]Policy 42 includes specific instructions for how to get permission to read a blog, or a letter to the editor.) I'd like Levine and Skedsvold to elaborate definitions to avoid this kind of hyper-regulation.

Enhancing the Educative Function of IRBs

The final suggestion is the most timid, and the least helpful. Levine and Skedsvold suggest education as a panacea:

> Local IRBs could sponsor a monthly open meeting to answer questions about federal regulations, local policies, and/or issues relating to specific protocols. Developing opportunities for education and advisement could assist institutions in creating a positive climate for improving human research protections. While educating investigators about the overall system, IRB members and investigators can discuss ideas about, for example, reducing risk or enhancing confidentiality protections as researchers are developing protocols. (503)

This reminds me of earlier calls for simple cooperation between IRBs and researchers, for example, Robert Cleary's 1987 suggestion:

> Fundamentally, [IRBs'] work aims at the heightening of sensitivity among researchers to the need to protect human subjects. Thus the main problems involving the work of IRBs in political science seem to be perceptual and informational, rather than regulatory. Fortunately, these are the kinds of problems that people of good will can solve. And in my opinion the positive results for the protection of human subjects make it worthwhile to try! [Robert E. Cleary, "The Impact of IRBs on Political Science Research," IRB: Ethics and Human Research 9 (May-June 1987), 10.]

But such calls for communication and discussion ignore the profound differences that divide IRBs and social researchers. Pick any horror story you want–[8]Tony Porter's, [9]Tara Star Johnson's, [10]Scott Atran's–and you'll find a researcher who knows what she's doing confronting an IRB that does not. IRBs cannot educate investigators about the overall system because they don't know very much about the overall system–if the "overall system" is taken to include the ethics and methods of various branches of the social sciences and humanities. Nor do they have much incentive to learn anything.

I refer Levine and Skedsvold to the ethnographic studies of IRBs by [11]Laura Stark and [12]Maureen Fitzgerald. Both found that IRBs' public policies had little bearing on their actual decision processes. An IRB that holds a monthly open meeting to expound on fundamental ethical principles, then retreats behind closed doors to reject proposals based on spelling errors, is not going to instill the kind of respect among researchers that Levine and Skedsvold want.

An alternative would be to require that IRBs document their reasons for decisions on each proposal, creating what Jack Katz has called a system of "legality." Katz explains:

> Legality changes the interaction environment of decisionmaking by creating a series of processes in which the reviewed become capable of examining and publicly criticizing the review to which they are subjected, both on a retail, case-by-case basis, and on a wholesale, policymaking level. [Jack Katz, "Toward a Natural History of Ethical Censorship," Law & Society Review 41 (December 2007), 805.]

Katz presents legality primarily as a way to protect researchers against IRB censorship, but it would also be an excellent way to provide the kind of education Levine and Skedsvold want. For example, in the early 1970s, the Berkeley IRB assembled a handbook based on 2500 cases it had decided. By showing in concrete, not hypothetical, terms what the IRB considered to require review and what qualities it looked for in a proposal, the handbook both empowered and educated Berkeley researchers. But the handbook was part of a broader effort that excused some researchers from IRB review, and Chalkley's OPRR killed that too.

OHRP's Role

The authors acknowledge that IRB overregulation emanates from Bethesda, and they conclude that the ball is in OHRP's court.

> By acknowledging that there are multiple ways to protect human research participants within the parameters of the federal regulations, OHRP would provide needed reassurance for institutions and investigators. Furthermore, to promote new ideas in this area, OHRP could develop a call for reform models and thereby signal to institutions its support for change. (504)

I agree that OHRP is crucial here; one cannot expect local IRBs–vulnerable as they are to OHRP's wrath–to stick their necks out with new initiatives. But how likely is OHRP to lead the cause of reform?

As Levine and Skedsvold concede, OHRP has ignored earlier calls–going back to 2002–for some of the very reforms they advocate. The authors are silent on why that should be, or why we should expect better treatment now. OHRP's record of ignoring social scientists' calls for reform challenges the overall assumption in this article that OHRP is interested in helping social scientists with their research. Here's a case where they could have used some of the more skeptical perspective of [13]Tony Porter.

Let's face it: the regulation of medical research is a lot more important, in lives and dollars, than the kinds of work that Levine, Skedsvold, and I care about. Whatever the regulations say, whatever "flexibility" they offer, we can expect OHRP to keep its eye on medical research, and to issue rules solely with medical research in mind. Serious reform may take much bolder restructuring than Levine and Skedsvold admit.

1. http://www.apsanet.org/imgtest/PSJuly08LevineSkedsvold.pdf
2. http://www.institutionalreviewblog.com/2008/07/biomedical-ethics-juggernaut.html
3. http://www.institutionalreviewblog.com/2008/07/ideas-on-fieldwork-are-oldies-but.html
4. http://www.institutionalreviewblog.com/2007/08/macquaries-respect-for-expertise.html
5. http://books.google.com/books?id=hTKrkBmYKDQC
6. http://www.institutionalreviewblog.com/2008/04/do-ucla-researchers-have-permission-to.html
7. http://oprs.ucla.edu/human/documents/pdf/42.pdf
8. http://www.institutionalreviewblog.com/2008/07/biomedical-ethics-juggernaut.html
9. http://www.institutionalreviewblog.com/2008/06/irb-disciplines-and-punishes.html
10. http://www.institutionalreviewblog.com/2007/05/scott-atran-research-police-how.html
11. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
12. http://www.institutionalreviewblog.com/2008/03/maureen-fitzgeralds-ethics-project.html
13. http://www.institutionalreviewblog.com/2008/07/biomedical-ethics-juggernaut.html

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Levine & Skedsvold (2008-07-16 17:07:00)

We appreciate your taking seriously, and commenting on, the recommendations we offer for change. Unfortunately, short of significant regulatory reform (which is not likely) or other creative solutions, social scientists will find themselves at this same place years from now. Even Congressional action (e.g., at least one bill is being redrafted now) is not likely to help matters. Our approach was to attempt to identify areas in which institutional change could occur now without regulatory change. We are not insensitive to (or naïve about) the troubled relationships between social science researchers and IRBs. These troubled relationships have been present from the creation of the human research protections system in this country and have been the subject of much discussion over recent years. And historians, for one, have been particularly effective in raising their concerns. Despite these power dynamics, however, there is room for change. Our article is directed at trying to focus on some feasible changes and to move beyond problem specification to problem solving. Also, we do not see "education as a panacea," but we do think that providing opportunities for the exchange of ideas around methodological or regulatory issues could lay the groundwork – at least at some institutions – for positive change. Our illustrations were not just empty calls for education, but steps that could change how IRBs come to understand their role (e.g., providing advice as protocols are developed). We cite research showing the benefits of a more transparent, open, and legitimate process. Indeed, a panel of social scientists assembled by the National Academies has also called for researchers and IRBs to seek a better understanding of the functions and constraints on each other as a way to improve the process.

Levine and Skedsvold

Zachary M. Schrag (2008-07-16 23:16:00)

Thank you for your essay and for this helpful comment.

I am glad your comment makes explicit your assumption that we are unlikely to achieve positive regulatory or legislative change any time soon. Perhaps I am the naive one, but I think such change is actually more likely than the kind of enlightened leadership you seek from OHRP. At today's meeting of the Secretary's Advisory Committee on Human Research Protections, several committee members expressed their frustration with the current regulations, while also noting that OHRP's limited resources prevent it from leading reform efforts. Nor do OPRR/OHRP's actions in the past give me much hope. So I don't think I'm alone in thinking that we need at least to consider strategies for changing the regulations, and perhaps the statute which they

claim to implement.
Of course, efforts at incremental and radical reform can proceed simultaneously, which is why I was glad to read your article. But I would like to know why you think your proposed reforms are any more likely to be adopted than those of the 2003 National Academies panel. As you note in your article, "good ideas . . . are yet to be tested or implemented on a wide scale." (502) That may be an understatement; in five years, has OHRP made any effort to implement any of the National Academies panel recommendations?
In sum, you two and I share some basic hopes for a reformed system. I think we would all like to see a greater role for review at the department level, ethical training for researchers tailored to their own methods and topics, and some way of holding IRBs to standards of procedural justice. And we may be equally pessimistic about achieving such outcomes nationwide. But while you direct your pessimism at Congress and the Common Rule signatories, I'll target mine at OHRP and the local IRBs.
Zach

3.7.9 Political Scientists to the Rescue? (2008-07-17 21:51)

The final essay in the PS symposium is Sue Tolleson-Rinehart, "[1]A Collision of Noble Goals: Protecting Human Subjects, Improving Health Care, and a Research Agenda for Political Science."
Tolleson-Rinehart addresses the question of quality improvement in health care, such as the checklist publicized by Atul Gawande. As she notes, her "essay is not about the influence of IRBs on political science research" and is therefore largely outside the scope of this blog. That said, she makes some observations relevant to the regulation of social science research.
While sympathetic to individual IRB members, Tolleson-Rinehart takes a dim view of the system as it now operates:

> IRBs are understandably, and necessarily, driven by their limiting case: the possibility of invasive or dangerous procedures performed with vulnerable individuals or populations, without adequate regard for the hallmarks of protection, respect for persons, beneficence and nonmaleficence, and justice elucidated in what is widely known as the Belmont Report, and adopted from the time of the Belmont Report's release as our fundamental ethical principles. It is not surprising, given IRBs' role as the protector of the vulnerable, that the general IRB perspective on "minimal risk" and risk-benefit comparisons is a conservative one.
> IRBs are also terrified. All IRB professionals I know work in real fear that their IRBs could be the next ones to cause an entire university's research to be shut down. Shutdowns in recent years at Harvard, Duke, and Johns Hopkins give IRBs every reason to be fearful of making what OHRP considers to be an error. The reasonable suspicion that researchers regard IRBs as obstacles to, rather than facilitators of, research, must further IRB professionals' sense of being embattled.
> Reviewers on IRB committees are our very hardworking colleagues who are usually not given adequate release time to meet their committee responsibilities, and who are not able to benefit from truly extensive and nationally standardized training, nor do they have anything like a consensus metric for evaluating the spectrum of risk in different research contexts and for different populations.
> All these sources of strain might determine the conservative approach to human subject protections. When social science research (including quality-improvement research) occurs in a biomedical context, or when health care and health policy require evaluation, the conservative stance can become dysfunctional. IRB assessments of my own students' work provide a clear example of one of the ironic and unintended consequences of the absence of agreed upon and broadly understood metrics for assigning risk in different research contexts. IRBs have a comparative lack of familiarity with how social science methods— such as those used in quality-improvement research—may differ from some other methods of clinical research in the risks they pose to subjects. (508)

She adds that while her own students submit "substantially similar" protocols, their

> IRB determinations range from declarations that the project is “not human subjects research” at all to “research that requires full consent,” with every intermediate determination. I frequently have students working simultaneously on very similar projects, one of whom must go through a tedious consenting process taking as much as four to five minutes of the beginning of telephone interviews (with the busy elites at the other end chafing at these long and unnecessary prefaces to the first question), while another student researcher is not required to secure any kind of consent at all. The single source of variation across these cases is not the research question or the method, but the IRB reviewers and their familiarity or lack thereof ! with in-depth interviewing and the unique protections already available, via one’s position, to the “powerful research subject.” (509)

This is damning enough, but Tolleson-Rinehart insists that the "point of this vignette is not to criticize IRBs." (509) Rather, she argues that

> political science is well prepared to analyze and make normative (but evidence-based) recommendations about the politics of human subjects research. We can help define what it is, and the circumstances under which it is generalizable knowledge, even though it may not necessitate a conservative approach to protections. We can construct frameworks to achieve a more precise understanding of how to balance risks and benefits. Those frameworks might even lead us to formulate what would amount to a multidimensional risk scale. Finally, political science can contribute to the construction of theoretical and methodological underpinnings for the content of truly national standards for IRB training curricula. These would improve IRB reviewers’ understanding of different research methods to go beyond mere compliance with federal regulations and become real resources and decision aids for hard-pressed reviewers who may have to evaluate research they aren’t familiar with. (509)

Finally, Tolleson-Rinehart notes that while the Association for the Accreditation of Human Research Protection Programs and Public Responsibility in Medicine and Research mean well, both emphasize regulatory compliance over actual research ethics. She argues that political scientists can go beyond compliance questions to work on "a common epistemology of the philosophical, ethical, and political foundations of human subjects research." (510)
All of this sounds fine, and I hope that Tolleson-Rinehart and her colleagues get to work on her agenda. But as my [2]recent exchange with Levine and Skedsvold suggests, the most immediate question for political scientists may be to figure out how to make the regulatory system more responsive to developments in research. We seem stuck with a 1974 law and 1991 regulations that cannot be changed, even when everyone agrees they need updating.

1. http://www.apsanet.org/imgtest/PSJuly08Tolleson-Rinehart.pdf
2. http://www.blogger.com/comment.g?blogID=52577829256555451 9&postID=4693306898310512811

3.7.10 Report from SACHRP, Part 1: A Systems Level Discussion (2008-07-23 16:04)

On July 16 I attended the second day of the open meeting of the [1]Secretary’s Advisory Committee on Human Research Protections (SACHRP, pronounced sack-harp) in my home town of Arlington, Virginia. This was the first time I have observed such a meeting, and I am sure there is much I missed for want of context. But in this and following posts, I will record a few impressions.

The most interesting part of the meeting came at the end, when the committee's chair, Samuel Tilden, invited committee members to participate in "a systems level discussion" of today's human subjects protection regime. Not all committee members offered comments, and I was disappointed that anthropologist Patricia Marshall, the sole social scientist on the committee, did not do so. But the members who did speak displayed a range of viewpoints.

The most enthusiastic advocates of the status quo were Jeffrey Botkin and Daniel Nelson. Botkin described himself as an "unabashed advocate of current system." He noted that IRBs rose in response to documented abuses in medical research, such as those detailed by Henry Beecher in 1966 ["Ethics and Clinical Research," New England Journal of Medicine 274 (16 June 1966): 1354-1360]. Today, he noted, most researchers know the rules. While the system may let an occasional unethical project slip through, there is no "hidden underbelly of unethical research."

This is an important point, and I remain agnostic about whether IRBs are appropriate for medical research. But I am also sure that Dr. Botkin understands that even beneficial drugs can have nasty side effects, and that he would not prescribe the same drug to treat all ailments. I would be interested to know what he considers the social science analogue to Beecher's article. For if we are to judge today's system by its ability to avoid documented problems of the past, we need to know what we are trying to avoid for every type of research we regulate.

Nelson declared that the "Subpart A Subcommittee" he co-chairs decided early in its existence that "there is general consensus that the Common Rule is not 'broken.'" Yet in his system-level talk, he conceded that the power granted by the Common Rule to local IRBs results in arbitrary decisions (he called this "variability") and "well-intended overreaching." He noted that the only sure way to eliminate all risky research is to eliminate all research.

Other committee members, while not calling for changed regulations, were more explicit about current problems. Lisa Leiden, an administrator at the University of Texas, has heard from a lot of upset faculty, and she is looking for ways to relax oversight. This would include "unchecking the box," that is, declining to promise to apply federal standards to research not directly sponsored by a Common Rule agency. Without going into specifics, she suggested that the federal standards are too stringent, and that the University of Texas system, if freed from them, would craft exemptions beyond those now offered by the Common Rule. Overall, she is looking for ways to move from a "culture of compliance to one of conscience."

Liz Bankert, Nelson's co-chair of the subcommittee, also showed her awareness of the overregulation of social research, and her frustration with IRBs' emphasis on regulatory compliance. "I've gone to IRBs all over the country," she reported. "They are thoughtful, sincere, really intelligent groups. To have all this brainpower sucked into the vortex of minimal risk research is not efficient." It also contributes to what Bankert sees as a lack of mutual respect between IRBs and reseachers. She blamed the problems on a "fear factor which has been developing over the past several years."

Both Leiden and Bankert implied that it was the interpretation of the regulations, not the regulations themselves, that caused the problems they have identified. Without saying so explicitly, they seemed to blame the OPRR of the late 1990s for scaring IRBs all over the country into letter-perfect regulatory compliance, at the expense of research ethics.

In contrast, two committee members seemed willing to reconsider the regulations themselves. David Strauss hoped for a system that was "clinically and empirically informed," terms that no one could apply to the regulation of social research. And he recognized that the regulations are not divine revelation. "We shouldn't be reviewing research that we don't think needs to be reviewed because some folks 30 years ago, at the end of a long, hot day, decided to use the word 'generalizable,'" he explained. "We have to have language that makes sense to us."

Finally, Tilden himself described the Common Rule as largely broken. He noted that the 1981 regulations–which have changed only slightly since–were accompanied by the promise that most social research would not have to undergo IRB review. The fact that so few social science projects escape review, he concluded, showed that the exemption system has collapsed. Rather than try to shore it up again, he suggested that concerns about confidentiality be separated from other risks, and that projects whose only risks involved breaches of confidentiality be evaluated only for the adequacy of their protections in that area.

This last proposal interests me, because when scholars talk seriously about the wrongs committed by social science researchers, they almost always come back to questions of confidentiality. If IRBs were restrained from making up other dangers–like interview trauma–and instead limited to more realistic concerns, they could potentially do some good.

In sum, I did not get the impression that, in Nelson's words, "there is general consensus that the Common Rule is

not 'broken.'" Strauss and Tilden, in particular, seem to understand that the present system has wandered far from the stated intentions of the authors of the regulations, and from any empirical assessment of the risks of research or the effectiveness of IRBs. I hope they will continue to think about alternative schemes that would keep controls on medical experimentation without allowing federal and campus officials free rein to act on their fears.

1. http://www.hhs.gov/ohrp/sachrp/index.html

3.7.11 Report from SACHRP, Part 2: The Calcified Common Rule (2008-07-25 21:52)

Part of the [1]SACHRP discussion last week concerned a provision of the Common Rule to which I had not paid much attention. As the Subpart A subcommittee noted, [2]45 CFR 46.117(c)(1) provides that

> An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds . . . that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern . . .

Several committee members noted that this last bit–about asking the subject if she wants the documentation that an IRB has determined will put her at risk–is pretty stupid. David Forster noted that offering a signed document can create unnecessary distrust. Neil Powe and Daniel Nelson suggested that it would be a significant burden for a researcher to devise and gain approval for a consent form on the off chance that a subject will demand one. Everyone seemed to agree that this provision is never enforced, and that it would be a bad idea if it were.

But what to do about it? As members of an official body, the committee members were clearly uncomfortable recommending that IRBs ignore a provision of the Common Rule. Yet they all seemed to think that amending the Common Rule was impossible.

This kind of defeatism distresses me. Since the Common Rule was promulgated in 1991, we've amended the Constitution, added an executive department to the cabinet, and brought professional baseball back to Washington, D.C. I'm sure it's a pain in the neck to bring together all the Common Rule signatories, but can't it be done every seven years, or ten? Or are we to endure these kinds of errors for a century?

I have not yet figured out who put in the provision that subjects be offered documentation even when it threatens them. The National Commission recommended no such requirement, yet it appeared in the draft regulations of August 1979. Someone in the Department of Health, Education, and Welfare made a mistake thirty years ago, and now we're stuck with it.

1. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-1-systems-level.html
2. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117

3.7.12 Report from SACHRP, Part 3: When Consent Means Censorship (2008-07-26 20:57)

A third item of interest from this month's SACHRP meeting concerns rules about research on Indian reservations. According to a handout provided at the meeting, in March 2008, Dr. Francine Romero–an epidemiologist and former member of SACHRP–proposed that the Common Rule be amended to specify that

> For human subject research to be conducted wtihin the jurisdiction(s) of federally recognized American Indian or Alaska native (AIAN) Tribal government(s), the IRB shall require documentation of explicit Tribal approval for the research. This approval shall come from the Tribal Council or other agency of the Tribal government to whom such authority has been delegated by the Council.

The Subpart A Subcommittee decided that while amending the Common Rule was neither "efficacious, expeditious, nor appropriate," it apparently thought the overall idea a good one, and recommended that OHRP develop guidance to assure that researchers get permission from Tribal governments to do research within their jurisdiction. In the general discussion, various SACHRP members and other federal officials debated whether OHRP was the right office to handle the task, and they modified the recommendation to include other HHS agencies.

As I pointed out during the public comment period, similar rules in Canada have [1]deterred historians from including First Nations Canadians in their research, and give Band Councils veto power over who in their communities gets to talk with a university researcher. And in California, a Tribal government used an IRB to [2]suppress research on labor conditions in casinos. But at no point during the SACHRP discussion did anyone consider the effect the recommendation would have on social science research.

Since 1966, IRB policies have been determined by bodies dominated by medical researchers, and SACHRP is just the latest in a long list. However much medical researchers and administrators may want the trust and respect of social researchers, they simply cannot keep in mind the rights and responsibilities of social scientists when something like this comes up. For medical researchers, it seems, more consent is always better, and they forget that one person's consent is another's censorship.

In related news, today's New York Times reports that the U.S. military has suppressed photographs of American casualties in Iraq by insisting that photojournalists obtain written consent from the troops they photograph:

> New embed rules were adopted in the spring of 2007 that required written permission from wounded soldiers before their image could be used, a near impossibility in the case of badly wounded soldiers, journalists say . . . Two New York Times journalists were disembedded in January 2007 after the paper published a photo of a mortally wounded soldier. Though the soldier was shot through the head and died hours after the photo was taken, Lt. Gen. Raymond T. Odierno argued that The Times had broken embed rules by not getting written permission from the soldier.
> [Michael Kamber and Tim Arango, "[3]4,000 U.S. Deaths, and Just a Handful of Images," New York Times, 26 July 2008]

1. http://www.institutionalreviewblog.com/2007/01/nancy-janovicek-offers-canadian.html
2. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html
3. http://www.nytimes.com/2008/07/26/world/middleeast/26censor.html

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3.7.13 The Dormant Right to Ethical Self-Determination (2008-07-29 12:05)

The Common Rule, in [1]45 CFR 46.103(b)(1), requires that each institution receiving funding from a Common Rule agency must submit an assurance that includes

> A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing

> code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.

In contrast, OHRP's [2]Federalwide Assurance requires U.S. institutions to pledge that

> All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.

Curious about the discrepancy, I submitted a Freedom of Information Act request for a list of those institutions that selected something other than the Belmont Report. In response, I received a letter, dated July 15, with a list of 36 institutions, mostly health clinics and hospitals. Of teaching institutions, only two–Langston University and Northeast Iowa Community College–had declined to endorse the Belmont Report. Langston listed the Common Rule itself as a statement of ethical principles. I have not gotten a reply to my query to Northeast Iowa, but I must suppose it likewise does not challenge the Belmont Report meaningfully.

Thus, with two possible exceptions, it's fair to say that OHRP has persuaded every college and university in the United States to promise that the Belmont Report will guide all "human subjects research activities."

Let's review.

1. The Common Rule (46.101) exempts a broad range of activities from IRB review. These exemptions were granted in response to a hard fight by social scientists, and they came with the promise that they would "[3]exclude most social science research projects from the jurisdiction of the regulations." But since 1995, OPRR/OHRP has rendered these exemptions meaningless by insisting that [4]researchers cannot themselves determine if the exemptions apply. As a result, [5]IRBs routinely ignore the exemptions.
2. The Common Rule (46.102) applies only to "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Rather than trying to understand what the National Commission meant by this, OHRP officials redefine "generalizable" based on a [6]phone call from [7]the nation's worst IRB or an [8]awkward medical analogy.
3. The Common Rule (46.103) gives institutions the choice of any ethical principles they like; they can even write their own. OHRP imposes the Belmont Report.
4. The Common Rule (46.107) promises that IRBs will include members expert in all the research they review. But [9]OHRP does not enforce that requirement for the social sciences.

No, the Common Rule doesn't look so bad on paper. But since the mid-1990s, its alleged enforcers at OPRR and OHRP have ignored the provisions crafted in 1981 to address the concerns of social scientists, the President's Commission, and members of Congress. I am pessimistic about OHRP's capacity to fix a broken system, because OHRP itself has done so much to break it.

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103
2. http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm
3. http://www.hhs.gov/ohrp/documents/19810126.pdf
4. http://www.institutionalreviewblog.com/2007/08/guidance-creep.html
5. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
6. http://www.oprs.ucla.edu/human/documents/pdf/oral-history-031209.pdf
7. http://www.institutionalreviewblog.com/2008/04/do-ucla-researchers-have-permission-to.html
8. http://www.institutionalreviewblog.com/2006/12/carome-cohen-and-normal-science.html
9. http://www.institutionalreviewblog.com/2007/10/dormant-right-to-expertise.html

3.8 August

3.8.1 Social Scientists Debate Defense Department Funding (2008-08-03 20:53)

Today's Washington Post reports contrasting reactions to a Department of Defense plan to give $50 million in grants to social scientists to study such issues as China's military and political violence in the Islamic world. [Maria Glod, [1]Military's Social Science Grants Raise Alarm," Washington Post, 3 August 2008]

Some anthropologists quoted in the story seem to reject any military sponsorship as unethical. David Price, whose book on anthropologists during World War II is on my reading list but not yet in my library, objects that the program "sets up sort of a Soviet system, or top-down system. If you look at the big picture, this will not make us smarter – this will make us much more narrow. It will only look at problems Defense wants us to in a narrow way." By contrast, Rob Townsend of the American Historical Association notes that "hopefully, a project like Minerva will provide some historical perspective before, rather than after, it is needed."

The Post correctly explains that this debate is a replay of controversies in the 1960s, when the Pentagon and CIA sponsored studies of Latin America and Southeast Asia, including the infamous "Project Camelot." Throughout the 1960s and 70s, scholars struggled to find ways to lend their skills and insight to sound public policy without sacrificing their intellectual independence and integrity. Obviously, this is not an easy thing to do, and questions of sponsorship remain among the most difficult ethical problems faced by social scientists.

For a blog about IRBs, the salient point is the irrelevance of the Belmont Report to such questions. The authors of that report were steeped in the history of medical experimentation, and the report reflects their concerns about past abuses of poor ward patients, Nazi concentration camp prisoners, and the rural black men enrolled in the Tuskegee syphilis study. They knew nothing of Project Camelot, anthropology's "Thai affair," or less spectacular concerns about corporate sponsorship. As a result, the Belmont Report, while getting rather specific about such medical concerns as selection of subjects, says nothing about the conflicting duties to sponsors, subjects, and the truth. When applied to social science, the report gives the wrong answers to some questions, and no answers to others. And if anyone were to attempt to write a Belmont-style report on the ethics of social science, they would find various scholarly disciplines clashing over programs like this one.

1. http://www.washingtonpost.com/wp-dyn/content/article/2008/08/02/AR2008080201544.html

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3.8.2 The New Bureaucracies of Virtue (2008-08-10 12:44)

Pity the poor blogger. When I started this blog, I expected to report on the occasional journal article on IRB review of the social sciences. Instead, I find that journals insist on publishing special symposium issues with several articles on the topic. Rather than sipping a beer I must down a six-pack.

In the coming weeks I plan to take on the November 2007 issue of [1]PoLAR: Political and Legal Anthropology Review (Vol. 30, Number 2), which includes eight articles totally 147 pages, some of them based on an October 2006 symposium at Cornell. In their introduction to the symposium, organizers Marie-Andrée Jacob and Annelise Riles, write,

> Although we certainly do not defend the current regulatory framework of research, we also wanted to press the pause button on the ambient criticism of IRBs and accompanying expressions of fears and anxieties about their impact on research and free speech. Instead, we wanted to trigger a discussion that would harness, among other things, these practical anxieties in the service of a larger theoretical and epistemological inquiry. (183)

As someone more interested in the practical than the theoretical or epistemological, I'm not sure this is my thing, but I'll do my best. And while I can't promise to comment on all the essays, here's the table of contents:

- Marie-Andrée Jacob and Annelise Riles, "The New Bureaucracies of Virtue: Introduction"
- Charles L. Bosk, "The New Bureaucracies of Virtue or When Form Fails to Follow Function"
- Amy Swiffen, "Research and Moral Law: Ethics and the Social Science Research Relation"
- Jennifer Shannon, "Informed Consent: Documenting the Intersection of Bureaucratic Regulation and Ethnographic Practice"
- Marie-Andrée Jacob, "Form-Made Persons: Consent Forms as Consent's Blind Spot"
- Stefan Sperling, "Knowledge Rites and the Right Not to Know"
- Adriana Petryna, "Experimentality: On the Global Mobility and Regulation of Human Subjects Research"
- Rena Lederman, "Comparative 'Research': A Modest Proposal concerning the Object of Ethics Regulation

1. http://www3.interscience.wiley.com/journal/120707003/issue

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3.8.3 Reform or Revolution? Comment on Bosk, "The New Bureaucracies of Virtue" (2008-08-10 12:46)

Following the introduction, the first substantive piece in the [1]PoLAR symposium is Charles L. Bosk, "The New Bureaucracies of Virtue or When Form Fails to Follow Function."
In the past, Bosk has advocated living with IRB review. As he wrote in 2004

> Prospective review strikes me as generally one more inane bureaucratic requirement in one more bureaucratic set of procedures, ill-suited to accomplish the goals that it is intended to serve. Prospective review, flawed a process as it is, does not strike me as one social scientists should resist. After all, we agree with its general goals: that our informants should not be subject to untold risks, that they be treated with decency, that their confidentiality and anonymity be safeguarded, when feasible. Given this, we should not waste our energies resisting a process that has an enormous amount of both bureaucratic momentum and social consensus behind it. Instead, we should focus our energies on reforming and revising procedures; we should fix the system where it is broken.
> [Charles Bosk, "The Ethnographer and the IRB: Comment on Kevin D. Haggerty,'"Ethics Creep: Governing Social Science Research in the Name of Ethics'," Qualitative Sociology 27 (December 2004), 417.]

But at some point in 2005 or 2006, an IRB seems to have really pissed him off. In this essay, he writes that "having now been on the receiving end of IRB objections that I find incomprehensible, I appreciate my colleagues' multiple frustrations." (204) He now seems to think the system is not merely broken, but so defectively designed that it cannot be repaired:

> The presumption of prospective review—that our subjects are in need of protection— has embedded within it an insulting distrust of our integrity and motives. The insult inherent in a regulatory regime based on distrust deepens when the barriers the review system places between us and the doing of our research

> appear to protect powerful institutions from close scrutiny more than they guarantee the well-being of our research subjects. For me, the most serious defect of the current regulatory system is that the requirements of policy reduce and trivialize the domain of research ethics. In the process, our ability to conceptualize, discuss, and make sense of the ethical problems of ethnographic work is dulled. As we do our work, we face ethical dilemmas aplenty, almost none of which have to do with the dual mandate of prospective research review—the adequacy of the consent process, which is invariably reduced to concern about a "formal document" or potential risks to subjects. (194)

Bosk's essay is rich in ideas–too many, really, for an essay of this length. I will do my best to unpack them.

What is the problem?

Bosk helpfully outlines six elements he finds most common in social science critiques of the IRB system, critiques so numerous that they amount, he writes, to a "chorus of complaint."

> 1. "The mission creep or bureaucracy run amok complaint: The process of prospective review is unwarranted. There is no convincing evidence that the risks attached to social science research justify it . . .
> 2. "The inappropriate model argument: Even if what we did was sufficiently risky to warrant prospective review, the model that we are saddled with is so rooted in the model of the biomedical randomized clinical trial that we cannot use it sensibly . . .
> 3. "The fetish of written consent objection . . .
> 4. "Journalists are allowed to do what we seek to do without fetters . . .
> 5. "The chilling effect fear . . .
> 6. "There is no evidence that IRBs have been very successful in preventing just those abuses that they were designed to create argument." (200)

This is a pretty good list, though I think it omits two important elements. First, Bosk writes of the "biomedical model" only as one in which "an empirical risk calculation is available." That overlooks another element of the biomedical model: that risks are better known to the researcher than the subject. That is, an oncologist testing a cancer drug is expected to know much more about the risks of the drug than the subject taking it. By contrast, an informant in an ethnographic study will often know more about the risks of sharing a particular bit of information than does the ethnographer.

Second, Bosk's "chilling effect fear" element conflates two separate arguments. One is that ethnographers do not share the physician's duty to do no harm, and should be free to hold individuals, organizations, and communities to account for their behavior. The other, more properly labeled a chilling effect, is that scholars will be deterred from controversial research. These are distinct complaints. The first, for example, complains that IRBs might prevent researchers from studying the police, lest they harm the police–the subjects of their research. The second complains that IRBs might prevent researchers from studying victims of police brutality–claiming to protect the victims, but in effect protecting the police.

Bosk seems to find this six-part argument convincing, noting his "general agreement with its basic thrust." (196) This is something of a contrast to his position in 2004, in which he rejected comparisons between ethnographers and journalists. [Charles L. Bosk and Raymond G. De Vries , "Bureaucracies of Mass Deception: Institutional Review Boards and the Ethics of Ethnographic Research," Annals of the American Academy of Political and Social Science 595 (2004), 255.]

But Bosk is not satisfied to leave the complaint there. He writes, "the problem with the chorus of complaint is that it fails to explain the organizational logic that enabled, even encouraged, such pernicious 'mission creep' or what to do about it now that it has become an inescapable part of the lived experience of ethnographic research." (200) In the rest of the essay, he addresses those two questions.

Whose fault is the problem?

Bosk offers two sets of culprits.
The first are the IRB administrators who have flourished at research universities.

> The system of IRB review is often described as a peer review system. In reality, it is faux peer review. The labor of preparing documents, communicating negative judgments to researchers, and then negotiating with outraged, disgruntled faculty thrown off schedule by niggling objections falls to personnel that faculty most likely perceive as "merely" secretarial. The standard complaints about prospective review of research fail to mention the officeholders that administer the IRB system. IRBs are spoken of as monolithic entities. Two features of the administrative structure necessary to make compliance with federal regulation deserve underscoring. First, new occupations, training programs, and career ladders provide a great deal of practical authority to the new functionaries. Second, the functionaries who staff the new bureaucracies of virtue are able to create the impression of efficiency by shifting burdens directly to researchers and their staff. Action on proposals, a measure of administrative activity, occurs when proposals are returned to researchers for reasons no more serious than incorrect font size, incorrect pagination, or other niggling matters. (198)

Such "bureaucratic organization," he warns, "leads workers to ignore goals and focus on, even sanctify the means or operating rules and procedures. The forms properly filled out and filed, the meeting of organizational timetables, and the exercise of authority by those who possess it—all have a value that transcends the original motives and intentions that created the formal organization." (202)
In making this argument, Bosk seems to lean heavily on Caroline Bledsoe et al., "[2]Regulating Creativity: Research and Survival in the IRB Iron Cage." I don't get the sense that he has done any original research into university IRB offices and the trans-university organizations (PRIM &R, AAHRPP, etc.) that drive them. That's a pity, because more work could be done there.
Oddly, having argued that real power lies with the "functionaries," Bosk goes on to write that "we seem to forget that those who serve on IRBs are our colleagues, that their service spares us unwanted burdens, and that they deserve a civil dialogue." (205) That is hard to square with his argument that the real problems in prospective review come from administrators who–in effect–are not our colleagues, whose work creates unnecessary burdens, and whose "niggling" concern over typography does not constitute a civil dialogue.
Bosk is not content to blame the bureaucrats; he believes that ethnographers are somehow responsible for their own problems. He laments that the "chorus of complaint" fails to understand "why researchers did not more actively resist their own silencing." (207)
More active than what? The current IRB regime dates back only to 1998, and the OPRR crackdown against several research universities. In November 1999 and May 2000, the American Association of University Professors met with representatives of the American Anthropological Association, the American Historical Association, the American Political Science Association, the American Sociological Association, the Oral History Association, and the Organization of American Historians, after which the AAUP produced its 2000 report, "[3]Institutional Review Boards and Social Science Research." In April 2000, Murray Wax outlined many of the standard arguments Bosk cites, testifying to the [4]National Bioethics Advisory Commission that "the gravest ethical problem facing the people studied by anthropological research is posed by unknowing and overzealous IRB's and by governmental regulators attempting to force qualitative ethnographic studies into a biomedical mold."
This is not to say that ethnographers did all they could to fight IRB oversight. But it's not clear from Bosk's essay that he is familiar to the resistance going back to 1966.

What is to be done?

Bosk's real grievance with the chorus of complaint is not that it is inaccurate, but that "the problem with complaint, the undeniable compensatory charm that a sputtering public moral outrage provides notwithstanding, is that it does not

create a viable alternative to the status quo." (200) Perhaps, but Bosk is less clear than many choristers about his own ideas for reform. In particular, I could not determine from his essay if he still believes, as he did in 2004, that social scientists should accept prospective review, or if he now seeks to free them from IRB jurisdiction.

Parts of the present essay suggest that Bosk still seeks accommodation, as when he suggests that the problems with IRBs are so small that they "might be remedied by educating better IRB members about the nature of qualitative methods or of the regulations themselves." (206) But when he writes of flaws "inherent" and "embedded" in the present regime, that suggests a wish for exclusion. Does Bosk endorse the AAUP's 2006 [5]recommendation that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption"? I can't tell.

Instead of a clear program for reform, Bosk calls for

> an expanding collection of narratives that describe and analyze experiences with prospective review . . . By continuing to collect narratives, we will be in a better position to distinguish common problems generic to the review process across institutions from those resulting from idiosyncratic local interpretations. In the generic cases, we are then in a position to separate those that might be remedied by educating better IRB members about the nature of qualitative methods or of the regulations themselves. Idiosyncratic local problems require local solutions. (206)

This leaves open some important questions.

First, what makes an effective narrative? Bosk's own essay begins with two anecdotes, one of which hinges on the very fetishization of written consent that Bosk identifies as one of the elements of the "chorus of complaint." But the anecdote, while attributable to the University of Pennsylvania, bears no date or student name. As Bosk probably understands (though he doesn't say so here), it takes some courage for a researcher, especially a student, to come forward with complaints about powerful figures in one's own university. But without specifics, the narrative may lack authority. Does Bosk's anecdote meet Bosk's own standards?

Second, how many narratives do we need? We don't lack for them; follow the links on this blog, and you'll find dozens. The August 2005 issue of the Journal of Applied Communication Research alone contains twenty anonymous narratives along with several signed articles. Will a hundred narratives do more work than fifty?

Third, and most importantly, whom are these narratives intended to persuade? If we believe Bosk's claim that the real power lies in the hands of functionaries who value the forms of bureaucracy more than the function of research ethics, then no number of complaining narratives is likely to change anything. And if we believe that power lies in the hands of well-meaning but ignorant IRB members, then the current chorus of complaint should be sufficient to alert them to the problems of prospective review.

Bosk paraphrases Marx to say that "the point . . . is not simply to complain about the world but to change it." (196) But his call for more narratives is more a means to amplify the chorus of complaints than to effect change itself. The chorus of complaint has, in fact, suggested several alternatives to the current regime. Bosk has not.

1. http://www.institutionalreviewblog.com/2008/08/new-bureaucracies-of-virtue.html
2. http://www.institutionalreviewblog.com/2007/09/bledsoe-et-al-regulating-creativity.html
3. http://www.aaup.org/AAUP/comm/rep/A/protecting.htm
4. http://bioethics.georgetown.edu/nbac/transcripts/apr00/apr_6.pdf
5. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm

3.8.4 AHA Calls for Comments on Training (2008-08-13 17:08)

At [1]AHA Today, the American Historical Association's blog, Rob Townsend calls for responses to OHRP's recent invitation to comment on training for IRBs. As Townsend notes, the very phrasing of OHRP's questions suggest a

continued inability to remember that the office's policies have effects beyond medical research. On the other hand, he notes, some kind of training mandate is likely, so it would be best for historians not to remain silent.

1. http://blog.historians.org/profession/578/trained-to-review-oral-history

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3.8.5 Critiques of Consent Forms (2008-08-18 22:42)

Two items in the November 2007 [1]PoLAR symposium question the utility of written consent forms. Both offer important insights about the difficulty of relying on written consent, though neither presents a persuasive alternative.

Shannon, "Informed Consent"

Jennifer Shannon's contribution is "[2]Informed Consent: Documenting the Intersection of Bureaucratic Regulation and Ethnographic Practice." Shannon contrasts two experiences she had preparing written consent forms for interviews with American Indians.

From 2001 to 2003, Shannon worked as a fieldworker for the National Museum of the American Indian, part of the Smithsonian. Working with curator Cynthia Chavez, she modified an existing museum consent form to stress that the museum would seek additional approval if it wanted to use the informant's interview or image aside from a planned exhibit and related publications. This did the trick:

> Whether because it was written with the aim to increase participant's control over their contributions, the reputation of the Smithsonian was changing in Indian country, or because it was necessary in order to participate in the exhibition, in the process of fieldwork, the . . . release form was not met with resistance; Native people read the form carefully and signed it willingly. (233)

In 2004, Shannon had a new role: graduate student at Cornell University, and when she returned to fieldwork, she sought approval from the university IRB. Though "wary of inserting documents between my interlocutors and myself because of the sense of formality it introduced," she followed the IRB instructions to produce a written consent form. (236).

It bombed. Though the IRB let her write her own consent form, experts didn't like it. Joe Podlasek, the director of a Chicago nonprofit, and two National Museum curators all warned her that the document was too "legal looking," that "it inserted the institution of Cornell between community members and myself, and that once 'institutions' come into the mix, Indians are very, and rightly, 'skeptical.' [A curator] also pointed out the manipulative power inherent in saying "sign these documents, or you can't participate." (234) Fortunately, the IRB let her modify her proposal and substitute verbal, recorded consent.

What's interesting about this story is that no IRB member of staffer led Shannon astray. Rather, it was the IRB's standard operating procedures that made her write the bad consent form: "When preparing for the [IRB] requirements, I produced the consent form in a routine way according to guidelines for recorded interviews. It did not occur to me to make a case for exemption . . . " (235) This kind of IRB-caused harm is impossible to track, but I suspect it is rather common. When you flood the Web with bad advice about research ethics, it is bound to cause unknown harms.

On the other hand, I am a bit wary of Shannon's easy acceptance of the experts' claims that Indians don't like written consent forms, especially after her good experience with the Smithsonian form. With the exception of Podlasek, she doesn't report anyone expressing their own unwillingness to sign a written form, only people guessing that other people wouldn't like the Cornell form. That's like letting one person guess that another person will find a survey invasive. At the very least, this seems worthy of an empirical study. Of course, it would be great fun trying to devise the consent procedure for a study about consent.

Nor does Shannon convince me that verbal consent is taken any more seriously than written consent. She writes

> In one interview with an anthropologist who was working on an upcoming exhibition, after she agreed to be recorded, I said, "OK, then I have to say my little spiel" about the ways in which the recording could be used. She laughed, and asked, "Human subjects?" And I said yes, laughing apologetically. It was a moment where we were both complicit, in our joking, critical of the bureaucratic hoops we must jump through. There was no resistance or negotiating. She said she had had to do the same thing when she did research for her degree. This eye-rolling compliance to formalized consent occurred a number of times during my interviews with NMAI staff . . . . (235)

How is this an improvement over written consent?
And while Shannon endorses Podlasek's claim that her verbal script "was more 'flexible' and community members could discuss their own stipulations for consent and use of the material" (234), she does not report what stipulations community members imposed or why it would be easier to do that on a recording rather than on paper.

Jacob, "Form-Made Persons"

A second item, Marie-Andrée Jacob's "[3]Form-Made Persons: Consent Forms as Consent's Blind Spot," suggests how little attention research participants or patients give to consent forms.
Jacob observed the use of consent forms in transplant units in American and Israeli hospitals. As part of her work in the U.S., she had to devise a consent form that met an IRB's strict guidelines:

> My forms would be approved as ethical only if I was to mechanically mimic the aesthetics of a template form's rubrics, classification, and styles, even if it meant that some categories and boxes were bound to remain blank. This aesthetic work of uniformity had to be done in very literal ways, and features such as fonts, margins, and subtitles were of great importance. One could not change the order of the presentation of the bullet points, of information points. The ethical approval of a project can be conditional upon one's respect of the "template" and the "boiler" provided by the institution in question. This seems to imply that bureaucratic cleanliness is conflated with consent ethics, and both are purposefully composed as clear, transparent. (253)

Donors and recipients of organs were faced with even more elaborate forms, warning "Do not sign this form without reading and understanding its contents." (255)
Yet patients, research subjects, and even donors–people who were giving up major chunks of their bodies–spent little time on the forms:

> A high-level administrator and transplant surgeon, who in his work maneuvers consent forms on a daily basis, performed crisp sarcasm by signing the consent form to participate in my research without even looking at it and saying to me and to a few colleagues standing by, "Oh, I feel much more protected now that I signed this." In signing, this surgeon both reiterated his authority above the researcher within the hospital bureaucracy and submitted to the powerful yet familiar rigor of this same bureaucracy. Here, the performance of sarcastic humor appeared as a way to defuse the submission inherent in signing itself but also to assert his authority in a rubber-stamp form, about what seemed inconsequential to him. (260)

And

> An American mother who at the time of my fieldwork was undertaking medical tests to see if she could donate a kidney to her son characterized all the procedures and form filling as "just something to go through." Patients expressed this sense of "going through" recurrently to me. This mother, for example, was frustrated that the screening and evaluations take so much time: "It's like, can't you get me through this quickly?" she lamented. (257)

In an extreme case, organ donors in an Israeli hospital willingly signed a consent form that had been through so many generations of photocopies that neither doctor nor donor could read it. Since neither Americans nor Israelis read the forms they signed, Jacob finds the illegilble Israeli form the more honest.

What is the Alternative?

While both authors present the problems inherent in written forms, I don't think either author grapples with the real purposes of such forms.

The first is to clarify responsibility when something goes wrong. If the interview or the transplant goes fine, then no one needs the form. It's when one party feels ill-used that both parties to an agreement go to their files to figure out if a promise was broken. Since neither Shannon nor Jacob observed such a dispute, it's hard to accept their dismissal of written consent. It's like hearing someone complain about how uncomfortable motorcycle helmets are, without discussing the protection they offer in a crash. Yes, they are uncomfortable, and usually unnecessary, but that's not the point.

As counter-examples, I would offer the cases of two academic psychologists: [4]J. Michael Bailey and [5]Elizabeth Loftus, both of whom were the subjects of formal complaints by people they had interviewed. Bailey faced an investigation by his university, and Loftus's interview became part of a $1.3 million lawsuit against her and other defendants. In both cases, interviewer and interviewee had very different memories about the circumstances of the interview.

Written forms would not have provided full information about those circumstances, and a signed consent form cannot prove that the signer read the form carefully. But, as Shannon observed, some signers do read carefully, while others at least have the opportunity to do so. Thus, written forms in those cases might have avoided or helped resolve the dispute. It's not a perfect system, but neither Shannon nor Jacob present a superior one.

A second purpose for written forms is to allow access by other researchers, an important goal of oral history interviews. Neither Shannon nor Jacob address this issue, and Shannon's essay is particularly troublesome in this regard. The written form she developed at the Smithsonian states that "images, tapes, and transcripts of interviews will be placed in the Archives of the NMAI," (247) but it provides no mechanism for those images, tapes, and transcripts to be used by researchers. That is, even if a researcher is required to seek permission before using an interview in a publication, how is that researcher to know which interviews are of interest if not even a summary can be released without permission? What happens if an interviewee cannot be located to grant permission? What happens if an interviewee dies? Is the Smithsonian required to archive the interview in perpetuity, knowing that no one will ever be allowed to listen to it?

As [6]John A. Neuenschwander has shown, no one has yet drafted an oral history consent form that accounts for all the important contingencies without growing into a long, tangled, and legalistic contract. I'm sure that Shannon and Jacob could poke holes in any of the forms he presents, but I'm not sure they could improve on them.

1. http://www.institutionalreviewblog.com/2008/08/new-bureaucracies-of-virtue.html
2. http://www.anthrosource.net/doi/abs/10.1525/pol.2007.30.2.229
3. http://www.anthrosource.net/doi/abs/10.1525/pol.2007.30.2.249
4. http://www.institutionalreviewblog.com/2008/06/psychologist-who-would-be-journalist.html
5. http://www.psychologicalscience.org/observer/getArticle.cfm?id=2339
6. http://www.institutionalreviewblog.com/2007/11/neuenschwander-on-irbs-and-oral-history.html

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3.8.6 Oral History Association Plans Revised Guidelines (2008-08-19 17:29)

The Oral History Association has posted a [1]call for suggestions for revision of its [2]Principles and Standards. Oral historians who find themselves trying to explain their work to IRBs often rely on this statement, so it needs to be as clear as possible. I encourage concerned oral historians to join in the revision process.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=0808&week=c&msg=I6CGPO2CIZOy6hjVEAFuQA
2. http://alpha.dickinson.edu/oha/pub_eg.html

3.8.7 Can Satire Match IRB Reality? Comment on Lederman's "Modest Proposal" (2008-08-25 20:55)

The last entry in the [1]PoLAR symposium for which I will offer comments is Rena Lederman's "[2]Comparative 'Research': A Modest Proposal concerning the Object of Ethics Regulation."
Lederman, an anthropologist and sometime member of the Princeton University IRB, challenges the regulatory defintion of research: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." She correctly notes that the definition was crafted to distinguish the practice of medicine from biomedical research. As she puts it,

> U.S. human subjects research regulations (known since 1991 as the "Common Rule" but formally set in place in the early 1970s) derive from earlier National Institutes of Health guidelines based on specifically biomedical experience and ethical problematics. Their logic goes something like this: First, medical therapy is appropriately evaluated in terms of individual patient interests, because its central concern is the direct improvement of individual patient well-being. Second, medical research is appropriately evaluated in terms of society's and science's interests, because its central concern is the production of knowledge "generalizable" beyond individual cases. And third, although physical risks to persons are inherent in both medical research and therapy, the risks to individuals are qualitatively greater in research (where individual persons are not the central concern) than in therapy (where they are). Consequently, research needs special oversight. (312)

[It's worth noting that the research definition entered the regulations as a result of congressional mandate; the National Research Act of 1974 instructed the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to consider "the boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine." The result was the defintion of research now encoded in regulations.]
Lederman then explains that the boundaries between research and therapy remain fuzzy even for biomedical topics. A case study of an individual patient offers some contribution beyond therapy, but is it generalizable? What about quality improvement, like the [3]Johns Hopkins checklist?
Finally, Lederman produces her "modest proposal":

> If there are indeed other ways of knowing the world that are similarly entangled in the everyday but not yet benefiting from IRB oversight, doesn't fairness dictate that all of these modes be surveilled in the same manner? What would happen if ethnographers made common cause—all in (or all out)—not just with ethnographically inclined sociologists, political scientists, religion scholars, and folklorists but also with urban planners, architects, engineers, literary and cultural studies scholars, and colleagues in college and university writing programs—all of whom are engaged in varieties of research-with-human-participants? (320)

She then goes on to note similarities between the methods of ethnographers and novelists, asking why the latter have not been swept into the IRB dragnet.
The problem with Lederman's self-described "parodic" comparison is that some regulators and IRBs are already enacting parody as policy. As Lederman notes, "IRBs are already involving themselves in the lives of writing teachers, journalists, and others who had not heard of "human subjects research" until their own work came under scrutiny." (324, n. 10)
Other countries have taken this further. The Australian [4]National Statement on Ethical Conduct in Human Research

(2007) observes that the British definition of human subjects research "could count poetry, painting and performing arts as research," then fails to offer a defintion of human subjects research that clearly excludes those endeavors. It then goes on to state that "the conduct of human research often has an impact on the lives of others who are not participants," raising the possibility that a novelist might violate Australia's ethical standards without even talking to anyone. (p. 8) More recently, in February 2008, a Canadian committee proposed adding a chapter on [5]Research Involving Creative Practices to Canada's Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The draft chapter suggests that some creative processes are outside the purview of ethics boards, but it does not make a good case for any review of creative work, except that "researchers from a wide range of disciplines" would feel cheated if artists got special treatment.

It's too late for reductio ad ridiculum; the ridiculous is at the gates.

Like [6]Bosk's essay, Lederman's expresses frustration with IRB oversight of ethnography without clearly calling for an end to such oversight, much less offering a strategy to achieve that goal. She reports, offhand, that when oral historians seemed to have escaped IRB jurisdiction, the anthropologists she knew "were briefly thrilled, but there was no notable effort to follow suit." (318) Why this passivity? I am less interested in why ethnographers have not made common cause with novelists than in why they have not made common cause with themselves.

1. http://www.institutionalreviewblog.com/2008/08/new-bureaucracies-of-virtue.html
2. http://www.anthrosource.net/doi/abs/10.1525/pol.2007.30.2.305
3. http://www.nytimes.com/2007/12/30/opinion/30gawande.html
4. http://www.nhmrc.gov.au/publications/synopses/e72syn.htm
5. http://www.pre.ethics.gc.ca/english/workgroups/sshwc/Creative_Practices.cfm
6. http://www.institutionalreviewblog.com/2008/08/reform-or-revolution-comment-on-bosk.html

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3.9 September

3.9.1 Draft Comments on Training Requirements (2008-09-10 09:22)

Back in July I reported that [1]OHRP was seeking comments on its requirements for human subjects training for investigators and IRB members. The deadline for comments is September 29.

Here is a draft of of my comments. I would appreciate comments on the comments prior to the deadline.

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Dear Dr. Carome,

Thank you for the Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs, published in the Federal Register on July 1. I would like to offer some brief comments on this issue.

In tracing the debate over IRB review of the humanities and social sciences as it developed over the past forty years, I have yet to come across anyone who suggests that scholars should conduct research without first receiving training of some sort. The whole purpose of a university is to teach researchers to form their inquiries along lines that will produce the best results, in ethics as well as knowledge. When it comes to human subjects protections, the question is what form of training will produce those results. So far, two general models have been proposed, and I would like to offer a third.

One model demands that every university researcher, regardless of her scholarly discipline or her subject of study, complete a basic, online course in medical ethics and regulatory compliance. The CITI Program, founded by a medical researcher and a medical research administrator, exemplifies this approach. The CITI Program has the great virtue of administrative convenience. A university research office can, in a single memo, declare that all investigators must complete the program, and it can easily monitor that they have done so. But it is not clear that such mandates serve the cause of ethics, particularly when researchers are not conducting medical or psychological experiments. While the program makes efforts at including non-biomedical perspectives, the sections on such disciplines as oral history and

anthropology are written by people with no expertise in those fields. The result is that much of the material in those sections is irrelevant, inaccurate, or highly dubious in its interpretations. Such programs also reduce complex ethical problems to simplistic statements to be chosen on a multiple-choice test. While I cannot offer published citations or hard data, I know anecdotally that the requirement to complete such training breeds contempt for the whole review process in many researchers.

In 2002, the Social and Behavioral Sciences Working Group on Human Research Protections pioneered an alternative approach. Rather than preparing the same curriculum for all fields, it devised reading lists specific to each discipline. For example, materials prepared for the American Sociological Association included that association's code of ethics and essays written by sociologists (see http://www.aera.net/humansubjects/courses/asa _notebook.htm). Scholars asked to complete such training are likely to take it far more seriously than a program whose medical origins cannot be disguised. On the other hand, devising a single training regime for an entire discipline will still subject some researchers to a great deal of irrelevant material. For example, an ethnographer may not need nuanced instructions on forming survey questions, nor a survey researcher instructions about participant observation.

Finally, I would like to propose a third model that goes beyond the Working Group's approach. When scholars describe the training that most influenced their ethical decisions, they are less likely to cite general codes and principles than the work of other researchers who faced very similar challenges. Criminologist Michael Rowe put this very well in his essay, "Tripping Over Molehills: Ethics and the Ethnography of Police Work," International Journal of Social Research Methodology 10 (February 2007): 37-48. Rowe wrote,

> It is the nature of ethnographic research that the principles contained in methodological textbooks or professional codes of conduct will be stretched and perhaps distorted as they are applied in dynamic situations. Since policing is unpredictable, the ethical dilemmas police researchers might face cannot be easily anticipated . . . If an absolute code of ethics is not feasible, researchers must be prepared to be reflexive in terms of ethical dilemmas and the methodological difficulties experienced in securing informed consent and meaningful access to research subjects. (48)

The best preparation for observing police work, he explains, is reading other accounts of observing police work. I believe this emphasis on specificity would hold true for most qualitative research (and a great deal of quantitative work as well).

I would suggest, then, that rather than impose universal, top-down training like the CITI Program, or even more specific top-down training like the Working Group curricula, OHRP empower researchers to devise their own ethical reading lists of materials most relevant to their work, just as they choose their own methodological models. A researcher seeking IRB certification could present an annotated bibliography, showing that he had investigated the problems he was most likely to encounter and the ways that other scholars had dealt with those problems. Researchers should also be able to use courses and seminars they have completed as evidence of their prepraration.

I assume the goal of any training requirement would be to get researchers to think seriously about the ethical problems they will face. Asking them to research those problems themselves will be far more effective than any multiple-choice test.

1. http://www.institutionalreviewblog.com/2008/07/ohrp-seeks-comment-on-training-and.html

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Melissa Schlenker (2008-09-16 23:07:00)

Dear Mr. Schrag,

Your response to the OHRP request for public comment in regard to training requirements for investigators is well researched and eloquently drafted. I must ask if you have drafted your response from an academic perspective based on the review of the literature or if you speak from personal Human Research Protection Program (HRPP) training experience?

As an individual who has done both, I must share with you, that in my experience in a non-University affiliated community teaching hospital with seven active residency programs requiring scholarly activity, your proposed solution would never occur.

Residents are limited to 80 duty hours and a 60 hour limit is under consideration. There is just not enough time left in their schedule to provide HRPP training. The residency program directors just don't allow it. Another problem we experience is the first time principal investigator who is interested in research or mandated to conduct research that does not know where to begin but has a sponsor ready to send them a regulatory binder the next day. Another is that the IRB members find it difficult to review all the research for the meeting. How would they identify the current literature and then find time to actually read it?
In my opinion, your proposal grants the investigators and IRB members the right to self determine what is important and what is not. This lack of knowledge and understanding of the Federal regulations and OHRP guidance has caused the shut down of some prominent academic institutions.
My recommendations are that a certification process should exist for investigators and IRB members. Most study coordinators are (or should be) certified by professional societies such as ACRP and SoCRA. Why shouldn't the investigators and IRB members have the same requirements? Research is all about determining gold standards and comparing novel ideas to them. A certification process would set the standard and provide the means of measuring the knowledge of the applicant. Recommended curricula could be provided in preparation of the certification and a requirement for continuing education would ensure that the individual would stay current with the regulations and literature.
These are just my thoughts on the topic. I find your proposal to be thoughtful but not practical in some environments. I do believe that this is a topic in which there will be no right answer for every situation.
Respectfully,
Melissa Schlenker

Zachary M. Schrag (2008-09-17 15:59:00)
Thank you for your comment.
To answer your first question, I was required to complete online ethics courses at Columbia University and George Mason University, which uses the CITI Program. Out of curiosity, I also completed the course at UCLA, and looked at courses offered by other universities. While the UCLA course was better than the others, I found all of them heavy with information that was irrelevant to much social science work and, in some cases, inaccurate or misleading.
I am troubled by your description of ethical training at your hospital. As I understand you, first-time investigators cram their ethical study into a short time, perhaps the night before they receive a grant. And IRB members can't find the time to learn about the research whose ethical merit they are judging. If these researchers and reviewers are looking for a quick way to get their ticket stamped, then the CITI Program is just the thing. But you don't claim that such training leads to serious consideration of the ethical challenges posed by each project. Indeed, your proposals for a certification process, recommended curricula, and continuing education suggest that you would like to see both researchers and reviewers spend more time studying.
That leads to a second question–what should they learn? You write that "research is all about determining gold standards and comparing novel ideas to them." That's fine, so long as the emphasis is on the plural in standards. I believe that the gold standard for ethical training in genetic therapy is rather different from that in the ethnography of underground economies. And where are novel ideas to come from, if not the researchers who have invested the most in a given scholarly problem?
Zachary Schrag

3.9.2 Final Comments on Training Requirements (2008-09-24 14:04)

A couple of readers told me my [1]Draft Comments on Training Requirements
proposed an unrealistically burdensome training regime. I don't think that asking researchers and IRBs alike to learn about the documented ethical challenges of a given line of research is unduly burdensome, and neither did the architects of the present system. I have added the following to my comments, which I submitted today:

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Lest all this sound like too much work, let me quote the Belmont Report's own recommendations:

> the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the

> accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments . . . The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Standardized training does not produce "the accumulation and assessment of information about all aspects of the research," it does not make explicit the "method of ascertaining risks," and, most significantly, it does not provide the IRB or the investigator with "known facts or other available studies." What it does produce is a false sense of expertise among IRB board members, leading to the very "misinterpretation, misinformation and conflicting judgments" against which the National Commission warned.

1. http://www.institutionalreviewblog.com/2008/09/draft-comments-on-training-requirements.html

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3.9.3 AHA Comments on IRB Training (2008-09-29 14:46)

The American Historical Association has posted a copy of the [1]comments on IRB training and education it sent to OHRP in response to the [2]July notice in the Federal Register. The AHA letter states that historians "are concerned that the proposed training program will reinforce the tendency to treat all research as if it was conducted in the experimental sciences" and that "the proposed training program would only cover what should be assessed by the review boards, and does not include room for discerning among different types of research methods."

1. http://blog.historians.org/profession/618/training-discernment-and-oral-history-review
2. http://www.institutionalreviewblog.com/2008/07/ohrp-seeks-comment-on-training-and.html

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3.9.4 Crackdown at Indiana University (2008-09-30 10:49)

The Bloomington Herald-Times reports (August 10-12) on problems with human subject reviews at Indiana University in Bloomington (IUB). Though the paper does not give details of what went wrong, it does state that in the summer of 2008, two whistleblowers in the human subjects office successfully the appealed negative evaluations they had received after airing complaints. Their immediate supervisor, Carey Conover, has been reassigned, But Conover's boss, Eric Swank, has been promoted to executive director for research compliance for Bloomington and other Indiana campuses, with a salary bump from $79,000 to $119,600.

Moreover, the university has moved to protect itself by layering on more administration. According to an August 17 Herald-Times column by the university provost, Bloomington's new president "has expanded the budget for research compliance by $4.3 million - the single largest addition to his budget - in order to create a university-wide organization of well over 100 people, professionals whose sole mission is to preserve and protect the university's research mission." And starting July 1, all IUB studies have been sent to the Indiana University-Purdue University Indianapolis (IUPUI) IRB, where, the [1]university promises, they will be met with an "AAHRPP-accredted HRPP" and legions of "CIP-certified staff members." Meanwhile, Bloomington IRB members and staff were sent for reeducation by Jeffrey Cohen, who, no doubt, told them to review oral history.

None of this is reassuring to social scientists back at Bloomington. Writing in the Herald-Times on September 14, Noretta Koertge, a specialist in research ethics, urged "the university to take this opportunity to resist bureaucratic mission creep." Lower on the chain, informatics [2]PhD student Kevin Makice frets that the dust-up will delay his research to the point that he will have to rely on theory and public data to meet a conference deadline. He writes,

"The human-computer interaction crowd often goes to [the Computer/Human Interaction conference] talking about the woes of the research approval process only to hear how much simpler it is on other U.S. campuses and seemingly non-existent off the continent. Now, with IUPUI overburdened by serving multiple campuses–which apparently is in the long-term restructuring plans anyway–we miss the days of it just being too complicated."
Back in 2005, the Illinois White Paper on IRBs complained that the "death penalty" of shutting down all research at a university in response to a single IRB violation. This penalty, the paper warned, was largely responsible for IRBs' terrified emphasis on regulatory compliance. It looks like Indiana researchers will suffer for the sins of the research administrators.

1. http://www.heraldtimesonline.com/stories/2008/08/10/0808_allegations0811.pdf
2. http://www.blogschmog.net/2008/08/10/taking-the-h-out-of-hci/

3.10 October

3.10.1 A Conscientious Objector (2008-10-06 15:42)

In a column in the Hastings Center's [1]Bioethics Forum, historian and ethicist Alice Dreger explains why she declines to submit oral history proposals to IRBs:

> To remain "unprotected" by my university's IRB system—to remain vulnerable—is to remain highly aware of my obligations to those I interview for my work. Without the supposed "protection" of my IRB, I am aware of how, if I hurt my interviewees, they might well want to hurt me back. At some level, I think it best for my subjects that I keep my kneecaps exposed.

Compare this stance to the position put forward by [2]Charles Bosk in 2004:

> Prospective review strikes me as generally one more inane bureaucratic requirement in one more bureaucratic set of procedures, ill-suited to accomplish the goals that it is intended to serve. Prospective review, flawed a process as it is, does not strike me as one social scientists should resist.

Who takes research ethics more seriously: the researcher who submits to inane requirements, or the researcher who resists?
For more on Dreger's work, see [3]The Psychologist Who Would Be Journalist.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=2476
2. http://www.institutionalreviewblog.com/2008/08/reform-or-revolution-comment-on-bosk.html
3. http://www.institutionalreviewblog.com/2008/06/psychologist-who-would-be-journalist.html

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3.10.2 Treeroom Trade (2008-10-15 09:15)

John Mueller kindly alerted me to Gautam Naik, "[1]Switzerland's Green Power Revolution: Ethicists Ponder Plants' Rights," Wall Street Journal, 10 October 2008.

Naik reports that the government of Switzerland has required researchers to "conduct their research without trampling on a plant's dignity," based on an April 2008 treatise, [2]The Dignity of Living Beings With Regard to Plants.
The treatise itself notes that the members of the Federal Ethics Committee on Non-Human Biotechnology could not reach consensus on most of the moral questions they considered, and some worried about over-regulation. Nevertheless, "The Committee members unanimously consider an arbitrary harm caused to plants to be morally impermissible. This kind of treatment would include, e.g. decapitation of wild flowers at the roadside without rational reason," though even then the committee members disagreed over why such decapitation is impermissible. Nor does the report lay out criteria for a "rational reason." What if it's fun to decapitate wildflowers?
[Disclosure: As a boy, I liked to knock the heads off dandelions with a stick. Guess I won't be getting a visa to Switzerland any time soon.]
Naik's article focuses on the threat to genetic research, but if there's anything that four decades of human subjects regulation has taught us, it's that government officials refuse to recognize distinctions between lab experimentation and social science. Perhaps we should expect restrictions on the observation, surveying, and interviewing of plants as well. In six months Washington's cherry blossoms will be out, and I pity all those poor trees, left helpless as hundreds of thousands of people come to gawk at their exposed genitals.

1. http://online.wsj.com/article/SB122359549477921201.html?mod=googlenews_wsj#articleTabs=article
2. http://www.ekah.admin.ch/uploads/media/e-Broschure-Wurde-Pflanze-2008.pdf

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3.10.3 AAAS Hears Clashing Views on IRBs (2008-10-19 22:35)

The American Association for the Advancement of Science (AAAS) has posted a summary of a September 22 meeting on IRBs and the social sciences, in which I took part.
As the press release, "[1]AAAS Meeting Explores Ways to Improve Ethics Panels that Oversee Social Science Research," notes, "from both researchers and administrators alike, there was general agreement that the system can and should work better," but participants disagreed about what a better system would look like.
Social researchers recounted some horror stories, the most vivid of which was Gigi Gronvall's:

> Gigi Gronvall, a senior associate at the Center for Biosecurity of the University of Pittsburgh Medical Center, recalled her efforts to do a survey of scientists who do dual-use research in biology, such as work on viruses that might have military as well as civilian application. The IRB at Johns Hopkins University, where the biosecurity center was located at the time, asked Gronvall to give a three-page consent form to all those she interviewed. It included a warning that the respondent, in agreeing to answer Gronvall's questions, ran the risk of being investigated by government agencies, being "exploited by hostile entities," or even being kidnapped.
> The IRB's members, Gronvall said, "were totally over-identifying with my subject population." The result was a six-month delay in the survey project, during which Gronvall almost lost her funding. "The IRB should be on your side," she said. "That's not how I felt during this."
> Gronvall said that blocking or delaying research on a controversial topic can mean that it will be explored only in the news media, without any IRB-style protections for those being interviewed.

In addition to such personal experiences, some participants warned of fundamental flaws in the IRB system. I described the origins of IRB review as the work of physicians, psychologists, and bioethicists who had no understanding of the methods and ethics of social scientists, and assembled no evidence of widespread abuse by them. Joan Sieber, editor of the Journal of Empirical Research on Human Research Ethics, suggested that the horror stories are not abberations, but common.

IRBs had their defenders, particularly from scholars and consultants with a background in medicine. Anne N. Hirshfield, associate vice president for health research, compliance and technology transfer at the George Washington University, claimed that "IRBs can only work if there is mutual attention to a common goal—conducting ethical research that protects the rights and welfare of participants." But she also argued that "it is the obligation of the P.I. to know what the IRB needs and to stage the argument. Give the citations to show that your work is not risky." In other words, researchers must prove a negative, while IRBs are free to conjure up scientist-kidnappers.
Perhaps the most impressive presentation was that of Janet DiPietro, associate dean for research at Johns Hopkins University's Bloomberg School of Public Health, who described her efforts to reform the IRB there. If all IRBs were managed by someone as thoughtful as she, we'd have far fewer complaints. But there aren't enough DiPietros to go around, so her achievements do not make a good case for granting administrators nationwide such power.
The press release concludes with a statement from Mark Frankel, staff officer for the AAAS's Committee on Scientific Freedom and Responsibility:

> Some Committee members believe that the balance is awry because IRB's are imposing unwarranted and arbitrary demands on proposed research by social and behavioral scientists. This raises serious issues related to scientific freedom insofar as such actions lead to potentially valuable research that is inappropriately altered, unduly delayed, or not done at all.

While noncommital about specific policy recommendations, this recognition that IRB review is a threat to scientific freedom is in itself an important finding. I look forward to further AAAS efforts to explore this problem and contribute to its resolution.

1. http://www.aaas.org/news/releases/2008/1007irb.shtml

3.10.4 45 CFR 46.101 Is Still Dead (2008-10-22 10:24)

At the September AAAS meeting, I learned of the June 2008 report, "[1]Expedited Review of Social and Behavioral Research Activities," put out by the Social and Behavioral Research Working Group, Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council. The brief report (11 pages, including a great deal of white space) offers thirteen "brief illustrative examples" of "social and behavioral research activities [that] qualify for expedited review . . . assuming that they also meet the standard of minimal risk."
While presenting itself as an effort to help researchers, administrators, and reviewers "avoid needless misunderstanding and delays in the review process," the document threatens to add misunderstandings and delays by suggesting review for many projects that should be exempted from IRB oversight.
Here are the thirteen examples, to which I have added numbers for discussion purposes. The categories listed at the end indicate the reasons the working group believes the examples are eligible for expedited review, based on the [2]1998 list of categories.

> 1. An analysis of student educational records to explore the relationship between student mobility from district to district and student academic achievement for students from various economic and ethnic backgrounds. [Category (5)];
> 2. A study of prison administration records to explore the relationship between inmates' individual background characteristics, type of criminal violation, and acquisition of a Graduation Equivalent Development (GED) credential10. [Category (5)];
> 3. A study of medical records and survey data to compare people's weight with the cultural attitudes of different subpopulations toward diet and exercise. [Category 5].

4. A study using video recordings to examine communication styles used by cooperating employees in a variety of business organizations. [Category (6)];
5. A laboratory study comparing patterns of eye movement and reading comprehension performance among novice and competent readers. [Categories (6) and (7)];
6. A study in experimental economics in which people play an economic game that involves offering and/or accepting amounts of cash provided as part of the experiment. [Category (7)];
7. A study of adults' ability to identify accurately the perpetrators of staged thefts. [Category (7)];
8. A study attempting to validate a previously tested measure of extroversion/introversion with members of a previously untested cultural group. [Category (7)].
9. A research study using telephone surveys of persons who provide their names and information about their background characteristics, political beliefs, and voting behavior. [Category (7)];
10. An online internet study in which undergraduate students view a video clip about economic theory and then respond to computer-simulated scenarios about individual spending decisions. [Category (7)];
11. An ethnographic field study using un-structured interviews to explore the interrelationship between family life and involvement in religious activities. [Category (7)];
12. An ethnographic study using participant-observation where the researcher participates in the subject's activities of daily life, such as an anthropologist studying an agrarian market place by sitting in the respondent's market stall, observing interactions and sometimes selling items to help out. [Category (7)];
13. A participatory action research project in which middle school teachers and students use group discussions, surveys, and interviews to evaluate the school's social studies curriculum and develop recommendations for improvements. [Category (7)];

Examples 1-3 are pretty clearly within IRB purview under existing regulations. The Common Rule covers research using "information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)." Unless such information has been stripped of identifiers or is already publicly available, a researcher needs approval to use it.
Examples 6 and 10, the economics experiments, are systematic investigations designed to develop or contribute to generalizable knowledge, not covered by any specific exemption. Though the experiments do not seem risky, the regulations cover such research.
By contrast, the remaining eight examples all should be exempt under 45 CFR 46.101.
Examples 4, 5, 7, 8, 9, 11, and 12 should be exempt under §46.101(b)(2) as

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Example 13 should be exempt under §46.101(b)(1) as "Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."
Though the report makes a few passing mentions of §46.101, it offers no explanation of why the examples given would not be exempt under that section. And presenting these exempt projects as eligible for review is bound to suggest that they are not, in fact, exempt. An IRB using this document as guidance may well insist on reviewing projects that should be none of its business.

I cannot say that I am shocked; the §46.101 exemptions have been meaningless since 1995, when OHRP decreed that researchers cannot be trusted to apply the exemptions themselves, and hinted that IRBs should be consulted. As Samuel Tilden put it at the [3]July 2008 meeting of SACHRP,

> In 1981, HHS amended its 1974 policy . . . including exemptions from the policy. In its explanation of the final regulations, HHS anticipated ~~no~~ [most] social, economic, and educational research would be exempted from coverage. I ask you, is that the case today?

It is not, and the only news in this report is the brazenness with which representatives of the signatory agencies disregarded the regulatory language they claim to uphold.

Note: This post was originally posted on 22 October 2008. It was edited on 26 November 2008 to include my analysis of example 10, which I erroneously left out of the original.

Note 2 [30 August 2010]. In reviewing this post, I realized that the official SACHRP transcript misquoted Dr. Tilden. I am rather sure he said "most social, economic, and educational research would be exempted from coverage," since this is the language in the [4]Federal Register announcement of 26 January 1981. I have amended the quotation accordingly.

1. http://www.nsf.gov/pubs/2008/nsf08203/index.jsp
2. http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm
3. http://www.dhhs.gov/ohrp/sachrp/mtgings/mtg07-08/mtg07-08.html
4. http://www.hhs.gov/ohrp/documents/19810126.pdf

Kip Austin Hinton (2009-01-07 03:53:00)

i am developing an activist participant-observation project in a high school. according to all the federal regulations i read, it is exempt under 45 CFR 46.101(b)(1).

the IRB refused, though. and they quoted a specific line of the regulation about children:

"The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed."

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm #46.101

ethnography, by definition, demands participation. these 2 categories of exemption are widely conflated, MISinterpreted to become meaningless, EXCEPT for college or adult education. legally, category 1 permits participation with children; category 2 forbids it.

as long as no testing is involved, educational settings SHOULD be exempt. right now, though, universities imagine that note refers to exemption categories 1 and 2.

long-term, the IRBs should either follow the law, or petition the federal government to change to law and exclude children from exemtion categories in general.

but i'm not going to argue with the IRB, i'm just going to complete the additional forms and resubmit. i must devote time to my own research, not to teaching law to board members.

Zachary M. Schrag (2009-01-08 07:06:00)

Thank you for your comment.

You are quite right that the exemption in 45 CFR 46.101(b)(1) applies even to research with minors; see 45 CFR 46.401(b). I confess, however, that I can't see how "activist participation-observation" would constitute "normal educational practices."

Best,

ZMS

3.10.5 Menikoff to Head OHRP (2008-10-26 13:53)

The Department of Health and Human Services has announced the appointment of Dr. Jerry Menikoff as the director of the Office for Human Research Protections (OHRP). Menikoff holds degrees in medicine, law, and public policy, and has served as a law professor and public official.

A quick glance at Dr. Menikoff's CV suggests that while he has published extensively on the ethics of medical experimentation, he is written little on questions of the regulation of social science. The exception is his article, "[1]Where's the Law? Uncovering The Truth About IRBs and Censorship," Northwestern University Law Review 101 (2007): 791-799, which I described in a [2]January 2007 blog entry. In that article, Menikoff suggested that the 46.101 exemptions were sufficient to avoid any conflict with the First Amendment.

Menikoff does understand that many IRBs have abused social researchers. "There are surely too many instances in which IRBs and others fail to understand, and properly administer, the regulations," he writes. (793, n. 9) Later, in a response to an [3]Inside Higher Ed article about this blog, he wrote, "As to social science and behavioral studies, I do support reforms to relax the rules somewhat, though the claims that the system constitutes censorship under the U.S. Constitution are overkill."

It is not clear, however, that Menikoff understands how rarely the 46.101 exemptions are applied, and how much responsibility OHRP bears in their disappearance. And in his Northwestern piece, Menikoff praises OHRP for "concluding . . . that much of the work performed by oral historians, in sitting down with people and getting information from them, does not fall within the category of doing 'research.'" (798) He seems not to know that OHRP so contradicted itself that its pronouncement had no effect on most universities.

If Menikoff uses his position to [4]revive 45 CFR 46.101, to restore the agreement with oral historians, and to correct other [5]lapses between the regulations as written and as enforced by OHRP, his accession to the OHRP directorship will be great news not only for scholars in the social sciences and humanities, but also to participants in medical research, since resources can be reprogrammed for their protection. Under the leadership of a lawyer, perhaps OHRP will begin to obey the law.

1. http://www.law.northwestern.edu/lawreview/v101/n2/791/LR101n2Menikoff.pdf
2. http://www.institutionalreviewblog.com/2007/01/menikoff-wheres-law.html
3. http://www.insidehighered.com/news/2007/01/19/irb
4. http://www.institutionalreviewblog.com/2008/10/45-cfr-46101-is-still-dead.html
5. http://www.institutionalreviewblog.com/2008/07/dormant-right-to-ethical-self.html

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3.10.6 Report from SACHRP, October 2008 (2008-10-27 22:19)

Today I attended the public meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP). Most of the day's discussion concerned the slow pace with which SACHRP's recommendations over the years have been implemented in any way; some have been sitting for years without action. OHRP officials offered detailed explanations of the complexity of policy-making process and OHRP's lack of resources. While these issues help explain OHRP's neglect of questions important to the social sciences and humanities, today's discussion had little of direct importance to scholars in those fields.

Here are a few tidbits of potential significance.

What is the difference between guidance and regulation?

Christian Mahler, a lawyer with HHS's Office of General Counsel, explained that only regulations can be enforced; as a legal matter, institutions are free to ignore OHRP guidance documents. But he and other officials acknowledged that in practice, the difference may not be great. As acting OHRP director Ivor Pritchard conceded, "when we issue guidance . . . people look at every phrase, clause, use of punctuation to see what was meant by OHRP." He noted that institutional officials may believe the safest course is to comply with all OHRP guidance.

Pritchard said that OHRP tries to differentiate, when drafting guidance, between "must" statements (that indicate OHRP's interpretations of the regulations) and "should" statements that can be ignored if an institution has good reason. He also stated that the best course might be to issue guidance documents that offer multiple ways to comply with the regulations, though it's not clear that OHRP has ever issued such guidance.
Finally, Mahler pointed to the Office of Management and Budget's 2007 "[1]Final Bulletin for Agency Good Guidance Practices." That bulletin notes that

> The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the [Admistrative Procedure Act]'s notice-and-comment requirements, regardless of how they initially are labeled. More general concerns also have been raised that agency guidance practices should be better informed and more transparent, fair and accountable. Poorly designed or misused guidance documents can impose significant costs or limit the freedom of the public.

Despite that last sentence, the bulletin seems designed more to limit regulation of economic affairs than to safeguard the freedom of the public. Still, if its approach were followed, OHRP might not be able to get away with so many arbitrary decisions.

What is research?

In February 2007, then-OHRP director Bernard Schwetz told the [2]New York Times that OHRP would, by the end of 2007, issue guidance on what is and is not research under the regulations. OHRP is almost a year overdue in keeping that promise, but apparently it is still at work. Pritchard noted that "We have been working on a guidance document on the definition of 'research' for several years now." Pritchard did not indicate how far along that process is, or whether OHRP will solicit public comment before promulgating that document.

What is an ideal consent process?

In her presentation, Elizabeth Bankert, co-chair of SACHRP's Subpart A Subcommittee, addressed the problem of IRB insistence on long, complex consent forms. She noted that while the regulations requiring consent forms have not changed since 1991, IRBs have been demanding ever more detailed forms, and have gained a reputation for "word-smithing" and "nit-picking." Not only does this erode investigator trust and respect for IRBs, but it also "diminishe[s] the consent process for subjects."
Bankert–drawing on work by subcommittee member Gary Chadwick–challenged the presumption that "the form must contain every piece of information and in the same detail as required in the consent process," which leads to such long forms. She called upon OHRP and FDA to endorse the use of shortened consent forms: about 3-4 pages for a clinical trial, and just one for "surveys, etc."
Bankert offered these suggestions as a way to decrease some burdens on IRBs and investigators, but she then suggested that IRBs would still need to review the consent process. She did not explain how the same incentives for nit-picking wouldn't lead to endless fretting about the consent process, rather than the consent form. As SACHRP member Jeffrey Botkin pointed out, IRBs and investigators turn to long forms out of self-preservation. And as David Foster noted, FDA inspectors and AAHRPP accreditors have demanded ever longer forms. Before Bankert and Chadwick can address the problem of silly forms, they need to understand the system that produces them.
Predictably, almost all the discussion of consent forms centered around clinical trials. For example, Bankert offered sample executive summaries for a drug trial and a request to store blood or tissue for future research, but no comparable document for a social science project. And one committee member, expressing her concerns, forgot to speak of "human subjects" and instead started talking about protecting "patients." Given the complexity of the issue, and the dominance of SACRHP by medical researchers and bioethicists, I would expect that any change will be designed for clinical trials, and then imposed on social researchers.

1. http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf
2. http://www.nytimes.com/2007/02/28/arts/28board.html

3.11 November

3.11.1 Chronicle of Higher Education on OHRP Training Comments (2008-11-04 10:32)

The Chronicle of Higher Education quotes your faithful blogger in "[1]Scholars Mull Rules for Training in Research Ethics," by David Glenn, 4 November 2008.
The story concerns the eighty or so comments received in response to OHRP's July call for comments on education and training requirements. Glenn notes that by and large, the comments were skeptical about the need for new guidance, and particularly skeptical about regulations. As he reports, "the American Association for the Advancement of Science, the Association of American Universities, the Association of American Medical Colleges, and a consortium of large social-science organizations [all] said that before the federal government issues new rules, it should carefully study whether training actually improves researchers' conduct."
I will offer some of my own comments on the comments in coming posts.

1. http://chronicle.com/daily/2008/11/6530n.htm

3.11.2 Comments Oppose New Regulations on Training (2008-11-15 20:58)

As [1]reported by the Chronicle of Higher Education, OHRP recently released the replies it had received in response to its July call for comments on education and training requirements. I thank Chronicle reporter David Glenn and OHRP associate director Michael Carome for supplying me with copies of the comments.
As I see it, the comments pose three main questions.

1. What kind of training?

The chief substantive question is what kind of training should investigators, IRB members, and administrators receive. Few if any of the comments suggested that these folks should act in ignorance, but the authors disagreed over what types of training are appropriate, and how to judge the system which is currently in place, which most typically consists of online readings followed by a multiple choice test. While the mostly widely used system is the CITI Program, the comments mentioned some variants of this system.
Many seem satisfied with such training. The CITI Program itself submitted a comment citing a presentation, "[2]Instruction in The Protection of Human Research Subjects: A web based model," that finds broad satisfaction among those receiving the training. For example, when asked if they agreed with the statement "The time spent doing the course was well justified," "social-behavioral" researchers gave an average response of about 7.5 on a 1-10 scale. I'd like to see this figure disaggregated. How does it break down by discipline? And does an average of 7.5 mean that everybody gives the program a 7 or 8, or that 75 percent give a 9 or 10 while 25 percent rate it a 1?
Indeed, some of the comments (my own included) mocked the idea of multiple choice tests for ethics training. As Jeffrey Spike of the Florida State College of Medicine put it,

> All that is required [is] to read a few a few paragraphs and then parrot back the words on a multiple choice quiz . . . This is a shameful failure to take the material seriously, and one which would NEVER be acceptable for the teaching of clinical ethics to future doctors."

Jonathan Baron, a University of Pennsylvania psychology professor, writes,

> I did the PI training that was required by NIH. I found that it was more like brainwashing than education. I had to take a test, and, in order to pass the test, I had to express agreement with ethical statements that I thought were wrong. I did it, but it did not endear me to the process. It got me angry.

Two former federal officials are also skeptics. Greg Koski, former director of OHRP, writes on behalf of the Academy of Pharmaceutical Physicians and Investigators,

> Many academic institutions mistakenly believe that a physician's ability to pass the [CITI] exam is sufficient to assure that an investigator has a comprehensive knowledge of Good Clinical Practices. The CITI exam and other limited training courses and examinations cannot serve as a substitute for an exam that evaluates all clinical research topics, including human research protections.

Likewise, Charles McCarthy, one of the architects of the present IRB system, writes that online courses "tend to promote the mistaken assumption that the required level of ethical conduct of research can be mastered by taking a three or four hour on-line training session repeated every two or three years. IF SUBJECTS ARE TO BE ADEQUATELY PROTECTED, THE RESEARCH COMMUNITY MUST DO BETTER THAN THAT!"

Even fans of CITI seem to recognize its ability to antagonize researchers. Michael Gillespie, the IRB Coordinator for California State University, San Bernardino, believes that implementing the CITI program led to improved applications, yet he also claims that CSU faces "an increasing problem with faculty understanding the requirements . . . including those that ignore the rules."

What, then, are the alternatives?

Some want training to be more like a college course. Spike suggests 28 hours of course time, ideally taught by real bioethicists. McCarthy also wants college level courses for at least some members of each institution. Howard Stone, of the University of Texas Health Science Center at Tyler, describes 1-2 day courses as "wildly successful." The IRB Sponsor Roundtable wants the flexibility to offer retreats, role-playing exercises, or other formats.

Other comments (including mine) stress the need to match the training to the type of research to be conducted. The American Psychological Association reminds OHRP of the National Bioethics Advisory Committee's recommendation that academic and professional societies be included in developing curricula. The American Historical Association agrees.

2. Regulations or guidance?

Beyond the substantive question about what kind of training is needed is the procedural question of whether OHRP should mandate training, recommend it, or leave institutions alone. Unsurprisingly, the universities and their associations resist the idea of a formal regulation, which could be enforced against them.

For researchers, however, such distinctions may not matter, if university administrations impose OHRP guidance as university policy. As the University of West Florida put it, "the UWF IRB treats OHRP recommendations as regulations and routinely adds them to the UWF IRB Policy and Procedures."

I am frustrated by letters like the joint comment of the Council on Governmental Relations, the Association of American Universities, and the Association of American Medical Colleges. These organizations claim that "institutions are best able to determine the content and extent of relevant training according to an individual's role in the research process." But they also point to the CITI Program as an example of improved training. If institutions are best able to devise training for their people, why have so many delegated the task to CITI? These organizations aren't opposed to

inflexible training per se; they just don't want to be legally responsible for imposing it.

3. Guesswork or empirical research?

The final question, also procedural, is whether OHRP should base its policies on empirical research. As the American Psychological Association put it,

> As a scientific organization APA values decisions based on empirical research. Thus, the question of whether additional guidance or new regulations for institutional training and education programs on compliance with federal human research protection regulations are required might be answered best by first undertaking a systematic and comprehensive analysis of objective data that are collected by OHRP in the course of its compliance activities, to determine if the underlying cause of noncompliance is a lack of education and training or a combination of these and other factors.

Writing on behalf of the American Educational Research Association, the American Political Science Association; American Sociological Association, and several other organizations, Felice Levine argues that "before determining what forms education should take and what needs to be required of whom, having a base of knowledge on which to determine educational and other needs is critical in order to promote ethically sound research and review practices and to avoid wasting limited resources." The American Academy for the Advancement of Science concurs, noting "a lack of evidence-based studies documenting where and how further training could be most effectively implemented. . . . In the absence of such evidence, it would be premature to issue a regulation."

Sympathetic as I am to such arguments, I must note that a lack of evidence has never deterred regulators from setting human subjects policy. Neither OHRP, its predecessors, or Congress has ever conducted an investigation of the need to regulate social science research. And while they have devoted somewhat more attention to the question of ethical review of medical research, the comments correctly note that existing reports on the efficacy of the IRB system are thin and sporadic. If OHRP were to take these comments seriously, it would have to rethink its entire policy making process.

I have posted all the comments, as well as those submitted in responses to the October 2007 announcement about expedited review, on a new page: [3]http://www.schrag.info/irb/ohrpcomments.html

1. http://www.institutionalreviewblog.com/2008/11/chronicle-of-higher-education-on-ohrp.html
2. http://citiprogram.org/citidocuments/aahrpppbfinal.ppt
3. http://www.schrag.info/irb/ohrpcomments.html

3.11.3 Can IRBs Handle the Nuances of Anthropological Ethics? (2008-11-21 13:49)

In a November 14 essay in the Chronicle of Higher Education ("[1]New Ethical Challenges for Anthropologists"), Carolyn Fluehr-Lobban reports on the work of the Commission on Engagement of Anthropology with the U.S. Security Community, of which she is a member. The commission was established by the American Anthropological Association in 2006, in response to complaints that anthropologists had acted unethically by participating in the Department of Defense's Human Terrain System and other national security programs.

Fluehr-Lobban offers a carefully nuanced discussion of the questions of secret research and research that harms its subjects. Both require subtlety. As she notes,

> even in agencies well known for their secrecy, like the Central Intelligence Agency, such terms as "transparency" and "disclosure" have become more common, and secrecy less easy to define; "classified"

> government documents can be accessed by scholars and journalists, while truly top-secret materials deal with intelligence research rather than anthropology. Moreover, scholars may not be able to discern whether their work contains secret material when projects are compartmentalized, and when their contribution is only a segment of a project whose wider mission is unknown. In short, anthropologists who provide "subject matter expertise" may not know the direct or indirect impact of their engagement.

Likewise, harm can be hard to predict, or even define. As Fluehr-Lobban explains,

> Anthropologists have been deployed to Iraq and Afghanistan as part of Human Terrain Teams embedded with combat troops. Part of the work they do unquestionably causes harm to some people – but it may prevent harm to others. In addition, we know so little about what the teams do, or the projects they are part of, that objective evaluation is impossible at present.

What does this tell us about IRB review of social science research? Well, that's not clear either.
On the one hand, the commission asks anthropologists to "be assured that adequate, objective review of the project has been conducted, ideally by external reviewers."
On the other hand, Fluehr-Lobban suggests that such review would require expertise not found on the typical IRB. She concludes,

> Ideally, decision making occurs in a group process where the relevant disciplinary, cultural, and government-agency stakeholders are at the table . . . Consultation with professionals in related disciplines who have been grappling with issues of engagement – for example, psychologists who have debated their role in identifying what would constitute "soft torture" and their alleged involvement in interrogations in Abu Ghraib and Guantánamo – is also recommended, as well as with those who have been historically engaged without serious controversy – for example, political scientists working as consultants on terrorism for defense and intelligence agencies.
> Perhaps the best advice will come from one's own disciplinary colleagues. To that end, a group, "Friends of the Committee on Ethics," may be set up to offer informal, private advice about research ethics. As we think through the various issues that secrecy and doing no harm demand of us, such a committee will have an important role to play in helping define increasingly complex anthropological practice.

These latter recommendations do suggest a role for interdisciplinary consultation, but they are no endorsement for the current IRB system, which makes no provision for assuring review by relevant stakeholders, professionals who have grappled with the issues, or disciplinary colleagues. I hope that Fluehr-Lobban's commission will explore the implications of its findings for the appropriate mechanisms of ethical review.
(Thanks to the [2]Research Ethics Blog for bringing this to my attention.)

1. http://chronicle.com/weekly/v55/i12/12b01101.htm
2. http://www.researchethics.ca/blog/2008/11/revised-code-of-ethics-for.html

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3.11.4 OHRP Continues Indiana-Bloomington Investigation (2008-11-22 14:43)

In September I reported on the [1]OHRP investigation of Indiana University-Bloomington, ably covered by the [2]Bloomington Herald-Times. Along with several stories, an editorial, and at least two op-eds, the newspaper posted heavily redacted copies of the [3]OHRP letter and the [4]IU reply.
On October 3, I submitted a Freedom of Information Act request for the unredacted OHRP complaint. This week,

I received a reply, dated November 17, stating that "the subject matter of your request is the subject of an open and ongoing investigation. Release of any additional information at this time could reasonably be expected to interfere with ongoing proceedings." Hence, I received no information. We still don't know what Indiana-Bloomington did to bring down the federal hammer, or if the hammer will strike again.
Meanwhile, the crackdown has disrupted research, especially for social scientists. As the Herald-Times reported on October 8 (Nicole Brooks, "IU Research Oversight Office Has More Staff, But Projects Still Delayed"),

> The need to "attend to the compliance issue speedily" led to Bloomington researchers using the same proposal forms as IUPUI faculty, according to [Research Affairs Committee chairman Stephen] Burns. These forms are designed for medical research, and are "more complex than needed," especially for social science researchers.
> This has caused some faculty — and students — to not bother with some research projects, Burns said. And some students are changing their thesis topics so they don't include human subjects research, he said.
> Before the compliance issue came into play, when Bloomington campus faculty used their own form and not IUPUI's, this was a problem, Burns said. Research topics are becoming more and more diverse, and the divide between what information is necessary for different kinds of research is widening, he said.

The upshot is that faculty and students at a major research university are abandoning their research because of secret allegations against their university's administration. It's all very well for OHRP to claim (as Ivor Pritchard did at the October SACHRP meeting) that OHRP enforcement actions are rare. But even the rare crackdown, if as severe as this one, is enough to have IRBs nationwide quaking in fear, and putting regulatory compliance above all other considerations.

1. http://www.institutionalreviewblog.com/2008/09/crackdown-at-indiana-university.html
2. http://www.heraldtimesonline.com/
3. http://www.heraldtimesonline.com/stories/2008/08/10/0808_inspection0811.pdf
4. http://www.heraldtimesonline.com/stories/2008/08/10/0808_allegations0811.pdf

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3.11.5 IRBs vs Law and Society (2008-11-26 15:45)

The Law and Society Association (LSA) has posted "[1]The Impact of Institutional Review Boards (IRBs) on Law & Society Researchers," a 2007 report by the association's Membership and Professional Issues Committee.
In the spring of 2007, the committee put out a general call for comments from association members, receiving 24 replies. Committee members also interviewed association members, taking special interest in those who had served on IRBs. This produced some accounts of frustrating encounters that led to the destruction of research, especially cases involving research on crime and punishment, a special concern of the association.
One particularly sad story came from "Respondent 019":

> I knew when completing my [questionnaire] that I would have some difficulty getting my topic approved because it related to a protected population. I completed the [questionnaire] honestly and accurately and finally heard back that I had to make substantial revisions to my proposal. Not only did I take all of the IRB's recommendations for review into account when completing a second questionnaire, but I even had frequent contact with the compliance coordinator and the secretary to make sure I was doing everything correctly. I submitted a second [questionnaire] that covered all the areas that caused problems with my first proposal. Finally, I heard back, and I was rejected on a whole other set of criteria that IRB

never mentioned when they rejected me the first time. Finally I ended up changing my topic enough so that I no longer had to deal with IRB because they had pushed back the start date of my research so far that I couldn't risk not getting approved again.

Other accounts describe IRB blocakge of research concerning mental health facilities that house sex offenders and prisons in the United States and Turkey.

The report concludes with three sets of recommendations:

First, it wants to restrict IRB jurisdiction: "the LSA should strive to minimize the scope of the IRBs regulations over non-behavioral studies and make the procedures of approving behavioral studies as smooth and expedient as possible."

Second, the report calls for a program of research and education, ranging from conference panels and publication to a statement of best practices for research. The goal is "a nuanced and contextual view of the IRB process, one that moves away from hard and fast 'rules' for most social science research, allowing for optimal protection of human subjects without inhibiting research goals."

Finally, the report claims that "the most successful IRBs (in terms of 'customer satisfaction') are those with a decentralized 'sub-board' system," citing UCLA and Macalester as examples. I find this unpersuasive, given that the report is based on part of the work of Jack Katz of UCLA, who seems pretty unsatisfied with his IRB.

While not directly inconsistent, these three recommendations are in some tension with each other, as well as with the evidence presented in the report and positions taken by the LSA. The report's collection of horror stories–unrelieved by any reports of IRB contributions to ethical research–calls into question the propriety of any IRB review of social research, and the report's analysis suggests that there is no legal requirement for such review. Put together, these sections of the report support Katz's conclusion that "the optional decision to push all ethical review of social science and humanistic research through a prior review sieve is not only massively inefficient, it is also counterproductive where risks are most serious." ["[2]Toward a Natural History of Ethical Censorship," Law & Society Review 41 (December 2007), 807.]

By contrast, the calls for additional research, a more flexible IRB process, and decentralization all resemble the [3]stance of Felice Levine and others, who advocate working within the current system.

In particular, the report raises the question of LSA's position on the scope of the "behavioral research"mentioned in the National Research Act and other forms of interactions with human beings. "There has been no mention, or expressed intention regarding human subject research in law and the social sciences," the report notes, "and clearly not all research in law and society is 'behavioral.'" If this is the case, then many of OHRP's policies and interpretations of the Common Rule lack a statutory basis. Yet in December 2007, five months after the report was presented to the association, the Association signed onto [4]Levine's comment to OHRP, in which she wrote of "social and behavioral sciences (SBS)," conflating the very categories the report wishes to keep distinct.

The [5]July 2008 newsletter of the association mentions the report, but it does not state whether the association has accepted its committee's position or taken any action in response. I hope the LSA will continue work in this field, and that it will consider further the question of whether all survey, interview, and observational research should be made subject to a law governing "behavioral research."

1. http://www.lawandsociety.org/LSA_MPIC_Report.pdf
2. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html
3. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html
4. http://www.schrag.info/irb/Expedited%20Review%20List%20Comments%2025%20Jan%2008.doc
5. http://lawandsociety.org/newsl/July08/July08.pdf

3.12 December

3.12.1 Burris on Compliance vs. Conscience (2008-12-14 14:37)

Scott Burris, a law professor and author of at least three earlier articles on IRBs and human subjects regulation, takes on the Common Rule in "[1]Regulatory Innovation in the Governance of Human Subjects Research: A Cautionary Tale and Some Modest Proposals," Regulation & Governance 2 (March 2008): 65-84.
Burris begins with a bleak picture of the status quo:

> The IRB is not purely or even primarily a body for deliberating ethical questions. Though ill-equipped for the task, the IRB is now an oversight agency expected to spot bad actors and monitor researcher behavior. The IRB may engage in rich ethical deliberation, but it is not a dialogic institution with respect to the researcher, who generally takes no part in the IRB's deliberations. No mechanism informs IRBs of the real cost of the "small" changes they demand. From the researcher's point of view, the IRB can be a faceless bureaucracy at its most unchecked, not required to give reasons for arguably arbitrary decisions from which there is no clear right to appeal.
> Nor is it a particularly efficient or effective bureaucracy. The level of paperwork required to conduct research has grown steadily, even as it is widely agreed that researchers, IRBs, and the OHRP spend too much time documenting routine compliance. Agonizing over the paperwork problem does serve one purpose: it takes attention away from more fundamental problems. Foremost among these is the sparse evidence that the system is actually protecting research subjects. (67)

Burris blames these troubles on what he sees as fundamental flaws in the Common Rule.

> The Common Rule system was not designed by people thinking about regulatory technique. To the extent there was a design at all, the Common Rule reflected a dream of radical regulatory purification. This was to be a legal system without lawyers, a political system without politics. Values would be aired, and fair decisions made, by sensible people of good will. Consistency and fairness would arise naturally from the process and principles deployed. (68)

Such expectations, he suggests, were naive, for they left IRBs with two, incompatible missions: "virtue promotion and oversight" (78). In other words, he doubts that the current system can follow Greg Koski's call to "move beyond the culture of compliance, to move to a culture of conscience and responsibility." [Philip J. Hilts, "New Voluntary Standards Are Proposed for Experiments on People," New York Times, 29 September 2000.]
Instead, Burris write,

> As a deliberative body, the IRB has been deeply compromised by its authority. If we leave aside the apparently rare cases of extreme conduct, reasonable minds can and generally do differ on the application of principles such as justice, beneficence, and autonomy . . .
> Ethical principles are about illumination, not adjudication . . . Yet the IRB, in spite of its roots in philosophical deliberation, is structurally required to act as an adjudicatory body. At the end of whatever thoughtful discussion takes place, it must produce a "right answer," telling the investigator whether the protocol must be changed or abandoned. Even to the extent that deliberation does illuminate key issues, the typical absence of the researcher, the key moral agent in the matter, undermines the value of the exercise in promoting virtue.
> The same features that might, in the absence of authority, make the IRB a fruitful deliberative body – its diverse composition and informal decision-making style – are toxic to its capacities as an overseer of research. (70)

Burris makes several interesting proposals, including "breaking the current regulatory system in two, building one regulatory approach for biomedical experimentation and another for social, behavioral, and epidemiological research." (74) But the key recommendation is "to keep ethics separate from the power to control the design and conduct of research." Burris wants to

> deprive IRBs of the power to independently stop or alter a study at all, placing a burden on the IRB to make a case for changes to a higher authority (such as a university administrator). Such constraints would, in practical terms, require the IRB to persuade the investigator through discussion that a study had ethical problems. This would not only be likely to reduce erroneous changes but also give the researcher the opportunity to take part in ethical deliberation as an autonomous agent. As side benefits, an IRB speaking directly with the researcher might be better able to make credibility determinations or uncover mistakes, and would certainly get a better idea of the costs its proposed alterations would impose. (76)

In January 2007, I proposed an even bolder shifting of the burden, by making IRB review [2]voluntary, at least for social science projects. And Burris might well agree; he isn't sure that any regulation is necessary for "social, behavioral, and epidemiological research, where there is virtually no risk of death or serious injury." (77)

I am intrigued by Burris's analysis of the tensions inherent in the IRB enterprise, but I am left with three questions.

First, how different is the IRB regime from what Burris describes as "traditional top-down regulation and hard law"? (66) Presumably regulators with other missions, like food safety and pollution control, would like to promote virtue as well as overseeing behavior. For example, the Code of Federal Regulations includes many requirements that manufacturers use "good engineering judgment." Is it any easier to reach consensus on engineering judgment than on matters of research ethics? It may be; the Common Rule's demands that "risks to subjects are minimized" and that "risks to subjects are reasonable in relation to anticipated benefits" are quite possibily vaguer and more ambitious than anything that engineers face. But if this is the case, it would be nice for Burris to show that the internal tensions of the Common Rule are worse than those afflicting other regulatory regimes.

Second, does Burris think that IRBs ever functioned well? The federal government has required IRB review of some research since 1966, yet almost all of Burrris's citations concerning the problems of IRB review were written after 1998. Robert Levine and Jonathan Moreno argue that before the crackdown of 1998 there were some "good old days" of "moderate protectionism." [Robert J. Levine, "Empirical Research to Evaluate Ethics Committees' Burdensome and Perhaps Unproductive Policies and Practices: A Proposal," Journal of Empirical Research on Human Research Ethics 1 (September 2006), 3; Jonathan D. Moreno, "Goodbye to All That: The End of Moderate Protectionism in Human Subjects Research," Hastings Center Report 31 (May-June 2001): 9-17.] Does Burris agree? If so, it's a little harder to blame today's problems on flaws inherent in a decades-old system. Harder, but perhaps not difficult. Burris writes of a "a one-way ratchet increases the number of reviews, the paperwork, and required training with each major scandal." (73) So he may believe that the ratchet was always waiting, and that the good old days were inevitably numbered.

Third, what is to be done with Burris's insights? Burris concedes that he doesn't know how to put his proposals into effect. "Ideas are a good start," he writes, "but the political and social forces that produced the current system continue to exert their powerful influence. People seem to like regulatory systems that purport to prevent all bad outcomes. They like to have institutions to blame when unavoidable harms transpire, and they want to be told that changes have been made to make us all safe again." (80) And "stopping this one-way ratchet . . . would require what has so far been absent: support of the political leadership in the face of public intolerance of even a small rate of error." (73) Without quite saying it, Burris is calling for legislative overhaul.

Burris's article makes an interesting contrast to Felice J. Levine and Paula R. Skedsvold, "[3]Where the Rubber Meets the Road: Aligning IRBs and Research Practice," PS: Political Science & Politics 41 (July 2008): 501-505. In their reply to my comments on that article, Levine and Skedsvold wrote that "short of significant regulatory reform (which is not likely) or other creative solutions, social scientists will find themselves at this same place years from now. Even Congressional action (e.g., at least one bill is being redrafted now) is not likely to help matters."

While not as pessimistic as Levine and Skedsvold, I do agree that regulatory or legislative change would be difficult. Whateve the merits of Burris's plan to strip IRBs of their coercive power, his proposals are anything but modest.

1. http://www.ingentaconnect.com/content/bpl/rego/2008/00000002/00000001/art00005
2. http://www.institutionalreviewblog.com/2007/01/why-not-make-irb-review-voluntary.html
3. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html

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3.12.2 The Costs of Ethical Review (2008-12-25 13:35)

In his article on "Regulatory Innovation," [1]discussed here earlier, Scott Burris complains that

> the core problem with the Common Rule is the IRB's power to treat its insights and risk–benefit calculations as "right answers" that may be imposed at no cost to the IRB upon researchers whose own ethical reflection may have led to different, equally defensible conclusions.

Robert Dingwall concurs in his essay, "[2]The Ethical Case Against Ethical Regulation in Humanities and Social Science Research," 21st Century Society 3 (February 2008): 1-12. Though Dingwall is British, he notes that the system there looks "very like US Institutional Review Boards, and their analogues in Canada and Australia." (4) British boards, and British rules in general, fail to account for the costs of ethical review.
This has real consequences. Dingwall relates his own experience:

> A colleague and I were recently commissioned by the NHS [National Health Service] Patient Safety Programme to study the national incidence and prevalcence of the reuse of single-use surgical and anaesthetic devices, and to consider why this practice persisted in the face of strict prohibitions. Part of this involved an online survey, using well-established techniques from criminology to encourage self-reporting of deviant behaviour, so that relevant staff in about 350 hospitals could complete the forms without us ever needing to leave Nottingham. However, a change in NHS ethical regulation meant that we needed approval from each site, potentially generating about 1600 signatures and 9000 pages of documentation. Although we never planned to set foot in any site, it would also have required my colleague to undergo around 300 occupational health examinations and criminal record checks. As a result, we were unable to carry out the study as commissioned and delievered a more limited piece of work. Other estimates suggest that the practice we were studying leads to about seven deaths every year in the UK and a significant number of post-operative infections. The ethical cost of the NHS system can be measured by the lives that will not be saved because our study could not investigate the problems of compliance as thoroughly as it was originally designed to. (10)

This is a stark example, but Dingwall sees it as emblematic of a general drag on social research that has consequences for the future of free socieites. Ethical regulation of humanities and social science research, he argues, contributes to "a waste of public funds, serious information deficits for citizens, and long-term economic and, hence, political decline . . . " (10)
Dingwall discounts the need for oversight, arguing that humanities and social science researchers "do nothing that begins to compare with injecting someone with potentially toxic green stuff that cannot be neutralised or rapidly eliminated from their body if something goes wrong. At most there is a potential for causing minor and reversible emotional distress or some measure of reputational damage." (3) I think this takes the case too far. See Sudhir Venkatesh's Gang Leader for a Day for a recent example of a social scientist who seriously hurt people by breaking their confidences. (The book is recent; the incident took place in the early 1990s.) Dingwall's own research, had it exposed a physician who was illegally re-using devices, would have done irreversible harm to that physician. Rather than arguing that such harms are impossible, Dingwall would be better off arguing that they are a) rare, and b) not likely to be prevented by

the forms of prior review now in place.

The Belmont Report calls for "systematic, nonarbitrary analysis of risks and benefits . . . This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically." If we were to hold regulatory regimes to the same standard, we would find ample risks, few documented benefits, and no consideration of alternatives.

1. http://www.institutionalreviewblog.com/2008/12/burris-on-compliance-vs-conscience.html
2. http://www.informaworld.com/openurl?genre=article&issn=1745%2d0144&volume=3&issue=1&spage=1

Chapter 4

2009

4.1 January

4.1.1 Happy New Year, OHRP (2009-01-01 20:00)

In February 2007, the [1]New York Times reported on scholars' frustration with IRB review of social research. OHRP assured reporter Patricia Cohen that it was working on the problem:

> Bernard A. Schwetz, director of the federal Office for Human Research Protections, which administers the regulations, acknowledges that the guidelines covering the boards' actions have not been clear enough and says he intends to make public new proposed guidelines before the end of the year.

Later in the article, Schwetz "said the new guidelines 'will give a lot of examples and will give more guidance on how to make the decision on what is research and what is not.'" This makes it clear that the 2007 call for comments on expedited review is not what he had in mind.
With the end of 2008, the promised guidelines are more than a year late.
This may be for the best. Schwetz seemed determined to continue OHRP's history of trying to regulate everything, while under Menikoff, we might expect better results. But OHRP and its predecessors have made a lot of empty promises over the years, and it's frustrating to see that tradition continued.

1. http://www.nytimes.com/2007/02/28/arts/28board.html

4.1.2 OHRP to Revise Website (2009-01-10 23:33)

[1]OHRP has called for feedback on the "content, format, navigation or any other aspect" of its website. Below are the comments I sent in.

Dear OHRP,
Thank you for your invitation for suggested improvements to the OHRP website. Before making any suggestions, I must first thank you for the existing website, which contains a great deal of extremely valuable information. As a historian, I particularly appreciate the historical material, including the Belmont Report oral history section, and the

compilation of key notices from the Federal Register dating back to 1973.
With this in mind, let me suggest some additional material that would be helpful.

1. Responses to calls for comments

When OHRP issues calls for comments in the Federal Register, it routinely advises that "comments received within the comment period, including any personal information provided, will be made available to the public upon request." While I am grateful to OHRP staff for sending me electronic versions of these comments in replies to my requests, I suggest that all comments be posted on the OHRP website as well. The comments I have seen constitute thoughtful, informed positions on the regulation of human subjects research and mark significant contributions to the debate on the subject. They have been the subject of reporting in the press, suggesting the wide interest in them.
Placing the comments on the website would insure equal access to those comments by all concerned, and would solve the problem of electronic files that are too big for easy transmission by e-mail. Posting would also preserve the comments for future readers, a key concern given that many issues crop up repeatedly. For example, in 2007, OHRP requested comments on expedited review. Anyone responding to that call would have benefited from access to the comments received in reply to the similar call of 1997. But those earlier comments seem to have been lost to history.

2. Reports to which OHRP has contributed

In June 2008, the Human Subjects Research Subcommittee published a report called "Expedited Review of Social and Behavioral Research Activities." Perhaps this is not technically an OHRP report, but the Subcommittee was co-chaired by the acting director of OHRP, and both he and Mr. Drew of OHRP were members of the working group that produced the report. Yet there is no link to the report on the OHRP website, nor did I receive notice of it from the OHRP-L@LIST.NIH.GOV mailing list. When OHRP staff, acting in their official capacities, contribute to a report like this, it should be announced on the list and a link added to the OHRP site.

3. A complete copy of the Bell Report

Your current page, http://www.hhs.gov/ohrp/related.html, includes a copy of "Evaluation of NIH Implementation of Section 491 of the PHS Act, Mandating a Program of Protection for Research Subjects," published in 1998. But it does not include the technical appendices mentioned on page ii of that report, nor have I been able to locate a copy of those appendices. Posting them would be of value.

4. A link to OPRR Reports

The section on "Historical Documents" on the page http://www.hhs.gov/ohrp/related.html does not mention the OPRR Reports posted at http://www.hhs.gov/ohrp/dearcoll.htm. As the latter page indicates, most of these documents exist "solely as a reference for historical purposes." I am very glad that these documents are online, but I suggest that as historical documents, they deserve a link under the "historical documents" section. For that matter, I'd like to see the "Historical Documents/Information" section, including the Federal Register notices, given its own page, but I realize this wish may reflect my unusual perspective as a historian. I would also like a note added clarifying if the OPRR Reports now online represent all or just some of the OPRR Reports sent out during that office's existence.
Thank you again for this opportunity to comment on the website. If I think of additional suggestions, I will be sure to send them in.
Sincerely,
Zachary M. Schrag
Assistant Professor of History, George Mason University

1. http://transparency.cit.nih.gov/ohrp/feedback.cfm

4.1.3 Canada Considers a New TCPS (2009-01-22 21:53)

The [1]Research Ethics Blog alerted me to the relase of the [2]Draft 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), Canada's manifesto of research ethics. The document is strong in its recognition of critical inquiry. But it is weak in establishing mechanisms to meet its stated goals of proportionate review and reasoned decision-making. It fails to address some of the key concerns in the 2004 report, [3]Giving Voice to the Spectrum, and threatens to leave social scientists not much better off than they are today.

Valuing Critical Inquiry

The new draft recognizes differences among the various activities that go by the name "research." Like the Belmont Report, it offers three core principles: concern for welfare, respect for autonomy, and respect for the equal moral status of all humans. Unlike Belmont (and particularly unlike 45 CFR 46), it recognizes that

> these principles are not absolute. They may, at times, conflict. They do not apply in all circumstances, to all types of research, as is set out in the following chapters. How they apply and the weight to be accorded to each one will depend on the nature and context of the research being undertaken. (2)

Such insight is elaborated in sections on social research. In particular, the draft Statement embraces "critical inquiry," in passages longer and stronger than those in the existing Statement:

> Research based on critical inquiry – focusing, for example, on public policy issues, modern history, or literary or artistic criticism – may involve interaction with living individuals, notably through interviews. Where the aim of the researchers is to engage in a critical examination of a body of artistic work, a public policy, other comparable types of work, the role of the REB should be limited to ensuring that researchers conduct their work respecting the professional standards of their discipline(s) or field(s) of research. The need to ensure freedom of inquiry and to protect the ability of researchers to criticize the work (or organization, political party, corporate enterprise, etc.) they are examining takes precedence over the need to protect individual parties from harm. (9)

Alas, the authors of the draft are inconsistent in their understanding of the role of critical inquiry. They write,

> In certain areas of research in the social sciences and humanities, such as political science, economics or modern history (including biographies) . . . the purpose of the research may be to cast a critical eye on organizations, political institutions, or systems or individuals in public life. The outcome of these types of research may harm the reputation of public figures or institutions in politics, business, labour, the arts, or other walks of life. Such harm may, however, be an unavoidable outcome of research that seeks to shed light on or to critically assess the work of a public figure or institution. Where the purpose of the research is to advance knowledge about the workings, for example, of a public office or a public figure, the risk–benefit analysis by the REB should focus on whether the approach they have adopted respects the professional standards of the researcher's discipline or fields of research. Just as a bruise is an unavoidable risk of research that requires a needle-stick, so harm to reputation is an unavoidable risk of certain types of social science inquiry, and it must be treated as such. (14)

That's fine until the last sentence, which suggests that the authors don't understand critical inquiry at all. A bruise is an unfortunate byproduct of a needle-stick. A harm to reputation is often the deliberate objective of critical inquiry.

The trick, [4]William Potter, is not minding that it hurts.

Seeking Proportionality

The draft Statement concedes that too much review can be a bad thing, stating that

> The scope and intensity of ethics review should be proportionate to the level of risk involved. When those involved in the review of research tailor their level of scrutiny to the level of risk, they reduce unnecessary impediments and facilitate the progress of worthwhile and ethical research. This is the crux of proportionality, and it is a message that recurs throughout this Policy.
> It is equally important that ethics review be appropriate to the disciplines, fields of research and methodologies of the research being reviewed. This means that REBs must understand the discipline and methodology under review and be able to assess the research on its own terms. (5)

To give researchers a fair shot, the Statement insists that "at least two members should have the relevant knowledge and expertise to understand the content area and methodology of the proposed or ongoing research, and to assess the risks and benefits that may be associated with the research," and that it seek ad hoc advisors when necessary. (58) It even requires "an established mechanism and procedure in place for entertaining appeals" (69), even permitting ad hoc appeals board, something forbidden by the existing statement.

Unfortunately, the draft does little to ensure "a proportionate approach to ethics review" or even to consider what that means. There's nothing in the statement to suggest that ethics boards are uniquely suited to uphold ethical standards, or that they are necessary for all kinds of human subjects research. So why must all research pass through an REB? While the idea of proportionality recurs throughout the document, when we get to its actual application (p. 63) we find only two levels of review: delegated REB review of minimal-risk research, and full REB review of everything else. A two-speed transmission is not very proportionate.

Giving Voice to the Spectrum called for "different approaches to ethics review that would allow REB blanket approval of programs of research based on the overall ethics strategy of the researcher (or team of researchers), within specified parameters" as well as "exemptions from review for social science and humanities research that involves standard practice in the discipline involved." (6)

Along these lines, a more proportionate system would allow for several levels of review, e.g.,

1. No review–for activities even a middle-schooler can do (e.g., conversations with family members)
2. Researcher certification–for activities where the key thing is to be sure the researcher is familiar with professional standards. The draft itself suggests that this is appropriate for much interview research.
3. Departmental committee review.
4. Delegated review.
5. Full board review.
6. Full board review plus outside consultation–for the riskiest research.

Another problem with proportionality is its dependence on the threshold of "minimal risk," which doesn't map well onto the type of critical inquiry that the policy seems to endorse. As noted above, the draft states that "where the aim of the researchers is to engage in a critical examination . . . the role of the REB should be limited to ensuring that researchers conduct their work respecting the professional standards of their discipline(s) or field(s) of research." That would seem to imply that the intent of the research, as well as its level of risk, should determine the level of review.

Ignoring Evidence?

Another big concern is that the document makes no requirement that REBs base their decisions on empirical reality. Giving Voice to the Spectrum called for "a shift in onus where, in order to require changes to a research proposal, an REB would be obliged to explain what identifiable harm has not been addressed, and how their proposed solution will ameliorate the problem." (6) That has not happened.

Article 6.13 of the draft provides that "the research ethics board shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions." But what does "appropriately documented" mean here?

The 2005 TCPS also required "reasoned and well-documented decisions" (Article 1.9). But much conflict between REBs and researchers takes place when they cannot agree on what is meant by reasoned and documented. For example, when [5]Tony Porter wanted to do some interviews about the governance of research ethics, his REB demanded that it be allowed to scrutinize the questions in advance, looking for some mysterious risk. Would such behavior count as a fair hearing with reasoned and appropriately documented opinions and decisions? Are boards empowered to dream up fantastic risks? Or should the standard be higher, demanding that ethics boards operate according to scholarly standards, and document the risks that they attribute to a project?

Again, compared to the Belmont Report, the ethics sections of this new TCPS are relatively nuanced, reflecting long thought and the input of a great many scholars. I'd like to see American universities list the TCPS as the "statement of principles" on their Federalwide Assurances. (See [6]The Dormant Right to Ethical Self-Determination".) But by assuming the need for board review, and by failing to set standards for board decision-making, the draft leaves research vulnerable to the "unnecessary impediments" it seeks to eliminate.

1. http://www.researchethics.ca/blog/2009/01/canadian-research-ethics-coming-soon-to.html
2. http://www.pre.ethics.gc.ca/english/newsandevents/newsreleases/draft_2nd_ed_of_TCPS.cfm
3. http://www.pre.ethics.gc.ca/english/workgroups/sshwc/reporttopre.cfm
4. http://www.youtube.com/watch?v=tY6iKJn-HK4
5. http://www.institutionalreviewblog.com/2008/07/biomedical-ethics-juggernaut.html
6. http://www.institutionalreviewblog.com/2008/07/dormant-right-to-ethical-self.html

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4.1.4 IRB Says Women Can't Be Photographed (2009-01-26 22:50)

The New York Times reports IRB interference with a study that combines medical and social research. (Gina Kolata, "[1]Fitness Isn't an Overnight Sensation," 21 January 2009).

> Carl Foster, an exercise physiologist at the University of Wisconsin, La Crosse, was amused by ads for a popular piece of exercise equipment. Before-and-after photos showed pudgy men and women turned into athletes with ripped bodies of steel . . .
>
> "We said: 'Wait a minute. You can't change yourself that much,' " Dr. Foster said. So he and his colleagues decided to experiment. Suppose they recruited sedentary people for a six-week exercise program. Would objective observers notice any changes in their bodies?
>
> The plan was to photograph volunteers wearing skimpy bathing suits and then randomly assign them to one of three groups: cardiovascular exercise, weight lifting or control. Six weeks later, they would be photographed again.
>
> Their heads would be blocked out of the photos, which would be shuffled. Then the subjects and judges would rate the body in each photo on a scale of 1 to 10, with 10 being spectacular.
>
> The volunteers were men, age 18 to 40 (the university's human-subjects review board looked askance at having women photographed and rated like that).

This is another case where Canada's TCPS (even the existing version) shows a more sophisticated undertsanding of research ethics than does the Belmont Report or the U.S. regulations. Whereas the Belmont authors were concerned about vulnerable populations being inappropriately targeted for medical studies, they did not think about the arbitrary exclusion of populations, or the stigmatization of competent adults as incompetent. By contrast, Article 5.2 of the

2005 version of the TCPS states that "women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity."
I am unaware of any U.S. regulation or guidance that so specifically forbids the kind of sexism displayed by the La Crosse IRB. Still, it's disappointing that that IRB thinks adult women incapable deciding for themselves whether to participate in a study open to men.
For this study's implications for advertising law, see [2]Rebecca Tushnet's 43(B)log.

1. http://www.nytimes.com/2009/01/22/health/nutrition/22best.html?em
2. http://tushnet.blogspot.com/2009/01/where-advertising-law-and-irbs-collide.html

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4.1.5 Blame the ESRC? (2009-01-27 20:41)

David Hunter kindly alerted me to Sarah Dyer and David Demeritt, "[1]Un-Ethical Review? Why It Is Wrong to Apply the Medical Model of Research Governance to Human Geography," Progress in Human Geography 33 (2009).
Dyer and Demeritt attack the Economic and Social Research Council's 2005 [2]Research Ethics Framework, the basic document guiding British Research Ethics Committees (RECs) in their oversight of social research. Some of this attack strikes me as misplaced, since it ignores elements of the Framework that address the authors' concerns.
For example, the authors complain that

> in the case of critical social science, the aim of the research is typically to expose wider social injustices and in that way actually harm those who benefit from them. But, following the injunction of the ESRC (2005: para 3.2.5) that '[p]articipants' interests or well-being should not be damaged as a result of their participation in the research', it would be impossible to secure permission to interview employers whose discriminatory practices a researcher was hoping to expose and thereby end. (55)

But the ESRC understands this (somewhat), noting,

> Much social science research has a critical role to play in exploring and questioning social, cultural and economic structures and processes (for example relating to patterns of power and social inequality), and institutional dynamics and regimes that disadvantage some social groups over others, intentionally or not. Such research results may have a negative impact on some of the research subjects. (22)

Likewise, Dyer and Demeritt write,

> there are times when safety, either of the investigator or of research subjects themselves, means that research subjects cannot be informed about the true nature of research [such as] studies of human trafficking, illegal workers' gang masters, and so on. In such cases the notion of asking participants to sign a consent form of the sort envisioned by the ESRC (2005) is ridiculous, and the ill of deception balanced by the importance of the research and a commitment to protecting anonymity. (57)

But the Research Ethics Framework recognizes this problem, stating, "informed consent may be impracticable or meaningless in some research, such as research on crowd behaviour, or may be contrary to the research design, as

is often the case in psychological experiments where consent would compromise the objective of the research. In some circumstances – such as users of illegal drugs – written consent might also create unnecessary risks for research subjects." (21)
The real problem, it seems, is not the ethical content of the Research Ethics Framework, but the structure it employs to promote those ethics. Project-by-project committee review may be unable to handle the complexity and unpredictablity of social science research. As Dyer and Demeritt write,

> Whereas drugs trials involving vast sums of money, or biomedical research on extremely vulnerable people in enormous pain need only gain anticipatory approval, the ESRC argues that because 'purposes, methods, and intended uses' of qualitative research evolves as it proceeds, this kind of research should be required to seek REC approval on multiple occasions. Such a disproportionate response is itself unethical if it overburdens researchers such that worthwhile research does not get done. (57)

The underlying issue is that committee review is a process specifically tailored to experimental research. The more a researcher fits the experimental model, the more detailed her protocol will be, and the more amenable to prior review. It's the open-ended, qualitative researcher who has the low signal-to-noise ratio, and for whom ethics committee represent such a waste of time.

1. http://phg.sagepub.com/cgi/content/abstract/33/1/46
2. http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf

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4.1.6 And the Bush Was Not Consumed (2009-01-31 16:47)

Robert Dingwall kindly alerted me to Scott Kim, Peter Ubel, and Raymond De Vries, "[1]Pruning the Regulatory Tree," Nature 457 (29 January 2009), 534-535.
The authors have complex disciplinary backgrounds. Kim has an MD and a PhD in philosophy, and teaches psychiatry. De Vries has a PhD in sociology and the title of associate professor of bioethics/medical education. And Ubel has an MD and describes himself as a "physician and behavioral scientist." Together, they are unusually well prepared to think about the full range of disciplines affected by human subjects regulations.
The authors complain that IRB review of minimal risk research wastes time and money, infringes academic freedom, and threatens public health by impeding important research. They conclude that "it is unethical to support a system that creates a significant financial, scientific, clinical and ethical burden with virtually no counterbalancing good."
To fix this, they propose "a simple regulatory change that is far-reaching, equitable and yet low risk: exempt minimal-risk research from IRB review." In their scheme, researchers would still "complete a brief application describing research procedures, risks, burdens and the potential loss of otherwise expected benefits to the subjects. An institution-designated person reviews the application, and exempted protocols would not be subject to further IRB review. The application becomes the project's registration and serves as an accountability document."
This sounds fine on the surface, but the proposal raises some questions.

1. How can we change the Common Rule?

The authors propose a change in the regulations, but they do not address the difficulty of getting agreement from all Common Rule signatories. In 2002, [2]Marjorie Speers of AAHRPP testified that " there is no effective means to [revise policy]; the agencies who are signatories to the Common Rule have not been able to make changes to it in the last 11 years even though the need for changes has existed." That was nearly seven years ago, and nothing has improved. See [3]The Calcified Common Rule.
Under the circumstances, we may need new legislation, rather than regulation.

2. Would OHRP and institutions respond to changed regulations?

The authors recognize that even if the regulations were changed, "institutions have a tendency to impose on themselves requirements that are even more stringent than those required by law," so they might impose review on minimal-risk research anyway. Indeed, the [4]1998 Bell study found that less than half of protocols eligible for exemption actually received it. I imagine that percentage has gone down in the past decade, considering [5]regulators' hostility to the existing exemptions.

To address this problem, the authors claim that "a new regulation that exempts minimal-risk research from IRB review would send a clear and unambiguous message that the government's priority is not on intense oversight of low-risk research." Perhaps, but the government does not speak with one voice, and regulators have resisted earlier calls for deregulation. The greatest effort at deregulation–the 1981 exemptions–was followed within months by OPRR suggestions that universities act more stringently than required by the regulations. The 1995 ACHRE recommendation for "[6]alternative mechanisms for review and approval of minimal-risk studies" was followed by the OPRR crackdown that led to far more burdensome review of minimal risk research.

If the authors are serious about reform, they should seek not a "message," but rather a law that restrains OHRP and penalizes interference with minimal risk research.

3. Would exemption be any better than expedited review?

As noted above, when the authors call for "exemption," they use the term in the specialized way introduced by OPRR in 1995. Rather than meaning that a researcher is free from IRB jurisdiction, they mean that a researcher would still have to write up an application and submit it to an "institution-designated person." The authors claim that "substantial resources would be freed for better uses."

The authors base this claim in part on a 2005 finding that in US medical schools, the average expedited review cost more than the average full review ($1,060 vs. $1,021). [See Jeremy Sugarman, Kenneth Getz, Jeanne L. Speckman, Margaret M. Byrne, Jason Gerson, and Ezekiel J. Emanuel, "[7]The Cost of Institutional Review Boards in Academic Medical Centers," New England Journal of Medicine 352 (April 28, 2005), 1825-1827.] But that study did not estimate the cost of reviews for exemptions.

Indeed, the system the authors propose is not very different from the [8]current system for expedited review; the big difference being that the authors would delegate authority to an "institution-designated person" who might not be an IRB member. But their proposal would still require a good deal of paperwork and staff time, as well as the review by a single person, so it might not cost much less than the expedited system they seek to replace.

This question is open to empirical research. The authors, or someone else, could repeat the Sugarman analysis, but studying institutions that require staff review for proposals that are exempt under the existing 45 CFR 46.101 clauses.

4. Is pruning enough?

In sum, the regulatory tree may be tougher to prune, and to keep pruned, than the authors suppose. Here's a counter proposal adapted from advice concerning a [9]similar growth:

> For successful long term control of human subjects regulations, the extensive root system must be destroyed. Any remaining root crowns can lead to reinfestation of an area. Mechanical methods involve cutting vines just above ground level and destroying all cut material. Close mowing every month for two growing seasons or repeated cultivation may be effective. Cut human subjects regulations can be fed to livestock, burned or enclosed in plastic bags and sent to a landfill.

1. http://www.nature.com/nature/journal/v457/n7229/full/457534a.html
2. http://help.senate.gov/Hearings/2002_04_23_a/Speers.pdf
3. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-2-calcified.html

4. http://www.hhs.gov/ohrp/policy/hsp_final_rpt.pdf
5. http://www.institutionalreviewblog.com/2008/10/45-cfr-46101-is-still-dead.html
6. http://www.hss.energy.gov/healthsafety/ohre/roadmap/achre/chap18_2.html
7. http://content.nejm.org/cgi/content/extract/352/17/1825
8. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.110
9. http://www.nps.gov/plants/alien/fact/pumo1.htm

4.2 February

4.2.1 PRIM&R Plans SBER Webinar (2009-02-05 22:51)

On February 25, PRIM &R will host a "webinar" entitled "[1]New Solutions to Ongoing Problems When Reviewing Social, Behavioral, and Educational Research." The two faculty are Mary Marshall Clark, who successfully liberated oral history from IRB oversight at Columbia, and J. Michael Oakes, whose chapter in Institutional Review Board: Management and Function more or less claims that questionnaires can drive people to suicide. That's an interesting contrast, though not interesting enough for me to pay $175 to participate.

1. http://www.primr.org/Conferences.aspx?id=6389

4.2.2 PRIM&R Plans SBER Webinar (2009-02-05 22:51)

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1. http://www.primr.org/Conferences.aspx?id=6389

Anonymous (2009-02-06 21:54:00)
My university is paying for the webinar (ack! an awful pseudo-word), so I will view it. Your description of the presenters leaves me at once optimistic and pessimistic. What are the odds that Oakes will persuade IRBs that they should be more cautious? Mine is already too cautious, it seems to me.

Zachary M. Schrag (2009-02-06 23:29:00)
Thanks for your comment. I hope to hear more after the webinar.
Zach

4.2.3 Oral History Wins and Loses (2009-02-06 23:33)

Two large public universities have recently announced policies concerning IRB review of oral history. It was a split decision.
The University of Nebraska-Lincoln (UNL) promulgated [1]Policy # 001: IRB Review of Oral History Projects, dated 1 October 2008. The policy is based on [2]Columbia University's 2007 oral history policy. According to the Nebraska

policy,

> Oral history interviews, that only document specific historical events or the experiences of individuals or communities over different time periods would not constitute “human subjects research” as they would not support or lead to the development of a hypothesis in a manner that would have predictive value. The collection of such information, like journalism, is generally considered to be a biography, documentary, or a historical record of the individual’s life or experience; or of historical events. Oral history interviews of individuals are not usually intended to be scientific or to produce generalizable information and hence are not usually considered “research” in accordance with the federal regulations or UNL policy. Therefore, such oral history activities should not be submitted to the UNL IRB for review.

The explanatory memo borrows two explanatory examples from Columbia, without attribution. It does cite [3]OHRP’s 22 September 2003 letter to the Oral History Association and American Historical Association, in which Dr. Michael Carome promised that "most oral history interviewing projects . . . can be excluded from institutional review board (IRB) oversight because they do not involve research as defined by the HHS regulations."

So far so good. But less than four months later, the University of Illinois at Chicago (UIC) released a policy statement, "[4]IRB Review of Oral History and Other Social Science Projects" and an accompanying [5]Tip Sheet: IRB Review of Oral History and Other Social Science Projects." This policy demands that "investigators wishing to perform oral histories or other social science projects must complete and submit the Determination of Whether an Activity Represents Human Subjects Research form to the [Office for the Protection of Research Subjects]."

UIC claims that "increasingly . . . the application of qualitative research methodologies may render studies that typically would not have required IRB review and approval to be submitted for IRB review or, at least, to require a determination from the IRB as to whether the study is subject to human subjects protection regulations." If anyone at UIC can show me that this statement is based on a study of trends in historical scholarship (rather than being made up to justify the policy), I will send a small box of [6]good chocolates.

Follow a few links, and you can find the real basis for the UIC policy: [7]Dr. Carome’s December 2003 e-mail to Lori Bross of Northern Illinois University, in which he backed way from his September 2003 promise to the historians and embraced a set of [8]nonsensical examples first proposed by the UCLA Office for Protection of Research Subjects.

In short, OHRP’s perfidy of 2003 still echoes across the country. Depending on whether you believe Michael Carome’s statements of [9]September 2003, [10]October 2003, [11]December 2003, or [12]January 2004, you may come away with very different understandings of the federal government’s policy toward oral history, and the leeway allowed to institutions.

1. http://research.unl.edu/orr/docs/UNLOralHistoryPolicy.pdf
2. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/Policy#001
Title: IRBReviewofOralHistoryProjects
3. http://www.historians.org/press/IRBLetter.pdf
4. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html
5. http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0902.pdf
6. http://www.artisanconfections.com/
7. http://www.nyu.edu/ucaihs/forms/oralhistory/email.php
8. http://www.oprs.ucla.edu/human/documents/pdf/oral-history-031209.pdf
9. http://www.historians.org/press/IRBLetter.pdf
10. http://www.oprs.ucla.edu/human/documents/pdf/oral-history-031209.pdf
11. http://www.nyu.edu/ucaihs/forms/oralhistory/email.php
12. http://alpha.dickinson.edu/oha/org_irbupdate.html

Anonymous (2009-02-07 09:58:00)
This might be due, at least in part, to UIC's experience with having research on campus shut down because of IRB problems that occurred a few years ago.
Still, it is disappointing. :-(

Zachary M. Schrag (2009-02-07 14:05:00)
That sounds like a reasonable hypothesis. UCLA came close to a shutdown at some point in the 1990s, which may explain the hyper-compliant culture that led to the oral history nonsense.
Zach

4.2.4 More Comments on Maryland's IRB Law (2009-02-10 21:12)

In [1]January 2008, I commented on Adil E. Shamoo and Jack Schwartz, "Universal and Uniform Protections of Human Subjects in Research," American Journal of Bioethics 7 (December 2007): 7-9. That essay applauded a 2002 Maryland law that seeks to impose federal regulations on all human subjects research conducted within the state, even if not conducted at an institution with an FWA. As I noted at the time, the law is of dubious constitutionality, and it has probably survived this long only because it has never been enforced.
The [2]November 2008 issue of the same journal reprints the Shamoo/Schwartz essay as a "target article," along with eight invited commentaries. Several of the commentaries complain that the federal regulations–and therefore the Maryland law–are insufficiently protective, rather than overly broad, but none of these address social science.
Three commentators do address Shamoo and Schwartz's failure to consider the impact on social science research. Neil W. Schluger complains that "their solution will do very little to protect human subjects, and perversely, it may actually make the situation worse by simply piling more studies into an overburdened and flawed system." (13) He notes that

> a very large percentage of studies that IRBs review are studies involving minimal risk to subjects. Many of these are observational studies, reviews of existing data, studies in which the only intervention is administration of a questionnaire, or other types if studies where there really is no reasonable expectation that any harm could result. Although such studies can be reviewed by the use of expedited review procedures without convening the full IRB, they still require considerable administrative and regulatory oversight by IRB staff. Further efforts should be made to reduce the work associated with these harmless studies. (14)

David B. Resnik notes that the idea of regulating all research nationwide has been kicking around since 1995, and has been the subject of six failed bills in Congress. But, he continues, "it is not obvious that society would gain much by requiring an organization, such as Gallup or ABC News, to submit a proposal to an institutional review board (IRB) to conduct an anonymous survey each time that it decides to gauge public opinion on a particular issue. Social resources might be better spent overseeing riskier research, such as clinical trials." (6) He concludes that "Any proposal that is made into a law should include adequate provisions for exempting some low risk research and clarifying the definitions of important terms." (8)
Lisa M. Rasmussen complains that the Shamoo/Schwartz position "makes no distinction between highly risky biomedical research and, on the opposite end of the spectrum, research that involves no more risk than we all accept daily. Does beneficence really require that human subjects be protected from answering questionnaires or being interviewed? If so, why does this protection not extend to marketing, polling, or journalism?" (18)
Instead, Rasmussen proposes

the one-time approval of research "templates." Taking advantage of the fact that a great deal of research follows traditional disciplinary methods, this model suggests that IRBs could approve a variety of research templates (written, for example, by discipline-specific bodies such as the American Psychological Association (Washington, DC), or by a researcher whose classes may repeat experiments semester after semester), and grant automatic exemption to any researcher using such templates. Accountability and oversight could be ensured by requiring the researcher to submit a simple form to the IRB agreeing to use such a template (which would also include provisions for protecting confidential data). Were this form electronically based, research could proceed as soon as the form was submitted, without requiring submission of a protocol or awaiting approval. This achieves the goals of both minimizing bureaucracy and protecting human subjects. It meets our moral obligations to human subjects of research without uniformly requiring IRB oversight of research. (18)

Rasmussen concludes that "universal and uniform regulation of all human subject research is well-meaning but unnuanced." (18)
It is a pity that the journal does not print a reply by Shamoo and Schwartz. As I noted in my post last year, Shamoo himself has suggested that what he terms "low-risk research" is overregulated. I remain puzzled why he favors state laws that promise even more regulation of such research.

1. http://www.institutionalreviewblog.com/2008/01/how-state-irb-laws-threaten-social.html
2. http://www.bioethics.net/journal/index.php?jid=51

4.2.5 AAUP's Rhoades Takes Soft Line on IRB Training (2009-02-13 12:19)

In an essay on compulsory sexual harassment training ("[1]Sexual Harassment and Group Punishment," Inside Higher Ed, 12 February 2009), the new AAUP general secretary, Gary Rhoades, offers side comments on human subjects research training:

In research universities (where professors' work routinely involves human subjects, though even there literary and some other scholars are not required to undergo such training), perhaps the most obvious example of this is the human subjects training surrounding research grants and activity. Prior to getting grants approved by the sponsored projects division of a university, an investigator must have undergone human subjects training. Although the training varies by university, there are common patterns nationally. Typically, for example, such training is online, and is not particularly rigorous, to put it mildly. Indeed, the format involves investigators taking an exam by reading some written passages and then answering questions about them. After each section or module the person finds out whether he or she missed too many questions in a section, and proceeds. If they have missed too many questions in a section they simply backtrack, get the same questions in a different order, and retake the quiz, until they pass. A widely used set of exams (which are specified to social/behavioral and biomedical research) are those offered by the Collaborative Institutional Training Initiative, which over 830 institutions and facilities (including a very large number of research universities, and indeed including the University of California at Irvine) utilize. The modules for the CITI quiz typically include three to six questions.
For the most part, although faculty complain about the inconvenience and irrelevance of the training, I do not know of anyone who would suggest that such training should be required only of investigators found to have violated the rights of human subjects. The more important questions of process and principle surround the institutional review board activities that regulate the approval of an investigator's proposal. Here, serious questions have been raised about compromising investigators' academic freedom to engage

> in certain types of research and to research certain subject matter. But the controversy is not, for the most part, about the human subjects training per se. Indeed, I would venture to say that for colleagues in the social and behavioral sciences, among the most common comments and complaints about human subjects training are that it is ineffective, that it does little by way of actually protecting human subjects and seems to be geared more to protecting the institution.

Apparently, Dr. Rhoades is unfamiliar with the [2]widespread, principled opposition to CITI and other online training programs. That is worrisome, if it signals the retreat of AAUP from its longtime leadership in the fight against overly broad human subjects regulations and requirements.

1. http://insidehighered.com/views/2009/02/12/rhoades
2. http://www.institutionalreviewblog.com/2008/11/comments-oppose-new-regulations-on.html

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Gary (2009-02-14 11:44:00)
Zachary,
Let me assure you that I am fully aware of the opposition your refer to, which exists on my own campus, the University of Arizona. But the larger point I was making about these exams, which is a major point in the link you provided in your comment, has to do with the inadequacy of these exams in protecting human subjects, in addition to the restrictions the IRB process provides with regard to academic freedom. So rest assured that neither I nor the AAUP are backing down on overly broad regulations that compromise academic freedom. Indeed, we have ongoing activities underway in quite the opposite direction.
Yours,
Gary Rhoades

Zachary M. Schrag (2009-02-14 14:40:00)
Thank you for your comment.
You are quite right that many scholars and public officials deride human-subjects training programs as ineffective. But your essay downplayed the threat to academic freedom posed by such programs. As Professor Baron, the author of a book on bioethics, described his training, "it was more like brainwashing than education. I had to take a test, and, in order to pass the test, I had to express agreement with ethical statements that I thought were wrong."
I am delighted that the AAUP will continue to oppose overly broad regulations. I hope that this effort will include opposition to stupid training programs, not just because they are ineffective, but also because they force scholars to abjure their ethical principles.

4.2.6 Less Flexibility, More Freedom (2009-02-14 14:43)

Defenders of the present IRB system often boast of the "flexibility" offered by current regulations. (See, for example, [1]Dr. Jeffrey Cohen's report from the November PRIM &R meeting.)
But flexibility–when combined with the possibility of punishment–can actually empower censorship. Here is how Human Rights Watch describes an analogous system, [2]China's censorship of the Internet:

> The display of politically objectionable content can result in reprimands to company management and employees from the MII, the State Council Information Office, the Communist Party's Propaganda Department, and/or various state security organs, accompanied by warnings that insufficient controls will result in revocation of the company's license. In order to minimize reprimands and keep their licenses in good standing, BBS and blog hosting services maintain lists of words and phrases that either cannot be posted or which cause monitoring software to "flag" the content for manual removal by employees.

> Search engines likewise maintain lists of thousands of words, phrases and web addresses to be filtered out of search results so that links to politically objectionable websites do not even appear on the search engine's results pages, even when those websites may be blocked at the backbone or ISP level . . . Such lists are not given directly to Internet companies by the Chinese government; rather, the government leaves the exact specifics and methods of censorship up to companies themselves. Companies generate their "blocklists" based on educated guesswork plus trial-and-error: what they know to be politically sensitive, what they are told in meetings with Chinese officials, and complaints they may receive from Chinese authorities in response to the appearance of politically objectionable search results.
> But the complicity of companies is even more direct: they actually run diagnostic tests to see which words, phrases, and web addresses are blocked by the Chinese authorities at the router level, and then add them to their lists, without waiting to be asked by the authorities to add them. And because they seek to stay out of trouble and avoid complaints from the authorities, many businesspeople who run [Internet Content Providers] in China confess that they are inclined to err on the side of caution and over-block content which does not clearly violate any specific law or regulation, but which their instincts tell them will displease the authorities who control their license. In all these ways, companies are doing the government's work for it and stifling access to information. Instead of being censored, they have taken on the role of censor.

In other words, by keeping secret the exact terms that will trigger a license revokation, the Chinese government achieves more censorship than it could by publishing a list of forbidden terms, and it makes Google, Yahoo!, and other U.S. companies complicit in the censorship. Similarly, OHRP's vagueness about what will trigger a shutdown fails to assure universities that they can safely deregulate research, so universities restrict research that should be exempt from review.
Fortunately, OHRP's new director, Jerry Menikoff, understands this. In the [3]Winter 2009 issue of AAHRPP Advance he writes,

> We often hear that it's better not to provide specific guidance—that the absence of guidance allows people greater flexibility in interpreting the regulations. In my experience, the opposite can be true. Guidance can empower individuals and advance both research and research protections. In the absence of guidance, people tend to be reluctant to take certain actions out of fear that they are violating the rules. In some instances, important research is not even attempted, all because of a misunderstanding. Guidance could eliminate the misconception and clear the way for research.

I'm delighted that Dr. Menikoff takes this approach, and I look forward to more specific guidance from OHRP that would clear the way for research.
[Thanks to Rob Townsend for altering me to Menikoff's comments.]

1. http://hrpp.blogspot.com/2008/11/prim-thoughts.html
2. http://www.hrw.org/en/node/11259/section/4
3. http://www.aahrpp.org/Documents/D000176.PDF

Pete Jones (2009-02-14 18:56:00)
In reference to your comments on Chinese censorship, I just read a fascinating study by Rebecca Mackinnon entitled [1]China's Censorship 2.0: How Companies Censor Bloggers.
It goes into greater detail on the mechanisms of censorship than the discussion you quote, but comes to the same conclusions-that flexible guidelines, instead of providing flexible responses to a "problem" instead cause inappropriately harsh reactions and censorship of legitimate work.

1. http://firstmonday.org/htbin/cgiwrap/bin/ojs/index.php/fm/article/view/2378/2089

Zachary M. Schrag (2009-02-14 21:22:00)
Thanks for the link.
ZMS

JJ_slim (2009-02-17 14:02:00)
Interesting post. I take your point, but it's not clear to me that the problem is with flexibility, rather than uncertainty.
The problem with censorship regimes isn't that the criteria for censorship are flexible, it's that they're unclear.
Why can't the problem be described as follows: IRB's are charged with applying a set of rules, if those rules are unclear, then they feel they have to come down on the side of 'caution'. The problem is epistemic: they do not know what the rule is so they worry about breaking it.
Where a system is properly flexible it is clear where decision makers have discretion.

Zachary M. Schrag (2009-02-17 20:48:00)
Thanks for the comment.
I think that in these cases, "flexibility," "uncertainty," and "obscurity" are all names for the same phenomenon: the failure of rulemakers to demarcate acceptable and forbidden behavior.
ZMS

JJ_slim (2009-02-18 18:35:00)
Maybe, but I'd argue that the problem is that ethics review is thought of as a matter of applying rules, rather than as a collaborative process for ensuring that research is done in the most ethical way.
I wonder what would count as adequate rules here? You wouldn't want, for instance, to say 'there must always be an information sheet', because although that's usually a good idea it isn't always the best way to do things (I'm sure you can think of lots of examples).
But maybe that's your point? If you treat ethics review as just a matter of applying a system of rules, then you need impossibly precise rules– so best not have that sort of review system?

Zachary M. Schrag (2009-02-21 22:01:00)
Dr. Menikoff's comment about guidance came in an essay in which he also called for the deregulation of low-risk research. His point, I believe, was that giving institutions the confidence to deregulate requires specific guarantees that they won't be punished for doing so. OHRP, and its predecessors, have done a poor job of this.
ZMS

4.3 March

4.3.1 Canadian Criminologists Decry TCPS Draft (2009-03-18 09:17)

Back in January, [1]I mentioned the release of the [2]Draft 2nd Edition of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, prepared by Canada's Interagency Advisory Panel on Research Ethics, or PRE.
Ted Palys and John Lowman of the School of Criminology, Simon Fraser University, kindly alerted me to their critique of the draft, or TCPS-2, as they term it. (They even more kindly cited this blog in their work.) They find that TCPS-2 "poses a significant threat to academic freedom in Canada." (3)
Their 20-page critique, "[3]One Step Forward, Two Steps Back: Draft TCPS-2's Assault on Academic Freedom," is all meat and no fat, and I recommend that it be read in its entirety. But here are a few salient points.

1. TCPS-2 Tells Researchers Not to Fight Subpoenas

TCPS 2 states that "researchers may face situations where they experience a tension between the requirements of law and the guidance of ethical principles. In such situations, researchers should do their best to uphold ethical principles while complying with the law." (p. 17, lines 598-602).
Palys and Lowman note that such advice yields what they consider to be the wrong answer to the only recent incident involving a Canadian social researcher who came into conflict with the courts: Russell Ogden's studies of assisted suicide. Palys and Lowman have written about that case [4]at length, and they applaud Ogden's refusal to testify about information given to him after he promised confidentiality.
While I understand the authors' wish that TCPS-2 include room for such principled stances, I had some trouble following their critique on this point. The authors warn that "because it implies that when there is a conflict law must always prevail, Draft TCPS2 embodies a doctrine that represents a significant threat to academic freedom." (5) But they go on to note,

> Of the hundreds of thousands of studies in Canada over the past few decades that collected personal information about one or more participants, we are aware of only one researcher who has ever received a subpoena from a third party seeking the disclosure of confidential research information, and he has received three. Three subpoenas in the history of all types of research in Canada. How many times was the subpoenaed researcher ordered to disclose information? Not one. (10)

If subpoenas for confidential information are rarely issued and never enforced, how can a requirement that researchers submit to the law be "a significant threat to academic freedom"?
Perhaps there are situations other than defending confidential information from subpoenas that would put social researchers in conflict with laws, but they are not detailed in the critique. If the policy fails only Russell Ogden, it is certainly a threat to his academic freedom, but a minor threat to academic freedom in Canada in general.

2. TCPS-2 Requires "Anticipating That Which Cannot be Anticipated"

Palys and Lowman complain that "Draft TCPS2 sets researchers an impossible task by requiring them to anticipate the unanticipated by requiring them to inform participants what they will do if they make incidental findings." (12)
For example, the TCPS-2 section on informed consent notes that

> it is not always possible to anticipate with any specificity the nature of the incidental findings that may surface in the course of research. It is therefore not possible to inform prospective participants in anything but the most general terms of what the research may reveal, beyond the realm of the research question itself.
> So, for example, social science researchers embarking on questions of a personal nature should inform prospective participants of the legal obligations they are under to reveal information concerning certain types of abuse. (p. 37, lines 909-916)

The two parts of this quotation contradict each other; the first requires only the "most general" warnings, while the second demands warnings "concerning certain types of abuse" that must be revealed.
Palys and Lowman explain how this contradiction could play out:

> Consider what could happen if a Muslim student submitted an application to an REB [research ethics board] to interview other Muslim students about their encounters with nonMuslims in Canada. Can the REB argue that these universityage Muslims fit the demographic profile for possible terrorist activity?

> Can they require the student to put in a caution that, if her subjects tell her anything about terrorist involvements, she will feel obliged to report this to an authority? Criminologists at SFU [Simon Fraser University] sometimes encountered precisely this kind of problem when REB members, none of whom had any experience doing criminological research, sometimes brought outlandish stereotypes to the review process. (14)

Or,

> Take, for example, the possibility of "incidentally finding" child abuse in research about coaching children's sports. At the time of securing consent, the draft policy requires a researcher to say something like the following to each coach: "Even though my research is about coaching and I will treat what you say as confidential, if you tell me about situations where you abuse children, I will have to report you." Notwithstanding the way this approach appears to violate the principle of respect for participants — it treats all persons who have any contact with children as possible abusers — the ironic ethical consequence of treating informed consent as an absolute value rather than balancing it with other ethical principles is the harmperpetuating consequence of Draft TCPS 2's imposed limitation on confidentiality. If the researcher declares that he/she will report all incidents of child abuse, the chances are that any child abuser would not divulge that piece of information, with the result that the abuse continues. As abuse is not the focus of the research, an alternative ethical approach would be to say nothing. That way the researcher maintains respect for the participants' integrity unless there is some concrete reason to do otherwise and would allow him/her to deal with the ethical dilemma of "incidental discovery" of child abuse at the point of discovering it unwittingly. (14)

Palys and Lowman are highlighting a structural problem in the TCPS-2: its assumption that prior review of a project can highlight the most significant ethical dilemmas. Ethics boards may make sense for lab experiments, but the PRE offers no reason to believe that they serve fieldwork. This brings us to the third point:

3. TCPS-2 Lacks a Factual Basis

Palys and Lowman note that

> At least REBs have to justify their decisions. By contrast, Draft TCPS2 too often imposes "right answers" that do not reflect the diversity of the research enterprise, and offers no explanation for its recommended changes. To facilitate feedback, PRE should have provided an annotated draft. Because of its failure to do so the first time around, PRE should produce an annotated second draft TCPS2 explaining why it is recommending certain changes and inviting a second round of commentary . . . Can PRE provide any examples of incidental findings in social science research that resulted in a researcher violating confidentiality? If it cannot, why does Draft TCPS2 not walk its own talk by considering the degree of risk that is driving its approach to incidental findings? (15)

Worse still, while offering doubtful solutions to problems that may not exist, TCPS-2 fails to offer solutions to a problem that has been relatively well-documented: abuse of power by by research ethics boards. Palys and Lowman write that the Social Sciences and Humanities Research Ethics Special Working Committee's 2004 report, Giving Voice to the Spectrum,

> reported many examples of social science researchers facing REB ethics creep and experiencing infringements of academic freedom as a result of REB activity that had little or nothing to do with ethics. Why does Draft TCPS2 spend considerable time outlining putative limitations to confidentiality for threats that have never occurred while doing nothing about REB policy violations and infringement of academic freedom that SSHWC documented? (17)

Though TCPS-2 provides some appeals, "the proposed appeal process also is highly inequitable: an REB can say 'no' in five minutes, while the appeal process can take a year or more, during which time the REB continues to function — and may continue to contravene policy — while the researcher is unable to proceed."
Unlike the authors of TCPS-2, who may have been presenting hypothetical harms, Palys and Lowman write from their own experience and that of their students.
In raising these questions, Palys and Lowman point to a much larger problem with TCPS-2 and its analogues in other nations: a lack of empirical investigation. TCPS-2 makes vague gestures toward empirical grounding, as when it claims that "history offers unfortunate examples where participants in research have been needlessly and at times profoundly harmed by research." (p. 1, lines 21-22) Maybe so, but good historians cite their sources, and the authors of TCPS-2 have not.
Sound policy relies on sound research. As Palys and Lowman note, there is nothing in the TCPS-2 to
suggest that its authors are sufficiently familiar with the real problems faced by social scientists to offer real solutions. They complain,

> PRE's strategy is that of an ethics deity imposing its own "right answers" rather than fulfilling its mandate to educate, promote discussion, respect disciplinary and methodological diversity, build consensus, and cultivate a culture of research ethics in Canada. (21)

If PRE is a deity, it is not omniscient. Let us hope it is not omnipotent either.

1. http://www.institutionalreviewblog.com/2009/01/canada-considers-new-tcps.html
2. http://pre.ethics.gc.ca/eng/policy-politique/initiatives/draft-preliminaire/
3. http://www.sfu.ca/~palys/Palys-LowmanCommentsOnDraftTCPS2.pdf
4. http://www.sfu.ca/~palys/OgdenPge.htm

Lowman and Palys (2009-03-20 18:01:00)
Professor Schrag:
Thanks for reviewing our commentary on Draft TCPS-2. We would like to clarify our position given your query, "If subpoenas for confidential information are rarely issued and never enforced, how can a requirement that researchers submit to the law be 'a significant threat to academic freedom'?"
The threat to academic freedom is not subpoenas or the courts. The threat is the limited confidentiality doctrine that arises when universities, and now PRE, attempt to force researchers to warn prospective participants of "legal limits" to confidentiality created by "incidental discoveries" i.e. information that might be subject to mandatory reporting laws, such as laws requiring reporting of child abuse, or research information that is potentially subject to subpoena and court-ordered disclosure, i.e. all confidential research information.
When the spectre of court-ordered disclosure arose at Simon Fraser University, the first Canadian university to experience such a threat, the administration attempted to force researchers to promise confidentiality to the extent permitted by law, accompanied by a warning that a court might order disclosure of confidential research information. The implication was that, if ordered to disclose confidential research information, a researcher would comply. This "Law of the Land" doctrine subordinates ethics to law. However, just like journalists, "ethics-first" researchers would feel ethically obliged to protect research information even in the face of a court order to disclose it.
The threat to academic freedom is the attempt to impose the law of the land perspective on ethics-first researchers, because their

research would be made impossible by these a priori limitations to confidentiality.
The threat to academic freedom is PRE's "limited confidentiality" doctrine, not subpoenas or the courts.
John Lowman and Ted Palys

Zachary M. Schrag (2009-03-21 14:24:00)
Thank you for this clarification. This is an interesting illustration of a chilling effect at work, showing how a rare incident can lead to widespread suppression of inquiry.
Part of my confusion stemmed from the fact that subpoenas are more common in the United States. Social scientists don't receive subpoenas every year, but as Charles Knerr and Andrew Sommerman have documented, the subpoenas arrive every few years.
On the other hand, Knerr and Sommerman also note that only two social scientists–Samuel Popkin and Rik Scarce–have been imprisoned, and neither surrendered confidential information. Three other scholars did reveal such information, but one was able to strip identifiers first, and a second did so only after receiving permission from the research participant. Thus, only once in the past forty years has an American social scientist surrendered a research participant's personal information to a court without the participant's permission.
[I draw this from Charles Knerr and Andrew Sommerman, " Social Scientists v. the US Courts: Subpoenas for Research Data and Research Sources," presented at the Western Political Science Association, 2008. Professor Knerr kindly shared this important paper with me, and I hope he and Professor Sommerman will soon publish a version.]
Thus, your argument–that the warnings which ethics boards require of researchers are disproportionate to the threat of disclosure–appears to apply to the United States as well.
ZMS

4.3.2 Deadline Extended for TCPS Comments (2009-03-29 13:56)

John Lowman kindly alerts me that Canada's Interagency Advisory Panel on Research Ethics has extended the deadline for comments on the draft second edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). Comments will now be accepted through 30 June 2009, though the PRE encourages comments by March 31, since the next round of revision will begin in April.
An official announcement of the deadline extension is online at the PRE's [1]French-language website. I could not find an English-language version on the PRE website, but the [2]University of Western Ontario has posted one.
A form for online comments, and instructions for submitting comments by mail, fax, or e-mail, is [3]online.
I have sent in a version of the [4]comments posted on this blog. As I prefaced my comments to the PRE, I write as a non-Canadian. But the regulation of research ethics is an international endeavor. Just as TCPS draws heavily from the Belmont Report and 45 CFR 46, so can we expect TCPS to influence American policy and guidance. I therefore consider myself to have some stake in the outcome of the TCPS revision.

1. http://www.ger.ethique.gc.ca/fra/resources-ressources/news-nouvelles/nr-cp/2009-03-26
2. http://researchofficer.wordpress.com/2009/03/27/draft-2nd-edition-of-the-tcps-expanded-opportunity-to-comment/
3. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/feedback-retroaction
4. http://www.institutionalreviewblog.com/2009/01/canada-considers-new-tcps.html

4.4 April

4.4.1 Training Day (2009-04-10 13:38)

Peter Klein of the [1]Organization and Markets blog offers a sad account of what it takes for a University of Missouri economist to gain permission to interview entrepreneurs or hand out surveys to corporate executives. Like many scholars across the country, he was directed to an online training system, which demanded that he provide correct answers to questions like the following:

> 32. The investigator is a 1/8th V.A. employee. She proposes to recruit MU outpatients into a study conducted exclusively at MU facilities. Which of the following groups must approve the research project before participants can be enrolled?
> The MU Health Sciences Center IRB
> The V.A. Research and Development Committee
> Both a. and b.
> Neither a. nor b.

While such knowledge may be of critical importance to health researchers at Missouri, it is irrelevant to social scientists not doing medical work. The lesson Klein takes away from such an experience is not that he must be sure to obey laws and ethics standards while doing his research, but that his campus IRB administrators do not respect him enough to provide relevant ethical training.
Administrators take note: you are making fools of yourselves, and earning your faculty's contempt.
See [2]Comments Oppose New Regulations on Training.

1. http://organizationsandmarkets.com/2009/04/09/irbs-gone-wild/
2. http://www.institutionalreviewblog.com/2008/11/comments-oppose-new-regulations-on.html

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4.4.2 Macquarie's Innovative Ethics Training (2009-04-17 06:36)

In previous [1]posts and my 2007 essay, "[2]Ethical Training for Oral Historians," I have complained about standardized, medicine-centric ethics training systems like the [3]CITI Program and called for training programs better tailored to individual disciplines.
Lisa Wynn of Macquarie University (also known as MQ) has alerted me to just such a program she created with Paul H. Mason and Kristina Everett. The online module, [4]Human Research Ethics for the Social Sciences and Humanities, has some elements that I find inappropriate. Overall, however, it is vastly superior to the CITI Program and comparable ethics programs I have seen, and it deserves attention and emulation.

Strengths

Relevant Examples

The CITI Program's "History and Ethics" module offers five "Events in Social & Behavioral Research" as cautionary tales. Two concern psychological experiments (Milgram and Zimbardo), two concern decades-old observations using deliberate deception (Wichita Jury and Laud Humphreys) and the last is Francis Flynn's more recent, but also deliberately deceptive, study of restaurant responses to customer complaints. This choice of examples suggests that the only ethical dilemmas facing ethnographers concern deception, and that they do not occur frequently. The University of Iowa's [5]Ethical and Regulatory Issues in Ethnographic Human Subjects Research is broader in its concerns, but

offers few concrete examples.

The MQ program, by contrast, offers two old stories (Zimbardo and Humphreys), but it freshens them with stories of two recent controversies: the U.S. Army's recruitment of social scientists for its Human Terrain System initiative and Sudhir Venkatesh's doctoral research in underground economies in Chicago. Another case study appears in the section on "Research with Aboriginal and Torres Strait Islander Peoples," describing the collection of stories, songs, and artifacts by anthropologist Ted Strehlow. These collections have become the subject of considerable controversy, and the program offers both Strehlow's perspective and that of his critics. Beyond these case studies, the MQ program offers short vignettes in which ethnographers had to decide how to conduct research without hurting their informants or themselves. In some cases, the researchers are given pseudonyms; in others, real names. The authors even include accounts of dilemmas they themselves have faced.

The stories that make up the bulk of the MQ program are more relevant to today's ethnographers than hearing about what Laud Humphreys did forty years ago, or about recent medical research gone wrong. They show that ethical challenges are not confined to the distant past, but face social scientists today. And they broaden the challenges facing scholars to questions of confidentiality, government sponsorship, intellectual property, and other contemporary concerns.

Best of all, these stories emphasize real ethics, rather than the [6]regulatory compliance at the heart of the typical program. When I went back to the CITI Program to write this entry, I was immediately confronted with a quiz question about whether a hypothetical foreign institution needed its own federalwide assurance for a hypothetical project. I'm sure this is very important to some IRB administrators, but it is absurd to demand that every researcher master such arcane requirements. The MQ program is not wholly free of this dross, but it is better than others I have seen.

Like other training programs, the MQ program is heavy on examples of what not to do. But it also offers something else: a positive example. One section describes how medical anthropologist Paul Farmer not only studied tuberculosis in Haiti, but also established a medical clinic there. As inspirational as this story is, I think this section could be expanded to offer stories of ethnographers who helped communities simply by doing good ethnography–not by providing medical care. Oral historians often get to work with people who are happy to have their words recorded for posterity. I would hope that sociologists and anthropologists have equally gratifying experiences. The MQ program does offer additional readings, which may contain these kinds of examples.

Room for Debate

The CITI Program lists "Events in Social & Behavioral Research" with attendant "ethical problems." The MQ program, by contrast, describes "ethics controversies" and "debates about the ethics," suggesting that there is no single right answer to the conundrums faced by scholars in the field.

To emphasize that point, the MQ program rejects the single-answer, multiple-choice quizzes that are the staple of the CITI Program. Instead, the MQ program offers questions like this:

> Say you are doing research on cigarette smoking, but as you talk to the smokers, they start telling you about the illicit drugs they use. What do you do? (47)

There are no multiple choices here, just a stark presentation of an ethical challenge a scholar might reasonably face.

Elsewhere, the program does offer multiple choice quizzes, but not with the simplistic approach of the CITI Program. For example, one screen invites the user to choose one of four strategies for avoiding the revelation of confidential information. Whatever one chooses, the program replies that "any of the above are possible strategies for protecting your informants' identities, but some are better strategies than others," and then elaborates.

The program even admits that university ethics committees don't have all the answers, and sometimes have the wrong answers. It offers the example of Kristina Everett, one of the program's authors, who offended a longtime friend by confronting her with the written consent form demanded by her university. The program concludes,

> Institutional ethics rules can . . . fall short of researcher's own moral responsibilities and commitments to a particular cause. Ultimately, researchers must make their own decisions about what is ethical in the context of the particular research situation, in dialogue with their research participants. (103)

Scholarly Norms

The MQ program respects its students by adhering to two basic norms of scholarly writing.

The first is citation. Many of the CITI Program's statements are unattributed, and in some cases factually inaccurate. When a statement is attributed, the program often gives just a single source. The MQ program, by contrast, provides several readings for each of the case studies it presents, in some cases with alternative viewpoints.

The program also provides citations for statements throughout the text, adding authority. A warning that the U.S. government might seize a scholar's laptop at an airport might sound alarmist were it not for a link to a [7]news article on the subject.

Another norm is that of open access. Many ethics training programs are open only to affiliates of a single university or, in the case of CITI, to affiliates of institutions that subscribe to the service. This robs scholars of the chance to compare and critique rival systems, to find areas of agreement and disagreement, to check facts, and to do all the other work that scholars usually do in their quest for truth and wisdom.

The MQ program requires registration, but that registration is free and open to all. Better still, the authors have [8]licensed the text under a Creative Commons Attribution Non-Commercial Share Alike license, giving others the chance to "download, redistribute, remix, tweak, and build upon the text of this work non-commercially, as long as they credit the original authors and license their new creations under the identical terms." These two decisions offer the opportunity and the challenge for other institutions and disciplines to provide even better training.

The downside of such openness is that it leaves a training program open to criticism from cranky bloggers halfway around the planet. Let's move on to some of the program's weaknesses.

Areas for Improvement

Irrelevant History

The first section of the Macquarie program takes readers through about 15 screens concerning the history of abuses by medical researchers–Nazis, Tuskegee, and the more recent, dubious drug trials in Africa–along with descriptions of the various ethical codes designed to prevent recurrences. I hate this. It presents biomedicine as the archetype of research and social research as a deviation from that norm. And it's just bad pedagogy to start a course with material not important to the student.

If this is truly training for the social science and humanities, why not tell just the story of ethical debates in the social sciences and humanities? Or, if social scientists must know about Nuremburg and Tuskegee in order to communicate with university ethics officers, why not leave that to the end?

Disciplinary Bias

The MQ program is entitled "Human Research Ethics for the Social Sciences and Humanities" and it notes that "social science research – including psychology experiments, quantitative surveys, oral history collection, and ethnographic research or participant observation – raises its own peculiar problems for ethical research practice." (24) But the program does not give equal weight to the problems of each type of research or the ethics embraced by its practitioners.

The case studies include no examples of psychological experimentation since Zimbardo's prison study, or any survey or oral history research, or other fields not included in the list, such as geography, journalism, and creative writing. (Keep in mind that the Australian [9]National Statement on Ethical

Conduct in Human Research concedes that its broad definitions "could count poetry, painting and performing arts as research." [2:8]) Instead, almost all of its examples, and its quotations from ethics statements, come from anthropology.

Presenting case studies and ethical statements from all the fields in the social sciences and humanities would bloat the training program beyond usefulness. Rather than add more content, the program should strip references to survey and oral history research and adopt a more humble title: "Human Research Ethics for Ethnography."
Even this might be problematic, given the divergence in research ethics among various stripes of ethnographers. In particular, the program ignores debates over the principle of beneficence. In describing the controversy over the Pentagon's Human Terrain System (HTS), the authors write:

> The reason for anthropological opposition to the Human Terrain System (HTS) lies in the discipline's code of ethics. Specifically, HTS opponents charge that Human Terrain Teams cannot guarantee several basic tenets of ethical research, including 'Do no harm,' the principle of informed consent, and freedom from coercion. (40)

Since when are these "basic tenets" of ethical research? For anthropology, the answer would seem to be only since the 1990s. [Carolyn Fluehr-Lobban, "Ethics and Professionalism in Anthropology: Tensions Between Its Academic and Applied Branches," Business and Professional Ethics 10 (1991): 57-68.] For other scholarly disciplines, the answer is not yet, particularly since the idea of "do no harm" would preclude investigative journalism and other critical inquiry. For many scholars, bringing harm to a malfeasor is highly ethical practice, but the MQ program seems to think that all scholars have embraced anthropology's gentleness.
I find this narrowness particularly disappointing because just last summer, Wynn herself raised the question of disciplinary differences in a post about HTS on [10]Culture Matters. She understands that anthropologists are unusual in some of their ethical beliefs, and I wish that insight had made it into the MQ training.
(See "[11]My Problem with Anthropologists.")

Incomplete Accounts

I have additional concerns about the treatment of two of the four social-science case studies in the program.
The section on Laud Humphreys is somewhat ahistorical, neglecting the ethics debates that were raging through sociology at the time Humphreys planned his work. I'm also perplexed by the statement that "Humphreys argued that the deception was justified, because there was no other way to obtain such information in a consented way because such sex practices were so highly stigmatized." (37)
Really? Here's what he wrote in 1975: "I am forced to agree with my critics regarding that part of my study in which I traced license numbers and interviewed respondents in their homes . . . I now think my reasoning was faulty and that my respondents were placed in greater danger than seemed plausible at the time." [Laud Humphreys, [12]Tearoom Trade: Impersonal Sex in Public Places, enlarged ed. (Chicago: Aldine, 1975), 230.]
As for the section on the Human Terrain System, it is based almost entirely on the writings of critics. For example, the program asks,"If the anthropologist has no control over what the military will do with the information, then how can an anthropologist fully explain to people the real risks involved in research?" Not only does this question ignore the fact that not all Human Terrain team members are anthropologists, it also assumes that those members do not control the information they gather. For a challenge to this assumption, see Adam Silverman, "[13]The Why and How of Human Terrain Teams," Inside Higher Ed, 19 February 2009.

Awkward Layout

Writing this review was slowed considerably by the poor design of the MQ program's site. The program consists of 103 screens which must be viewed one at a time. Since one must often scroll down to reach the "next" link, it took hundreds of mouse actions to get through the site. With a big enough monitor, you can enlarge the window to include all the text and the navigation links without scrolling, but then you end up with line lengths of 100 or more characters, making the text hard to read.

If you stop clicking for a while, the site logs you out. And while you can return to the chapter you were on, you cannot navigate straight to the page. So if you pause to take notes, as I have while writing this entry, you may need several hundred mouse clicks to get through the whole program. I also found a noticeable pause after each screen, further delaying my reading. There is no way to print or download the site's text in large chunks.
Text this important shouldn't be an ordeal to read, and I am sure than the authors would never try to publish a journal article of comparable length in this format. They need to find a better way to present this material. For example, they could collapse the 100+ screens into just six pages–one for each of the six major sections–allowing users to view on screen, print, or save as needed.

Trivia Quiz

The MQ program ends with a quiz composed of a few dozen multiple-choice questions about the material covered in the main text. In several cases, I found none of the answers satisfactory. In other cases, the quiz presented two opinions as choices and demanded the "right" one. More frequently, the quiz posed silly questions, like asking about what provisions are included in which codes. Much as I believe in the power of historical knowledge, knowing whether the Nuremberg code included the right to withdraw from an experiment is of no obvious use to an ethnographer working today. And the quiz didn't even tell me which questions, if any, I got wrong. The quiz section was also heavy with typographical errors, making me wonder if it was written by someone other than the main authors of the MQ program. It is a shame to end such an innovative program on so sour a note.
There may be a bureaucratic need to include a quiz at the end; some administrator at MQ can now check that I have completed the training. But I see little pedagogic need for the quiz, since the program itself (after the medical ethics portion) is bound to be compelling to any ethnographer concerned with ethical research.

Ethical Education

Wynn, Mason, and Everett have put tremendous thought and effort into determining what ethnographers need to know about research ethics, and packaging that knowledge in a way that is respectful of researcher's learning, intelligence, curiosity, and desire to act ethically. They go too far when they claim that the ethics currently embraced by Australian and American anthropologists are universal to social scientists, and they at times make statements that lack nuance. But rather than proclaim these ideas as gospel, they have designed a training program that itself invites debate. I hope that other universities and other scholarly disciplines will follow their example.

1. http://www.institutionalreviewblog.com/search/label/training
2. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm
3. http://www.citiprogram.org/
4. http://www.mq.edu.au/ethics_training/
5. http://research.uiowa.edu/hso/resources/ethnographic/
6. http://organizationsandmarkets.com/2009/04/09/irbs-gone-wild/
7. http://aaanewsinfo.blogspot.com/2008/07/aaa-responds-to-laptop-searches.html%20
8. http://www.mq.edu.au/ethics_training/copyright.php
9. http://www.nhmrc.gov.au/publications/synopses/e35syn.htm
10. http://culturematters.wordpress.com/2008/07/30/the-disciplinary-terrain-of-objections-to-hts/
11. http://www.institutionalreviewblog.com/2007/03/my-problem-with-anthropologists.html
12. http://books.google.com/books?id=nmXpmXqxT4UC
13. http://www.insidehighered.com/views/2009/02/19/humanterrain

4.4.3 Deregulation "Is Not Going to Happen" (2009-04-21 22:01)

Linda Shopes kindly alerts me to the April 20 issue of [1]COSSA Washington Update, the newsletter of the Consortium of Social Science Organizations, which reports on an April 1 meeting of the National Academies' Board on Behavioral, Cognitive, and Sensory Sciences, at which IRBs were discussed.
Here's the key passage:

> Philip Rubin, CEO of Haskins Laboratories in New Haven, CT, and former director of the National Science Foundation's (NSF) Division of Behavioral and Cognitive Sciences, chairs the Board. He began the session with a review highlighting the difficulties social/behavioral researchers have had with the current system under the Common Rule regulation and its interpretation by campus Institutional Review Boards (IRBs). Complaints have been loud, but mostly anecdotal . . . Once again the bottom line is that despite efforts by Joan Sieber and the Journal of Empirical Research on Human Ethics, which she edits, there are still large gaps in our empirical knowledge of how the system works for social and behavioral scientists.
> Rubin was followed by Jerry Menikoff, new head of the U.S. government's Office of Human Research Protections (OHRP). Menikoff announced that he was all for "flexibility" in the system and that "changes can be made." He also endorsed conducting more research. He rejected the arguments of the American Association of University Professors and Philip Hamburger of Northwestern University Law School that IRBs violate researchers' first amendment rights. He acknowledged the importance of expedited review, but stated quite clearly that "removing minimal risk research from the system is not going to happen."

I don't want to make too much of these comments; an OHRP spokesperson tells me that they were an extemporaneous response to Rubin, and not prepared remarks. Still, I am disappointed. Menikoff's comments suggest a retreat from his earlier concession that [2]"flexibility" often can be code for arbitrary power. And it's a pity for a public official to insist that a given policy "is not going to happen" even as he endorses more research. Wise governance depends on making policies after finding facts, not before.

1. http://www.cossa.org/volume28/28.8.pdf
2. http://www.institutionalreviewblog.com/2009/02/less-flexibility-more-freedom.html

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4.4.4 UMKC's Respectful Oral History Policy (2009-04-25 23:26)

The University of Missouri-Kansas City (UMKC) has posted a promising new policy: "[1]Social Sciences IRB and Oral History."
The policy has a number of elements that set it apart from the typical university policy, which seeks to cram oral history into a system designed for medical experimentation. Instead, it adapts only those elements of the medical IRB system that encourage historians to follow their own discipline's ethics and best practices.
I suggest that readers of this blog read the whole policy, but here are some highlights:

1. Respect for Critical Inquiry

As I have written repeatedly on this blog, historians do not take the Hippocratic Oath, and should not promise not to harm the people they interview. Any IRB that imposes the Belmont Report on historians is asking them to forswear their own ethics.
UMKC understands this. Its policy notes that

> akin to a journalist or lawyer, an historian is also responsible to a wider public to recover a shared past "as it really happened." In keeping with the public role of an historian in a democratic society, these responsibilities, especially when conducting narrative interviews, can necessitate a confrontational style of critical inquiry. So while historians do not set out to hurt their interviewees, oral historians are expected to ask tough questions in their interrogation of the past.

2. Respect for Peer Review

The UMKC neither subjects oral historians to the whims of board members unfamiliar with their field, nor does it leave them on their own. Instead, it offers scholars a number of relevant readings, including publications of the Oral History Association, and then encourages them to talk to colleagues knowledgeable about interviewing:

> After reviewing these resources on their own, the researcher is strongly encouraged to discuss their research protocol with peers before implementing their research protocol. In some cases, peer review by members of one's own department would be most useful; in other cases, a researcher might be better served by seeking review from a colleague in a different department.
> To foster these kinds of conversations among the faculty, the Social Sciences IRB Subcommittee for Oral History will hold two meetings per semester . . . to discuss "Best Practices" in oral history. Faculty experts in oral history will guide these conversations . . . These meetings are designed to meet the needs of researchers seeking advice and peer review for their research protocols. They are also designed to meet the needs of Chairs and/or designees interested in learning how to advise researchers in their departments to make responsible decisions regarding oral history.

3. Respect for OHRP's Pledge

UMKC takes seriously the carefully negotiated [2]2003 agreement between the American Historical Association and the Oral History Association and OHRP, even posting a copy on its website. The university elaborates on that agreement:

> At UMKC, we draw a distinction between idiographic research that uses oral histories to describe the unique story of some particular social group or individual, which does not constitute "human subjects research"; and nomothetic research that employs oral histories in the hopes of contributing to a general theoretical or comparative debate about the human nature or behavior, which does fall under the category of "human subjects research."

While I confess that the terms idiographic and nomothetic are not in my working vocabulary, I believe they do express a real difference between the ethics of oral historians and those of other scholars. If one is interested in a general theoretical or comparative debate about the human nature or behavior–as many social scientists seem to be–then it makes less sense to single out individuals for potential honor or calumny. Writing about unique individuals or groups changes one's responsibility toward the individuals interviewed.

4. Respect for Researchers

Policies like [3]UCLA's infantilize researchers, making them submit every judgment to an administrator. By contrast, UMKC trusts its scholars:

> The bottom line is that the researcher makes these determinations in careful consultation with the Chair of the department or another official designee appropriate to the kind of study being planned. Together this determination is based on shared understanding of all relevant guidelines and their shared expertise in their specialized field of scholarship.

5. Respect for the IRB

Even as it empowers historians, the UMKC policy keeps the IRB involved, making it a resource, rather than an obstacle. Researchers still have to learn something about human subjects regulations, and they must complete a [4]form explaining why they have determined that their policy does not fall under federal regulations.
(The form's demand for an explanation of "no more than 1500 characters" sounds suspiciously bureaucratic, but it's a good length for the presentation of a single idea–about the same as the [5]150-word limit for a New York Times letter to the editor.)
More importantly, the frequent meetings of the Social Sciences IRB Subcommittee on Oral History suggest that some scholars at UMKC have devoted their time to helping colleagues deal with the real ethical challenges of oral history.
The website explaining the policy notes that it was developed by "a group of faculty and administrators involved with the Social Science Institutional Review Board (SSIRB) . . . with input from members of the SSIRB, the College of Arts & Sciences, and the Faculty Senate at UMKC." I congratulate all the scholars and administrators who developed this innovative system, and I hope it works as well in practice as it reads on the screen.
With this policy, UMKC joins [6]Amherst College, [7]Columbia University, the [8]University of Michigan-Ann Arbor, and the [9]University of Nebraska-Lincoln Policy on a small but growing list of schools that have adopted OHRP's 2003 position removing most oral history research from IRB jurisdiction. Five schools not very many, but it's [10]five more than the AHA could find in February 2006. Who will be number six?

1. http://www.umkc.edu/Research/Support/IRB/SS/OralHistory.html
2. http://www.historians.org/press/IRBLetter.pdf
3. http://www.institutionalreviewblog.com/2008/04/do-ucla-researchers-have-permission-to.html
4. http://www.umkc.edu/Research/Support/IRB/SS/OH/Oral%20History%20Form.pdf
5. http://www.nytimes.com/ref/membercenter/help/lettertoeditor.html
6. https://www.amherst.edu/academiclife/funding/irb
7. http://www.columbia.edu/cu/irb/policies/documents/OralHistoryPolicy.FINAL.012308.pdf
8. http://www.research.umich.edu/hrpp/Documents/Research-Not%20Research.pdf
9. http://research.unl.edu/orr/docs/UNLOralHistoryPolicy.pdf
10. http://www.historians.org/Perspectives/issues/2006/0602/0602new1.cfm

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4.5 May

4.5.1 DeGette Still Doesn't Get It (2009-05-05 08:35)

Representative Diana DeGette (D-CO) has introduced the Protection for Participants in Research Act (H.R. 1715), which would impose IRB requirements on all human subject research supported by the federal government or affecting interstate commerce.
As [1]amp &rsand notes, this is the sixth time DeGette has introduced this bill. And I don't think that counts earlier submissions of similar bills by Senator John Glenn. None of these previous efforts went far, so there's no particular reason to fear this bill's passage.
Still, it is disappointing that DeGette has introduced this bill six times without understanding its potential consequences. Her [2]press release states that "I think one thing we can all agree on in a bipartisan way is that we need to encourage medical experimentation but we need to do it in a way that both protects the patients and gives them informed consent about what they are getting into," as if the bill would affect only medical experimentation. It points to medical trials in 1999 and 2006 as evidence of insufficient oversight, and argues that "research is the key to innovation and discovery, including curing deadly disease." Nowhere in the press release is a hint that DeGette understands that her bill would outlaw most journalism, not to mention further inhibiting social science and humanities research.
Thirty-five years after the passage of the National Research Act, Congress still doesn't know what it has done.

Bonus question for [3]Rebecca Tushnet's 43(B)log: Is the copyright claim on DeGette's press release–the work of a federal employee in her official capacity–illegal, or merely false?
Update 8 May 2009: A correspondent notes that the copyright statement is no longer on the site. If DeGette removed the statement in response to this blog, good for her. I have a PDF of the press release as it appeared on May 4, if anyone is interested.

1. http://primr.blogspot.com/2009/04/sixth-times-charm-degette-hopes.html
2. http://degette.house.gov/index.php?option=com_content&view=article&id=472:protecting-research-participants-a-priority&catid=76:press-releases-&Itemid=227
3. http://tushnet.blogspot.com/

4.5.2 Journal of Policy History (2009-05-08 21:43)

The Journal of Policy History has published my article, "How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965–1991." As permitted by the transfer of copyright, I have posted a PDF on my personal website: [1]http://www.schrag.info/research/howtalking.html.
Not much has changed since I posted a version on [2]SSRN in April 2008. The major changes come in the "medical origins" section; the earlier draft underestimated the strength of social scientists' opposition to IRB rules in the late 1960s. Also, the new version better explains the origins of Ithiel de Sola Pool's concern about IRBs (see p. 18).

1. http://www.schrag.info/research/howtalking.html
2. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1124284

4.5.3 A Horror Anthology (2009-05-13 22:28)

Mark Kleiman takes on IRBs at [1]The Reality-Based Community. On April 14 [2]he asked his readers for IRB horror stories, and on May 2 he posted some of the [3]responses.
The saddest concerns a group of law students who wished "to send testers of different races in different styles of clothing to the restaurant over some period of time to test whether they enforced their dress code in a discriminatory manner." Law school administrators told them they would have to secure IRB approval. This discouraged the students, who did not want to go through the time and effort of the approval process.
This was not the intent of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. At its 15 April 1978 meeting, the commission discussed just such a scenario (pp. II-5 to II-21 of the transcript), and all the members seemed to agree that such testing for discrimination should not require IRB review. But, [4]as I've noted before, the commission wrote a definition of human subjects research that plausibly includes a great deal of activity the commission did not seek to regulate. Thirty years later, justice suffers as a result of the commission's sloppiness.
NOTE: In honor of Professor Kleiman's search, I have gone back through this blog to add the "[5]horror stories" tag to some posts that should have had it to begin with. Clicking on that tag now yields more than a dozen posts, with even more documented horror stories.

1. http://www.samefacts.com/archives/science_and_its_methods_/2009/05/the_irb_horror_show.php
2. http://www.samefacts.com/archives/science_and_its_methods_/2009/04/bleg_irb_horror_stories.php
3. http://www.samefacts.com/archives/science_and_its_methods_/2009/05/the_irb_horror_show.php
4. http://www.institutionalreviewblog.com/2008/01/must-employees-consent.html
5. http://www.institutionalreviewblog.com/search/label/horror%20stories

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Anonymous (2009-06-24 18:00:55)
I have a horror story, but this is from the IRB side of things. I work for an IRB. We recently received a study funded by a federal agency (not NIH). The proposal clearly does not fit the definition of research as defined in the Common Rule, but could be classified as journalism. We wrote the investigator and told her that she did not need IRB review for her project. Almost immediately we heard from the funding agency accusing us of not doing our job. We provided the agency with our policy on the review of journalism, oral history and ethnography. However the agency is insisting on review. Unfortunately, because of the way the exempt and expedited categories are set up, it does not qualify for either. So this journalism project now needs full Board review. Gaining written informed consent would be inane and, while we can grant waivers of consent, there is absolutely no reason this project needs IRB review. So this is an illustration of how one IRB is trying to combat mission-creep and was thwarted by a federal agency.

Zachary M. Schrag (2009-06-25 22:25:26)
Thank you for this comment. I am sorry you feel unable to identify yourself or the agency involved.
ZMS

4.6 June

4.6.1 Lisa Wynn's Words and Pictures (2009-06-05 16:26)

In April I commented on the [1]ethics training program for ethnographers developed by Lisa Wynn of Macquarie University with some colleagues.
At [2]Culture Matters, the blog of the Macquarie anthropology department, Wynn described the ideas that led her to develop the program.
Now, at [3]Material World, a blog hosted by the the anthropology departments of University College London and New York University, Wynn describes another aspect of the training program: the pictures.
Wynn explains that along with its medical-centered ethics and jargon-laden text, the standard NIH ethics training program suffers from clip art in which people are depicted as faceless cartoons–probably not the best way to get researchers thinking about others as autonomous individuals. So for her program, Wynn offers pictures of real researchers and research participants, from Laud Humphreys to Afghan school administrators.
Gathering these photos–about a hundred in all–wasn't easy, but they contribute meaningfully to the warmth and depth of the site. And it put Wynn in touch with some prominent scholars.
[Side note: Professor John Stilgoe tells his students that it's rare to have enough photos of yourself at work. That's a good admonition; you never know when someone will want to show you doing controversial research.]
In [4]another posting on Culture Matters, Wynn describes her continuing research on research ethics. She notes that ethics-committee oversight of ethnography is a relatively recent phenomenon. While it was debated as early as the mid-1960s, only in the 1990s did it become widespread. Thus, in studying the effect of ethics committees,

> We've got a perfect "natural" control: an older generation of researchers who spent most of their careers not seeking ethics clearance, a younger generation for whom it is standard operating procedure, and a "middle-aged" group of researchers like myself who started their research under one regime and now live under another (I swear, this is the first time I've thought of myself as middle-aged). By correlating responses with different regulatory regimes, we can ask questions like: do researchers who never got ethics clearance have different ideas about what is ethical than researchers who go through ethics review? Does one group consider itself more or less ethical than the other? Or do they feel like ethics oversight hasn't made any difference to their research practice?

Wynn plans to contact scholars in Australia and the United States to see how the spread of ethics review affected ideas about research ethics. I'm quite excited by this work; in fact, I plan to publish it in a special issue of the Journal of

Policy History I am editing on the general topic of the history of human research ethics regulation.
How many pictures should I demand?

1. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html
2. http://culturematters.wordpress.com/2009/04/23/making-ethics-ethnography-friendly/
3. http://blogs.nyu.edu/projects/materialworld/2009/05/protected_open_access_material.html
4. http://culturematters.wordpress.com/2009/04/29/embodied-ethics-oversight/

L.L. Wynn (2009-07-22 07:43:45)
Zach! What a nice post. I just came across it. Can you believe that I still haven't applied for ethics approval to do that embodied ethics project? I just got so swamped by the past semester. But it's over now, and that's on my to-do list this week. Fingers crossed for quick approval from our Ethics Committee! You've given me such great ideas for how to develop this project and the right questions to ask.
And speaking of ethics oversight, I've just posted something else on Culture Matters about the way I negotiated pre-approved ethics clearance for my students to do their own research projects....

Zachary M. Schrag (2009-07-22 08:35:41)
Editor's note: The Culture Matters post is online at http://culturematters.wordpress.com/2009/07/22/ethics-bureaucracies-and-student-research/ . It's good reading, and I hope to comment on it at some point.

4.6.2 Menikoff to Critics: "Yes, We Hear You" (2009-06-17 08:54)

Theresa Defino kindly alerted me to the streaming video feed of Dr. Jerry Menikoff's May 14 address at the University of Michigan, "[1]The Legal Assault on the Common Rule." The speech was an impressive acknowledgment of the widespread criticism of the foundations of the IRB system, and it ended with the promise of some substantive improvement. But by listing some of the most common critiques of the IRB system without attempting to rebut them, Menikoff fell short of the dialogue he seeks to foster.
Menikoff began his speech with a word for IRB critics: "Yes, we hear you." He then spent most of his hour summarizing some of the more prominent critiques of the U.S. IRB system. Among them:

- Carl Schneider, [2]Personal Statement, in President's Council on Bioethics, The Changing Moral Focus of Newborn Screening: An Ethical Analysis by the President's Council on Bioethics, 2008.
- Department of Health and Human Services. Office of Inspector General, [3]Institutional Review Boards: A Time for Reform (1998)
- Philip Hamburger, "[4]The New Censorship: Institutional Review Boards" (2005).
- [5]University of Illinois, The Illinois White Paper. Improving the System for Protecting Human Subjects:. Counteracting IRB "Mission Creep" (2005).
- Northwestern University Law Review, [6]Symposium on Censorship and Institutional Review Boards (2006)
- American Association of University Professors, [7]Research on Human Subjects: Academic Freedom and the Institutional Review Board (2006)

(As Menikoff noted, challenges to the legality of the IRB regime are only one component of this broad critique, and Menikoff declined to go into detail about them. This makes the title of his speech an odd one.) For most of the speech, Menikoff was carefully respectful of the authors of these documents, noting their prominent positions and

accomplishments in other areas of scholarship. The only real rebuttal he made was to suggest that some critics are too quick to assume that an IRB would demand to review, or even deny, a particular study. That's a good point; it's always better to critique the system with a real horror story about thwarted research, rather than a hypothetical one. What Menikoff didn't say is that there are plenty of real horror stories to go around. Menikoff offered one important concession. In his 2007 article, "[8]Where's the Law? Uncovering The Truth About IRBs and Censorship," he had suggested that if an institution required IRB review of research exempted by the Common Rule, researchers at that institution shouldn't blame the feds:

> An institution can choose to impose rules that are more restrictive than [federal] regulations. But complaints about censorship resulting from such a circumstance would seem more appropriately directed at the specific institutions that are choosing to do this, rather than the IRB system itself, as created by the federal regulations. (792, n. 6)

Such analysis ignored the role of OPRR/OHRP in encouraging institutions to impose requirements beyond those in the regulations. In particular, in 1995, OPRR advised institutions "[9]that investigators should not have the authority to make an independent determination that research involving human subjects is exempt." More recently, OHRP contributed to a 2008 report that recommended expedited review for [10]several hypothetical projects that would seem to merit exemption. In his Michigan speech, Menikoff did better. He conceded that OHRP continues to recommend that researchers should not make exemption determinations. But he also noted, "it's just a recommendation. You don't have to follow it." He pledged that OHRP would clarify this. While this concession is welcome, it is pretty small stuff. Even on the narrow issue of the Common Rule exemptions, it ignores the question of why OHRP continues to promulgate guidance that [11]contradicts the intent of the authors of the exemptions and that originally emerged from the panic of the mid-1990s that almost everyone agrees led to the overregulation of human subjects research. Nor can I put much faith in a promise that [12]new guidance from OHRP is just around the corner. More importantly, it's frustrating that Menikoff missed the opportunity to address the central problem posed by the critics he cited: there is no evidence that the IRB system does more good than harm. The question of self-exemption is important, but in the context of the overall critique of the system outlined in the speech, Menikoff's emphasis on this one point becomes a bit of a red herring. Finally, I must object to Menikoff's patronizing remarks about the emotional state of IRB critics:

> It's not as if everything or even the bulk of what these people are claiming is necessarily true or valid, but nonetheless we again have to be aware of the strength of their feelings and the source of it. There is this heartfelt feeling about at least parts of the human protection system that they are wrong.

Yes, critics are angry, but it is insulting to portray us as so overcome with emotion that we cannot form "true or valid" complaints. It is not the strength of our feelings that should concern Menikoff, but the accuracy of our facts and the logic of our arguments.

1. http://lecb.physics.lsa.umich.edu/wl/carma/2009/OHRP/20090514-umwlcd0011-081223/real/f001.htm
2. http://www.bioethics.gov/reports/newborn_screening/schneider_statement.html
3. http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf
4. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=721363
5. http://www.law.uiuc.edu/conferences/whitepaper/
6. http://www.law.northwestern.edu/lawreview/issues/101.2.html
7. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm
8. http://www.law.northwestern.edu/lawreview/v101/n2/791/LR101n2Menikoff.pdf
9. http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm
10. http://www.institutionalreviewblog.com/2008/10/45-cfr-46101-is-still-dead.html
11. http://www.institutionalreviewblog.com/2007/08/guidance-creep.html
12. http://www.institutionalreviewblog.com/2009/01/happy-new-year-ohrp.html

Anonymous (2009-07-13 13:49:38)
OHRP would also need to modify the terms of FWAs (or finally admit that FWAs are worthless- why does there need to be an additional promise to follow regulations by which an institution is already bound?). While the terms do not explicitly require review of exempt research, the terms could easily serve as the basis for OHRP to hold an institution accountable for an exempt project that was not sufficiently "guided" by the Belmont Report (emphasis added below)...
"A. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INSTITUTIONS WITHIN THE UNITED STATES
1. Human Subjects Research Must be Guided by Ethical Principles
All of the Institution's human subjects research activities, **regardless of whether the research is subject to federal regulations**, will be guided by the ethical principles..."

Zachary M. Schrag (2009-07-14 08:38:52)
Thank you for your comment.
I fear I don't understand your claim that "FWAs are worthless." Many regulations require that persons or institutions sign promises to obey them. Drivers' licenses, tax returns, and building permits, for example, all serve this function.
And as you point out, FWAs serve an additional purpose: they allow OHRP regulators to extend their power beyond the scope of 45 CFR 46, by extracting additional promises. Regulators have been playing this game since 1981. See E. L. Pattullo, "How General an Assurance?," IRB: Ethics and Human Research 3 (May 1981): 8-9.

4.6.3 Finnish Group Warns Against Unnecessary Bureaucracy (2009-06-29 09:08)

Klaus Mäkelä and Kerstin Stenius kindly alerted me to their paper, "[1]A New Finnish Proposal for Ethical Review in the Humanities and Social Sciences," which they presented in London in April. The paper describes a draft report by a working group of Finland's National Advisory Board on Research Ethics, which examined the need for ethics review in the humanities and social sciences.
In its draft report, issued in January, the working group adopted some principles that would be familiar to ethics committees and regulators in the United States and other countries. The report stresses the importance of voluntary participation, informed consent, the confidentiality of information, the avoidance of "undue risk and harm," and the need for special care when researching minors. It sees ethics review committees as part of a process to effect these goals.
On the other hand, the working group recognizes that too much oversight presents its own problems:

> 5. It is important to respect the autonomy and good sense of research subjects. In social research, participants usually are fully competent to assess the risks involved without outside expertise. Ethics committees should avoid paternalism.
> 8. Clear criteria should be formulated for what kinds of projects require ethical review, but it should be up to the researcher to determine whether a project meets these criteria.
> 10. The work of ethics committees should be as transparent and open as possible and a system of appeals should be put in place.

The second part of principle number 8 is particularly significant. U.S. regulators have, since 1995, insisted that researchers cannot be trusted to determine when their research is subject to review under the Common Rule. Recently, Jerry Menikoff of OHRP noted that [2]institutions are not legally required to strip researchers of the power to make these determinations, but OHRP will continue to recommend that they do so.
The Finnish working group, by contrast, sees a greater danger in giving that power to committee members and staffers who will likely err on the side of too much review:

> It is a matter of judgement to decide what kinds of stimuli are 'exceptionally strong'. To avoid unnecessary bureaucracy, it nevertheless should be up to individual researchers to decide whether their project falls into the categories listed above and needs to be submitted to ethical review. It is highly unlikely that this will lead to transgressions, and ex post facto sanctions will be enough to keep any exceptions under control.

In short, the working group understands that in this case, the dangers of too much bureaucracy outweigh the dangers of too little.
I should note that the London conference at which Mäkelä and Stenius presented their work was the Third Working Meeting of the International Study of Ethical Codes and Ethical Control in the Social Sciences, the previous conferences having been held in London in 2007 and 2008. The meetings have brought together scholars from several northern European countries to discuss social science ethics and regulations across international borders. It is splendid that these scholars are at work on so important a topic, and I look forward to learning more from them.

1. http://nat.stakes.fi/SV/arkivet/2009/stenius.htm
2. http://www.institutionalreviewblog.com/2009/06/menikoff-to-critics-yes-we-hear-you.html

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4.7 July

4.7.1 (2009-07-03 22:08)

The Systematic Threat to Academic Freedom
Lisa Rasmussen kindly alerted me to her essay, "[1]Problems with Minimal-Risk Research Oversight: A Threat to Academic Freedom?" IRB: Ethics & Human Research 31 (May 2009): 11-16. The essay mostly seeks to rebut the AAUP's 2006 report, "[2]Research on Human Subjects: Academic Freedom and the Institutional Review Board." Rasmussen identifies some important shortcomings in that report, and she raises key questions about the relationship between IRBs and academic freedom. But I am unpersuaded by her central arguments.
Before I address them, I should note the repeated disclaimers within the essay. "I will not settle here the fundamental issue of whether a convincing argument exists that IRB review poses a threat to academic freedom," Rasmussen writes. "A longer explanation of the [AAUP report's] failures is beyond the scope of this paper, but a brief outline is possible." I am disappointed by these limits. Rasmussen devotes significant space to matters peripheral to the question of academic freedom, such as her assertion that researchers whose work was approved by a department–rather than a central IRB–would necessarily merit less legal protection, a point whose weakness she acknowledges in a footnote. Given only six pages, Rasmussen would have done better to focus on the question posed in her title.
Rasmussen's main argument is that the AAUP report "does not demonstrate that IRBs pose a threat to academic freedom." As Rasmussen notes, such a demonstration would require a definition of academic freedom, something lacking in the AAUP report. She offers a passage from the AAUP's "[3]1940 Statement of Principles on Academic Freedom and Tenure": "Institutions of higher education are conducted for the common good and not to further the interest of either the individual teacher or the institution as a whole. The common good depends upon the free search for truth and its free exposition." Emphasizing the grounding of this argument in the search for the "common good," Rasmussen then concludes that "there is a prima facie claim that research can be subjected to assessment regarding whether it threatens to harm the common good via harm to individuals."
I believe this is a misreading of the 1940 Statement, for it suggests that any policy aimed at safeguarding the common good is consistent with academic freedom. For example, she could have written, "there is a prima facie claim that research can be subjected to assessment regarding whether it threatens to harm the common good via the promotion of communist overthrow of the government," and that therefore a prohibition on the use of Marxist analysis is consistent with academic freedom.
A more relevant definition of academic freedom can be drawn from the AAUP's [4]1915 Declaration of Principles on

Academic Freedom and Academic Tenure":

> The liberty of the scholar within the university to set forth his conclusions, be they what they may, is conditioned by their being conclusions gained by a scholar's method and held in a scholar's spirit; that is to say, they must be the fruits of competent and patient and sincere inquiry, and they should be set forth with dignity, courtesy, and temperateness of language.
> It is, however . . . inadmissible that the power of determining when departures from the requirements of the scientific spirit and method have occurred, should be vested in bodies not composed of members of the academic profession. Such bodies necessarily lack full competency to judge of those requirements; their intervention can never be exempt from the suspicion that it is dictated by other motives than zeal for the integrity of science; and it is, in any case, unsuitable to the dignity of a great profession that the initial responsibility for the maintenance of its professional standards should not be in the hands of its own members. It follows that university teachers must be prepared to assume this responsibility for themselves.

As Matthew W. Finkin and Robert C. Post write in their new book, For the Common Good: Principles of American Academic Freedom, freedom of research depends on [5]a framework of accepted professional norms that distinguish research that contributes to knowledge from research that does not." (54) While these two experts on academic freedom decline to offer a firm opinion on the legitimacy of IRBs, they take the AAUP's concerns far more seriously than does Rasmussen (69).

At some level, Rasmussen understands the danger of non-scholars overseeing the work of scholars, and she suggests that IRBs merely maintain scholarly standards: "The source of the threat to academic freedom via oversight by one's colleagues is far from clear," she writes, "especially since researchers undergo peer review for research funding and when submitting their manuscripts for publication." But IRB review is not peer review, since it is conducted mostly by people ignorant of the scholarly methods they are reviewing. (See "[6]Why IRBs Are Not Peer Review," and other posts tagged "[7]peer review.") Like the boards of trustees that concerned the authors of the 1915 statement, IRBs "lack full competency to judge of [scholarly] requirements."

To make this a bit more concrete, we can examine exemplary "horror stories" included in the 2006 AAUP report. Rasmussen describes these only as "unelaborated anecdotes with no documenting citations," rather than examining their implications for academic freedom.

Here's one: "A Caucasian PhD student, seeking to study career expectations in relation to ethnicity, was told by the IRB that African American PhD students could not be interviewed because it might be traumatic for them to be interviewed by the student." Or another: "A campus IRB attempted to deny an MA student her diploma because she did not obtain IRB approval for calling newspaper executives to ask for copies of printed material generally available to the public." No peer review process would impose such conditions. If these are not infringements of academic freedom, then nothing is.

Rasmussen is quite right that we should not equate "inconvenience and hassle with abridgement of academic freedom." Yet nor should we dismiss the abridgement of academic freedom as mere inconvenience and hassle. When IRBs impose conditions on research that prevent researchers from conducting the basic tasks of scholarship–talking to people of varied backgrounds, recording interviews, or telephoning for information–they abridge academic freedom. The more interesting questions are how often this occurs, and why it happens.

Throughout the essay, Rasmussen presents IRB abuse as a somewhat random process: "IRBs can function well or poorly, and which is true for a given IRB depends on many factors, not least of which are institutional support and member training." This suggests that IRB abuses are individual anomalies, rather than a pattern.

By contrast, the AAUP detects a systematic bias toward the infringement of freedom. This is better developed in the AAUP's 2000 report (cited by Rasmussen) which includes such observations as "no one is likely to get into trouble for insisting that a research proposal is not exempt" and "no university is likely to want to explain to either the government or the public why its commitment to avoid harming the human subjects of research is limited by the source of funding for the research." In these and other cases, the AAUP recognizes that the IRB system punishes individuals and institu-

tions only for approving research, not for restricting it.
There is plenty of evidence of a pattern. Read [8]Maureen Fitzgerald and [9]Laura Stark, both of whom observed repeated abuses by the IRBs they studied. Read [10]Linda Thornton, whose work was thwarted at 15 of 24 institutions she contacted. Read [11]Jack Katz, who shows that IRBs are particularly likely to pounce on controversial topics. IRBs can function well or poorly, but the system is weighted toward poor function.
At some level, Rasmussen gets this. She concedes that the "lack of an [IRB] appeals process may threaten academic freedom." And she also details the way that departmental-level review might systematically hamper research. And she ends her essay with a promising proposal for “template review:"

> Disciplines at the national level might formulate templates to guide very common research approaches. For example, a research template for oral historians could stipulate that the researcher will interview individuals, record their answers, refer them to counselors if the questions have provoked strong emotions, procure consent forms, lock the transcripts securely, and identify what will happen to the transcripts at the close of research. IRBs at individual institutions would review the template once and approve it (or even decide to accept any templates from given professional societies). Thus, a researcher would simply submit a form to the IRB stating her agreement to abide by the format of the template. Upon receipt of the form, the IRB would approve the protocol.

If IRBs are not threatening academic freedom, why propose this reform? Inside this proposal is an acknowledgment that disciplinary experts and professional societies in the social sciences and humanities have been excluded from the present IRB system. While such exclusion does not automatically threaten academic freedom, whe should not be surprised when it does. For all her skepticism of the AAUP report, Rasmussen has presented her own suggestion that the current system is rotten at the core.

1. http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=3422
2. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm
3. http://www.aaup.org/AAUP/pubsres/policydocs/contents/1940statement.htm
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6. http://www.institutionalreviewblog.com/2007/03/why-irbs-are-not-peer-review-reply-to-e.html
7. http://www.institutionalreviewblog.com/search/label/peer%20review
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9. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
10. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
11. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html

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4.7.2 (2009-07-04 09:04)

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Before I address them, I should note the repeated disclaimers within the essay. "I will not settle here the fundamental issue of whether a convincing argument exists that IRB review poses a threat to academic freedom," Rasmussen writes. "A longer explanation of the [AAUP report’s] failures is beyond the scope of this paper, but a brief outline is

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The design flaws in the system have yielded a pattern of abuse. Read [8]Maureen Fitzgerald and [9]Laura Stark, both of whom observed repeated abuses by the IRBs they studied. Read [10]Linda Thornton, whose work was thwarted at 15 of 24 institutions she contacted. Read [11]Jack Katz, who shows that IRBs are particularly likely to pounce on controversial topics. IRBs can function well or poorly, but the system is weighted toward poor function.

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2. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm
3. http://www.aaup.org/AAUP/pubsres/policydocs/contents/1940statement.htm
4. http://www.aaup.org/AAUP/pubsres/policydocs/contents/1915.htm
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6. http://www.institutionalreviewblog.com/2007/03/why-irbs-are-not-peer-review-reply-to-e.html
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4.7.4 AAHRPP Proposes Revised Standards (2009-07-15 09:35)

Robert Townsend, PhD, kindly alerted me to the [1]Proposed Revised Accreditation Standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The revisions are largely cosmetic, grouping many of the existing standards under new headings. As far as the review of social science and humanities research goes, I see no drastic departures from previous AAHRPP positions. This is a pity, since the standards need more substantive revision to meet the goals that AAHRPP has set for itself.

AAHRPP is accepting [2]comments until July 30. My comment follows.

To the AAHRPP,

Thank you for the opportunity to comment on your proposed revised accreditation standards. If enforced, these standards would provide researchers with some protections against arbitrary actions by IRBs and human research protections staff. But they fail to look at the bigger picture and ask why so elaborate a structure is necessary to oversee areas of research with sparse record of doing wrong, or whose ethical challenges are too unpredictable to be spotted in advance by an ethics committee. Moreover, the standards fail to take seriously the suggestions of some of the most informed critics of the present structure.

Researchers in the social sciences and humanities have long complained that their work was being reviewed by committees that lacked the necessary expertise. I am therefore glad to see that Element II of the new standards requires that "the IRB or EC has and follows written policies and procedures requiring protocols or research plans to be reviewed by individuals with appropriate scientific or scholarly expertise . . . " It also insists that "the IRB or EC is comprised of members to permit appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster," a criterion currently violated by most IRBs that review ethnographic and humanities research.

I would like to suggest that Element II be strengthened by requiring IRBs and ECs to base their evaluations on documented benefits and risks. Many committees demand precautions against risks that are largely chimerical, such as

the possibility that an interview will re-traumatize victims of earlier trauma. As noted in the March 2008 issue of the Journal of Empirical Research in Human Research Ethics, empirical study suggests that such people are much more likely to be benefited than harmed by interviews. AAHRPP should insist that IRBs and ECs keep current with such literature and base their judgments on its findings. AAHRPP should also prohibit IRBs and ECs from judging proposals on irrelevant criteria, such as the number of typographical errors in a proposal.

The standards also provide a measure of accountability. Element I.5 insists that "based on objective data, the Organization identifies strengths and weaknesses of the Human Research Protection Program, makes improvements, when necessary, and monitors the effectiveness of the improvements." It also provides that "the Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process." Again, many universities currently fail to meet these standards.

I would be more encouraged by these standards if AAHRPP would pledge to enforce them. I suggest that as part of its system of maintaining accreditation, AAHRPP establish a mechanism by which researchers can bring violations of these elements directly to the attention of the association. Researchers at accredited institutions should be guaranteed that AAHRPP will investigate their complaints.

More significantly, I am disappointed to see that the proposed standards reject two of the most prominent suggestions for taming overregulation put forward by IRB critics: allowing researchers to apply clearly worded exemptions to their own research, and limiting the application of federal rules to federally-funded research. AAHRPP promises policies and procedures based on "objective criteria and measurable outcomes." What objective criteria suggest that researchers cannot apply the exemptions, or that federal regulations are necessary for all research?

Prominent members of the IRB community, including a former director of OHRP, and current members of SACHRP, have conceded that overregulation and hyper-protectionism are problems that must be addressed. Restoring the exemptions of 45 CFR 46 to their original intent, and allowing institutions to experiment with ways to oversee non-federally-funded research, are among the most constructive suggestions put forward to address these problems. The proposed standards reject these proposals out of hand. In doing so, they fail to meet AAHRPP's professed ideal of performance-based policies.

Finally, while you have not sought comment on your current Accreditation Principles, let me express my hope that you will find some room in them for the promotion of academic freedom. A university or research center that fails to incorporate this ideal into its human research protection system cannot be faithful to its core mission.

1. http://www.aahrpp.org/www.aspx?PageID=296
2. http://www.aahrpp.org/www.aspx?PageID=297

4.7.5 AAHRPP and the Unchecked Box (2009-07-17 10:57)

Regular readers of this blog likely know that most United States universities submit "[1]federalwide assurances" (FWAs) pledging to abide by the Common Rule for research funded directly by federal agencies that have adopted that rule.

Section 4 of the standard assurance includes an optional pledge that "This Institution elects to apply . . . to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance" either the Common Rule or the Common Rule and subparts B, C, and D of 45 CFR 46. Institutions that check this box–as seems to have been common in the past–with one stroke of the pen eliminate one of the major concessions made by federal regulators in 1981, when they promised that non-federally-funded research would not be regulated.

Recently, however, at least 164 universities have "unchecked the box," declining to promise to apply the regulations to all research. The [2]American Association of University Professors has strongly recommended that universities uncheck the box as a first step toward devising procedures less burdensome than those specified in the regulations.

[3]Malcolm Feeley has noted that unchecking the box could also yield important empirical data:

> If there are few reports of negative consequences . . . they might encourage national officials to rethink the need for such an expansive regulatory system . . . On the other hand, if opt-out results in increased problems, the findings might help convince Katz, Dingwall, me, and still others of the value of IRBs.

Nor are such comments confined to outsiders. At the [4]July 16, 2008, meeting of the Secretary's Advisory Committee on Human Research Protections, committee member Lisa Leiden of the University of Texas system spoke of her own interest in freeing nonfunded research from direct federal regulation:

> We have talked about limiting the federal wide assurances, unchecking the box, and I believe the position that we're going to be taking is to advocate in a gentle way thinking about doing that. We have heard both sides of the story or maybe just a few sides, but we think that there are certainly some advantages. And one of the advantages might be . . . what can we do with the expedited review level. It seems that there is a lot of flexibility in that, and we might be able to increase some of that by unchecking the boxes and adding different categories for that.

Unchecking the box is therefore one of the most promising incremental reforms now on the table. This is why I was disappointed to see that the [5]AAHRPP's proposed revised standards, described in my previous post, seem to preclude this option.

A correspondent questioned this assertion, noting that AAHRPP president Majorie Speers had mentioned unchecking the box in her presentation, "[6]Finding Flexibility in the Regulations." But there's nothing in the slides to suggest that AAHRPP or Speers approves of such a practice, and a [7]July 2008 memo from the University of California states that AAHRPP site visitors have told university administrators "that in order for a human research protection program to be accredited, it must apply the Common Rule and its subparts to all human research at the institution, irrespective of funding."

Either AAHRPP forbids accredited organizations from unchecking the box, or its policies are so unclear that its site visitors are giving out bad information. Either way, I suggest that the revised standards permit unchecking the box as a means of reform.

1. http://www.hhs.gov/ohrp/assurances/assurances_index.html
2. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm
3. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html
4. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-08/mtg07-08.html
5. http://www.institutionalreviewblog.com/2009/07/aahrpp-proposes-revised-standards.html
6. http://www.aahrpp.org/www.aspx?PageID=235
7. http://www.ucop.edu/research/documents/memoRLtoIRBDirsreuncheckingthebox7708.doc

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4.7.6 U. of California Shouldn't Avoid Debate (2009-07-20 16:47)

In my previous post, [1]AAHRPP and the Unchecked Box, I mentioned a 2008 memo, "[2] "Unchecking the Box" on the FWA – Issues and Guidance," by Rebecca Landes, research policy coordinator at the University of California's Office of Research and Graduate Studies.

The memo deserves a second look, since it shows the tensions within a university administration when faced with challenges from social scientists.

On the one hand, the memo acknowledges the complaints:

> There is increasing pressure of late from social science, behavioral and humanities researchers to modify IRB review of research in these disciplines. While there may be good reasons to apply different review standards to different types of research, changes in the application of subject protection rules at UC should be effected through systemwide discussion and consensus. Campus by campus modifications to subject protection rules for nonfederally funded research would lead to confusion and chaos.

I do not see why campus-by-campus modifications in this area should sow more confusion than already exists. I doubt, for example, that [3]UCLA's absurd policies were cleared with other campuses before being promulgated. But at least this portion of the memo calls for "systemwide discussion and consensus."
But continue reading, and you get to a section on "Pros and Cons" of promising to apply federal regulations no nonfunded research. And here's one of the "pros": "Avoids opening up the debate on differing protections for different disciplines, e.g., social science, behavioral and humanities research."
So which is the real goal of the University of California administration: to foster "systemwide discussion," or to avoid opening up a debate? Only one choice is worthy of a great university system.

1. http://www.institutionalreviewblog.com/2009/07/aahrpp-and-unchecked-box.html
2. http://www.ucop.edu/research/documents/memoRLtoIRBDirsreuncheckingthebox7708.doc
3. http://www.institutionalreviewblog.com/2008/04/do-ucla-researchers-have-permission-to.html

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4.7.7 Oral History Update (2009-07-25 13:50)

Linda Shopes revises and expands her 2007 essay, "[1]Negotiating Institutional Review Boards" in a page on the [2]Oral History Association website.
Shopes, who spent years negotiating with federal officials, now despairs of that route: "After more than a decade of largely ineffective advocacy vis-à-vis OHRP and its predecessor, oral historians are not likely to gain many concessions from federal regulators."
I must agree with Shopes's pessimism. As Michael Carome conceded in October 2008, [3]OHRP has taken action on only a handful of the 147 recommendations put forward by the Secretary's Advisory Committee on Human Research Protections. If regulators cannot or will not implement the recommendations of their own official advisory body, they are unlikely to prove more responsive to the concerns of a group of scholars whom they have ignored for years.
Instead of looking to OHRP for relief, Shopes suggests that "if we must live within a regulatory system that is, at best, incongruent with our ways of working, perhaps the best we can do is work within our individual institutions to develop a measure of mutual accommodation." She notes the progress historians have made at Amherst, Columbia, UMKC, Michigan, and Nebraska. Here's hoping the next update of her essay has a longer list.

1. http://www.historians.org/perspectives/issues/2007/0703/0703vie1.cfm
2. http://www.oralhistory.org/do-oral-history/oral-history-and-irb-review/
3. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg10-08/present/Carome.html

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4.7.8 A Defense of RECs (2009-07-28 08:49)

Professor Adam Hedgecoe of Cardiff University kindly pointed me to his article, "[1]Research Ethics Review and the Sociological Research Relationship," Sociology 42 (2008): 873-886.
The article is a response to longstanding criticisms of British research ethics committees (RECs), especially those affiliated with the National Health Service (NHS). For example, Sue Richardson and Miriam McMullan surveyed "UK academic social researchers working in Health, or health services researchers, who had experience of using the NHS

research ethics process prior to March 2004," in "[2]Research Ethics in the UK: What Can Sociology Learn from Health?," Sociology 41 (2007): 1115-1132. Fifty-one percent of their respondents reported degrading their research design as a result of the committee approval process, while only 32 percent reported making changes for the better. Overall, 59 percent offered negative comments, while only 15 percent offered positive comments. And Richardson and McMullan set a pretty low bar for a positive comment, counting this: "It's a lot of paperwork but once you know what is required, it's acceptable." Overall, it seems, NHS RECs are inhibiting the sociological study of health care in the United Kingdom.

Hedgecoe seeks to rebut this impression, based on his observation of three NHS RECs in 2005 and 2006, and some follow-up interviews. He argues that "NHS RECs are not inherently hostile to social science research, especially qualitative research." (882) The double-negative construction of that thesis suggests Hedgecoe's problem: he's trying to prove that something doesn't happen, or at least not as often as ethics-committee critics believe. That's not an easy task, and I congratulate him for trying. But I find the article unpersuasive.

The article offers mostly generalities, rather than the detailed stories that are the heart of a good ethnography. For example, though telling us he "took extensive notes (including verbatim quotes)" (876), Hedgecoe offers only two vertbatim quotes from committee meetings in the whole piece. It's also short on quantitative data. Hedgecoe notes that he observed 33 committee meetings, but he doesn't say how many ethnographic projects came up for review. He describes only four, one of which, his own, wasn't technically part of his study.

Here are the four:

1. Hedgecoe's own research on RECs.

After begging to have his project reviewed by an REC, Hedgecoe received approval, including permission to sit in on committee meetings without the consent of the researchers applying for approval for their own projects. Instead, he boasts, he needed only to anonymize the people and institutions he observed. (881) Of course, Hedgecoe's determination to anonymize "people, places, and events" may have resulted in the vagueness of his findings, so I'm not sure I count this as a win. Rather, it may be an example of the blandness that critics see as one of the results of ethics review.

2. A cancer ward study:

> When reviewing an application proposing qualitative interviewing of nursing staff working on a cancer ward about the impact of their work on their lives, Coastal MREC presented the applicant with a technical bureaucratic problem caused by the researcher's independent status. The chair's reaction to the researcher's concern over this point was to say, 'This is not a problem we are throwing at you, but a problem we are trying think round', and indeed the solution suggested by one member (which was to affiliate with an academic institution the researcher had previously collaborated with) solved this particular problem. (879

Here the committee offers not ethical judgment, but advice on how to deal with an ethically empty bureaucratic rule. Who is forbidding independent research in the UK?

3. "A proposal to study specialist paramedics with a view to evaluating the role, seeing whether it reduced the number of people who were repeatedly admitted to A &E (so called 'frequent flyers')." (881)

Did you notice the word "number" in that description? Why is Hedgecoe using a quantitative project to show that RECs are friendly to qualitative research? It sounds to me as though a medical REC would have no trouble fitting this study into the clinical model.

4. Finally, the most interesting case, the "nurses study":

> a senior nurse applied to do research as part of an MSc, looking at nurses' attitude towards performance-related pay. Although the study was going to be on the nurse's own team, the committee was generally inclined to approve the application since the results would be restricted to a dissertation. But when the applicant came before the committee it became clear that she had wider goals for the results of this work, including feeding into policy decisions. She also made statements that worried the REC,

> about wanting to work with 'people I trust and who trust me'. The REC suggested that the applicant study a team at another hospital, to avoid the issues of conflict of interest, but the applicant was not happy, claiming the REC was 'stifling research'. The committee directed her to the head of nursing research and apparently the applicant went so far as to complain to COREC, NRES's predecessor. (879)

Hedgecoe applauds the REC, describing its decision as "deft" and writing that "researchers are often oblivious to the potentially coercive nature of supervisors asking those they manage to take part in research, especially research which may require them to reflect on their practice." (880)

I'm not persuaded that the REC made the right call; it seems like the nurses were denied a chance to collaborate in research and to shape policy in their workplace. But the bigger question, which Hedgecoe does not explore, is why the researcher felt stifled, rather than enlightened, by the guidance she received. Wouldn't an effective committee be able to persuade her that her project was flawed, rather than leading her to file a formal complaint?

Hedgecoe's silence on this question may result from his research design. While he interviewed "policy-makers, pharmaceutical industry researchers and executives, and, most pertinently for this article, members of research ethics committees themselves," it is not clear that he spoke with any of the social science researchers who sought approval from the committees he observed. They might have a thing or two to say about the way they were treated. (875) But Hedgecoe's comments about getting informed consent from everyone except researchers suggests he avoided them.

That's a pity. Hedgecoe cites with approval the "rigorous empirical data gathering" of Bradford Gray (874), without absorbing one of Gray's key arguments: it's not enough to observe an ethics committee; one must also talk to those affected by its work. For Gray, that primarily meant research participants, but it also meant researchers, at least in his work for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (I'm afraid I don't have handy a copy of Gray's 1975 book, Human Subjects in Medical Experimentation, so I can't recall if he spoke to researchers for that, or only committee members and research participants.) Instead of talking to researchers, Hedgecoe imposed his own judgment that they were being treated fairly.

I am glad to learn that some NHS RECs allowed two or three projects to proceed without much difficulty. But given the much more extensive data–qualitative and quantitative–in the Richardson and McMullan study, I am little reassured by Hedgecoe's assertions that RECs are doing just fine.

1. http://soc.sagepub.com/cgi/content/abstract/42/5/873
2. http://soc.sagepub.com/cgi/content/long/41/6/1115

Adam (2009-08-24 06:31:46)

Response part i)

Hi Zach

I must confess to being a bit bemused by your dyspeptic response to my article on NHS RECs' evaluation of qualitative research. It's a shame you have adopted such a snide tone in your commentary on my work (I was 'boasting' when I pointed out that my own work got through REC review. Really?); I was always taught that the best academic arguments are those that give the most generous reading of their opponents' position. You clearly abide by another set of principles.

Be that as it may, I wanted to clarify a few points in my article that you seem to be a bit confused about. Firstly, you make rather a banal point about my article lacking "than the detailed stories that are the heart of a good ethnography". Well quite, but then special issues of _Sociology _ have a 6,000 word limit, which rather cramps one's style on the ethnographic detail front. The issue of word length is a common problem faced by those of us writing ethnographic articles for journals, and is, perhaps, why ethnographers still place so much value on book length presentations of their work, given the space these give us.

Secondly, you rather miss the point about the cancer ward study. You correctly note that "Here the committee offers not ethical judgment, but advice on how to deal with an ethically empty bureaucratic rule", but fail to accept that this emphasises the generally supportive attitude RECs have towards (all) research. One problem with your wide critique of research ethics review, certainly as it pertains to the UK, is a failure to distinguish between committees, and the system of rules within which they operate (which are drawn up and revised by the Department of Health). To some extent, they are in tension (as is often the case in bureaucracies). A more generous reading than yours would accept that this description of REC behaviour (helpful, supportive of research) is at odds with the general picture painted of RECs by social scientists (and other researchers) who have applied to

such committees, and thus worthy of interest....(tbc)

Adam (2009-08-24 06:32:55)
Response Part II
Thirdly, in your keenness to suggest bad faith on my part ("Why is Hedgecoe using a quantitative project to show that RECs are friendly to qualitative research?") you simply parade your own ignorance about social science methodologies or, alternatively, your failure to read my article properly. You seem to assume that because the overall goal of this study was to reduce the number of a particular event, that ONLY quantitative methods can be used. This is plainly daft: as I say in my paper, the application assessed by the REC was a QUALITATIVE observational study of paramedic behaviour, within the context of a broader piece of work that sought to reduce the incidence of A &E 'frequent flyers'. Methodologically it makes no sense to claim, as you seem to do, that because the overall study has something to do with numbers, the individual study assessed by the REC must therefore be a "quantitative project". There are more methodological problems with your assumption that Richardson and McMullan's questionnaire survey of researchers' opinions of REC review somehow tells us something about the INTERNAL processes that RECs use to make their decisions. While such surveys of researchers' opinions are interesting and useful, they do not investigate the way in which RECS make decisions, only researchers' views on REC decisions and the public reasons given for them. My research was interested in the INTERNAL processes by which RECs reach their positions (in the case of this article, with regard to qualitative research), and thus Richardson and McMullan's work has little to say about the content of my research . It certainly doesn't 'trump' it, as you seem to think.
You cite Gray's work without noting that he didn't _observe _ IRB decision-making in his study, but rather drew on external data about IRB performance. The methodological question is this: which is the best source of data on the way in which RECs actually make decisions. Is it: a) to draw on the views of people who were not present at the REC meeting and only have access to the formal justifications for the decision or b) attending REC meetings to see how they make decisions and interviewing members of those committees afterwards? I think the answer is b) and that the data gathered by a), while interesting, does not tell us much about the internal mechanics of REC decision-making.
Unlike you, I do not have an axe to grind with regard to research ethics review bodies (IRBs, RECs, whatever). I think they are interesting and I carry out empirical research on them to find out how they work, and how they have developed over time. I don't have an ideological stance with regard to these bodies. I try and follow the evidence.
regards
adam hedgecoe.

Zachary M. Schrag (2009-08-25 08:08:30)
Thank you for these comments.
I am surprised by your statement that "my research was interested in the INTERNAL processes by which RECs reach their positions," since the article has so little to say about those processes. It presents the RECs' positions on four studies without telling us how the RECs reached those positions: who initially proposed the recommendation, who opposed it, what alternatives were considered, and so on. A contrast is the work of Laura Stark, who explains in detail the sorts of interactions that take place among committee members.
Perhaps 6000 words is insufficient to present both your argument and supporting evidence. If this is the case, you can hardly expect a 6000-word presentation of your views to persuade someone not already sympathetic to them.
ZMS

4.8 August

4.8.1 UT Knoxville's IRB Joins "Collective Mobbing" (2009-08-11 11:54)

Over at [1]Counterpunch, anthropologist David Price reports on the case of Janice Harper, an anthropologist recently dismissed from the University of Tennesee Knoxville.
According to Price, Harper's troubles began in 2007, when she reported sexual harassment by a colleague. Despite a

unanimous vote from her college's tenure and promotion committee and strong outside letters of support, her associate dean opposed her bid for tenure. Worse still, she was accused of mental instability. As Price reports, "like a textbook discussion of collective mobbing behavior, the act of investigation brought more accusations," including student allegations that Harper planned to build a hydrogen bomb. This led to an FBI investigation, which found no criminal activity.

All of this would be bad enough, but then the IRB decided to make it worse. As Price explains,

> Dr. Harper says that in early June, the University of Tennessee's Institutional Review Board (IRB) revoked her standing research clearance on the grounds that the police and FBI investigations and the seizure of her research materials exposed her informants to risks. She was told that she "could not use my data until I had assurance from the FBI and university that I was no longer under surveillance." As these investigations continued, however, they found nothing to indicate that she had made threats or was somehow building a hydrogen bomb. Yet, Dr. Harper was caught in a classic double-bind. Although the FBI did not find that she had done anything wrong, she could not complete her work simply because this investigation had opened her private research records up to FBI scrutiny. This, of course, seriously imperiled her professional activity and development. Last fall, Dr. Harper learned that the faculty in her department voted to deny her tenure application.

Price suggests that the IRB's action was a major element in the collapse of Harper's career. He writes that "the loss of a scholar's IRB clearance because of an FBI investigation that found no wrong doing ought to be an issue of central importance to such professional organizations, and I would hope that the AAUP, AAA and SFAA would recognize the need for them to weigh-in on this and other procedural aspects of her case. This is a case that impacts us all."

Price complains about the heavy hand of the "National Security State," and he titles his post "Trial by FBI Investigation." But in his account, the FBI was not Harper's biggest problem; it investigated a threat of nuclear terrorism and closed the case with reasonable efficiency. The IRB, by contrast, apparently offered no such resolution. Perhaps Price needs to worry less about the National Security State and more about the Human Subjects Protection State.

[Editor's Note: The Institutional Review Blog opposes letting anthropologists acquire thermonuclear weapons.]

1. http://www.counterpunch.org/price08102009.html

L.L. (2009-08-13 00:27:23)

I see you posted about this before I could even send you the link to Price's article! I thought you'd be interested in the peculiar ethics twist (sorry, make that "Ethics") to this case, and I was right.

Indeed, when I first read Price's article, that was the thing that most vividly grabbed my attention: the fact that her tenure bid must have certainly been affected by the fact that her IRB had rescinded not only her permission to conduct research, but even her right to use previously collected data.

Zachary M. Schrag (2009-08-14 09:57:27)

Thank you for this comment.

While we have only sketchy details from Price's account, I think this case suggests that IRBs are the wrong tool for protecting confidentiality.

The UT IRB did not, it seems, warn the participants in Harper's original research that her notes would be seized on the grounds of nuclear terrorism, since no one could have foreseen such a bizarre chain of events. The IRB did not prevent the seizure of the materials, for it had no such power. And it did not find a way to allow Harper's research to proceed.

Since the early 1970s, scholars concerned with the question of confidentiality have argued that if state and federal governments are serious about protecting confidentiality, they will pass laws shielding the research notes of social scientists, just as many states now have shield laws protecting journalists. Instead, governments have imposed IRB mandates that offer a false sense of security for research participants and can be used to stifle the work of ethical researchers.

4.8.2 Psychologist Blasts "Taxonomic Chaos" (2009-08-16 15:31)

John J. Furedy, Emeritus Professor of Psychology, University of Toronto, has posted, "[1]Implications for Australian Research of the Taxonomic Chaos in the Canadian Bioethics Industry: Après Moi le Deluge," originally presented at a June 2009 ethics conference in Australia. Though Furedy's expertise is in experimental psychology–a field outside the scope of this blog–his paper is relevant to the social sciences and humanities as well.

Furedy, who himself served for decades on ethics committees, argues that Canadian research ethics boards worked pretty well until the early 1990s. But since then bioethicists "have created taxonomic chaos by conflating such distinctions as the distinction between ethical and epistemological issues, or the differences among medical drug evaluation studies, psychological experiments, and sociological surveys."

He offers three specific complaints:

1. "REBs have taken it upon themselves to judge not only whether the proposed research is ethical, but also whether it is scientifically valid. But research-design issues for a particular piece of research require a specific sort of epistemological expertise which most REB members do not possess."
2. "The Tri-Council committee has succeeded in persuading governments and universities to treat a sociological opinion survey and a drug evaluation study, as if they were all part of 'human subject research,' that can be evaluated by the same all-knowing REB, using criteria that may apply to medical treatment-evaluation studies, but that do not apply to most social science research."
3. Though the Tri-Council agreed to drop the term "code" (with its suggestion of mandatory rules), "it was made clear to REBs, that if a researcher did not follow the so-called "statement", the right to apply for funding would be denied, because the REB would refuse to accept the proposed research."

Furedy stresses that all of this is relatively new, but that new scholars may not understand that. He writes,

> senior investigators are likely to be able get their research proposals through, even though they know, in their heart of hearts, the significance of distinctions such as the one between ethical and epistemological or research-design issues. But for younger researchers, and especially those who are currently students, the distinction between ethical and epistemological issues has been conflated, and so they lack a memory of how research used to be conducted. So researchers of the future are likely to succumb to the bioethics industry. They will, in the epistemological sense, be corrupted by these developments. Current senior researchers, then, who are in control to-day, are acting like France's Louis XV, who was said to have said "Après moi, le deluge."

As a historian, I applaud both the reference to the Bourbon monarchy and Furedy's emphasis on the need for historical consicousness. If younger researchers understand that scholars did not always operate under today's restrictive conditions, they are more likely to imagine alternatives.

1. http://www.psych.utoronto.ca/users/furedy/Papers/be/June09_full.doc

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4.8.3 Survey Seeks Ethnographers' Experiences with Ethics Oversight (2009-08-27 11:05)

Lisa Wynn of Macquarie University has posted an [1]online survey asking for ethnographers' "subjective experience of ethics oversight – their memories of when and how they first became aware of ethics oversight, what they think and feel about it, whether and how they comply with it, and whether they think it makes ethnographic research more ethical or not."

Since I will publish Wynn's findings in the special issue of the Journal of Policy History I am editing, I naturally hope that researchers embrace this opportunity to help us understand the evolving role of IRBs and other ethics oversight

bodies in the social sciences.
Note that Wynn defines ethnography broadly to include "any discipline that uses ethnographic research methods, including, but not limited to, anthropology, sociology, political science, history, geography, linguistics, Indigenous studies and area studies."

1. http://www.surveymonkey.com/s.aspx?sm=N1v1MJvyg3USMopDA0QV3g_3d_3d

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4.9 September

4.9.1 Internet Survey Sparks Outrage (2009-09-04 09:33)

Two newly PhD'd "cognitive neuroscientists"–Ogi Ogas and Sai Gaddam–got a book contract (rumored to be quite lucrative) with a popular press to write a book called "Rule 34: What Netporn Teaches Us About The Brain."
As part of their work, they launched an online survey aimed at authors of sexually explicit, online fan fiction. Many people who read the survey found it to be poorly designed and offensive, and anger grew as fan authors came to fear that the book would present erroneous information about their community.
The study was not IRB approved. Because the researchers had graduated from Boston University by the time they launched the survey, BU's IRB has disclaimed any authority over the matter, though it may have asked the researchers to stop using presenting themselves as being affiliated with the university. While some of the commentary on the event has included discussions about what the IRB might have done had it been presented the protocol, we can only speculate about whether IRB review would have changed the project for better, worse, or not at all.
Moreover, the chief concern of critics seems not to be that individual survey respondents would be harmed, but that their community as a whole would be harmed by a mass-market book written by inept, ignorant authors. Since the National Commission, policy makers have generally agreed that IRBs should not try to defend whole communities against mischaracterization by scholars.
Still, readers of this blog may be interested in a case where researchers' lack of preparation irreparably alienated the very people whom they wished to study.
For a good introduction, see Alison Macleod's [1]human element blog. Many links follow.

1. http://mackle.wordpress.com/2009/09/03/the-curious-case-of-the-game-show-neuroscientists-or-how-not-to-research-an-online-community/

Alison (2009-09-04 12:54:39)
Hi there - just a quick comment. I followed this debacle 'live', so to speak, and read a great many comments on Ogi Ogas' blog as he replied to critics. I also tried taking the survey in 'real time', and it was beyond offensive.
It was so offensive that I initially wondered whether the whole thing was a flimsy guise for the collection of explicit personal information - it was rather like a market research call that descends into a dirty phone call.
While the writers expressed fundamental anxiety about the purpose of the research and how they would be portrayed, there was also plenty of disquiet about basic anonymity/confidentiality. These researchers also used a picture link from a Harry Potter film to attract attention from passing fans: there are very many Livejournal users under 18, and there was no warning upfront of quite the kind of adult detail being collected here.
In short, it was an utter mess, and it would have failed any set of research standards, let alone the IRB's.

Anonymous (2009-09-04 13:30:45)
I am active in LJ media fandom, and an academic who does fan studies. I've been following the whole debate closely, but I would say that beyond the idea of "they will stereotype the community unfairly," there were a number of specific human subjects concerns raised by those of us who are academics and who are trained in human subjects protections in different disciplines. These were communicated to Drs. Ogas and Saddam and ignored, except for Ogas' later accusation about "anonymous

purported academics" trying to sabotage them.
I suppose the sabotage refers to queries sent to Boston University's IRB board by email and phone when the researchers refused to answer questions about IRB oversight regarding the major problems with their instrument (including the lack of warning against minors taking it, given that questions involved sexual imagery such as "do you have rape fantasies.).
A copy of the email I sent to the head and ass't head of the IRB committee, which I also copied to Dr. Ogas is in the next post because of comment length.
I am removing links that I sent because of moderation concerns and because many are now dead since Ogas shut down his posts.
I am using my real name and leaving my academic affilitation in the email (which I also sent to the head of my university IRB since I was in effect writing as a member of that committee).

Anonymous (2009-09-04 13:31:26)
Robin Anne Reid part 1
Dear Professor Berndt:
I am a professor in the Department of Literature and Languages, A &M-Commerce. As a new media and fan studies scholar, I serve as my department's IRB committee chair, and am a member of the IRB committee on campus. My area of IRB specialization is the issue of human protection standards in the emerging fields of internet research.
I have become aware of a "Fan Fiction Survey" being administered by Dr. Ogi Ogas and Dr. Sai Gaddam, Department of Cognitive and Neural Systems, Boston University. It may be that only Dr. Ogas is a faculty member; Dr. Gaddam is a recent graduate, according to his campus page.
BU WEB PAGE URLs DELETED; PAGES DELETED
They have circulated news of this survey widely among online fans and fan communities, on LiveJournal, and elsewhere.
I have not taken the survey, nor have I participated in any discussion on Dr. Ogas' LiveJournal (LJ) which he set up to accompany the survey. I have read the discussion on the LJ and will be linking to some threads below.
The survey site is here: DELETED CAN BE SUPPLIED UPON REQUEST

Anonymous (2009-09-04 13:31:42)
Robin Anne Reid part 2
What I have seen has caused me to have some concerns which echo those raised by a number of people posting on Dr. Ogas' LJ, especially those who are, like me, academics doing scholarship in a variety of disciplines and active members of fandom. Besides issues not relevant to the Institutional Review Board (the badly written questions, the complete lack of knowledge concerning fanfiction), I am most concerned the cavalier approach to questions concerning human subject projection in this project being expressed by the academics doing the research. .
I acknowledge that the survey is anonymous, containing no request for information, and I gather from discussions in Dr. Ogas' LJ that they plan to erase the data afterwards. I also understand that this project is for a popular book rather than an academic article or journal although that information was not made readily available to participants. However, neither of those factors excuse the lack of a clear statement of age restriction on the survey (no minors), nor the triggering nature of questions, some of which involve possible illegal activities.
The content of the questions (including questions about respondent's sexuality, desires, and fantasies–including on question about whether they have rape fantasies–and a question about illegal drug use) is problematic *especially* because Drs. Ogas and Gaddam have taken no steps to warn minors away from the survey. They say they do not plan to survey minors, but they are posting in places where minors under 18 do post fan fiction on the internet, and there is no warning/statement about the age limit.
Here is the LJ post which includes all the questions of the survey and some critiques (posted after extensive feedback given on an earlier post):
OGAS LJ LINK DELETED: POST CLOSED
One among many critiques of the methodology and lack of ethical scholarship was raised on this thread:
OGAS LJ LINK DELETED: POST CLOSED
By the strict letter of the law, Drs. Ogas and Gaddam may be acting appropriately in their research, but their lack of concern regarding the age of respondents, the apparent duplicity about the nature of the product of the research, and their interactions

with the very fans they are asking to participate in their research would cause me concern were they faculty on my campus. There have been past abuses of human subjects principles in fan studies, and online/media fandom is as a group well aware of past history and well read in much of the published scholarship concerning fan culture and fans. I am concerned about possible damage both to academic scholarship on fandom(s) and to fans who may be harmed by this research, especially if sloppily done work is distributed in a popular book that has not been subjected to academic peer-review. Nothing Dr. Ogas has said in his LJ has even begun to address these concerns which is why I decided to contact the IRB.
I hope that you can advise Drs. Ogas and Gaddam as to how they could improve their project with regard to human subjects issues.

Elf (2009-09-04 20:23:55)
This post has been included in [1]a linkspam roundup.

1. http://linkspam.dreamwidth.org/8690.html

Jonquil (2009-09-04 21:39:44)
The community as a whole was concerned about mischaracterization, but many people, including me, worried about the consequences of sloppy or absent confidentiality, data security, and anonymity. The survey writers put all the burden of confidentiality on the respondents – the only advice was to remove cookies. The survey FAQ did NOT warn against filling out the survey on shared machines/ or where users could be seen.
The survey asked many possibly damaging questions, including whether respondents had ever used marijuana or alcohol while reading fanfic; the former, of course, is a Federal crime.
Many of us worried about the security of the data; others worried about the failure to make any attempt to exclude minors from the survey, which asked some explicit questions. And finally, we were concerned because at least twice Dr. Ogas appeared to have connected people's LJ postings with their survey responses, which could only have involved IP logging; again, this breaches confidentiality.
I can give you links substantiating all of these complaints, if you like; it will take a little digging, but the data is available.

Anonymous (2009-09-04 22:55:25)
We are also outraged that there was no disclaimer for adult content and that it allowed people of any age to access and answer (imagine your 13 year old coming across the question "do you have rape fantasies?").

Anonymous (2009-09-05 00:40:38)
"Moreover, the chief concern of critics seems not to be that individual survey respondents would be harmed, but that their community as a whole would be harmed by a mass-market book written by inept, ignorant authors."
This summary of subject concerns is incorrect and misleading. It was widely-reported within the subject community and widely-believed by the study population that identifying material was being garnered at the survey site, both through IP Logging and internet "bots", that would allow Drs. Ogas and Gaddam to attach legal names to internet "nicks". These concerns were never addressed in any fashion by Drs. Ogas and Gaddam, nor was there any indication at any time from the researchers that the anonymity of the participants would be maintained. Since the absence of participant anonymity would constitute participant "outing", previously seen by this subculture to lead to loss of employment, lost of custody rights to children, and even litigation, survey participants were concerned, and many of them expressed concern with the eventual book publication rather than with the methodology of data collection.
It is very clear that this survey was not conducted using IRB guidelines or oversight: lack of explicit opt-out information, lack of gatekeeper protocols, and most troubling of all, potential inclusion of minors in sexually-explicit anecdotal data collection due to both the absence of an age statement requirement for the survey, and the solicitation for participants in internet venues known to be frequented by minors.

Anonymous (2009-09-05 01:43:41)
As a member of the community surveyed, I can assure you that many community concerns applied to individual harms, particularly given the nature of the survey. There were no informed consent procedures; dubious protections of anonymity and

confidentiality; study questions specifically asked about illegal drug use and sexual practice, placing individuals at risk for harm if identities were revealed; there was no attempt to screen out minors, and the survey recruited from some on-line communities where minors were known to be active.

Anonymous (2009-09-05 04:38:00)
As someone who has been following this débacle attentively from the beginning, I can't help but feel that you're simplifying the reason for the fanfic-writers' outrage. Dr Ogas is on record as presenting himself as "a neuroscientist from Boston University", i.e. implying that his survey was for peer reviewed research. He also failed to inform people of his book contract - in other words, he lied to his potential subject, both in the form of direct lies as well as lies by omission.
Furthermore, there were no attempts at screening out under-18's from a survey that included questions about illegal drug use and sexual habits, yet Dr Ogas assured those who raised their voices in concern that he was "not doing research on minors". Most of the fury seemed to stem from the pure ineptness of the research, as well as the utter arrogance of Dr Ogas in failing to accept criticism.

neededalj (2009-09-05 15:59:00)
I would also like to point out that the criticism of Ogi Ogas and Sai Gaddam does not just come from a social science/human subjects research viewpoint, but that there were very serious concerns with their basic theories themselves. At best, what they were proposing to do would be considered pseudoscience and at worst a fairytale.
A complete outsider's take on the "neuroscience" of the proposed research is here:
http://neurocritic.blogspot.com/2009/09/rule-34-what-netporn-tells-u s-about.html
and my own critique is here:
http://neededalj.livejournal.com/940.html

Manna Francis (2009-09-06 07:13:46)
If you honestly think that there's nothing which needed IRB oversight in a research survey which:
- was posted in a place with a high proportion of users under 18,
- solicited participation with a link graphic including Harry Potter and Buffy the Vampire Slayer characters,
- had no age warning or content warning for participants,
- had no warning that the survey results would remain visible on the computer used unless the cookie associated was deleted,
- may possibly have allowed linking by the researchers between the survey answer and LJ identity,
- ask questions about rape fantasies, drug and alcohol use, pornography use and masturbation habits,
then I can see why such a lot of people I know in research have problems with IRBs. Good Lord.

Zachary M. Schrag (2009-09-07 20:54:43)
Thanks to everyone for all of these comments.
Ogas and Gaddam went wrong in many various ways, some of which I was not aware of before reading these comments. Still, I think it is worth distinguishing those misdeeds that threatened the privacy of research respondents from the pseudoscientific methodology that distressed folks like neededalj, and which struck me as the main theme in much of the commentary I had seen. I am heartened by the care with which many of these comments–particularly Professor Reid's letter to BU–make just this distinction.
The alternative is to try to make the IRB an all-purpose research police. For example, J. Michael Oakes has suggested that IRBs must watch out for surveys that "may inappropriately create a social stigma that affects the entire . . . community." [J. Michael Oakes, "Survey Research," in Robert J. Amdur and Elizabeth A. Bankert, Institutional Review Board: Management and Function (Sudbury, Mass.: Jones and Bartlett, 2002), 431.] An IRB that measures surveys by such a standard may indeed spare some people pain, but only at the expense of negating academic freedom.

4.10 October

4.10.1 Oral History Association Considers Guideline Revisions (2009-10-09 15:21)

At its annual meeting next week, members of the Oral History Association will vote on a set of [1]General Principles for Oral History and Best Practices for Oral History.

The most striking feature of the new guidelines is that they avoid the confusing format of the existing [2]Evaluation Guidelines, which pose dozens of questions without offering the proper answers or explaining whether answers might vary by project. Instead, the new guidelines present clear, declarative statements about how best to conduct oral history.

A more substantive change concerns harm. The existing guidelines state that "interviewers should guard against possible exploitation of interviewees and be sensitive to the ways in which their interviews might be used," and they suggest that interviewers must endeavor "to prevent any exploitation of or harm to interviewees." While the new guidelines offer many specific protections to narrators, they eliminate this vague language of exploitation and harm. And they caution that interviewers cannot guarantee control over the interpretation and presentation of interviews.

More generally, while the guidelines reflect historians' concerns with informed consent, they show the irrelevance to historical research of the biomedical concerns of risk/benefit analysis and equitable selection of subjects. There is more to research ethics than what is contained in the Belmont Report.

1. http://www.oralhistory.org/?page_id=359&preview=true
2. http://www.oralhistory.org/do-oral-history/oral-history-evaluation-guidelines/

4.10.2 OHRP Grudgingly Okays Self-Exemption (2009-10-18 10:49)

In his May 14 speech, "[1]The Legal Assault on the Common Rule," OHRP director Jerry Menikoff pledged that his office would issue new guidance on the Common Rule exemptions. While OHRP would still recommend that investigators not be empowered to decide for themselves whether their research is exempt, it would also emphasize that "it's just a recommendation. You don't have to follow it."

Five months later, OHRP has kept that promise, issuing a new document entitled [2]FAQs: Exempt Research Determination. While the new guidance continues to recommend that "because of the potential for conflict of interest, investigators not be given the authority to make an independent determination," it makes clear that this is not a regulatory requirement. It even goes further, offering a somewhat detailed scenario that would satisfy regulatory requirements:

> For example, an institution might craft a checklist for certain exemption categories, with questions that are easily answered "yes" or "no" by an investigator, with certain answers leading to a clear conclusion that the study is exempt. The institution might allow a researcher to immediately begin a study after having completed such a checklist and filed it, together with accompanying documents, with an appropriate institutional office, without waiting for or requiring any prior review of that filing. Similarly, a web-based form might be created that served the same purpose, allowing the researcher to begin the research immediately after submitting the required information using the web form. In both instances, the key issue would be whether these procedures lead to correct determinations that studies are exempt.

While this is certainly a step in the right direction, it leaves unanswered the question of why OHRP still deprecates such a system of "independent determination." In particular, the new guidance claims that "an institutional policy that allowed investigators to make their own exemption determinations, without additional protections, would likely risk inaccurate determinations." What is the basis of this claim? Has anyone done a study showing that investigators make poor determinations? What does it even mean to make an inaccurate determination, when [3]federal officials

themselves appear unable to apply the exemptions to hypothetical projects?
The truth is that OPRR's 1995 guidance was less a response to any misapplication of the exemptions than part of a larger effort to look busy amid national concern about human radiation experiments conducted decades before OPRR's creation. Rather than reconsidering its panicked advice from that period, OHRP has merely acknowledged that its recommendation has no basis in the regulations.
Note: As of this posting (18 October 2009), the bottom of the page with the new guidance reads "Last revised: April 20, 2009." An OHRP representative tells me this is an error, and that the new guidance was in fact posted on 14 October 2009.

1. http://www.institutionalreviewblog.com/2009/06/menikoff-to-critics-yes-we-hear-you.html
2. http://www.hhs.gov/ohrp/policy/exempt_res_det.html
3. http://www.institutionalreviewblog.com/2008/10/45-cfr-46101-is-still-dead.html

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4.10.3 AAHRPP Policy on FWAs Remains Blurry (2009-10-28 15:41)

Back in July, I reported on the [1]AAHRPP's ambiguous position on whether the institutions it accredits may "uncheck the box" on their federalwide assurances.
AAHRPP's new [2]Final Revised Accreditation Standards fail to resolve this ambiguity. They require that an accredited organization apply "its HRPP [Human Research Protection Program] to all research regardless of funding source, type of research, or place of conduct of the research," but do not state not whether that HRPP must track federal regulations in all cases.
Interviewed for the October 2009 [3]Report on Research Compliance, AAHRPP President Marjorie Speers had this to say:

> We believe an organization must protect participants in all of the human research it conducts, whether or not it receives federal funding . . . As an accrediting organization, we don't have an opinion on whether or not an institution should 'check the box,' on their FWAs to OHRP. If an institution 'checks the box,' then we hold the institution to follow the regulations to all research to which 'the box' applies. If the boxes are unchecked, we hold the organization to have equivalent protections in place for all research.

This does little to clarify matters. What are "equivalent protections" to those specified in federal regulations? Were AAHRPP site visitors correct to tell the University of California "that in order for a human research protection program to be accredited, it must apply the Common Rule and its subparts to all human research at the institution, irrespective of funding"? Or can a university add new categories for exemption and expedited review, as advocated by Lisa Leiden, and consider those equivalent to the federal categories?
Unchecking the box is one of the leading proposed remedies for IRB overreach. It is a pity that AAHRPP has missed this opportunity to address this movement more directly.

1. http://www.institutionalreviewblog.com/2009/07/aahrpp-and-unchecked-box.html
2. http://www.aahrpp.org/www.aspx?pageid=316
3. http://www.reportonresearchcompliance.com/

4.10.4 AAHRPP Retreats from "Objective Data" (2009-10-31 23:08)

In July I posted [1]my comments on AAHRPP's Proposed Revised Standards. At the time, I applauded [2]Element I.5.B for insisting that "based on objective data, the Organization identifies strengths and weaknesses of the Human

Research Protection Program, makes improvements, when necessary, and monitors the effectiveness of the improvements."
How disappointing, then, to find that the [3]Final Revised Accreditation Standards omit the phrase about objective data. Are we to infer that AAHRPP considers objective data too difficult a standard, and wants institutions to base their programs on subjective impressions? Of course, most of the IRB regime is based on such guesswork, but I had thought that AAHRPP seeks to raise the level of IRB review.

1. http://www.institutionalreviewblog.com/2009/07/aahrpp-proposes-revised-standards.html
2. http://www.aahrpp.org/www.aspx?PageID=296
3. http://www.aahrpp.org/www.aspx?PageID=318

4.11 November

4.11.1 Former IRB Chair Decries Inconsistency (2009-11-06 13:27)

Jim Vander Putten, Associate Professor of Higher Education at the University of Arkansas-Little Rock, kindly alerted me to his essay, "[1]Wanted: Consistency in Social and Behavioral Science Institutional Review Board Practices," Teachers College Record, 14 September 2009.
Vander Putten, who chaired his university's IRB for six years, complains that IRBs fail to make decisions consistently. He accuses them of both under- and over-protection, and then offers two suggestions for reform.

Under-Protection

Vander Putten's case for under-protection concerns two invitations to take online surveys, both of them aimed at university administrators and faculty. He is upset about their lack of informed-consent apparatus:

> Although these were low-risk social and behavioral science studies, IRBs should not be absolved from ensuring that researchers will fully inform prospective participants about specifics of the research tasks. I deserve to know the answers to a number of questions before I decide whether to participate in a study: What is the nature of my involvement? Will survey completion take 5 minutes of my time or 35 minutes? How (not just if) will my identity be protected and confidentiality maintained in this study? In a web-based survey, am I required to respond to each question before proceeding to the next? Perhaps most importantly, what will researchers do with my responses if I decide to cease participation before completing the research task? Will they be kept or discarded? Do I have a voice in the matter? As a result of the absence of this information, I declined to participate in both studies.

There are certainly some [2]nasty online surveys out there, that fail to screen for minors or that ask highly personal questions midway through the survey. And when I am asked to participate in a survey, I often appreciate an estimate of the time it will take. But I can't share Vander Putten's outrage about the two invitations he received to participate in surveys specifically aimed at university professionals. Without any IRB intervention, he proved capable of deciding for himself not to answer the surveys.
Consider that Vander Putten's own e-mail to me failed to warn me how long it would take to read his essay (5 minutes of my time or 35 minutes?), whether I was required to read each paragraph before proceeding to the next, or how (not just if) would my identity be protected and confidentiality maintained should I reply to his message. Instead of infantalizing me with such precautions, Vander Putten respected me as an autonomous adult.

Over-Protection

The case for over-protection is stronger:

> A few years ago, another faculty member and I conducted a qualitative research study at five different Doctoral/Research institutions in the Southeast. As a professional courtesy, we informed each institution of our plans to interview faculty and staff on their campuses, and noted that the study had already been approved by our institution's IRB. I was surprised when each institution required us to submit 'Exempt From Full Board Review' IRB proposals for review and approval as a precursor to conducting the research on their campuses. With my knowledge and expertise as a sitting IRB Chair, I volunteered to complete the proposals to increase the likelihood of IRB approval upon first review.
> You can imagine my surprise when several of the IRBs rejected the proposals on the basis of an inconsistent array of style issues, such as consent forms not cumulatively paginated (e.g., 1 of 3, 2 of 3, etc) and either written or not written in the past tense. The time delays associated with revision and re-submission of these IRB proposals (some of which were rejected a second time) were measured in months, and would have been even longer had we been required to complete each institution's responsible conduct of research training program. These delays began a chain reaction of subsequent delays in data collection, research conference proposal submissions and presentations, and manuscript submissions for publication consideration. For untenured faculty, these delays can present formidable obstacles to meeting institutional expectations for scholarly productivity leading to tenure and promotion.

Multi-campus projects like this one and those conducted by [3]J. Paul Grayson and [4]Linda Thornton are particularly good at exposing the arbitrary nature of much IRB decision-making. When one IRB insists on the past tense and another forbids it, you know that at least one board, if not both, has no idea what makes for good informed consent, yet it is willing to impose its guesswork on researchers.

Reform

Vander Putten concludes with two suggestions for reform.
The first is an endorsement of the [5]Illinois White Paper's call for a national clearinghouse for IRB best practices. He writes, "Based on my experiences as an IRB Chair, researcher, and research study participant, this would be a useful development and should include guidance on consistent expectations for the use of informed consent documents regardless of research risk, data collection method, or funding source to provide optimal protection for prospective research participants."
There are two parts to this recommendation. One is for a clearinghouse, which is all to the good. The second part is for specific practices, which he recommends using the same guesswork that produced the inconsistent responses to his study proposal. Just as one board guessed that consent documents should be written in the past tense and another guessed that they should be written in the present, Vander Putten guesses that that every study should use informed consent documents, as opposed to unscripted explanations, or simple reliance on the context of the study. Such universality produces bad results. I hope, for example, that he would not expect researchers to hand out informed consent documents to people being observed in a public place.
Best practices cannot be determined a priori; they need research. If Vander Putten is serious about the clearinghouse idea, he needs to hold off on specific prescriptions for IRBs until competing proposals have been gathered and compared.
Vander Putten's second recommendation calls for

> the expansion of federal regulations requiring researchers to complete training in the responsible conduct of human participants research before conducting research. This expansion should include minimum

> requirements for researchers to actually implement the ethical practices regarding informed consent that they learned in their institution's training program. In education terms, it is inappropriate to train researchers on the history of informed consent and methods to incorporate specific elements of informed consent into their research, and then decline to hold researchers accountable for doing so. If a specified set of minimum requirements are implemented nationwide, then IRB review would begin to approximate peer review systems that are the bedrock of scholarly quality and integrity.

Though Vander Putten begins his essay with several links to IRB-related reportage in the Chronicle of Higher Education and Inside Higher Ed, he apparently missed David Glenn's November 2008 story, [6]Scholars Mull Rules for Training in Research Ethics," and [7]my own reportage about the replies received in response to OHRP's call for comments. Those replies showed significant frustration, among institutions and individual researchers, about the quality of existing training programs, making a regulatory mandate seem unwise.
While well intended, both of Vander Putten's recommendations show a lack of familiarity with the existing debates over IRB inconsistency. More reading might produce more nuanced suggestions for reform.

1. http://www.tcrecord.org/Content.asp?ContentID=15767
2. http://www.institutionalreviewblog.com/2009/09/internet-survey-sparks-outrage.html
3. http://www.universityaffairs.ca/ethics-boards-harming-survey-research-says-york-professor.aspx
4. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
5. http://www.law.uiuc.edu/conferences/whitepaper/
6. http://chronicle.com/article/Scholars-Mull-Rules-for/1297
7. http://www.institutionalreviewblog.com/2008/11/comments-oppose-new-regulations-on.html

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4.11.2 Princeton IRB Delays Student Research (2009-11-10 13:27)

The [1]Daily Princetonian reports a sociology major's difficulties getting IRB approval for her senior thesis on Brazilian immigrants' changing perceptions of gender roles.

> "It's such a long process that it thwarts your field work efforts," [Christine] Vidmar said, noting that the review board does not meet to approve proposals during the summer. "I've been waiting since I got back to school. The first deadline that I could apply for was in October. It's November now, and I still can't officially go do my interviews."
> . . .
> Vidmar noted that a well-researched thesis may require up to a year of field work, adding that review board hurdles make it more challenging to complete sufficient research. "If you're a senior and you don't have a thesis chosen by the spring of junior year then you can't start field research until November or December of senior year, which is really late," she said. "You need to be in the field in order to know what questions you're going to ask, but in order to be in the field you need to have given the IRB your questions ahead of time."

As horror stories go, this one is mild. But consider the following:

- While details are lacking, Vidmar's proposed research sounds to be exempt under federal regulations; she's just interviewing adults about their perceptions of gender.

- Princeton demands full board review for "[2]almost all proposals," offering expedited review only on "an exception basis."
- [3]The IRB does not meet for three and a half months in the summer and requires proposals to be submitted two weeks in advance of the meeting. Hence, a student who misses the late-May deadline must wait almost four months until late September for review.

Put these together, and it seems that Princeton has built a substantial impediment to students who would like to interact with people as a capstone to their undergraduate training but are unable to write detailed research protocols six months in advance.
This is not to say that undergraduates should be sent into the field without training or supervision. But [4]review by at the department level, as suggested by Felice Levine and Paula Skedsvold; [5]subcommittee review, as practiced at Macquarie University; or [6]researcher certification as permitted at the University of Pennsylvania, might well achieve the same or better levels of oversight as full-board review without delaying the work and discouraging the curiosity of a student researcher.

1. http://www.dailyprincetonian.com/2009/11/09/24347/
2. http://www.princeton.edu/orpa/memos/IRB%20annual%20letter.htm
3. http://www.princeton.edu/orpa/irb.htm
4. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html
5. http://www.institutionalreviewblog.com/2007/08/macquaries-respect-for-expertise.html
6. http://www.upenn.edu/almanac/volumes/v53/n06/or-hsresearch.html

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4.11.3 Brown Pledges IRB Reform (2009-11-18 12:11)

The Brown Daily Herald reports "a series of reforms" at Brown University, intended to "streamline Institutional Review Board procedures." (Sydney Ember, "[1]Reform in the Works for Research Review Board," 13 November 2009.) The process started in 2007, when [2]Brown faculty complained that IRB operations were inhibiting research, especially by undergraduates. Brown's Research Advisory Board convened a four-person, ad hoc subcommittee to investigate. That subcommittee released a draft report, "[3]Undergraduate Research in the Social Sciences and the Institutional Review Board at Brown" in January 2009.

The January 2009 Report

The draft report found:

> Many faculty members from the social sciences report some aspect of the IRB to be or to have been a burden, and a significant fraction feel that IRB practices are having or have had some dampening effect on the quality or availability of undergraduate research opportunities. There is the widely held belief that many social science projects typically consisting of interviews or surveys, have a low intrinsic risk. Most faculty members, however, do recognize the existence of some risk, depending on the nature of the activity, and the need for some type of oversight. Many faculty members believe that the formal and rigidly structured IRB process is not an optimal way to oversee and regulate undergraduate work, due to variable levels of organization, knowledge, and professionalism among the undergraduates, and the special time constraints associated with the undergraduate senior year.

The subcommittee offered three policy options:
A. "Brown adopts IRB review as the standard procedure for undergraduate theses and non-classroom projects dealing

with human subjects."
B. "Continue the current system, but clarify several points and communicate the policy more explicitly to avoid faculty and student confusion."
C. "Adopt and communicate a policy in which non-federally-funded undergraduate work is not subject to IRB review, but rather to some other educational and oversight system tailored for undergraduates, to be defined."
It recommended Option B "as the best near-term solution," while keeping C open as a longer-term option.
Brown's Faculty Executive Committee (FEC) received the draft report at its January 2009 meeting. According to the [4]minutes of that meeting, "The FEC was disappointed that the report did not address some of the larger issues. It appears that the definition of research is getting broader so that the IRB has their hand in every aspect of research." As far as I can tell, the report has still not been finalized.

Changes Since January 2009

According to the Daily Herald story, the university's Research Protections Office (RPO) claims that it has implemented many of the recommendations in the report, primarily by updating its [5]website. Since many of the pages on that website are undated, it's hard to know how many have been changed since the release of the draft report in January.
Some of the report's recommendations do seem to have been implemented. For example, the report called for the prominent placement of the information that faculty advisors get to decide whether an undergraduate project needs IRB review. That information is now indeed [6]prominently displayed.
In contrast, the report specifically objected to the assertion that "obvious examples of dissemination [and therefore generalizability] are publication in a scholarly journal, presentation at a professional conference, or placement of a report in a library." It recommended the deletion of the references to conferences and libraries, but as of today, [7]they remain on the RPO website. Given that this was one of the most concrete, immediate proposals of the subcommittee, I suggest that the Daily Herald may have been premature in its announcement of reform.

Erroneous Assertions

Not mentioned in the faculty report are three significant misstatements about federal regulations in the RPO's document, [8]Frequently Asked Questions.
1. "Federal Regulations are clear that it is not up to the investigator alone to determine if a project is exempt."
Federal regulations specify no such thing, as recently [9]reiterated by OHRP.
2. "In certain situations, all involving no more than minimal risk, the IRB can waive the requirement that you obtain the participant's signature on the consent form."
In fact, 45 CFR 46.117(c)(1) also allows IRBs to waive the signature requirement when "the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality." This is true even when the risk is greater than minimal.
3. "As long as your research involves collecting data or information from or about living individuals, you need to have it reviewed by the IRB."
This would put reading a newspaper under the jurisdiction the IRB. Brown's RPO doesn't really believe this, but it hasn't been careful with its explanations.

Unfinished Business

It's great that a Brown faculty committee has taken a look at IRB operations, and that the administration has made some changes in response. But the report indeed failed to address some of the big issues at stake, and the administration has failed to implement some of the minor reforms suggested ten months ago. This case suggests the difficulty of restoring the principle of faculty governance when it comes to social science research.

1. http://www.browndailyherald.com/reform-in-the-works-for-research-review-board-1.2060928
2. http://www.institutionalreviewblog.com/2007/10/brown-u-irb-chair-system-is-broken.html
3. http://research.brown.edu/pdf/IRB-subcommittee-draft-report_1_23_09.pdf

4. http://facgov.brown.edu/FEC/minutes/FECmins012709.pdf
5. http://research.brown.edu/rschadmin/hrpo.php
6. http://research.brown.edu/rschadmin/hrpo_undergraduate%20guidance.php
7. http://research.brown.edu/rschadmin/hrpo_generalizable.php
8. http://research.brown.edu/pdf/RPO%20FAQ%20-%20rev%202-09.pdf
9. http://www.institutionalreviewblog.com/2009/10/ohrp-grudgingly-okays-self-exemption.html

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4.11.4 Draft TCPS Allows Critical Inquiry of Aboriginal Governments (2009-11-20 21:30)

In 2006, Canadian historian Nancy Janovicek complained that ethics polices designed to protect Aboriginal peoples could allow Aboriginal governments to [1]silence their critics by denying researchers permission to speak with them. A new [2]draft revised version of Chapter 9 of the Tri-Council Policy Statement addresses that problem. While it calls for researchers to secure the permission of Aboriginal governments for most types of research, it recognizes that this may be inappropriate when those governments themselves are being critically examined:

> Article 9.7. Research that critically examines the conduct of public institutions or persons in authority may do so ethically, notwithstanding the usual requirement, in research involving Aboriginal peoples, of engaging representative leaders.

As I have written before, [3]the draft TCPS is inconsistent in its respect for critical inquiry, and ethics committees may not give sufficient weight to the disclaimers like this one. But such statements do give researchers a foothold in arguing for the freedom of inquiry.

1. http://www.institutionalreviewblog.com/2007/01/nancy-janovicek-offers-canadian.html
2. http://www.pre.ethics.gc.ca/eng/resources-ressources/news-nouvelles/nr-cp/2009-11-06/
3. http://www.institutionalreviewblog.com/2009/01/canada-considers-new-tcps.html

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4.12 December

4.12.1 Survey: Most IRBs Lack Sociologists (2009-12-02 13:12)

The Western Massachusetts Institute for Social Research kindly alerted me to its [1]survey of socioogists, conducted in the summer of 2009. Of the 98 respondents who have conducted research in the past five years, 90 reported that they had undergone IRB review.

The survey found that IRBs are more likely than sociologists to judge a study risky. Only 13 respondents "said that they believe that some harm could have come to respondents as a result of their involvement in the research," but 20 reported that a member of the IRB believed there was such a risk.

This is not surprising. The premise of IRB review is that committees are better able to flag potential harms than are individual researchers, so the higher levels of risk seen by the IRBs could indicate that they are working well, or that they are overestimating the risks of research.

To distinguish the two possibilities, it would help to know why the IRB members saw risk. In 1979, for example, Lauren Seiler and James Murtha showed that IRB chairs commonly insisted on modifications even though most had never heard of harm coming to a participant in sociology research. [Lauren H. Seiler and James M. Murtha, "Federal Regulation of Social Research," Freedom at Issue, Nov-Dec 1979.] Is that still the case?

Another finding of the Western Massachusetts survey is that a minority (44 percent) of respondents reported that the IRB that reviewed their research included a sociologist. Federal regulations require IRBs to include members "with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution." This was one of the few protections offered to social scientists worried that their research would be subject to the whims of people outside their field. But it appears that many or most IRBs have failed to meet this standard.

1. http://mysite.verizon.net/vzeq5cg0/id3.html

4.12.2 Hooah! (2009-12-12 10:54)

Google Alerts uncovered an April 2008 memo from the Army's chief of military history, explaining that while Army historians are obliged to obtain the informed consent of anyone they interview, [1]the U.S. Army's Historical Program does not consider oral history to be under IRB purview:

> Given that oral history is the collection of personal and unique insights on events, it does not fit the definition of scientific research as outlined in 45 Code of Federal Regulations 46 that is at the center of the Department of Health and Human Services regulations of the issue. Oral histories are not a "systematic" attempt to gather data from "human subjects" that can be used in any way to contribute to "generalizable" knowledge. They are therefore exempt from HRPP oversight and IRBs.

[2]Happy Birthday, Institutional Review Blog!

1. http://www.usma.edu/opa/hrpp/documents/Army/Policy%20Letter%20on%20Oral%20History%20and%20IRB%20Apr%2028%202008.pdf
2. http://www.institutionalreviewblog.com/2006/12/introduction.html

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4.12.3 Is Documentary Film Human Subjects Research? (2009-12-19 19:53)

Kimberlianne Podlas, a lawyer and an assistant professor of media studies at the University of North Carolina, Greensboro, argues that "virtually all journalistic inquiry and nonfiction filmmaking . . . are not subject to IRB jurisdiction." ("[1]This Film Has Been Rated 'Approved': Are Documentary Films Subject To Institutional Review Board Approval and Federal Human Subjects Research' Rules?")
To reach this result, Podlas argues that documentary films fail one or more of five tests necesary to trigger IRB jurisdiction:

> First, the general type of undertaking must be one that is directly regulated by a federal agency. Second, the activity must be "human subjects research"; This requires the undertaking to conform to the regulatory definition of "research." Third, that research must collect information from or about living individuals. Fourth, that information must be either "data" or "private information." And finally, the "human subjects research" must be either biomedical or behavioral.

Let's take these in order.

1. Is documentary film the general type of undertaking that is directly regulated by a federal agency?

Podlas cites 45 C.F.R.§ 46.102 (e) to suggest that only if an agency is "statutorily charged" by Congress with regulating an activity can it do so. And since "there is no US Department of Film or Agency of Television News," no agency has the responsibility to regulate documentary film.

As a factual matter, this is doubtful. Common Rule signatories do sponsor documentary filmmaking. For example, the[2]National Science Foundation has supported movie and television documentaries about Appalachia, the aftermath of Hurricane Katrina, and other topics about human events and society.

More importantly, neither 45 C.F.R.§ 46.102 (e) nor any other section of the Common Rule says that an agency must be statutorily charged with a responsibility in order to have that responsibility. To the contrary, 46.101 explains that "this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research" (emphasis added). So as far as the Common Rule is concerned, any Common Rule agency can decide for itself what types of research activities are covered.

2. Is documentary film "human subjects research"?

Here Podlas presents the familiar–and I think correct–view that activities like filmmaking are not intended to produce generalizable knowledge and are therefore not human subjects research under 46.102 (d).

She buttresses this argument by alluding to the Belmont Report's report definition of research: "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective." Since documentary filmmakers do not test hypotheses or write formal protocols, she reasons, they do not conduct human subjects research.

That's true enough, but there's one problem: the Belmont Report is not 45 CFR 46, and only the latter has legal force. The question, then, is to what degree the intent of the National Commission, as expressed in the Belmont Report, should inform a court's reading of the regulations' definition of research. For a work of legal scholarship, Podlas's essay is disappointingly silent on this issue.

3. Does documentary film collect information from or about living individuals?

Podlas does not dispute that it does, and I don't think anyone would.

4. Does documentary film collect data or private information?

Podlas argues that documentary film interviews do not collect "data": "when interviewing is used to collect data, it is not unstructured, common conversation, but standardized or somewhat regimented so that the researcher can elicit and obtain specific information." That's an intriguing idea, but I'd want to learn a lot more about regulatory and legal uses of the term "data" before agreeing.

Podlas then argues that "if an individual makes a disclosure about herself to another individual, even a reporter, the speech act is not behavior taking place in private. Obviously, when the individual speaks to a reporter or filmmaker, she knows she can be seen, heard, and recorded." Only if an interviewer misleads someone into thinking that her responses are private does the interviewer invade privacy. Here Podlas is on firmer legal ground, for she cites a good deal of case law.

5. Is documentary film behavioral research?

Podlas notes that the federal law governing IRBs, 42 U.S.C. § 289, covers only "biomedical or behavioral research involving human subjects." "Congress spoke, and spoke clearly," she writes. "It directed the President's Commission,

HHS, and IRBs to regulate biomedical and behavioral human subjects research, and only biomedical and behavioral research." She then suggests that in order to trigger IRB review, "a film would not only need to meet the definition of research, but also its purpose and subject matter would have to be biomedical or behavioral investigation. It is difficult to imagine instances in which this would be so."
The question here is what did Congress, or anyone, mean by behavioral research? IRB proponents, such as Robert Amdur and Elizabeth Bankert, insist that there is no difference between "behavioral science" and "social science." ([3]Institutional Review Board: Management and Function, 105.) I think they're wrong, but I would have liked more careful legal analysis of the point. Given Congress's failure to define behavioral research, how much leeway do agency heads have to define the term?
Podlas has posed important questions, but except for the section on private information, she does not explain how courts have interpreted the meanings of various terms used in federal laws and regulations, nor how much deference they would likely grant to OHRP's own interpretations. There is much work yet to be done along these lines.

1. http://works.bepress.com/kimberlianne_podlas/2/
2. http://www.nsf.gov/news/now_showing/
3. http://books.google.com/books?id=Ff-RPWd-JYkC&lpg=PA105&ots=eR9juHUVSr&dq=amdur%20behavioral%20social%20irb&pg=PA105#v=onepage&q=amdur%20behavioral%20social%20irb&f=false

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4.12.4 Grad Student Needed 80 IRB Approvals (2009-12-22 13:59)

In an account apparently posted in July 2008, [1]Jennifer M. Purcell describes what she went through to get approval for her dissertation research in education at the University of South Florida. Purcell was investigating the apparent disparity between the knowledge and skills needed by college faculty, and the knowledge and skills taught in doctoral programs. She wanted to ask college professors what they thought faculty and students should know and who should teach it. A typical question asked how important these professors considered the ability to "appreciate the history and purposes of higher education." (Jennifer M. Purcell, "Perceptions of Senior Faculty Concerning Doctoral Student Preparation For Faculty Roles," Ph.D. diss., University of South Florida, 2007.)
As she describes it,

> I was interested in surveying senior faculty at a stratified random sample of 80 research institutions around the nation for my dissertation research. Participation was voluntary, responses were anonymous, the questions posed no risk to participants, and faculty could quit at any time. If any group understands the research process and can make an informed decision to participate, it would be a member of the academy, right?

Rather than declaring the study exempt, her IRB

> required that I contact the IRB office at every institution in my sample to be sure I was in compliance with their policies. Too late to back out at that point, I embarked on the tedious, time consuming, and almost comical task of contacting each school. This process took an additional seven weeks to complete. Seven weeks may not appear to be much in the grand scheme of things, but it was one of several unexpected hurdles that did delay my graduation.

Worried that she would not get enough approvals for a valid sample, Purcell added another 42 institutions to her initial pool. Of the 122 institutions, only 35 determined that they were not engaged in the research, and had no business telling an outside student whether she could or could not interview their faculty. Another 35 granted quick approval or

accepted the University of South Florida IRB's decision. One rejected the proposal (I would love to see that letter), and three demanded that "one of their faculty members to serve on the committee." Purcell deleted these from her sample. Most disheartening to Purcell was the failure of almost a third of the IRBs she contacted to reply to her initial request; some did not even reply to her second request. While she sympathizes with IRB workload, she expects better professional courtesy than this. And while she eventually completed her work in good time, as of her writing she faced the prospect of having to file dozens of final reports.
Purcell ends with the recommendation that

> that the approval of the home institution IRB serve as an umbrella document for research falling in the exempt, or even expedited, categories even if members of another institution are being solicited for participation. This might encourage more doctoral students in education – and possibly other disciplines as well – to design studies that reach beyond the walls of their own institutions.

The literature of medical IRBs–outside the scope of this blog–is rich in comparable proposals for streamlining review of multi-site studies. But Purcell's study should never have gotten to that point. It should instead have been granted swift exemption with no further oversight.

1. http://asstudents.unco.edu/students/AE-Extra/2008/7/purcell.html

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4.12.5 After Human Terrain, Will AAA Debate IRBs? (2009-12-25 09:30)

Earlier this month, the American Anthropological Association's Commission on the Engagement of Anthropology with the US Security and Intelligence Communities (CEAUSSIC) issued its [1]Final Report on The Army's Human Terrain System Proof of Concept Program.
The report argues that the Human Terrain System (HTS) combines scholarly research and military information-gathering in a way that muddles ethical issues:

> HTS ethnographers attempt to juggle dual loyalties both to civilian populations and to their military units, under conditions which almost inevitably lead to conflicting demands. Potentially conflicting demands (between serving occupied, studied populations, and serving the needs of the military with whom [Human Terrain Teams] embed) almost necessitates that HTS social scientists choose between multiple interests in ways that stand to undermine basic ethical principles that govern research with human subjects among anthropologists and among government researchers. (52)

Significantly, the report more or less recognizes that the choice of interests could go either way. One possibility would be to bring HTS wholly into the realm of scholarly research, with all of its ethical codes and legal regulations, including IRBs:

> If HTS carries out a research function as advertised, and if it encourages its social scientists to use ethical research practices, then it should comply with 32CFR219, regulations issued by the Office of the Secretary of Defense (OSD) that address human subjects protection. (47)

Alternatively, the report hints that the real problem is merely a poor choice of words. "We should consider the work of HTTs to be sharply different, in its goals, from conventional disciplinary ethnographic pursuits and not to be 'ethnography' in any credible sense." (54) If HTS were re-branded to avoid the terms "anthropology," "ethnography," and "social

science," and instead present itself as a counterinsurgency program pure and simple, then–it seems–CEAUSSIC would not expect it to follow either the AAA ethics codes or the Common Rule. All of this points to the need for clear definitions when discussing ethical and legal obligations.
For the purposes of this blog, a more interesting document is the October 13 blog post, "[2]Why not Mandate Ethics Education for Professional Training of Anthropologists?" by CEAUSSIC member Carolyn Fluehr-Lobban.
Fluehr-Lobban calls for "ethics education as a mandatory part of anthropology curricula." As she describes it,

> A future standard ethics curriculum would minimally include a history of the discipline and ethics– this would help to correct misconstruing history, as has been the case in security engagement polemics where a standard of "voluntary informed consent" is often cited as 'traditional' or normative when, in fact, language on informed consent appears for the first time in the 1998 AAA code. It would also include case studies representing a realistic spectrum of scenarios and dilemmas where mixed outcomes are the likely norm, and clear positive or negative outcomes are likely exceptions.

But while Fluehr-Lobban seems open to questioning such standards as "informed consent" and to exploring the nuances of real-world research, she is dismissive of comparable discussion of the legitimacy of IRBs:

> There is still a tradition of resistance to the annoyance of having to go before an IRB. Part of this history rests with anthropology as the study of "the other," of "subjects," using "informants," whereby the anthropologist is ideally unfettered with unlimited freedom to conduct research. But, clearly, this is not the world we live in. As standard practice, all anthropological research is, or should be, subject to external review.

In other words, Fluehr-Lobban suggests that anyone who doesn't like IRBs wants unlimited freedom to study "the other." This is an insult to the many thoughtful critics who, over the decades, have shown that IRBs and their attendant apparatus can be a barrier to true ethical reflection. It is also an indicator of how entrenched the belief in IRBs has become within the AAA leadership. But has the organization ever really debated whether IRBs are the best way to promote its ethical standards? If not, CEAUSSIC should seize this opportunity for such a discussion within the profession.

1. http://www.aaanet.org/cmtes/commissions/CEAUSSIC/upload/CEAUSSIC_HTS_Final_Report.pdf
2. http://blog.aaanet.org/2009/10/13/ceaussic-mandating-ethics-education/

Anonymous (2009-12-26 14:39:43)
HTS trainees do undergo ethical training. HTS also has an ethical guideline document. There are reviews of case studies and of projects, and further, more strenuous review is underway. HTS Social scientists who are behavioral scientists have already undergone IRB training as per their own professions and all social scientists adhere to the ethical guidelines of their professions, not just what HTS has in place. There are informed consent protocols that are in place and used with each person interviewed. Therefore, HTS does participate in as strenuous, if not more strenuous training than most anthropology students undergo in their education and most professionals undergo at university.
If you read the IRB you will see that HTS is exempt; but even if HTS registered and made every social scientist take the certification courses, the AAA would still have issue with them. The AAA did not do their due diligence in their research on HTS and wrote a highly biased report that only references the works of members on the CEAUSSIC board. How is THAT ethical? It is certainly not impartial. Furthermore, they use the works of "indy-bloggers" and "indy-media" as their source for factual material. The AAA has gotten caught up in a poor educational exercise, bad media, and misinformation. This in many ways may be HTS's fault for not responding to many of the comments about them as they should, however, for a proof of concept program that is bound to have growing pains, how often should we expect some commentary? As a taxpayer, if the govt. is dead-set on having this program to see it to fruition for usefulness, I want program managers to focus on missions,

training, and effectiveness than responding to a group of disgruntled anthropologists who have no interest in listening to their side anyways.

I think the AAA needs to focus on something- anything to help revive the field and right now, HTS is it. They used to be against "applied anthropology" in any form, and were having issues with forensic anthropology because they don't get informed consent from family members before working a forensic case. The AAA had issues with forensic anthropologists working in Bosnia, Serbia, Croatia, Guatemala, and Iraq on mass graves work even though the international community was clamoring for it. Had the physical anthropological community paid much attention to the AAA, war crimes in those countries would not have been prosecuted unless it was by military personnel with little to no forensic training; which then would have led to faulty cases and criminals getting away with murder. In a nutshell; how much attention should the profession as a whole pay to the AAA board right now? Are they really in touch with the actuality of the field itself, and are they truly able to speak for the professionals who are out there working anthropological jobs every day?

Zachary M. Schrag (2009-12-27 17:12:28)

Thanks for these comments.

I'm curious how you reached the conclusion that HTS is exempt from IRB requirements. In October 2007, [1]Col. Steve Fondacaro argued for an exemption based on 32 CFR 219.101(b)(2). Since that exemption only applies to research whose disclosure cannot reasonably place subjects at risk, and since the Army has conceded that HTS gathers information that could make informants the targets of violence (CEAUSSIC report, p. 32), I don't think that argument holds water.

Another possibility is 32 CFR 219.101(c), which states that "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy." Thus, the secretary of the army could simply pronounce HTS off limits to IRBs. But so far as I know, he has not done so. Indeed, Army lawyers could only tell CEAUSSIC that they were "reviewing this matter." (CEAUSSIC report, p. 49), the same response that Thomas Strong received two years earlier.

I agree with your broader point that, over the decades, the AAA's ethics codes have been drafted by and for academic anthropologists, with little consideration for the challenges faced by applied anthropologists. CEAUSSIC chair Robert Albro recognized this problem in his September 2009 Anthropology News essay, "[2]Ethics and Dual-Identity Professionals." He writes, "at present our ethics conversation has not balanced the patrolling of our disciplinary boundaries with the varieties of ethical and legal requirements within which extra-academic anthropologists now routinely work." Whether the AAA will fix that is another story.

It is inaccurate and ungenerous to claim that the report "only references the works of members on the CEAUSSIC board." If there are available sources on HTS overlooked by the Commission, I'd appreciate a list.

1. http://www.institutionalreviewblog.com/2007/10/pentagon-says-irb-review-not-needed-for.html
2. http://www.aaanet.org/cmtes/commissions/CEAUSSIC/upload/an-sept-2009-albro.pdf

Chapter 5

2010

5.1 January

5.1.1 Two Years' Inaction at OHRP (2010-01-01 10:59)

On October 26, 2007, OHRP [1]formally requested "written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the Federal Register on November 9, 1998 (63 FR 60364)."
By the December 26, 2007, deadline, [2]65 people and institutions submitted comments, two-thirds of which concerned oral history or folklore.
That was two years ago. And as far as I can tell, OHRP has taken no action on these comments.
Meanwhile, OHRP's new guidance on what constitutes research subject to regulation, which [3]Bernard Schwetz promised before the end of 2007, is now two years overdue.

1. http://www.hhs.gov/ohrp/documents/20071026.htm
2. http://www.institutionalreviewblog.com/2008/02/historians-flood-ohrp-with-comments.html
3. http://www.institutionalreviewblog.com/2009/01/happy-new-year-ohrp.html

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5.1.2 United States Handicapper General (2010-01-14 16:38)

Writing in the Journal of Broadcasting & Electronic Media, Ruthann Weaver Lariscy of the University of Georgia argues that "Communication journal editors and concerned participants in the system should implement a policy that assures non-U.S. generated communication scholarship report procedures for assuring the protection of human subjects, the use of informed consent, and compliance with comparable IRB protocols."
[Ruthann Weaver Lariscy, "[1]IRBs and Communication Research: Some Perplexing Issues," Journal of Broadcasting & Electronic Media 53 (October 2009): 668 - 671.]
Lariscy notes that IRB review degrades research. She recalls helping to plan a study of eighth-graders in Georgia, only to find that "the human subjects protection protocol required for this study made the research more difficult and depressed response rates," so that she and her colleagues got a participation rate of only 30 percent. In contrast, she refereed a study–apparently done abroad without IRB intervention–which got a participation rate of more than 85 percent. "I am left to conclude that IRB controls may have a considerable impact on our data collection, and the claims we make based on the data," she writes.
She does not claim that such IRB restrictions protect participants in communication research. To the contrary, she applauds the Illinois White Paper's position that "not all methodologies require the same rigorous overview and approval by IRBs, and that procedural changes should be made that acknowledge such methodological and content area

differences."
If IRB review is degrading research without protecting anyone, why does Lariscy want journals to impose it on scholars who are currently free of such review?
First, she argues, "Failure to have uniform reporting requirements tarnishes the blind review process. Once a reviewer can identify that a piece of work originated either domestically or internationally, there is potential for bias." Well, yes. But there are dozens of factors that can flag a manuscript as originating outside of the U.S., including the spellings of words, the places studied, the literature cited, and even the proportions of the document. (While I am doing less work on paper, I still notice when a manuscript is formatted for A4.) This is a pretty thin benefit for a significant cost.
And a cost-free alternative exists. Journals could ask that U.S. authors omit descriptions of human protections procedures from their submissions, just as they now omit their own names. This would retain blind review without destroying data.
Bad as her first argument is, Lariscy follows it with an even worse one: "A non-level playing field exists for those of us conducting human subjects studies in the United States compared to the relative ease of conducting similar studies elsewhere." In other words, IRBs are wrecking our research, so let's be sure they wreck everyone's else's.
If Lariscy wants to make the case that journals should insist on IRB review of non-U.S. research in order to protect children, then let her do it. But it is unworthy of a scholar to advocate interference with research for the sake of interference itself.

1. http://www.blogger.com/http://www.informaworld.com/openurl?genre=article&issn=0883-8151&volume=53&issue=4&spage=668

5.1.3 Canadian Historians Ponder Exclusion from Ethics Board Review (2010-01-24 16:31)

Google rather belatedly alerted me to the [1]Canadian Historical Association's comments on the December 2008 draft of the Tri-Council Policy Statement; I am told the comments were posted on the association's website in late June 2009. Since late is better than never, I mention them now.
The historians are "supportive of the changes that have been made in the second edition and consider it a very good policy paper." They particularly appreciate the various passages sprinkled throughout the statement noting that not all research fits into a standard form, and that research ethics boards need to maintain flexibilility.
But, taking a broader view, the historians are dismayed that these passages appear as mere exceptions to general rules designed for quantitative, especially medical, research. As they put it:

> While there is no question that the ethical issues arising from clinical or quantitative research must be addressed, the effect of this emphasis is to marginalize qualitative research in the humanities and some social sciences. Indeed, the TCPS-2 casts all qualitative research as the exception; something best exemplified by the inclusion of Chapter 10, "Qualitative Research." There is no parallel explanation of quantitative research; perhaps because it is considered the "normal" research practice everyone is familiar with.
> Casting qualitative research as exceptional puts individuals undertaking such research – like historians – in the position of asking for exemptions from REBs. REBs, like all administrative tribunals, are likely to look on requests for an exemption from the guidelines with suspicion, making the bar higher for those undertaking qualitative research higher – simply because of the kind of research they are doing, not its quality. Not only will historians have to demonstrate the soundness of their particular research designs, but they will also have to establish that the norms of their professional practice are legitimate. In our view, this places an undue burden on our profession and on all those engaged in qualitative research.

This passage neatly summarizes most of what has gone wrong in the regulation of research in the social sciences and humanities over four decades in countries around the world. Medical regulators have written rules based in clinical medical practice, then imposed them on other fields in a way that defines those fields as abnormal, and therefore suspect. Seeing this flaw as intrinsic to the ethics review system, the Canadian Historical Association understandably "urge[s] the Advisory Panel to consider the position of the Oral History Association (US) which since 2003 has argued that oral history should be excluded from institutional review boards."

1. http://www.cha-shc.ca/en/Advocacy_51/items/14.html

5.2 February

5.2.1 AAHRPP Urges Extra Care When Talking to Pregnant Women (2010-02-01 09:50)

As I mentioned in [1]October, Marjorie Speers, president of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), has stated that her organization permits institutions it accredits to submit Federal-wide Assurances (FWAs) that do not pledge to impose federal regulations on all research not directly funded by the federal government. In otherwords, institutions may "uncheck the box" without losing accreditation.
At the same time, Speers insisted that "if the boxes are unchecked, we hold the organization to have equivalent protections in place for all research." In my earlier post, I asked what an equivalent exemption might look like.
AAHRPP takes a stab at answering this in the [2]Winter 2010 issue of AAHRPP Advance.
"To Check or Uncheck the FWA Boxes" (p. 6) notes that "The regulations that come into play when the FWA boxes are checked were written primarily with clinical research in mind. Thus, if an organization checks Subpart B of the FWA, for example, it will not be allowed to conduct SBER studies that involve pregnant women, because any study involving pregnant women is required to advance biomedical knowledge."
To give institutions more flexibility, the article claims,

> AAHRPP has designed its standards to apply as much to protecting participants in SBER as they apply to protecting those in biomedical research. When organizations have unchecked the boxes, AAHRPP allows them to provide protections that are appropriate to the level and nature of the risk involved in the study and meaningful to the type of research. Under the accreditation standards, an organization could require that the results of a SBER study that includes pregnant women, for example, must contribute to general knowledge or knowledge that is beneficial to society, rather than to biomedical knowledge.

While any concession is welcome, this one is unimpressive. The regulation in question, [3]45 CFR 46.204 states that "pregnant women or fetuses may be involved in research" only if the research holds out the prospect of direct benefit to the pregnant women or fetus or if "risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means."
Changing "biomedical" to "general" here yields a requirement that researchers meet a higher standard if they want to interview, survey, or observe pregnant women than if they want to interview, survey, or observe non-pregnant women, prospective fathers, or other autonomous adults. Such a requirement violates the rights of both researchers and women.
While I appreciate AAHRPP's understanding that much of the Common Rule is inappropriate when applied to non-biomedical research, the example it has chosen suggests that as an organization, AAHRPP still lacks a basic grasp of some of the issues surrounding IRB review of social science research. What is needed is not mere tinkering with the Common Rule, but wholesale reconsideration of the rights and responsibilities of social scientists.
I thank Rob Townsend for bringing this to my attention.

1. http://www.institutionalreviewblog.com/2009/10/aahrpp-policy-on-fwas-remains-blurry.html
2. http://www.aahrpp.org/Documents/D000242.PDF
3. http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb

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Catherine (2010-02-01 13:19:33)
So if I upset a potential interviewee who happens to be pregnant by telling her that I'm not allowed to do interviews with pregnant women, and she complains to my institution, that's *more* ethical than doing the interview?

Zachary M. Schrag (2010-02-01 13:28:18)
Don't ask me. I might be pregnant.

5.2.2 (2010-02-05 22:58)

Research Ethics—Now with Academic Freedom?
Canada's Panel on Research Ethics has released a new [1](December 2009) draft of the Second Editon of the Tri-Council Policy Statement (TCPS). It is accepting comments until March 1. Below are mine.
To the Panel on Research Ethics,
Thank for the opportunity to comment on the Revised Draft 2nd Edition of the TCPS (December 2009). As with my March 2009 comments on the first draft, I offer the following comments as an American, an oral historian, and as a scholar who has written extensively about the history of the regulation of social science, primarily in the United States but with attention to Canada and other nations.

Improvements

The revised draft makes some progress addressing the concerns of scholars in the social sciences and humanities. Particularly welcome is its new endorsement of academic freedom in chapter 1:

> A fundamental premise of this Policy is that research can benefit human society. In order to maximize the benefits of research, researchers must have certain freedoms. These freedoms include freedom of inquiry and the right to disseminate the results of that inquiry, freedom to challenge conventional thought and freedom from institutional censorship. Collectively, these are generally referred to as "academic freedom."

Such a recognition of research as both a freedom and a right is notably absent in many comparable documents, including the famed Belmont Report.
I also appreciate the revision of the support for critical inquiry in Article 2.8, which states that

> "REBs should also be aware that some research, particularly in the social sciences, when conducting critical assessments of, for example, political or corporate institutions, may be legitimately critical and/or opposed to the welfare of those who are the focus of the research, and may cause them some harm. Such research should be carried out according to professional standards of the relevant discipline(s) or field(s) of research, but it should not be blocked through the use of risk-benefit analysis. In such cases, the balance of risks to those who are the focus of the research is mainly weighed against the potential benefit of new knowledge to society and the indirect benefits to the population to which the participant belongs."

This is an improvement over the 2008 language which, as I noted in my earlier comments, described "harm to reputation is an unavoidable risk of certain types of social science inquiry" rather than a desired outcome of much research.
Chapter 2's "Approach to REB Review" now suggests that "An assessment of [risk] may be based on the researcher's past experience conducting such studies, or the review of existing publications that provide rates of the relevant harms in similar issues."
While this is a step in the right direction, I would suggest that stronger language–that risk-assessment must be based on empirical evidence–would better guard against REBs' documented tendency toward guesswork.
Finally, I m heartened by the requirement that "Institutions should support their researchers in maintaining promises of confidentiality." (Article 5.1) As Ted Palys and John Lowman of Simon Fraser University noted in their comments on the previous draft, Canadian institutions have a poor record in this regard.

New Concerns

I am concerned, however, that the revised draft weakens protections for social scientists, scholars in the humanities, and journalists in at least four ways.
First, the new draft appears to require IRB review for any photography or filming of people in public places. (Article 2.3, 10.4) This would seem to outlaw the standard practices of photojournalists, television crews, and documentary film crews.
Second, the new draft weakens the protection for critical inquiry by deleting the 2008 draft's provision (Article 2.3) that "Research ethics board review is usually not required for research involving public policy issues, the writing of modern history, or literary or artistic criticism."
Third, the new draft (Article 4.6) states that "Individuals or groups whose circumstances may make them especially convenient for researchers to recruit into research projects shall not be included in research solely on the basis of these convenient circumstances."
Taken literally, this would seem to preclude researchers from choosing to study the communities in which they reside as a means of avoiding travel. Such choice of topics has been a staple of social science since Mayhew ventured among the London poor.
My most serious concern about the new draft concerns the "Key Definitions and Principles" section of Chapter 5.
The 2008 draft stated that "Privacy concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual by exposing them to embarrassment, stigma, discrimination or other detriments."
The 2009 draft replaces this statement with the following language:
"Ethical concerns regarding privacy decrease as it becomes more difficult or impossible to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group by exposing them to embarrassment, stigmatization, discrimination or other detriments."
This change is of enormous potential significance, for it brings into question the kinds of harms that are the proper concern of an REB.
Before implementing this change, the PRE may want to consider the U.S. experience. In 1972, the chancellor of the University of California, Berkeley, proposed an ethics policy that stated that

> "Even when research does not impinge directly on it, a group may be derogated or its reputation injured. Likewise, an institution, such as a church, a university, or a prison, must be guarded against derogation, for many people may be affiliated with, or employed by, the institution, and pejorative information about it would injure their reputations and self-esteem."

Scholars at Berkeley and elsewhere immediately realized that such a policy would prohibit social scientists from reporting their findings if those findings might offend anyone. After a national outcry, the policy was withdrawn. (See

Edward Shils, "Muting the Social Sciences at Berkeley," Minerva 11 (July 1973): 290-295.)
Forcing researchers to protect groups as well as individuals violates the TCPS's broader commitments to academic freedom and critical inquiry.

Old Concerns

Finally, please let me reiterate my concern that this draft of the TCPS, like its predecessors, fails to answer the biggest questions surrounding the ethical review of research in the social sciences and humanities: what ethical errors do researchers in these fields commonly commit, and what structures might reduce those errors? Without substantial empirical investigation of the problems posed by research and a wide range of solutions, PRE cannot claim that ethics-board review is either necessary or sufficient to ensure ethical research.

1. http://pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/Default/

5.2.3 Research Ethics–Now with Academic Freedom? (2010-02-06 11:04)

Canada's Panel on Research Ethics has released a new [1](December 2009) draft of the Second Editon of the Tri-Council Policy Statement (TCPS). It is accepting comments until March 1. Below are mine.
To the Panel on Research Ethics,
Thank you for the opportunity to comment on the Revised Draft 2nd Edition of the TCPS (December 2009). As with my March 2009 comments on the first draft, I offer the following comments as an American, a historian, and as a scholar who has written extensively about the history of the regulation of social science, primarily in the United States but with attention to Canada and other nations.

Improvements

The revised draft makes some progress addressing the concerns of scholars in the social sciences and humanities. Particularly welcome is its new endorsement of academic freedom in chapter 1:

> A fundamental premise of this Policy is that research can benefit human society. In order to maximize the benefits of research, researchers must have certain freedoms. These freedoms include freedom of inquiry and the right to disseminate the results of that inquiry, freedom to challenge conventional thought and freedom from institutional censorship. Collectively, these are generally referred to as "academic freedom."

Such a recognition of research as both a freedom and a right is notably absent in many comparable documents, including the famed Belmont Report.
I also appreciate the revision of the support for critical inquiry in Article 2.8, which states that

> REBs should also be aware that some research, particularly in the social sciences, when conducting critical assessments of, for example, political or corporate institutions, may be legitimately critical and/or opposed to the welfare of those who are the focus of the research, and may cause them some harm. Such research should be carried out according to professional standards of the relevant discipline(s) or field(s) of research, but it should not be blocked through the use of risk-benefit analysis. In such cases, the balance of risks to those who are the focus of the research is mainly weighed against the potential benefit of new knowledge to society and the indirect benefits to the population to which the participant belongs.

This is an improvement over the 2008 language which, as I noted in my earlier comments, described "harm to reputation is an unavoidable risk of certain types of social science inquiry" rather than a desired outcome of much research.
Chapter 2's "Approach to REB Review" now suggests that "An assessment of [risk] may be based on the researcher's past experience conducting such studies, or the review of existing publications that provide rates of the relevant harms in similar issues."
While this is a step in the right direction, I would suggest that stronger language–that risk-assessment must be based on empirical evidence–would better guard against REBs' documented tendency toward guesswork.
Finally, I m heartened by the requirement that "Institutions should support their researchers in maintaining promises of confidentiality." (Article 5.1) As Ted Palys and John Lowman of Simon Fraser University noted in their comments on the previous draft, Canadian institutions have a poor record in this regard.

New Concerns

I am concerned, however, that the revised draft weakens protections for social scientists, scholars in the humanities, and journalists in at least four ways.
First, the new draft appears to require IRB review for any photography or filming of people in public places. (Article 2.3, 10.4) This would seem to outlaw the standard practices of photojournalists, television crews, and documentary film crews.
Second, the new draft weakens the protection for critical inquiry by deleting the 2008 draft's provision (Article 2.3) that "Research ethics board review is usually not required for research involving public policy issues, the writing of modern history, or literary or artistic criticism."
Third, the new draft (Article 4.6) states that "Individuals or groups whose circumstances may make them especially convenient for researchers to recruit into research projects shall not be included in research solely on the basis of these convenient circumstances."
Taken literally, this would seem to preclude researchers from choosing to study the communities in which they reside as a means of avoiding travel. Such choice of topics has been a staple of social science since Mayhew ventured among the London poor.
My most serious concern about the new draft concerns the "Key Definitions and Principles" section of Chapter 5.
The 2008 draft stated that "Privacy concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual by exposing them to embarrassment, stigma, discrimination or other detriments."
The 2009 draft replaces this statement with the following language:

> Ethical concerns regarding privacy decrease as it becomes more difficult or impossible to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group by exposing them to embarrassment, stigmatization, discrimination or other detriments. (My emphasis.)

This change is of enormous potential significance, for it suggests that REBs be allowed to block projects not because they threaten to harm any identifiable individuals, but because of the much vaguer concern that they may stigmatize whole groups.
Before implementing this change, the PRE may want to consider the U.S. experience. In 1972, the chancellor of the University of California, Berkeley, proposed an ethics policy that stated that

> Even when research does not impinge directly on it, a group may be derogated or its reputation injured. Likewise, an institution, such as a church, a university, or a prison, must be guarded against derogation, for many people may be affiliated with, or employed by, the institution, and pejorative information about

it would injure their reputations and self-esteem.

Scholars at Berkeley and elsewhere immediately realized that such a policy would prohibit social scientists from reporting their findings if those findings might offend anyone. After a national outcry, the policy was withdrawn. The PRE should likewise understand that forcing researchers to protect groups as well as individuals would violate the TCPS's broader commitments to academic freedom and critical inquiry.
[See Edward Shils, "Muting the Social Sciences at Berkeley," Minerva 11 (July 1973): 290-295.]

Old Concerns

Finally, please let me reiterate my concern that this draft of the TCPS, like its predecessors, fails to answer the biggest questions surrounding the ethical review of research in the social sciences and humanities: what ethical errors do researchers in these fields commonly commit, and what structures might reduce those errors? Without substantial empirical investigation of the problems posed by research and a wide range of solutions, PRE cannot claim that ethics-board review is either necessary or sufficient to ensure ethical research.
Thank you for consideration of these issues.

1. http://pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/Default/

5.2.4 IRBs Unfamiliar With Internet Research Ethics (2010-02-13 21:26)

Two experts in Internet research ethics find "that IRBs generally do not know what . . . protections apply strictly to online research, and such boards often ignore the complexities of such research and thereby risk harming subjects while also violating federal regulations, or, they apply such restrictive models that inhibit researchers from pursuing important online endeavors."
[Elizabeth A. Buchanan and Charles M. Ess, "[1]Internet Research Ethics and the Institutional Review Board: Current Practices and Issues," ACM SIGCAS Computers and Society 39 (December 2009): 43-49.]
In 2006, the authors sent surveys to more than 700 US-based IRBs, of which they received responses from 334. The learned that

> Few boards were aware of extant guidelines such as the Association of Internet Researchers Ethical Decision Making document, and 74 % did not provide specific training around Internet research issues, and that less than half (42 %) felt the Office [for] Human Research Protections or other regulatory documents were useful in Internet research reviews. These data suggest that ethics boards may not be fully informed when reviewing such research. We must consider on what bases are review boards making decisions around [Internet research ethics]? Of particular concern, our qualitative data provided indications that many boards were "unsure of who to ask," "we don't even know what questions to ask of the researcher," and, "we rely on the IT department to advise us on such IT related issues."

This is typical of an IRB system that rewards members and, especially, staffers who can recite the Common Rule from memory but imposes no real incentive to read the ethics literature of the disciplines over which they claim power.
See also: [2]The Dormant Right to Expertise
and [3]In Search of Expertise.

1. http://doi.acm.org/10.1145/1713066.1713069
2. http://www.institutionalreviewblog.com/2007/10/dormant-right-to-expertise.html
3. http://www.institutionalreviewblog.com/2007/02/in-search-of-expertise.html

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5.3 March

5.3.1 A Few More Words on TCPS 2009 (2010-03-01 20:53)

Ted Palys and John Lowman of Simon Fraser University kindly sent me a copy of [1]their comments on the latest draft of the TCPS. The also alerted me to the [2]Novel Tech Ethics site, which is publishing various comments on the draft. Palys and Lowman find the latest draft to be an improvement over the December 2008 version, but they remain dissatisfied with elements of its treatment of social science research. Their main concern is that REBs will remain "dominated by members who have no specialized knowledge of the practices in a particular discipline can undermine the integrity of ethics review and, all too often, make it a process to be undertaken and survived instead of a discussion to be welcomed." To remedy this, they suggest that institutions be encouraged to establish multiple REBs with expertise in particular areas. They also make a number of suggestions for smaller reforms.

While Palys and Lowman have a number of significant concerns, it's worth noting that their comments on this draft are generally much warmer than their [3]critique of the 2008 draft. This confirms my sense that while the latest TCPS has serious flaws, it is the best effort yet to include the concerns of social scientists into a general research ethics document.

Since today is the deadline for comments, I submitted an addendum to my February 6 comments:

To the Panel on Research Ethics,

On February 6 I submitted comments on the Revised Draft 2nd Edition of the TCPS (December 2009). I would like to amplify those comments slightly.

In my earlier comments, I noted my concern with Chapter 5's language warning about the possible stigmatization of groups. As I stated, I believe that this should not be the basis for restricting research in the social sciences and humanities.

Since then, I have reread the report, and I came across the following language in chapter 1:

> The welfare of groups can also be affected by research. Groups may benefit from the knowledge gained from the research, but they may also suffer from stigmatization, discrimination or damage to reputation. Engagement during the design process with groups whose welfare may be affected by the research can help to clarify the potential impact of the research and indicate where any negative impact on welfare can be minimized. Researchers must also consider the risks and potential benefits of their research and the knowledge it might generate for the welfare of society as a whole. Where research on individuals may affect the welfare of a group(s), the weight given to the group's welfare will depend on the nature of the research being undertaken and the individuals or group in question. This consideration does not imply, however, that the welfare of a group should be given priority over the welfare of individuals.

Again, let me emphasize that legitimate, critical research in the social sciences and humanities often is damaging to groups. As Edward Shils noted in 1973, "Any factual description, however objective and true, might be offensive to those who are sensitive and whose actions and qualities are such as to fall short of reasonable standards." I therefore do not consider the passage on group harms to reflect "core principles [that] transcend disciplinary boundaries and therefore, are relevant to the full range of research covered by this Policy."

1. http://www.noveltechethics.ca/pictures/File/Health_Policy/TCPS_2010/PalysLowman.pdf
2. http://www.noveltechethics.ca/site_beyond.php?page=486
3. http://www.institutionalreviewblog.com/2009/03/canadian-criminologists-decry-tcps.html

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5.3.2 IRB Warns That Opinions May Vary (2010-03-04 20:47)

Michael Bugeja, director of the Greenlee School of Journalism and Communication at Iowa State University, reports a run-in with his IRB.

[Michael Bugeja, "[1]Avatar Rape," Inside Higher Ed, 25 February 2010.]
Bugeja was interested in "avatar rape": forced, simulated sex in a virtual environment such as Second Life. As a journalism professor, he wanted to know what other university scholars and administrators thought about the problem. But his IRB imposed conditions that discouraged responses.

> In researching the phenomenon, I sought viewpoints from directors of information technology and women's studies at Big XII and other peer institutions. My research assistant Sam Berbano and I spent two months working with our Institutional Review Board, seeking approval to post our survey online.
> Given the sensitive nature of the topic, the IRB asked us to warn survey participants about possible harm to their reputations should their responses be published. To lessen risk, the IRB also required signed copies of consent to anyone responding to our survey. So we opted for a snail mail version with a disclaimer: "A risk of participation in this survey may arise if some may find your opinions in the free-response section at variance with their own."
> My research assistant wondered how a survey measuring opinion about avatar rape could have more potential for harm than participation in a virtual environment in which such a digital act could occur.
> As it turned out, only one respondent out of 43 provided comments for this essay.

Is variance of opinion the kind of risk to "reputation" against which 45 CFR 46 is supposed to protect? I don't think so, but who knows? The interagency group that inserted "or reputation" into the 1991 regulatory amendments never explained its decision, even in the face of an objection that "[2]reputation is a subjective term that is difficult to define operationally."
What I can say is that as a scholar and educator, I strive to expose people to opinions they do not share. At Iowa State University, such an outcome is classified as a hazard.

1. http://www.insidehighered.com/views/2010/02/25/bugeja
2. http://www.hhs.gov/ohrp/documents/19910618.pdf

5.3.3 Sociologists Split on Ethics Review (2010-03-15 16:02)

Two researchers from the University of Toronto find Canadian qualitative sociologists divided in their responses to research ethics boards.
[Judith Taylor and Matthew Patterson, "[1]Autonomy and Compliance: How Qualitative Sociologists Respond to Institutional Ethical Oversight," Qualitative Sociology, published online 23 February 2010, DOI: 10.1007/s11133-010-9148-y]

Three Ethics Orientations

Judith Taylor and Matthew Patterson interviewed one qualitative sociologist from each of 21 of Canada's 22 PhD-granting sociology departments. They found that respondents fell into three general groups of "ethics orientations," which they characterize as "active engagement, apparent accommodation, [and] overt opposition."
The angriest sociologists are "overt opposers" who "passionately defend unencumbered intellectual pursuit, sociological traditions of inquiry, experiments and innovations in inquiry, the primacy of sociological understandings of ethics, faculty discretion, and critical or autonomous sociology. Such scholars see institutional ethical review as putting intellectually-credible human-based sociology and academic freedom in peril, threatening the nature and legacy of the discipline of sociology and the job of sociologists." Faced with IRB/REB requirements, they do whatever they can to resist, even deceiving the boards when necessary.

At the other extreme, "active engagers believe regulators and practitioners can collectively manage conflicts by working together as virtual peers within the same committees and institutional settings." They welcome ethics review and may even serve on boards themselves.

In the middle, "apparent accommodators accept the necessity of ethics regulation, but fret over the practical implications of these regulations for their research and teaching." This is the largest group, comprising ten of the 21 responses, with six opposers and five engagers making up the rest. As the authors note, this split means that while three-quarters of sociologists think ethics review is necessary, two-thirds of those are also engaged in "some form of resistance toward ethical oversight."

Though Taylor and Patterson "argue that the ways in which academics understand and act toward ethical oversight is far more complex and variable than is represented in the current literature," the range of responses they report closely resembles the range of viewpoints I have reported on this blog and in my forthcoming book. For example, "Communication Scholars' Narratives of IRB Experiences," Journal of Applied Communication Research 33 (August 2005): 204-230, are not broken down into categories, but they express views quite similar to those found here.

Where You Stand Depends on Where You Sit

More intriguing are Taylor and Patterson's explanations of why scholars think as they do. They attribute viewpoints to scholars' age and status, noting that "Overt opposition tends to be exhibited mostly by senior men in the discipline who began teaching in the 1970s or 1980s, although some senior women are also opposers. Overt opposers also tend to hold appointments at the most research-intensive and elite institutions." The more tolerant apparent accommodators "tend to be mid-career scholars at research-intensive institutions who share their oppositional colleagues' analyses while also internalizing blame for the transgressions of their predecessors." And active engagers "tend to be younger, untenured women faculty with less than a decade of teaching experience, holding positions at less research-intensive universities."

Taylor and Patterson suggest that as the youngest cohort, the engagers will inherit sociology. "As the generation of opposers retires and engagers increase in prevalence and power, the range of available orientations and methodological approaches may markedly narrow, with possible effects on the production of sociological knowledge."

A Liberal Is a Conservative Who Has Been Arrested

Another possibility, however, is that attitudes toward ethics boards reflect knowledge gained from reading and experience. Direct experience with ethics boards breeds skepticism. Only one respondent is quoted as having direct knowledge of sensible advice dispensed by an ethics committee: the suggestion of a "graduated consent form." But many faced inappropriate demands by ethics boards, either regarding their own research or that of their students. As the authors note, when accommodators "sense that those reviewing their ethics protocols do not share [their] understanding of sociology, they lose faith in the ethics review process." One or two incidents of "decisive trespass" may be forgiven. But the reality of ethics review eventually may wear out their trust.

The only thing that keeps these frustrated accommodators from becoming opposers is their belief that "a history of ethical violation" by sociologists "prevents them from more outwardly opposing their boards." I would be curious to know just what the respondents believed about the history of their discipline, and how they had come to those beliefs. Do they get their history from historians, from sociologists, or from ethics boards?

If attitudes toward ethics boards are shaped by experience, rather than status, then opposition may not fade as today's opposers retire. Graduate students may enter the profession as idealistic engagers. But as they pursue their careers, the missteps of ethics committees (and perhaps a better grasp of history) could drive them into the camps of accommodation, then opposition. Today's engagers may be tomorrow's accommodators, and today's mid-career accommodators could be tomorrow's senior opposers.

1. http://www.springerlink.com/content/cg9821604883070h/

5.3.4 Twenty-Six Percent of Boxes Go Unchecked (2010-03-19 10:10)

Approximately 74 percent of U.S. institutions with federalwide assurances apply all or part of 45 CFR 46 to all research regardless of support, down from more than 90 percent of such institutions a decade or so ago, according to OHRP officials.
[Carol Weil, Lisa Rooney, Patrick McNeilly, Karena Cooper, Kristina Borror, and Paul Andreason, "[1]OHRP Compliance Oversight Letters: An Update," *IRB: Ethics & Human Research* 32, no. 2 (2010): 1-6.]
The authors write that since their previous review of determination letters, published in 2003 and covering the period 1998-2002,

> more institutions have decided not to extend their FWA to research not supported by HHS, which means that OHRP has jurisdiction over fewer research studies than in the past. Based on an informal review of a sample of institutions, approximately 74 % of domestic institutions currently holding an FWA that formerly held a Multiple Project Assurance (MPA) apply either subpart A or subparts A, B, C, and D of 45 CFR 46 to all research regardless of support. On the other hand, greater than 90 % of those same institutions applied 45 CFR 46 to all research regardless of support when they held MPAs.

Along with that finding, the authors "describe [their] review of 235 compliance oversight determination letters that the Office for Human Research Protections (OHRP) issued to 146 institutions between August 1, 2002, and August 31, 2007." Such a large dataset would seem to be a rich source of information for those interested in how researchers and institutions go wrong.
Unfortunately, determination letters are generally opaque documents that fail explain the events leading up to a complaint. For example, OHRP's March 2007 letter to New Mexico State University tells us a bit about office procedure at New Mexico State, but nothing about the design of a project called "The Impact of Education in Navajo Nation Border Community Public Schools on the Hearts, Minds, and Spirits of Navajo Students," or whether that project violated any research ethics.
Because of this opacity, a review of determination letters can tell us that 56 percent of institutions were cited for problems with the "IRB initial review process" while only 3 percent were cited for misapplication of exempt categories of research. But it can't tell us what percentage of citations concerned ethnographic fieldwork, what percentage involved graduate students, or what percentage involved questions of whether data were publicly available. Nor can it tell us whether any one of these 235 letters documented actual harm to a research participant.
(I am puzzled by the finding that OHRP issued 260 citations for deficient "IRB-approved informed consent documents/process" but only 19 for "Failure to obtain informed consent of subjects." Does that mean that deficient processes still work 93 percent of the time?)
OHRP is missing an important opportunity. When courts rule on cases, they take care to explain not only the legal principles involved, but also the underlying facts, so that other courts can understand which principles should be applied to certain fact patters. By failing to document the substantive concerns that led to its investigations, OHRP has failed to educate researchers and IRBs about what kinds of research are most likely to lead to trouble.

1. http://www.thehastingscenter.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=4558&libID=4562

5.4 April

5.4.1 More Universities Deregulate Oral History (2010-04-07 12:03)

The University of Texas at Austin has ruled that "[1]Biography or oral history research involving a living individual is not generalizable beyond that individual. Therefore, it does not meet the definition of research and does not require IRB review and approval." This is based on the recommendations of a University of Texas System task force report whose public release I am trying to secure. It is a stronger than Texas's [2]earlier statement that oral history "in general" did not require review.
Also deregulating oral history are [3]Brigham Young University and [4]Princeton University. Princeton's policy is particularly clear:

> Proposed research including journalistic interviews, oral histories, biographical profiles, or other forms of nonfiction narratives, normally does not fall within the jurisdiction of the IRB. In these cases, the individuals being interviewed understand that they are being quoted, and have every expectation that their views will be made known. The interviewees are advised of their right to remain anonymous, to have their remarks printed without attribution, or kept 'off the record'. If the interviewee is directly quoted, they are allowed to read or hear the quotations attributed to them. The interviewee will also be advised of any publication plans for the project. Most projects from Humanities meet the above criteria; therefore they do not qualify for the IRB review, and do not need to submit their project to the IRB for approval.

[5]Other colleges and universities that have cleared oral history include Amherst College, Columbia University, University of Missouri-Kansas City, the University of Michigan, and the University of Nebraska-Lincoln.
This is still not a long list, but the field is shifting from early 2006, when [6]the American Historical Association struggled to find such unambiguous statements.

Update, 4 May 2010: I have posted a copy of the [7]Texas report.

1. http://www.utexas.edu/research/rsc/humansubjects/mayormaynot.html
2. http://www.historians.org/perspectives/issues/2006/0602/0602new1.cfm
3. http://orca.byu.edu/IRB/GettingStarted.aspx#oral
4. http://www.princeton.edu/orpa/compliance/IRB%20flowchart%20memo.htm
5. http://www.oralhistory.org/do-oral-history/oral-history-and-irb-review/
6. http://www.historians.org/perspectives/issues/2006/0602/0602new1.cfm
7. http://www.institutionalreviewblog.com/2010/05/texass-all-star-irb-report.html

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Catherine (2010-04-07 13:39:51)
...but still none in the UK?

Zachary M. Schrag (2010-04-08 12:29:17)
I am unaware of any UK universities that have similar policies. Nor am I aware of UK universities that explicitly require review of oral history projects.

Dan (2010-04-21 21:01:52)
Has there been any talk about the relationship between, on the one hand, "journalist interviews," "oral histories," and the others on the list, and on the other hand, "open-ended interviews" that anthropologists and sociologists sometimes find themselves doing?

Zachary M. Schrag (2010-04-23 21:17:16)
While many argue that anthropology and sociology should not be subject to regulation, few dispute that they are, since that was the intent of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
The same commission fairly clearly did not intend to regulate journalism or oral history, and the university policies reflect that.

Adam (2010-04-27 09:56:30)
In the UK it may depend on whether your oral history is funded by the ESRC (Economic and Social Research Council) or not. The ESRC rules require all the research it funds to go through ethics review, either by an NHS REC(if it's working on patients/doctors/records) or an University REC (most of which were set up in 2005 following the first edition of the ESRC's Research Ethics Framework: http://tinyurl.com/2uayvg6). So the answer is, as so often the cas ein the UK, sometimes you do, sometimes you don't...

5.4.2 Chronicle Readers Vent IRB Complaints (2010-04-13 14:02)

The Chronicle of Higher Education's "Chronicle Forums" features a discussion of the question, "[1]Do IRB's Go Overboard?" Unsurprisingly, several off the discussants answer yes. Among the angriest:

1. "I supervised an MA student a few years ago whose ethics proposal was sent back seven times. By the end they were asking questions like "what if you become really famous from this research and then the police decided to subpeona your records and the confidentiality of your sources was comprised?". Sadly, that's not even a made up question (and this was for an MA in English lit, btw). Obviously, the student was freaked and the process took seven months and almost scuttled her plans. We were drawing up a Plan B for her thesis to become about the review process, since she wouldn't have time to do the actual research. In the end she got what she wanted, did an excellent thesis and kissed academia good-bye rather than pursue a PhD since she thought the whole process of doing research is clearly deranged."
2. "IRBs are better some places than others, and it depends on the discipline. At my current institution, humanities scholars are subject to an IRB that only makes sense for scientists collecting blood and doing life-threatening experiments on small children. Yet, most of the major ethical concerns that are well known and of the greatest importance and concern in my discipline, those aspects of tangible risk resulting from research, are outside the purview of the IRB forms/processes. The policies change every year without notice, meaning it's very hard to teach our grad students how to successfully navigate the IRB process. It's become an arbitrary affair."
3. "ARGH YES. A network ("snowball") sample (so I don't know exactly who or how many yet!), semi-structured exploratory interview protocol that will evolve during the course of data collection–it was just too much for them. In principle, I'm OK with them watching out for ethical stuff, of course, but when they start questioning my research methods, they've gone too far. Back off. You're a chemist. The advice to be as vague as possible–yes. What I really want is exempt status when I'm talking to professionals about their professional roles–I've heard of it at other universities."
4. "My subjects are often powerful people doing bad things. It is quite reasonable to suppose that as a result of my research they could lose their jobs (it hasn't happened so far, but it could). And I wouldn't necessarily think that was a bad thing. From my own perspective, research ethics means making sure interviewees understand the implications of being interviewed, know the potential uses to which the data could be put, and that any deals I make with them about anonymization, or not writing about certain topics, or whatever, are kept. If they don't want to be interviewed, sometimes I use other ways to find out about what they are up to, and write about them anyways. Which often makes them prefer to be interviewed, because at least then they can put their view across.

"It seems to me that in an environment where the standard assumption is that no harm can come to research

subjects as a result of the research, this kind of research is right out. Which pretty much means that I can't come back to the USA. Which is ok, since its not like there are any jobs there anyways."
5. "A new pernicious IRB trend is to need to get targeted organizational sign off on research about an organization, even if you interview individuals who work for it in their homes or in a coffee shop off campus. Clearly, this is to protect one's own campus from lawsuits, but I'm not sympathetic. (Key is the more important and latent function of IRBs– protecting one's organization, not the subjects.)"

The discussion also features some defenses of IRBs, but they are vaguer and less eloquent. In particular, none tells a story of an IRB review that proved necessary.

1. http://chronicle.com/forums/index.php?topic=68012.0

5.4.3 I See Dead People (2010-04-27 09:59)

A history professor at Central Connecticut State University and one of his graduate students, a retired corporate lawyer, spent months persuading the state Freedom of Information Commission to release medical records from hospitalized Civil War soldiers and veterans.
[Thomas B. Scheffey, "[1]A Legal Skirmish Over Civil War Records," Connecticut Law Tribune, 26 April 2010. Thanks to Josh Gerstein for the reference.]
The case is a reminder that ethics rules can interfere with the scholarly study of not only the living, but also the dead. For an excellent introduction to this issue, see Susan C. Lawrence, "[2]Access Anxiety: HIPAA and Historical Research," Journal of the History of Medicine and Allied Sciences 62 (2007): 422-460.

1. http://www.ctlawtribune.com/getarticle.aspx?ID=36927
2. http://jhmas.oxfordjournals.org/cgi/content/abstract/62/4/422

5.5 May

5.5.1 Texas's All-Star IRB Report (2010-05-03 21:23)

In February 2008, the University of Texas System formed an IRB Task Force to examine ways to improve IRB operations throughout the UT System. In April 2009, that task force issued its report: "[1]IRB TASK FORCE REPORT: Trust, Integrity, and Responsibility in the Conduct of Human Subjects Research."
I recently obtained a copy of that report. While it has not previously been posted on the web, a University of Texas official assured me that a final policy report like this is public information under Texas law. So to make this important public document freely available, I have posted a copy on my website. (See link above.)
The report offers an exceptionally thorough and thoughtful consideration of how IRBs should work at great research universities. While some of its recommendations may be inapplicable to univerisities that are not part of larger systems or do not operate a medical campus, many of the task force's procedures and recommendations offer a model for others. I salute all those who were involved in the report's preparation.
In particular, I commend the following elements of the UT task force and its report.

Procedures

The UT system carefully set up the task force in a way that would build respect for its findings. In particular, it managed to:

1. Represent Multiple Disciplines
UT included task force members "representing a variety of academic disciplines," among them SACRHP member Lisa Leiden. (3, 24) It also sought help from a range of consultants, including such "national experts" Tina Gunsalus; John Heldens, Moira Keene, Dan Nelson, Ivor Pritchard, and Marjorie Speers. (8)
2. Include Stakeholders
At each UT campus, the task force solicited comments from university officials, IRB chairs, investigators, and other interested parties. (8)
3. Allow Adequate Time
The UT task force completed its deliberations over the course of a year, from February 2008 to February 2009, then released its report in April 2009. A report with so broad a scope cannot be rushed.

Recommendations

Careful investigation led to thoughtful recommendations. The report suggests that the UT system:
1. Employ Faculty Expertise
The UT report recognizes that researchers are often expert in a particular area of human subjects research, and it recommends that faculty experts be identified to prepare standards for specific types of research (e.g., research involving subjects with impaired capacity, internet research) and to consult on individual projects as needed. (10)
2. Utilize Flexibility and Empirical Evidence
The report recommends that the university encourage IRB staff to provide "an efficient level of regulatory review compatible with adequate protection of human subjects," rather than the most stringent level of review. In particular, it suggests that IRB staff and members employ empirical evidence when determining risk, by consulting experts or scholarly literature. (11) The report also suggests that IRBs rely strongly on experts when determining the scientific soundness of a proposal. (14)
3. Uncheck the Box
The UT report notes that, according to Speers, fewer than 50 percent of AAHRP accredited institutions check all the box on their federal-wide assurances, and that it is "primarily the major research universities that are considering unchecking the box," thus maximizing their flexibility in handling projects not directly funded by a Common Rule agency. (12) (More on this in an upcoming post.)
4. Diversify the IRB
The UT report recommends that "Institutional Officials should ensure that the institution's disciplines are well represented in the IRB." (18)
5. Provide IRB Oversight
The UT report recommends that institutions "consider the implementation of a research ombudsperson to increase the opportunity for rapid resolution of issues involving human subjects research." (21) It also suggests an ongoing "IRB Advisory Group" to implement recommendations and assist with human subject policy issues. (23)
6. Define Key Terms
The UT Report includes definitions of key terms. Among other things, these definitions make clear that information-gathering interviews, service surveys, and classroom activities may not meet the definition of human subjects research, and that biography and oral history interviews do not meet that definition. (27) As I mentioned earlier, this recommendation has already led to the [2]deregulation of oral history at the University of Texas at Austin.
7. Explore Alternatives
The report include an appendix on "alternative IRB models," based on the November 2006 "National Conference on Alternative IRB Models." While it is promising that the task force is willing to consider such alternatives, I would have liked it to pick up on that conference's call for [3]"further exploration" of models for social and behavioral research. The [4]University of Pennsylvania policy on research in the sociobehavioral sciences might be such a model.

Goal

Most importantly, the UT task force understood the IRB problem as something larger than an administrative challenge.

While it explored ways to increase IRB "effectiveness, efficiency, and productivity," it went beyond such managerial concerns to probe big questions about "IRB authority, mission, and functions," the "unnecessary obstruction of research and lapses of effective human subject protection," and best practices from the available literature. (8)
The task force hoped to foster a "culture of conscience" rather than a "culture of compliance," and it understood that conscience cannot be dictated from above. (20) If other universities also seek to promote a culture of conscience, they must give a voice to all those involved with human subjects research.

1. http://schrag.info/irb/UT_Sytem_IRB.pdf
2. http://www.institutionalreviewblog.com/2010/04/more-universities-deregulate-oral.html
3. http://www.institutionalreviewblog.com/2007/04/alternative-irb-models-conference.html
4. http://www.upenn.edu/almanac/volumes/v53/n06/or-hsresearch.html

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5.5.2 Researchers Deceive Thousands of Professors (2010-05-08 07:33)

[1]Professor Andrew Gelman reports that he was sent a deceptive e-mail as part of a research project by two business professors, Katherine Milkman and Modupe Akinola. Milkman and Akinola wished to see if "students from under-represented groups" (presumably racial and ethnic minorities, and perhaps women) would be less likely to gain the interest of doctoral faculty than "other students" (i.e., white guys). So they sent e-mails to Gelman and about 6300 other professors in PhD-granting departments at American universities. The messages, purportedly from a student planning to apply to PhD programs and wishing for a brief meeting, varied by the name of the student and by the time of the proposed meeting. When a professor answered, they replied to cancel the meeting. The idea was to see if students with white-guy names received more or fewer invitations to meet than others.
After receiving a debriefing e-mail explaining the sham, Gelman replied to the authors that "My helpful impulses toward inquiring students are being abused by this sort of study, which I think belongs in the trash heap of ill-advised research projects along with Frank Flynn's notorious survey from a few years ago when he tried to get free meals out of NYC restaurants by falsely claiming food poisoning." He later elaborated on his blog, "What bothers me is that we were involuntary participants in the study. The researchers took advantage of our time and our good nature (that we were willing to meet with an unfamiliar student). Not cool."
[2]Gelman's post has spurred several comments. Some feel the study should not have been conducted at all: "I really want . . . a formal apology from both institutions, and an acknowledgment that this project should never, ever have gotten IRB approval." And "Since the researchers took the subjects' time without asking, I think they're guilty of stealing something of this magnitude. People often get put in jail for less."
Others think Gelman is being too sensitive: "Everyone is so precious about this. . . . The fact everyone here wrote, read or commented on this blog post suggests that a few minutes here and there don't cost anyone much." Another cites the work of Peter Riach and Judith Rich, who found that the "minimal inconvenience" imposed on the unwitting subjects of such field experiments can be justified by the "degree of accuracy and transparency which is not available from any other procedure." [Peter A. Riach and Judith Rich, "Deceptive Field Experiments of Discrimination: Are They Ethical?" Kyklos 57 (2004): 457-70.]
Gelman himself is in the middle; he thinks that deceptive surveys are OK, he just wants the researchers to send $10 in compensation to everyone who received the e-mail. "Then, after they send us the study results, if we think the findings are interesting, we can each individually decide whether to send the $10 back to them."
The lesson here is that just because a study is approved by an IRB (two, in this case), doesn't mean it won't leave some participants feeling abused. Nor should IRBs strive for such innocuity; they need to weigh the values of free choice and honesty against the values of knowledge and freedom.
I would be curious to see the original protocols and to learn what reactions Milkman, Akinola, and the two IRBs expected. If they did in fact anticipate that a number of recipients would feel as Gelman does–misused, but only to the extent of $10 in damage–the idea of a compensation fund for the outraged isn't bad. (Though perhaps it could require participants to ask for the money rather than having payment as the default.) If the researchers and the IRBs

didn't expect this reaction, there's an opportunity here for some good empirical research. Or, as one commenter put it, "Maybe it's a double dummy study design where they wanted to see how easy it is to annoy professors with email."

1. http://www.stat.columbia.edu/~cook/movabletype/archives/2010/05/63000_worth_of.html
2. http://www.stat.columbia.edu/~cook/movabletype/archives/2010/05/63000_worth_of.html#comments

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PCM (2010-05-10 01:52:04)
Too precious indeed. It would be unethical only if they didn't cancel the appointment. It would also be unethical if they named or accused individual professors of being something (like being racist) based on their response to an email.
But I for one am curious about the aggregate results. And while I do not wish to receive any more emails than I do, nor would I welcome deceitful email, there is benefit in this study. And that benefit should be weighed with the (minimal) level of inconvience to the subject. I assume that's what the IRB did.
Besides, this study is very similar to many that have asked for job-interview call backs. I didn't hear any objection to that study. Is the time of a corporate PR people so less important than overworked professors?

Zachary M. Schrag (2010-05-10 20:32:36)
I see your point. This evening a door-to-door solicitor awoke me from a much-needed nap. I thought about demanding $10 in compensation, but then I remembered that I live on Planet Earth.

Michael H. Court (2010-05-12 11:10:35)
I was actually one of the subjects of the study - and based on the "debriefing" message I was sent the actual purpose of the study was to see if there was a difference between being asked to meet the prospective student "now" (today) versus "later" (next week). Based on reading the PIs published worked - mostly popular press articles - it seems that this has something to do with "impulse buying" - which I guess makes sense for a business school researcher.
The effect of minority/gender was stated as an afterthought (secondary hypothesis) - perhaps in response to initial IRB review.
I don't mind being deceived in this fashion provided it is a well-designed study that is intended to benefit society as a whole - presumably criteria that the IRB should have considered. However, I don't see that either of these criteria were fulfilled.

Zachary M. Schrag (2010-05-12 16:40:52)
Thank you for this comment.
I rather doubt this is a study of impulse buying. Professor Akinola's website explains that she "explores biases that affect the recruitment and retention of minorities in organizations," and she has published in that area. Professor Milkman recently co-authored a paper entitled, "Will I Stay or Will I Go? Cooperative and Competitive Effects of Workgroup Sex and Race Composition on Turnover." So I am inclined to assume, as do the commentators on Professor Gelman's blog, that the researchers' interest in "various backgrounds" is far more than an afterthought.
Your comment raises the question of whether subjects of an IRB-approved study should have the right to review the protocol. Currently, the IRB system is not well set up to consume or produce empirical research, and making protocols public would be a step in the right direction.

Anonymous (2010-05-14 15:06:01)
Even if each of the 6300 recipients averaged only five minutes to read the email, check their calendar, make a decision, and respond (and I spent considerably more time, as did manyothers , lining up resources from administrators and lab operators), then the total time wasted comes out to more than one dozen full work weeks. All in service to the selfish interests of these researchers.

Anonymous (2010-05-16 20:31:08)
I too was subject to this email scam, and am amazed that an IRB could approve direct lies to participants - it certainly would not get by a review board in communication disorders where I do my research. But I guess telling lies is par for the course in business.
I emailed to complain and of course was ignored by these scam artists.

Anonymous (2010-11-23 02:02:42)
Sounds like quite an interesting study. I'd be a little bit annoyed by the fake email, but I'll be interested to see the results.
I am a little surprised that this passed the ethics review, but it should be interesting to read!

5.5.3 APA Launches Committee on Human Research (2010-05-24 11:51)

John Mueller kindly alerted me to the formation of the American Psychological Association's [1]Committee on Human Research, which met for the first time in March. The committee expects to work for the next 3-5 years on various issues, including, at the top of the list, "interpreting federal regulations for psychological research."
Among the committee members is Miriam F. Kelty, who, as an NIH psychologist, served on the staff of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the 1970s.

1. http://www.apa.org/science/about/psa/2010/05/human-research.aspx

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5.6 June

5.6.1 It Can Happen to Anyone (2010-06-07 21:53)

On Saturday, my Journal of Policy History article, "[1]How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965–1991," was honored with that journal's [2]Ellis Hawley Prize. In presenting the prize, Professor Hawley–one of the leaders of my profession–mentioned that he himself used to ask his students to interview someone who had lived through the Great Depression. On being told that he would have to submit to IRB review, he abandoned the assignment. If IRBs can deter Ellis Hawley from learning more about the 1930s, we have a problem.

1. http://zacharyschrag.com/institutional-review-boards/
2. http://www.slu.edu/departments/jph/2010%20Awards.html

Anonymous (2010-06-09 18:17:20)
You may have seen the following comment on the Washington Post online, responding to an op ed piece about Bush and torture: "The notion that "human experimentation", rather than torture, abduction, or organ failure-like pain would be the thing to get Bush is not surprising. Even in a world of grand juries, special prosecutors, and congressional investigations nothing is as blunt a weapon as an American IRB."
Thought of your blog immediately!

PCM (2010-06-24 22:21:09)
Nice article and congrats on the prize.

5.6.2 NYU IRB Withdraws Demand that Field Notes Be Shared (2010-06-10 10:02)

Professor Deborah Padgett of the Silver School of Social Work, New York University, posted a [1]query on H-MedAnthro concerning her IRB's demand that she allow her informants to review her ethnographic field notes.
Readers of that forum encouraged her to resist the demand. Simon Lee, a medical anthropologist and an IRB member, was [2]particularly emphatic:

> Field notes are raw data, much like a lab notebook in bench science. Raw data is private and not appropriate to share, precisely because lay people draw conclusions from looking at fieldnotes that pre-empt the anthropological analysis. Sharing raw field notes during an active (in process) study is really only appropriate for a safety/audit process: that is, the IRB can request to review your field notes for example if there was a concern about confidentiality and you needed to explain what precautions you were taking. But generally field notes should not be available for review by informants on a required or routine basis. The whole point of protecting raw field notes is so that ONLY the anthropological team sees the raw data and no one makes assumptions about their observations: not informant's colleagues, not informant's supervisors etc. To make them available creates both a chilling effect on your ability to collect data, and can in fact promote misunderstanding because it is raw data.

Others pointed out that sharing the notes would allow informants to see what their coworkers had said, perhaps in confidence, thus adding rather than decreasing risk.
Having read these replies, Padgett

> crafted a response to the IRB asserting that this was not appropriate and a troublesome precedent for other ethnographers. The Chair (a psychologist) replied graciously and said that the committee was in error as they had assumed field notes were the equivalent of a video (which the 'subjects' are allowed to view and amend/erase).

While this story has a happy ending, it is still troubling that an IRB at a leading research university would make such an inappropriate, ill-informed demand. A less self-assured, perhaps less senior, researcher might well have bowed to the requirement, at the expense of both the research and the welfare of the people being studied.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-MedAnthro&month=1005&week=d&msg=y0qeXnU%2bP3briAafSJt8ZQ&user=&pw=
2. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-MedAnthro&month=1005&week=e&msg=j%2bfmv8GUddyESABuw/051A&user=&pw=

5.6.3 A Plea for "Networked Learning" (2010-06-26 21:36)

Alexander Halavais reports on a [1]recent workshop sponsored by the Digital Media and Learning Research Hub, which brought together experts to discuss the challenges that IRBs pose to research in digital media.
Having agreed that IRB review sometimes produces unnecessary delays, particularly when multiple IRBs must sign off on a collaborative project, the workshop participants

> found that while there might be some fairly intractable issues, as there are for any established institution, some of the difficulties that IRBs and investigators encountered were a result of reinventing the wheel locally, and a general lack of transparency in the process of approving human subjects research. The elements required to make good decisions on planned research tend to be obscure and unevenly distributed across IRBs. From shared vocabularies between IRBs and investigators, to knowledge of social computing contexts, to a clear understanding of the regulations and empirical evidence of risk, many of the elements that delay the approval of protocols and frustrate researchers and IRBs could be addressed if the information necessary was more widely accessible and easily discoverable.

> Rather than encouraging the creation of national or other centralized IRBs, more awareness and transparency would allow local solutions to be shared widely. Essentially, this is a problem of networked learning: how is it that investigators, IRB members, and administrators can come quickly to terms with the best practices in DML research? Not surprisingly, we think digital media in some form can be helpful in that process of learning.

That is not an implausible idea. Plans for IRBs to share problems and solutions date back to the early 1970s, and they resulted in such institutions as PRIM &R and the journals, IRB: Ethics & Human Research and, more recently, the Journal of Empirical Research on Human Research Ethics. But these are fairly low-bandwidth channels: infrequent conferences and journal issues, with a few dozen sessions or articles per year, and devoted primarily to biomedical research. Hardly enough to generate a sustained discussion of an issue like social computing.
Alternatively, there exist online exchanges, like the [2]IRB Forum. But these may lack the rigor of the journals. Rather than offering "empirical evidence of risk," as Halavais wants, they can amplify unrealistic fears. As Norman Bradburn testified before the [3]National Bioethics Advisory Commission in 2000:

> What is bothersome to me is that – and the trend that I see in IRB's – is that they are becoming more and more conservative, that is there is a kind of network at least in the ones that – there is a kind of – I do ont know what you call it – ListServ kind of network that administrators of IRB's communicate with one another and they sort of say here is a new problem, how do you handle that, and then everybody sort of responds. And what happens is the most conservative view wins out because people see, oh, gee, they interpret it that way so maybe we better do it too. So over time I have seen things getting more and more restrictive . . .

May I suggest, then, that without proper supervision, digital media can be a liability rather than an asset. The challenge for Halavais and his colleagues is to build a conversation that combines immediacy and scholarly care.

1. http://dmlcentral.net/blog/alexander-halavais/rethinking-human-subjects-process
2. http://www.irbforum.org/
3. http://bioethics.georgetown.edu/nbac/transcripts/apr00/apr_6.pdf

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Anonymous (2010-07-02 23:36:31)
Nothing anybody else's IRB does is of any interest whatsoever to my IRB. They are autonomous judge, jury, and firing squad–and they like it that way. Network away: so long as IRBs exist, there will be egregious examples of arbitrary and capricious censorship.

5.7 July

5.7.1 Librarians Ponder IRB Resolution (2010-07-02 13:04)

On June 29, at the American Library Association's Annual Conference, Melora Ranney Norman proposed a "[1]Resolution on Institutional Review Boards and Intellectual Freedom."
Norman, a former chair of the ALA's Intellectual Freedom Round Table, noted that

> Despite the fact that walking down the street is more dangerous than any conversation could ever be, on some college and university campuses, assertions of liability or vague, unproven risk are allowed to trump any actual proof of risk or danger, to the detriment of the preservation of knowledge and the human record.
>
> Libraries are all about preserving and providing access to the human record with all its pimples, bumps, and bruises. Many of us have heard a quote attributed to Jo Godwin asserting that "A truly great library contains something in it to offend everyone." If the human record is not created to begin, how can we collect, preserve, and provide access to it?

She then called for the ALA to "[support] the American Historical Association in its position on oral history Institutional Review Board exemption, and [join] with the American Association of University Professors in recommending that 'research on autonomous adults whose methodology consists entirely in collecting data by surveys [or] conducting interviews . . . be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.'"
The [2]ALA Council voted to refer the resolution to the Intellectual Freedom Committee, the Library Research Roundtable, the Library History Roundtable, and the Committee on Professional Ethics. The American Historical Association hopes [3]"they will reconsider the decision and support our efforts after further review."
Norman has also posted a [4]Q & A, IRBs and Intellectual Freedom.
Hat tip: Rob Townsend.

1. http://emelora.typepad.com/librarystuff/2010/06/institutional-review-boards-and-free-speech.html
2. http://alaohchapcoun.wordpress.com/2010/06/29/ala-council-iii/
3. http://blog.historians.org/what-we-are-reading/1082/what-were-reading-july-1-2010-edition
4. http://emelora.typepad.com/librarystuff/2010/07/q-a-irbs-and-intellectual-freedom.html

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5.7.2 Social Work Research Gets Few Exemptions (2010-07-12 11:34)

Stephanie Valutis and Deborah Rubin, both of Chatham University, sought "to explore the attitudes toward, knowledge about, and practices of IRBs across colleges and universities as reported by BSW [bachelor of social work] and MSW [master of social work] program directors as they pertain to faculty and student research."
[Stephanie Valutis and Deborah Rubin, "[1]IRBs and Social Work: A Survey of Program Directors' Knowledge and Attitudes," Journal of Social Work Education 46 (Spring/Summer 2010): 195-212, DOI 10.5175/JSWE.2010.200800059.]
They sent a survey to social work programs around the country, receiving 201 responses. They asked both factual questions about the composition and operations of the IRBs, and questions about the program directors' attitudes.
Among the key findings:

- Familiarity improves attitudes. "Respondents who reported higher levels of knowledge about their IRBs had more positive responses to several attitude questions." (201)
- IRBs grant few exemptions for three types of social work research: closed case files (28 percent of IRBs consider them exempt from review), satisfaction surveys (23 percent), and staff interviews (16 percent). The article does not go into depth about what each type of research entails, why an IRB might choose to require review, or whether social work program directors believe such research should be exempt. (205)
- IRBs take a long time to approve research. While about half of program directors reported that the exempt and expedited reviews took less than two weeks, 17 percent reported exempt reviews taking one month or longer,

and 11 percent reported expedited reviews taking that long. Thirty-seven percent reported full reviews taking one month or longer. And this question produced many "Do not know" responses, so the true level of delay may be much higher. (205)

- Some students aren't allowed to do research with human subjects. Seven percent of program directors reported that "social work students were not permitted to do research that required IRB approval." (206)

I have my doubts about the usefulness of this survey, for two reasons. First, the survey posed factual questions (e.g., "How long does it take for initial review of an expedited submission?") to program directors who had no easy way of finding out this information. The authors rightly note that "the many 'don't know' responses" suggest a lack of transparency in IRB operations. But a better survey would have reached IRB administrators or chairs as well, allowing for some comparison. [For an example of this type of survey, see Robert E. Cleary, "The Impact of IRBs on Political Science Research,"IRB: Ethics and Human Research 9 (May-June 1987): 6-10.]

As for the attitudinal questions, they only allowed respondents to agree or disagree with positive statements about IRBs, e.g., "The IRB process helps students learn research ethics." I can't credit the conclusion that "We did not find the frustration with the process and scope of IRB reviews discussed in the broader social science literature," when the survey offered no opportunity to register such frustration. In his pioneering IRB survey of 1976, Bradford Gray understood the need to give respondents a chance to react to more critical statements, e.g., "The review procedure is an unwarranted intrusion on an investigator's autonomy–at least to some extent." [Bradford H. Gray, Robert A. Cooke, and Arnold S. Tannenbaum, "Research Involving Human Subjects," Science, new series, 201 (22 September 1978): 1094-1101] This survey should have done the same.

Indeed, while Valutis and Rubin cite a fair amount of IRB-related scholarship, it is not clear that they read any previous surveys of this sort before designing their own. Rather, they report concerns about the use of "a new survey instrument." (209)

The article also shows some confusion about federal regulations. It states that "Calling research 'exempt' by federal guidelines means that the research poses no risk to human subjects." While it is true that the 1981 Federal Register announcement of the exemptions describes them as exempting "broad categories of research which normally present little or no risk of harm to subjects," little risk is not the same as "no risk." And the regulations themselves exempt some research, e.g., interviews with public officials, regardless of risk. Later, the article claims that "an example of criteria for exemption by federal guidelines is research that does not pose more than minimal risk to human subjects." Actually, that's the criterion for expedited review, not exemption. Finally, the article claims that "Federal regulations require that IRBs make IRB membership available by name, role on the board, and earned degrees, but this information may not be widely disseminated." Indeed, that information is included on federal assurances, but those assurances are rarely made public.

Valutis and Rubin have raised important questions about how IRB oversight affects the education of social work students. But complete answers will require further research.

1. http://cswe.metapress.com/content/k215255011v83424/

5.7.3 Librarian Urges Cooperation with IRBs (2010-07-16 08:09)

Maura Smale, information literacy librarian at the New York City College of Technology, suggests that librarians "embrace research involving human subjects" and seek IRB approval to do so.

[Maura A. Smale, "[1]Demystifying the IRB: Human Subjects Research in Academic Libraries," portal: Libraries and the Academy 10 (July 2010): 309-321, DOI: 10.1353/pla.0.0114]

Smale notes that librarians can interact with IRBs in two ways. First, they can serve as IRB members or consultants, helping researchers and reviewers inform themselves about a proposal. Better library research, she suggests, [2]could have prevented the 2001 death of Ellen Roche, a volunteer in a Johns Hopkins University asthma study. Smale could also have mentioned that better library research might prevent unreasonable IRB demands.

Second, librarians can act as researchers. Smale offers as examples two of her own studies of student and faculty users of her library. She found value in the approval process:

> While it was a lengthy and labor-intensive process, obtaining IRB approval was an experience with real value, not simply a bureaucratic hurdle to overcome. Applying to the IRB required us to think deeply and critically about the goals for our research project while still in the early planning stages of the study; navigating the IRB approval process helped us make our research project both stronger and more relevant. Additionally, because we created all of our materials for the IRB application, we were ready to get started on our project as soon as the IRB approval came through, which saved us time at the beginning of our study. (317)

Smale does note that approval took five months, leading the skeptic to ask whether the same deep thinking could have been achieved in less time by another form of review.
Most of Smale's article is less of an argument than an introduction to IRBs for librarians new to the concept. (309). While it serves reasonably well for this purpose, the article unfortunately includes some factual errors that deserve correction:

- "Any study involving human subjects that meets the definition of research in the Belmont Report requires review by the IRB." (312) In fact, the Belmont Report has no legal force, and it is the definition of research in 45 CFR 46 that determines the need for IRB review. That this definition does not match the definition in the Belmont Report suggests the imprecision of the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (More on this in [3]Ethical Imperialism.)
- "There are three levels of IRB review—exempt, expedited, and full. The IRB evaluates each research project and determines the level of review required; researchers may not make this determination on their own." (312) Exempt means exempt; it is not a level of IRB review. The regulations do not forbid researchers from making the exempt determination. And not even [4]OHRP's recommendations insist that an IRB be involved in that determination.
- "Certain types of studies automatically meet the criteria for exemption set forth in the Common Rule, including research on 'normal educational practices' such as curriculum design, instruction, and assessment. Research involving use of previously collected data is also usually exempt. In both cases the subjects' anonymity must be preserved." (313) The "normal educational practices" exemption, [5]45 CFR 46.101(b)(1), imposes no requirement of anonymity. The existing data exemption, 45 CFR 46.101(b)(4), does not require anonymity if the data are publicly available.
- "Library research projects that include procedures in which the researcher is in direct contact with the subject will usually be required to undergo expedited review by the IRB." (315) Perhaps this is the practice at Smale's institution, but the regulations exempt this kind of research unless "any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation." [45 CFR 46.101(b)(2)]. This would not seem the case in the kind of research Smale proposes concerning "the use of space in the library" or "collaboration between the library and the campus writing center." (318)
- "It is worth noting that the underlying principles used by the IRB to evaluate projects involve ethical treatment of subjects and preservation of privacy and are similar to the recommendations of many discipline-specific professional organizations, including the Oral History Association and the American Anthropological Association." (316). For over a decade, the [6]Oral History Association has been fighting IRB requirements and insisting

on the differences between the ethics of medical research and the ethics of oral history. ~~Smale does cite the CITI Program in support of this assertion, but she fails to notice that the CITI Program offers no support for its statement.~~ {See comments for a correction.]

I am grateful to Smale for sharing her experience and for her kind citations to this blog and to my scholarship. But I fear that she has too readily accepted the claims of IRB administrators and training programs, leading her to advise librarians to tolerate months of delay when they should be demanding swift exemption.

1. http://muse.jhu.edu/journals/portal_libraries_and_the_academy/v010/10.3.smale.html
2. http://newsbreaks.infotoday.com/nbreader.asp?ArticleID=17534
3. http://jhupbooks.press.jhu.edu/ecom/MasterServlet/GetItemDetailsHandler?iN=9780801894909&qty=1&source=2&viewMode=3&loggedIN=false&JavaScript=y
4. http://www.institutionalreviewblog.com/2009/10/ohrp-grudgingly-okays-self-exemption.html
5. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101
6. http://www.oralhistory.org/do-oral-history/oral-history-and-irb-review/

Maura (2010-07-16 19:11:44)
Thanks for reviewing my article, Zachary. I enjoyed your article in the Journal of Policy History and look forward to reading your book.
I'd like to respond to your notes about my article:
My understanding from the training I attended is that the definition of research is essentially the same in the Belmont Rule and the Common Rule. Thanks for the clarification.
I agree that level is a poor word choice–my intention was to convey that once an application is submitted to the IRB there are usually three outcomes, which I believe is still clear. At my university researchers are not permitted to determine whether their study meets the criteria for exemption.
Another case in which my institution's requirements differ from the Common Rule.
You're right that this is the practice at my university. From what I've read about librarian researchers' experiences at other institutions (which is admittedly limited–there's not much published), it's the practice as well. My IRB's comments about these projects centered on whether revelations about students' academic behaviors/performance could impact their reputation/employability.
I know that oral historians (and anthropologists) have been protesting IRB requirements, but I thought it was worthwhile to point out that protection of research subjects is important to both researchers and the IRB. I'm not sure I understand the relevance of the CITI Program here – in the citation for this sentence I include the AAA's Code of Ethics and an article by Rachel Vagts, an archivist, in which she discusses the OHA (the [1]OHA Evaluation Guide's Principles and Standards offers similar information).
You are correct that my primary goal for the article was to introduce the IRB process to librarian researchers, many of whom (especially junior faculty) are new to human subjects research and are likely not familiar with the IRB.
I completely agree that the IRB process is flawed for much research in the behavioral and social sciences as well as unnecessarily lengthy. (Believe me, those 5 months stretched on.) But that discussion didn't fit within the scope of my article, so I included only a brief introduction to the topic in the endnote. Fear of the complexity of IRB regulations has led librarian researchers I know to simply avoid any research involving library users. I felt that a lengthy catalog of problems with IRB approval in the social sciences and humanities would discourage human subjects research in libraries.
I would rather encourage librarians to undertake these kinds of projects. Once engaged, I suspect that many librarian researchers will become interested in working for change in the IRB process (as you note re: [2]the ALA resolution proposed recently).

1. http://www.oralhistory.org/wiki/index.php/Evaluation_Guide
2. http://www.institutionalreviewblog.com/2010/07/librarians-ponder-irb-resolution.html

Zachary M. Schrag (2010-07-19 13:05:49)
Thank you for these comments.
I think it important to distinguish between the provisions of 45 CFR 46 and the additional requirements imposed by your institution. Not all academic librarians will face a regime as burdensome as yours. And even those who do will need to decide whether to accept or challenge the strictures on their research. They deserve the most precise information possible.
As for oral history, I am afraid I misread footnote reference 39 as 30, leading me to misunderstand the source of your claim. That said, I don't think the brief mention of oral history does justice either to the Vagts article or to the broader debate about

IRBs and oral history. Moreover, the 2000 OHA Evaluation Guidelines you cite in your comment are no longer in effect. In 2009, the OHA replaced them with its [1]Principles and Best Practices. By removing the language about exploitation, the new document further distanced the OHA from the medical ethics of the Belmont Report.
I would be interested to learn more about your own research, whether you agree that students faced a realistic risk of unemployability as a result of discussing their use of the library, and why it took the IRB five months to find a way to mitigate that risk.
I applaud your wish to encourage research by librarians. But I don't think that goal is best served either by understating the difficulties they will face or overstating the legal or empirical bases of IRB power.

1. http://www.oralhistory.org/do-oral-history/principles-and-practices/

Maura (2010-07-21 14:47:57)
The main reason that it took so long for the project to go through review is that the IRB requested that I submit a complete list of interview and survey questions that I planned to use in my study, so there was one set of revisions during the process. My current research includes interviews with students to discuss their scholarly habits, how they complete coursework and their study strategies. It's difficult to say whether the details that students discussed with me during their interviews could have a negative impact on them during their college careers or on their future employability. I learned about the courses they took and they ways they prepared (or didn't) for their assignments, in addition to their library use (or non-use). That knowledge might affect the way those students are perceived by faculty or employers if they were able to identify individual students. In this case it didn't feel particularly onerous to obtain informed consent and to protect students' anonymity.

Zachary M. Schrag (2010-07-21 22:05:22)
Thank you for this comment. I would suggest that demanding "a complete list of interview and survey questions" in advance is a particularly inefficient form of human subjects protections. A better system would have let you proceed with your research, and then reviewed your manuscript prior to publication to see if it contained anything hazardous to the participants. See Carole Gaar Johnson, "Risks in the Publication of Fieldwork," in Joan E. Sieber, ed., The Ethics of Social Research: Fieldwork, Regulation, and Publication (New York: Springer-Verlag, 1982), 87. Such a system could have reduced the time of review from months to hours.

Maura (2010-07-23 13:04:29)
Thanks for recommending the Johnson article, Zachary, I'll take a look.

5.7.4 SACHRP to Discuss Internet Research (2010-07-19 14:25)

[1]The July 21 meeting of the Secretary's Advisory Committee on Human Research Protections will sponsort a panel entitled "The Internet in Human Subjects Research," featuring Elizabeth Buchanan, Montana Miller, Michael Zimmer, and John Palfrey. It should be an interesting session. Unfortunately (and ironically), SACHRP has stopped posting transcripts of its meetings, so it's not clear how much of the content will be available to Internet researchers. I am told the [2]meeting minutes will be posted at some point.

1. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-10/agenda.html
2. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-10/mtg07-10.html

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5.7.5 Hospital IRB Forbids Interviews with Patients (2010-07-28 12:11)

The Yale Interdisciplinary Center for Bioethics offers an interview project as one of its [1]Cases in Research Ethics, which describe choices faced by hospital IRBs in Connecticut.
[2]Case 3 concerns a nurse who was also a divinity school student, and who gained approval from her hospital's

IRB to interview fifteen "hospital patients who were suffering from a progressive and/or life-threatening disease such as cancer" about their religious beliefs and practices and the role of religion in their feelings about their illnesses. Patients agreed to participate after "a thorough review of the purpose of the study, the nature of the questions and the time involved for participation."

Eleven interviews went fine. Then the twelfth patient "became agitated and demanded the researcher leave immediately. The researcher spoke with the hospital nurses and was informed that this subject had 'fallen away' from her prior religious involvement and had wondered if her malignancy was divine retribution for her lapse."

The researcher dutifully reported this as an adverse event. The IRB then reconsidered the project and voted 10 to 1 to forbid the researcher from interviewing the three additional patients.

As described in the case study, the IRB recognized that, collectively, it knew little about this kind of research. "While this IRB was routinely accustomed to addressing the standard types of adverse medical events seen in oncology drug trials, it did not consider the possibly significant adverse psychological consequences of asking these same subjects about their religious and spiritual beliefs vis-à-vis their disease."

Yet the IRB's awareness of its ignorance did not prevent it from stopping the research project. The case study does not give the reason for this decision.

Was the IRB constrained by federal regulations? No, 45 CFR 46 exempts interview research unless it "could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation." There is nothing in the case study to indicate that was a concern.

Did the IRB conclude that any study that might agitate a patient is unethical? One hopes not, for such a decision would prevent just about any discussion with any patient, particularly seriously ill ones.

Did the IRB decide that such research is permissible, but only if the researcher takes specific measures to avoid upsetting an interview participant? This seems not to be the case, for the IRB did realize that no protocol can predict who will become upset by a question. According to the report, the IRB "concluded it was highly unlikely for the researcher to reliably have screened and thus excluded subjects who may have been troubled by this line of questioning or to have predicted which subjects might have been at highest risk of experiencing such reactions. In addition, screening and thus excluding such patients from study participation might seriously have undermined the scientific validity of the study." Moreover, if the IRB had thought of some additional measures the researcher could have taken, it could have allowed the remaining three interviews under those conditions.

Perhaps the IRB decided that because "the researcher did not precisely delineate a research hypothesis," her research was not valuable enough to risk upsetting another patient. But how can an IRB that has admitted its own unfamiliarity with social research judge the value of such research?

There may be additional details, not included in the case study, to explain the IRB's decision. But I fear that this IRB shut down the research not because it had upset a patient, but because it had upset the IRB. The IRB system is premised on the idea that risks and benefits are predictable. By challenging that premise, this project forced the IRB to face its own limits. And while the IRB reacted by pledging "to seek consultative advice in the future when faced with certain types of socio-behavioral studies," it apparently stopped the project without such consultation.

This decision to block future interviews punished not only the researcher but also the three patients denied a chance to talk to her. By forbidding these adults from deciding for themselves whether they wished to speak with someone about their disease and their beliefs, even if it upset them, the hospital failed to treat its patients with the respect they deserve.

Forbidding consenting adults from talking with each other is a grave act. While there may be occasions when it is necessary to shield patients from an incompetent or unethical researcher, this case study does not provide the justification for this measure.

NOTE: Another case in the series, "[3]An ethnographic study of homeless adolescents, describes an IRB with a much better sense of what prospective review of a protocol can and cannot do. Through careful reading of the federal regulations, it was able to approve a plan for a challenging ethnography with no major modifications.

1. http://www.yale.edu/bioethics/research_irbcases.shtml
2. http://www.yale.edu/bioethics/irbcase3.htm
3. http://www.yale.edu/bioethics/irbcase7.htm

Alan (2010-07-28 14:44:12)

Is this a real case or one created for training purposes? I couldn't tell.

As someone who has been both in the research role and IRB reviewer role on similar studies this strikes me as an account of the IRB failing to recognize that it lacked the experience and knowledge to do a proper review. The problem is compounded by the fact the interviewer also seems to lack experience. And, when a problem arose, the IRB failed to address it appropriately. It should have sought the necessary expertise, and required changes to the protocol and consent process.

You write: "The IRB system is premised on the idea that risks and benefits are predictable." Well unexpected things happen, and that's recognized in the regulations, but in this case it shouldn't have been that hard to say "Gee, this person is interviewing people who may be dying about their religious beliefs in relation to their illness. Maybe that might bring up thoughts of impending death that could be distressing. Has the researcher considered this possibility and has she considered how to conduct these interviews in a way that minimizes the risk of distress to the subject?"

Usually in interview studies where there is a possibility, even a small one, that the interviewee might become upset, there should be some type of contingency plan in the protocol if the interviewee appears to be showing signs of distress. The interviewer may be required by the protocol to ask the interviewee if they wish to continue or the interviewer may on their own accord decide it is best to terminate the interview. In some research interviewees may be offered access to counseling and other services. And all this should be covered in the informed consent i.e. the subjects should be informed that there is a possibility that the questions might cause distress, that participation is voluntary, that they can refuse to answer specific questions and that they can stop at any time.

IRBs are not perfect but this strikes me as a good example of why some sort of independent review of social science research, in accord with the regulatory requirements, which was not the case in this instance, is important. True, much social science research doesn't involve significant risk and should probably be treated as exempt, but there are plenty of research activities undertaken by social scientists where the IRB has an important role in identifying risks that the researchers have failed to consider and prepare for.

Zachary M. Schrag (2010-07-28 21:39:59)

Thank you for these comments.

First, my impression is that the Yale case studies are based on real events. They have been anonymized, though unless details have been substantially changed, it should be possible to identify the researchers involved once they publish their findings, if not before.

Second, I agree with you that strategies exist to prepare a researcher for this kind of interview. [1]Dr. Lois Sadler's comment on this case cites some literature offering such strategies, of which the most relevant appears to be Karen Kavanaugh, and Lioness Ayres, "[2]Not as bad as it could have been: Assessing and mitigating harm during research interviews on sensitive topics," Research in Nursing and Health 21 (1998): 91-97. But Kavanaugh and Ayres do not claim that any strategy will prevent all participants from getting upset. People who are in pain will, at times, express that pain, and there is nothing wrong with that. And keep in mind that this researcher, a trained nurse, did have a plan: she explained to the patients what the project was about, and when one asked her to leave, she left. It's not clear to me that any other action would have been better.

Finally, it would be lovely if IRBs played "an important role in identifying risks that the researchers have failed to consider and prepare for." But the system we have now gives IRBs enormous power to shut down research without requiring them to know anything about that research. This mismatch between knowledge and power regularly produces the kind of arbitrary decision-making we see here.

1. http://www.yale.edu/bioethics/comment1case3.htm
2. http://www3.interscience.wiley.com/journal/33709/abstract

5.7.6 Smithsonian Frees Oral History, Journalism, and Folklore (2010-07-30 09:15)

The Smithsonian Institution has posted a document entitled "[1]HUMAN SUBJECTS RESEARCH FAQs." Although undated, the document appears, from its metadata, to have been last modified on 11 June 2010.

The document makes the Smithsonian the latest in [2]a growing number of prestigious research institutions to provide oral historians, journalists, and folklorists explicit permission to do their work without contacting the IRB. Here are

the key questions and answers:

> 6. Are there any examples of activities that aren't considered Human Subjects Research?
> The following are specifically excluded from the definition of Human Subject Research and do not need to be reviewed by the IRB:
> • interviews used to provide quotes or illustrative statements, such as those used in journalism;
> • collection(s) of oral histories and cultural expressions (e.g., stories, songs, customs, and traditions and accounts thereof) to document a specific historical event or the experience of individuals without intent to draw statistically or quantitatively-based conclusions or generalizations;
> • gathering of information from a person to elucidate a particular item (or items) in a museum collection;
> • gathering of information from a person to assess suitability for and/or supplement a public program, publication, or cultural performance; or
> • survey procedures, interview procedures, or observations of public behavior that are conducted for Smithsonian internal purposes only, the results of which will not be published or presented in a public setting (e.g., at conferences or professional meetings).
> 7. I think my project is an "oral history" and doesn't need to be reviewed by the IRB. How can I be sure?
> The hallmark of an oral history is that it stands alone as a unique perspective rather than an item of data that can be qualitatively analyzed to reach a general conclusion or explanation. If your intention is to interview people who have a unique perspective on a particular historical event or way of life, and you also intend to let the individuals' stories stand alone, with no further analysis, the research is most likely oral history and you do not need to have the research reviewed by the IRB. However, if the surveys or interviews are conducted with the intention of comparing, contrasting, or establishing commonalities between different segments or among members of the same segment, it is safe to say your research will be regular survey/interview procedures, because you will be generalizing the results and your research may need IRB review.

While it is welcome, I can't say this is the most elegant policy. It is hard to track a researcher's intentions and post-interview decisions, rather than his or her conduct of the interviews themselves. And wouldn't a journalist gathering reactions to an event be "comparing, contrasting, or establishing commonalities between different segments or among members of the same segment"?
By contrast, [3]Princeton University distinguishes among types of interviews based on the likelihood that the people being interviewed will understand that they are speaking for the record.

1. http://www.si.edu/osp/Compliance/Human%20Subjects%20in%20Research/HUMAN%20SUBJECTS%20RESEARCH%20FAQs.doc
2. http://www.institutionalreviewblog.com/2010/04/more-universities-deregulate-oral.html
3. http://www.princeton.edu/orpa/compliance/IRB%20flowchart%20memo.htm

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5.8 August

5.8.1 Like the blog? You'll love the book! (2010-08-02 21:45)

I am proud to announce the publication of my book, Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009.
The book and the blog are complementary. The former traces the history of IRB review of research in the social sciences and humanities from its origins in the mid-1960s through last year, while the latter documents the ongoing

debate over such review. I hope that everyone with an interest in the present debate will share my interest in its past. The Johns Hopkins University Press has graciously offered a 25 percent discount to readers of this blog: [1]please download the "Now Available" flyer. Books should begin shipping by the end of next week.

1. http://zacharyschrag.com/files/ethical_imperialism_flyer.pdf

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Anonymous (2010-08-03 10:31:35)
Amazon sell it for a couple of dollars cheaper than the JHUP discounted price and there's a free shipping option.

Zachary M. Schrag (2010-08-03 11:00:06)
Thanks for pointing this out. Amazon's prices fluctuate widely and mysteriously, so it may or may not be the cheapest option at any given time.

5.8.2 More Universities Uncheck Their Boxes (2010-08-06 16:10)

In 2006, the American Association of University Professors filed a Freedom of Information Act request for a list of all U.S. colleges and universities whose Federalwide Assurances (FWAs) did not check the box on the form pledging to apply federal regulations to all human subjects research, regardless of funding. The list contained 174 entries, though 12 of those were duplicates. (See "[1]IRB Documents" for these lists. _
In March 2010, I reported that [2]OHRP estimated that 26 percent of U.S. institutions had unchecked their boxes, up from only about 10 percent in the late 1990s. Curious about this trend, I requested an updated list, and in April 2010 I received a spreadsheet showing all institutions (including hospitals, health departments, commercial labs, and other health institutions) with unchecked boxes.
Making sense of this list took some processing, which accounts for the delay between my receiving the spreadsheet and this post. I did my best to extract institutions of higher learning, and came up with a list of 207 colleges and universities. Then I compared that list to the 2006 list sent to the AAUP.
Only 60 institutions appear on both the 2006 and 2010 lists. One hundred and two had unchecked boxes in 2006 but not 2010, while 147 unchecked their boxes between 2006 and 2010.
Major research universities appear on both lists. Between 2006 and 2010, William & Mary, Johns Hopkins, Princeton, and the University of Connecticut, went from unchecked to checked. Meanwhile, those unchecking boxes included Arizona, Boston University, Brandeis, Emory, George Washington University, Illinois at Urbana-Champaign, Indiana, Michigan State, Minnesota, Northwestern, Notre Dame, Ohio State, University of Pennsylvania, Texas at Austin, Tufts, UCLA, and the University of Southern California. This suggests that the trend is for major research institutions to uncheck. (Apologies to major universities not mentioned; this is my eyeball list, not an effort to correlate the list to Carnegie rankings or anything.)
An unchecked box minimizes a university's exposure to federal oversight and sanction. It does not, however, necessarily change anything for a university's researchers. My own institution, George Mason University, unchecked its box sometime between 2006 and 2010, but the administration has told faculty that it intends to apply all federal regulations to all research, regardless of funding. I imagine the same is true at many of the institutions that have unchecked their boxes.
Update, 15 May 2012, to fix link to "IRB Documents."

1. http://zacharyschrag.com/irbs/irb-documents/
2. http://www.institutionalreviewblog.com/2010/03/twenty-six-percent-of-boxes-go.html

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5.8.3 After Lawsuit, Arizona State IRB Hindered Native American Interviews (2010-08-11 11:58)

Kimberly TallBear, assistant professor of science, technology, and environmental policy at Berkeley, describes her encounters with IRBs there and at Arizona State University. At the latter, the IRB imposed conditions that made her abandon plans to interview Native Americans.
["[1]Interview with Kimberly TallBear," GeneWatch, May/June 2010.]
As she puts it:

> IRBs vary from university to university, and some are much stricter than others. For example, the Arizona State University IRB is, after the [2]Havasupai lawsuit, incredibly strict where tribes are concerned. If you're going to do research with native populations, whether it's biological research or even social science research, you have to get approval from the tribal council before the university will even look at your protocol. On the other hand, I'm doing a project at Berkeley where I'm interviewing both genetic scientists and tribal government people, and Berkeley didn't look twice at my interview with indigenous people. I asked if they require some sort of documentation that I got approval from the tribe, and they said, "No, no, no, that's not a problem." So there are differences between IRBs as well as between disciplines . . .
>
> I'm not an expert on IRBs, but I can speak from personal experience—I have worked at both Arizona State and Berkeley, so I have seen the huge differences in IRBs. In short, the difference is that ASU has been sued. Before the Havasupai suit, ASU was lax as well.
>
> I was at ASU in 2006 and 2007. As a social scientist, I was interviewing a range of people—native people, scientists, regulators—and the IRB was very strict about allowing me to talk to tribes. I had interviewees at five or six tribes, which meant I would have had to go through each one of those tribes to get approval for those interview questions. So, in order to get approval for my science piece, I backed out of the Native American community member questions.
>
> This was also really interesting: I study the culture and politics of genetic science, and I think they should have been more strict and careful about my research questions for scientists. In my work, scientists are potentially vulnerable subjects. Now, I don't actually think they are very vulnerable—I think they actually have a lot more cultural authority than I do in the broader world—but I'm a potential critic. While the native populations were seen as potentially vulnerable subjects, it didn't seem to have crossed the IRB's minds that scientists could be potentially vulnerable subjects, too.
>
> It was the opposite at Berkeley, actually: they were much, much more concerned about my questions for scientists and protecting their confidentiality, and they seemed not at all concerned about my questions for indigenous people, at least from my perspective.

TallBear does not appear angry that the the ASU IRB's strictness forced her to "back out" of planned interviews. Rather, she seems to wish that IRBs were even stricter: "What IRBs require is a bare minimum of the standards that you have to meet to conduct ethical research. IRB approval doesn't constitute a thorough process." And, later, "you see people who have just decided they don't want to work with tribes, because they don't want to have to go through a tribal research review board, they don't want to let a tribal council or a tribal IRB have a say over whether they can publish something or not. I think that's a good thing . . . Go do something else!"
It is not clear from the published interview whether she believes that such discouragement is appropriate only for geneticists and other biomedical researchers, or if she is happy to let tribal governments control the writings of social scientists and journalists as well.

1. http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=265
2. http://www.nytimes.com/2010/04/22/us/22dna.html

Anonymous (2010-08-12 07:57:01)
She also does not indicate whether ASU won or lost the suit, but it does underscore that a major issue with IRBs is not the protection of research subjects, but the protection of the university.

Zachary M. Schrag (2010-08-12 10:48:32)
Thank you for your comment.
The lawsuit was settled in April 2010; see the Amy Harmon, "[1]Indian Tribe Wins Fight to Limit Research of Its DNA," New York Times, 21 April 2010.
I do think this is an illustration of a university restricting social scientists after the misdeeds of biomedical researchers.

1. http://www.nytimes.com/2010/04/22/us/22dna.html

Anonymous (2010-08-13 07:40:03)
Thanks for the link. I was struck by a charge mentioned in the article, that one form of "harm" experienced by the Havasupai was that the DNA evidence contradicted their origin myths. An interesting point – presumably anthropologists studying native peoples will have to be cautious not to publish anything that contradicts their traditional beliefs. And historians will have to be careful not to publish facts that contradict popular stories.

Zachary M. Schrag (2010-08-13 10:13:09)
Thank you for this comment.
Federal regulations specify that an IRB "should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility." [[1]45 CFR 46.111] But since the early 1970s, there have always been some people who do want to restrict research on such a basis.
Another wrinkle here is that had TallBear followed her IRB's instructions to seek approval for interviews from a tribal IRB, it might have been powerless to impose any restrictions on her research, due to the [2]Indian Civil Rights Act. I do not know of any case law on this.

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111
2. http://www.law.cornell.edu/uscode/25/usc_sec_25_00001302----000-.html

5.9 September

5.9.1 Oral Historians Open Discussion on Principles and Best Practices (2010-09-03 11:06)

[1]As noted on this blog, in October 2009, the Oral History Association replaced its Evaluation Guidelines with a new set of [2]Principles and Best Practices. The new guidelines are considerably clearer in format, and they distance oral history from the biomedical assumptions of the Belmont Report.
Now the Oral History Association is further distancing itself from the Belmont Report by opening an [3]ongoing discussion of the principles, including suggestion for additional revisions. Whereas the Belmont Report was prepared by a small group of people and has not been amended since 1978, the OHA Principles can remain a living document, revised in response to a discussion that is open to all.
Hat tip: [4]AHA Today.

1. http://www.institutionalreviewblog.com/2009/10/oral-history-association-considers.html
2. http://www.oralhistory.org/do-oral-history/principles-and-practices/
3. http://www.oralhistory.org/2010/08/10/general-principles-and-best-practices-on-line-discussion/
4. http://blog.historians.org/what-we-are-reading/1121/what-were-reading-august-26-2010-edition

Alan (2010-09-03 11:20:12)
"...the biomedical assumptions of the Belmont Report". Such as?
The distinctions and ethical principles outlined in the Report have broad applicability to both biomedical and behavioral science.

Zachary M. Schrag (2010-09-03 11:26:41)
See my [1]earlier post on the OHA Principles and Chapter 4 of Ethical Imperialism.
Thanks.

1. http://www.institutionalreviewblog.com/2009/10/oral-history-association-considers.html

Alan (2010-09-04 15:24:08)
I haven't got a copy of your book but don't see how the earlier post answers the question. In the post you talk about the "biomedical concerns of risk/benefit analysis and equitable selection of subjects". And why aren't these concerns applicable to most social and behavioral science? I don't have an argument with you about the general lack of applicability of the Belmont Report, 45CFR46 etc. to historical research but, as a social scientist, it feels to me that you to engage in a little "ethical imperialism" of your own on this issue.

Zachary M. Schrag (2010-09-04 18:29:14)
Thanks for your comment. The two posts specifically concern the newly revised principles agreed upon by oral historians, not "most social and behavioral science."
I do not know your own discipline (or last name), so I am unable to comment on whether it has embraced risk/benefit analysis and equitable selection of subjects as criteria for ethical research. I can say that the various disciplines have their own ethical traditions, and that the authors of the Belmont Report almost wholly ignored these, investigating only the ethics of medical and psychological research.

5.9.2 IRB is No Substitute for Shield Law (2010-09-05 20:08)

Education Week reports that researchers are dismayed by the release of data about teachers and students.
[Sarah D. Sparks, [1]L.A. and Ariz.: Will Data Conflicts Spur a Chill Effect?," Education Week, 3 September 2010.]
The article discusses [2]the decision by the University of Arizona to release some data in response to a subpoena. It claims that "The Code of Federal Regulations for the Protection of Human Subjects delegates confidentiality decisions to university institutional review boards, or IRBs, but in Arizona, the IRBs released the full data over the researchers' opposition." I believe this is incorrect on three counts:

1. The Common Rule gives power to IRBs to review and approve research. Once the research was complete, it was up to the universities to decide whether to comply with the subpoenas, not the IRBs. Indeed, the [3]open letter from the researchers states that "lawyers at the University of Arizona," not the IRB, turned over information. (The letter does complain that "researchers have received little or no support from their campus IRB, lawyers, or administration," but that's a different thing.)
2. The use of the plural "IRBs" suggests that more than one university released data. As [4]Education Week itself made clear, Arizona State did not release any data, and the Arizona State professor involved withdrew as an expert witness.
3. Also [5]as reported Education Week, the University of Arizona did not hand over "full data," but rather only the names of schools and school districts, not individuals.

That said, Gary Orfield, one of the researchers in the Arizona case, hits on a larger truth when he complains of the University of Arizona's behavior:

> "I think it's tragic and very dangerous," Mr. Orfield said. "I was shocked at the way the [State of] Arizona people went after this data and that the universities just went along with it. It really calls into question not just the access to schools but the integrity of the IRB process." Mr. Orfield, Ms. Hannaway, and other researchers suggested researchers may need a federal shield law similar to state laws that protect reporters from being compelled to name sources. "We thought the IRBs served that purpose for us, but we were wrong," Mr. Orfield said.

Indeed, since the 1970s, social scientists have argued that shield laws make more sense for protecting the participants in social science research than do IRBs. [James D. Carroll and Charles R. Knerr, Jr., "A Report of the APSA Confidentiality in Social Science Research Data Project," PS 8 (Summer 1975): 258-261 and James D. Carroll and Charles R. Knerr, Jr., "The APSA Confidentiality in Social Science Research Project: A Final Report," PS 9 (Autumn 1976): 416-419.]

I haven't figured out how a shield law would apply to expert witness testimony. (Anybody looking for a good law review topic?) And even without such a law, [6]Judge Collins's order seems to strike a good balance between the rights of research participants and those of parties to the lawsuit.

Still, it seems that in this case the IRB process left Orfield with a dangerously false sense of security.

NOTE:

The Education Week article also mentions an analysis of teacher effectiveness published by the Los Angeles Times based on [7]1.5 million test scores.. It quotes Felice Levine, the executive director of the American Educational Research Association, on the L. A. Times study: " think it would really have a crippling effect on all social science, education, and health enquiry if public employees in the sector couldn't be guaranteed the same confidentiality as any other research participant . . . In this economy, people are feeling pressed in a number of ways, and being a participant in a voluntary study is probably lower on one's list of priorities than is providing for oneself and one's children."

But the newspaper analysis was not based on a voluntary study, but rather on scores obtained under the California Public Records Act. Making the scores public in this manner may have been bad policy or bad journalism for [8]other reasons, but I don't see what it has to do with voluntary participation in research.

1. http://www.edweek.org/ew/articles/2010/09/03/03privacy.h30.html?tkn=LROFSvn%2BAuYVqd6Fk1txPtTewTHqmn%2F5OQnc&cmp=clp-edweek
2. http://www.insidehighered.com/news/2010/08/23/arizona
3. http://esolfl.blog.com/az-horne-v-flores-letter-from-drs-patricia-gandara-and-gary-orfield-aug-11-2010/
4. http://blogs.edweek.org/edweek/learning-the-language/2010/09/arizona_state_didnt_turn_over.html
5. http://blogs.edweek.org/edweek/learning-the-language/2010/09/arizona_state_didnt_turn_over.html
6. http://www.edweek.org/media/order8-19-10.pdf
7. http://www.latimes.com/news/local/la-me-teachers-value-about-20100815,0,3603373.story
8. http://voices.washingtonpost.com/answer-sheet/teachers/new-study-blasts-popular-teach.html

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5.9.3 e-Thical Imperialism (2010-09-10 22:42)

Ethical Imperialism: [1]now on Kindle.

1. http://www.amazon.com/Ethical-Imperialism-ebook/dp/B0040ZN31O/ref=tmm_kin_title_0?ie=UTF8&m=AG56TWVU5XWC2

5.9.4 Survey Consent Form Language May Not Matter Much (2010-09-20 10:29)

Eleanor Singer and Mick P. Couper of the Survey Research Center of the Institute for Social Research at the University of Michigan find that the wording used to describe the confidentiality offered to survey participants may not play a big role in their decision to participate.
[Eleanor Singer and Mick P. Couper, "[1]Communicating Disclosure Risk in Informed Consent Statements," Journal of Empirical Research on Human Research Ethics 5, no. 3 (Sept. 2010): 1–8.]
Singer and Couper sent out more than 150,000 e-mails to get 9,206 responses to a questionnaire about willingness to participate in a hypothetical survey. Respondents were significantly more likely to say they'd be willing to answer questions about work and leisure than about the more sensitive topics of money and sex. In contrast,

> the precise wording of the confidentiality assurance has little effect on respondents' stated willingness to participate in the hypothetical survey described in the vignette. Nor does adding a statement on the organization's history of assuring confidentiality appear to affect stated willingness. However, these experimental manipulations do have some effect on perceptions of the risks and benefits of participation, suggesting that they are processed by respondents. And, as we have found in our previous vignette studies—and replicated in a mail survey of the general population—the topic of the survey has a consistent and statistically significant effect on stated willingness to participate.

Singer and Couper hint that researchers and IRBs should spend less time fretting about the wording of consent forms used by survey researchers, since it does not affect decisions and since it is hard to estimate the risk of disclosure. Rather, the real burden on survey orgnizations is to take precautions once they have collected the data.

1. http://caliber.ucpress.net/doi/abs/10.1525/jer.2010.5.3.1

5.9.5 Unfair IRBs Provoke Misbehavior (2010-09-26 16:13)

"Researchers who perceive that they are being unfairly treated are less likely to report engaging in 'ideal' behaviors and more likely to report misbehavior and misconduct," according to a survey of faculty at fifty top research universities in the United States.
[Brian C. Martinson, A. Lauren Crain, Raymond De Vries, Melissa S. Anderson, "[1]The Importance of Organizational Justice in Ensuring Research Integrity," Journal of Empirical Research on Human Research Ethics 5, no. 3. (Sep 2010): 67–83.]
As the authors note, this is mostly a quantitative confirmation of earlier findings. Most relevant for this blog, they cite a 2005 article by Patricia Keith-Spiegel and Gerald P. Koocher that found that "[2]The efforts of some institutional review boards (IRBs) to exercise what is viewed as appropriate oversight may contribute to deceit on the part of investigators who feel unjustly treated."
Like the [3]Singer and Couper article in the same issue, this article presents a mass of quantitative data in a difficult form. Let me suggest that the Journal of Empirical Research on Human Research Ethics invest some money in [4]decent graphs.

1. http://caliber.ucpress.net/doi/abs/10.1525/jer.2010.5.3.67
2. http://www.ethicsresearch.com/images/IRB_Paradox_EandB.pdf
3. http://www.institutionalreviewblog.com/2010/09/survey-consent-form-language-may-not.html
4. http://www.stat.columbia.edu/~cook/movabletype/archives/statistical-graphics/

5.9.6 Thanks, Law Professors! (2010-09-28 16:56)

Concurring Opinions, which describes itself as "a multiple authored, general interest legal blog," features [1]an interview with your humble blogger, while the [2]Legal History Blog also takes notice of Ethical Imperialism.

1. http://www.concurringopinions.com/archives/2010/09/bright-ideas-zach-schrags-ethical-imperialism.html
2. http://legalhistoryblog.blogspot.com/2010/09/schrag-on-irbs-and-social-sciences.html

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5.9.7 OHRP Issues Guidance on Withdrawal (2010-09-29 13:05)

On September 21, OHRP posted new "[1]Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues." The document makes it clear that if a research participant in a social science study wishes to withdraw, the researcher is not obliged under federal regulations to throw out information that has already been collected:

> May an investigator retain and analyze already collected data about a subject who withdraws from the research or whose participation is terminated by the investigator?
> OHRP interprets the HHS regulations at 45 CFR part 46 as allowing investigators to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.

Of course, in some cases, researchers may still choose to discard such data:

> For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, certainly can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis. Nothing in this document is intended to discourage such a practice. For example, an investigator studying social networks in a community may agree to omit all of the data they have collected from a subject of the study at the request of that subject.

(The clause about the FDA is due to the FDA's concern that [2]withdrawals can skew the findings of clinical trials.) This guidance strikes me as helpful. When reading sample consent forms, e.g., [3]Cornell's, I am often left wondering what is meant by the boilerplate, "you are free to withdraw at any time," especially when it comes to interviews. If a researcher does a great interview and writes a dissertation chapter around it, can the narrator show up at the dissertation defense and pull the information? (This is apparently the case with [4]undergraduate research at Bard College.) Fortunately, OHRP says no.

1. http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html
2. http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0576-gdl.pdf
3. http://www.irb.cornell.edu/forms/sample.htm
4. http://inside.bard.edu/irb/consent/ExampleInterviewConsentForm.shtml

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Anonymous (2010-10-27 10:36:45)
Thanks for this. Someone in my dept is facing this problem, and it seems that in the UK participants can withdraw and have the data collected on them also withdrawn and destroyed *at any time* in the process, even as the book manuscript is going off to print. It looks like this is not the case here in the States, though this seems to apply mostly to medical and health data. Do you know if there are any cases of this being tested or challenged in regards to a social science research project?

Zachary M. Schrag (2010-10-27 13:07:30)
I'm sorry to learn of the situation in the UK, and I hope someone brings the US decision to authorities there.
I am not aware of specific cases in the US, nor of other policies as disruptive to research as those at Bard .
Best,
ZMS

5.10 October

5.10.1 U.S. Apologizes for 1940s Human Subjects Research (2010-10-01 13:57)

This is a little off topic for the blog, but today [1]Secretary of State Hillary Clinton and Health and Human Services Secretary Kathleen Sebelius apologized to Guatemala for experiments done there in the late 1940s. Researchers led by a Public Health Service doctor conducted various studies of syphilis, some of which included the deliberate infection of people without their consent.
The story was brought to light by Susan M. Reverby, Marion Butler McLean Professor in the History of Ideas and Professor of Women's and Gender Studies at Wellesley College. Her article, "'[2]'Normal Exposure' and Inoculation Syphilis: A PHS 'Tuskegee' Doctor in Guatemala, 1946-48, will appear in the Journal of Policy History in 2011, in a special issue on human subjects research that I edited.
UPDATE: The [3]New York Times has a more complete story, including a nice mention of the Journal of Policy History.

1. http://voices.washingtonpost.com/checkup/2010/10/us_apologizes_for_1940s_experi.html
2. http://www.wellesley.edu/WomenSt/Reverby%20Normal%20Exposure.pdf
3. http://www.nytimes.com/2010/10/02/health/research/02infect.html

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5.10.2 Tell OHRP Belmont Isn't Everything (2010-10-04 22:33)

On September 23, [1]OHRP posted drafts of new FWA form and FWA Terms of Assurance. It is collecting comments on the forms until October 25.
Here is what I have come up with so far. I would welcome comments on this draft for the next couple of weeks; I'd like to submit this comment by October 15 to be sure I make the deadline.

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To the Office for Human Research Protections:
Thank you for the opportunity to comment on the draft revision of the "Terms of the Federalwide Assurance for the Protection of Human Subjects." I have two comments on this draft.
1. THE DRAFT SHOULD BE REVISED TO REFLECT THE PROVISIONS OF 45 CFR 46.103(b)(1)
I am disappointed that the current draft fails to correct a longstanding discrepancy between the Common Rule and OHRP's forms. 45 CFR 46.103(b)(1) requires that each institution receiving funding from a Common Rule agency submit an assurance that includes

> A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.

By contrast, the draft Federalwide Assurance requires U.S. institutions to pledge that they will be guided either by the Belmont Report, the Declaration of Helsinki, or "other appropriate international ethical standards recognized by U.S. federal departments and agencies that have adopted the Common Rule." I am unaware of any documents in this third category, nor of any element of the Common Rule that requires federal approval of a statement of principles.
Thus, while the Common Rule offers institutions complete freedom in their choice of ethical principles, the current and proposed Terms of the Federalwide Assurance limit them to one or two documents. This is like guaranteeing the freedom of religion, then requiring every citizen to adhere to either the Lutheran Book of Concord or the Articles of Religion of the Methodist Church.
Instead, the first paragraph should reflect the provisions of the Common Rule. I suggest the following language:

> "All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101(b) or (i)."

2. THE DRAFT SHOULD BE REVISED TO REFLECT ACCURATELY THE AUTHORSHIP AND EVOLUTION OF THE TRI-COUNCIL POLICY STATEMENT
The current draft allows non-U.S. institutions to comply based on "The 1998 (with 2000, 2002, and 2005 amendments) Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans."
This statement has two inaccuracies. First, the Medical Research Council no longer exists; it was replaced in 2000 with the Canadian Institutes of Health Research (CIHR). Second, the TCPS is authored not only by the CIHR but also by the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). (That is what makes it a tri-council policy.)
Moreover, the Panel on Research Ethics plans to release a second edition of the TCPS in December 2010, and may amend it further while the new Terms of the Federalwide Assurance are still in effect. Rather than limit institutions to an outdated version of the TCPS, OHRP should allow non-U.S. institutions to abide by the current version.

1. `http://www.hhs.gov/ohrp/requests/com0910rev.html`

5.10.3 Stark Wants to Scrap IRBs (2010-10-13 11:45)

Sociologist Laura Stark is a careful observer of the IRB system, having based her dissertation on archival research and direct observations of three university IRBs. In 2008, [1]I complained that the dissertation, "Morality in Science," reported but failed to condemn bad IRB behavior. In a newly published essay, Stark takes a more critical stance.
[Laura Stark, "[2]Gaps in Medical Research Ethics," Los Angeles Times, 8 October 2010.]
In her essay, Stark traces today's IRB system back to systems established in the 1960s at the NIH Clinical Center,

which performed experiments on "hundreds of healthy prisoners, conscientious objectors, unemployed people and students living in their hospital as subjects." She finds that system included two basic flaws: it failed to inform the public about what was going, and it gave no voice to dissenting members of ethics boards. These flaws, she argues, remain in today's system of ethics review.
To remedy them, Stark proposes that the new Presidential Commission for the Study of Bioethical Issues "rebuild the regulations from the ground up." She writes,

> New rules should include these changes:
> Replace the thousands of local review boards that labor independently at universities and hospitals here and abroad with a small number of ethics-review networks organized around specific research methods rather than around institutions. The networks would be better equipped to handle multi-site studies that are now commonplace, and would remove the political biases of some outlier institutions.
> Consider the advantages and disadvantages of outsourcing ethics review to private companies, which review research for a fee.
> Finally, empower research participants by posting the results of ethics reviews online. The current system includes community representatives who presumably speak on behalf of research participants, but that's not good enough.

Though the essay does not specifically mention IRB review of research in the social sciences and humanities, the dissertation gives examples in which the lack of transparency and lack of expertise impeded such projects. Thus, Stark's call for expert boards and published results of ethics review could address non-biomedical research as well as the medical research that is her chief concern. And while Stark presents her proposals as ways to ensure better protection for research participants, they could also benefit those researchers who now fall victim to inexpert boards. Because the current system fails both researchers and participants, reform can benefit them both.
Stark should realize that the changes she proposes would require more than "rebuild[ing] the regulations from the ground up," since the requirement for local IRBs is encoded in federal statute, not just regulations. But a wholesale reconsideration of the IRB system by the presidential commission would be a fine first step.

1. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
2. http://www.latimes.com/news/opinion/commentary/la-oe-stark-nih-20101008,0,3205598.story

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5.10.4 Dreger Wants to Scrap IRBs (2010-10-26 10:22)

On the heels of [1]Laura Stark's Los Angeles Times op-ed calling for the replacement of local IRBs with centralized boards of experts, historian Alice Dreger has published her own call for a national system of ethics review based on expertise and transparency.
[Alice Dreger, "[2]Nationalizing IRBs for Biomedical Research – and for Justice," Bioethics Forum, 22 October 2010.]
Troubled by her IRB's approval of a project she considers unethical, and by Carl Elliott's White Coat, Black Hat: Adventures on the Dark Side of Medicine, Dreger concludes that the system of local review is ineffective:

> We've reached the point where many people in medicine and medical ethics don't even expect IRBs to act as something other than liability shields for their universities. But do patients who come to us only to be turned into subjects know that? Do they know that there is literally a price on their heads put there by research recruiters?
> I've come to believe we need a radical solution. Maybe what we need is a nationalized system of IRBs for biomedical research, one that operates on the model of circuit courts, so that relationships cannot easily

develop between the IRBs and the people seeking approval. This system could be run out of the Office for Human Research Protections and involve districts, similar to the federal courts system. Deliberations would be made transparent, so that all interested parties could understand (and question) decisions being made.
Think of the advantages: the possibility of actually focusing on the protection of human subjects first and foremost, free of conflicts of interest; the possibility of having nothing but trained professionals (not rotating unqualified faculty and staff) sitting on review panels; the possibility of marking biomedical research as clearly different from the social science and educational research unreasonably managed by many IRBs; the possibility of much greater transparency to those interested in seeing what's going on; the possibility of having multi-center trials obtain a single approval from one centralized IRB, rather than trying to manage approvals from multiple local institutions. And the possibility of shutting down the deeply opaque, highly questionable private IRBs Elliott describes as being increasingly used by universities. (Go ahead, call me a Communist for caring about the Common Rule.)

Her Communist leanings aside, I don't know why Dreger presents her argument as a defense of the Common Rule, which fails to distinguish between biomedical and social research, puts ethics review in the hands of rotating unqualified faculty and staff, and keeps deliberations opaque. But her wish for the kind of coordination and transparency provided by the court system has a long lineage. I've [3]quoted it before, and I'll quote it again:

> The review committees work in isolation from one another, and no mechanisms have been established for disseminating whatever knowledge is gained from their individual experiences. Thus, each committee is condemned to repeat the process of finding its own answers. This is not only an overwhelming, unnecessary and unproductive assignment, but also one which most review committees are neither prepared nor willing to assume.
> [Jay Katz, testimony, U.S. Senate, Quality of Health Care—Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, Part 3 (93d Cong., 1st sess., 1973), 1050].

It is not lack of good intentions or hard work that leads IRBs to restrict ethically sound surveys while permitting unethical experimental surgery. It is the ignorance and isolation identified by Katz in 1973 and still in place today.

1. http://www.institutionalreviewblog.com/2010/10/stark-wants-to-scrap-irbs.html
2. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4939&blogid=140
3. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html

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5.10.5 Ohio State Restricts LGBTQ Research, Ponders Reforms (2010-10-28 09:58)

Two Ohio State University professors, James Sanders and Christine Ballengee-Morris, complain about IRBs' impacts on research and teaching in their fields and report on efforts at reform.
[James H. Sanders III and Christine Ballengee-Morris, "[1]Troubling the IRB: Institutional Review Boards' Impact on Art Educators Conducting Social Science Research Involving Human Subjects," Studies in Art Education: A Journal of Issues and Research in Art Education 49 (2008): 311-327. Yes, it's two years old, but I just found out about it recently.]
Many of the complaints are familiar enough. The authors–one in arts policy, the other in art education–lament biomedical models, delays in approvals, and "lengthy boiler-plate consent forms." Yet the article advances the conversation about IRBs in two interesting ways.

First, the article highlights the difficulty of getting IRB approval to study lesbian, gay, bisexual, transgender, and queer self-identified youth. The authors would like to know "how LGBTQ students experience the World Wide Web, art and culture, and their self-image, or how they establish resilient behaviors." But, they find, "Conservative IRB interpretations of federal regulations requiring parental consent of all human subjects under 18, may have failed to protect the rights and welfare of LGBTQ adolescent research participants, and further dissuade researchers from studying all but (safe) consenting adult heterosexual subjects."
Second, the article describes reform efforts at Ohio State. Advised by colleagues to "be intentionally vague . . . speak in generalities, or simply not tell what we were actually doing," the authors did consider "lying to a repressive and controlling body that claims to care about human subjects' protections and then denies autonomy or voice to those living with repression." Instead, they joined 160 faculty members to petition their Office of Research to reconsider its policies.
The result was the issuance in 2007 of the [2]Report of the IRB Working Group for Research in the Social and Behavioral Sciences." That report offers a number of constructive suggestions. For example,

- Relaxing the requirement that all changes to a protocol be reported to the IRB, even if they "have absolutely no material impact on a human subject's participation in a study."
- Accepting that interviewers cannot foresee in advance all the topics they may raise in a conversation.
- Informing investigators about their right to appeal decisions to the IRB chair, the full board, or the institutional official.
- Listing approved protocols, so researchers do not have to reinvent the wheel when submitting their own projects.

The 2007 report ends with a strong call for IRB policy to be shaped by the faculty. It specifically recommends the active participation of the [3]University Research Committee, which is comprised mostly of regular facutly:

> It is also important that there be continuing transparency and communication of IRB policy and procedure development among the faculty, the Office of Research, the IRB Policy Committee, and ORRP [Office of Responsible Research Practices]. To ensure that such consideration and implementation occurs, we recommend that an ad-hoc subcommittee of the University Research Committee be appointed for this purpose. This subcommittee should receive regular reports from the IRB Policy Committee regarding the development of new policies related to the Working Group's recommendations and suggestions, and from the ORRP staff regarding progress in staffing, website development, and electronic submission procedures.
> In the longer term, it is important for the University Research Committee to participate actively in the human subject protection program at Ohio State, and to assess and suggest additional improvements to the operations of ORRP and the IRB. We strongly encourage the University Research Committee to set up a means to do so.

As of their writing, however, Sanders and Ballengee-Morris had yet to see improvement:

> In short, one is required to think through every possible contingency and clearly communicate how such contingencies would be addressed. While the process itself strengthens the research design, the unreasonableness of some alternative scenarios posed by those unfamiliar with the researchers' field of study have been stifling. In response, many students and colleagues have chosen to change methods or abandon their research problems, rather than be subjected to this arduous, frustrating, and at times, humiliating process.

1. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/www.eric.ed.gov/ERICWebPortal/recordDetail?accno=EJ875601
2. http://research.osu.edu/files/2007/06/ReportoftheIRBworkinggroup.pdf
3. http://trustees.osu.edu/rules5/ru5-48.14.php

5.11 November

5.11.1 Hear Me Talk About My Book (2010-11-04 11:25)

Online Programming for All Libraries (OPAL) has posted [1]recordings of my October 27 discussion of Ethical Imperialism as full streaming audio with text chat and a downloadable MP3 audio recording. The presentation lasts 64 minutes.

1. http://www.opal-online.org/archivebooks.htm

5.11.2 IRBs and Procedural Due Process (2010-11-04 16:13)

A law student finds that "current IRB regulations fail to provide procedural due process as guaranteed by the Fifth and Fourteenth Amendments of the United States Constitution."
[Daniel G. Stoddard, "[1]Falling Short of Fundamental Fairness: Why Institutional Review Board Regulations Fail To Provide Procedural Due Process," Creighton Law Review 43 (June 2010): 1275-1327]
Stoddard notes a number of measures that might protect researchers against capricious IRBs but which are not currently required:

> Federal IRB regulations are silent . . . regarding a number of specific aspects of IRB function including public attendance of IRB functions, a researcher's opportunity to hear and cross-examine information opposing that researcher's research, and a researcher's right to privacy with regard to an IRB's media interaction. IRB regulations additionally fail to address whether an IRB should base its decision exclusively on evidence presented to it, whether a researcher should have a right to a hearing before the IRB suspends research, whether a researcher has a right to judicial review of an IRB decision, and whether a researcher has a right to an attorney. Federal IRB regulations also fail to include a researcher's right to have informal communications with an IRB, a researcher's right to present further evidence to an IRB following a rejection, a researcher's right to consult with personnel opposing that researcher's research in an effort to understand and prepare to challenge them, and an IRB's obligation to evaluate its own functioning procedures periodically. (1290)

All of these measures could be helpful, but the question for Stoddard is whether their absence violates procedural due process. His main argument is that "The inability to contest or appeal an IRB decision is a substantial procedural shortcoming when evaluated under the three prong Mathews [v. Eldridge] balancing test." In particular, he finds that "Because current institutional review board ('IRB') regulations do not provide a researcher the right to appeal an IRB's decision to disapprove, terminate or suspend research, they do not satisfy the requirements of procedural due process under the [2]Mathews v. Eldridge balancing test." (1310)
Stoddard would be more persuasive had he addressed head-on what I take to be the federal court decision that most directly addressed due process and IRBs: Halikas v. University of Minnesota. Though Stoddard cites the district

court's denial of a preliminary injunction to the plaintiff in that case, an aggrieved researcher, he does not analyze the court's reasoning behind that denial: "An IRB proceeding is, simply, not a federal criminal prosecution. Such a proceeding is governed by contracts and federal regulations which do not require, or provide, the full panoply of criminal procedural rights . . . Dr. Halikas voluntarily entered into an employment contract and conducted his research under the aegis of the University and its research-regulatory regime. He received the process which is his due." [[3]Halikas v. University of Minnesota, 856 F. Supp. 1331; 1994 U.S. Dist.]

Nor does Stoddard analyze the final judgment in that case, which was not published. [[4]Case number 4-94-CV-448, Federal District Court, Fourth Division, District of Minnesota; filed 18 May 1994; Judgment entered 9 June 1996. I am very grateful to Dr. Dale Hammerschmidt, one of the named defendants in the Halikas suit, for providing me with a copy of this document, and for his thoughtful comments on the case.] In that judgment, the court found that "as the Eighth Circuit Court of Appeals has determined in similar cases, the Constitution requires only that Dr. Halikas receive: (1) clear and actual notice of the charges against him; (2) notice of the names of those bringing the charges and the specific nature and factual basis for the charges; (3) a reasonable time and opportunity to respond; and (4) a hearing before an impartial board or tribunal." It did not include the right to appeal as a component of procedural due process under the Constitution.

The "similar cases" which Judge James Rosenbaum used to reach this result were two cases in which employees of public universities contested their firing: [5]Riggins v. Board of Regents of Univ. of Neb., 790 F. 2d 707, 712 (8th Cir. 1985) and [6]King v. University of Minn., 774 F. 2d 224, 228 (8th Cir. 1985), cert. denied, 475 U.S. 1095 (1986).

This comparison casts doubt on Steven Peckman's claim, based on Halikas, that "human-subejcts research is a privilege and not a right. A federal court determined that human research is not a right, such as the right of intellectual inquiry embodied in academic freedom." ["[7]A Shared Responsibility for Protecting Human Subjects," in Institutional Review Board: Management and Function, ed. Robert J. Amdur, Elizabeth A. Bankert (Jones & Bartlett Learning, 2006), 17.] To the contrary, Riggins specifically states that "Public employees may have a property right in continued employment." And King involved the dismissal of a tenured professor. By invoking these precedents, the Halikas decision suggests that researchers do have rights comparable to public employees and tenured professors.

But are the procedural protections set forth in King and Riggins adequate to protect the right to research, academic freedom, or a property right in continued employment? Do professors in their capacity as researchers deserve more, less, or equivalent protections as professors in their capacity as teachers? What rights, if any, might student-researchers claim? Would Halikas or King have been decided differently had the plaintiffs offered free-speech claims? Does the "human research" in the judgment refer to social research as well as the medical research that was the subject of the IRB proceedings against Halikas? (The final judgment describes the IRB as a "medical research review body.")

Halikas leaves all these questions unanswered. A careful analysis of that case would be a good starting place for further legal scholarship on the due process implications of IRB policies.

1. https://litigation-essentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&doctype=cite&docid=43+Creighton+L.+Rev.+1275&srctype=smi&srcid=3B15&key=17d40b919d8e712c5281c52b9431a97a
2. http://scholar.google.com/scholar_case?case=10296811528183203766
3. http://scholar.google.com/scholar_case?case=13458906729446809063
4. http://zacharyschrag.com/files/Halikas_Summary_Judgement.pdf
5. http://ftp.resource.org/courts.gov/c/F2/790/790.F2d.707.85-1943.html
6. http://scholar.google.com/scholar_case?case=5241254860287355412
7. http://books.google.com/books?id=ZVByC6VVsl0C&pg=PA17e

5.11.3 IRBs and Procedural Due Process (2010-11-05 08:45)

A law student finds that "current IRB regulations fail to provide procedural due process as guaranteed by the Fifth and Fourteenth Amendments of the United States Constitution."

[Daniel G. Stoddard, "[1]Falling Short of Fundamental Fairness: Why Institutional Review Board Regulations Fail To

Provide Procedural Due Process," Creighton Law Review 43 (June 2010): 1275-1327]
Stoddard notes a number of measures that might protect researchers against capricious IRBs but which are not currently required:

> Federal IRB regulations are silent . . . regarding a number of specific aspects of IRB function including public attendance of IRB functions, a researcher's opportunity to hear and cross-examine information opposing that researcher's research, and a researcher's right to privacy with regard to an IRB's media interaction. IRB regulations additionally fail to address whether an IRB should base its decision exclusively on evidence presented to it, whether a researcher should have a right to a hearing before the IRB suspends research, whether a researcher has a right to judicial review of an IRB decision, and whether a researcher has a right to an attorney. Federal IRB regulations also fail to include a researcher's right to have informal communications with an IRB, a researcher's right to present further evidence to an IRB following a rejection, a researcher's right to consult with personnel opposing that researcher's research in an effort to understand and prepare to challenge them, and an IRB's obligation to evaluate its own functioning procedures periodically. (1290)

All of these measures could be helpful, but the question for Stoddard is whether their absence violates procedural due process. To answer that question, he turns to [2]Mathews v. Eldridge (424 US 319 - Supreme Court 1976), a 1976 Supreme Court case named for the same HEW secretary who was sued for violating IRB procedures in Crane v. Mathews, [3]417 F. Supp. 532 - Dist. Court, ND Georgia 1976.
Mathews states that

> the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Stoddard, it turn, argues that "The inability to contest or appeal an IRB decision is a substantial procedural shortcoming when evaluated under the three prong Mathews [v. Eldridge] balancing test."
The problem with this argument is that Mathews does not require the right to appeal, nor do other key precedents. In particular, Stoddard would be more persuasive had he addressed head-on what I take to be the federal court decision that most directly addressed due process and IRBs: Halikas v. University of Minnesota. Though Stoddard cites the district court's denial of a preliminary injunction to the plaintiff in that case, an aggrieved researcher, he does not analyze the court's reasoning behind that denial: "An IRB proceeding is, simply, not a federal criminal prosecution. Such a proceeding is governed by contracts and federal regulations which do not require, or provide, the full panoply of criminal procedural rights . . . Dr. Halikas voluntarily entered into an employment contract and conducted his research under the aegis of the University and its research-regulatory regime. He received the process which is his due." [[4]Halikas v. University of Minnesota, 856 F. Supp. 1331; 1994 U.S. Dist.]
Nor does Stoddard analyze the final judgment in that case, which was not published. [[5]Case number 4-94-CV-448, Federal District Court, Fourth Division, District of Minnesota; filed 18 May 1994; Judgment entered 9 June 1996. I am very grateful to Dr. Dale Hammerschmidt, one of the named defendants in the Halikas suit, for providing me with a copy of this document. I have posted it on my website (see previous link) so it will be easier to find in the future.]
In that judgment, the court found that "as the Eighth Circuit Court of Appeals has determined in similar cases, the Constitution requires only that Dr. Halikas receive: (1) clear and actual notice of the charges against him; (2) notice of the names of those bringing the charges and the specific nature and factual basis for the charges; (3) a reasonable

time and opportunity to respond; and (4) a hearing before an impartial board or tribunal." It did not include the right to appeal as a component of procedural due process under the Constitution.
The "similar cases" which Judge James Rosenbaum used to reach this result were two cases in which employees of public universities contested their firing: [6]Riggins v. Board of Regents of Univ. of Neb., 790 F. 2d 707, 712 (8th Cir. 1985) and [7]King v. University of Minn., 774 F. 2d 224, 228 (8th Cir. 1985), cert. denied, 475 U.S. 1095 (1986).
This comparison casts doubt on Dr. Hammerschmidt's claim that Judge Rosenbaum "formally recognized the concept that the opportunity to conduct research upon human subjects is a privilege, rather than a right." ["'[8]There is no substantive due process right to conduct human-subject research': The Saga of the Minnesota Gamma Hydroxybutyrate Study," IRB: Ethics and Human Research. 19 (May - Aug., 1997): 13-15. This is amplified in Steven Peckman, ["[9]A Shared Responsibility for Protecting Human Subjects," in Institutional Review Board: Management and Function, ed. Robert J. Amdur, Elizabeth A. Bankert (Jones & Bartlett Learning, 2006), 17.]
To the contrary, Riggins specifically states that "Public employees may have a property right in continued employment." And King involved the dismissal of a tenured professor. By invoking these precedents, the Halikas decision suggests that while research is not a substantive due process right, researchers may have procedural due processs rights comparable to those enjoyed by public employees and tenured professors. Halikas makes no mention of research as a "privilege."
Though the Halikas judgment was sufficient to decide the case before the court, it left unanswered many questions about the rights of researchers who face IRBs. Are the procedural protections set forth in King and Riggins adequate to protect the right to research, academic freedom, or a property right in continued employment? Do professors in their capacity as researchers deserve more, less, or equivalent protections as professors in their capacity as teachers? What rights, if any, might student-researchers claim? Would Halikas or King have been decided differently had the plaintiffs offered free-speech claims? Does the "human research" in the judgment refer to social research as well as the medical research that was the subject of the IRB proceedings against Halikas? (The final judgment describes the IRB as a "medical research review body.") Does a board or tribunal have to be competent as well as impartial?
Halikas leaves all these questions unanswered. A careful analysis of that case would be a good starting place for further legal scholarship on the due process implications of IRB policies.

1. https://litigation-essentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&doctype=cite&docid=43+Creighton+L.+Rev.+1275&srctype=smi&srcid=3B15&key=17d40b919d8e712c5281c52b9431a97a
2. http://scholar.google.com/scholar_case?case=10296811528183203766
3. http://scholar.google.com/scholar_case?case=1130961476537518855
4. http://scholar.google.com/scholar_case?case=13458906729446809063
5. http://zacharyschrag.com/files/Halikas_Summary_Judgement.pdf
6. http://ftp.resource.org/courts.gov/c/F2/790/790.F2d.707.85-1943.html
7. http://scholar.google.com/scholar_case?case=5241254860287355412
8. http://www.jstor.org/stable/3564519
9. http://books.google.com/books?id=ZVByC6VVsl0C&pg=PA17e

5.11.4 Comments: FWA Forms Should Reflect Common Rule (2010-11-10 14:33)

On [1]October 4, I reported that OHRP was inviting comments on drafts of new FWA form and FWA Terms of Assurance.
Prior to the October 25 deadline, OHRP received comments from only five individuals and two professional organizations, all of which are posted at [2]regulations.gov.
Of these seven comments, three (including mine, of course) complained that the draft Terms of Assurance, like the existing ones, violate the Common Rule's pledge that an institution's statement of principles "[3]may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself." No one made a case for retaining the discrepancy between the regulations and the forms.

1. http://www.institutionalreviewblog.com/2010/10/tell-ohrp-belmont-isnt-everything.html
2. http://www.regulations.gov/search/Regs/home.html#docketDetail?R=HHS-OPHS-2010-0023
3. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103

5.11.5 Comments: FWA Forms Should Reflect Common Rule (2010-11-10 14:33)

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1. http://www.institutionalreviewblog.com/2010/10/tell-ohrp-belmont-isnt-everything.html
2. http://www.regulations.gov/search/Regs/home.html#docketDetail?R=HHS-OPHS-2010-0023
3. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103

5.11.6 Is Facebook Data Mining Human Subjects Research? (2010-11-18 09:52)

Recent law-school graduate Lauren Solberg finds that "data mining on Facebook likely does not constitute research with human subjects, and therefore does not require IRB review, because a researcher who collects data from Facebook pages does not 'interact' with the individual users, and the information on Facebook that researchers mine from individual users' pages is not 'private information.'"
[Lauren Solberg, "[1]Data Mining on Facebook: A Free Space for Researchers or an IRB Nightmare?" article under review, University of Illinois Journal of Law, Technology & Policy 2010 (2). The article has been accepted for publication, but the journal is still [2]soliciting comments.]
Solberg challenges policies now in place at [3]Indiana University and the [4]University of Massachusetts Boston, where researchers must get Facebook's written permission or the written permission of every individual who is studied. These policies, she argues, impose unnecessary burdens on researchers and IRBs alike. (The two policies are identical, but it's not clear which university borrowed from the other.)
She argues that most data mining projects do not meet the regulatory definition of human subjects research. Reading existing profiles is not interaction with an individual. Nor is a Facebook profile that is open to strangers private information, i.e., "[5]information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)." If a college admissions officer or a potential employer can read your profile, you've lost little by having an anthropologist read it as well.
This analysis seems sound, but it's not clear to me that anyone disagrees. In particular, the third university Solberg mentions, Washington University in St. Louis, applies its policy only to "[6]
Any activity meeting the definition of 'human subject research' which is designed to recruit participants or collect data via the Internet." It then lists several examples, most of which involve interaction with living individuals. Thus, I doubt Solberg's claim that "researchers at Washington University need only inform Facebook users that they are recording information that is posted on their pages." Rather, if the project does not meet the definition of human subject research, then Wash U. researchers need not do even that much.
Solberg's article skirts some interesting questions. One concerns the boundaries of a reasonable expectation of privacy. Thus, [7]Michael Zimmer gives the example of a study by Harvard graduate students of the Facebook profiles of Harvard undergraduates. If an undergraduate had made some information visible only to other Harvard students (a choice

Facebook's software allows), and a Harvard student-researcher sees it, does that change Solberg's analysis?
A second question concerns the authority of university research offices and IRBs to insist that researchers abide by website terms of service. Notably, the Indiana and UMASS policies do not cite federal human subjects regulations as their authority. Rather, they claim that Facebook and Myspace "explicitly state that their sites are not intended for research but for social networking only."
Solberg writes that evaluating such claims is "outside the scope of this article," but they are interesting in three ways. First, they may be factually false; I could find no such explicit statements in the [8]Facebook or [9]Myspace terms of service. Second, they are divorced from federal regulation. For example, the Facebook terms of service do not distinguish between living and dead Facebook members, whereas federal human subjects protections apply only to the living. Finally, they are internally inconsistent. If Facebook and Myspace did prohibit the use of their sites for research, would not researchers still be violating the terms of service even if they got signed consent from individual members, as allowed by the policies? Just who are these two universities trying to protect?
Solberg concludes that "Unfortunately, and somewhat surprisingly, the OHRP has issued no guidance pertaining to Internet research in general, let alone guidance specifically relating to the issue of data mining on the Internet." To give the feds some credit, in summer 2010 (after Solberg wrote her article), SACHRP did sponsor a panel on [10]the Internet in Human Subjects Research. It can take [11]a long time from a SACHRP presentation to OHRP guidance, but the wheels may be moving on this one.

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Note, 19 November 2010: The original version of this post identified Ms. Solberg as a law student. She has in fact graduated. I have also changed the link about Michael Zimmer's work from his [12]SACHRP presentation to his article, "[13]'But the data is already public': on the ethics of research in Facebook," Ethics and Information Technology 12 (2010): 313-325.

1. http://www.jltp.uiuc.edu/works/Solberg.htm
2. http://www.jltp.uiuc.edu/works.htm
3. http://www.researchadmin.iu.edu/HumanSubjects/IUB/hs_ic_infomine.html
4. http://www.umb.edu/system/templates/research/uploads/ORSPNewsletterJune2009.pdf
5. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102
6. http://hrpohome.wustl.edu/study_team/guidelines/Internetguideline.rtf
7. http://www.springerlink.com/content/q1v7731u26210682
8. http://www.facebook.com/terms.php
9. http://www.myspace.com/help
10. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-10/present.html
11. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg10-08/present/Carome.html
12. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-10/ZimmerSACHRP20100721.ppt
13. http://www.springerlink.com/content/q1v7731u26210682/

5.11.7 La Noue Reviews Ethical Imperialism (2010-11-21 23:06)

Political scientist George La Noue terms Ethical Imperialism "a powerful indictment of the IRB regime."
[George R. La Noue, [1]Review of Zachary M. Schrag, Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009, Law & Politics Book Review 20 No. 11 (October, 2010): 616-618.]
La Noue, who has himself written about the IRB controversy, notes that "Universities might seem to be a most unlikely place to welcome and implement a process that is in effect a form of prior censorship. Reconciling the IRB process with legal or professorial concepts of academic freedom is extremely difficult." He finds that "Schrag provides a carefully researched and well written historical perspective providing all members of the academy with essential information to reconsider the role of IRBs."
La Noue calls for more study of the constitutionality of current IRB regulations and practices, a subject I would prefer

to leave to the law professors. He also concludes that

> What is missing is comparative empirical research about the standards and procedures of a variety of IRBs in different settings. While it seems intuitively unlikely that the process is always fair, objective and consistent, from IRB committee to committee, campus to campus, beyond anecdotes what proof exists? Without an appropriate factual basis, courts would struggle with both the compelling interest and narrow tailoring prongs that constitute the strict scrutiny test that should apply to censorship. Schrag's book provides a necessary and very carefully researched historical context for the debate about IRBs, but the next step needs to be taken by professional associations and social scientists to study their actual practice to see if the current system can be improved.

I concur, though I would suggest that we in fact need two separate branches of such emprical study. One would continue the work of [2]Maureen Fitzgerald and [3]Laura Stark, both of whom have observed committees in action without finding huge variation from campus to campus, or even–in Fitzgerald's case–country to country.
A second branch would look at the development of human research protections policies. Read through this blog, and you will find enormous variation in casts of characters involved in shaping university policies on human subjects, from [4]research offices that feel free to make up whatever rules they want, to the participation of [5]university-level faculty committees, to the [6]involvement of departments most affected by a given policy.. I don't know of any scholarship that has examined this variation in depth.
I hope that other scholars heed Professor La Noue's call.

1. http://www.lpbr.net/2010/11/ethical-imperialism-institutional.html
2. http://www.institutionalreviewblog.com/2008/03/maureen-fitzgeralds-ethics-project.html
3. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
4. http://www.institutionalreviewblog.com/2008/04/do-ucla-researchers-have-permission-to.html
5. http://www.institutionalreviewblog.com/2009/11/brown-pledges-irb-reform.html
6. http://www.institutionalreviewblog.com/2009/04/umkcs-respectful-oral-history-policy.html

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5.11.8 Survey: One-Third of UConn Researchers Dislike CITI Program (2010-11-26 11:42)

A [1]2007 survey of researchers at the University of Connecticut found that more than one third were dissatisfied with the Collaborative Institutional Training Initiative (CITI) program in human subjects research.
The UConn IRB and Office of Research Compliance offered the survey to about 350 researchers, of whom 114 (33 percent) returned it. Part of the survey asked respondents about the CITI Program:

> 7 Questions asked respondents to rate different aspects of the CITI course on a scale of 1-7 (1=least, 7=most). 4 out of these 7 questions asked if the CITI course increased understanding of risks and protections for human subjects in research. There were no statistical differences in the answers received on this group of 4 questions.
> 53 % rated this group 5 or above
> 16 % rated this group 4, moderate
> 31 % rated this group 3 or below
> Similar rates were received for overall satisfaction with the CITI course:
> 54 % rated it 5 or above
> 9 % rated it 4, moderate
> 37 % rated it 3 or below

The course did appear to have an impact on the respondent's understanding of the Federal Regulations. On this criteria,
72 % rated it 5 or above
4 % rated it 4, moderate
24 % rated it 3 or below
The course had a negative impact on the respondents' willingness to join an IRB:
29 % rated it 5 or above
13 % rated it 4, moderate
58 % rated it 3 or below

These figures suggest wider dissatisfaction with CITI than one of its founders, Paul Braunschweiger, admitted in a [2]2006 presentation. That presentation (slide 60) reported that principal investigators gave the program an average of about 7.8 on a 10 point scale on overall satisfaction. Though the presentation did not show the distribution of researchers' responses, it would be difficult to get so high a mean if 37 percent of researchers offered negative assessments. We need more data.

The UConn survey also offered researchers the chance to write open-ended comments. The most common suggestions were that the training should be shorter, and that the course content "should be limited to a researcher's area of research." Researchers were happy with the online form of the course, with 74 asking for no change, and only 12 choosing the next most popular option: video instruction.

All of these results suggest the potential for online courses that are shorter than CITI and targetted to a specific research discipline, such as Macquarie University's [3]Human Research Ethics for the Social Sciences and Humanities.

UConn also surveyed researchers on their [4]views of the UConn IRB. But the university has only reported the mean ratings, not the distribution of responses, so it is impossible to say if the IRB earned as many unsatisfactory grades as did the CITI program.

1. http://irb.uconn.edu/survey.html
2. http://citiprogram.org/citidocuments/aahrpppbfinal.ppt
3. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html
4. http://irb.uconn.edu/documents/irb_rat_graphs.pdf

5.11.9 Belmont's Ethical Malpractice (2010-11-30 15:08)

I complain about the Belmont Report in an essay published today in [1]Bioethics Forum.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4999&blogid=140

5.12 December

5.12.1 Menikoff Passes the Buck (2010-12-07 15:03)

Joseph Millum, bioethicist at the National Institutes of Health, and Jerry Menikoff, director of the Office for Human Research Protections, acknowledge the widespread dissatisfaction with present human subjects regulations and wish that "ethics review could be streamlined under the current regulations if institutions, IRBs, and researchers adhered strictly to the definition of human subjects research and used the available options for exemptions, expedited review, and centralized review—options that remain underused in biomedical research." But they put too much blame for this

overregulation on IRBs and research institutions rather than on their own agencies.
[Joseph Millum and Jerry Menikoff, "[1]Streamlining Ethical Review," Annals of Internal Medicine 153, no. 10 (November 15, 2010): 655-657.]
Millum and Menikoff call for institutions to offer exemptions and expedited review whenever possible, not just to placate researchers but to protect research participants:

> Following these measures is unlikely to reduce human subject protections. The categories of research that are exempt or eligible for expedited review are unlikely to include highly unethical studies. For example, studies in these categories almost always pose no more than minimal risk to participants, which should ameliorate concerns about participant harm. Thus, the absolute probability of increased use of these measures leading to more unethical research is low.
> In addition, IRBs always have constraints on their time and resources, and any time they spend reviewing one protocol takes away time from reviewing others. Institutional review boards should prioritize their time to focus on protocols that are more likely to generate ethical issues but need a way to determine whether a study will raise ethical issues without actually reviewing the full protocol. The regulatory measures we have detailed identify categories of research that are unlikely to be ethically problematic. Using them therefore frees up resources for reviewing riskier research.

So far so good. But the article overlooks four ways in which the federal government, and OHRP in particular, encourages institutions to overregulate.

1. Federal Agencies Don't Gather Data

To address the problem of overregulation, it would be nice to know how big a problem it is. The best that Millum and Menikoff can say is that "A 1998 report found that for each category of exempt or expedited research, 25 % to 77 % of U.S. IRBs 'practice some form of review that was more rigorous than specified by the regulations.' There appear to be no data that contradict this picture today."
While that's true enough, should OHRP be satisfied with a [2]single, 12-year-old report sponsored by NIH? Might not a more regular system of data collection help us understand why IRBs act the way they do? And who is to sponsor this, if not OHRP and NIH?

2. OHRP Presents Exemption Determinations as Difficult, But Does Nothing to Clarify Them

OHRP's guidance on "[3]Exempt Research Determination" claims that "an institutional policy that allowed investigators to make their own exemption determinations, without additional protections, would likely risk inaccurate determinations." So far as I can tell, this claim is based on no empirical data. But it serves to present exemption determination as a risky business, one apt to go wrong, thus discouraging institutions from applying the exemptions.
It's true that the exemptions are poorly written. For example, [4]45 CFR 46.101(b)(2) exempts many studies unless "information obtained is recorded in such a manner that human subjects can be identified," but 46.101(b)(4) exempts projects when "information is recorded by the investigator in such a manner that subjects cannot be identified." Why does "by the investigator" appear in (b)(4) but not (b)(2)? If a research participant takes notes during an interview, or writes about the event in his diary, is the researcher now subject to IRB review?
If OHRP were serious about getting projects exempt, it would tell everyone what the exemptions are supposed to mean. Then it would study–not guess–if researchers are capable of applying those standards.

3. Federal Officials Model Overregulation

Millum and Menikoff ignore the terrible guidance issued by the federal government over the years. For example, in June 2008 OHRP and NIH contributed to a report on [5]Expedited Review of Social and Behavioral Research Activities. That report offered thirteen hypothetical projects it termed "eligible for expedited review," overlooking the fact

that [6]eight of the thirteen were in fact exempt from any review.

Ironically, Millum and Menikoff provide the latest example of this problem. They write that "the work of a researcher who interviewed patients with HIV/AIDS about their medications and recorded their names would not be exempt under category 2, because disclosure of the patients' HIV/AIDS status could harm them. However, if the researcher conducted the interviews anonymously and never recorded the patients' names or other identifying information, the study would probably be exempt."

No, if the researcher conducted the interviews anonymously and never recorded the patients' names or other identifying information then the study would be exempt, not just probably be exempt. If Menikoff, free to invent whatever hypothetical study he wishes, and immune from OHRP sanction, still can't manage to declare this project unambiguously exempt, then how can he expect real institutions to exempt real projects?

4. OHRP Second-Guesses Exemption Determinations

Millum and Menikoff write that "regulatory bodies need to reassure the research community that their primary concerns lie not with meeting bureaucratic requirements but with genuinely protecting human participants."

Yes, that would be lovely. But in the most high-profile case concerning exemptions in recent years, [7]OHRP rejected Johns Hopkins University's determination that Peter Pronovost's to effort reduce the incidence of catheter-borne infections in ICUs was exempt from IRB regulations. After [8]getting slammed in the press, OHRP retreated and decided that "[9]regulations that govern human subjects research no longer apply." Still, the lesson for IRBs was that if they err on the side of exemption, they risk the whip.

All that happened before Menikoff's arrival. But in the two years under Menikoff, OHRP has kept issuing determination letters warning not of failures of genuine protection but instead of [10]failures to meet bureaucratic requirements:

> HHS regulations at 45 CFR 46.109 require that continuing review of research be conducted by the institutional review board (IRB) at intervals appropriate to the degree of risk, but not less than once per year. The regulations make no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval. We determine that during the period from 1991-1999 when the above-referenced research was conducted at UI, continuing review for the above-referenced research did not always occur at least once per year. For example, the first continuing review occurred on February 27, 1992 and subsequent continuing reviews apparently occurred on April 1, 1993, May 12, 1994, May 10, 1995, June 27, 1996, June 26, 1997, July 9, 1998, and July 15, 1999.

The article ends with the disclaimer that "The views expressed in this commentary are those of the authors and are not necessarily those of the U.S. Department of Health and Human Services or its operating divisions, the National Institutes of Health and the Office of the Assistant Secretary for Health." No, an article designed to "to extol the virtues of [streamlining] measures" is certainly not the view of HHS and its operating divisions.

1. http://www.annals.org/content/153/10/655.abstract
2. http://www.hhs.gov/ohrp/policy/hsp_final_rpt.pdf
3. http://www.hhs.gov/ohrp/policy/exempt_res_det.html
4. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101
5. http://www.nsf.gov/pubs/2008/nsf08203/index.jsp
6. http://www.institutionalreviewblog.com/2008/10/45-cfr-46101-is-still-dead.html
7. http://www.hhs.gov/ohrp/detrm_letrs/YR07/nov07c.pdf
8. http://www.nytimes.com/2007/12/30/opinion/30gawande.html
9. http://www.hhs.gov/ohrp/news/recentnews.html
10. http://www.hhs.gov/ohrp/detrm_letrs/YR09/sep09a.pdf

5.12.2 George Mason University Posts Consultant Report (2010-12-10 16:22)

The George Mason University [1]Office of Research & Economic Development has posted the following:

> The Huron Consulting Group's final report on the Office of Research Subject Protections and the Human Subjects Review Board is now available. The results are available in two formats: A comprehensive[2] Final Report (PDF) and a [3]Faculty Report Presentation (PPT)

As a Mason faculty member, I am involved in the continuing discussions of human research protections at the university. I will therefore refrain from comment except to applaud the university administration for posting these documents where they can inform decisions here and at other universities.
For comparable reports, see [4]Institutional Review Boards at UC [University of California]: IRB Operations and the Researcher's Experience, Report of the University Committee on Research Policy (UCORP), endorsed by the Academic Council, April 25, 2007, and University of Cincinnati, [5]Final Report: Task Force on IRB and Compliance Roles and Responsibilities, May 2009.

1. http://research.gmu.edu/
2. http://research.gmu.edu/docs/HuronHSRB_FinalReport.pdf
3. http://research.gmu.edu/docs/HuronHSRB_FacultyReport.pptx
4. http://www.universityofcalifornia.edu/senate/committees/council/ac.irb.0507.pdf
5. http://researchcompliance.uc.edu/irb/IRB%20and%20Compliance%20Task%20Force%20Report%206%2014%20091.pdf

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5.12.3 Van den Hoonaard Reviews Ethical Imperialism (2010-12-12 18:25)

Will van den Hoonaard reviews Ethical Imperialism for the [1]Canadian Journal of Sociology. The CJS blog asks that readers not quote or cite the advance version now online, but I suppose linking is OK.
[2]Happy Fourth Birthday, Institutional Review Blog!

1. http://www.cjsonline.ca/advancepub/hoonaard10.html
2. http://www.institutionalreviewblog.com/2006/12/introduction.html

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Chris (2010-12-21 16:51:17)
Happy fourth birthday! Didn't realize your blog had been around that long. Incidentally i'm trying to get our university library to purchase your book right now.

5.12.4 First, Do Some Harm, Part I: Denzin's Qualitative Manifesto (2010-12-22 14:36)

Three recent documents demonstrate the confusion that arises when people try to apply medical ethics to non-medical fields. I will describe them in individual entries.
In June 2010, [1]Norman Denzin, Research Professor of Communications at the University of Illinois at Urbana-Champaign, published [2]The Qualitative Manifesto: A Call to Arms (Left Coast Press). Chapter five seeks

> to outline a code of ethics, a set of ethical principles for the global community of qualitative researchers. I want a large tent, one that extends across disciplines and professions, from anthropologists to archeologists, sociologists to social workers, health care to education, communications to history, performance studies to queer and disability studies.

Part of the impetus for this effort is Denzin's recognition that IRB guidelines may not match "guidelines grounded in human rights, social justice considerations" or disciplinary codes. He is familiar with the debate concerning IRBs, having read the Illinois White Paper, the AAUP reports, and "even a humanities and IRB blog where complaints are aired."

Denzin is also familiar with oral historians' concerns that IRBs impose inappropriate requirements, as well as statements of ethics from other qualititative researchers. He seeks to synthesize what he has learned in a footnoted dialogue, part of a "one-act play" entitled "Ethical Practices":

> SCENE FOUR: Oral Historians
>
> . . .
>
> Speaker Two:: We do not want IRBs constraining critical inquiry, or our ethical conduct. Our commitment to professional integrity requires awareness of one's own biases and a readiness to follow a story, wherever it may lead. We are committed to telling the truth, even when it may harm people ([3]Shopes, 2007a, p.4).
>
> Speaker One:: When publishing about other people, my ethics require that I subject my writing to a fine-mesh filter: do no harm ([4]Richardson, 2007, p. 170).
>
> Speaker Two:: So there we have it. A set of methodological guidelines. (83)

No. What we have is a debate between Linda Shopes, a historian, and Laurel Richardson, a sociologist, about the ethical responsibility of an interviewer to a narrator. Their perspectives reflect important differences between their professions. They also refelct the particulars of the book in which Richardson's statement appears, an account of the last months of a dying friend–hardly the typical oral history or sociological study.

Denzin turns a blind eye to this debate, instead seeming to endorse both sides. In the play, Speaker Two states that "Beneficience, do no harm, is challenged in the oral history interview, for interviews may discuss painful topics, and they [sic] have the right to walk away at any time." That seems to endorse Shopes's position. But they book closes with a proposed ethical code that leans toward Richardson, calling on all qualitative researchers to "strive to never do harm." (122)

How can Denzin read and reprint historians' arguments, then reject them without even realizing he is doing so? Is the historians' position so hard to understand? Or is the lure of innocuity so powerful?

1. http://media.illinois.edu/faculty/detail/norman_denzin
2. http://www.lcoastpress.com/book.php?id=292
3. http://www.oralhistory.org/do-oral-history/oral-history-and-irb-review/
4. http://books.google.com/books?id=2uzDBiQLQJYC&lpg=PP1&ots=CtVWOJtEb4&dq=laurel%20richardson%20%22last%20writes%22&pg=PA170#v=onepage&q=harm&f=false

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5.12.5 First, Do Some Harm, Part II: The AAA Ethics Task Force (2010-12-23 12:59)

In mid-October, the [1]Ethics Task-Force of the American Anthropological Association solicited comments on the following text, a section of a draft Code of Ethics now being written:

Do No Harm

Anthropologists share a primary ethical obligation to avoid doing harm to the lives, communities or environments they study or that may be impacted by their work. This includes not only the avoidance of direct and immediate harm but implies an obligation to weigh carefully the future consequences and impacts of an anthropologist's work on others. This primary obligation can supersede the goal of seeking new knowledge and can lead to decisions not to undertake or to discontinue a project. Avoidance of harm is a primary ethical obligation, but determining harms and their avoidance in any given situation may be complex.

While anthropologists welcome work benefiting others or increasing the well-being of individuals or communities, determinations regarding what is in the best interests of others or what kinds of efforts are appropriate to increase well-being are complex and value-laden and should reflect sustained discussion with those concerned. Such work should reflect deliberate and thoughtful consideration of both potential unintended consequences and long-term impacts on individuals, communities, identities, tangible and intangible heritage and environments.

As of December 13, 33 people (presumably all anthropologists, but I'm not sure) had posted comments. The comments are often nuanced, making it hard to say whether they endorse the language or not. But they broke down roughly as follows:

Do No Harm

Significantly, the most wholehearted supporters of the "do no harm" proposal are those who uncritically embrace the Belmont Report and the Common Rule. "'Do no harm' is an IRB principle, and so it should be in our code," writes Bethe Hagens. Four other responses, from Chip Colwell-Chanthaphonh, mkline, Robert T Trotter II, and Simon Craddock Lee, all seem to suggest that the AAA code should conform to those documents, without asking much about their origins or their fit to the practices and beliefs of anthropologists.

Four other responses–from Barbara Rose Johnston, Seamus Decker, socect, and Vicki Ina F. Gloer–endorse Hagens's idea that anthropologist should "intend no harm." Despite the Belmont Report's description of "the Hippocratic maxim "do no harm" [as] a fundamental principle of medical ethics," this form is more faithful to the Belmont's overall section on beneficence.

Do Some Harm

Eight responses–almost as many–appear to reject the "do no harm" idea on the grounds that neutrality is impossible, and anthropologists should not hesitate to harm those who deserve it. "A blanket edict to 'Do No Harm' could easily lead to a professional paralysis when one considers that a few steps away from the person giving you this interview is someone who will not like, will want or need to fight, or will suffer consequences for what is said much further down the line," writes Benjamin Wintersteen. Murray Leaf concurs. "Do no harm is fine as principle of medical practice," he writes, "where you are working with a single individual. It is nearly meaningless when you (we) work with human communities, in which what is good and what is harm is usually in contention. As some of these posts suggests, what we do is often a matter of helping some while undermining the position of others. No harm at all, in such a context, would almost always be also no help at all–and no effect at all."

Bryan Bruns offers an example. "I work, in conjunction with communities and a government agency, to design and support a process in which communities are likely to, in a reasonably democratic way, act to restrain the behavior and thereby (harm) reduce the benefits of a few people (upstream irrigators, large landowners) who currently take advantage of others, it's not clear how a principle of 'do no harm' would allow any practical engagement."

I would say that the responses by Dimitra Doukas, Joan P Mencher, Moish, Noelle Sullivan, and Ray Scupin all fall in this general category of respecting critical inquiry. Margaret Trawick's comment is harder to categorize. "I have been teaching 'Do no harm' to my students as the first ethical principle for anthropological fieldwork, for many years," she

writes. "It is a difficult principle to follow, precisely because you never know what might cause harm, and therefore you have to THINK about what you are doing in the field more carefully than you might in everyday life. Good intentions are not enough. Additionally, 'harm to whom' is a good question . . . Sometimes to protect and advocate for one party (.e.g. Untouchables in India) is to, at the least, offend some other party – e.g. high caste Hindus." Given her understanding of this problem, I'm not sure why she teaches "do no harm" rather than something like "think about whom you are harming."

It's the Wrong Question

An even greater number of responses suggest that, in the words of Carl Kendall, "This principle is way too vague and self-directed to be practically useful." Kendall hints, perhaps cynically, that anthropologists need one set of principles these ethical principles to "pass IRB muster" and a second set "to protect communities and fieldworkers." Carolyn Fluehr-Lobban argues that "'Harm' should be problematized—are there agreed upon universal standards of harm, and where is there discussion of reasonable disagreement."

James Dow rejects the medical language of IRBs: "'Do no harm' is an good ethical principle to be applied to individual social relationships, which we hope that we understand; however, there is a problem when applying it to larger societies and cultures." Likewise, David Samuels writes that "The place where you need to get informed consent is at the point at which you have turned people into characters in your story. The medicalized pre-framing of the IRB process doesn't cover that at all."

Taken as a whole, the responses suggest that only a minority of those commenting embrace the Belmont Report and the IRB process as enthusiastically as the AAA did in its [2]2004 statement that presents the active involvement of IRBs as a positive good. I hope the Task Force recognizes this, and takes the opportunity to reconsider the AAA's overall position in regard to IRB review.

[Hat tip to Alice Dreger. For a historical perspective on another discipline's efforts to craft a research ethics code, see Laura Stark, "[3]The Science of Ethics: Deception, the Resilient Self, and the APA Code of Ethics, 1966–1973," Journal of the History of the Behavioral Sciences 46 (Fall 2010): 337–370.]

1. http://blog.aaanet.org/ethics-task-force/
2. http://www.aaanet.org/stmts/irb.htm
3. http://onlinelibrary.wiley.com/doi/10.1002/jhbs.20468/abstract

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Simon Craddock Lee (2011-01-07 17:03:01)

Hi Zachary (really enjoying your book btw.) I agree I sidestepped the origin and relevance of Belmont/IRB to the beliefs of many anthropologists about their practice. In retrospect, my comments weren't on topic (re: harm) but I see this in terms of pragmatics. I don't believe anthropologists (in my case federally funded) get to side-step IRBs by saying our work doesn't apply and I wrote in that vein. There are differences in methodologies but the spirit of an IRB as I see it is to provide external peer review of plans to engage with human subjects. Just like grant review, other people evaluate my proposal because my own subjective opinion that it's worth doing needs to be balanced by experts who don't have a direct stake in my project. In my mind, the reciprocal obligation of the IRB is that they must have experts who are qualifed in the relevant approach who can make the case to non-anthropologists– just as an oncologist might need to explain the intricacies of a drug trial to a exercise physiologist. And that is admittedly where many IRBs fall down.

Zachary M. Schrag (2011-01-08 10:12:00)

Thank you for your comments and for your kind words about my book.

I'm afraid I am having some trouble following your argument. On the AAA website, you wrote that "No work involving human subjects is a priori categorically exempt." But the Common Rule states that "research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy." If work is exempt because it fits into one of the six categories, then it would indeed appear to be "categorically exempt."

Nor do the regulations state that (in your words) while "some research could be exempt (technical determination by the IRB), you still have to demonstrate this is the case." Rather, as OHRP made clear in 2009, "[1]the regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt."

Beyond these regulatory specifics, keep in mind the bigger picture. The 1981 regulations came with the promise that the exemptions would "[2]exclude most social science research projects from the jurisdiction of the regulations." And just last November, [3]OHRP director Jerry Menikoff reaffirmed that "The categories of research that are exempt or eligible for expedited review are unlikely to include highly unethical studies . . . Using [the exemptions] therefore frees up resources for reviewing riskier research."

Thus, it is not only anthropologists who are saying that most of their work should not be subject to IRB review. It is the text accompanying the regulations, it is statements by members of the [4]Secretary's Advisory Committee on Human Research Protections and the director of OHRP himself, and, I might add, the report of the [5]University of Texas IRB Task Force.

If IRBs had a great track record reviewing anthropological research, they would not need to claim regulatory authority to get anthropologists to submit projects for approval. But the fact that "many IRBs fall down" when reviewing research social science is further reason for anthropologists–individually and collectively–to seek to limit their reach.

As for the comparison to peer review, please see my 2007 post, "[6]Why IRBs Are Not Peer Review."

1. http://answers.hhs.gov/ohrp/categories/1564
2. http://www.hhs.gov/ohrp/archive/documents/19810126.pdf
3. http://www.institutionalreviewblog.com/2010/12/menikoff-passes-buck.html
4. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-1-systems-level.html
5. http://www.institutionalreviewblog.com/2010/05/texass-all-star-irb-report.html
6. http://www.institutionalreviewblog.com/2007/03/why-irbs-are-not-peer-review-reply-to-e.html

5.12.6 First, Do Some Harm, Part III: Loosies in San Francisco (2010-12-26 11:08)

The third recent document illustrating the problem of applying the Hippocratic maxim to non-medical research is Leslie E. Wolf, "[1]The Research Ethics Committee Is Not the Enemy: Oversight of Community-Based Participatory Research," Journal of Empirical Research on Human Research Ethics 5, no. 4 (December 2010): 77–86. It offers a clear example of the kind of valuable research that is impeded by simplistic medical ethics.

The background is this: in an effort to discourage smoking, California law prohibits the sale of single cigarettes, known as "loosies." Nevertheless, store owners in predominantly poor, African American neighborhoods in San Francisco sell them. In 2002, a group of University of California, San Francisco researchers teamed up with a public health group and residents of the neighborhoods to study the problem, creating Protecting the 'Hood Against Tobacco project, (PHAT). At first, they proposed merely to observe the sale of loosies, and they got the UCSF IRB's approval. But then the researchers realized that this was impractical; it would require observers to loiter for a long time in the hopes of seeing a spontaneous sale. So they returned to the IRB, this time asking that members of the community be allowed to request cigarettes and record the result. The IRB refused to allow this under UCSF auspices, though it could not stop community members from proceeding on their own.

In 2006, four of the researchers–R. E., Malone, V. B. Yerger, C. McGruder, and E. Froelicher– complained in print about their treatment at the hands of the IRB. ["'[2]It's like Tuskegee in reverse'": A case study of ethical tensions in institutional review board review of community-based participatory research," American Journal of Public Health 96 (2006): 1914–1919.] While conceding that some readings of federal regulations could justify the IRB's actions, they suspected that the IRB was not simply protecting the human subjects of research:

> The early IRB referral to the university's risk management department whence we were referred to the legal department, suggests that the project was regarded in some way as a legal risk and a financial threat to the university. The subsequent legal analysis—which opined that community research partners might be hurt (and thereby possibly put the university at an economic or legal risk because it would be considered a university project)—supports this interpretation. This raises the question about whether such concerns represent an institutional conflict of interest, because the decision about whether the study was ethical appears to be associated with institutional self-protection. (1918)

In her article, Wolf states that "I do not intend to provide a rebuttal to Malone et al. or a defense of the REC decision." She does seek to explain the IRB's decision as follows:

> In this particular case, there were a relatively small number of stores in a limited geographic area. As a result, identification of stores might be possible, even if their identities were withheld from publication, at least within the community, which could lead to adverse consequences for them. In addition, the information sought pertained to illegal activity. The researchers had obtained an agreement from the district attorney that the office would not prosecute store owners or clerks for illegal activity uncovered by the study. While this agreement is helpful in minimizing the risk of prosecution, it did not fully eliminate it; another district attorney might not honor the agreement or the information from the study could trigger monitoring by law enforcement after the study. In light of these circumstances, the UCSF REC [research ethics committee, i.e., IRB] felt that the store personnel and owners must be afforded protection under the federal regulations.

She continues,

> Some of the problems between the UCSF REC and the PHAT researchers may have stemmed from confusion regarding the definition of "community." For those involved in the PHAT study, the community comprised those residents of Bayview–Hunters Point who had participated in the research collaboration through their engagement in deciding on a research question, and developing and carrying out the research protocol. The REC, on the other hand, had a broader view of what constituted the community. In addition to the Bayview– Hunters Point residents who had collaborated with the academic researchers, the REC felt it had to consider the interests and well-being of those who owned, operated, and worked for the stores from whom data were obtained. Even if they were not human subjects as defined by the federal regulations, they were members of the Bayview–Hunters Point community whose interests and trust in research could be jeopardized if the REC approved the researchers' amendment regarding illegal sales of loose cigarettes. Thus, the REC felt an ethical obligation to consider the interests of the broader community in addition to the interests of the community members participating directly in the study conduct. (79)

This is not a credible explanation of UCSF's actions. If the IRB was worried that documenting the sale of loosies by identifiable stores would lead to consequences too adverse to be accepted, it would have blocked the original proposal, in which hoped to provide that documentation solely through observation. That the IRB would allow the damaging information to be collected through observation but not through actual purchase of cigarettes suggest that the denial was based either on the determination that the second version turned the store employees into human subjects under federal definitions, or a more general form of institutional ass-covering.

Wolf presents the whole affair as a misunderstanding. "Most of these challenges can be met if we engage in an open dialogue among RECs, academic researchers, and community partners, both formally and informally," she writes. "If the parties engage each other openly and respectfully, their collaboration will enable important CBPR research to go forward with appropriate review and oversight." (82) In other words, [3]What we've got here is a failure to communicate.

But the researchers understood that they faced not a failure of communication, but an ethical debate. "From a biomedical ethics perspective that is based on principlism and proceduralism, the IRB's decision appears reasonable, even necessary," they wrote. (1917) The problem is that applying biomedical ethics to social questions led to a "decision [that] protected the interests of the tobacco industry and other industries whose representatives wink at illegal cigarette sales." (1918)

On the other hand, the researchers's 2006 article does fail to articulate the core ethical problem. When the researchers seek to justify work that might harm store owners and employees, they defend their research proposal in terms not far

removed from those of a medical researcher.
First, they emphasize "the guaranteed immunity from prosecution" based on the study. (Individuals won't be hurt.) Second, "Ethicists already consider it reasonable that concem for individuals may become secondary to public health priorities during public health emergencies." (OK, individuals may be hurt, but people are dying!)
Finally, "the object of our study was to assess institutional practices within a community, not the responses of individuals within those institutions—a distinction the IRB dismissed as irrelevant . . . By their very nature, institutions have distinct legal and social identities that are something other than a collection of individual legal and social identities, and institutional practices transcend and do not necessarily equate with individual beliefs or behaviors." This puts more distance between the ethics of medical research and that of social research, but it is a hard distinction to maintain when the businesses involved are neighborhood convenience and liquor stores, whose institutional practices are in fact quite likely to equate with individual beliefs or behaviors.
What is needed is a justification for harming individuals, even deliberately doing so. In 1967, Lee Rainwater and David J. Pittman offered one ["[4]Ethical Problems in Studying a Politically Sensitive and Deviant Community," Social Problems 14 (Spring 1967), 363]:

> sociologists have the right (and perhaps also the obligation) to study publicly accountable behavior. By publicly accountable behavior we do not simply mean the behavior of public officials (though there the case is clearest) but also the behavior of any individual as he goes about performing public or secondary roles for which he is socially accountable—this would include businessmen, college teachers, physicians, etc.; in short, all people as they carry out jobs for which they are in some sense publicly accountable. One of the functions of our discipline, along with those of political science, history, economics, journalism, and intellectual pursuits generally, is to further public accountability in a society whose complexity makes it easier for people to avoid their responsibilities.

In the absence of such clear statements in favor of doing harm, we get articles like Wolf's, suggesting no limits on an IRB's ability to restrict research that could cause someone harm. Particularly chilling is Wolf's response to the charge that it was silly for the IRB to forbid UCSF researchers from participating while allowing community partners to proceed. (As the researchers noted, this had the effect of depriving the community partners of expertise while depriving store owners of the protections worked out between university researchers and prosecutors.)
Wolf concedes this point, and wishes for "a consistent set of ethical standards for all research, and I join the call of others to extend the scope of the federal regulations." (82) In other words, this law professor wants a world in which IRBs can forbid citizens from taking notes about the crimes committed in their neighborhoods, lest it "lead to adverse consequences" for the criminals.
I would prefer the world of Rainwater and Pittman, in which those business owners who break the law and poison their communities face some risk of exposure. To achieve such a world, researchers must, at times, intend harm.

1. http://caliber.ucpress.net.mutex.gmu.edu/doi/abs/10.1525/jer.2010.5.4.77
2. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1751809/
3. http://en.wikipedia.org/wiki/What_we've_got_here_is_(a)_failure_to_communicate
4. http://www.jstor.org/pss/798849

Jeffrey Cohen (2010-12-28 12:33:53)
I feel I must correct a misconception that forms the basis for these posts "First, Do Some Harm". Namely, that "do not harm" is a standard by which the IRB makes decisions regarding whether to approve research. This is not the case. Nowhere in the Belmont Report or the federal regulations does it say that research should be risk free.
The Belmont Report does not state "do no harm" as a principle. The Belmont principle is beneficence, which is more than non-maleficence or "do no harm". In its discussion on the assessment of risks and benefits, which is based on the principle of beneficence, the Belmont Report clearly indicates that research that increases risk to subjects can be justified by the benefits of

such research to the individual subject or to society.
With regard to the regulations, the Belmont principles are implemented in Section 111 of the regulations, "Criteria for IRB Approval of Research." It is these criteria which serve as the standards for IRB review. The first two criteria in Section 111 are about risk. The first criterion is that risks to subjects are minimized. Note that it does not say that there should be no risk. Rather, it says that there should be the least possible risk to obtain sound results. There is no ethical basis for conducting research that exposes subjects to more risk than is necessary to obtain valid results. The second criterion is that risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. This means that research should not subject subjects to risk without a sufficiently good reason. There is no ethical justification to subjecting subjects to potential harm without sufficient benefit. The purpose of research is not to harm people but to further human knowledge. We have the court system to punish people for their misdeeds. Research must be able to justify that there is sufficient benefit which can be derived from the research to warrent the risks in the research.
So, holding up "do no harm" as an IRB standard is a misunderstanding of both the Belmont Report and the federal regulations.

Zachary M. Schrag (2010-12-29 08:26:42)
Thank you for these comments.
I quite agree that the Common Rule does not include the admonition to "do no harm," but rather calls on researchers to minimize risks "by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk." Indeed, Wolf seems to recognize that, by denying researchers a sound research design, her IRB acted contrary to the guidance of the regulations. "The regulations provide a framework for decision-making and provide the minimum requirements for ethical conduct of human subjects research," she writes. "An REC can impose more stringent requirements on a study than are specified in the regulations if it feels that doing so is necessary to protect human subjects." (79) In other words, never mind the Common Rule; we'll do as we please.
The Belmont Report is another matter. Its section on beneficence uses the phrases "do not harm" and "do no harm," both with apparent approval. That section sketches only two narrow exceptions. First, "even avoiding harm requires learning what is harmful," i.e., clinical equipoise. And second, the example of risky research on children "without immediate prospect of direct benefit to the children involved" if such research promises "great benefit to children in the future."
Neither exception applies to research on criminal shopkeepers. No one argued that "what is harmful" was unknown; both sides in the debate understood that having one's crimes aired was bad for the criminals. Nor did anyone argue that the research on criminal shopkeepers would be of great benefit to criminal shopkeepers in the future. Rather, the proposal was to imperil one group–the shopkeepers–for the benefit of another: those neighborhood residents not wishing to suffer tobacco-related diseases. [1]The Belmont Report ignores the ethics of such "muckraking sociology."
Thus, I cannot agree with your claim that "the Belmont Report clearly indicates that research that increases risk to subjects can be justified by the benefits of such research to the individual subject or to society." Perhaps some IRBs read it that way, but if so, they are reading between the lines. More commonly, "do no harm" appears as a bullet point on IRB websites around the country; try a search for "IRB" and "do no harm." This leads intelligent people like [2]Bethe Hagens to conclude that "'Do no harm' is an IRB principle."
I don't know if the obscure and somewhat contradictory language of the Belmont Report was responsible for the decision by the UCSF IRB, whose principle seems to have been, "first, do no harm to the University of California, San Francisco." But a better ethics document, such as the Canadian Tri-Council Policy Statement, would at least have given researchers and reviewers a common vocabulary for discussing a project involving critical inquiry.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4999&blogid=140
2. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-ii-aaa-ethics.html

5.12.7 NIH Bioethicist Grady Questions IRB Effectiveness (2010-12-30 23:06)

JAMA has published an interesting exchange concerning the lack of data about IRB effectiveness.
[Christine Grady, "[1]Do IRBs protect human research participants?," JAMA 304 (2010):1122-3; James Feldman, "[2]Institutional Review Boards and Protecting Human Research Participants," and Christine Grady, "[3]Institutional Review Boards and Protecting Human Research Participants—Reply," JAMA 304 (2010): 2591-2592.]
In the September 8 issue, Christine Grady of the Department of Bioethics, National Institutes of Health Clinical Center,

quotes David Hyman's charge that "[4]Despite their prevalence, there is no empirical evidence IRB oversight has any benefit whatsoever—let alone benefit that exceeds the cost." Grady is less blunt, but her message is the same:

> Without evaluative data, it is unclear to what extent IRBs achieve their goal of enhancing participant protection and whether they unnecessarily impede or create barriers to valuable and ethically appropriate clinical research. This lack of data is complicated by the reality of no agreed-on metrics or outcome measures for evaluating IRB effectiveness. Although available data suggest a need for more efficiency and less variation in IRB review, neither efficiency nor consistency directly gauges effectiveness in protecting research participants. Protection from unnecessary or excessive risk of harm is an important measure of IRB effectiveness, yet no systematic collection of data on research risks, no system for aggregating risks across studies, and no reliable denominator of annual research participants exist. Even if aggregate risk data were easily available, it may be difficult to quantify the specific contribution of IRB review to reducing risk because protection of research participants is not limited to the IRB.
> Serious efforts are needed to address these concerns and provide evidence of IRB effectiveness.

The December 15 issue features a reply by James Feldman of the Boston University School of Medicine. Feldman makes two points.
First, he doubts that IRBs cause that much trouble:

> The critique of IRBs by Bledsoe et al, which was cited as evidence that they stifle research without protecting participants, is based on a single-site report of the results of an e-mail survey mailed to 3 social science departments with a total of 27 respondents. The evidence that IRBs have "disrupted student careers [and] set back tenure clocks" should also meet a reasonable standard of evidence.

OK, but what is that standard of evidence? In the absence of federal funding to study systematically a problem created by federal regulations, how much are frustrated researchers expected to do to demonstrate the problem? In other words, how many [5]horror stories would Feldman need to change his views?
Having insisted that evidence is necessary to show the costs of IRB review, Feldman then asserts that no evidence is needed to show its benefit:

> I believe that the effectiveness of IRBs in protecting human participants from research risks is analogous to preventive medicine. It is difficult to derive evidence that can quantify the effectiveness of a specific preventive intervention (new cases of HIV prevented? new injuries prevented?). However, evidence of preventable injury or illness makes a case for the need for effective prevention. Similarly, the tragic and prevalent cases of research abuse and injury make a compelling case for more rather than less review by IRBs that are independent, experienced, and knowledgeable.

As Grady points out in her [6]reply to the letter, even if we accept the analogy, the IRB system does not meet the standards we impose on preventive medicine. She writes, "clinicians and public health officials do rely on evidence of the risks, benefits, and effectiveness of an intervention in preventing HIV or injuries or other conditions to justify adopting one particular preventive intervention rather than another and to defend the necessary investment of resources."
Exactly. As it stands, IRBs are the [7]Avandia of ethics.

1. http://jama.ama-assn.org/content/304/10/1122.extract
2. http://jama.ama-assn.org/content/304/23/2591.extract

3. http://jama.ama-assn.org/content/304/23/2592.1.extract
4. http://www.law.northwestern.edu/lawreview/v101/n2/749/LR101n2Hyman.pdf
5. http://www.institutionalreviewblog.com/search/label/horror%20stories
6. http://jama.ama-assn.org/content/304/23/2592.1.extract
7. http://www.nytimes.com/2010/09/24/health/policy/24avandia.html

Chapter 6

2011

6.1 January

6.1.1 Three Years' Inaction at OHRP (2011-01-01 09:27)

On October 26, 2007, OHRP [1]formally requested "written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the Federal Register on November 9, 1998 (63 FR 60364)."
By the December 26, 2007, deadline, [2]65 people and institutions submitted comments, two-thirds of which concerned oral history or folklore.
That was three years ago. And as far as I can tell, OHRP has taken no action on these comments.
Meanwhile, OHRP's new guidance on what constitutes research subject to regulation, which [3]Bernard Schwetz promised before the end of 2007, is now three years overdue.

1. http://www.hhs.gov/ohrp/documents/20071026.htm
2. http://www.institutionalreviewblog.com/2008/02/historians-flood-ohrp-with-comments.html
3. http://www.institutionalreviewblog.com/2009/01/happy-new-year-ohrp.html

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6.1.2 OHRP's New Website (2011-01-06 10:07)

On January 3, the Office for Human Research Protections launched its [1]redesigned website.
Of particular note to those interested in the history of IRBs is the new section on [2]Related Resources, which contains more key documents than the previous website did, including [3]all the reports (with appendices) produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
I am sorry to see that the website features none of the [4]four items I requested when OHRP asked for comments in January 2009.
Moreover, the "Human Subjects Protection Federal Register Notices 1973 - 2007" on the Related Resources page overlooks [5]Department of Health, Education, and Welfare, "Secretary's Interpretation of 'Subject at Risk,'" Federal Register 41 (28 June 1976): 26572, despite my drawing that omission to OHRP's attention in a follow-up e-mail to my comments.
The 1976 notice includes the curious claim that "The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 USC 2891-3 (added by Pub. L. 93-348) . . ."

As I note in my book, neither before or after this notice did federal regulators restrict their rule-making to areas of concern addressed in congressional hearings.

1. http://www.hhs.gov/ohrp
2. http://www.hhs.gov/ohrp/archive/related.html
3. http://www.hhs.gov/ohrp/archive/nationalcommission.html
4. http://www.institutionalreviewblog.com/2009/01/ohrp-to-revise-website.html
5. http://zacharyschrag.com/files/19760628_secretarys_interpretation.pdf

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6.1.3 UConn IRB Encouraged Failed Effort at Insitutional Anonymity (2011-01-09 11:43)

Professor George R. La Noue of the University of Maryland, Baltimore County, who so kindly reviewed my book, also alerted me to a case of IRB interference in a significant work of sociology. [He mentions the case in George R. La Noue and Alexander Bush, "Institutional Review Board Rules: Should One Size Fit All Disciplines?" presented at Fifth Annual Conference on Interdisciplinary Social Sciences, Cambridge University, August 2-6, 2010. The paper is available on request from [1]Professor La Noue.]

In 2009, Gaye Tuchman, a University of Connecticut sociologist, published [2]Wannabe U: Inside the Corporate University, which the University of Chicago Press calls an "eye-opening exposé of the modern university."

The book describes the growing power of central administrators at a public university and is based in large part on participant observation. Rather than identify the university she studied, Tuchman uses the term "Wannabe University" and creates fictitious names for everyone involved, including the presidents and provosts. In the book, Tuchman notes that "as my university's institutional review board had specified, I never taped or took pictures of anyone or anything on the campus." (17) Presumably, the prohibition on photography of even inanimate objects was designed to obscure the identity of the institution.

This was a fool's errand. As Harold Orlans put it in a manuscript first written in 1954,

> "It is a popular pastime of academic cognoscenti to disclose 'anonymous' towns and authors. . . . Without undertaking any special search, we have noticed the real names of 'Middletown,' 'Southerntown,' 'Cotton,' 'Yankee City,' 'Cantonville,' 'Elmtown,' and 'San Carlos' identified in print: it is standard form for book reviewers to reveal the name of an 'anonymous' community."
> [Harold Orlans, "Ethical Problems and Values in Anthropological Research," in U.S. Congress, House Committee on Government Operations, Research and Technical Programs Subcommittee, The Use of Social Research in Federal Domestic Programs: Part IV—Current Issues in the Administration of Federal Social Research (90th Cong., 1st. sess., 1967), 362.]

More recently, [3]anthropologist Cathy Small failed miserably in her attempts to disguise herself and the site of her research—Northern Arizona University. [4]Studies of allegedly anonymized high schools and universities contain enough information to identify them.. And Tuchman herself "knew that the reception of ethnographies had included attempts to identify their locale and even the identity of the people discussed in the book." (16)

Despite Tuchman's effort to preserve institutional anonymity, the fate of her work was no different; Inside Higher Ed quickly noted that "[5]an abundance of evidence points to Wannabe's identity as UConn, Tuchman's employer." What a surprise.

It is not clear from the book the degree to which Tuchman resisted the IRB's request that she disguise the identity of the university. We can, however, say that the IRB encouraged her in the foolish belief that the university would remain anonymous.

Her decision to attempt anonymity had the following effects:

- It prevented Tuchman from presenting visual evidence, like screen captures of websites or photogaphs of the UConn campus.
- It reduced the accuracy of Tuchman's quotations by denying her the chance to record conversations.
- It encouraged Tuchman to think that the identities of major figures in her work, e.g., university presidents and provosts, might remain hidden, rather than writing the book in the full knowledge that she was holding these public figures accountable for their public actions.
- It prevented Tuchman from citing the published sources she used to flesh out her story. For example, she [6]quotes stories about UConn from the Hartford Courant. (98) One can [7]look up these quotations on Google (thus further identifying UConn as the site of Tuchman's research), but that's no substitute for proper footnotes to all published documents.
- Finally, it may have threatened the rights and welfare of any informant who spoke candidly to Tuchman in the naive belief that UConn's identity would remain hidden. Fortunately, most of the people she spoke with–especially the social scientists–appear to have been more realistic than Tuchman herself (16-17).

Tuchman also notes that "I have not interviewed current administrators, though I did feel free to ask them informal questions when I encountered them on campus or at committee meetings." (18) Tuchman does not detail the reason behind this decision, or whether the IRB was involved. But the decision reduced the book's ability to explain the events and trends at the heart of the narrative. And it is a particularly ironic decision, in that the second paragraph of the book complains that "no one ever had the audacity to ask publicly, 'Just what do you mean, President Whitmore?'" (1)

As a member of the faculty of a large public university that is perpetually "in transformation," I found some important insights in Wannabe U. But much of the book did not reflect my experience at Mason, leading me to conclude that this is not, in fact, a book about ambitious public universities in general, but rather a book about the corporatization of the University of Connecticut in particular, under the leadership of presidents Philip E. Austin and Michael J. Hogan and provosts John D. Petersen and Peter J. Nicholls. A book that acknowledged that fact, and did not avoid interviews with its central characters, would have been more respectful to its subjects and readers alike.

In her introduction, Tuchman mourns the "accountability regime" at her university and asks "why . . . has the faculty been so compliant?" (24) It is a question one could ask of her own interactions with the IRB.

1. http://www.umbc.edu/pubpol/glanoue.php
2. http://www.press.uchicago.edu/presssite/metadata.epl?mode=synopsis&bookkey=342121
3. http://www.nysun.com/new-york/on-the-trail-of-an-undercover-professor/18869/
4. http://33bits.org/2008/12/15/the-fallacy-of-anonymous-institutions/
5. http://www.insidehighered.com/news/2009/10/06/wannabe
6. http://books.google.com/books?id=g-dOYdf27LYC&lpg=PP1&ots=YA-X08qXdD&dq=wannabe%20u&pg=PA98#v=onepage&q=state%20legislature%20added%20$8&f=false
7. http://articles.courant.com/1993-10-09/news/0000003706_1_faculty-family-studies-academic-departments

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6.1.4 Sociologists Find IRBs Serve Organizational Interests, Not Professional Ethics (2011-01-11 08:14)

Sociologists Carol Heimer (Northwestern) and JuLeigh Petty (Vanderbilt) find that IRBs "substitute bureaucratic ethics for professional ethics."

[Carol A. Heimer and JuLeigh Petty, "[1]Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research," Annual Review of Law and Social Science 6 (2010): 601-626.]

Much of the article consists of concise, accurate summaries of many of the complaints lodged against IRBs, including

some by your humble blogger. (The bibliography lists well over 100 works on IRBs and research ethics.) Heimer and Petty categorize these complaints as "critiques of IRB law as law, critiques of IRBs as regulation, and critiques of IRBs as a system of norm making." Critics have charged that IRBs act lawlessly, do more harm than good, and deny researchers the opportunity to shape the norms that govern them. "IRBs seem to have lost sight of their original objective," Heimer and Petty state, summarizing some of this work. "No longer collective bodies of researchers deliberating together about the ethical dilemmas they encounter, IRBs are instead agents of the university (or research center). Rather than protecting research subjects from harm, they now seem especially focused on protecting universities and research centers."

To these complaints (which they mostly seem to endorse), Heimer and Petty add three of their own.

First, they employ the "lens of inequality," finding that "the regulations fail in part because the research process does not go as the regulators imagine and because the regulations do not address the social sources of the big inequalities. Furthermore, the regulations support inequality when they prevent research on powerful groups who harm others." IRBs fret over the details over consent forms, ignoring evidence that "potential research subjects actually pay little attention to consent forms and later do not even remember the details in them." At the same times, IRBs ignore "structural inqualities" (most notably, "the big inequality that the majority of the global research funds address the health problems of the wealthy few") while perpetuating inequality by preventing social researchers from studying powerful groups, including [2]sellers of loose cigarettes.

I find the section on "the big inequality" the least persuasive part of this article. Heimer and Petty too readily accept the claims of [3]Jill Fisher and [4]Adriana Petryna that (in the words of Heimer and Petty) "the focus on abstract, universal principles in the Belmont Report deflects attention from the structural conditions and inequalities under which the unethical treatment of research subjects has taken place." Fisher and Petryna mischaracterize both the Belmont Report and the Common Rule by claiming (in Petryna's words) that "so long as an investigator [can] document that his or her subjects could deliberate about personal goals and act 'under the direction of such deliberation,' it [is] ultimately up to the subjects themselves to judge the acceptability of the risks they [take]."

In fact, the [5]Belmont Report specifically warns against imposing the burdens of research "upon poor ward patients, while the benefits of improved medical care [flow] primarily to private patients," and the [6]Common Rule requires IRBs to determine that "risks to subjects are reasonable in relation to anticipated benefits" and that "selection of subjects is equitable," independently of ensuring informed consent.

Whether IRBs are able to do this, and to do this without inappropriately restricting a great deal of ethical research, is another question. But it's unfair to charge the National Commission or the authors of the regulations with ignoring the problem of structural inequality and the challenge it poses to a consent-based model.

After the section on the "lens of inequality," Heimer and Petty "look at IRBs through the lens of professions." Noting that "the regulation of human subject research is a growth industry," they warn that rather than cede the power to declare a project exempt (as suggested by accommodationist reformers like [7]Levine and Skedsvold), "IRB professionals [may] defend and perhaps seek to expand their jurisdiction." In doing so, they are protecting "their livelihood, a secure niche on the edges of the research and scholarly world." And they will have help: "OHRP's focus on documentation helps explain why IRB professionals and not bioethicists are the growth sector in human subjects regulation."

Finally, Heimer and Petty "examine IRBs and research enterprises as organizations." Here they find that "a complex mixture of coercion by the government, fear of loss of funding, individual professional self-interest . . . and a desire not to be seen to be on the wrong side of a key cultural divide" do more to explain the growth of IRBs than do the Nuremberg Trials and other documented cases of unethical research.

They conclude with a grim assessment:

> As the regulation of human subjects research has been institutionalized, professional competition and the protection of organizational interests seem to have carried the day. A bureaucratized research ethics is essentially an ethics of documentation. The task of translating the principles of autonomy, beneficence, and justice was never going to be easy. But translations that ignore structural inequalities, delay or reduce valuable research, and substitute bureaucratic ethics for professional ethics may not bring as much progress as we hoped.

1. http://www.annualreviews.org/doi/abs/10.1146/annurev.lawsocsci.093008.131454
2. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-iii-loosies-in.html
3. http://books.google.com/books?id=Tczn9GwcPikC&lpg=PP1&ots=9nD0jeiwIt&dq=%22Medical%20Research%20for%20Hire%3A%22&pg=PA28#v=onepage&q=belmont&f=false
4. http://books.google.com/books?id=BnG1-VigFi8C&lpg=PP1&ots=x3n-J9vlQF&dq=%22When%20Experiments%20Travel%22&pg=PA67#v=onepage&q=belmont&f=false
5. http://ohsr.od.nih.gov/guidelines/belmont.html
6. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111
7. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html

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6.1.5 No, Seriously (2011-01-14 08:15)

Irena Grugulis, Professor of Employment Studies at Bradford University in the United Kingdom, complains that an ethics committee imposed medical standards on her organizational research.
[Irena Grugulis, "[1]Research Ethics and James Bond," Social Science Spaces, 6 January 2011.]
She writes,

> My own work is probably about the least harmful you can imagine. I spent last year conducting an ethnography of a computer games company, watching the way people learned skills and the way they were managed. No under-18s, no members of vulnerable groups, no illegal activities. Everyone was told who I was in advance by the company, both company and individuals would be anonymised in any publications and before observing anyone I would ask their permission. So far so unexceptional, and the only problem I anticipated was whether informants would be happy to accept Krispy Kreme doughnuts in exchange for being mithered at work.
> Enter the ethics committee. They insisted on full written consent from every worker in the offices (about 250), every delivery person and – on the occasions I went off for a chat with informants – every barrista who served us coffee and waitress who brought us pizzas (no, seriously). An extensive correspondence later, since that would have effectively made an ethnography impossible, they grudgingly agreed to let me proceed and turned their attention to other social science projects. They queried the relevance of research into trade unions and advised that researcher to take steps to ensure their personal safety (because union members are sooooo dangerous), issued formal guidance that interviews over 30 minutes required special permission from the committee and, in the famed Battle of PostModernist Hill, decided that auto-ethnography should be barred.

As Grugulis notes, such restrictions violated the guidelines of both the British Sociological Association and the Economic and Social Research Council. This shows that even in countries such as Canada and the United Kingdom, where social scientists have worked out ethics guidelines nominally more pluralist than the Belmont Report, ethics committees continue to impose medical rules on non-medical fields.
[Note, 14 January 2011: I originally entitled this post, "Ethics Committee Hampered Management Research." On reflection, I realized that that headline did not do justice to the wit and exasperation of Professor Grugilis's story.]

1. http://www.socialsciencespace.com/2011/01/research-ethics-and-james-bond/

6.1.6 Obama's Impossible Request (2011-01-19 11:54)

Bioethics Forum has published my essay, "[1]Obama's Impossible Request," which concerns the president's November 24 charge to the Presidential Commission for the Study of Bioethical Issues.
President Obama asked the commission for "a thorough review of human subjects protection to determine if federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the federal government." I term this an impossible request.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5107&blogid=140

6.1.7 Does the NSF Have an Oral History Policy? (2011-01-27 21:18)

An independent scholar has been told by a National Science Foundation program officer that if she plans to do oral history she should "[1]speak in the application to the problem of IRB review."
If the NSF is requiring IRB review of oral history, it is out of step with the recent actions other federal agencies, including the [2]Smithsonian, the [3]Army, and the [4]Office for Human Research Protections.
I am not aware of any NSF policy document on this issue, so it is not clear if the program officer's statement represented the NSF position or the officer's personal views.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=1101&week=d&msg=L2RfvranN2metCQdjYK1mQ&user=&pw=
2. http://www.institutionalreviewblog.com/2010/07/smithsonian-frees-oral-history.html
3. http://www.institutionalreviewblog.com/2009/12/hooah.html
4. http://www.institutionalreviewblog.com/2007/01/generalizable-revisited.html

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Anonymous (2011-01-28 09:51:10)
My guess is that program officers have little understanding of the regulations. What they do understand is that when they are processing an award they have to document whether human subjects research is involved or not, whether it is exempt or otherwise, etc. So the PO is probably just looking for an acceptable piece of paper that tells him or her what to tick and provides appropriate CYA. Normally a letter or form from the IRB would accomplish this. Of course if the PO understood the regulations he or she would know that the regs are silent on how an activity is determined to not involve human subjects research or meets the requirements for exemption–although NSF may require this come from an IRB. This is problematic for independent researchers involved in an activity where there is no institutional involvement. If there was an institution involved in the activity then he or she could just sign an independent investigator agreement, have the institution's IRB write a letter stating that the activity doesn't involve human subjects research because, presumably in this case, the activity isn't a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". My guess is that the fact that the activity involves oral history is irrelevant. They don't care what you call it; they just want their paperwork.

Anonymous (2011-01-28 10:07:38)
Looking at her original post again, she appears to be in the application submission stage. I think she just needs to make a case in the application that the activity isn't HSR because it doesn't meet the regulatory definition of research. She'll need to read the regulations and OHRP guidance and quote appropriate parts (e.g. §46.102(d)) to make a convincing case why this isn't research and why involvement of an IRB is therefore unnecessary. Of course if they decide to fund her, they may still come back and bug her for independent documentation.

Zachary M. Schrag (2011-01-30 11:17:43)
Thank you for these comments.
What is alarming about this case is that the program officer is demanding that the researcher meet a standard without articulating

that standard.
Why should an independent scholar speak to the problem of IRB review of oral history any more than she should speak to the problem of IRB review of reading a newspaper? There should be no problem.
As Jerry Menikoff noted in 2009, "[1]In the absence of guidance, people tend to be reluctant to take certain actions out of fear that they are violating the rules. In some instances, important research is not even attempted, all because of a misunderstanding. Guidance could eliminate the misconception and clear the way for research."

1. http://www.institutionalreviewblog.com/2009/02/less-flexibility-more-freedom.html

Anonymous (2011-01-31 05:58:15)
I wonder if part of the difficulty here might be the slightly ambiguous nature of "oral history". NSF may not regard the simple collecting of oral history as 'science' – if there is an analysis phase of the proposed research (a 'science' component to the proposal) it might then be subject to IRB approval. Anthropologists ran into this kind of problem with NSF for a long time – simply collecting data was not necessarily regarded as sufficiently scientific for the cultural anthro program officer who was in place for years. But that's essentially why "oral history" is exempt from IRB review: it's just collecting data.
Certainly our experience with NSF and oral history would lead me to conclude that the policy is something like: "Oral history" is supported by NEH or NEA. If you want NSF support you should go beyond oral history, and at that point you are into an IRB realm.

Zachary M. Schrag (2011-01-31 07:59:54)
I think NSF values oral history more than that. But as an agency, it has not developed a coherent policy about IRB review of oral history.

6.2 February

6.2.1 Library Research Round Table Calls for Papers on IRBs (2011-02-03 16:02)

Melora Norman kindly forwarded the following:
Call for Presentations
2011 Library Research Round Table Forums at ALA Annual Conference,
New Orleans, LA
June 23-28,2011
The Library Research Round Table (LRRT) will sponsor the Chair's Research Forum at the 2011 American Library Association Annual Conference in New Orleans, LA (June 23-28). The LRRT Forums are a set of programs at the ALA Annual Conference featuring presentations of LIS research, in progress or completed, followed by discussion.
Chair's Forum Topic: Institutional Review Boards
Institutional review boards (IRBs) are a common fixture in institutions of higher education and play a central role in academic research. Modern-day scholars must account for IRB guidelines when planning a research project. To better understand the IRB process and its implications for scholarship, we are interested in proposals that focus on the purpose and functionality of IRBs. Proposals may address, but are not limited to:
IRBs and protection of subjects
IRBs and student researchers
Social science and IRB approval
Oral history and privacy concerns
The chilling effect of IRB restrictions
IRBs with a disciplinary focus
All researchers, including practitioners from all types of libraries, library school faculty and students, and other interested individuals are encouraged to submit proposals. LRRT Members and nonmembers of LRRT are invited and welcomed to submit proposals.

Please submit a two-page proposal by Monday, February 21, 2011. Late submissions will not be considered, and submissions must be limited to two pages in length. On the first page, please list your name(s), title(s), institutional affiliation(s), and contact information (telephone number, mailing address, and email address). The second page should NOT show your name or any other identifying information. Instead, it must include: 1) The title of your project, and 2) A 500-word abstract. Previously published research or research accepted for publication by December 15, 2010, will not be considered.
Notification of acceptance will be made by Monday, February 28, 2011. Please send submissions (via email or snail mail) to:
Linda L. Lillard, Ph.D.
Library Research Round Table Chair
Associate Professor
205 Carlson Library
Department of Library Science
Clarion University
Clarion, PA 16214
Phone: 814-393-2383
Email: llillard@clarion.edu

6.2.2 Cautious Optimism on Canada's TCPS2 (2011-02-04 10:29)

Ted Palys and John Lowman of the School of Criminology, Simon Fraser University, find that the [1]second edition of Canada's Tri-Council Policy Statement (TCPS2), released in December 2010, offers significant improvements over the first edition of 1998.
[Ted Palys and John Lowman, "[2]What's Been Did and What's Been Hid: Reflections on TCPS2," 18 January 2011]
On the positive side, they find that "The section that has been one of our primary foci over the years – the policy's provisions regarding privacy and confidentiality – has improved to the point where it is respectful of different epistemological and moral perspectives, offers protections for research participants, and reminds both researchers and the institutions in which they work of their duties and obligations. To that extent, TCPS2 represents an exemplary policy that other nations can emulate." While they would have liked the document to offer better legal advice, they appreciate the ethical advice it gives to researchers and institutions about their duty to honor pledges of confidentiality.
They also applaud TCPS2's new Chapter 10 on qualitative research, provided it is correctly employed:

> To the extent that Chapter 10 elaborates principles that differentiate qualitative from quantitative and/or experimental research designs – for example, it allows an emergent research design, and authorizes researchers to avoid the legalistic relationship implied by a signed consent form – it will force REBs to be more sensitive to the protocols of qualitative methods. To the extent that it adequately captures qualitative approaches, it may serve as an example of the sort of experience and expertise that is required on REBs that review qualitative research. However, if REB members use the chapter on qualitative methods as a "Coles Notes" course enabling them to claim that they have developed that expertise, we will all be in trouble.

Palys and Lowman are less sanguine about TCPS2's efforts to combat "the inappropriate imposition of biomedical practices and solutions that may make sense in relation to biomedical/experimental research, but would be epistemologically inappropriate and sometimes unethical in a more qualitative field-based context."
For example:

- Though senior university officials, such as vice presidents for research, are prohibited from attending REB meetings, their appointees can and do. How does this prevent conflict of interest?
- REB "community members" are supposed to represent the perspective of research participants, but they are never recruited from the ranks of homeless persons, intravenous drug users, drug dealers, sex workers, and prisoners studied by criminologists.
- TCPS fails to give adequate "guidance about when establishing multiple REBs would be desirable," so that qualitative researchers may still find themselves at the mercy of quantitative, medical researchers who do not understand the work they are reviewing.

Still, they end on a hopeful note. While TCPS2 is flawed, it is an improvement over TCPS1. And the three councils that created the policy statement can continue to collect feedback, eventually leading to an even better TCPS3.
I share their cautious optimism. The final version does include some troubling language. [3]In their comments on an earlier draft, Palys and Lowman noted that it could promote "ethics creep" by "broadening the concept of 'welfare' to include not only the individual research participant but also everything of concern in that person's life world." The final TCPS 2 does just that, stating that

> The welfare of groups can also be affected by research. Groups may benefit from the knowledge gained from the research, but they may also suffer from stigmatization, discrimination or damage to reputation. Engagement during the design process with groups whose welfare may be affected by the research can help to clarify the potential impact of the research and indicate where any negative impact on welfare can be minimized. Researchers must also consider the risks and potential benefits of their research and the knowledge it might generate for the welfare of society as a whole.

On the other hand, chapter 10 does take pains to explain to REBs how qualitative researchers work, and the differences between their ethics and methods and those of biomedical researchers. REBs, it cautions, should accept projects that focus on just a few people, or people more powerful than the researchers. They can expect some reaserchers to produce "research that is critical of settings and systems, or the power of those being studied." Consent may be "dynamic, negotiated, and ongoing," rather than spelled out in advance. While some qualitative researchers may offer confidentiality, others (including oral historians) show "respect for the participant's contribution . . . by identifying the individual in research publications, or other means of dissemination of the results from the research." REBs should not expect fixed protocols, since "Specific questions or other elements of data collection may be difficult to anticipate, identify and articulate fully in the research proposal in advance of the project's implementation."
In short, TCPS2 calls on REBs to evaluate qualitative research in ways wholly unlike the ways they evaluate quantitative, biomedical research.
Whether that will happen is another question. Canadian researchers have told me that in practice, university REBs ignore the TCPS in favor of American-style ethical imperialism.
Nor has the Panel on Research Ethics explained why we need REB review of qualitative research in the first place. Forcing every project to go through the REB is a massive burden, even if the REB finds the right clause in TCPS2 that will allow the project to proceed as designed. If qualitative researchers had an established record of abusing research participants, and if REBs had an established record of preventing such abuses, that would be one thing. But in the absence of such evidence, I don't see why all of this is necessary.
Still, so far as recognition of ethical and methodological pluralism goes, I am inclined to regard TCPS2 as the state of the art. More sophisticated than the Belmont Report or equivalent documents in the United Kingdom or Australia, it suggests what can happen when social scientists are allowed to participate in discussions of research ethics, and when government bodies revise their guidance in light of experience.

1. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
2. http://www.sfu.ca/~palys/PalysLowmanCommentsOnTCPS2-2011.pdf
3. http://www.sfu.ca/~palys/Palys-LowmanCommentsOnDraftTCPS2.pdf

6.2.3 Anxious Pessimism on UK's New Framework for Research Ethics (2011-02-18 14:42)

In March 2010, the United Kingdom's Economic and Social Research Council (ESRC) released its [1]Framework for Research Ethics (FRE) as a successor to its 2005 Research Ethics Framework (REF).
David Erdos kindly alerted me to the November 2010 (Volume 15, Issue 4) issue of [2]Sociological Research Online, which devotes a special section to essays about the new framework.
The six essays in the section suggest that British sociologists are wary of their research ethics committees and the expanded authority granted to them by the new framework.

Stanley and Wise: In Search of "Real Expertise"

In the lead article, "The ESRC's 2010 Framework for Research Ethics: Fit for Research Purpose?," Liz Stanley and Sue Wise–guest editors of the special section–find that "the Framework for Research Ethics must be responded to as bad in its entirety and lobbied against by the social science community."
Stanley and Wise are no fans of ethics review. Citing critical literature from the United Kingdom, Canada, and the United States, they warn of "the probability . . . of RECs finding appropriate work to do to justify their resourcing, the training received, the workload and administrative relief given, and over time acting around their own rules of thumb and custom and practice, including by making use of external expert advisors, and with significant differences in the practices of different RECs coming into existence . . . We do not accept 'good intentions', then, as anything other than platitudes which cannot be guaranteed to translate into longer term REC practice."
They point to three worrisome changes from the 2005 FRE:

> firstly, the system is to be fully mandatory, in the sense that it is no longer possible, as previously, for research applications to make the case that no out of the ordinary ethical issues arise; secondly, the Research Ethics Committees (RECs) set up in the ESRC's 2005 document have been reconfigured, with their extended remit including reviewing all research proposals accepted by the ESRC and other funding bodies; and thirdly, funding will depend on the REC review, with its purview extending through a project's life.

Stanley and Wise are particularly contemptuous of the FRE's assumption that multidisciplinary committees can muster the expertise necessary to review a wide range of project.

> The RECs are seen, through their committee constitution, to have some kind of free-floating 'expertise' providing competence to evaluate the specificities of particular located pieces of research. We reject this notion of ethics as a general 'expertise', for a committee cannot build up supposed competence without the contextual and disciplinary know-how that real expertise comes from.

Review by pseudo-experts, they fear, could undercut the true peer review that can provide sound advice on matters both methodological and ethical: "why would someone agree to act as an ESRC assessor of research proposals, when the RECs can change or overturn the considered scholarly judgements of assessors reporting on a particular proposal?"
Stanley and Wise wish for a regime that would respect disciplinary differences. "There is not one social science community," they argue, "with very different approaches existing which impact on all aspects of research, differentiating the social sciences from each other, differentiating even different paradigms and methodologies from others in the same discipline. These particularities matter because they relate to fundamental matters of how epistemology and ontology are conceived . . . " They also note, "The professional bodies of sociologists, anthropologists, political

scientists and social policy specialists have no place within the FRE framework, while for us an ethics framework that does not proceed from the ethical guidelines of the relevant professional associations is deficient and lacks intellectual credibility. This ignoring of disciplinary guidance is also a failure to recognise how 'light-touch' approaches could be better implemented by some deference/recognition of difference amongst research communities and also provide RECs with the opportunity to appropriately refer to and make use of disciplinary guidelines."
Stanley and Wise's faith in disciplinary expertise leads them to hope that the British Sociological Association will lead the attack on the new FRE. Here's hoping.

Holmwood: Beware Specialists in Research Ethics

John Holmwood's "Research Ethics Committees (RECs) and the Creaking Piers of Peer Review," generally shares Stanley and Wise's concerns. Holmwood is particularly worried about

> the apparent need for a researcher to be able to identify all the possible 'harms' in advance of beginning the research or prior to seeking informed consent from participants. In Section Two of the FRE (2010: 28), where risks in the dissemination of research are discussed, possible 'harms' to elite interviewees are identified. It is acknowledged that it may be important to publish critical findings about policies and organisations. However, it appears with the qualification, "but was this within the original remit of the research" (2010: 28). By implication, possible criticism of commercial and government organisations needs to be flagged up when negotiating consent. Not only does this seem to be an undue protection of the powerful, but the FRE thereby provides recourse for complaints to be made against researchers. In this context, it becomes even more important that there be an independent body to adjudicate such cases, since an individual's own institution may be inclined to accommodate commercial and government concerns, given the importance of the impact agenda.

Like Stanley and Wise, Holmwood is also worried about ethics review by committees that don't understand the research they are reviewing.

> As Michèle Lamont ([3]2009) has shown, interdisciplinary peer review can work very effectively (under certain conditions, which includes the presence of a subject specialist in the reviewing group), but the risk is that RECs will not be conceived in this way, since their members will be encouraged to regard themselves as specialists in research ethics, rather than the subjects in which those ethics are embedded. Indeed, this was a feature of all the training I received as part of my recruitment to a REC, where any argument that there might be alternative standards for different kinds of research began a search for a 'proxy' for the preferred standard. Equally, the argument that we might learn from journalistic ethics – that exploratory research might have something akin to investigative journalism – was regarded as inappropriate. There was a clear boundary circumscribing social scientific research and then an issue of establishing standards across the research within that boundary.

As an REC chair, Holmwood was able to break through these boundaries by insisting that proposals be reviewed by experts not on his REC. But he acknowledges that this practice put additional burdens on scholars already struggling with requests for reviews of articles, grants, and other academic projects.

Reed: "We need to actively resist ethics creep"

Kate Reed complains of "a Taylorist approach to research evaluation" in her essay, "The Spectre of Research Ethics and Governance and the ESRC's 2010 FRE: Nowhere Left to Hide?"
Like Stanley and Wise, Reed fears review "by people who know little about the research

field/discipline." A veteran of "somewhat farcical" review by a hospital ethics committee, she now fears that review of social science will be even more onerous than that of health-related research, where ethics review and funding consideration remain separate. "Social research can be and often is a very positive experience for many people - respondents and researchers alike," she notes. If the new FRE reduces the amount of social research attempted, research participants will be among the losers.

Hammersley: Accountability vs. Independence

Martyn Hammersley's essay, "Creeping Ethical Regulation and the Strangling of Research," points up the contradictions that result from the ESRC's halfhearted effort to address the concerns of social scientists:

> For example, the discussion of gaining informed consent in the FRE suggests that 'typically' this should be done in written form, with agreement being 'signed off' by participants (ESRC 2010:28), yet only a little later we are told that 'highly formalized or bureaucratic ways of securing consent should be avoided in favour of fostering relationships in which ongoing ethics regard for participants is to be sustained […]' (p29). In another place, it is insisted that 'innovative' research is to be facilitated (p2), but then researchers are instructed that 'risks should be minimized' (p3). Later it is recognized that 'not all risks can, or in some cases, should be avoided' (p26), indeed that:
>
> > research may be 'deliberately and legitimately opposed to the interests of the research participants/organizations' in cases where the objectives of the research are to reveal and critique fundamental economic, political or cultural disadvantage or exploitation' (ESRC 2010:27).

However, on the next page we are informed that:

> political sensitivities may arise when findings are contrary to local or national policy. It may be important to publish critical findings about policies and organisations, but was this within the original remit of the research? Were the participants aware that this could be a consequence of their participation?

As Hammersley notes, the phrase, "deliberately and legitimately opposed to the interests of the research participants/organizations" is borrowed from the 2002 Tri-Council Policy Statement. He could have added that that document, as well as the latest TCPS, features contradictions similar to those she documents in the new FRE.
Hammersley puts the expansion of ESRC and REC power into the broader context of the corporatization of the university, which prefers audits to autonomy:

> The chances of successfully resisting the creep of ethical regulation are low given that it is part of a much wider shift in the whole character of universities, and of the research that is carried on within them ([4]Hammersley 2010). Moreover, the extension of ethical regulation is lubricated by an ideology that is hard to challenge. This assumes, rightly, that there are genuine ethical concerns associated with social research, but exaggerates them, and also assumes, wrongly, that these can be eliminated or minimised through establishing accountability regimes. It is striking that the FRE formulates ethics in terms of 'protecting' all involved from the 'risks' associated with research through demanding 'compliance' with 'good practice'. As already noted, there is an exact parallel here with similar ventures in other parts of the public sector where 'transparent accountability' regimes have been set up in order to deal with problems or to 'ensure' improvement. The fact that, generally speaking, these policies have failed to achieve their goals – and have, generally, undermined good practice and commitment to it – does not terminate belief in the driving ideology. People want to believe that accountability procedures work, because they find the alternative – trusting professional judgment – unacceptable.

Orton-Johnson: Not All Internet Research Is Risky

Kate Orton-Johnson's "Ethics in Online Research; Evaluating the ESRC Framework for Research Ethics Categorisation of Risk" takes particular offense at the Framework's requirement of full committee review for "Research involving respondents through the internet, in particular where visual images are used, and where sensitive issues are discussed." "In its assumption that all forms of internet research are inherently problematic," Orton-Johnson writes, "the FRE neglects the methodological and disciplinary breadth of web-based enquiry and, in doing so, threatens to tar a number of research settings and tools with too strict an ethical brush."

Full review may not be necessary, she suggests, for research that merely "employs the global reach of the internet as a cost effective survey tool." And RECs who face internet-based protocols are likely to apply the FRE's rigid requirements of written, informed consent rather that the more flexible approach advocated by the Association of Internet Researchers.

"Rather than contributing to lively debate and tackling some of the emergent, complex and contested understandings of what ethical online research might look like," she concludes, "the ESRC FRE framework unhelpfully proposes a formal review structure that is reminiscent of early moral panics around the potential social impacts of new technologies."

Rustin: Pick Your Battles

The final essay, "The Risks of Assessing Ethical Risks" by Michael Rustin, notes the lack of empirical evidence for the need for ethics review "in the form of reports of actual harms suffered in consequence of research projects having been approved without formal ethical scrutiny. (Some reference is made in FRE 2010 to information being internally available about these matters, but no indication is given of what this was.)" Nor has there been any empirical study comparing various forms of regulation, such as "light touch" vs. full committee review, or ethical review by scientific reviewers.

Nevertheless, Rustin is more hopeful (or less gloomy) than the other authors in the section about the actual effects of the new FRE:

> It is clear that according to the ESRC 2010 Framework, and in the real world of today, the crucial institutions and processes are those of the university and other RECs, and it to the operations of these that practical attention must be given. FRE 2010 seems to me to be more pragmatic in this respect than Stanley and Wise allow. In one part of the document at least, it does provide for RECs to be constituted on a Faculty or discipline basis, so far as their detailed consideration of projects is concerned, and proposes that second-tier RECS working at an institution-wide level should confine themselves to broad oversight, to a quality assurance function in effect, and should not engage in consideration of specific research proposals. The provision for review of ongoing projects suggests only 'occasional' investigations, against suggesting that the ESRC is anxious to cover every theoretical eventuality, without wanting to submerge research under a burden of continuous surveillance. (One could make a logical case for researchers having to report every year – every three months – on their own ethical conduct, but even the most anxious regulators can see the need for some proportionality).

[Note: Rustin's mention the "one part of the document [that] proposes that second-tier RECS working at an institution-wide level should confine themselves to broad oversight" would appear to be a reference to Section 1.3.1.1 of the FRE, which allows a faculty-, school-, or department-based committee "defined by an area of substantive and methodological
expertise." Yet Section 1.5.2 states that "RECs should be multidisciplinary." As Professor Hammersley notes, internal consistency is not the FRE's strong suit.]

The real problem, Rustin suggests, lies not with the national FRE, but with the operations of local RECs, which even before the release of the FRE were imposing restrictive demands. He counsels social scientists that while it might be nice to have research reviewed by subject experts alone, "this argument has been lost, and it has now become the

conventional wisdom that ethical issues must be dealt with as a specialist function," and that working toward a less restrictive FRE is equally futile. He concludes, "I doubt if there is now any way forward for researchers but to seek to make this REC system work constructively, thereby building into it the elements of trust and responsibility which are the essence of ethical practices of any kind."

Schrag: The Question is Who, Not When

For the most part, I share the authors' pessimism about the expanded reach of British RECs. I do not, however, share the hostility to the idea of ongoing review expressed by Stanley and Wise, Hammersley, and Reed. Reed, for example, interprets the FRE's requirement that investigators inform RECs of new developments as an invitation to "extensive micro-management through auditing places incredible constraints on research projects. Not
only will researchers be constrained at the start of the project but also during and after it, as plans for dissemination now also comes under the purview of ethics . . . Faced with such endless bureaucracy and surveillance, many social researchers will simply give up on data collection or produce research of questionable validity that tells us very little about what actually exists out in the field."
Perhaps. But I would point out that the effort to assess all risks in advance is one of the vices of ethics committees. Encouraing committees to let researchers write up their studies and then engage in [5]ethical proofreading, that is, to put ethics review at the end of a project rather than the start, might help some projects.
Of course, pre-publication review would still depend on forming committees of people knowledgeable about the ethics of a particular discipline. As the authors of these essays point out, there is little hope of such committees being formed under the new FRE.
NOTE: The six essays cite a fair number of articles by the authors and other British scholars that are new to me, suggesting I need to work harder to keep up with the British literature on RECs. In related news, Robert Dingwall has started a thread on the new Sage site, social science space inviting readers to relate [6]Absurd decisions by Ethics Committees.

1. http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx
2. http://www.socresonline.org.uk/welcome.html
3. http://www.hup.harvard.edu/catalog.php?isbn=9780674057333
4. http://www.uk.sagepub.com/books/Book234194
5. http://www.srainternational.org/sra03/uploadedfiles/T69a.pdf
6. http://www.socialsciencespace.com/groups/research-ethics/forum/topic/absurd-decisions-by-ethics-committees/

6.2.4 Jessee Reviews Ethical Imperialism (2011-02-21 16:48)

Dr. Erin Jessee of Simon Fraser University reviews Ethical Imperialism for the [1]Oral History Review. [First published online February 15, 2011, doi:10.1093/ohr/ohr027.]
She finds the book "an impressive assessment of IRBs, from their tenuous beginnings in the early 1960s as a practical response to a perceived threat to the public from medical research to its present status as a threat to academic freedom in the social sciences" and "a significant contribution to those oral historians and related practitioners who would seek to challenge IRB's right and ability to adequately evaluate their research projects, particularly before the research has been conducted."
On her blog, [2]Jessee offers additional kind words: "this was one of the more enjoyable book reviews I've had to write. Schrag writes clearly, and has an immense knowledge of the history of institutional review boards (IRBs) based on archival research and interviews with key decision makers in the US government and US universities and research institutions."
Jessee would have liked more prescriptive analysis in the book's conclusion:

> Schrag is justified in calling "for Congress to relieve health regulators of the responsibility for overseeing the social sciences, a task they have mishandled for decades" (191). But what would present alternatives to IRB regulation look like? It is on this point that Schrag's analysis falls short. He expresses approval for the work of anthropologists (46–47) and oral historians (152–59) who have attempted to return responsibility for designing and implementing ethical research projects to the individual researcher and their immediate peers (who presumably will have a better understanding of the discipline and its foibles than the interdisciplinary representatives typically found on IRBs). Yet he is strangely silent regarding possible alternatives to IRBs.

This raises the question of voice in a book that mostly subordinates its prescriptive judgments to its historical analysis. Pages 184-186 of the book present a section entitled "Alternative Models," where I outline several proposals that I believe have real merit. But because that section appears in the body of the work, rather than the conclusion, I did not signal my approval as clearly as I could have. Jessee's review suggests that while I am getting better at writing conclusions, I still have much to learn.

1. http://ohr.oxfordjournals.org/content/early/2011/02/15/ohr.ohr027.extract
2. http://www.erinjessee.com/?p=316

6.3 March

6.3.1 Who Should Investigate Research Misconduct? (2011-03-01 22:12)

Two recent items do not directly involve IRBs, but they raise broader issues of accountability for research misconduct. [Erin O'Connor and Maurice Black, "[1]Save Academic Freedom," Inside Higher Ed, 28 February 2011; Alice Dreger, "[2]Darkness's Descent on the American Anthropological Association: A Cautionary Tale," Human Nature (published online 16 February 2011).]
Erin O'Connor and Maurice Black, research fellows at the American Council of Trustees and Alumni, argue that "disciplinary societies should define and enforce ethical standards."
They assert, with some plausibility but without much evidence, that scholars are doing a poor job policing each other's misconduct. [For example, they note that "Forty percent of professors say their work has been plagiarized." But that doesn't mean that forty percent of professors say their work has been plagiarized by other scholars.]
O'Connor and Black mostly want the American Association of University Professors to pursue misconduct by scholars as vigorously as it pursues misconduct by administrators. In addition, they suggest that

> Every disciplinary society should have [a code of ethics]. Societies should emphasize education and enforcement, coordinate with institutions to set standards and evaluate wrongdoing, and publicly censure institutions and individuals when appropriate. And societies should recognize that failure to frame ethical standards and to engage meaningfully with institutional efforts to ensure professional integrity (whether as an independent watchdog, adviser, or partner) damages not only the society in question — but the discipline itself. (We have only to recall the instructive case of former Emory history professor Michael Bellesiles to see the truth of this. While Emory investigated credible charges that Bellesiles had falsified the research in his award-winning Arming America, the American Historical Association discredited itself in classic tu quoque form, accusing Bellesiles' accusers of harassment.)

This is a misleading account of the AHA's actions in the Bellesiles case. [3]The AHA's 2001 resolution stated that

> Although it is appropriate to subject all scholarly work to criticism and to evaluate that work's arguments and its sources, the Council of the American Historical Association considers personal attacks upon or harassment of an author, as we have seen directed at Michael A. Bellesiles following publication of Arming America: The Origins of a National Gun Culture, to be inappropriate and damaging to a tradition of free exchange of ideas and the advancement of our knowledge of the past.

The Association welcomed the sort of criticism that eventually discredited the book. It offered no tu quoque defenses, which would have required accusing Bellesiles' accusers of research misconduct. And it played a constructive role in the Emory investigation (see below).

That is not to say that all scholarly associations behave well. For a vivid example, read Alice Dreger's new article, "Darkness's Descent on the American Anthropological Association.

Dreger digs into the AAA's botched response to Patrick Tierney's 2001 book, Darkness in El Dorado, an apparently fraudulent, libelous attack on the work of Napoleon Chagnon and late James V. Neel. Asking why an AAA task force continued an inquiry based on a book the task force chair privately termed a "piece of sleaze," Dreger concludes that the anthropologists involved were too eager to show themselves to be on the side of indigenous peoples, even at the expense of the truth.

"Advocacy is not scholarship," she writes. "The former is specifically concerned with advancing human rights, the latter with the production of knowledge. To insist that scholars of a particular discipline adhere to and even advance preordained social politics looks to me frighteningly like the situation Galileo found himself in."

And she concludes,

> I understand that those who were involved in this controversy may have had good intentions. Many sought justice. But justice that is meted out according to politics and not according to facts is the justice of the Middle Ages. If justice is not based on the facts, if principles of justice are not applied universally, there is no real justice. Forms of "scholarship" that deny evidence, that deny truth, that deny the importance of facts—even if performed in the name of good—are dangerous not only to science and to ethics, but to democracy. And so they are dangerous ultimately to humankind.

While Dreger has less faith in scholarly societies (or at least the AAA) than do O'Connor and Black, they might all agree on the value of university-sponsored investigations informed by standards set by scholarly associations. O'Connor and Black do call for associations to "coordinate with institutions to set standards and evaluate wrongdoing," and Dreger applauds what she calls "the University of Colorado's top-notch work on Ward Churchill" as well as the University of Michigan's investigation of Neel's work in South America.

I remain troubled by Colorado's condemnation of Churchill for failing to meet the AHA's Standards of Professional Conduct. Those standards are explicitly designed for "professional historians," and that doesn't include Ward Churchill.

Emory's investigation of Bellesiles may be a better model. While the AHA was not directly involved, the [4]Emory investigative committee specifically noted its dependence on the AHA's Statement on Standards of Professional Conduct, since Emory's statement of Policies and Procedures "seems basically designed for the investigation of alleged misconduct in the life and physical sciences." [Sound familiar?]

In sum, when a university-affiliated scholar is accused of serious misconduct, the best outcome may well be a university-led investigation that uses standards set by a scholarly association, rather than by the university itself. Making such an outcome routine will require abandoning efforts at universal, one-size-fits-all ethics.

1. http://www.insidehighered.com/views/2011/02/28/a_call_for_the_aaup_to_speak_out_on_ethical_misconduct_in_the_profession

2. http://www.springerlink.com/content/1648u57278202674/

3. http://www.historians.org/perspectives/issues/2001/0109/0109aha2.cfm
4. http://www.emory.edu/news/Releases/Final_Report.pdf

Alice Dreger (2011-03-02 14:16:15)
Thanks, Zack, for this comparison and analysis. I think the thing worth remembering about Ward Churchill is that the investigation showed that what he did would offend any scholar who cares about truth, regardless of discipline or professional society affiliation. The report is really worth reading. The group that produced it did a terrific job sorting out politics from facts. Any scholar charged with misconduct who is innocent would welcome a group like that one. Thanks again. - Alice Dreger

Zachary M. Schrag (2011-03-05 08:10:47)
Thanks for this comment.
What frustrates me about the Churchill committee report is its failure to distinguish among various ways of looking at the past. On page 64, it condemns Churchill for basing some of his claims on Evan S. Connell's book, Son of the Morning Star:
"Professor Churchill's decision to rely upon Connell's book is puzzling. Connell is an acclaimed and highly respected author of novels, short stories, and essays. Son of the Morning Star, his dramatic and well-received book about Custer (later filmed for television), was written for the general public. Connell provides no notes to the sources of his information, and it is possible that parts of the book are slightly fictionalized. Thus it is not a scholarly source for the events Professor Churchill is describing."
This passage acknowledges that a "slightly fictionalized," unsourced book about the past can be well received and earn its author acclaim and respect. Why, then, hold Churchill to the standards of professional historians? Why not consider him a historical novelist?
This is not to say that Churchill's conduct was tolerable; I imagine he violated some of the standards of historical novelists as well. But I wish the investigative committee had spent more time pondering the implications of its own statement that "at the time he was hired, the University was aware of the type of writing and speaking he does." (8) In other words, the university hired Churchill to make provocative claims based on doubtful evidence. It awarded him tenure for making provocative claims based on doubtful evidence. It promoted him to full professor for making provocative claims based on doubtful evidence. And then it fired him for making provocative claims based on doubtful evidence.
If the University of Colorado had wanted a scholar who cared about the truth–the way you and I care about the truth–it would not have hired Ward Churchill to teach. Having done so, I think it should have done more to judge him on his own terms.

Anonymous (2011-03-15 15:19:46)
So, how does one go about filing a complaint when an organization does not follow IRB protocol? For instance, IRB approval was not sought at all and no informed consent was signed for a psychological survey given to children unbeknownst to their parents.

Zachary M. Schrag (2011-03-16 17:07:42)
If the project was conducted by university researchers, the university research office would be the best place to complain. Otherwise, one could try the sponsoring foundation or agency (if any) or the federal Office for Human Research Protections. As I will note shortly, the last investigates few complaints.

6.3.2 Professor Sues Brown University Over IRB Mission Creep (2011-03-13 10:53)

Jin Li, Associate Professor of Education at Brown University, has sued the university in federal court for forbidding her from using data from a study she conducted with private funding.
[Alexandria D'Angelo, "[1]Professor Says Brown U Has a Lot of Nerve," Courthouse News Service, 1 March 2011. Thanks to [2]Illuminata for catching this.]
Li obtained a grant from a private foundation for an investigation entitled "European American and Chinese Immigrant Children's Learning Beliefs and Related Socialization at Home."
According to the [3]complaint, which was filed on February 25, the study "essentially involved educational testing

of Chinese American children and interviews of their parents. Brown's IRB approved payment to each family in the amount of $600 per family for three years of participation in the investigation."
When Li found that lower income families were spending more time completing the surveys and interviews, she decided to pay those families the $600 per year but pay wealthier families only $300. Brown (it's not clear what office) approved her budget, and each family agreed to the payments. But in February 2010, the IRB denied a modification of the protocol and forbade Li from using the data she had collected.
Li has sued the university for $200,000 based on the following counts:
1. The Brown IRB does not meet the standards of 45 CFR 46.107, which requires sufficient "diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." According to the complaint, the IRB lacks minority members and is therefore unqualified to review research by a Chinese-born scholar of the Chinese immigrant community.
2. The university has "deprived the Plaintiff of any opportunity for internal review of the action of its IRB," despite provisions in 45 CFR 46.112 allowing such review. This, she claims, is a deprivation of due process.
3. The project "is exempt from IRB review pursuant to 45 C.F.R. Sec. 46.101 in that (a) it does not involve federal employees, federal funds, or regulation by any federal agency and (b) it involves education testing, surveys, and interviews and poses no threat to any human subject."
4. Brown's limits have imposed economic harm on Li by denying her the use of the information she obtained.
5. Brown has "interfered with the relationship between the Plaintiff and the foundation that awarded her the grant to conduct the investigation."
Li has demanded a jury trial.
The complaint is vague about what cause or causes of action are alleged, making me doubt Li's chances of recovery. But the case could remind liability-shy universities that too much IRB oversight, as well as too little, does real harm to researchers, research participants, granting organizations, and communities.

1. http://www.courthousenews.com/2011/03/01/34538.htm
2. http://www.illuminata-inc.com/News2011.html
3. http://zacharyschrag.files.wordpress.com/2011/06/li_v_brown_complaint.pdf

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Shirley Isbill (2012-01-21 14:07:26)
Where can I find the court's decision on this issue? OR whether it was settle out of court.

Zachary M. Schrag (2012-01-24 21:51:22)
Update [1]here.

1. http://www.institutionalreviewblog.com/2012/01/li-and-brown-continue-negotiations.html

6.3.3 Report from APPE (2011-03-14 11:29)

Earlier this month I traveled to Cincinnati for the [1]annual meeting of the Association for Practical and Professional Ethics. There I met a fascinating group of researchers, ethicists, university administrators, IRB staff, and IRB members–with significant overlap among those groups.
One conference panel was devoted to Ethical Imperialism. Lyndall Angel of Charles Sturt University chaired the session, and John J. Laukaitis (Elmhurst College), Douglas J. Adams, (University of Arkansas), and William L. Gannon (University of New Mexico) provided comments on the book.
The critics were most kind. Laukaitis, a historian, had tangled a bit with an IRB as a graduate student, and he found reading the book "cathartic." He noted his surprise that complaints about IRB restrictions are not evenly distributed, but instead suggest a pattern of challenges to particularly controversial research.
Adams, a sociologist and an IRB chair, was taken by the power dynamics at work in my story. For example, he com-

pared the politics of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to those of the 9/11 Commission, whose composition determined what questions were and were not explored. And he suggested that I might have paid more attention to both conflict theory and to the specific historical context of the 1970s (Watergate, Vietnam, etc.).

Finally, Gannon picked up on the question of transparency. Both he and Laukaitis were interested in the efforts at Berkeley in the early 1970s to provide such transparency by maintaining a file of previous IRB decisions, to be consulted by both researchers and the board itself. (A member of the audience asked how competitive researchers would react to their research agendas being made so public. It's a good question.)

The gentleness of these comments was representative of the impression I gained from the conference in general: that many people who are deeply committed to research ethics, many of whom themselves serve on IRBs, are quite aware of the flaws in the present system and curious about their origin.

They are not, however, ready to scrap the system we have now until presented with a better alternative. I will keep looking for better systems now in place.

1. http://www.indiana.edu/~appe/annualmeeting.html

6.3.4 AAHRPP and PRIM&R Plan Conferences (2011-03-15 09:44)

Both the Association for the Accreditation of Human Research Protection Programs, Inc ., (AAHRPP) and Public Responsibility in Medicine and Research (PRIM &R) plan conferences next month. AAHRPP's conference, "[1]Breaking Down Barriers, will be held in Washington, April 6-8, then PRIM &R meets in Boston, April 28-29, for a "[2]Social, Behavioral & Educational Research Conference."

Federal officials will participate in both conferences. The AAHRPP kicks off with an address by OHRP's director, Jerry Menikoff, and will include presentations from other representatives of OHRP as well as the departments of Defense, Education, Energy, Justice, Veterans Affairs, the EPA, FDA, and–most intriguingly from my view–an as yet unnamed official from the National Science Foundation who will discuss "Ethical Issues in Social Science Research."

PRIM &R will feature a keynote by OHRP's Ivor Pritchard as well as a session entitled "Talk to the Feds: A Dialogue with the Office for Human Research Protections," in which "OHRP staff talk about how the regulations and guidelines apply to SBER IRBs, including questions about implementing the recently issued OHPR guidances on continuing review and conditional approval. Attendees are encouraged to come with questions that will be of interest to all."

From what I understand, it is not unusual for federal regulatory officials to speak at conferences sponsored by the industries they oversee. But larger industries have an established trade press that will cover pronouncements by key officials.

It is not clear that statements by federal officials at either conference will be made public beyond the [3]fragmentary accounts of the sort we have gotten in the past. The question, then, is whether someone who doesn't want to spend $575 for the AAHRPP conference or $835 for PRIM &R can find out what federal officials think the Common Rule means.

Thanks to Theresa Defino and Ada Sue Selwitz for alerting me to these conferences.

1. http://www.aahrpp.org/www.aspx?PageID=201
2. http://www.primr.org/Conferences.aspx?id=9195
3. http://hrpp.blogspot.com/2006_11_01_archive.html

Anonymous (2011-03-15 10:31:03)

As someone who serves on an IRB I agree with you about PRIM &R's fees. Members who registered earlier could have done it a little cheaper than the figure you quoted but the cost is still expensive compared to comparable conferences. Last week they sent an amusing e-mail to conference participants asking for volunteer "Conference Greeters & Keynote/Plenary Session Ushers" and "PRIM &R Exhibit Booth Attendants" among other things.

To the best of my knowledge OHRP always has a Talk to the Feds session at PRIM &R conferences, and quite appropriately.

Other agencies have similar sessions depending on the PRIM &R conference but in the past there have been sessions involving NSF, VA, FDA, DoD, and NIH. Unlike some of the other sessions these are not recorded for later access, presumably because they aren't formal presentations. They are basically an opportunity for people to ask Federal officials whatever they want and have them respond.

Zachary M. Schrag (2011-03-15 10:38:45)
Thanks for this comment.
I do not think it appropriate for public officials to offer these sessions at expensive conferences when they have proven so slow to respond to letters from scholarly associations, Freedom of Information Act queries, and comments submitted in response to notices in the Federal Register. At the very least, PRIM &R and AAHRPP should record the sessions and make the freely recordings available to the public.

Anonymous (2011-03-15 11:06:04)
I don't understand how not having these sessions, where they answer audience questions, helps address the issue you have with their degree of responsiveness. All it would do is make them less accessible.
OHRP staff also make themselves available at their own workshops around–which are free– and various other events that are much more affordable than PRIM &R-organized events.

Zachary M. Schrag (2011-03-15 11:11:33)
The snarky answer would be that OHRP officials should stay home and use their time to respond to the Federal Register comments that have been sitting on the shelf since 2007.
More realistically, I would like transcripts of the sessions made public. Keep in mind that we are talking about an [1]agency that has not issued a press release since 2008.

1. http://www.hhs.gov/ohrp/newsroom/releases/index.html

6.3.5 Notre Dame Frees Oral History (2011-03-16 10:17)

I stumbled across the [1]Notre Dame Office of Research's IRB Procedures Manual & Guidelines. The manual, which bears no date, appears to give considerable leeway to oral historians:

> Chapter 20. Statement On Oral Histories
> The U.S. Office for Human Research Protection (OHRP), part of the Department of Health and Human Services (HHS), working in conjunction with the American Historical Association and the Oral History Association, has determined that oral history interviewing projects in general do not involve the type of research defined by HHS regulations and are, therefore, excluded from Institutional Review Board oversight.
> A decision whether oral history is subject to the policies and regulations outlined in an institution's FWA and HHS regulations for the protection of human research subjects is based on the prospective intent of the investigator and the definition of "research" under HHS regulations at 45 CFR 46.102(d), i.e., "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
>
> i. Oral history activities, in general, are designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge. Only those oral history projects that conform to that regulatory definition of research need to submit their research protocols for IRB review.
> ii. Researchers are urged to contact the IRB if in doubt about whether a project requires review.

> iii. Some oral history interviewing projects may meet the definition of research. Other activities involving open-ended interview that have similar characteristics can involve research as defined by the HHS regulations when the activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge.
> iv. The evaluation of whether oral history activities require IRB review hinges upon whether the person is engaged in the creation of "generalizable knowledge." In other words, does the activity represent a systematic investigation in which the historian intends to develop or contribute to generalizable knowledge?

While this is not the clearest policy I've seen, at least it establishes that it is up to the researcher to decide whether to consult the IRB at all.

1. http://or.nd.edu/compliance/irb-manual/considerations-irb-review/

6.3.6 Defino Notes Big Drop in OHRP Letters and Cases (2011-03-17 11:26)

Theresa Defino, editor of Report on Research Compliance, kindly alerted me to her recent analysis of OHRP activity and allowed me to post a reprint of the article.
["[1]Big Drop in OHRP Letters, Open Cases Raise Questions of Agency Commitment," Report on Research Compliance, March 2011, 1-3.]
Defino notes a drop in OHRP oversight activity:

> In 2010, the Office for Human Research Protections issued and posted 16 determination letters, the lowest number in its 11-year history and less than half the number issued in each of the previous five years. Since 2007, the office has averaged 35 letters a year, down from a peak of 146 in 2002 and another high of 86 in 2006.
> The number of determination letters is tied to the number of cases OHRP opens, and during the recent past, that number has also declined, RRC has learned, tumbling to an all-time low of six in 2009. Some tie the decline in activity to the arrival of Jerry Menikoff, whose tenure as OHRP director began in the late fall of 2008.

An accompanying table shows that in 2009, OHRP received 134 allegations of misbehavior but opened only six cases. (The figures for 2010 are incomplete.) Thus, a complainant had only an 4 percent chance of getting an investigation, compared to a 28 percent chance in 2005. If we expect cases to be opened in the year following a compaint, the numbers are closer, but still represent a decrease from 10 percent (2005-6) to 6 percent (2008-9).
Defino floats various explanations for these drops: a declining number of institutions that check the boxes extending OHRP jurisdiction to non-federally funded research, an increase in the percentage of cases referred to the FDA, efforts to resolve disputes informally, and the fact that the 2002 total represented an effort to work through a backlog of cases. The article quotes several people, named and unnamed, lamenting the decline in determination letters, which they call "educational tools." As someone [2]unable to figure out how the letters promote research ethics, I am less troubled by their decrease.

1. http://zacharyschrag.files.wordpress.com/2011/06/ohrpquestioned.pdf
2. http://www.institutionalreviewblog.com/2010/03/twenty-six-percent-of-boxes-go.html

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6.3.7 Inside Higher Ed Reports on Li v. Brown University (2011-03-19 23:36)

Inside Higher Ed reports on the [1]Brown University professor who is suing the university over IRB restrictions. The story quotes your humble blogger.
[Dan Berrett, "[2]IRB Overreach?," Inside Higher Ed, 18 March 2011.]

1. http://www.institutionalreviewblog.com/2011/03/professor-sues-brown-university-over.html
2. http://www.insidehighered.com/news/2011/03/18/brown_professor_sues_university_for_barring_her_from_using_her_research

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6.3.8 Bioethical Issues Commission Narrows Scope of Investigation (2011-03-21 22:36)

In January, [1]I complained that President Obama had asked the Commission for the Study of Bioethical Issues for "a thorough review of human subjects protection to determine if federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the federal government."
One of my complaints was that "the commission lacks the full range of expertise to review all the federal regulations and international standards that govern human subjects protection. Since the 1960s, committees and commissions composed of medical researchers, psychological researchers, and bioethicists have advised regulators and presidents about human subjects protections without adequately consulting researchers in the social sciences and humanities, who then find themselves subject to rules they were not allowed to shape."
Fortunately, the commission has addressed, if quietly, this particular concern. In a recent [2]press release, the commission announced the formation of an International Research Panel that will "convene in a series of meetings, or Consultation, that will examine:

- "The dominant norms, and competing alternatives, driving the ethics of medical research in different global regions outside of the U.S.;
- "The conflicts, if any, between U.S. norms and international standards;
- "The challenges facing researchers conducting U.S.-funded research in global settings; and
- "How best to address any major differences in regional norms for medical research."

Thus, the "scientific studies supported by the federal government" in Obama's charge have become "medical research" in the commission's plans. With luck, this means that the social sciences will be left alone.
I still don't see how a group that may meet only three times and has only nine months to work can expect to make a serious contribution to complex debates over medical research. But at least the commission seems to have narrowed the scope of the investigation to something more relevant to the Guatemala revelations and its own expertise.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5107&blogid=140
2. http://www.bioethics.gov/news/2011/03/presidents-bioethics-commission-names-international-research-panel.html

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6.4 April

6.4.1 The Costs of Ethical Review, Part II (2011-04-03 16:13)

Researchers on both sides of the Atantic are trying to measure how the delay due to ethics review in medical research can harm or kill those who would benefit from innovative therapy.

[Ian Roberts, David Prieto-Merino, Haleema Shakur, Iain Chalmers, Jon Nicholl, "Effect of Consent Rituals on Mortality in Emergency Care Research," Lancet 377, no. 9771 (26 March 2011): 1071-1072, doi:[1]10.1016/S0140-6736(11)60317-6; S. N. Whitney and C. E. Schneider, "Viewpoint: A Method to Estimate the Cost in Lives of Ethics Board Review of Biomedical Research," Journal of Internal Medicine 269, no. 4, (April 2011): 396-402, doi: [2]10.1111/j.1365-2796.2011.02351 _2.x See also [3]The Costs of Ethical Review. Hat tips to Rebecca Tushnet and Simon Whitney.]

Writing in the Lancet, Ian Roberts, David Prieto-Merino, Haleema Shakur, Iain Chalmers, and Jon Nicholl report on the [4]CRASH-2 trial, in which tranexamic acid was administered to trauma patients at risk of significant bleeding. Because this was a clinical trial, hospitals were required to secure written consent from relatives before administering the treatment. The authors estimate that this process delayed treatment by about an hour or two, reducing the benefit: "Whereas the relative risk of death from bleeding with tranexamic acid was estimated in the CRASH-2 trial as 0·85 (95 % CI 0·76—0·96), the corresponding relative risk in the presence of a 1-h delay is 0·96 (0·86—1·08)." Moreover, they argue, "the delay in starting treatment can obscure a real treatment benefit from the administration of a time-critical treatment. In the CRASH-2 trial, the requirement for written informed consent probably means that the trial has underestimated the beneficial effect of tranexamic acid in trauma patients with bleeds, which would be given without delay in normal clinical practice."

They conclude that "the need for an urgent trial treatment, even in patients who are conscious and whose relatives are available, by itself excludes the possibility of fully informed consent. If consent rituals delay the start of a trial treatment such that the treatment effect could be reduced or obscured, we maintain that seeking consent is actually unethical."

Meanwhile, Simon Whitney and Carl Schneider offer a more general exploration of the costs of ethics review. Building on the work of Collins, Doll, and Peto, they note that major studies, like the ISIS-2 trial of the effect of thrombolytics on the mortality of hospitalized heart attack patients, can radically change the standard of care for a given condition. Since differences across countries suggest that detailed consent procedures can delay recruitment for such trials, they conclude that these procedures delay the eventual introduction of new therapies, costing thousands of lives.

Whitney and Schneider conclude that "the cost of research-ethics regulation is great enough" to require urgent inquiry into the number of lives lost to regulatory delay.

Commentators on both projects note that one can imagine a system of ethics review that offers more flexible consent procedures, thus securing the benefits of ethics review at a lower cost in lives. Responding to an account of the Lancet study [Ben Goldacre, "[5]When Ethics Committees Kill," The Guardian: Bad Science, 26 March 2011], a commenter ("Dingleford") suggests that a problem with the way ethics committees handle emergency treatment does not discredit the system as a whole. And a response to the Whitney and Schneider piece [S. Holm, "Commentary: Systems, rules and the costs of being ethical – a response to D. Chalmers and to S. Whitney and C. Schneider," Journal of Internal Medicine 269, no. 4, (April 2011): 403-406, doi: [6]10.1111/j.1365-2796.2011.02351 _3.x] suggests that the problem lies not with the principles of the Helsinki Declaration or the concept of ethics review, but rather "a belief that all decisions need to be consistent, and wrongly believing that consistency is, in this case, a matter of linguistic conformity," resulting in long and hard-to-understand consent forms.

While any improvement is welcome, I think that these comments overlook a basic finding of the two articles: that regulators have failed to assess either the costs or the benefits of ethics review. Whitney and Schneider offer a 2007 statement by Greg Koski, the former director of OHRP: "We still don't have direct evidence that the current process is actually preventing harm. We need solid empirical research on whether the IRB process is actually working." If a regulatory regime has demonstrably deleterious effects on human health and no clear evidence of benefit, does it not make sense to devote some public resources to exploring its worth and that of possible alternatives?

It will be harder to make the case that the restrictions on social science kill people, but I don't think it is out of the question. [7]Had Scott Atran been allowed to interview more failed suicide bombers, might he not have helped avert a bombing, saving dozens or hundreds of lives? [8]Had Robert Dingwall had an easier time studying the reuse of single-use surgical and anaesthetic devices, might he not have prevented more deaths from post-operative infections?

More typically, though, the real, unmeasured cost of IRB review of the social sciences comes in lives diminished, not lost. [9]Had Linda Thornton and Martin Bergee been able to conduct a richer study of why students major in music education, they would have prevented no hemmorages, heart attacks, infections, or suicide bombings. At most, they

might have gained insight that would have helped some people avoid a career not suited for them, and steered other young people with the knack toward a life as a music teacher, bringing song, joy, and enhanced cognitive skills to hundreds of children over the course of decades. I would like to think that this, too, merits attention.

1. http://linkinghub.elsevier.com/retrieve/pii/S0140673611603176
2. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2796.2011.02351_2.x/abstract
3. http://www.institutionalreviewblog.com/2008/12/costs-of-ethical-review.html
4. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60835-5/fulltext
5. http://www.badscience.net/2011/03/when-ethics-committees-kill/
6. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2796.2011.02351_3.x/full
7. http://www.institutionalreviewblog.com/2007/05/scott-atran-research-police-how.html
8. http://www.institutionalreviewblog.com/2008/12/costs-of-ethical-review.html
9. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html

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Anonymous (2011-04-04 11:00:11)

Research is not therapy! Thinking otherwise is falling victim to therapeutic misconception. Until you've done the research you don't know that the drug or intervention is effective. That's the whole point of clinical trials, to figure out if it works or it doesn't. And most of them don't work or worse. And it's often a big problem getting people, both patients and often the doctors conducting the trials, to understand this.

Of course in some situations the researchers may be doing research on an intervention that's already in common use to establish whether it works or not. (A lot of medical practice has undergone rigorous evaluation–and a lot of it isn't good for you.) In those cases the researchers shouldn't be asking for consent to do the intervention if it would have been done anyway.

Zachary M. Schrag (2011-04-04 23:02:58)

Thank you for these comments.

I don't think that either the Roberts article or the Whitney article claim that research is therapy. Rather, they claim that research saves lives, and that, by hampering research, ethics review and consent requirements cost lives. Though their examples are studies that proved the benefits of certain treatments, their claim would be true even for studies that show that a given intervention is ineffective or harmful. The sooner we learn that, the better off we will be. The costs of ethics review must be measured against whatever gains can be established for it.

By contrast, [1]Beauchamp does claim that the distinction between research and therapy has been taken too far. "The distinction between therapeutic and nontherapeutic research has a considerably diminished presence in biomedical ethics today," Beauchamp writes. "No doubt we need to be cautious about this distinction, but I am not convinced that the language of 'therapeutic research' is illogical or a poor way to understand how research functions in many settings. Instead of abandoning the therapeutic-nontherapeutic research distinction, we might consider resuscitating it for today's medical environment."

1. http://www.institutionalreviewblog.com/2011/04/beauchamp-derides-federal-definition-of.html

6.4.2 Beauchamp Derides Federal Definition of Research (2011-04-04 09:39)

Along with [1]Whitney and Schneider's article on the cost in lives of ethics board review of biomedical research, the "ethics symposium" in April 2011 issue of the Journal of Internal Medicine features an intriguing essay by Tom Beauchamp, Senior Research Scholar at the Kennedy Institute of Ethics and Professor of Philosophy at Georgetown University.

[T. L. Beauchamp, "Why Our Conceptions of Research and Practice May Not Serve the Best Interest of Patients and Subjects, Journal of Internal Medicine 269, no. 4, (April 2011): 383-387, doi: [2]10.1111/j.1365-2796.2011.02350_1.x]

As a staffer of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the 1970s, Beauchamp played a key role in the development of the Belmont Report. Yet in this essay, he disparages one of the National Commission's most enduring legacies: the definition of research encoded in today's federal regulations.

Beauchamp writes,

> In the Code of Federal Regulations in the United States, the term 'research' means 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge'. This conception still today is the received view. However, there are many problems with this definition. First, it uses the notion of research to define the term 'research,' creating problems of circular definition. Second, it does not define any of the several important terms (the key conceptual conditions) used in the definition, such as 'systematic investigation,' 'testing' and 'generalizable knowledge,' and these terms can be understood in several ways. Third, the definition is vague and overly broad because it is not clearly confined to biomedical research, clinical research and behavioural research – or even to scientific research, more generally. Its scope is left unclear. Fourth, and perhaps most importantly, it does not preclude 'research' from having a very close tie to 'practice.'
> Because the definition is so nonspecific, regulatory requirements that use the definition may judge that some activities that are questionably research involving human subjects nonetheless must be treated as such. Government requirements are today commonly applied even if 'human subjects' may not need to be protected by the rules of human-subjects research. A sweeping – that is, all-inclusive conception – of 'human-subjects research' can have immediate and unjustifiable practical impact on attempts to upgrade medical care . . ."

Beauchamp goes on to relate the experience of Peter Pronovost's study of infection-control, that was temporarily halted by OHRP on the grounds that the Johns Hopkins University had incorrectly interpreted federal regulations. Beauchamp argues that "There were no new interventions with patients. There were not even subjects in any meaningful sense. In my view, such work should not need an institutional review board approval even as expedited review." Like Whitney and Schneider, he warns that human subjects regulations can kill.
Beauchamp does not expand on his third point, that the federal definition of research is not confined to the "biomedical and behavioral research" specified by the National Research Act and embedded in the National Commission's title. Nor does he mention that the commission offered two competing definitions of research, one in the [3]Belmont Report and another in its [4]IRB Report. Still, it is nice to have so prominent a bioethicist admit that the definition of research at the center of the Common Rule is so poorly worded.

1. http://www.institutionalreviewblog.com/2011/04/costs-of-ethical-review-part-ii.html
2. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2796.2011.02350_1.x/abstract
3. http://videocast.nih.gov/pdf/ohrp_belmont_report.pdf
4. http://videocast.nih.gov/pdf/ohrp_institutional_review_boards.pdf

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Anonymous (2011-04-04 10:22:52)
As someone who has to apply the regulations I would agree that the wording, lack of examples examples, and lack of guidance is very problematic.
Some of the better discussion of 'research' and 'non-research', at least as it applies to public health, is to be found on the CDC's site. See http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishi ng-public-health-research-nonresearch.pdf
And it's not just the definition of research. There needs to be much clearly guidance on the application of exempt categories, as identified by SACHRP (http://www.hhs.gov/ohrp/archive/sachrp/mtgings/mtg10-07/present/S ubpartAEXEMPTIONS.doc), to mention one other area that causes lots of headaches. Read the literature and it becomes clear that even the 'experts' don't agree on the interpretation of the exemptions. E.g. some people apply b1 independently of b2 and Subpart D limitations and some don't.

Zachary M. Schrag (2011-04-04 22:42:43)
Thanks for these comments. I quite agree that clarity would require not only better definitions of research and the various

exemptions, but also realistic examples and continuing guidance from OHRP. See http://www.institutionalreviewblog.com/2-010/12/menikoff-passes-buck. html

The SACHRP document offers some helpful suggestions. But I can't agree with its recommendation that "research conducted under the exempt categories be determined to be no greater than minimal risk"; I do not think that appropriate for the public-official exemption in particular. And it is telling that SACHRP did not offer specific recommendations on "focus groups; ethnography; oral history," choosing instead only to call for guidance from OHRP. The fact is that both SACHRP and OHRP lack sufficient expertise to offer meaningful guidance and should seek the input of the National Science Foundation, other agencies that sponsor such research, and disciplinary bodies such as the American Historical Association.

6.4.3 Law Professor Sees Broad Role for IRBs in Virtual Worlds (2011-04-06 22:23)

Professor Joshua A. T. Fairfield of the Washington & Lee University School of Law explores the law of research in virtual worlds.

[Joshua Fairfield, "Avatar Experimentation: Human Subjects Research in Virtual Worlds." (November 29, 2010). U.C. Irvine Law Review, Symposium Issue, 2011; Washington & Lee Legal Studies Paper No. 2010-14. Available at SSRN: [1]http://ssrn.com/abstract=1717057.]

Fairfield makes some important points about how researchers interested in these environments might apply ethical guidelines developed for older forms of research. But the article also pays insufficient attention to the limits of ethical guidance developed to govern medical experimentation, misstates some of the provisions of current regulations, and downplays the troubles Internet researchers have faced with IRBs.

Ethical Issues

Fairfield raises important points about the ethical challenges of research into virtual worlds. He notes, for example, that elements of a virtual world can be valued as much as more tangible assets:

> An avatar, for example, does not merely represent a collection of pixels—it represents the identity of the user. The user is known by the avatar's name and is represented in the virtual world by the avatar. The avatar is the connection of the user to her online social community. Likewise, virtual reputations and trust are costly to generate, but easy to lose. If an avatar is identified as having harmed the community through interactions with a researcher, the human being behind the avatar will certainly suffer harm to her identity, reputation, and community.
>
> In the same vein, the accumulation of property in virtual worlds often reflects very real economic interests of the human subject. Many virtual worlds have in-world economies. These virtual economies have grown rapidly, and began interacting with the real-world economy. People now routinely use real dollars to purchase virtual land, goods, and services.

As an example, Fairfield offers the case of Elizabeth Reid, [2]who found that her research disrupted an online community.

These strike me as fair points that should be kept in mind by researchers wishing to avoid harm to research participants. Fairfield is less persuasive when he suggests that the Belmont Report offers helpful guidance to such researchers. He offers a somewhat odd account of the the report, describing it in a section entitled "Law," though the report has no legal force. And he has subsections entitled "autonomy," "beneficence," and "justice," though the Belmont Report's three principles are respect of persons, beneficence and justice.

"Researchers should account for the communal nature of virtual worlds," he writes, under the beneficence heading. "They should take precautions to safeguard the community as a whole, in addition to those individuals directly participating in the research." Maybe so. But as commentators have pointed out, [3]the Belmont Report does not address

questions of community.
And Fairfield himself notes that the Belmont Report's concern for "fair procedures and outcomes in the selection of research subjects" is not clearly relevant to research on virtual worlds. "It is important not to overstate the issue," he writes. "Human subjects research is conducted on narrow population segments all the time."

Legal and Regulatory Issues: Private Information

"The law governing human subjects research in virtual worlds is wide-ranging and complex," Fairfield proclaims. True enough. Unfortunately, he oversimplifies that law, potentially misleading his readers.
The first set of claims concerns data saved by the companies that run virtual worlds ("game gods") and shared with researchers. Fairfield claims that "Commercial databases are increasingly relevant to virtual worlds research. Game gods license enormous collections of data to researchers for secondary analysis." Moreover, he claims, "Secondary data sets can include the extremely private conversations of millions of virtual world users over a period of years." Finally, he states that "in general it is not possible to obtain blanket consent from everyone in a virtual world," suggesting that there is no ethical or legal way to conduct analysis of large datasets from server logs.
There are several problems with this analysis. First, the facts about the collections may be wrong. Fairfield attributes his factual claims to a [4]2009 article, describing Sony's sharing of four years of data of EverQuest 2. But the article he cites does not support the claims. For one thing, Sony shared data for "over 400,000 players," not "millions." Second, the article mentions only one such collection of data–for Everquest 2–and notes that and most companies "haven't been interested in sharing their logs or the logs themselves don't contain the sort of data that would make for fruitful research." Thus, the plurals in the article ("databases" and "data sets") may be inaccurate.
Moreover, Fairfield ignores a follow-up post stating that [5]the logs were "scrubbed of all PII (Personally Identifiable Information) prior to being provided to the researchers." Presumably this would include "extremely private conversations."
Second, the article offers a brief analysis of whether research using such logs would constitute human subjects research under the Common Rule. Unfortunately, this analysis seems uninformed by current OHRP guidance. For one thing, Fairfiled claims that because the Common Rule provides for expedited review of research involving data that has been collected for nonresearch purposes, such work must be research under the Common Rule definition. "Expedited review under the Common Rule is only available for human subjects research," he writes, "so any listed categories represent the narrowest subset of data analysis that can be considered research under the regulations."
OHRP has rejected such reasoning. "The fact that an activity, such as oral history, appears on the list of activities that may be reviewed by an IRB through an expedited review procedure does not mean that such an activity always involves research," [6]wrote Michael Carome in 2005. "For example, collection of blood samples; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing are also on the expedited review category list; however, the use of these procedures most commonly occurs outside the research context."
Third, Fairfield dances around the question of whether the server logs contain the "identifiable private information" necessary to trigger IRB jurisdiction under the Common Rule. Even if the logs did include messages from one player to another, 45 CFR 46.102 defines "private information" as "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)." And, as Fairfield notes, virtual worlds typically require users to agree to licenses "inform users that their personal and private information may be given to third parties."
Fairfield suggests that though these license agreements may be legally binding, no one reads them and "these users have not meaningfully consented to the use of their private communications as research fodder, nor would ethical researchers make use of such data since it contravenes the users' expectations of privacy."
Perhaps. But this does not answer Fairfield's question of "whether secondary research data gathered by a third party and then licensed to the researcher is likewise covered by the Common Rule." In particular, the Common Rule does

not require IRB review when there is no reasonable expectation of privacy.
Of course, a researcher can choose to respect even unreasonable expectations of privacy. But conflating what is ethical and what is legal, Fairfield risks confusing his readers.
Fairfield would be on stronger ground had he explored how medical researchers, IRBs, and regulators have made use of datasets containing sensitive medical information. His use of "general judicial decisions" to understand what "obtains" means in the context of human subjects research, rather than OHRP's [7]Guidance on Research Involving Coded Private Information or Biological Specimens, suggests that there is much more work to be done to figure out what "realspace research" can tell us about the study of virtual worlds.

Legal and Regulatory Issues: When is Informed Consent Necessary?

The article misrepresents the regulations when it claims that "The Common Rule requires full and documented informed consent to all human subjects research." The accompanying foonote (137) reads: "("[N]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject of the subject's legally authorized representative.")."
Why is that capital "N" in brackets? Because the actual regulation reads, "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." And those exceptions include all the exemptions of 45 CFR 46.101. Thus, the regulations do not require researchers to obtain informed consent for an enormous range of human subjects research in virtual worlds.
I could not find a reference to 45 CFR 46.101 anywhere in the article. This is a serious oversight.

Strategic Issues

If ethics committees had a good record of offering sound advice to Internet researchers, those researchers would not need to insist on their rights under the Common Rule. But ethics committees have compiled a poor record. As [8]"Elizabeth A. Buchanan and Charles M. Ess noted in 2009, "IRBs generally do not know what . . . protections apply strictly to online research, and such boards often ignore the complexities of such research and thereby risk harming subjects while also violating federal regulations, or, they apply such restrictive models that inhibit researchers from pursuing important online endeavors." [9](British researchers have similar complaints.)
Fairfield briefly alludes to researcher complaints about IRBs, though not specifically to their treatment of Internet research. But he offers little in the way of solutions, except to promise that "A well-informed IRB will better understand the ethical issues in virtual worlds research and will be able to issue strong recommendations to improve an inadequate proposal." While he is imagining such an IRB, Fairfield may as well assume a can opener.

What Experimentation?

Finally, I must note the oddity of the title; though the article is entitled, "Avatar Experimentation," it does not describe any experimentation taking place in these vitual world. The first paragraph claims "a significant increase in the number of virtual world human subjects experiments," but it cites [10]an article that does not mention experimentation, but rather interview and observational research. By conflating all interaction with experimentation, Fairfield risks perpetuating a system of ethics that takes medical experimentation as a norm and other forms of research with people as deviations. This has had poor results in realspace, and is likely to work just as badly in other worlds.
All told, Fairfield has raised some important questions of how human subjects regulations and research ethics might constrain research on virtual worlds. But the article is not well grounded in either the facts or the law.

1. http://ssrn.com/abstract=1717057
2. http://www.indiana.edu/~tisj/readers/abstracts/12/12-2%20Reid.html
3. http://works.bepress.com/charlesweijer/130/
4. http://arstechnica.com/science/news/2009/02/aaas-60tb-of-behavioral-data-the-everquest-2-server-logs.ars

5. http://michaelzimmer.org/2009/02/25/sony-provides-complete-everquest-2-server-logs-to-researchers/
6. http://www.utexas.edu/research/rsc/humansubjects/forms/michael_carome_updated.pdf
7. http://www.hhs.gov/ohrp/policy/cdebiol.html
8. http://www.institutionalreviewblog.com/2010/02/irbs-unfamiliar-with-internet-research.html
9. http://www.institutionalreviewblog.com/2011/02/anxious-pessimism-on-uks-new-framework.html#more
10. http://arstechnica.com/tech-policy/news/2010/05/sociologists-invade-world-of-warcraft-and-see-humanitys-future.ars

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6.4.4 Law Professor Sees Broad Role for IRBs in Virtual Worlds (2011-04-07 17:27)

Professor Joshua A. T. Fairfield of the Washington & Lee University School of Law explores the law of research in virtual worlds.
[Joshua Fairfield, "Avatar Experimentation: Human Subjects Research in Virtual Worlds." (November 29, 2010). U.C. Irvine Law Review, Symposium Issue, 2011; Washington & Lee Legal Studies Paper No. 2010-14. Available at SSRN: [1]http://ssrn.com/abstract=1717057.]
Fairfield makes some important points about how researchers interested in these environments might apply ethical guidelines developed for older forms of research. But the article pays insufficient attention to the limits of ethical guidance developed to govern medical experimentation, misstates some of the provisions of current regulations, and downplays the troubles Internet researchers have faced with IRBs.

Ethical Issues

Fairfield raises important points about the ethical challenges of research into virtual worlds. He notes, for example, that elements of a virtual world can be valued as much as more tangible assets:

> An avatar, for example, does not merely represent a collection of pixels—it represents the identity of the user. The user is known by the avatar's name and is represented in the virtual world by the avatar. The avatar is the connection of the user to her online social community. Likewise, virtual reputations and trust are costly to generate, but easy to lose. If an avatar is identified as having harmed the community through interactions with a researcher, the human being behind the avatar will certainly suffer harm to her identity, reputation, and community.
> In the same vein, the accumulation of property in virtual worlds often reflects very real economic interests of the human subject. Many virtual worlds have in-world economies. These virtual economies have grown rapidly, and began interacting with the real-world economy. People now routinely use real dollars to purchase virtual land, goods, and services.

As an example of the perils of research into such worlds, Fairfield offers the case of Elizabeth Reid, [2]who found that her research disrupted an online community.
These strike me as fair points that should be kept in mind by researchers wishing to avoid harm to research participants. Fairfield is less persuasive when he suggests that the Belmont Report offers helpful guidance to such researchers. He offers a somewhat odd account of the the report, describing it in a section entitled "Law," though the report has no legal force. And he has subsections entitled "autonomy," "beneficence," and "justice," though the Belmont Report's three principles are respect for persons, beneficence and justice.
"Researchers should account for the communal nature of virtual worlds," he writes, under the beneficence heading.

"They should take precautions to safeguard the community as a whole, in addition to those individuals directly participating in the research." Maybe so. But as commentators have pointed out, [3]the Belmont Report does not address questions of community.

And Fairfield himself notes that the Belmont Report's concern for "fair procedures and outcomes in the selection of research subjects" is not clearly relevant to research on virtual worlds. "It is important not to overstate the issue," he writes. "Human subjects research is conducted on narrow population segments all the time."

Legal and Regulatory Issues: Private Information

"The law governing human subjects research in virtual worlds is wide-ranging and complex," Fairfield proclaims. True enough. Unfortunately, he oversimplifies that law, potentially misleading his readers.

The first set of claims concerns data saved by the companies that run virtual worlds ("game gods") and shared with researchers. Fairfield claims that "Commercial databases are increasingly relevant to virtual worlds research. Game gods license enormous collections of data to researchers for secondary analysis." Moreover, he claims, "Secondary data sets can include the extremely private conversations of millions of virtual world users over a period of years." Finally, he states that "in general it is not possible to obtain blanket consent from everyone in a virtual world," suggesting that there is no ethical or legal way to conduct analysis of large datasets from server logs.

There are several problems with this analysis. First, the facts about the collections may be wrong. Fairfield attributes his factual claims to a [4]2009 article, describing Sony's sharing of four years of data of EverQuest 2. But the article he cites does not support the claims. For one thing, Sony shared data for "over 400,000 players," not "millions." Second, the article mentions only one such collection of data–for Everquest 2–and notes that and most companies "haven't been interested in sharing their logs or the logs themselves don't contain the sort of data that would make for fruitful research." Thus, Fairfield's plurals ("databases" and "data sets") may be inaccurate.

Moreover, Fairfield ignores a follow-up post stating that [5]the logs were "scrubbed of all PII (Personally Identifiable Information) prior to being provided to the researchers." Presumably this would include "extremely private conversations."

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OHRP has rejected such reasoning. "The fact that an activity, such as oral history, appears on the list of activities that may be reviewed by an IRB through an expedited review procedure does not mean that such an activity always involves research," [6]wrote Michael Carome in 2005. "For example, collection of blood samples; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing are also on the expedited review category list; however, the use of these procedures most commonly occurs outside the research context."

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Fairfield suggests that though these license agreements may be legally binding, no one reads them and "these users have not meaningfully consented to the use of their private communications as research fodder, nor would ethical researchers make use of such data since it contravenes the users' expectations of privacy."

Perhaps. But the Common Rule does not require IRB review merely because an individual expects privacy; the individual must reasonably expect privacy, and I wonder if such expectations are reasonable in this case. Of course, a researcher can choose to respect even unreasonable expectations of privacy. But conflating what is ethical and what is legal, Fairfield risks confusing his readers.

Finally, it is odd to see Fairfield disparage the legalistic license agreements that no one reads only to champion IRB-approved consent forms, which [7]are also ignored or misunderstood by their intended readers.

Fairfield would be on stronger ground had he explored how medical researchers, IRBs, and regulators have made use of datasets containing sensitive medical information. His use of "general judicial decisions" to understand what "obtains" means in the context of human subjects research, rather than OHRP's [8]Guidance on Research Involving Coded Private Information or Biological Specimens, suggests that there is much more work to be done to figure out what "realspace research" can tell us about the study of virtual worlds.

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1. http://ssrn.com/abstract=1717057

2. http://www.indiana.edu/~tisj/readers/abstracts/12/12-2%20Reid.html

3. http://works.bepress.com/charlesweijer/130/
4. http://arstechnica.com/science/news/2009/02/aaas-60tb-of-behavioral-data-the-everquest-2-server-logs.ars
5. http://michaelzimmer.org/2009/02/25/sony-provides-complete-everquest-2-server-logs-to-researchers/
6. http://www.utexas.edu/research/rsc/humansubjects/forms/michael_carome_updated.pdf
7. http://www.annualreviews.org/doi/abs/10.1146/annurev.lawsocsci.093008.131454
8. http://www.hhs.gov/ohrp/policy/cdebiol.html
9. http://www.institutionalreviewblog.com/2010/02/irbs-unfamiliar-with-internet-research.html
10. http://www.institutionalreviewblog.com/2011/02/anxious-pessimism-on-uks-new-framework.html#more
11. http://arstechnica.com/tech-policy/news/2010/05/sociologists-invade-world-of-warcraft-and-see-humanitys-future.ars

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no (2011-04-09 08:49:27)

Sorry if this is a double post, the comment system seems to interact badly with mobile.

I just wanted to thank you for your deep read of the draft, and I will make sure to address several of the issues you raise. It's wonderful when people read and take seriously scholarly work, so kudos to you. We will still disagree at the end of the day about some things, but there is question that your suggestions will make the draft a better paper.

6.4.5 Princeton Offers PhD Students Serious Training in Historians' Ethics (2011-04-08 17:06)

Google alerted me to an innovative effort to train historians in the responsible conduct of research.

[Angela Creager and John Haldon, "[1]Responsible Conduct of Research Workshop, June 14-15, 2010," Princeton University.]

Back in 2007, I argued that "[2]Though oral historians will always face difficult ethical decisions, they have wrestled with them enough to produce appropriate, relevant, and applicable guidance to scholars new to the field." Princeton's faculty in history and the history of science, led by Professors Angela Creager and John Haldon, have taken this idea much further, building a two-day, 12 hour training program for PhD candidates that explores all manner of research ethics, from copyright and oral history to the duties of an expert witness and a mentor.

The program is discipline-specific, based on scholarly accounts of real controversies, and taught in person by expert faculty. If the workshop went as well as the syllabus promised, this could be a splendid model for other history departments.

1. http://www.princeton.edu/gradschool/about/docs/academics/HIS-HOS_503_RCR_syllabus_Final.pdf
2. http://www.historians.org/perspectives/issues/2007/0703/0703vie3.cfm

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6.4.6 Perspectives on History Interviews Me (2011-04-10 13:35)

The April 2011 issue of Perspectives on History, the newsmagazine of the American Historical Association, features an [1]interview with your humble blogger by Robert B. Townsend, the AHA's assistant director for research and publications.

ETA (4-14-2011): The interview is currently viewable only by members of the AHA, but I understand it will become open to all on May 1.

1. http://www.historians.org/Perspectives/issues/2011/1104/1104con1.cfm

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6.4.7 Hope College Frees Oral History (2011-04-19 16:32)

Hope College, a liberal arts college in Michigan, has posted [1]Oral History Research Guidelines that give substantial leeway to oral history projects:'

> EXCLUDED
> If the intent is to interview informants who have a unique perspective on a particular historical event or way of life and/or the investigator intends to let the informants' stories stand on their own as a "testimony" or in an archive, with no further analysis, the research is most likely Oral History that is EXCLUDED from HSRB review. Hope College's HSRB has determined that this research WOULD NOT constitute "research" as defined in 45 CFR 46.102(d). Nevertheless, the treatment of participants in Oral History Research must conform to the standards of the Oral History Association. If your project falls into this category, please complete the simple HSRB Oral History Project Registration Form instead of completing a full HSRB application.
> NOT EXCLUDED
> If, unlike in projects described above, the investigator conducts the surveys or interviews with the intention of comparing, contrasting, or establishing commonalities between different segments or among members of the same segment, it is clear that the investigator will draw generalized conclusions from the results. This type of research is most likely Oral History that is NOT EXCLUDED from HSRB review. Because such research is designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings), Hope College's HSRB has determined that it WOULD constitute "research" as defined in 45 CFR 46.102(d). For example, knowledge gained from a study may be applied to populations outside of the specific study population. If your project falls into this category, please go to HSRB's Decision Tree to determine what type of HSRB application to submit.
> Whether or not your project is excluded, Hope College believes ethics and ethical principles should govern all of our educational and research activities.

The [2]HSRB Oral History Project Registration Form is indeed a simple, one page form, and it seems designed to distinguish between genuine oral history projects and other forms of interaction, allowing the former to proceed without further IRB involvement.
Unfortunately, the policy is less clear than other universities' about what triggers IRB jurisdiction. The policy refers to both "generalized conclusions" and "conclusions" (without a modifying adjective), while the registration form mentions "general conclusions." Are these the same thing? And why does the registration form suggest that work that "informs policy" counts as research, when this does not appear as a factor in the Belmont Report, the Common Rule, or any federal guidance?
I suspect that someone at Hope–perhaps a committee–has been trying to reconcile the contradictory statements put out by OHRP over the years. Good luck with that.

1. `http://www.hope.edu/admin/hsrb/Oral%20History%20Guidelines.html`
2. `http://www.hope.edu/admin/hsrb/Oral%20History%20Registration%20Form.doc`

6.4.8 University of Iowa: Ask IRB Before Researching Neanderthals (2011-04-26 14:01)

Someone at the University of Iowa apparently thinks that the IRB has jurisdiction over research with dead Neanderthals.
The university administers the [1]Stanley Graduate Awards for International Research, which are "given annually to

UI graduate students for the pursuit of international research / fieldwork and career interests."
The program's web page states that "Since IRB approval is important for ALL student research projects and must be obtained PRIOR to receiving funding, **PLEASE SEE THE IRB INFORMATION PAGE**." (Emphases in the original.)
The [2]IRB information page in turns tells applicants that they must

> Submit an online "Human Subjects Research Determination" form through HawkIRB. The IRB chair and/or their designees will determine if your study meets the definition of human subjects research. Federal regulations do not allow investigators to make this determination themselves. If a study does not qualify as human subjects research, Hawk IRB will issue a memo stating that the project does not require IRB review or approval.

To be sure, the list of [3]2009-10 grants suggests that a majority of sponsored projects involve research with human subjects as defined by the Common Rule. But the program has also sponsored students to read twelfthcentury church records, tour ancient Greek and Roman houses, and examine "similarities and differences in the organization of worked bone technology by Neanderthals and modern humans in the Early Upper Palaeolithic."
Thus, because of the blanket policy, students who have no intention of conducting human subjects research face considerable bureaucratic requirements. According to my correspondents, applicants must complete the multi-hour CITI program just to submit the form stating that they are not conducting research with human subjects.

Two Misconceptions

The University of Iowa's policies appear to be based on two misconceptions.
First, if the web page is to be believed, this requirement is based on someone's belief that "Federal regulations do not allow investigators to make this determination [of whether they are conducting human subjects research] themselves." This is, of course, simply false.
OHRP has made clear that "[4]the regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt." And that's for exemption, for which OHRP does recommend that "investigators not be given the authority to make an independent determination that human subjects research is exempt."
OHRP has, to my knowledge, never even recommended that researchers be forbidden to make an independent determination that they are not conducting human subjects research.
The University of Iowa appears to have borrowed the falsehood from the University of Southern California. USC's booklet, "[5]Is Your Project Human Subjects Research? A Guide for Investigators, makes the false claim in identical language, and it is repeated in the University of Iowa's derivative work, "[6]Do I need IRB Review? Is This Human Subjects Research? A Guide for Investigators."
The second misconception driving the policy is the apparent assumption that researchers' time has no value. As Scott Burris has noted, "[7]No mechanism informs IRBs of the real cost of the 'small' changes they demand." Iowa offers a perfect example; I can't imagine that the people who set up the determination system reckoned the inconvenience it would impose on researchers who had no business with the IRB.
According to the IRB's website, [8]Human Subjects Research Determination form was only added to the application system in October 2010. Rather than being an entrenched policy, the requirement may be just an unfortunate episode that will soon be remedied. But that remedy will come too late for those already inconvenienced.

1. http://international.uiowa.edu/grants/students/funding/graduate/stanley-awards.asp
2. http://international.uiowa.edu/grants/students/services/IRBReviewSteps.asp
3. http://international.uiowa.edu/grants/documents/2009-10StanleyAwards.pdf
4. http://www.hhs.gov/ohrp/policy/exemptfaqsmar2011.pdf
5. http://www.usc.edu/admin/provost/oprs/private/docs/oprs/NHSR_3_6_06_WEB.pdf

6. http://research.uiowa.edu/hso/docs/HSRD/HSRDeterminationBooklet.docx
7. http://www.institutionalreviewblog.com/2008/12/burris-on-compliance-vs-conscience.html
8. http://research.uiowa.edu/hso/index.php?get=hsrd&view=1

6.4.9 USC Frees Oral History (2011-04-27 14:29)

The University of Southern California has ruled that oral history projects are not subject to IRB review.
In [1]yesterday's post, I mentioned USC's booklet, "[2]Is Your Project Human Subjects Research? A Guide for Investigators.
The bad news about this booklet is that it makes the false claim that "Federal regulations do not allow investigators to make this determination [of whether they are conducting human subjects research] themselves."
The booklet does so in an odd context. The full passage reads:

> Certain studies may have the characteristics of human subjects research but may not meet the regulatory definition. Studies which meet the definition require IRB review. There are three categories to be considered:
>
> - studies that are human subjects research
> - studies that may be considered human subjects research (gray area)
> - studies that do not qualify as human subjects research
>
> Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" should contact the IRB office or submit an online "Request for Human Subjects Research Determination" through iStar (http://istar- chla.usc.edu). The IRB staff, Chair and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

This passage not only ends with a falsehood; it is internally inconsistent. If USC really believes that regulations forbid researchers from determining if their projects constitute human subjects research, it is not "any investigator who is unsure" who should contact the IRB office, but rather any investigator, period, even those who will never conduct human subjects research.
The good news about the USC booklet is that it lists several categories that do not need IRB review. Among them:

> 3. Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.
> 4. Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are not intended for use outside of the classroom. Example: instruction on research methods and techniques. Note: The IRB is only required to review studies that meet the Federal definitions of research and human subject, or "engaged in research".
> 5. Biography or oral history research involving a living individual that is not generalizable beyond that individual.

Unfortunately, while the University of Iowa decided to copy almost all the text of the USC document for its booklet, "[3]Do I need IRB Review? Is This Human Subjects Research? A Guide for Investigators," the Iowa version deletes "or oral history."
So oral history and biography are both free of IRB constraints at USC, but only biography at Iowa.

1. http://www.institutionalreviewblog.com/2011/04/university-of-iowa-ask-irb-before.html
2. http://www.usc.edu/admin/provost/oprs/private/docs/oprs/NHSR_3_6_06_WEB.pdf
3. http://research.uiowa.edu/hso/docs/HSRD/HSRDeterminationBooklet.docx

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6.4.10 Harvard Law Fellow Tweets PRIM&R SBER (2011-04-28 12:33)

[1]Michelle Meyer, an academic fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, is live tweeting the ongoing PRIM &R SBER conference in Boston.
To read her tweets, which so far include some especially interesting comments from Ezekiel Emanuel and C. K. Gunsalus, search the hash tag [2] #primr _sber11.
[Many thanks to Dr. Meyer for alerting me.]

1. http://www.law.harvard.edu/programs/petrie-flom/fellowship/meyer.html
2. http://twitter.com/#!/search/primr_sber11

6.5 May

6.5.1 University of Iowa: Ask IRB Before Reading Poetry (2011-05-01 09:33)

[1]I recently reported on the University of Iowa's [2]Stanley Graduate Awards for International Research, whose information page seems to require applicants to contact the IRB, even if they are studying twelfthcentury church records, ancient Greek and Roman houses, or Neanderthal worked bone technology. This requirement is based on the false assertion that "Federal regulations do not allow investigators to make this determination [of whether they are conducting human subjects research] themselves."
It turns out that the university's information page on [3]Fulbright Grants also refers applicants to the IRB page with the falsehood about the federal regulations.
That same Fulbright page includes a link to a [4]profile of UI alumnus Geoffrey Hilsabeck, who won a Fulbright to study Portuguese poetry at the University of Lisbon. Presumably anyone wishing to follow in Hilsabeck's path and study poetry abroad with Fulbright funds needs to first check in with the IRB.
If so, I suggest they borrow a line from the profile: "The approach Hilsabeck used in his research was fairly unsystematic – as it should be with poetry, he says."

1. http://www.institutionalreviewblog.com/2011/04/university-of-iowa-ask-irb-before.html
2. http://international.uiowa.edu/grants/students/funding/graduate/stanley-awards.asp
3. http://international.uiowa.edu/grants/students/funding/graduate/fulbright-grants.asp
4. http://accents.international.uiowa.edu/globetrotting/highlight-on-fulbright-%E2%80%93-ui-grad-discovers-poetry-in-a-new-language-and-land/

6.5.2 My Comments to the Presidential Commission (2011-05-01 23:11)

I rather belatedly learned that the [1]Presidential Commission for the Study of Bioethical Issues was seeking public comment on the Federal and international standards for protecting the health and well-being of participants in scientific studies supported by the Federal Government. The deadline for comments is tomorrow, May 2.
Here are my comments, hastily cribbed from the conclusion of my book:
To the Presidential Commission for the Study of Bioethical Issues,
Thank you for the opportunity to comment on the Federal and international standards for protecting the health and well-being of participants in scientific studies supported by the Federal Government.
Last year I published Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009 (Johns Hopkins University Press), a work of scholarly history. The book concludes with the following findings.
1. The present system of IRB oversight is not based on empirical investigation of ethical abuses committed by social scientists.
2. Policy makers failed to explore alternative measures to prevent such abuses as do occur.
3. Medical and psychological researchers have been well represented on almost every official body that has set IRB policy. In contrast, official bodies have included at most a token representation from the social sciences.
4. The extension of IRB oversight over most social science research was largely unintentional, or at least so flawed that no one has been willing to take responsibility for it. University officials point to federal rules, while the authors of those rules claimed they were powerless to avoid the creep of regulation. In contrast, health officials have repeatedly asserted their wish to deregulate most or all social research.
5. While some scholars look back to what Robert Levine terms "the good old days" of IRB review of medical research before the 1998 OPRR crackdown, there has never been a golden age of IRB review of the social sciences.
6. The creators of today's IRB system treated history carelessly. They claimed to learn from the past, pointing out the wrongs of the Tuskegee Syphilis Study and the human radiation experiments, and noting the longevity of the IRB system as a reason to continue it. But they have dismissed the past when it suited them.
For close to half a century, health officials have imposed a regulatory system designed for medical experimentation upon scholarly disciplines with wholly different ethics and methods. They have done so not by persuasion, but by denying scholars in the social sciences and humanities a chance to shape the rules under which they must work.
While regulators occasionally acknowledge this truth, they have offered meaningful relief only when pressured by Congress or the secretary of health and human services. Absent such pressure, the Office for Human Research Protections has consisently ignored the concerns of social scientists. In recent years, for example, it has failed to deliver promised guidance on the definition of research (Patricia Cohen, "As Ethics Panels Expand Grip, No Field Is Off Limits," New York Times, 8 February 2007); failed to respond to the dozens of comments it received in response to its 26 October 2007 Federal Register notice; and apparently endorsed contradictory statements about oral history.
To remedy such problems once and for all, Congress should amend the National Research Act to restrict its scope to the research discussed during the 1973 Senate hearings that still serve as the evidentiary record for that act. The wording of such a restriction can be drawn from E. L. Pattullo's formula of 1979: "There should be no requirement for prior review of research utilizing legally competent subjects if that research involves neither deceit, nor intrusion upon the subject's person, nor denial or withholding of accustomed or necessary resources."
Please also see American Association of University Professors, "Research on Human Subjects: Academic Freedom and the Institutional Review Board" (2006), http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm, and American Historical Association, "Statement on IRBs and Oral History Research," February 2008, http://www.historians.org/perspectives/issues/2008/0802/0802aha1.cfm .
Sincerely,
Zachary M. Schrag

1. http://www.bioethics.gov/documents/Federal-Register-Notice-PCSBI-Requests-Public-Comment-on-Human-Subjects-Protection-030211.pdf

6.5.3 Bersoff Reviews Ethical Imperialism (2011-05-05 13:30)

[1]Donald N. Bersoff, a professor of psychology and law at Drexel University, has reviewed Ethical Imperialism for PsycCRITIQUES, the American Psychological Association's online database of book reviews.

[Donald N. Bersoff, "[2]Common Rule or Common Ignorance? A Review of Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009 by Zachary M. Schrag," PsycCRITIQUES 56, Release 18 (4 May 2011), Article 3.]

Bersoff offers qualified praise for the book: "Schrag, as an academic historian, has an axe to grind. But he does it well. The book is exhaustively researched, drawing on articles and books from a wide array of resources, transcripts of proceedings from various governmental agencies and commissions, and personal interviews with the major (and minor) players." Bersoff concludes that there are reasons "for psychologists of all stripes to be interested in this book."

Bersoff also offers two critiques. First, he challenges my decision to exclude psychologists from the bulk of the narrative, arguing that I "mistakenly [assume] that psychologists do not engage in research involving surveys, observation, and interviews."

I should have been clearer about my thinking here. Certainly individual psychologists involved in the IRB debates did such research. For example, during the National Commission's IRB hearings in 1977, Linda Beckman, a social psychologist, complained of the way her survey research had been reviewed by UCLA's medical IRB.

But as a profession, psychologists focused mainly on research in controlled settings, such as labs or classrooms. At those same 1977 hearings, Charles Kiesler, the APA's executive director, did not discuss survey, interview, or observational research in the way his counterparts from the American Sociological Association and the American Anthropological Association did.

Nor did the APA join those associations, the American Political Science Association, the Association of American Geographers, the American Historical Association, and the Social Science Research Council in their [3]1979 request that the IRB regulations not be applied to "research using legally competent subjects that involves neither deceit nor intrusion upon the subject's person nor denial or withholding of accustomed or necessary resources."

The history of IRB review of psychological research is an important story. [4]Laura Stark has made a valuable start telling it, and I hope that others join her. But I do not regret excluding that story from my book about the experience of scholars in the social sciences and humanities.

Bersoff's second critique is that "if you are an IRB administrator or dedicated member, you will view this work as a biased diatribe intent on undermining the rights of human subjects to be protected from undue risks and inadequate information."

I am glad to report that, in my experience so far, this has not been the case. I have angered some IRB members and staff, but this is not a universal reaction. For example, at the 2011 meeting of the Association for Practical and Professional Ethics, Ethical Imperialism was the subject of [5]a session at which an IRB chair and an IRB member both offered warm praise. Also at that conference, I met an IRB administrator who had enjoyed the book enough to order several copies for her staff.

The lesson I draw from such encounters is that many IRB administrators and members find themselves acting not to protect human subjects, but to respond to the murky regulations, inept guidance, and capricious enforcement decisions of the Office for Human Research Protections and other federal actors. Nor am I alone in such suspicions; this view has been [6]endorsed, to a degree, by members of the Secretary's Advisory Committee on Human Research Protections, the federal body charged with thinking about such questions.

No, I am not a fan of IRBs. But even people who believe in the general idea of ethics review wonder why they are required to impose silly restrictions on research in the social sciences and humanities. These are among my favorite readers.

1. http://www.apa.org/monitor/2011/05/bersoff.aspx
2. http://psycnet.apa.org/critiques/56/18/3.html
3. http://www.jstor.org/stable/3564447
4. http://onlinelibrary.wiley.com/doi/10.1002/jhbs.20468/abstract
5. http://www.institutionalreviewblog.com/2011/03/report-from-appe.html
6. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-1-systems-level.html

6.5.4 Australian Political Scientist: "Causing Harm . . . May Be the Whole Point" (2011-05-13 13:40)

Anthony Langlois, Associate Professor in the Department of International Relations at Flinders University, Adelaide, Australia, and a former member and chair of that university's Social and Behavioural Research Ethics Committee, finds that Australia's 2007 National Statement on Ethical Conduct in Human Research is an improvement over earlier policies, but that it still leaves an "ill fit between the requirements of [the medical] model of research ethics review and the nature of humanities and social sciences research."

[Anthony J. Langlois, "[1]Political Research and Human Research Ethics Committees," Australian Journal of Political Science 46 (2011): 139-154, DOI: 10.1080/10361146.2010.544287. Also available as a [2]preliminary preprint. Thanks to Professor Langlois for mentioning the essay on [3]socialsciencepsace.com.]

Langlois credits the drafters of the 2007 statement, who "took seriously the concerns of those working in the humanities and social sciences, and engaged directly with many of the issues and dilemmas that had been evident for some time." Most helpfully, they added a chapter on qualitative research. As a Human Research Ethics Committee (HREC) chair, he found that "Many of the more egregious offenses of the medical model of research ethics had been eliminated or clearly demarcated as not applcable."

But Langlois notes two major areas in which medical assumptions continue to vex non-medical researchers.

Methodological Misfit

The first is methodological. The medical model implicit in the National Statement assumes that researchers will work on their own schedule, so they can plan their proposals to be ready for the next monthly meeting of the HREC. Political researchers, by contrast, may react to breaking news, such as the April 2010 plane crash that killed much of Poland's political elite. These researchers have no time to get HREC clearance, especially when, as Langlois has been told, ethics committees "have flatly refused to consider urgent requests for expedited review of research proposals."

(Langlois does not mention the flip side of this issue. Just as political research may move too fast for ethics review, it may also move too slowly. As Christopher Leo has written, "[4]Many researchers concerned with politics and policy stay in regular touch with politicians and public servants and, in the process, ask them questions the answers to which may well be used in future publications." Thus, rather than starting suddenly in response to a plane crash, research may begin so gradually that the researcher does not notice.)

Ethical Misfit

Langlois's second concern is ethical. He argues that the National Statement constructs research participants "as vulnerable private individuals toward whom researchers have especial responsibilities which are derived from the power they hold in their role as researchers. More than this, human research participants are conceptualised primariliy in the role that they play within society as patients or clients or as some other form of unequal (meaning, that is, less powerful), dependent, vulnerable, private individual."

But for political researchers, "a research participant may be a voter—and ordinary private person. But they may also be an electoral representative, a Minister of the Crown, a judge, a public broadcaster, a private broadcaster with much political influence, a Chief Executive Officer of a company which employs a major percentage of the population, a terrorist, an enemy combatant, an economic adviser, a novelist, a Vice Chancellor . . . the list could go on interminably. For each of these, the relationship which the person has to society is different, not just in degree, but in kind, to the relationship which a medical patient or a therapist's client has to society."

Studying powerful people challenges the implied meanings of two of the [5]National Statement's four principles: beneficence and respect.

What does it mean to require researchers to "minimise the risks of harm or discomfort to participants" in such research? As Langlois notes, "For a series of types of political research (and indeed for other activities which today are increasinly counted as research outputs when they are engaged in by academics, such as journalism), causing harm (or

at least discomfort) may be the whole point of the exercise. If one is engaged in research about political corruption, human rights abuses, the influence of unions or industry barons over policy, branch stacking, political intrigue and so on, one may have an eminently justifiable intention to cause harm to one's research participant."

As for respect, Langlois writes, "Rather than the relationship between researcher and research participant being one of 'trust, mutual responsibility and ethical quality', as envisaged by the National Statement, it is far more likely to be one of suspicion, dissimulation, or even—. . . in relation to freedom of information laws—coercion."

In practice, Langlois thinks that HRECs already understand these problems, and they deal with these problems informally. But, he contends, "the National Statement is supposed to operate as a national guideline for HRECs, not as a document which spawns a host of under-the-counter practices and procedures which are undocumented, inconsistent with one another, and philosophically contradictory."

Solutions

Langlois notes that Australia intends to revise its National Statement "at least every five years." (Take that, you thirty-year-old 45 CFR 46!) In preparation for the 2012 revision, he offers two suggestions.

To fix the methodological problem, he suggests that alongside the current scheme of project accreditation, the statement create a system of researcher accreditation. "Rather than submitting an ethics clearance application before each 'project', researchers would be required to maintain a running log of research activity, and to submit an annual report of research activity," which could be scrutinized by an HREC.

And to fix the ethical problem, he suggests that the statement "providing guidelines for interpreting the Statement's research ethics review principles" for "research participants who were public, political, social, corporate and powerful agents of the body politik."

Both of these sound like significant improvements. I would, however, offer two caveats.

First, I am not sure that it is possible to reconcile the ethical gap by merely "interpreting the Statement's research ethics review principles" in new ways. Beneficence is beneficence, and it is a pillar of medical research. It is not a principle of all research, and it might be better to exempt critical inquiry from this principle than to twist words so that exposing someone's misdeeds becomes a form of beneficence. ([6]Canada's TCPS2 more or less takes this approach, stating, in effect, that a researcher should not harm a participant, except in those cases where a researcher should harm a participant.)

Second, I am not sure it is right to categorize the appropriate targets of such critical inquiry as "public, political, social, corporate and powerful agents of the body politik," that is, distinguishing the person rather than the action. A tobacco baron on vacation might deserve more privacy than [7]a humble storekeeper selling illegal cigarettes.

I think I prefer the formula suggested in 1967 by Lee Rainwater and David Pittman, who called for sociologists to "study publicly accountable behavior. By publicly accountable behavior we do not simply mean the behavior of public officials (though there the case is clearest) but also the behavior of any individual as he goes about performing public or secondary roles for which he is socially accountable—this would include businessmen, college teachers, physicians, etc.; in short, all people as they carry out jobs for which they are in some sense publicly accountable." [Lee Rainwater and David J Pittman, "Ethical Problems in Studying a Politically Sensitive and Deviant Community," Social Problems 14 (Spring 1967), 365.]

Overall, Langlois's essay is an elegant statement of how hard it is to adapt an ethics-review process designed for medical research ethics to other disciplines. In other words, ethical imperialism runs strong.

1. http://www.informaworld.com/smpp/content~db=all~content=a933407853~frm=abslink
2. http://www.flinders.edu.au/flinders/people/misc/lang0173_Political%20Research%20and%20Human%20Research%20Ethics%20Committees%20--%20AJ%20Langlois.pdf
3. http://www.socialsciencespace.com/2011/02/absurd-decisions-by-ethics-committees/
4. http://www.institutionalreviewblog.com/2007/08/evolving-research.html
5. http://www.nhmrc.gov.au/publications/ethics/2007_humans/section1.htm#b
6. http://www.institutionalreviewblog.com/2011/02/cautious-optimism-on-canadas-tcps2.html
7. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-iii-loosies-in.html

Jeffrey (2011-05-17 08:15:47)

Once again you have dragged out the straw man of "do no harm" to make the case for exempting social science research. The principle of beneficence does not mean that research cannot harm subjects. It means that the risks of the research are reasonable in relation to the benefits of the research. The benefits of the research can be directly to the subjects or the importance of the knowledge to be obtained. If you are studying malfeasance in a public official, then the social benefit of the knowledge to be obtained can justify the risk to the subject. The requirement to be minimize risks means that the research uses the least risk possible to obtain valid resulting. The purpose of research is not to punish people, it is to find out important information. Inflicting more harm than is necessary is just cruelty.

With regard to his methodological concern, any review committee that refuses to review research on breaking events because it does not meet its schedule is not fulfilling its obligations. This is not because of regulations, it is because of institutional bureaucracy. There are lots of institutions that have developed procedures for reviewing breaking events.

Zachary M. Schrag (2011-05-19 07:49:44)

Thank you for these comments.

"Do no harm" is not a straw man but a principle embedded in both the Belmont Report and the National Statement.

The Belmont Report offers a two-part definition of beneficence: "In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms."

The National Statement also offers a two-part definition:

" 1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

"1.7 Researchers are responsible for:

a. designing the research to minimise the risks of harm or discomfort to participants;

b. clarifying for participants the potential benefits and risks of the research; and

c. the welfare of the participants in the research context."

As Robert Veatch has noted, such formulas aren't really expressions of beneficence alone; they present two distinct principles: beneficence and nonmaleficence. ["Ranking, Balancing, or Simultaneity: Resolving Conflicts among the Belmont Principles," in Belmont Revisited: Ethical Principles for Research with Human Subjects, Childress, Meslin, and Shapiro, eds, 186-7.] And it is the nonmaleficence clauses that pose problems for social researchers.

What you describe is something else still. You write, "The principle of beneficence does not mean that research cannot harm subjects. It means that the risks of the research are reasonable in relation to the benefits of the research." But as Veatch explains, "if one believes that doing good and avoiding harm are merely two poles of a utility calculation, then the misleading term beneficence should be replaced with a term that avoids implying that only the positive dimension is being considered. The principle of utility is the obvious choice . . ." Thus, you are really describing utility, not beneficence.

I also suspect you are thinking not of the Belmont Report or the National Statement, but of the Common Rule, which does not use the term "beneficence." When you write of "the least risk possible to obtain valid result[]," you may be thinking of 45 CFR 46.111(a)(1)(i), which indeed calls for risk minimization to be weighed against "sound research design."

Neither Belmont nor the National Statement offer such a qualifier. Can we agree that both documents would be improved by the insertion of a "sound research design" qualifier that would replace beneficence and nonmaleficence with utility?

I agree with you that the HRECs that failed to respond to urgent requests from researchers were not fulfilling their obligations under the National Statement (particularly section 5.1.28(d) which requires that "review processes and procedures are expeditious.") Chapter 5.6 of the National Statement does require "procedures for receiving, handling and seeking to resolve complaints about the conduct of review bodies in reviewing research proposals." It would be interesting to hear from Professor Langlois whether researchers whose work was derailed by dilatory ethics committees took advantage of these procedures.

6.5.5 Ethics Experts Stupefied by a "Nitpicking Monster" (2011-05-19 15:26)

blog.Bioethics.gov, the official blog of the Presidential Commission for the Study of Bioethical Issues, reports on [1]two experts' frustration with the gap between the good intentions behind the IRB system and the depressing reality faced by researchers. Describing the 18 May 2011 Commission meeting in New York City, the blog explains:

> One of the themes in the discussion today at the Presidential Commission for the Study of Bioethical Issues: Why did proper concerns for protecting human subjects in trials lead to the creation of a regulatory structure that makes so many researchers cringe?
> Researchers equate dealing with Institutional Review Boards (IRBs) as like "going before a (New York City) co-op board or before an IRS auditor," said Ronald Bayer, professor and co-chair of the Center for the History of Ethics of Public Health at the Mailman School of Public Health at Columbia University.
> Bayer said he hears endless grumbling about IRB's "picayune questions." "I am concerned," he said. "Is the structure we created something very different than what we wanted it to be?"
> He said the the challenge to this commission is "to revisit in a fundamental way the institutions we have created. Something is off when people see the entire process as something we are not proud of, but as a process they find, well, stupefying."
> Commission member Dr. John D. Arras, a professor of biomedical ethics and philosophy at the University of Virginia, said he wondered whether the concern about protecting vulnerable populations in medical trials had "given rise to a backlash."
> "We pushed for an ethical reform of system, real oversight, and now we are left with this bureaucratic system, really a nitpicking monster," Arras said, addressing Bayer. "And I am as stupefied as you are."
> Their concerns ranged from overzealous IRB oversight to requirements of taking standardized tests on ethics.

So, you want to understand change over time? [2]Summon the historians!

1. http://blog.bioethics.gov/2011/05/18/professor-irb-irs-whats-the-difference/
2. http://blog.bioethics.gov/2011/05/19/at-meeting-one/

Anonymous (2011-05-23 14:59:34)

I used to have a position in which I prepared clinical research studies for IRB review. Regarding IRB bureaucracy, I've seen IRB members make comments that I found less than rational. But people who are interested in seeing their studies pass can attend the meetings and discuss the issues with the board members (at least where I worked). Many wanted someone to get their worked passed through the board and didn't bother to even attend the meetings. Their schedules might be busy, but certainly an appearance of one of the PIs to defend the study and answer questions always helps.

I have also had the misfortune of witnessing doctors trying to get around IRB issues, reporting things to the IRB and FDA when really there would have been few repercussions for the researcher since many of the patients were terminal. When research interests trump patient rights the system has a big problem. When there is financial incentive for the research (as in payment from pharmaceutical companies for each patient enrolled), then the problem might be financial greed rather than bureaucratic IRBs. Separating the financial system from research would be impossible at this point, but I think people really have to question what's going on with the research. When something that is almost standard care but still in "experimental" phases is blocked by absurd regulation that's one thing. When

there is money on the table for what truly is experimental and might shorten a patient's life, that is something totally different.

Having read through some of your other posts, I have to say that I think that all nonconsensual experimentation (biomedical, behavioral, social science, experimental psychology) that intends to harm the subject should be banned across the board. That type of legislation should have been in place years ago and the fact that it is not is IMO indicative of something quite serious. Not only should it be banned, but it should be criminalized and prosecuted. I don't like to see the issue of "harm" be reduced to

philosophy. There are studies that involve intentional harms to innocent persons who did not volunteer. The "benefits to society" do not matter if the research is involuntary and harmful.

Zachary M. Schrag (2011-05-24 13:31:09)
Thanks for these comments.
I wonder what kinds of research you have in mind when you propose to criminalize "all nonconsensual experimentation (biomedical, behavioral, social science, experimental psychology) that intends to harm the subject." Most of my posts on beneficence and nonmaleficence concern consensual interaction, as when a researcher gives a suspected wrongdoer the chance to defend his or her actions in an interview.
An exception is [1]my discussion of the effort to investigate the sale of loose cigarettes in San Francisco. The storekeepers willingly sold the cigarettes, but perhaps you consider their participation nonconsensual, since they were not informed that they were being researched. If so, then under your proposal, citizens would face jail for exposing such criminal behavior in their community.

1. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-iii-loosies-in.html

Anonymous (2011-06-02 13:44:00)
In reply to your response, I am trying to address things that haven't been exposed yet as well as some that were exposed and there were no repercussions for the experimenters.
The US has conducted experiments in the past that would not have passed through a review board based on both their potential (and real) harm to subjects as well as the ambiguous sense of benefience to society. The exposure of some of this experimentation in the 1970s lead to the adoption of the Common Rule by some but not all Federal agencies.
The exposure of the radiation experiments in the 1990s under Clinton led to no changes in regulation and oversight that I'm aware of; though the DOE has a complicated "roadmap" to the experiments. Would someone deem those experiments to have been worth the health risk to subjects less important that societal benefits? Who has the right to make that decision when the outcome of experimentation can be costly, harmful or deadly to the subject? In my opinion, no one - no group, individual, agency, or country - has the right to make that determination. And if other laws are being broken to carry out the research, then there should be full execution of those laws. Otherwise the whole system is a hypocrisy.
In the US, there is no one place for oversight of human experimentation. IRBs are generally attached to institutions but there is no federal law that all institutions that conduct research must have an IRB. Generally institutions that receive Federal funding have IRBs but where is there both oversight of review boards and assurances that all human subjects research that involves more than minimal risks actually passes through a review board?
Several states have specific laws dealing with clinical and/or nonclinical research and their own consent requirements, but most states have nothing to this end. In addition, the language covering medical experimentation lags far behind the technologies used in medical research. Examples of this are "non invasive" techniques used for both imaging and effects on the human body. Who has the right to use these and under what conditions?
If these laws don't exist does that mean that no unethical experimentation is going on? Why have previous attempts in Congress (in the 90s Senator Glenn, in the 2000s Representative DeGette) to pass stricter legislation on human research been tabled?
I speak as a victim of both nonconsensual biomedical and experimental psychology experimentation that has caused severe harm. I think if others are really concerned about the possibility of harmful research then they should investigate why there isn't better legislation in the US. For a victim the only option at the moment is to save up to move to a country with better laws that are actually enforced.

Zachary M. Schrag (2011-06-02 16:20:51)
Thanks for these comments.
Though you are correct that the work of the Advisory Committee on Human Radiation Experiments (ACHRE) in the 1990s did not lead to new legislation, it did lead to greater oversight, much to the dismay of many researchers. Among the eventual changes was the replacement of the Office for Protection from Research Risks with the Office for Human Research Protections. (See Ethical Imperialism, chapter 6.)
The debate over the radiation experiments also led to the formation of the National Bioethics Advisory Commission (NBAC), which in 1999 offered [1]recommendations much like your own. But NBAC also conceded that "the current Federal regulations have served to prevent most recurrences of the gross abuses associated with biomedical research in the earlier part of this

century," which may explain the lack of interest in Glenn and DeGette's efforts.
Professor Bayer's point (which led to my original post) was that "[2]what began as a venture in confronting abuse – the misuse and abuse of research subjects – has become something very different. And that is a beaurocraticized [sic] system of regulation that often misses the core of what the mission had began to do, and that actually has turned itself into an object of ridicule and sometimes contempt in a way that I think is dangerous to those who believe in the ethical conduct of research.." Other critics have noted that [3]IRBs approve studies of dubious ethics.
Thus, the kind of legislation proposed by Glenn and DeGette could prove counterproductive unless accompanied by [4]a more rigorous rethinking of the IRB system.

1. http://www.onlineethics.org/cms/17163.aspx
2. http://bioethics.gov/cms/node/229/
3. http://motherjones.com/environment/2010/09/dan-markingson-drug-trial-astrazeneca
4. http://www.institutionalreviewblog.com/2010/10/stark-wants-to-scrap-irbs.html

6.5.6 Sex Researcher Calls for "An Evidence-Informed Process" (2011-05-26 21:52)

Brian Mustanski, Associate Professor, Department of Medical Social Sciences, Feinberg School of Medicine, Northwestern University, calls for "moving the IRB process of risk/benefit assessment from being entirely subjective to being evidence-based."
[Brian Mustanski, "[1]Ethical and Regulatory Issues with Conducting Sexuality Research with LGBT Adolescents: A Call to Action for a Scientifically Informed Approach," *Archives of Sexual Behavior*, published online 29 April 2011.]
Mustanski is particularly conerned with research on lesbian, gay, bisexual, and transgender (LGBT) youth. Such youth, especially men who have sex with men (MSM), are at elevated risk of illness, especially HIV infection. But researchers have done relatively little to study interventions targeted at adolescent MSM. More generally, scholars' failure to study LGBT adolescents weakens "our basic understanding of diversity in the development of core aspects of sexuality, like sexual attractions and orientation, gender identity and expression, and romantic relationships."
Why this lack of research? Mustanski (a former IRB member himself) believes that IRBs are a big part of the problem. He cites studies showing that psychologists have modified or abandoned plans for fear of IRB rejection.
As he puts it,

> It can be extremely frustrating to agonize over perfecting every detail of a protocol to only then have it repeatedly questioned by anonymous individuals who may not have the same subject matter expertise. The standard IRB approach of written correspondence with long delays can be exasperating and is not designed to facilitate a collaborative relationship between IRBs and investigators. Investigators may be disturbed by requirements to make protocol changes that they perceive as decreasing the quality of the science without apparent reduction in risks or increasing protections. Communication can sometimes be unclear and, if a board has limited experience with the LGBT community, questions may seem uninformed, insensitive, or even homophobic. Community partnerships may be strained by the need for investigators to comply with IRB mandates over the recommendations of community members with expertise in serving the target population.

Mustanski notes his own involvement on a project that was funded for two years; IRB approval ate ten of those twenty-four months. Among the problems:

- The IRB applauded portions of the application in one round, then found those same portions unsatisfactory in a following round.

- The IRB labeled LGBT people as a vulnerable population, despite the fact that federal regulations do not list them as such. Mustanski notes that the regulatory categories are based on groups' inability to make decisions based on cognitive disability or a lack of power. "I know of no evidence that demonstrates such decisional impairment" with LGBT people, he writes, "and I believe many LGBT individuals would be insulted to have it implied otherwise."
- The IRB required the consent process to include the warning that some questions "could make you feel uneasy or embarrassed" and that counseling services would be available. But 89 percent of those interviewed found the experience no more uncomfortable than "a typical visit to your physician, doctor, psychologist, or counselor."

One could see why researchers would be tempted to achieve less scrutiny by limiting their surveys to respondents over age 18, or agreeing to parental consent for studies of younger people. But Mustanski warns that either approach would shortchange communities. Younger adolescents face challenges that their 18-year-old counterparts will remember less clearly, or–because of the changing culture–that 18-year-olds did not experience in the same way. And a "parental consent requirement will tend to underrepresent many of the youth who are most in need of the benefits of research, such as the development and validation of targeted health programs."

To improve the chances of future research making it through the IRB with less difficulty, Mustanski offers a list of recommendations to investigators. Mostly he thinks that if investigators become expert in the empirical data about risks and benefits of their research as well as relevant federal and local laws and regulations, and offer to share that information in in-person meetings with IRB staff and the board itself, everything will be fine.

I do hope so, though I fear that these recommendations may overlook the power dynamic involved. I am reminded of the 2007 University of California [2]Academic Council Report on Institutional Review Boards at UC:

> The challenge of training faculty IRB members is exacerbated by the extreme time commitment of serving on the IRB. There is little time available to faculty to be trained on subject protection beyond the time committed to protocol review. Some campuses include training in the IRB meetings, devoting 5 to 15 minutes of meeting time to developments in subject protection. However, IRB staff report that when training is on the agenda of the IRB meeting, faculty members often skip that part of the meeting because they are so busy. Rarely is there funding to train faculty IRB members.

Mustanski offers no mechanism by which IRBs would be required to deploy or even read the information he wants investigators to compile. For example, he could have endorsed the 1999 proposal of the Working Group of the Human Subjects Research Subcommittee of the National Science and Technology Council that:

> [3]In determining whether there might be a reasonable risk or damage related to divulging the sensitive information, etc., it is not enough that there be merely some hypothetical possible risk that can be construed. Rather, the risks resulting from disclosure must be readily appreciable and significant.

Still, even a cynic can join a call for emprical data, which could be useful to researchers even if IRBs fail to do their homework. So my favorite recommendation is number three. Researchers should

> help advance knowledge about the risks and benefits of participating in research by asking participants how they felt about their participation in your study. Publish the results so as to build a corpus of knowledge that will allow for evidence-based determinations about risks and benefits. As scientists, we are in a unique position to bring to bear our expertise in understanding how people respond in various situations and we should harness this expertise to help inform the IRB review process. Whenever possible, provide your IRB the empirical data about risks and benefits of sexuality research as they may be unfamiliar with this area.

Whatever one's feelings about IRBs, empirical research on the risks and benefits of different types of research is good for everyone. In some cases, this will take the form of projects designed specifically to measure the risks and benefits of research; many articles in the *Journal of Empirical Research on Human Research Ethics* take this form. But Mustanski's experience suggests that researchers who do not set out primarily to advance knowledge of research ethics nonetheless can accumulate valuable data as a byproduct of their main endeavor, e.g., by asking a question or two about how participants felt about participating.

Gathering and publishing such information (even informally, as on a blog), could indeed contribute to Mustanski's goal of improving IRB review "by transforming it into an evidence-informed process." And even if it doesn't, researchers would be better able to make their own ethical decisions.

Mustanski ends his article with sample language that could be included in an IRB application for a study of under-18 youth where parental consent is not being sought. This follows Rena Lederman's call for [4]IRB boilerplate. Of course, when someone actually tried Lederman's boilerplate for fieldwork, the [5]IRB responded by insisting on its own standard procedures. Maybe it's the thought that counts.

1. http://dx.doi.org/10.1007/s10508-011-9745-1
2. http://www.universityofcalifornia.edu/senate/committees/council/ac.irb.0507.pdf%20
3. http://www.usaid.gov/our_work/global_health/home/TechAreas/commrule.html
4. http://savageminds.org/2007/04/02/educate-your-irb-a-boilerplate-experiment/
5. http://savageminds.org/2007/04/02/educate-your-irb-a-boilerplate-experiment/#comment-73620

Anonymous (2011-05-27 11:01:03)

Our institution has been conducting this type of research for a couple of decades. Getting this research through the IRB isn't a huge deal. Yes, there are generally more concerns about these type of studies, given the nature of the information being collected, but I don't think this adds much to the review time.

If we are going to talk about evidence, where's the evidence that IRBs are a major barrier to doing this type research? CDC, NIH and other agencies have spent billions of dollars on behavioral and social science research associated with the prevention of STDs, HIV, etc. This research isn't being done or is suffering serious delays because of IRBs? Where's the evidence?

Zachary M. Schrag (2011-05-27 11:22:12)

In addition to his own experiences, Professor Mustanski offers two citations for his claim that research on LGBT youth is hampered by IRB review.

Fendrich, M. (2009, August). Empirical research on risks from studies of sexuality and other sensitive topics: What we don't know may be hurting us. Paper presented at the meeting of the International Academy of Sex Research, San Juan, Puerto Rico.

Miller, R. L., Forte, D., Wilson, B. D., & Greene, G. J. (2006). Protecting sexual minority youth from research risks: Conflicting perspectives. American Journal of Community Psychology, 37, 341–348.

I don't think he would dispute that "CDC, NIH and other agencies have spent billions of dollars on behavioral and social science research associated with the prevention of STDs, HIV, etc." His complaint is that much of this funding has been directed at adult populations that are at lower risk than the adolescents he wishes to help.

Anonymous (2011-05-31 15:46:12)

Look up the numbers and you'll find a lot of money is spent on adolescent public health, including HIV prevention in high risk groups such as YMSM.

http://www.cdc.gov/lgbthealth/youth-resources.htm

Zachary M. Schrag (2011-06-01 10:39:02)

Thanks for this comment and for the link to the CDC's page on "Lesbian, Gay, Bisexual and Transgender Health."

I did not see on that page any data indicating the levels of federal support for surveys of under-18 adolescents conducted without parental consent.

I did see a May 2009 fact sheet on [1]HIV/AIDS and Young Men Who Have Sex with Men. That fact sheet, in turn, features a 14-item bibliography.

The items that describe surveys of under-18 adolescents include:
MacKellar DA, Valleroy L, Secura G, et al. Unrecognized HIV infection, risk behaviors, and perceptions of risk among young men who have sex with men: opportunities for advancing HIV prevention in the third decade of HIV/AIDS. J AIDS 2005; 38:603–614.
This is based on data from the CDC's Young Men's Survey (YMS) which surveyed men under the age of 23 only in 1994-1998.
Garafolo R, Wolf RC, Kessel S, Palfrey J, DuRant RH. The association between health risk behaviors and sexual orientation among a school-based sample of adolescents. Pediatrics 1998;101:895–902.
This one was based on the the 1995 Massachusetts Youth Risk Behavior Survey (YRBS). Students needed parental consent to participate (though it is true that "fewer than 10 students were denied parental permission.")
Goodenow C, Netherland J, Szalacha L. AIDS-related risk among adolescent males who have sex with males, females, or both: evidence from a statewide survey. American Journal of Public Health 2002;92:203–10.
"Study participants were sexually experienced males from the sample of high school students who completed the 1995, 1997, or 1999 Massachusetts Youth Risk Behavior Survey (MYRBS)." Parental permission was required to participate.
Robin L, Brener ND, Donahue SF, Hack T, Hale K, Goodenow C. Associations between health risk behaviors and opposite-, same-, and both- sex sexual partners in representative samples of Vermont and Massachusetts high school students. Archives of Pediatric and Adolescent Medicine 2002;156:349–55.
Based on 1995 and 1997 data from the Vermont and Massachusetts Youth Risk Behavior Surveys. The article does not address the issue of parental consent, but the previous two citations indicate that parental consent was needed to participate in at least the Massachusetts version.
It seems, then, that the CDC is basing its advice to educators and school administrators on a small set of data from surveys conducted in the 1990s, most of which required parental consent to participate. Since IRBs became far more strict after the federal Office for Protection from Research Risks suspended funding at major institutions starting in 1998, it is plausible that new IRB rules are responsible for the absence of more recent data.

1. `http://www.cdc.gov/HealthyYouth/sexualbehaviors/pdf/hiv_factsheet_ymsm.pdf`

6.6 June

6.6.1 Dingwall on Isomorphism (2011-06-01 22:50)

Will Pakistan set up ethics committees for social science regardless of whether it has had problems with social research ethics?

6.6.2 Dreger on Naming Names (2011-06-02 15:23)

[1]Alice Dreger explains why historians are reluctant to promise either anonymity or nonmaleficence:

> Real accountability requires real names.
>
> A colleague of mine writes about this in his most recent book, where he discusses why we historians cannot promise our IRBs that we will not harm our subjects. He points out that sometimes we go into a project pretty much knowing that we're likely to harm some of our oral history subjects, because we're tracking an uncomfortable history where – almost by definition – somebody did some dumb or bad stuff. It's also really hard to appropriately laud those who did the right thing without naming the names of those who didn't along with those who did. For much needed inspiration and perspective, lately I've been reading the definitive biography of a particular founding father by an historian whose name you would surely know. Through it, I have been reminded how the stirring lessons we take from the history of our brave and wise founders is made possible by knowing who exactly said and did what to whom. We need to know the names of the cowards and traitors to really appreciate the heroes and martyrs.

Eloquent, but it's still hard to beat Tacitus: "[2]This I regard as history's highest function, to let no worthy action be uncommemorated, and to hold out the reprobation of posterity as a terror to evil words and deeds."
Dreger also throws in a bit of pedagogy:

> Years ago, I developed a little bit of fame at a certain Big Ten university for banning the word "society" from my course. I was teaching a course on something and something else, and I had grown weary of my students constantly saying, "Society thinks . . ." or, "Society says . . ." This was my students' way of seeing the world as hopeless in its oppression: Society was to blame for gender discrimination, for oppression of the poor, etc.
> As long as Society was to blame, no one was to blame. And no one had to change the status quo, because no one could change Society. Once I forced my students to start naming who exactly thinks or says this or that, their whole view of the world changed. Suddenly they realized who was responsible for promoting this (mis)representation or that ugly norm. And they realized you just had to change the behaviors of those people. Suddenly my students had power. The giant named Society had magically shrunk; the short guy with the slingshot had magically grown.

As my students (especially in HIST 332) well know, the forbidden word in my classroom is always. Claim that people have always behaved in a certain way, and I can find a point in a time for which that claim is false. (The planet is 4 billion years old, you know.) The study of history is the study of beginnings and of endings. This too, is the study of power: if the world was different once, it can be different again.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5389&blogid=140
2. http://books.google.com/books?id=GXhfAAAAMAAJ&lpg=PA107&ots=iCNQEG2rOS&dq=This%20I%20regard%20as%20history's%20highest%20function%2C%20to%20let%20no%20worthy%20action%20be%20uncommemorated%2C%20and%20to%20hold%20out%20the%20reprobation%20of%20posterity%20as%20a%20terror%20to%20evil%20words%20and%20deeds&pg=PA107#v=onepage&q=%22This%20I%20regard%20as%20history's%20highest%20function,%20to%20let%20no%20worthy%20action%20be%20uncommemorated,%20and%20to%20hold%20out%20the%20reprobation%20of%20posterity%20as%20a%20terror%20to%20evil%20words%20and%20deeds%22&f=false

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Jeffrey Cohen (2011-06-02 15:56:01)
Just a note to remind everyone that there is no requirement that research does not harm subjects. The only requirements are that risks are minimized - that is, the research inflicts the least amount of harm necessary, and that risks are reasonable in relation to the benefits of the research - that is, there is no harm inflicted that is not necessary to obtain important information. Also, there is no requirement that research participation be anonymous, only that subjects are informed about how their identity will be protected, if at all. As long as subjects know that their identity will be revealed and give their consent, then an IRB should have no problem approving the research.

Zachary M. Schrag (2011-06-02 16:23:37)
Dr. Cohen, what would it take to get you to read the Belmont Report?

Anonymous (2011-06-02 22:16:48)
Come on Zack, if you are going to make an argument, make it. Which part of the Report did you have in mind and why? Otherwise, let's just agree that Jeffrey is correct.

Zachary M. Schrag (2011-06-02 22:43:14)
Please see the following two posts, including the comments:
[1]Australian Political Scientist: "Causing Harm . . . May Be the Whole Point"
[2]First, Do Some Harm, Part III: Loosies in San Francisco

1. http://www.institutionalreviewblog.com/2011/05/australian-political-scientist-causing.html
2. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-iii-loosies-in.html

Jeffrey Cohen (2011-06-13 23:43:53)

Dr. Schrag, do not make this personal. I was reading and teaching the Belmont Report before you were out of elementary school.

The Belmont Report states that "do not harm" is only one part of two "complementary expressions" of the principle of beneficence, the other being "maximize possible benefits and minimize possible harms." It then goes on to explain, "The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks." Thus, it is clear that the drafters of the report did not intend research to be risk free.

Zachary M. Schrag (2011-06-16 10:02:18)

Thank you for your comment. It is always helpful to quotes sources.

I agree that the Belmont drafters did not intend research to be risk free. But that is not to say that they ever accepted the idea that some ethical researchers might deliberately harm their subjects. It seems that the [1]University of California-San Francisco IRB members read the report differently from you, and I can't say I blame them.

Indeed, your understanding of the Belmont Report appears to be at odds with that of some of its authors. In Belmont Revisited, Robert Levine writes, "The principle of beneficence, as interpreted by the National Commission, creates an obligation to secure the well-being of the individuals who serve as research subjects and to develop information that will form the basis of being better able to serve the well-being of similar persons in the future. However, in the interests of securing societal benefits, one should not intentionally injure any individual." This is not consistent with the ethics described by Dreger.

Similarly, Albert Jonsen told me, "We really should have made much clearer distinctions between the various activities called research. The principles of the medical model are beneficence—be of benefit and do no harm. I simply don't think that that applies to either the intent or the function of most people doing research."

Then there is the reaction of sociologist Albert Reiss, who attended the Belmont conference and contributed a paper to the National Commission. Having unsuccessfully called for the drafters to recognize the value of "muckraking sociology," he later denounced the Belmont Report as "ethical malpractice." [Albert J. Reiss Jr., "Governmental Regulation of Scientific Inquiry: Some Paradoxical Consequences," in Carl B. Klockars and Finbarr W. O'Connor, eds., Deviance and Decency: The Ethics of Research with Human Subjects (Beverly Hills: Sage, 1979), 67]

If you can find an explicit statement by any of the Belmont drafters calling for the "naming the names of those who didn't [do the right thing]," in Dreger's words, I would be grateful for the reference.

What the drafters of the Belmont really wanted was for the federal government to answer questions like this rather than leaving folks like you and me to guess what they meant. As Jonsen explains in his contribution to Belmont Revisited, "my colleagues and I fully anticipated that an Ethical Advisory Board (EAB) would he established as a standing agency within the Department of Health and Human Services. We had so recommended in almost all of our reports. We expected that such a Board could be the living oracle of Belmont's principles. Just as our Constitution requires a Supreme Court to interpret its majestically open-ended phrases, and, if I may allude to my own Catholic tradition, as the Bible requires a living Magisterium to interpret its mystic and metaphoric message, so does Belmont, a much more modest document than Constitution or Bible, require a constantly moving and creative interpretation and application."

Canada has revised its TCPS in the light of experience and debate, and in doing so it has explicitly recognized the value of critical inquiry. Australia has pledged to revisit its ethical guidelines periodically, giving researchers there the hope that they can amend the National Statement to match their principles. But in the United States, we are stuck with the Belmont Report, ambiguous in its language, inconsistent with federal regulations, in conflict with the ethics of social science, and impervious to change. It is time to rethink it.

1. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-iii-loosies-in.html

6.6.3 The CITI Program as Mortifyingly Stupid, Marxist Doxology (2011-06-04 09:39)

The Presidential Commission for the Study of Bioethical Issues has posted videos and transcripts of its Meeting Five, held May 18 and 19 in New York City. [1]I earlier linked to the Commission's summary of the statement by Ronald Bayer, professor and co-chair of the Center for the History of Ethics of Public Health at the Mailman School of Public Health at Columbia University. Now that we have the [2]verbatim text, it is worth quoting as well.

Overall, Bayer lamented that the IRB system has "turned itself into an object of ridicule and sometimes contempt in a way that I think is dangerous to those who believe in the ethical conduct of research."
Particularly choice is Bayer's description of the CITI Program, a widely used online training course in research ethics, which [3]Columbia University requires researchers to complete every three years.
(This passage appears at 6:33 in the [4]video for session 4. I have used the video recording to correct the transcript in a few places. In particular, on the video, and in the captioning, it is clear that Bayer used the term "doxology," though the official transcript reads "ontology." UPDATE, 10 June 2011: After I pointed out the errors to the Commission staff, they were speedily corrected.)

> I, like everyone else at the Mailman School of Public Health have to take an online test to guarantee that I have read the right things and understand the right things. I did it several years ago and just last month I was told we now have to do it every three years, so I had to do it again. I have to tell you, it is the most insulting experience to sit in front of a screen, to download a text and then a series of questions to which there is only one right answer, and if God forbid you think that there may be an ambiguity or an uncertainty, you get the answer wrong. What has happened, and I listen to people talk about taking these tests, and they talk about it the way Russian social scientists used to talk about having to learn the right Marxist [doxology] in the old Soviet Union. They have to learn something, spit it back and give the right answer, and if you don't get a good enough score, you can't do research, you have to take the test again.
> How it happened that we came to think educating people about doing research in an ethical way became so contorted that it becomes like the joke about how kids used to learn the Pledge of Allegiance and they didn't know what any of the words meant, and so they garbled it up in some funny way and you would hear versions of what the Pledge of Allegiance is. It is like that when people talk about ethics of research as they – look what you can do is you can download the text, put the question in front of you, read the text, find the answer. That's not education. And the reason I see it as a matter of concern is what it does is it raises contempt for the idea of education and becoming kind of sensitive to ethical complexities. And that's not where I think we should be going. It is in some way analogous to what has happened to the issue of privacy and the HIPAA regulations and the incessant plethora of pieces of paper from banks and insurance companies, printed and typed, I certainly can't read anymore, that tell you about their privacy protections. What do people think? All this privacy protection stuff is junk. Because it has become utterly bureaucratized.
> So, what's the challenge it seems to me to this commission? There are many big issues about what kinds of research internationally and globally in a world that is increasingly unequal is ethical, but it seems to me – it seems to me that it is time to revisit in a fundamental way both the institutions we've created, how they function, and how we educate people about fundamental ethical issues in research.
> I don't deny that there are certain fundamental things one can read and learn. One takes drivers test, one has to learn what a left hand signal is and what a right hand signal is. But there is something off when people see the entire process, not as something they feel proud about, but as something they experience[] as, in a way mortifyingly stupid, and stupefying – that is what it is, stupefying.

In subsequent questioning, commissioner John Arras asked about alternatives.

> Here is the problem. We're in a situation where we want mass education of people in a kind of fine tuned ethics of research and clearly the notion of these mechanistic web lessons is not the answer. But I'm wondering what is? Clearly, we want everybody to take your seminars at Columbia University for an entire semester. So I mean that would really do the trick, I think, right? But, so that's clearly not going to happen, right? It's incredibly hard to make room in a medical school curriculum for ethics and I think that my hunch is that the medical establishment allows us these pathetic web based tutorials, you know, in a

> grudging kind of way. You're taking up our valuable time, right? So the question is in between a seminar at Columbia and these web tutorials, what kinds of alternatives can we imagine?

Bayer responded,

> Professionally I feel a bit like a kibitzer here. But here is the – I think it would be good to look around the world, look to Western Europe, look to Canada. Whatever. It seems to me that we're not the only nation confronting this question of how best to kind of instantiate a respect for the ethics of research. It may be, it just may be that other people have come up with an answer we might learn from. And again I don't know what they have done, and I don't know how far it's gone, but certainly in the context of Europe, in the context of Canada, Australia, we might actually see something that is different from what we're doing that might be educated.

I don't know how much he will find abroad, but the Commission should take a look at [5]L. L. Wynn's efforts at Macquarie University to devise online training that allows for nuance. Closer to home, the Commission could explore the value of [6]two-day workshops in specific disciplines, like those offered at Princeton. And there are other possibilities along these lines, such as assembling bibliographies of the most important works in research ethics for each discipline and requring researchers to read them. None would require a semester-long seminar.
Bayer is right that many researchers hold ethics review in contempt. And he was right to trace much of that contempt to the terrible first impression made when smart researchers are compellted to complete [7]an insulting, pathetic, mortifyingly stupid online tutorial.

1. http://www.institutionalreviewblog.com/2011/05/ethics-experts-stupefied-by-nitpicking.html
2. http://bioethics.gov/cms/node/229
3. http://www.cumc.columbia.edu/dept/irb/education/documents/RevisedCITI_FAQs101910.pdf
4. http://www.tvworldwide.com/events/bioethics/110519/
5. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html
6. http://www.institutionalreviewblog.com/2011/04/princeton-offers-phd-students-serious.html
7. http://www.citiprogram.org/

6.6.4 U.S. and British Governments Subpoena Oral Histories (2011-06-13 16:50)

Last month, [1]the United States Attorney's office filed a subpoena for two tapes that were recorded as part of the Boston College's Oral History Archive on the Troubles in Northern Ireland. It did so at the request of the Police Service of Northern Ireland, part of the British Government. [2]As reported by the New York Times, British authorities apparently want the tapes for an investigation into murders and kidnappings committed decades ago.
According to the Times, interviewer Anthony McIntyre, described as "a former I.R.A. member who was imprisoned in the North and who has a doctorate in history," promised his narrators that the contents of their interviews would remain sealed until their deaths. I have not seen a detailed description of how this promise was conveyed, but it seems from the story that McIntyre did not warn participants that their words could be subject to a subpoena.
Predictably, someone has seen in this a reason for IRB review of oral history. Juliette Kayyem, former assistant secretary for intergovernmental affairs with the U.S. Department of Homeland Security, [3]wrote in the Boston Globe that

> The project managers may in some respects be the victims of inexact academic norms when it comes to narrative research. Universities have long struggled over how to address standards of research involving human subjects. The history is not pretty. At the end of WWII, the Nuremberg trials exposed a line

> of defense from Nazi physicians who forced prisoners to undergo appalling and inhumane procedures in the name of clinical research. Federal standards were established to protect the fundamental rights of scientific research subjects. Now, where subjects are utilized in research, institutional review boards are convened to ensure that the researcher is honest with his subjects.
> Over the years, these standards expanded to cover the social sciences as more and more academic institutions began to demand some oversight over the liberal arts. The Oral History Association balked at the notion, arguing in a 2003 statement that the nature of oral history does not lend itself to formalistic review. BC spokesman Jack Dunn confirmed that their decade-old oral history project was never reviewed by the board . . .
> Oral history may be a unique form of academic research, but well-known standards require notification that confidentiality cannot override a subpoena.

The question is, well known to whom? Not to the [4]University of Arizona, which released information from an IRB-approved study over the objections of the researchers. Not to the [5]IRBs whose forms were reviewed by John Neuenschwander.

In 2001, [6]Joan Sieber told the National Bioethics Adisory Commission, "There is now a literature of virtually hundreds of approaches to protecting privacy or assuring confidentiality. This literature is rarely sought out by IRBs, researchers, or teachers of research methods. Most are not even aware that it exists. . . . Many IRB chairs, members, and staff persons are not in a position to effectively guide or teach their clientele, or to gain the respect of their clientele." I have seen nothing to suggest that things have gotten better since.

Nor has the federal government offered the same protections to historical research it has to medical research. In particular, the NIH offers certificates of confidentiality only for studies "[7]within a mission area of the National Institutes of Health, including its Institutes, Centers and the National Library of Medicine."

Kayyem is quite right that the Boston College interviewers should have been more careful not to make promises they could not keep. But historians are more likely to get [8]sound advice from their professional organizations than from IRBs.

Ultimately, policy makers need to ask what will be gained if historians cannot offer confidentiality to the people they interview. If subpoenas like this become common, narrators will simply stop talking about crime. This would be a loss to posterity with no gain for the cause of justice.

1. http://www.bc.edu/publications/chronicle/FeaturesNewsTopstories/2011/news/irish052611.html
2. http://www.nytimes.com/2011/05/13/world/europe/13ireland.html
3. http://articles.boston.com/2011-05-23/bostonglobe/29574992_1_human-subjects-institutional-review-boards-oral-history-association
4. http://www.institutionalreviewblog.com/2010/09/irb-is-no-substitute-for-shield-law.html
5. http://www.institutionalreviewblog.com/2007/11/neuenschwander-on-irbs-and-oral-history.html
6. http://www.institutionalreviewblog.com/2007/01/why-not-make-irb-review-voluntary.html
7. http://grants.nih.gov/grants/policy/coc/faqs.htm#278
8. http://blog.historians.org/news/1334/british-request-for-oral-history-records-raises-complex-and-difficult-questions

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6.6.5 New FWA Terms Allow Alternatives to Belmont (2011-06-20 10:12)

In September 2010, OHRP posted drafts of new FWA form and FWA Terms of Assurance. In [1]my comments, I asked that the drafts be revised to make clear that under 45 CFR 46.103(b)(1), institutions have the right to choose any statement of principles they wish, including statements they formulate themselves. [2]Other comments also made this point.

I also asked that the FWA terms allow institutions to conform to the current version of Canada's Tri-Council Policy Statement, rather than the 2005 version mentioned in the OHRP draft.
OHRP has now released the [3]new version of the FWA terms. I am happy to report that both of my suggestions have been adopted.

1. http://www.institutionalreviewblog.com/2010/10/tell-ohrp-belmont-isnt-everything.html
2. http://www.institutionalreviewblog.com/2010/11/comments-fwa-forms-should-reflect.html
3. http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html

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6.6.6 Erdos: U.K. Data Protection Act May Stifle Research (2011-06-27 13:41)

[1]David Erdos of the University of Oxford kindly alerted me to two recent publications in which he warns that the United Kingdom's Data Protection Act 1998, which implements European Union requirements, could inhibit social research in much the same way human subjects laws and regulations have done in the United Kingdom, Canada, and the United States.
David Erdos, "Systematically Handicapped? Social Research in the Data Protection Framework, Information & Communications Technology Law 20, no. 2 (2011): 83-101,
[2]doi: 10.1080/13600834.2011.578925
David Erdos, "Stuck in the Thicket? Social Research under the First Data Protection Principle," International Journal of Law and Information Technology 19, No. 2 (2011), [3]doi:10.1093/ijlit/ear001.]
While going through the provisions of the act in detail, Erdos emphasizes two basic problems. The first is the extraordinary breadth of the act, which covers even public information.

> A great deal of data may still be covered including any records (including audio recording and photography) where an individual can be clearly distinguished and also certain deidentified data where the controller still retains the means of re-identification in manual form (Common Services Agency v. Scottish Information Commissioner, 2008). The meaning of 'relates to' presents further difficulties. Traditionally, this term has been interpreted extremely broadly. Under the Data Protection Act 1984 (which used the same statutory language) the office of the Data Protection Registrar (now ICO) determined that it encompassed even very innocuous public domain information, such as author and book title or the information about individuals included in Who's Who. (Systematically Handicapped?, 85)

The second basic problem is that rather than balancing the interests of individual subjects, research, and society at large, the act considers the interests of "data subjects" to be "paramount." (Stuck in the Thicket, 140)
Put these two elements together, and the act threatens to stifle legitimate critical research.

> The obtaining of data is the lifeblood of social research. A great deal of such information is obtained indirectly whether from published material or a third party. Beyond this there may also be a need to obtain data directly from data subjects but using clearly covert or even deceptive methodologies. Such data may shed critical light on socially problematic practices which would otherwise remain hidden from view (and possible remedy). These include discriminatory attitudes on the grounds of sex, ethnicity or race, the activities and outlook of members of extremist organizations, and police practices which conflict with the rule of law. For example, "[4]Simon Holdaway's seminal covert study of the British police uncovered both "very negative and suspicious attitudes towards black youths" and also evidence of 'verballing', a practice where the arresting or interviewing officer invented oral admission or incrimination and attrib- uted it to a

> suspect. Even in the case of relatively 'open' interviews or questionnaires, research design may mandate the provision of less than fully candid information. However, authoritative interpreters of the Act such as Jay have specifically held that these requirements make any covert research "almost certainly" illegal.

He also offers the example of Nigel Fielding's 1981 work, [5]The National Front. Fielding interviewed members of the National Front, read newspaper accounts of them, and examined court records, then published information about the criminal proceedings against them, using their real names. Such work, he warns, would be illegal under the current act.

Erdos does not offer a history of the European and British lawmaking, but it seems likely that the drafters of the act did not take into account the effect it would have on social, political, and historical research. By contrast, they did offer a "much less restrictive data processing regime for 'journalism, literature and art.'" (Systematically Handicapped?, 93) Presumably, then, someone raised the problems the rules would pose for a free press.

Thus, the press enjoys–at least in some circles–greater recognition of its role in a free society than does scholarly research. If lawmakers can be convinced that scholarly researchers often performs functions similar to those performed by the best journalists, Erdos's arguments may prove compelling. But if they believe that [6]newspapers are the backbone of democracy and scholarship a mere "shin bone," we can expect scholars to be cut off at the knees.

1. http://www.law.ox.ac.uk/profile/david.erdos
2. http://dx.doi.org/10.1080/13600834.2011.578925
3. http://dx.doi.org/10.1093/ijlit/ear001
4. http://books.google.com/books?id=Hc4TIQAACAAJ&dq=Inside+the+British+Police:+A+Force+At+Work,&hl=en&ei=VFsHTpflCILn0QGI1O3nCw&sa=X&oi=book_result&ct=result&resnum=1&ved=0CCoQ6AEwAA
5. http://books.google.com/books?id=ms8OAAAAQAAJ&dq=National+Front,&hl=en&ei=2lgHTtmIDeyz0AGKg53zCg&sa=X&oi=book_result&ct=result&resnum=1&ved=0CCoQ6AEwAA
6. http://www.institutionalreviewblog.com/2007/08/james-weinsteins-anti-intellectualism.html

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6.6.7 SACHRP Now Lacks Social Scientists (2011-06-28 09:59)

Anthropologist Patricia A. Marshall, the sole social scientist on the Secretary's Advisory Committee on Human Research Protections (SACHRP), [1]completed her term on the committee in March, along with three other members.

[2]OHRP has announced the four new members: Albert J. Allen, M.D., Ph.D.; Gary L. Chadwick, Pharm.D., M.P.H., C.I.P.; Susan Krivacic, M.P.Aff.; and Suzanne M. Rivera, Ph.D., M.S.W.

They are, respectively, a [3]child psychiatrist, a [4]pharmacologist, a [5]patient advocate, and an [6]expert in ethics and health policy. In my search for information about these new members, I did not come across anything indicating any expertise in the ethics and methods of social science.

Marshall herself is affiliated with a bioethics department, and I don't know that she spoke up for non-biomedical researchers while on the committee. And there is nothing in the [7]SACHRP Charter requring any diversity of expertise on the committee; the secretary of HHS could appoint eleven pharmacologists if she so chose. But I cannot see how a SACHRP lacking experts on social science can provide meaningful advice on the full range of "matters pertaining to the continuance and improvement of functions within the authority of the Department of Health and Human Services (HHS) directed toward protections for human subjects in research."

PS. [8]SACHRP has yet to post an agenda for its July meeting, to be held just over three weeks from now.

1. http://www.hhs.gov/ohrp/sachrp/members/committee/index.html
2. http://www.thompson.com/public/printpage.jsp?id=3509&pageid=newsbrief
3. http://www.liebertonline.com/doi/abs/10.1089/cap.2007.0031
4. http://www.urmc.rochester.edu/people/?u=22230645&s=researchers
5. http://www.linkedin.com/pub/susan-krivacic/1/a58/b71

6. http://blog.case.edu/case-news/2011/01/04/suzanne_rivera_joins_universitys_research_management_team
7. http://www.hhs.gov/ohrp/sachrp/charter/index.html
8. http://www.hhs.gov/ohrp/sachrp/mtgings/index.html

6.7 July

6.7.1 SACHRP to Hear from Presidential Commission (2011-07-01 12:48)

The Secretary's Advisory Committee on Human Research Protections (SACHRP)
[1]has posted the agenda for its July meeting. The committee will receive a briefing on the Presidential Commission for the Study of Bioethical Issues from the commission's executive director.
Any chance the phrases "[2]nitpicking monster" or "[3]mortifyingly stupid" will be used?
The committee will also get a report from its own Subcommittee on Harmonization.

1. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-11/agenda201107.html
2. http://www.institutionalreviewblog.com/2011/05/ethics-experts-stupefied-by-nitpicking.html
3. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html

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6.7.2 DOJ: "There Is No Academic Privilege" (2011-07-07 10:11)

As reported in [1]Inside Higher Ed, the Department of Justice has filed a brief in the [2]British government's effort to gain access to oral history records at Boston College. The Department asks the court to honor the U.S. attorney's subpoena on the grounds that "there is no academic privilege which shields the material from disclosure."
[h/t John Mueller]
The [3]DOJ brief argues in the alternative when it comes to the important question of whether oral historians are like journalists.
On the one hand, it suggests that the Boston College researchers are mere academics, and seizing information from them should be easier than prying it from reporters "because the Constitution and the courts have long recognized the unique role which news reporters play in our constitutional system. See, e.g., [4]Branzburg, 408 U.S. at 681; New York Times Co. v. Sullivan, 376 U.S. 254, 268-71 (1964). The limited protections afforded news reporters in the context of a grand jury subpoena should be greater than those to be afforded academics engaged in the collection of oral history."
The brief does not explain why this should be so. In Sullivan, the Court [5]applied the same reasoning to the four private individuals sued by Sullivan as it did to the New York Times.
(An [6]eminent legal scholar tells me that the DOJ is not idiosyncratic in its reading of Sullivan as celebrating the importance of newspapers. But I don't see it drawing a distinction betweeen journalists and scholars.)
And Branzburg, the other case cited, explicitly rejects a distinction between journalists and other investigators:

> The informative function asserted by representatives of the organized press in the present cases is also performed by lecturers, political pollsters, novelists, academic researchers, and dramatists. Almost any author may quite accurately assert that he is contributing to the flow of information to the public, that he relies on confidential sources of information, and that these sources will be silenced if he is forced to make disclosures before a grand jury.

Perhaps sensing this problem, the DOJ brief goes on to argue that even a journalist, if confronted by the same subpoena, could be forced to disclose the information under Branzburg.
According to Inside Higher Ed, Kathi Westcott, associate counsel of the American Association of University Professors,

> said that many courts have "recognized that academic scholarship is deserving of specified protection and that such protection requires a balancing approach in attempting to ensure that investigative demands are sufficiently factually based and narrow so as to limit the potential chilling effect these types of requests might have on future academic research."

I would be interested to see a full version of that argument.

1. http://www.insidehighered.com/news/2011/07/05/federal_government_questions_confidentiality_of_oral_history
2. http://www.institutionalreviewblog.com/2011/06/us-and-british-governments-subpoena.html
3. http://www.scribd.com/doc/59191594/Government-s-Opposition-to-Motion-to-Quash-and-Motion-to-Compel-7-1-11
4. http://www.law.cornell.edu/supct/html/historics/USSC_CR_0408_0665_ZS.html
5. http://www.law.nyu.edu/ecm_dlv4/groups/public/@nyu_law_website__journals__journal_of_law_and_liberty/documents/documents/ecm_pro_060916.pdf
6. http://www.ll.georgetown.edu/faculty/pubs.cfm?id=101

Boston College Subpoena News (2011-09-03 13:58:42)
[1]Boston College Subpoena News website following Boston College's motion to quash the DoJ subpoena. Court documents, background information and news media available on the site.

1. http://bostoncollegesubpoena.wordpress.com/

6.7.3 Alarmist Views on Harvard Facebook Study (2011-07-11 11:14)

The Chronicle of Higher Ed reports a debate over a study of Facebook profiles, started in 2006 by Jason Kaufman of Harvard's Berkman Center for Internet & Society. The debate suggests that researchers may not be aware of how easy it can be to identify allegedly anonymous institutions and individuals, but that neither IRBs nor outside critics may understand all the implications of a study either.
[Marc Parry, "[1]Harvard's Privacy Meltdown," Chronicle of Higher Education, 10 July 2011.]
[2]As I mentioned briefly last year, the Harvard researchers studied the Facebook profiles of undergraduates at "an anonymous, northeastern American university." In his June 2010 article, "[3]'But the Data Is Already Public': On the Ethics of Research in Facebook, Michael Zimmer of the University of Wisconsin at Milwaukee critqued the study design on two grounds. (If there is a more recent news hook to the Chronicle story, I missed it.)
First, Zimmer showed that Kaufman had failed to keep secret the identity of the university he was studying by including information about majors (er, concentrations) and housing choices that are unique to Harvard.
Second, Zimmer suggested that Kaufman had erred in letting Harvard researchers study Harvard students:

> A Facebook user might decide to share her profile information only with other Harvard students, but wants to remain private to the rest of the world. The RAs employed for the project, being from the same network as the subject, would be able to view and download a subject's profile data that was otherwise

> restricted from outside view. Thus, her profile data—originally meant for only those within the Harvard network—is now included in a dataset released to the public. As a result, it is likely that profile information that a subject explicitly restricted to only ”in network” participants in Facebook has been accessed from within that network, but then extracted and shared outside those explicit boundaries.

Kaufman apparently did not consider this possibility when designing the study, nor did he realize how easily information he did release about the university he was studying could be used to identify it as Harvard. By identifying individual students, the Chronicle showed that Zimmer was correct that the Kaufman team was wrong to claim that "all the data is cleaned so you can not connect anyone to an identity."

On the other hand, I believe Zimmer is simply wrong to suggest that it is possible to restrict one's profile only to other students at one's institution. So far as I know, Facebook makes no distinction among people using a given university's domain in their e-mail addresses. In other words, if a George Mason University undergraduate makes a profile visible only to members of the Mason network, I–as Mason faculty member–still get to see it. (Ick.) I don't know how long this has been the case, but I know it has been true since I joined Facebook some years ago. And I was able to join Harvard's network using my alumnus e-mail address.

I therefore question Zimmer's suggestion that students were "likely" to have posted significant information that they were unwilling to share with the general Facebook public but were willing to share with the tens of thousands of fellow Harvard students, staff, faculty, and alumni who presumably comprise the Harvard network on Facebook.

Zimmer may be right that "the IRB did not fully comprehend the complex privacy implications of this particular research project." But he goes too far in claiming that

> By failing to recognize that users might maintain strong expectations that information shared on Facebook is meant to stay on Facebook, or that only members of the Harvard network would ever have access to the data, the T3 researchers have failed in their duty to engage in ethically-based research.

I suppose the students might maintain such expections, but the Common Rule defines "private information" as "information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public." (Emphasis added.) [4]Facebook users can harbor no such expectations for their profiles.

As [5]one comment on the Chronicle article puts it, "Something has gone horribly wrong in academe when non-profit researchers seeking to expand human knowledge are disallowed from doing what for-profit marketing companies who have nothing but their own gain as motive are legally allowed to do."

So what do we learn?

1. [6]Researchers should not expect that the institutions and places they study will remain anonymous.
2. Researchers using cutting-edge methods, like the study of Facebook, may not appreciate all the privacy consequences of those methods.
3. Zimmer, the alleged expert in Internet privacy, is willing to speculate that Harvard students were "likely" to rely on a Facebook privacy setting that would afford them no real privacy. He apparently wants IRBs to forbid academic researchers from doing something that any advertiser could do (providing it hired a Harvard affiliate as an intern).
4. IRBs aren't much help. The article paraphrases Zimmer's judgment that IRBs "lack experience with Web-based research." [7]Elizabeth A. Buchanan and Charles M. Ess would agree.
5. The federal government isn't much help. The article states that Zimmer thinks the federal government should "do more to educate IRB's about Web research." And it quotes Harvard spokesman Jeff A. Neal saying that "Federal regulators, professional associations, and IRB's are all working to understand these risks and to develop guidelines."

Are they really? [8]Professional associations, perhaps. But regulators? [9]SACHRP invited Zimmer and other experts to talk about Internet research, but that was a year ago. Where is the guidance? And where is the guidance about the hopelessness of anonymizing institutions, which has been known for decades?

All of this comes down to basic flaws in the current system of human research protections: it neither learns nor teaches.

Harvard is a pretty good school, yet its IRB was unlikely to have an expert on Internet research or, better still, two Internet experts able to discuss the project in terms more measured than Zimmer's.
As [10]Alice Dreger and [11]Laura Stark have argued, serious expertise would require some kind of national coordination of knowledge. Canada's Panel on Research Ethics performs that role to a degree. But in the United States, the [12]Ethics Advisory Board died an early death, and local IRBs have been wandering in the fog ever since.
The good news is that at least one person involved in the Harvard study did possess expertise about privacy and Facebook. "Anything that's put on Facebook somehow will make it out into the general public, no matter what you attempt to do," says Sarah M. Ashburn, one of the students whose profile was studied and who was identified by the Chronicle. "So I never have anything on my Facebook profile that I wouldn't want employers, my grandmother, like anyone in the world to be able to see."

1. http://chronicle.com/article/Harvards-Privacy-Meltdown/128166/
2. http://www.institutionalreviewblog.com/2010/11/is-facebook-data-mining-human-subjects.html
3. https://springerlink3.metapress.com/content/q1v7731u26210682/resource-secured/?target=fulltext.pdf&sid=sl4iek55nlgz5pjoix0w2t45&sh=www.springerlink.com
4. http://online.wsj.com/article/SB10001424052748704513104575256701215465596.html
5. http://chronicle.com/article/Harvards-Privacy-Meltdown/128166/#disqus_thread
6. http://www.institutionalreviewblog.com/2011/01/uconn-irb-encouraged-failed-effort-at.html
7. http://www.institutionalreviewblog.com/2010/02/irbs-unfamiliar-with-internet-research.html
8. http://www.internetresearchethics.org/
9. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-10/present.html
10. http://www.institutionalreviewblog.com/2010/10/dreger-wants-to-scrap-irbs.html
11. http://www.institutionalreviewblog.com/2010/10/stark-wants-to-scrap-irbs.html
12. http://www.institutionalreviewblog.com/2011/06/dreger-on-naming-names.html?showComment=1308232938881#c4287209779531944336

6.7.4 U of Michigan Reports Some Progress (2011-07-21 09:51)

The University of Michigan has released the results of a 2009 survey of investigator experiences in human research. The survey suggests that matters have improved somewhat since the university launched its HRPP Policy Innovation and Demonstration Initiative in 2007, but that more work remains to be done.
[Survey Research Center, Institute for Social Research, University of Michigan, "[1]2009 Follow-Up Survey of Investigator Experiences in Human Research," December 2010. h/t: [2]Human Research Protections Blog.]
In 2007, the University of Michigan launched its [3]HRPP Policy Innovation and Demonstration Initiative (Michigan Initiative), intending "to identify and improve Human Research Protection Program (HRPP) policies and procedures to minimize administrative burden for investigators and the institution without compromising the protection of the human participants." In 2007, the university conducted an initial survey of its investigators, and in 2009 conducted this follow-up survey. The survey covered both the institutional review boards of the University of Michigan Medical School (IRBMED) and the Health Sciences and Behavioral Sciences Institutional Review Boards (HSBS). It offers some important lessons for all university programs.

Most investigators are satisfied

84 percent of HSBS researchers said they were very or somewhat satisfied with the IRB process, up from 78 percent in 2007. But only 67 percent were satisfied with full committee applications, down from 78 percent in 2007. Unsurprisingly, the higher the level of review, the less satisfied investigators were. When given open-ended questions, both medical and non medical researchers were apt to complain about the process. (Table 20)

Customer service matters

Researchers like having messages returned. "Taken altogether, 22 % of IRBMED investigators and 11 % of HSBS investigators reported either an unanswered telephone call that was never, rarely, or only sometimes returned or an email message that was not returned when a reply was expected . . . Unreturned inquiries are associated with much higher levels of dissatisfaction with the IRB review and approval process: the overall level of dissatisfaction with the IRB review and approval process was 21 % and increased to 51 % among investigators with unreturned inquiries." (Table 8)

Researchers also like approval within four weeks. One of the biggest improvements in the 2007 - 2009 span was the decrease in exempt applications that took more than four weeks to get approval. "The decrease in the percentage of HSBS exempt applications approved in more than 4 weeks was especially large, dropping from 28 % to 8 % between the 2 survey periods (i.e., 92 % were approved within 4 weeks . . .)" (Table 14)

The report explains,

> When applications took more than 4 weeks to approve, investigators were much more likely to say their applications were not approved in a timely manner and to be dissatisfied with the review and approval.
>
> Moreover, investigator attitudes towards the review and approval process for their most recent application were strongly associated with the number of weeks to obtain approval. When an application took more than 4 weeks to approve, investigators were much more likely to disagree that the changes required to their application were reasonable or clear and to agree that the changes required made it harder to achieve research goals and objectives and delayed the start of their research. (v)

It seems that the university still has work to do in cutting down the time needed to prepare an application. The report boasts that 74 percent of HSBS exempt applications took 10 hours or less to prepare. True, but 66 percent took more than four hours, which seems unreasonable for a process that should be mostly automatic. And 9 percent of exempt HSBS applications took two weeks or more to prepare. (Table 16)

Most researchers see IRB as a hurdle

79 percent of HSBS researchers agreed that "The IRB process is a hurdle to clear." 59 percent believe that "the IRB interprets regulations too strictly," and only 64 percent agree that the "IRB is an ally in my research." On the other hand, all of these numbers are improved since 2007. (Table 22)

Here's a fun one: more than 87 percent of investiagors–both medical and not–in both 2007 and 2009 agreed that IRB review in general adds to the protection of human subjects. But only 44 percent of researchers believed that the changes made to their projects improved the protection of participants.

One can read this in two ways. Perhaps the IRB is adding needed protections, and researchers are unable to see their own defects, the way that [4]only 1 percent of drivers rate themselves as worse than average. Or it could be that researchers have a better sense of the issues involved in their own research and are just guessing that the IRB does better with other kinds of research. (Table 15)

Perhaps these numbers would improve if IRBs could explain their actions. Only 50 percent of HSBS investigators agreed that the IRB explained the ethical reasons for changes, down from 54 percent in 2007. Only 59 percent said the IRB explained the regulatory reasons. That's pretty bad news: investigators should know why they are being led through hoops. (Table 15)

Many researchers are also unhappy with the training they must complete. The University of Michigan requires researchers to complete its Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS), an online program that [5]takes its content from the [6]mortifyingly stupid CITI Program. Only 63 percent of HSBS researchers agreed that "PEERRS contributes to ethical understanding." Asked if PEERRS was useful to the content

of their research, 52 percent of HSBS researchers disagreed. (Table 36)

Michigan is asking good questions, but not enough of them

I am disappointed by two silences in this report. First, the survey did not ask about investigator attitudes toward the new [7]IRB Council, which includes faculty representatives and might be expected to shape attitudes toward the HRPP in general. I imagine that faculty like having a voice in the apparatus that shapes their research, but this survey missed the opportunity to find out.

Second, while the survey asked respondents' gender age, rank, and years at the university, it did not ask their department or primary disciplinary affiliation. The HSBS IRB serves the A. Alfred Taubman College of Architecture & Urban Planning, the College of Engineering, the College of Literature, the Science, the and the Arts, the College of Pharmacy, the Gerald R. Ford School of Public Policy, the Horace H. Rackham School of Graduate Studies, the Law School, the School of Art & Design, the School of Dentistry, the School of Education, the School of Information, the School of Kinesiology, the School of Music, the Theatre & Dance, the School of Natural Resources & Environment, the School of Nursing, the School of Public Health, the School of Social Work, the Stephen M. Ross School of Business, the U-M Transportation Research Institute, and even the Institute for Social Research (ISR), which ran the survey.

Breaking down the investigators into rough groupings (e.g., health sciences, behavioral sciences, social sciences, humanities) would have gone far to make sense of some of the findings here.

Overall, however, the survey is remarkable for two reasons. First, that it was done at all, and second, that it was made public on the Internet. In a system not known for transparency, the Michigan HRPP has aired its laundry–both dirty and clean–in public. By doing so, it gives University of Michigan researchers and administrators a sense of what is working and what needs attention, and it points the way for similar efforts at other institutions.

The survey and its report refute [8]Laura Stark's claim that "like any bureaucracy, the best [IRBs] can aspire to be is well-oiled, smooth-running, and thus silent." No, the best bureaucracies–including those charged with the protection of research participants–can aspire to constant self-examination, accountability, and improvement.

1. http://ur.umich.edu/1011/Jun20_11/2437-report-on-investigator
2. http://humanresearchprotectionsblog.wordpress.com/2011/07/02/human-research-protections-round-up-july-2-2011/
3. http://www.hrpp.umich.edu/initiative/index.html
4. http://www.harrisinteractive.com/NewsRoom/HarrisPolls/tabid/447/mid/1508/articleId/836/ctl/ReadCustom%20Default/Default.aspx
5. http://my.research.umich.edu/peerrs/help.php
6. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
7. http://www.hrpp.umich.edu/om/Part2.html
8. http://www.jstor.org/stable/4623412

6.7.5 Feds Ponder Biggest IRB Rules Changes in 30 Years! (2011-07-23 15:16)

On Friday, the U.S. Department of Health and Human Services posted an [1]Advance Notice of Proposed Rulemaking (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, to be published in the July 25 Federal Register.

The ANPRM seeks to "enhance the effectiveness of the research oversight system by improving the protections for human subjects while also reducing burdens, delays, and ambiguity for investigators and research subjects." In 92 pages, it suggests dozens of potential changes, some of them quite major. They would represent the biggest regulatory changes to the US IRB system since the revision of 45 CFR 46 in 1981.

Watch this space for extensive and frequent commentary on specific provisions in the proposal as I draft comments prior to the end of the 60 day comment period. (September 22? How do they count these things?)

For now, I will just register my delight that the federal government has finally acknowledged that the flaws in the present system are not mere anomalies, but represent systematic problems that demand regulatory reform.
Oh, and thanks for the three citations to my work! Attention has been paid!

1. http://www.hhs.gov/news/press/2011pres/07/20110722a.html

Melora Ranney Norman (2011-07-23 16:12:43)
Hope this turns out to be great news–thanks for all your advocacy, Zach!

Anonymous (2011-07-23 22:05:56)
As chair of a university IRB I think these proposed changes are excellent.

Zachary M. Schrag (2011-07-23 23:30:20)
Thanks for these comments. I think the more comments HHS receives in the next 60 days, the better. I will be posting drafts of mine–section by section–on this blog as they are ready.

Anonymous (2011-07-25 16:41:49)
I work in the IRB world and have experience in large IRBs and small ones–as an Administrator, and as a Chair of an IRB. I'm very research friendly and don't really think there needs to be much review of social science research. Unfortunately, I think that the review of social science research is going to be just as problematic under the proposed/new regulations as the old regulations...sorry. For example, the first regulatory change is about protecting identifiable data. Since the identifiability of the data will be the deciding factor, the "risk" (whatever that really means–sensitivity of the data) won't be taken into account? Studies that used to be Exempt, even if they were identifiable, may still be exempt, but they will have to meet the security standards set for studies that have much more sensitive data. For example, identifiable data fro an online survey, in say, linguistics, will have to have the same level of security (likely encryption, etc.) as identifiable data about drug users. I can imagine that this might put an incredible (financial)burden on researchers, particularly social science researchers. How's this going to work with fieldwork studies?

Zachary M. Schrag (2011-07-25 17:07:24)
I agree that imposing the HIPAA standards on social science research, without any modification, would cause more problems than it solved. I had focused on the restriction on geographical identifiers, and I had overlooked the suggestion that "data security standards could require the use of reasonable and appropriate encryption for data maintained or transmitted in electronic form and strong physical safeguards for information maintained in paper form, audit trails, and access controls that allow only authorized personnel to have access to the information." Thank you for catching this.
I put little faith in the "reasonable and appropriate" qualifier, so I think you are right to worry about this suggestion.
ANPRM question 59 does ask if the HIPAA standards are "appropriate not just for studies involving health information, but for all types of studies, including social and behavioral research? Or might a better system employ different standards for different types of research?" I hope you will submit a comment in response to this question, drawing on your experience.

6.7.6 Washington Post Reports on ANPRM (2011-07-24 09:42)

David Brown, "[1]U.S. proposes rule changes for human-subject research," Washington Post, 23 July 2011.

1. http://www.washingtonpost.com/national/health-science/us-proposes-rule-changes-for-human-subject-research/2011/07/22/gIQA1IAhVI_story.html

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6.7.7 New York Times Reports on ANPRM (2011-07-25 10:23)

Andrew Pollack, "[1]Rule Changes Proposed for Research on Humans," New York Times, 24 July 2011.
Like the Washington Post story, this lacks any explanation of who wrote the ANPRM or why it came out now. But it does have some good quotations:

> "It's a terrible drag on getting good research done," said Dr. Robert J. Levine, a professor of medicine and a bioethicist at Yale who headed the university's institutional review board for 31 years. He said Sunday that while he had not thoroughly reviewed the government's lengthy proposal, he was encouraged by what he had seen.

and

> Carl Wieman, associate director for science at the White House Office of Science and Technology Policy, said it was now difficult to observe teachers and students in classrooms to help determine what makes a good teacher, given all the consent required. "You're not doing anything here except watching people," he said.

1. http://www.nytimes.com/2011/07/25/health/research/25research.html

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Anonymous (2011-07-25 11:47:36)
Our institution does a large amount of work on curriculum evaluation of the sort referenced in the Carl Wieman quote above. Practically all of it is determined to meet the criteria for exemption under §46.101(b)(1). Where just teachers are involved it usually meets the criteria for exemption under §46.101(b)(2) as well. We often make recommendations about appropriate consent procedures but don't formally review or approve consent procedures and forms for exempt studies.
The proposed revisions may in fact offer less than they appear with regard to social science research as most social science research can be treated as exempt under the current regulations but many institutions choose not to do so.

Zachary M. Schrag (2011-07-25 12:15:48)
Thanks for this comment.
I am glad to learn that the exemption process is working at your institution, but the ANPRM recognizes that not all institutions function so well. It addresses the problem of institutions' overregulating by seeking to "clarify that routine review by an IRB staff member or some other person of such minimal risk exempt studies is neither required nor even recommended." This is an important reversal of current guidance. Other potentially helpful measures considered in the ANPRM include the gathering of data, and the requirement that institutions distinguish between federal requirements and their own rules.
See "[1]Menikoff Passes the Buck."

1. http://www.institutionalreviewblog.com/2010/12/menikoff-passes-buck.html

Anonymous (2011-07-25 14:21:46)
I haven't worked my way through the whole document but I think it is wishful thinking to assume that clarifications and some rule changes will get rid of institutional dysfunction.
They are proposing a one page exemption registration. But that still leaves the problem that some researchers are not going to apply the criteria appropriately. They try to address this with "require random retrospective audits of a sample of exempt studies to assess
whether the exemptions were being appropriately applied." I think this is potentially more burdensome on everyone, and certainly opens the door to more dysfunction. I'd prefer sticking with a simple, independent check up front that asks

what type of data is being collected, how, from whom and where to ascertain that the project involves no greater than minimal risk and meets at least one of the exempt categories. I guess that could be one page, plus attached instruments in some cases.

Zachary M. Schrag (2011-07-25 14:44:28)
I think the idea is that the exemption (or excusal) criteria should be made clearer. Right now, no one knows what risk to reputation means, so researchers get in fights with IRB staff. The HIPAA criteria are clearer, so whether the review is done prospectively or retroactively, I would hope that the system would involve less guesswork.
I take your point that retrospective audits could be "potentially more burdensome" than prospective review. I wish the ANPRM included a mechanism by which new systems of oversight could be tested and refined through experience. Instead, it asks us to guess how an untried system might work.

Anonymous (2011-07-25 16:14:06)
I agree with you about new procedures and guesswork. It seems to me that there is a high risk of practice turning out to be something other than expected.

6.7.8 Emanuel and Menikoff Explain the ANPRM (2011-07-25 21:16)

Ezekiel Emanuel, head of the Department of Bioethics at NIH, and Jerry Menikoff, director of OHRP, explain the ANPRM for readers of the New England Journal of Medicine.
[Ezekiel J. Emanuel and Jerry Menikoff, "[1]Reforming the Regulations Governing Research with Human Subjects," *New England Journal of Medicine*, 25 July 2011. h/t Michelle Meyer]
The essay is a very helpful introduction to the ANPRM, clearer than the ANPRM itself. The authors conclude,

> After 20 years, and the introduction of significant changes to the research landscape, many believe that the Common Rule needs revision. The ANPRM offers a rare opportunity for needed modernization that is consistent with the President's mandate to enhance protections while simultaneously eliminating unreasonable burdens. Not everyone will agree with every proposed change. But the ideal should not be the enemy of substantial progress in achieving these two important goals. If this reform effort fails, 20 years from now, someone might write an article for the Journal to bemoan the fact that the Common Rule has undergone essentially no change in 40 years.

Fine, I'll say it. I agree with Jerry Menikoff.

1. http://healthpolicyandreform.nejm.org/?p=14979&query=OF

Anonymous (2011-08-05 15:01:38)
The problems are not with the existing "Common Rule" - the problems are in interpretation and enforcement of 45 CFR 46. IRBs need to be educated; the regs are flexible enough to allow research to be approved as quickly as the investigators are willing to make any needed changes and clarifications. And let's not overlook the fact that many a research delay is investigator-inflicted.
The current system works very well with competent, unbiased IRBs and proficient, thorough, and ethical researchers. In fact, the only changes needed are 1) the inclusion within 'Exempt category 4' of data that is not in existence when the proposal was developed, and perhaps 2) requiring written consent for secondary use of biospecimens. The Common Rule already allows deferral to a single IRB for multi-site studies – it should not be mandated. Nor should the simple requirement for a status report (continuing review) once every 365 days be considered so onerous it must be eliminated. And the very notion that exempt categories are being considered for research that combines the collection of personal identifiers with sensitive data that can affect employability, insurability, reputation, or legal liability, suggests either a lack of understanding of the 'informational' risks

associated with disclosure of such data or an undue indifference to those risks.

Anonymous (2011-08-05 15:02:46)
Establishing data security and information protection standards is both appropriate and warranted; however because such standards are neither self-implementing nor self-enforcing, nor would encompass all potential phases of the research effort, the notion that this would "eliminate the need for IRBs to review the informational risks of the research" is overly-simplistic at best and not at all representative of the review and verification of data confidentiality that IRBs have been and will continue to be responsible for. All data is vulnerable at time of collection, during conveyance to research facilities, at data entry, and during data analyses – as well as when stored on a secured computer. Further, if data is collected on a portable device (laptop, thumb drive, DVD, etc.), then that data is only as secure as is the portable device. IRBs would love to not have to be concerned with informational risks, but as long as sensitive information is being collected there will be risks associated with disclosure of that data. The notion that IRBs will not need to be concerned with data confidentiality issues once "HIPAA standards" are implemented is not borne out by the reality observable at many treatment facilities across this country that presently have such standards in place – and at which many staff are needed to implement and ensure compliance. The standards, in and of themselves, will not guarantee that no information risks will be associated with a research project.

Anonymous (2011-08-05 15:03:52)
The proposal to do away with Continuing Reviews for expedited review studies is bad policy on several different levels. Continuing Review submissions often indicate that investigators are unsure which are the most currently approved research procedures. The Continuing Review submission allows the IRB to obtain a status report on the study and re-focus investigators on what has been approved. As indicated in 45 CFR § 46.103, there is to be verification that no unapproved material changes in research procedures have occurred – the Continuing Review presents one opportune time to assess whether the conducted research is within the approved parameters.
By eliminating Continuing Reviews for minimal risk studies that received Initial Review by the expedited review process, this proposed policy change may actually make many initial reviews more burdensome/lengthy by decreasing the likelihood that the initial review will be conducted through the expedited review procedure. That is, if an IRB has to choose between 1) no continuing reviews and 2) having that initial review conducted by a convened board, they will likely choose the latter. While the proposed rule indicates that the initial expedited reviewer can "justify why continuing review would enhance protection of subjects," the default position in the proposed rule is still no continuing review for studies initially reviewed by Expedited Review.
This proposed policy change seems to confuse 'minimal risk' studies with 'no risk' studies. Under the categorization of minimal risk, the following study components can and often are approved: blood draws, nasopharyngeal specimen collection, sensitive medical data collection, surveys on drug use and or sexual habits, mild to moderate physical activities, and administration of supplements for which no IND application is required. None of these research procedures are without some real risk yet all might be classifiable as 'minimal risk'. To think that a reviewing IRB should not be entitled to an annual status report on such studies just because the initial review was conducted via expedited review procedures is at odds with what everyone intimately involved with the IRB process knows – investigator compliance with human subject protection regulations is partially, but substantively, predicated on the fact that there is continuing oversight.
Doing away with Continuing Reviews for any study is not appropriate. Rather than change this policy DHHS would be much better served by providing (and perhaps mandating) webinars for IRBs that could provide guidance on streamlining reviews. Knowledgeable IRBs are conducting most Continuing Reviews via the expedited review process. In a nutshell, the current Continuing Review process is not overly-burdensome and works very well when both IRBs and Investigators understand their roles and duties in the research review process. Doing away with Continuing Reviews will only encourage non-compliance by investigators who will take the policy change as evidence that DHHS thinks the whole notion of human subject protections is overblown.

Anonymous (2011-08-05 15:04:41)
Periodic updating of the categories of research eligible for expedited review would be a commonsensical, if belated, policy change. However, DHHS suggests that updating expedited review categories will provide for "streamlined document submission

requirements for review." The document submission requirements should not be lessened for those studies that an IRB decides to review through the expedited review procedures versus those taken to a convened board. Expedited reviewers still need all pertinent information to make a determination about the degree of risk, whether all appropriate safeguards are in place, and whether the merits of the proposed study outweighs the potential risk. DHHS webinars and online videos for IRBs to view that discuss methods of streamlining protocols and consent documents, within the current regulatory structure, is much more appropriate.

Anonymous (2011-08-05 15:05:40)
The notion that an investigator should be able to declare their own research 'exempt', submit a piece of paper, and then get underway should be quickly relegated to the dustbin of bad ideas. IRBs are quite often approached by investigators seeking 'exempt' status for research projects that do not qualify. Investigators largely do not understand the regulations (that is not to say that all IRBs do either) and tend to misinterpret them in the light most favorable to their research effort. Further, the proposed rule indicates that investigators would submit "essential information about the study, for example information about who will be the principal investigator, and the purpose of the study" and then begin. With all due respect to the writer(s) of the proposed rule, neither the name of the PI nor the purpose of the study will supply the type of information needed to determine exempt status, much less the actual risks associated with a proposed but not defined study. The devil is in the details, not in the PI's name or study purpose.
No research that involves specimens or data that are both sensitive (i.e., can potentially negatively impact individual's employability, reputation, insurability, financial standing, or legal liabilities) and identifiable should ever receive an exempt categorization.

Zachary M. Schrag (2011-08-07 22:00:15)
Thanks for these comments.
You raise some interesting points, particularly about HIPAA.
But I must say that I had hoped that the ANPRM, with its 88 footnotes, had moved us past the point where anyone would expect bald assertions like these to persuade a community of scholars.
You think IRBs are competent to conduct "the review and verification of data confidentiality"? Perhaps you should read the Institute of Medicine report, Beyond the HIPAA Privacy Rule, cited by the ANPRM, which found "extreme variability in the regulatory interpretations and approval decisions among IRBs and Privacy Boards."
You think that "investigator compliance with human subject protection regulations is partially, but substantively, predicated on the fact that there is continuing oversight"? What about the findings of [1]Keith-Spiegel and Koocher that "The efforts of some institutional review boards (IRBs) to exercise what is viewed as appropriate oversight may contribute to deceit on the part of investigators who feel unjustly treated"?
You think that "DHHS webinars and online videos" will fix the problem? Have you seen the [2]junk they have been distributing of late?
Most importantly, you think that "Investigators largely do not understand the regulations (that is not to say that all IRBs do either)"? I'm with you there; the regulations are so poorly written no one can claim with confidence to understand them. So why defend them?
Five years ago, Menikoff would have agreed with your claim that "The problems are not with the existing 'Common Rule' - the problems are in interpretation and enforcement of 45 CFR 46. IRBs need to be educated; the regs are flexible enough to allow research to be approved as quickly as the investigators are willing to make any needed changes and clarifications." But this Panglossian view has crumbled under the weight of evidence against it.
I hope that you will engage with the body of scholarship cited by the ANPRM and on this blog.

1. http://www.ethicsresearch.com/images/IRB_Paradox_EandB.pdf
2. http://www.institutionalreviewblog.com/2008/10/45-cfr-46101-is-still-dead.html

6.7.9 ANPRM Hits Federal Register; Comments Due September 26 (2011-07-26 08:22)

The ANPRM is in today's [1]Federal Register, Volume 76 Issue 143 (Tuesday, July 26, 2011)
Comments are therefore due before 5 p.m. on September 26, 2011.

1. http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm

6.7.10 Report on Research Compliance on ANPRM (2011-07-28 12:30)

The August issue of Report on Research Compliance covers ANPRM.
["Human Research Protections Prerule Mandates Regs for Non-Govt. Studies," [1]Report on Research Compliance, August 2011]
The report has a statement from Art Caplan:

> "These are long-overdue changes," Art Caplan, director of the Center for Bioethics at the University of Pennsylvania, told RRC. "The current system involves too much red tape and paperwork in proportion to the protection given to subjects. In some ways the system of human subjects protection — informed consent and review by IRBs [i.e., institutional review boards] — has been hijacked by legal concerns so that more attention is given to institutional and investigator protection than subject empower- ment. These changes help remedy that problem."

Your humble blogger is also quoted, complaining about the lack of attention to the experience of other countries. I did overlook ANPRM's footnote 28: "Cribb R. Ethical regulation and humanities research in Australia: Problems and consequences. Monash Bioethics Rev 2004;23(3):39–57." Other than that, has anyone found references to the workings of ethics committees in other countries?

1. http://www.reportonresearchcompliance.com/

6.7.11 Elliott Wants to Scrap IRBs (2011-07-29 10:17)

Carl Elliott, author of White Coat, Black Hat: Adventures on the Dark Side of Medicine, calls IRBs "incapable" and wants them replaced.
[Carl Elliott, [1]Useless Pharmaceutical Studies, Real Harm, New York Times, 29 July 2011.]
He writes,

> The main source of protection for research subjects is a patchwork system of ethics committees known as institutional review boards, or I.R.B.'s. These are small, federally empowered bodies that review research proposals before they are carried out, to ensure that the studies are ethically sound. But they don't typically pass judgment on whether a study is being carried out merely to market a drug. Nor do most I.R.B.'s have the requisite expertise to do so. Even worse, many I.R.B.'s are now themselves for-profit businesses, paid directly by the sponsors of the studies they evaluate. If one I.R.B. gets a reputation for being too strict, a pharmaceutical company can simply go elsewhere for its review.
> Last week, the federal government announced that it was overhauling its rules governing the protection of human subjects. But the new rules would not stop seeding trials. It is time to admit that I.R.B.'s are simply incapable of overseeing a global, multibillion-dollar corporate enterprise. They should be replaced with an oversight system that is financially and administratively independent of the research it oversees. The system must have the power to impose sanctions, and its responsibilities must extend to fraud, bribery and corruption.

See also, "[2]Dreger Wants to Scrap IRBs" and "[3]Stark Wants to Scrap IRBs." All of these scholars doubt the ability of local IRBs to police multinational corporations. And I think Elliott is right that the proposals in the ANPRM wouldn't fix that.

1. http://www.nytimes.com/2011/07/29/opinion/useless-pharmaceutical-studies-real-harm.html
2. http://www.institutionalreviewblog.com/2010/10/dreger-wants-to-scrap-irbs.html
3. http://www.institutionalreviewblog.com/2010/10/stark-wants-to-scrap-irbs.html

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Anonymous (2011-10-27 06:03:47)
As a former IRB employee, I will say studies that make money for the company will get approved, even if those studies are questionable. It's not really about the "rights of human subjects" as it is more about how much money can be made from the drug companies. I was totally shocked at the level of corruption that took place at this IRB. High employee turnover, lack of quality training, unqualified people in power who are making decisions, record sabotage...the list goes on. I did not want to be part of this atmosphere once I really saw the truth. I would NEVER trust being a subject in a study now. I agree with Elliott.

6.8 August

6.8.1 ANPRM's Problem Statement: Helpful but Incomplete (2011-08-01 10:10)

One of the many remarkable sections of the [1]July 26 advance notice of proposed rulemaking (ANPRM) is its admission that the Common Rule is flawed.
(Note: I have added a link to the ANPRM at the top of the link list in the sidebar.)
Since the 1970s, [2]IRB apologists have claimed that federal regulations are flexible enough, and that local IRBs are to blame for any problems. In 2007, for example, Jerry Menikoff [3]quoted with approval [4]Jeffrey Cohen's 2006 claim that "the regulations provide sufficient flexibility for the efficient and appropriate review of minimal risk research. IRB review of such research does not have to be burdensome or unreasonable if IRBs appropriately utilize the flexibility in the regulations." Menikoff reiterated his claim of "flexibility within the system" in his 2009 speech, "[5]The Legal Assault on the Common Rule."
After thirty years of such claims, it is wonderfully refreshing that the ANPRM takes so seriously many of the critiques leveled at the federal regulations themselves. And the ANPRM helpfully organizes those critiques into seven general categories.
On the other hand, ANPRM's problem statement (pages 44513-44514 in the Federal Register version) overlooks some major critiques. Fortunately, some of those critiques are implicitly recognized by some of the ANPRM's proposals.
The ANPRM acknowledges seven critiques of the current regulations.

1. "The system has been criticized as not adequately calibrating the review process to the risk of research. . . . **Over-regulating social and behavioral research** in general may serve to distract attention from attempts to identify those social and behavioral research studies that do pose threats to the welfare of subjects and thus do merit significant oversight."

2. "The inefficiencies of review by multiple IRBs for multi-site studies . . . add bureaucratic complexity to the review process and delay initiation of research projects without evidence that multiple reviews provide additional protections to subjects."

3. "In some research studies, **consent forms have become lengthy** and are often written in highly technical terms. Many also claim that consent forms have evolved to protect institutions rather than to actually provide salient information to potential human subjects.

4. "Increasing use of **genetic information**, existing (i.e., stored) biospecimens, medical records, and administrative claims data in research has changed the nature of the risks and benefits of research participation."

5. "Current regulations do not provide an ideal mechanism for the collection of information that would allow **evaluation of the effectiveness of the research oversight system** in protecting human subjects."

6. "Only some research studies **funded by certain Federal agencies** or those that involve the development of products subject to regulation by the FDA, are subject to the Common Rule or similar protections. As a result, there are many studies that are not subject to any such Federal oversight, even though they may involve substantial risks to the subjects.

7. "The **multiple, differing regulatory requirements** that can apply to a single research study have been criticized as complex, inconsistent, and lacking in clarity, which results in unwarranted variability across institutions and their IRBs in how the requirements are interpreted and implemented."

That's a pretty good list, and I am especially pleased that the over-regulation of social and behavioral research takes first place. But I am concerned about item 6, which threatens greater regulation rather than less.
Moreover, I can think of at least four major critiques not mentioned directly in this problem statement:

Lack of Expertise

The [6]Common Rule requires that

> IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

Does this make any sense? Can a group of researchers and laypeople, haphazardly drawn from an institution and the surrounding community, be expected to possess expertise in the wide range of studies–some of them in esoteric new areas–that can be expected from a research university or hospital?
[7]Carl Elliott, "[8]Alice Dreger, and "[9]Laura Stark say no. [10]So do I. And so, for that matter, does Ezekiel Emanuel, presumably one of the ANPRM's authors. In 2002, [11]he co-authored a paper arguing that "A single IRB often reviews research on a wide variety of scientific topics and research settings, some of which are not aligned with the scientific expertise of the board members . . . It is fair to say that IRBs are relatively passive, responding to the information provided rather than actively seeking information in addition to that submitted in the research protocol. Under these circumstances, IRBs can make poor decisions about the permissibility of a study that can sometimes result in avoidable harms to participants."
The ANPRM mentions this critique only briefly, noting that "IRB review or oversight of research posing informational risks may not be the best way to minimize the informational risks associated with data on human subjects. It is not clear that members have appropriate expertise regarding data protections." (44516) The ANPRM does not raise the more general question of whether IRBs have appropriate medical, psychological, ethical, legal, or any other form of expertise sufficient to the grave duty with which they are charged.

Unconstitutionality

Given Menikoff's awareness of the "Legal Assault on the Common Rule," the ANPRM curiously neglects charges by [12]Philip Hamburger, [13]Robert Kerr, and others that the regulation of speech–such as interviews, surveys, and

focus groups–violates the First Amendment.
This is especially significant given the ANPRM's threat to extend regulatory reach to all research at federally funded institutions, not just research sponsored by a Common Rule agency.

Lack of Attention to Critical Inquiry

Since the 1970s, IRB critics have complained that the medical ethics of the Belmont Report leaves no room for research–such as "muckraking sociology"–that may intended to criticize its subjects.
Canada's 2010 TCPS makes a start at recognizing the legitimacy of such research, noting that "Research in the form of critical inquiry, that is, the analysis of social structures or activities, public policies, or other social phenomena, requires an adjustment in the assessment of consent. Where the goal of the research is to adopt a critical perspective with respect to an institution, organization or other entity, the fact that the object of the research may not endorse the research project should not be a bar to the research receiving ethics approval."
But even that provision doesn't go far enough in recognizing the legitimacy of critical writing about individuals, as expressed recently by [14]Anthony Langlois.
Fortunately, ANPRM's Question 25 aks if their are fields that "may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule?" So someone is aware of the critique; it just didn't make it into the introductory section.

Procedural Injustice

Finally, the problem statement ignores the wish–so eloquently expressed by Jack Katz–for a "[15]culture of legality," in which IRBs would be required "to recognize formally that they cannot properly demand the impossible . . . to invite public discussion of policy alternatives, and . . . to open their files to public oversight."
The ANPRM's Question 28 does touch on one matter of procedural justice, when it asks, "Should the Common Rule include a requirement that every institution must provide an appropriate appeal mechanism?" And Question 29 asks if IRBs should be required to announce when they are departing from the requirements of federal regulations. These questions suggest that the authors of the ANPRM are aware that, having been granted unchallenged power, some IRBs and IRB offices abuse that power. I only wish that this awareness had been made explicit in the problem statement itself.
Again, this cup is well over half full. But as people prepare their comments, they should note that the ANPRM has not acknolwedged the full range of flaws in the present regulations.

1. http://federalregister.gov/a/2011-18792
2. http://hrpp.blogspot.com/2008/11/prim-thoughts.html
3. http://www.law.northwestern.edu/lawreview/v101/n2/791/LR101n2Menikoff.pdf
4. http://hrpp.blogspot.com/2006/03/mission-creep.html
5. http://lecb.physics.lsa.umich.edu/wl/carma/2009/OHRP/20090514-umwlcd0011-081223/real/f001.htm
6. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107
7. http://www.institutionalreviewblog.com/2011/07/elliott-wants-to-scrap-irbs.html
8. http://www.institutionalreviewblog.com/2010/10/dreger-wants-to-scrap-irbs.html
9. http://www.institutionalreviewblog.com/2010/10/stark-wants-to-scrap-irbs.html
10. http://www.institutionalreviewblog.com/search/label/expertise
11. http://www.institutionalreviewblog.com/2007/02/in-search-of-expertise.html
12. http://www.jstor.org/pss/3536972
13. http://www.tandfonline.com/doi/abs/10.1207/s15326926clp1103_4?prevSearch=kerr&searchHistoryKey=
14. http://www.institutionalreviewblog.com/2011/05/australian-political-scientist-causing.html
15. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html

Harry Perlstadt (2011-08-03 20:34:57)
Not only does Canada's TCPS recognizes the legitimacy of critical research and public policy analysis, it specifically mentions academic freedom, freedom of inquiry, freedom to challenge conventional through and freedom from institutional censorship.
TCPS states that in return researchers are expected to ensure that research involving human subjects meets high scientific and ethical standards. In addition, the peer review of research proposals, the findings and their interpretation contribute to accountability, both to colleagues and society.
Should a revision of the Common Rule explicitly acknowledge these freedoms as well as the obligations of researchers to high scientific and ethical standards? If so, it still is necessary to ensure that the review process is reasonable and decisions reviewable.
Harry Perlstadt, Dept of Sociology, Michigan State University

Zachary M. Schrag (2011-08-03 20:45:53)
Great comment! I hope you send it in to OHRP.
Thanks.

6.8.2 AHA Alerts Members to ANPRM (2011-08-01 10:41)

Robert Townsend, Deputy Director of the American Historical Association, alerts AHA members to the significance of the ANPRM in a blog post: [1]AHA Today: Getting Free of the IRB: A Call to Action for Oral History. The post points up the need for historians to think broadly as they prepare their comments on the ANPRM and not passively accept the categories devised by bioethicists.
Townsend notes the promise of Question 25, which ponders revising the Common Rule "to explicitly state that [field like classics, history, languages, literature, and journalism] are not subject to its requirements."
He notes,

> That seems like a wide open invitation to us, but there are some potential dangers here as well. In 2004, the AHA and Oral History Association worked with HHS on the formulation proposed here (that history does not constitute "research that creates generalizable knowledge"). Unfortunately, the argument prompted some derision from outside the field, from academics who interpreted the phrase to say simply "history is not research." (As a case in point, the vice president for research at my own university, after a fairly contentious meeting on the subject, wished me well on my "non-research dissertation.")
> We also received a number of complaints from within the discipline. Some historians argue that history does contribute generalizable knowledge, even if it bears little resemblance to the scientific definition of the word. And faculty members at history of medicine departments and in the social science side of history warned that this position undermined both their institutional standing and their ability to obtain grants. They made it clear that however finely worded, stating that history did not constitute research in even the most bureaucratic terms could have some real financial costs to the discipline.

I have just sent in a comment to the AHA blog, suggesting that historians should not be forced to choose between freedom from IRB interference and claiming the title of researchers. Federal law ([2]42 USC 289) does not call for IRBs to review "research," "research that creates generalizable knowledge," or even "research involving human subjects." Rather, it calls for the establishment of IRBs "to review biomedical and behavioral research involving human subjects."
Historians should propose regulatory language distinguishing between our research and "biomedical and behavioral research" and scrap "generalizable" as a distraction.
Nobody puts Baby in a corner!

1. http://blog.historians.org/news/1382/getting-free-of-the-irb-a-call-to-action
2. http://www.law.cornell.edu/uscode/42/usc_sec_42_00000289----000-.html

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6.8.3 Will ANPRM Limit the Use of Published Data? (2011-08-02 07:01)

Despite the ANPRM's general goal of "reducing burden, delay, and ambiguity for investigators," the proposed policy for the re-use of pre-existing data threatens to increase all of those by expanding the current definition of human subjects research.
The present Common Rule states that "Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." So if a data set has been stripped of its identifiers, it is no longer subject to regulation, no matter the circumstances in which the data were first collected.
The ANPRM proposes changing this so that some information that is not individually identifiable would be covered by the Common Rule:

> With regard to the researchers' use of pre-existing data (i.e. data that were previously collected for purposes other than the currently proposed research study):
> a. If the data was originally collected for non-research purposes, then, as is currently the rule, written consent would only be required if the researcher obtains information that identifies the subjects. There would accordingly be no change in the current ability of researchers to conduct such research using de-identified data or a limited data set, as such terms are used in the HIPAA Rules (see Section V), without obtaining consent.
> b. If the data was originally collected for research purposes, then consent would be required regardless of whether the researcher obtains identifiers. Note that this would be a change with regard to the current interpretation of the Common Rule in the case where the researcher does not obtain any identifiers. That is, the allowable current practice of telling the subjects, during the initial research consent, that the data they are providing will be used for one purpose, and then after stripping identifiers, allowing it to be used for a new purpose to which the subjects never consented, would not be allowed. (44519, emphases in original.)

The next several paragraphs of the ANPRM claim that this would not hinder research much, because "in most instances, the consent requirements described above would have been met at the time that the biospecimens or data were initially collected, when the subject would have signed a standard, brief general consent form allowing for broad, future research. This brief consent could be broad enough to cover all data and biospecimens to be collected related to a particular set of encounters with an institution (e.g. hospitalization) or to any data or biospecimens to be collected at anytime by the institution."
This is less than reassuring, since it suggests that this proposal was written for hospital-based research research with biospecimens. My sense is that it would be easier to secure "standard, brief general consent form[s] allowing for broad, future research" for such research than it would be for the more diffuse world of survey data, especially since the ANPRM itself stresses that "oral consent without written documentation would continue to be acceptable for many research studies involving educational tests, surveys, focus groups, interviews, and similar procedures."
So I am struggling to understand what the proposal on pre-existing data would mean for social research.
Let's say I read a study that finds that "[1]Researchers who perceive that they are being unfairly treated are less likely to report engaging in 'ideal' behaviors and more likely to report misbehavior and misconduct." Could I even report this finding, and some of the numbers behind it, without first determining if the initial research consent warned participants about snarky bloggers?

For that matter, could even qualitative information be subject to the rule? If a researcher interviews someone for a book and quotes him, can other authors not use the quotation for their own projects?
Can someone help me here?
UPDATE, 7:45PM
The relevant ANPRM questions read as follows:
Question 45: Under what circumstances should future research use of data initially collected for non- research purposes require informed consent? Should consent requirements vary based on the likelihood of identifying a research subject? Are there other circumstances in which it should not be necessary to obtain additional consent for the research use of currently available data that were collected for a purpose other than the currently proposed research?
Question 46: Under what circumstances should unanticipated future analysis of data that were collected for a different research purpose be permitted without consent? Should consent requirements vary based on the likelihood of identifying a research subject?

1. http://www.institutionalreviewblog.com/2010/09/unfair-irbs-provoke-misbehavior.html

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6.8.4 ANPRM: May I Be Excused? (2011-08-02 19:37)

One of the boldest proposals in the ANPRM, and one of enormous importance to social scientists, is the idea of replacing the current category of exempt reseach with a new category of "Excused" research. This proposal could reduce IRB and IRB-office intrusion into a great deal of social research. But, depending on the details, it could instead convert an enormous amount of presently exempt research into research subject to expedited or even full-board review.
Social scientists will need to be very careful as they respond to this proposal.

What Excused Means

Here are the basics of the Excused category, as described in Section 3 of the ANPRM.
The current exemptions would no longer operate. Instead, various types of research that present risks to privacy but not immediate psychological or physical risks would be deemed "Excused."
"Oral consent without written documentation would continue to be acceptable for many research studies involving educational tests, surveys, focus groups, interviews, and similar procedures."
Excused research would be subject to "mandatory data security and information protection standards for identifiable information and rules protecting against the inappropriate re-identification of de-identified information that is collected or generated as part of a research study to minimize informational risks and thereby eliminate the need for IRBs to review informational risks of the research. For purposes of the Common Rule, we are considering adopting the HIPAA standards regarding what constitutes individually identifiable information, a limited data set, and de-identified information, in order to harmonize these definitions and concepts."
Institutions might be required to audit a sample of excused research, but they would be discouraged from the "current practice of routinely requiring that research that meets the current exemption categories undergo some type of review before it is permitted to proceed."

How the Excused Category Could Help Social Science

* The criteria for excusal would be more objective than the current criteria for exemption.
The Common Rule currently exempts "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."

These ambiguous criteria now plagues social researchers. Iowa State's IRB, for example, ruled that a survey was non-exempt because it counted as a risk to reputation the danger that "[1]some may find your opinions in the free-response section at variance with their own." More generally, the exemption has always been somewhat nonsensical in that it does not require an IRB to determine what was risky, even though the point of the Common Rule is that only IRBs should determine what is risky. Replacing the vague language about risks of liability, reputation, and the like with more objective criteria would be helpful.

The Excused category would do this with three criteria:

1. The research would have to be conducted with legally competent adults, a category that the ANPRM asserts is relatively clear.
2. The research would have to conform to rules about identifiable information, most of which are fairly objective as well.
3. The research could involve only "the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior." The Excused category might also include some psychological tests, such as those in which "a researcher might ask subjects to watch a video, or read a paragraph or solve puzzles, and then ask them some questions to elicit word associations or time performance of activities."

That's it. No more judgment calls about the risks of liability or harm to financial standing, employability, or reputation. No more squabbling about what those terms mean.

Researchers could begin more quickly

Current regulations do not require administrative approval of exempt research, but OHRP recommends it, and that seems to be standard practice at most universities. Getting this approval is usually fairly quick, but not always. For example, at the University of Michigan [2]8 percent of exempt applications at the main-campus IRB took more than four weeks for approval, and more than half required some change to get approval.

Under the new system, "researchers would file with their institution or IRB a brief registration form (about one page long) that provides essential information about the study, including, for example, information about who will be the principal investigator, and the purpose of the study. The researchers would then be authorized to begin conducting the study after the filing (unless the institution chose to review that filing and determined that the research did not qualify as Excused)."

Oral consent might be highlighted

The current Common Rule does not require written consent forms for exempt research and allows IRBs to waive the requirement for written consent forms if "the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." But [3]this provision is easily overlooked in a system that presents written consent as the norm and oral consent as an exception.

Under the ANPRM, "oral consent without written documentation would continue to be acceptable for many research studies involving educational tests, surveys, focus groups, interviews, and similar procedures." Perhaps this provision could be made more prominent.

Real names might be explicitly allowed

The current Common Rule does not require that participants' identities be withheld, but its emphasis on confidentiality has led many IRBs to insist on inappropriate anonymity. ANPRM proposes that the rules for Excused research would explicitly "allow subjects to authorize researchers to disclose the subjects' identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition."

Pitfalls of the Excused Category for Social Science

* Subjective criteria for questions could be re-introduced

The ANPRM imagines a number of possibilities for the category, including denying Excused status for "surveys and

related methodologies" involving "topics that are emotionally charged, such as sexual or physical abuse." (Question 16) If this happens, we can imagine IRBs insisting that researchers write out all their questions in advance, so an administrator can screen them for questions about abuse, and we can expect long debates about what topics are emotionally charged. Once again, researchers who do not begin their projects with scripted questions will be turned into [4]low-level cheaters.

Geographical indicators would trigger IRB review

This is a big one. The ANPRM imagines that research in the Excused category would have to avoid sharing any of the [5]18 identifiers in the HIPAA Privacy Rule. That includes "all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes." (One can use the initial three digits of a zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people. I think this means that I can report I am studying people in zip code 222xx, but not in Arlington, Virginia. Go figure.)

This means that any community studies that identified their sites–like "[6]interviews with undocumented Latinos in Southern California" or [7]observations of the function of Maori meeting houses in Aukland–would have to go through expedited for full-board review simply because its geographical specificity. This would add to IRB and researcher burdens, contrary to the goal of the ANPRM.

Participant observation and focus groups might trigger IRB review

The proposal for the Excused category imagines that

> research involving the collection and use of identifiable data, as well as data in limited data set form, could be required to adhere to data security standards modeled on the HIPAA Security Rule.
> In particular, for research involving individually identifiable information, all biospecimens, and limited data sets, data security standards could require the use of reasonable and appropriate encryption for data maintained or transmitted in electronic form and strong physical safeguards for information maintained in paper form, audit trails, and access controls that allow only authorized personnel to have access to the information. (44526)

How would this work when information is gathered from groups? For example, members of a focus group see each others' faces. ["Communication Scholars' Narratives of IRB Experiences," Journal of Applied Communication Research 33 (August 2005), 204.] And a researcher doing participant observation might strike up a conversation within hearing of other research participants.

Perhaps the rule could be interpreted to mean that all participants in a research project could be considered "authorized personnel," but that would have to be made explicit.

Quasi-anonymous reporting might trigger IRB review

Some social scientists use pseudonyms to protect the privacy of their informants but still provide information that could be used to identify them, though with some effort. Take this passage from Kathryn Marie Dudley's [8]End of the Line: Lost Jobs, New Lives in Postindustrial America, which uses fictitious names but not "falsified biographies."

> "The mentality of many people in this community was that American Motors or Chrysler was going to be the salvation," says Ron Carleson, a business adminsitrator in the Kenosha school district. Ron grew up in Kenosha, and as the son of an optician who served many clients in the blue-collar community, he feels he has a special understanding of the day-to-day realities factory workers must deal with. (188)

Presumably, some of Carleson's co-workers and friends could identify him from this description, but most readers cannot.

I am not a big fan of such quasi-anonymity; I wonder if "Carleson" would have wanted a pseudonym had Dudley not presented that as the default choice. And maybe if a researcher concludes that a statement is so sensitive that a

pseudonym is called for, research including that statement should undergo some kind of [9]ethical proofreading before publication.

Still, social scientists preparing comments on the ANPRM should be aware that this kind of work might not be Excused.

Unreasonable data security requirements might be imposed

The ANPRM suggests requirements for "the use of reasonable and appropriate encryption for data maintained or transmitted in electronic form and strong physical safeguards for information maintained in paper form." This could be consistent with the professional practices of social researchers, but past experience has shown the danger of relying on IRBs' and administrators' sense of what is "reasonable."

(Thanks to an [10]anonymous commenter for pointing this out.)

A waiting period could delay research and increase administrative burden

Question 19 imagines "a brief waiting period (e.g. one week) before a researcher may commence research after submitting the one-page registration form, to allow institutions to look at the forms and determine if some studies should not be Excused."

This would immediately defeat the ANPRM's design to "discourage having each of these registration forms undergo a comprehensive administrative review prior to commencing the study or even afterward." For what is a determination that some studies should not be Excused if not an administrative review at least as comprehensive as the ones currently used for exemption? A waiting period risks imposing prior review on all studies and retrospective review on some, thus increasing, rather than decreasing, the administrative burden.

The requirement would be particularly onerous for researchers who want to react to breaking events or whose research builds on daily observations and lacks defined starting and ending points.

Conclusion

If the standards are rewritten so that IRB review is triggered only if a project crosses clearly defined thresholds, one can imagine a system that functions much more in the ways intended by the authors of the original Common Rule, who sought to "[11]exclude most social science research projects from the jurisdiction of the regulations."

But if the revision to the Common Rule imposes HIPAA standards, without modification, upon social science, it will be a disaster for researchers, administrators, and participants alike, since a great deal of research that is currently exempt would trigger expedited or full review on the grounds that it includes geographical information. Depending on the exact provisions concerning sensitive topics, anonymity, data security, and waiting periods, matters could be worse still.

My recommendation, then, is that while scholars in the social sciences and the humanities may be cautiously supportive of the Excused category proposal, their first choice should be a redefinition of the scope of the regulations to align them to federal law. More on that soon.

1. http://www.institutionalreviewblog.com/2010/03/irb-warns-that-opinions-may-vary.html
2. http://www.institutionalreviewblog.com/2011/07/u-of-michigan-reports-some-progress.html
3. http://www.institutionalreviewblog.com/2008/08/critiques-of-consent-forms.html
4. http://mailer.fsu.edu/~njumonvi/irb-article.htm
5. http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm#box2
6. http://www.asanet.org/images/journals/docs/pdf/asr/Aug11ASRFeature.pdf
7. http://onlinelibrary.wiley.com/doi/10.1111/j.1548-1425.2011.01314.x/abstract
8. http://books.google.com/books?id=-A96Q4O-w5AC&lpg=PA225&ots=skffpZu_gB&dq=dudley%20end%20of%20the%20line&pg=PA89#v=onepage&q=carleson&f=false
9. http://www.srainternational.org/sra03/uploadedfiles/T69a.pdf
10. http://www.blogger.com/comment.g?blogID=52577829256554519&postID=5122668605704369713
11. http://www.hhs.gov/ohrp/archive/documents/19810126.pdf

MontereyBayBliss (2011-10-20 12:53:00)
I stumbled on your blog today and I'm finding it very informative as I prepare my IRB for ANPRM response updates. The link you currently have for the Illinois white paper is no longer correct though. It's now at: http://www.primr.org/uploadedFiles/PRIMR _Site _Home/Resource _Center/Articles/11. %20Illinois %20Whitepaper.pdf

Zachary M. Schrag (2011-10-21 08:39:55)
Many thanks. I have updated the link.

6.8.5 Inside Higher Ed Reports on ANPRM (2011-08-03 10:01)

Inside Higher Ed reports on the ANPRM, with emphasis on concerns about the overregulation of the social sciences, humanites and journalism.
[Doug Lederman, "[1]Updating the Common Rule," Inside Higher Ed, 3 August 2011]
The story quotes C. K. Gunsalus, Felice Levine, and your humble blogger. Mostly they are positive about the ANPRM, but Gunsalus and I express reservations. Hers concerns the proposal to extend the regulations to all research conducted at federally funded institutions:

> "I have a hard time seeing how it makes sense to cover poets at universities but ignoring" surveys done by companies or research that takes place at fertility clinics or other entities that forgo federal funds. "I don't agree with this choice, and don't think it will solve the problem in the way they think it will."

1. http://www.insidehighered.com/news/2011/08/03/u_s_review_of_human_subjects_rules_could_ease_restrictions_on_researchers

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6.8.6 ANPRM: It's Time to Redefine Research (2011-08-05 12:49)

In an earlier posting, I warned that the [1]ANPRM's proposed "Excused" category could expand rather than diminish IRB interference with research in the social sciences and humanities.
Another option mentioned in the [2]ANPRM–a redefinition of the scope of the Common Rule–could do more to achieve the ANPRM's goals of "better protect[ing] human subjects who are involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." It could even the regulations with the statutes they claim as their basis.
I see several options here.

Problems with the Current Definition

The current [3]Common Rule "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research."
It defines "research" as

> a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research

> for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

and "human subject" as

> a living individual about whom an investigator (whether professional or student) conducting research obtains
> (1) Data through intervention or interaction with the individual, or
> (2) Identifiable private information.

The ANPRM offers the first chance in 30 years to rewrite these definitions. It does so with its Question 24 (about the application to "quality improvement, public health activities, and program evaluation studies") and the thrilling Question 25:

> Are there certain fields of study whose usual methods of inquiry were not intended to or should not be covered by the Common Rule (such as classics, history, languages, literature, and journalism) because they do not create generalizable knowledge and may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule? If so, what are those fields, and how should those methods of inquiry be identified? Should the Common Rule be revised to explicitly state that those activities are not subject to its requirements?

How should scholars in the social sciences, humanities, and journalism respond? Let me offer several alternative definitions of research that could work better than the one now in place. I do so with the caveat that I think any defintion with need interpretation. The TCPS offers a model of what this would look like: each "article" is followed by a longer section explaining its "application." I hope that with the revision of the Common Rule will come some mechanism by which the federal government can offer informed interpretations as questions arise.

Option 1: Deregulate "Two People Talking"

A longstanding complaint of researchers has been that the current regulations require official permission for two adults to talk to each other, a basic human activity that should not be regulated in a free society. As the [4]Illinois White Paper puts it:

> Considerations of what is research, when inquiry becomes research, and who we are trying to protect bear especially on certain areas of academic effort. There are many cases where two people are talking with each other: in journalism, oral history, anecdotal research, and so on. When the participants are capable adults and understand that their words are being recorded, why should the special obligations of the researcher not end with honesty and truthfulness? Many such conversations cannot even be categorized as an interview in any direct or intentional sense—or it may not be clear who is primarily interrogating whom (maybe both parties intend to write about the encounter!).

In 1979, twelve scholarly and educational organizations suggested addressing such encounters with the following formula:

> These regulations do not apply to research using legally competent subjects that involves neither deceit nor intrusion upon the subject's person nor denial or withholding of accustomed or necessary resources.

In 2006, the AAUP offered similar proposal:

> Research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, [shall] be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.

Either one of these would achieve the ANPRM's goal of "facilitating valuable research and reducing burden, delay, and ambiguity for investigators." There should also be a provision for community research that might involve children or adults who are not legally competent. For example, an anthropologist living in a community should not trigger IRB review simply because he or she occasionally speaks to a child.

These proposals would not require rewriting the definitions section of the regulations. Rather, they would constitute a bifurcation of the ANPRM's prosed category of "Excused" research.

The ANPRM's proposes that Excused research would have to strip HIPAA identifiers, employ data security, and remain subject to audit.

An alternative would be to leave those requirements only for interventional research with competent adults–in ANPRM's terms, "methodologies which are very familiar to people in everyday life and in which verbal or similar responses would be the research data being collected. For example, a researcher might ask subjects to watch a video, or read a paragraph or solve puzzles, and then ask them some questions to elicit word associations or time performance of activities."

Mere interactions–especially conversations–would not require even registration. That is, the regulations could recognize these interactions as research, but determine that they are not subject to any review, before or after the research takes place.

One trick here would be to distinguish psychological inventories from other forms of survey research, but I think that could be done. For example, HIPAA refers to "health information," so one could require registration, expedited, or full review for studies that involve questions primarily designed to learn about participants' physical or mental health.

In this case, oral history, journalism, and the like could be categorized as human subjects research, but that categorization would not come with any regulatory restrictions.

Option 2: Define Research to Match the National Commission's Intentions

As the ANPRM notes, the current Common Rule is based on the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. So one possibility would be to rewrite the regulations to govern only those fields that the National Commission wanted to regulate.

It's hard to say just what those fields are, since the National Commission never listed the kinds of information gathering it did and did not want IRBs to review. But we can gather hints from its deliberations and publications, especially its 1978 [5]Report and Recommendations: Institutional Review Boards.

At its June 1975 meeting, chairman Kenneth Ryan noted "the general Commission feeling that we are talking about biomedical, social, and behavioral research." And the 1978 IRB report makes glancing reference to both anthropology and survey research:

> The requirement for documentation may place an undue burden on the research while adding little protection to the subjects. Such burdens might include a negative impact on the validity of a survey sample or introduction of an element that is incongruent with the social relationships involved in the research (e.g., in anthropological research). For research that would be burdened by a requirement of written documentation of consent, such documentation may be waived, provided that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (For example, a physical intrusion into the body may generally require written consent, whether or not the intrusion is performed for purposes of research.) In many cases (e.g. , a survey using mailed questionnaires) it would be appropriate for the investigator to provide subjects with a written statement regarding the research, but not to request their signature. In other cases (e.g. , a telephone survey) an oral explanation might be sufficient,
> because subjects can readily terminate their involvement in the research. (28-29)

and

> Other situations in which informed consent might not be necessary arise in field research in the social sciences. Sometimes in such research, purely observational methods are supplemented by interaction with the persons being studied and therefore come within the Commission's definition of research involving human subjects. An IRB may waive the informed consent requirement in such research when it finds a number of factors to be present. The behavior to be studied must in some sense be public, e.g., responses of businesses or institutions to members of the public, or social behavior in public places. (30)

In its discussion of existing federal policies, the 1978 report notes that some agencies engaged in "survey research entailing no intervention in the lives or activities of the subjects. . . Although their activities fall within the Commission's definition of research with human subjects, it should be noted that data gathering, in and of itself, has not universally been considered 'research with human subjects.'" (This is from p. 56196 of the [6]Federal Register version of the report; the passage is cut off in the PDF of the original report.)
Finally, the Commission's IRB report complained that "when federal agencies conduct or support social experimentation, they may not consider it necessary to apply procedures for the protection of human subjects." (100) (That's pretty ironic, given that the Belmont Report claims that "Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time.")
All of this is quite confusing, but I think we can say that the Commission hoped that regulations would cover:

- "anthropological research"
- "a survey using mailed questionnaires"
- "a telephone survey"
- "responses of businesses or institutions to members of the public, or social behavior in public places"

I think we can also say that the Commission did not wish to regulate journalism, though that's murkier still. (See [7]Ethical Imperialism, page 62.)
And we have no evidence that the Commission sought to regulate history, folklore, or the humanities in general.
These latter fields–journalism and the humanities–were rarely if ever subject to IRB jurisdiction before 1994. And it is [8]these fields have put up the greatest resistance to the expansion of IRB jurisdiction since then. By contrast,

[9]sociologists and [10]anthropologists have proven more ambivalent about the process. They might prefer to have their work remain defined as human subjects research, though under an [11]"Excused" category that would reduce the burdens of that label.
Thus, we can imagine drawing a line between the social sciences on the one hand and journalism and the humanities on the other. This would honor both the intentions of the National Commission and the general sentiments of researchers. I see at least two ways to do this.

Option 2a: Deregulate the Humanities and Journalism as Non-Generalizable

ANPRM's Question 25 is clearly targeted to historians, humanists, and journalists. (How did classics get in there?) It hints that regulators are considering letting these folks off the hook by declaring their work to be non-generalizable, and therefore not subject to regulation under the Common Rule.
The advantage of this approach is that it has something of a track record. The idea that "journalism, history, biography, philosophy" generally fall outside of the regulatory definition of research because they are not generalizable dates back at least to the [12]1999 report of the Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council, which argued that

> a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the definite purpose of contributing to generalizable knowledge. Research can include a wide variety of activities including: experiments, observational studies, surveys, tests, and recordings designed to contribute to generalizable knowledge. It generally does not include such operational activities as: medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, program evaluation, fiscal or program audits, journalism, history, biography, philosophy, "fact-finding" inquiries such as criminal, civil and congressional investigations, intelligence gathering, and simple data collection or data collection for other purposes. However, some of these activities may include or constitute research in the specific circumstance where there is clear advance intent to contribute to generalizable knowledge with a formal scientific protocol.

In 2003, [13]OHRP ruled that "most oral history interviewing projects are not subject to the requirements" of the regulation "primarily on the grounds that oral history interviews, in general, are not designed to contribute to 'generalizable knowledge.'" Most of the [14]university policies excluding oral history from IRB jurisdiction do so on the grounds that it is not generalizable.
The ANPRM seems to suggest that the 1999 position might be "explicitly" written into the Common Rule, thus locking it in place and giving historians and narrators the freedom to converse without seeking official permission. For example, the Common Rule could be amended to read

> For purposes of this policy, research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. This policy does not cover such operational activities as: medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, program evaluation, fiscal or program audits, journalism, history, biography, philosophy, "fact-finding" inquiries such as criminal, civil and congressional investigations, intelligence gathering, and simple data collection or data collection for other purposes.

If this were to happen, it could be a boon for scholars, research participants, and administrators alike. So the obvious response would be for historians and others to reply, "Why, yes, now that you mention it, we do not create generalizable knowledge!"

Yet this would leave problems.

For one thing, non-generalizability has proven an unreliable tool. [15]OHRP has muddied the waters, apparently contending–for example–that "Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research" would constitute generalizable research because "the creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research."

Well, you can't believe that and believe that "oral history interviews, in general, are not designed to contribute to 'generalizable knowledge." If generalizable means that some future researcher might conceivably use the information, then nothing is non-generalizable. Do not daily newspapers; criminal, civil and congressional investigations; and disease monitoring all create an archive for future research?

Moreover, as [16]Rob Townsend noted on AHA Today,

> The argument [that oral history is not generalizable] prompted some derision from outside the field, from academics who interpreted the phrase to say simply "history is not research." (As a case in point, the vice president for research at my own university, after a fairly contentious meeting on the subject, wished me well on my "non-research dissertation.")
>
> We also received a number of complaints from within the discipline. Some historians argue that history does contribute generalizable knowledge, even if it bears little resemblance to the scientific definition of the word. And faculty members at history of medicine departments and in the social science side of history warned that this position undermined both their institutional standing and their ability to obtain grants. They made it clear that however finely worded, stating that history did not constitute research in even the most bureaucratic terms could have some real financial costs to the discipline.

More fundamentally, no one can be sure what generalizable means. It is left undefined in the Common Rule. The Belmont Report version is longer, but hardly more helpful:

> The term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

This goes some way to distinguish research from diagnosis of an individual patient–the main goal of that section of the Belmont Report–but I am not even sure of that; I would hope that an MRI operator diagnosing a patient has an objective and a set of procedures designed to reach that objective.

Nor does it distinguish science from journalism, which regularly permits conclusions to be drawn and expresses statements of relationships. Thus, a [17]debt-ceiling story in this week's Washington Post finds that "It was the new Washington that started this fight . . . Then, over three fast-moving days, the old Washington swooped in to save them." That's a conclusion, and a statement of a relationship.

Conversely, [18]qualitative social scientists debate whether their work is generalizable. So "generalizable" covers research that the National Commission did not want covered and leaves uncovered research that the Commission did seek to regulate.

Serious observers have noted the problem. [19]Tom Beauchamp recently complained that "generalizable knowledge," like other terms, "can be understood in several ways." [20]Rena Lederman has found that "the regulatory definition

did little to resolve the very ambiguities within medical practice for which it was designed. Heroic efforts of clarification can be found in works that interpret the Common Rule for IRBs. Nevertheless, to this day it continues to be a frequent topic of debate in IRB circles." And in 2008, [21]David Strauss of SACHRP complained that "we shouldn't be reviewing research that we don't think needs to be reviewed because some folks 30 years ago, at the end of a long, hot day, decided to use the word 'generalizable' . . . We have to have language that makes sense to us."
So, can we find sensible language to draw a distinction between the social sciences and humanities?

Option 2b: Deregulate the Humanities and Journalism as Research about Individuals

Perhaps the answer lies in [22]language used by Michael Carome in a 2003 message: "OHRP has noted that its position regarding oral history was not based upon the fact that oral history activities involve open-ended, qualitative interviews of a nonrandom sample of individuals." Could "sample" be the key?
Obviously, quantitative researchers use samples. And one could make the case that qualitative sociologists and anthropologists do as well. That is, when they write about people whose names they conceal, are they not presenting them as representatives of a broader group?
Oral historians, by contrast, research individuals as individuals. As the [23]Columbia University policy explains, "the scholarly oral history interview is rooted in particular recollections about history based on the individual perspective of the narrator." The "individual perspective" works for journalism and biography as well.
So perhaps we could advocate this definition:

> For purposes of this policy, research means a systematic investigation, including research development, testing and evaluation, that studies people as representatives of the species as a whole or of biological and social groups. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. This policy does not cover research about individuals' unique experiences and perspectives, such as journalism, history, biography, philosophy, "fact-finding" inquiries such as criminal, civil and congressional investigations, and intelligence gathering.

Option 3: Define Research to Match Congress's Intentions

The [24]National Research Act of 1974 (P.L. 93-348), established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and instructed it to

> (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary [of Health, Education, and Welfare] (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research (emphasis added).

So when Kenneth Ryan observed "the general Commission feeling that we are talking about biomedical, social, and behavioral research," he could just as well have said, "the general Commission feeling is that we should exceed the authority granted us by Congress." For Congress had not empowered the Commission–or the Secretary of HEW–to study or regulate social research.

Today's Common Rule claims the National Research Act (encoded as 42 USC 289) as its [25]statutory authority, but it does not limit itself to the scope of the law.
What would the Common Rule look like if it were grounded in the statute?

Option 3a: Limit the Regulations to the Concerns of Congress

One possibility was mooted in a [26]formal interpretation by the Secretary of HEW in 1976:

> The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 U.S.C. 289l-3 (added by Pub. L. No. 93-343), which forms part of the basis for the Departmental regulations at 45 CFR Part 46, and in the preambles to the proposed and final regulations at 45 CFR Part 46. The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psychosurgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devices; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study: the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human in vitro fertilization. The regulations were intended, and have been uniformly applied by the Department, to protect human subjects against the types of risks inherent in these types of activities.

In Ethical Imperialism I described this last sentence as "a poor description of DHEW's previous actions." In an earlier draft, I called it a lie, and maybe I should have left that blunt language, since the department had not in fact limited its application to the areas of concern raised in the 1973 hearings.
But perhaps the 1976 interpretation, though not implemented at the time, would still be a wise course. This would be a radical break; while Congress did take testimony about behavior control, it did not investigate other behavioral research, like Milgram's experiments. So aligning the regulations to the concerns of Congress would mean deregulating a great deal of psychological experimentation. I am going to leave this to the [27]psychologists to think about.

Option 3b: Limit the Regulations to the Language of the Statue

A less radical option would be to accept that HHS and other agencies have the authority to determine the scope of "behavioral research" under the statute, but that they must do so within the limits of ordinary understanding. Details can be found in my book, but suffice it to say that Ryan spoke for many when he broke research into three categories–"biomedical, social, and behavioral research"–only two of which appear in the statute. As the deputy general counsel of HEW noted in 1979, "If Congress had wished . . . to cover all human subjects' research, rather than just biomedical and behavioral, it could have done so." (Ethical Imperialism, 100.)
The question is how to distinguish between behavioral and social research. I propose borrowing language about "health information" from [28]46 CFR 160.103 and inserting in the Common Rule:

> For purposes of this policy, research means biomedical and behavioral research.
> Biomedical and behavioral research means an investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge by systematically collecting health information. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
> Human subject means a living individual about whom an investigator (whether professional or student)

conducting research obtains
(1) Health information through intervention or interaction with the individual, or
(2) Identifiable private health information.
Health information means any information, whether oral or recorded in any form or medium relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. It does not include incidental information about an individual's health, such as the mention of a past illness in the course of an interview about a broad range of subjects.

Either of these options–3a or 3b–would remove from IRB jurisdiction not only history, journalism, and the humanities (including classics!) but also most anthropology, sociology, political science, and the like.
Medical anthropology, medical sociology, and related fields might still face some forms of review, so it would be important to get the Excused category right. And we would probably need some interpretation down the road to make sure those retired Negro Leaguers could talk about their sprained ankles without triggering IRB jurisdiction.
Moreover, this broad deregulation might dismay some social scientists, particularly what I take to be a large number of anthropologists who have grown accustomed, even fond, of IRB review, and [29]see in the regulations the chance to police dodgy practices. To them I can only say, if the problem is so bad, why don't you persuade Congress to study it?
I find this last option–making the regulations conform to the law–the most appealing, since I don't believe executive agencies should regulate behavior that Congress has not found to be a problem through the regular process of hearings, reports, and legislation. I look forward to readers' reactions to these five options and others that they wish to propose.

1. http://www.institutionalreviewblog.com/2011/08/anprm-may-i-be-excused.html
2. http://federalregister.gov/a/2011-18792
3. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102
4. http://www.gunsalus.net/IllinoisWhitePaperMissionCreep.pdf
5. http://videocast.nih.gov/pdf/ohrp_institutional_review_boards.pdf
6. http://www.hhs.gov/ohrp/archive/documents/19781130.pdf
7. http://books.google.com/books?id=nSv83XkNq3gC&lpg=PA154&dq=ethical%20imperialism%20definition&pg=PA62#v=snippet&q=journalism&f=false
8. http://www.institutionalreviewblog.com/2008/02/historians-flood-ohrp-with-comments.html
9. http://www.institutionalreviewblog.com/2010/03/sociologists-split-on-ethics-review.html
10. http://dx.doi.org/DOI:10.1017/S0898030610000333
11. http://www.institutionalreviewblog.com/2011/08/anprm-may-i-be-excused.html
12. http://www.usaid.gov/our_work/global_health/home/TechAreas/commrule.html
13. http://grants.nih.gov/grants/policy/hs/Oral_History.pdf
14. http://www.institutionalreviewblog.com/2010/04/more-universities-deregulate-oral.html
15. http://www.nyu.edu/research/resources-and-support-offices/getting-started-withyourresearch/human-subjects-research/forms-guidance/clarification-on-oral-history/michael-caromes-email.html
16. http://blog.historians.org/news/1382/getting-free-of-the-irb-a-call-to-action
17. http://www.washingtonpost.com/politics/in-debt-deal-the-triumph-of-the-old-washington/2011/08/02/gIQARSFfqI_story.html
18. http://books.google.com/books?id=eYhW4bbsdBYC&lpg=PA420&dq=%22qualitative%20research%22%20generalizability&pg=PA420#v=onepage&q=%22qualitative%20research%22%20generalizability&f=false
19. http://www.institutionalreviewblog.com/2011/04/beauchamp-derides-federal-definition-of.html
20. http://www.institutionalreviewblog.com/2008/08/can-satire-match-irb-reality-comment-on.html
21. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-1-systems-level.html
22. http://www.nyu.edu/research/resources-and-support-offices/getting-started-withyourresearch/human-subjects-research/forms-guidance/clarification-on-oral-history/michael-caromes-email.

html
23. http://www.columbia.edu/cu/irb/policies/documents/OralHistoryPolicy.FINAL.012308.pdf
24. http://history.nih.gov/research/downloads/PL93-348.pdf
25. http://www.hhs.gov/ohrp/policy/common.html
26. http://www.hhs.gov/ohrp/archive/documents/19760628.pdf
27. http://hardsci.wordpress.com/
28. http://edocket.access.gpo.gov/cfr_2002/octqtr/45cfr160.103.htm
29. http://www.institutionalreviewblog.com/2009/12/after-human-terrain-will-aaa-debate.html

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6.8.7 Wall Street Journal Blogs ANPRM (2011-08-06 13:02)

Christopher Shea, author of the landmark 2000 article, "[1]Don't Talk to the Humans: The Crackdown on Social Science Research," notes Rob Townsend's [2]call to action on the ANPRM.
[Christopher Shea, "[3]Historians and Human-Subjects Research," Wall Street Journal: Ideas Market, 5 August 2011]
Shea writes,

> Understandably, some social scientists want to know why historians should get a pass on paperwork and oversight that takes up lots of their own time.
> So the question is: How can oral (or, more generally, contemporary) historians escape inappropriate IRB scrutiny without denigrating their own work? Or, to back up a step, should they, in fact, have to go through the same procedures as social psychologists doing lab studies?

Might I interest him in a [4]4,800-word answer?

1. http://linguafranca.mirror.theinfo.org/print/0009/humans.html
2. http://blog.historians.org/news/1382/getting-free-of-the-irb-a-call-to-action
3. http://blogs.wsj.com/ideas-market/2011/08/05/historians-and-human-subjects-research/
4. http://www.institutionalreviewblog.com/2011/08/anprm-its-time-to-redefine-research.html

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6.8.8 ANPRM: Organizations Seek Longer Comment Period (2011-08-06 20:54)

[1]Public Citizen and [2]PRIM &R have both requested that the ANPRM comment period be extended to 120 days. The more I grasp the complexities responding to the ANPRM, the less adequate 60 days seems to me.

1. http://www.citizen.org/documents/1959.pdf
2. http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/PRIMR_ANPRM_extension_request.pdf

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6.8.9 Chronicle of Higher Ed Reports on ANPRM (2011-08-08 09:32)

The Chronicle of Higher Education reports on the ANPRM, emphasizing historians' concerns.
[Ryan Brown, "[1]Historians Welcome Contemplated Changes in Human-Research Guidelines," Chronicle of Higher Education, 7 August 2011.]

Your humble blogger is quoted, as is Rob Townsend of the American Historical Association. The president-elect of the Oral History Association, Horacio N. Roque Ramírez, calls for some kind of review process to ensure that historians are familiar with the ethical implications of their work. But he agrees that current procedures are "tedious and nonsensical."
Agreed. I would go just a bit further, arguing that IRB oversight is a barrier to serious consideration of the ethics of oral history, since it has done so much to discredit the idea of ethics review.

1. http://chronicle.com/article/Historians-Welcome/128552/

6.8.10 Research Psychologist Blogs ANPRM (2011-08-09 08:22)

Sanjay Srivastava, associate professor in the Department of Psychology at the University of Oregon, has been posting some helpful observations about the ANPRM on his blog, [1]The Hardest Science:

- [2]When research is speech, should it be regulated?
- [3]Proposed federal IRB rule changes open for public comment
- [4]What the proposed human subjects rules would mean for social and behavioral researchers
- [5]The importance of trust and accountability in effective human subjects protection

I particularly appreciate his "first reactions" section of the "[6]What the proposed human subjects rules would mean" post:

> Overall I think this sounds like mostly good news for social and behavioral researchers, if this actually happens. It's possible that after the public comment period they'll drop some of these changes or do something completely different.
> I'd ideally like to see them recognize that certain research activities are protected speech and therefore should be outside of all federally mandated regulation. At the very least, universities have had to figure out whether to apply the Common Rule to activities like journalism, folklore and oral history research, etc. It would be nice to clear that up. (I'd advocate for a broader interpretation where interviews and surveys are considered protected speech regardless of who's doing them. "Do you approve of how the President is doing his job?" is the same question whether it's being asked by a journalist or a political scientist. But I'm not holding my breath for that.)
> The HIPAA stuff makes me a little nervous. It appears that they are going to require the same level of security for a subject's response to "Are you an outgoing person?" as for the results of an STD test. There also does not seem to be any provision for research where you tell subjects up front that you are not offering or guarantee confidentiality. For example, it's pretty common in social/personality psych to videotape people in order to code and analyze their behavior, and later in another study use the videotapes as stimuli to measure other people's impressions of their behavior. This is done with advance permission (I use a special consent form that asks if we can use videotapes as stimuli in future studies). Under the new rules, a videotape where you can see somebody's face is considered fully identifiable and subjected to the most stringent level of control. Even just giving your own undergraduate RAs access to code the videotapes might require a mountain of security. Showing it to new subjects in a new study might be impossible.
> So I do have some concerns, especially about applying a medical model of data security to research that has low or minimal informational risks. But overall, my first reading of the proposed changes sounds like a lot of steps in the right direction.

This is just what we need: scholars reading the ANPRM carefully and thinking about what its various proposals would mean for their research and teaching. Srivastava cares about the HIPAA restriction on "full-face photographic images and any comparable images"; other researchers will emphasize other details.
Srivastava has also posted some thoughtful comments on the [7]mortifyingly stupid CITI Program, including his frustrating correspondence with a CITI staffer who offered empty promises to revise misleading language.

- [8]CITI is still misrepresenting Milgram's obedience research
- [9]CITI update, and broader thoughts on ethics training and behavioral research

1. http://hardsci.wordpress.com/
2. http://hardsci.wordpress.com/2011/07/25/when-research-is-speech-should-it-be-regulated/
3. https://hardsci.wordpress.com/2011/07/26/proposed-federal-irb-rule-changes-open-for-public-comment/
4. http://hardsci.wordpress.com/2011/07/28/what-the-proposed-human-subjects-rules-would-mean-for-social-and-behavioral-researchers/
5. http://hardsci.wordpress.com/2011/08/04/the-importance-of-trust-and-accountability-in-effective-human-subjects-protection/
6. http://hardsci.wordpress.com/2011/07/28/what-the-proposed-human-subjects-rules-would-mean-for-social-and-behavioral-researchers/
7. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
8. http://hardsci.wordpress.com/2011/07/06/citi-is-still-misrepresenting-milgrams-obedience-research/
9. http://hardsci.wordpress.com/2011/07/08/citi-update-and-broader-thoughts-on-ethics-training-and-behavioral-research/

Sanjay Srivastava (2011-08-10 21:08:44)
Thank you for the shout-out, Zachary. I have really appreciated your coverage and commentary, particularly the "Quick Guide" you just posted.
On the subject of the CITI course, you might be interested in [1]an editorial my colleague Jennifer Freyd wrote for the Journal of Trauma and Dissociation, in which she criticizes the "McEthics" approach of CITI (if you follow the link, it's under the heading "Ethical Integrity in Research Also Requires Intellectuality").

1. http://www.tandfonline.com/doi/full/10.1080/15299732.2011.602290

Zachary M. Schrag (2011-08-11 10:34:17)
Thanks for this comment and for the very kind words on your blog.
Thanks also for pointing me to the Freyd editorial, which I will blog about soon. One of the reasons I began this blog is that thoughtful critiques of the IRB system were scattered among dozens of specialized journals, and no one was aggregating them. This editorial is a fine example, and I am delighted to publicize it.

6.8.11 A Quick Guide to the ANPRM (2011-08-09 10:02)

The ANPRM's 74 questions may overwhelm some scholars and scholarly organizations that might wish to respond; already several organizations have called for the comment period to be extended to 120 days.
In the hope of of making things easier, I have tried to lay out some of the most pressing questions in "[1]How should human subjects regulations change? A guide to "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" for scholars in the social sciences,

humanities, and journalism, and the organizations that serve them."
I welcome comments on this document.

1. http://zacharyschrag.files.wordpress.com/2011/06/how_should_human_subjects_regulations_change_8-9-11.pdf

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6.8.12 CITI Program as Mind-Numbing, Coercive, Counterproductive McEthics (2011-08-12 09:45)

Sanjay Srivastava of [1]The Hardest Science kindly alerted me to a newly published critique of the [2]mortifyingly stupid CITI Program.
[Jennifer J. Freyd, "[3]Journal Vitality, Intellectual Integrity, and the Problems of McEthics," Journal of Trauma & Dissociation, available online: 15 July 2011, DOI:10.1080/15299732.2011.602290]
Freyd, the editor of the Journal of Trauma & Dissociation, writes,

> Beginning a few years ago many researchers have also been required by their institutions to complete regular mandatory "education" in research ethics. Although the intentions of these requirements are surely good, the resulting implementation has created a new industry of mind-numbing on-line ethics training and testing.
> My own institution, like many others, requires all researchers to regularly complete testing using Collaborative IRB Training Initiative (CITI, www.citiprogram.org/) software. The problem is that passing the CITI tests is neither sufficient nor necessary for ethical behavior. Rather, this method of education and testing is so superficial and coercive that it is arguably counterproductive, promoting a false sense of security and even breeding cynicism. The information presented in the curriculum includes some valuable points, numerous irrelevant details, and a non-trivial amount of incorrect information and opinion labeled as fact. This information is then tested through multiple-choice quizzes shortly after presentation so that no long term retention is required. The only thinking occurs when disputable information is presented and tested; then the researcher must select between purposely entering a wrong answer in order to pass the test or possibly failing the test and thus being unable to do research.
> Furthermore, it is considered permissible by many research communities for researchers to scan the CITI study materials at the same time as completing the quiz, thus requiring no retention of study materials even in the short run. In still other research communities, answer sheets are circulated. Although these strategies are obviously against the rules and arguably unethical, the rates of such cheating are apparently very high, probably in part because researchers consider the whole endeavor a foolish waste of time and in part because people will conform to what they believe is normative no matter if it is technically prohibited. It is ironic than an education initiative focused on ethics promotes such unethical behavior. There is very little intellectual integrity in the CITI educational experience from either the perspective of the testing itself or the behavior of the test takers.
> Although knowledge is necessary, ethical behavior in research fundamentally involves motivation, problem-solving, and sometimes difficult cost-benefit analyses. What we need instead is a meaningful and intellectually honest educational experience: engage in a debate; serve on the IRB; conduct a study on research ethics. Like many of my colleagues I complete the required CITI training because I must in order to be allowed to conduct research, but each time I go through this process I come out feeling like I've been force-fed a high-fat low-nutrition meal at McEthics.

In case readers missed her point, she also terms the CITI program "hypocritical."
I can't argue with any of these characterizations, nor with Freyd's wish for more interactive ethics training, like

the [4]Princeton workshop for historians. But I hope that Freyd and other critics will consider the results of the [5]University of Connecticut survey and take a look at Macquarie University's [6]Human Research Ethics for the Social Sciences and Humanities. The former suggests that a large majority of researchers prefer online training, and the latter shows that web-based training need not be mired in irrelevant details, incorrect information, or opinion labeled as fact.

While we must do away with multiple-choice testing, the chief problem with the CITI Program is not its format but its content, which seems to have been written mostly by administrators and consultants, rather than scholars. If institutions were to allow their researchers to complete online training developed by experts in individual disciplines and written to scholarly standards, researchers could enjoy ethics meals at once [7]fresh, affordable, convenient, attractive, and nutritious.

1. http://hardsci.wordpress.com/
2. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
3. http://www.tandfonline.com/doi/full/10.1080/15299732.2011.602290
4. http://www.institutionalreviewblog.com/2011/04/princeton-offers-phd-students-serious.html
5. http://www.institutionalreviewblog.com/2010/11/survey-one-third-of-uconn-researchers.html
6. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html
7. http://justbento.com/

6.8.13 How Many Questions Must an ANPRM Ask? (2011-08-22 14:41)

Officially, the [1]ANPRM asks 74 questions. In an effort to simplify things for scholars in the social sciences and humanities, [2]I offered a list of just ten. The University of Rochester takes the other tack, counting [3]152 questions. However many questions you care to answer, you've got 35 days left.

H/T: [4]Human Research Protections Blog.

1. http://www.federalregister.gov/articles/2011/07/26/2011-18792/human-subjects-research-protections-enhancing-protections-for-research-subjects-and-reducing-burden
2. http://www.institutionalreviewblog.com/2011/08/quick-guide-to-anprm.html
3. http://www.rochester.edu/ohsp/documents/pdf/Response_grid_for_OHRP_ANPRM_glc_ur.pdf
4. http://humanresearchprotectionsblog.wordpress.com/2011/08/17/understanding-the-proposed-changes-to-the-common-rule/

6.8.14 Aristotle: History Is Not Generalizable (2011-08-25 11:40)

I stumbled across the following passage from [1]Aristotle's Poetics:

> It is not the function of the poet to relate what has happened, but what may happen–what is possible according to the law of probability or necessity. The poet and the historian differ not by writing in verse or in prose. The work of Herodotus might be put into verse, and it would still be a species of history, with meter no less than without it. The true difference is that one relates what has happened, the other what may happen. Poetry, therefore, is a more philosophical and a higher thing than history: for poetry tends to express the universal, history the particular.

So history is not subject to the Common Rule, but poetry is.

1. http://classics.mit.edu/Aristotle/poetics.1.1.html

6.8.15 Sociologist: IRBs Have Almost Killed Fieldwork (2011-08-26 09:53)

Laurie Essig, Assistant Professor of Sociology and Women's & Gender Studies at Middlebury College and a contributor to the Chronicle of Higher Education's [1]Brainstorm blog, complains that "IRBs have effectively shut down our ability to actually find out about people's lived experiences. IRBs have treated speaking with someone as equivalent to experimenting on them and have almost killed fieldwork in the process."
[Laurie Essig, "[2]The IRB and the Future of Fieldwork," Brainstorm: Ideas and Culture, 12 August 2011.]
She offers four examples:

1. "A friend, who used to interview prisoners, gave it up since prisoners are 'vulnerable populations' and getting IRB approval is far more difficult than getting through the prison doors."

2. "Another acquaintance who used to research sexuality among young people has had to give it up since if there's one thing you canNOT speak with people under 18 about it's sex."

3. Essig "was called in because I had interviewed people who identified as transgendered and did not treat these people as a 'vulnerable population,' which includes prisoners, terminally ill persons, children, people with mental illness, and pregnant women.

4. Essig "was told that I had to get cosmetic surgery patients to sign permission slips to speak with me even though the interviews would be anonymous and details would be changed in such a way as to protect everyone's identity . . . People love it when you offer them anonymity and then ask for a signature. Really makes them want to open up to you."

Essig calls the ANPRM "a huge improvement," though she does not offer specific proposals for reform. I fear she may be disappointed as she reads the ANPRM carefully, since none of the 74 (or [3]152) questions raises the possibility of redefining vulnerable populations as Essig and others might wish. [See also "[4]Sex Researcher Calls for "An Evidence-Informed Process".]
As for her fourth complaint, the existing Common Rule already encourages IRBs to "waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds . . . that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality." It's not clear how the ANPRM reforms would address basic IRB incompetence, though requiring an appeal mechanism (ANPRM Question 28) would be a good start.
I am disappointed that Essig derides the famous studies by Stanley Milgram and Philip Zimbardo, calling them not only "incredibly unethical" but also pointless. "After all," she writes, "these sort of human experiments were not just unethical, but ultimately gave us little information that we didn't already have: people basically suck and they more or less will do anything if a white guy in a lab coat tells them to."
In fact, while both studies remain controversial, they both contributed significantly to our understanding of human nature. See, e.g., Robert Levine, [5]review of Thomas Blass, The Man Who Shocked the World: The Life and Legacy of Stanley Milgram, American Scientist 92 (July-August 2004): 368-370; Rose McDermott, [6]review of Philip Zimbardo, The Lucifer Effect: Understanding How Good People Turn Evil, Political Psychology 28 (Oct., 2007): 644-646.
Nor should Essig claim that IRBs "protect research subjects from . . . the kind of researchers who would recreate prison situations to see how nasty humans could be to total strangers." Ethical or not, [7]Zimbardo's prison experiment was IRB approved.

1. http://chronicle.com/blogs/brainstorm/
2. http://chronicle.com/blogs/brainstorm/the-irb-and-the-future-of-fieldwork/38160
3. http://www.institutionalreviewblog.com/2011/08/how-many-questions-must-anprm-ask.html
4. http://www.institutionalreviewblog.com/2011/05/sex-researcher-calls-for-evidence.html
5. http://www.jstor.org/stable/27858427
6. http://www.jstor.org/stable/20447077
7. http://www.prisonexp.org/faq.htm#ethics

Sanjay (2011-08-26 19:50:48)
Maybe she thinks Milgram was unethical because her institution made her take the [1]CITI course.

1. http://hardsci.wordpress.com/2011/07/06/citi-is-still-misrepresenting-milgrams-obedience-research/

6.8.16 Emanuel: ANPRM Will End Reliance on Worthless Gut Reactions (2011-08-30 14:25)

I watched the webcast of this morning's appearance by Ezekiel Emanuel before the Presidential Commission for the Study of Bioethical Issues. There were no huge suprises in Emanuel's presentation; much of it repeated points he had made in the [1]New England Journal of Medicine. But I found some of his remarks, and the Commission's response, noteworthy.
(Parenthetical citations indicate the approximate time on the [2]recording posted on the Commission website)
First, Emanuel emphasized his wish for a "risk-based review process" (6:00) and "a learning process that would be constant and dynamic to reflect actual risk" (8:55) rather than what he termed "gut reactions . . . which is worthless." (10:20)
This was a bit of a surprise, since it seems more ambitious than the proposals in the ANPRM itself. For example, the ANPRM imagines that "all data on adverse events and unanticipated problems collected in a central database accessible by all pertinent Federal agencies," (Question 69), but it does not explain how that database would filter down to individual IRBs. True, the ANPRM proposes a permanent federal body to update the criteria for expedited review, but that is just one element of determining what research methods impose risks.
Second, Emanuel noted that "written consent would be required for all use of biospecimens." (7:40) He did not mention such a requirement for datasets. Does this represent a backing away from ANPRM Question 46, which imagines requiring written consent for "unanticipated future analysis of data"?
Third, Emanuel noted that covering all research nationwide would require an act of Congress, and that is unlikely to happen. (9:20) But, he claimed, HHS could impose the Common Rule on all research conducted by institutions that receive federal funding. He described this as "a regulatory way of trying to achieve the goal incrementally." (9:45).
I am puzzled by Emanuel's simultaneous deference and indifference to the limits of statutory authority. The [3]26 January 1981 Federal Register notice announcing the revised 45 CFR 46 stated:

> HHS has carefully considered its proposed policy regarding the regulation of non HHS-funded research in light of the comments received and the statutory basis for the more expansive interpretation. The public comment, including that of the President's Commission, revealed a broad based and significant amount of objection to the extension. Further, the HHS General Counsel has advised that there is no clear statutory mandate in the National Research Act to support a requirement for IRB review of other than Public Health Service-funded research. Therefore, the Secretary of HHS, after considering a number of possible options, has decided not to extend the requirements for prior IRB review and approval to non HHS-funded research.

The statute has not changed. Why does Emanuel think that HHS now has statutory authority to require IRB review of research not directly funded by the federal government?

Finally, I was heartened by the commissioners' reaction to Emanuel's presentation. While the commissioners asked tough, detailed questions, none of them displayed any knee-jerk defensiveness on behalf of the status quo. This is a relief, because the ANPRM is a bold document, and it may need the high-level support that the Presidential Commission can provide.

Note. Emanuel pronounced "ANPRM" as "ay-en-pee-ar-em." It strikes me that a community used to EN-back, NUR-pack, and SACK-harp could save time by saying "AN-perm."

1. http://www.institutionalreviewblog.com/2011/07/emanuel-and-menikoff-explain-anprm.html
2. http://www.tvworldwide.com/events/bioethics/110519/globe_show/default_go_archive.cfm?gsid=1743&type=flv&test=0&live=0
3. http://www.hhs.gov/ohrp/archive/documents/19810126.pdf

Roberto Veloso (2011-08-30 17:00:53)

"Why does Emanuel think that HHS now has statutory authority to require IRB review of research not directly funded by the federal government?"

Just a guess (observation really), but I think he is referring to the large number of institutions that have expanded the jurisdictional authority of IRBs through the creation of institutional policies. Call it IRB over-reach by institutional policy.

Zachary M. Schrag (2011-08-30 17:11:00)

No, the ANPRM goes further than that:

"We are considering . . . requiring domestic institutions that receive some Federal funding from a Common Rule agency for research with human subjects to extend the Common Rule protections to all research studies conducted at their institution."

Institutions would no longer have a box to uncheck.

The question is why Emanuel thinks that this would not require an act of Congress, given that in 1980 or 1981, the HHS general counsel determined that it would.

Roberto Veloso (2011-08-30 20:01:05)

I suspect Emmanuel and OHRP are after the elusive goal of "fostering a culture of the ethical conduct of research" at all institutions that receive federal funds. I think that's the same reason why many institutions impose IRB oversight over research that could clearly be considered exempt (depending on who is making that determination of course).

As to why Emmanuel thinks he wouldn't need Congress to act, I think it has to do with who is running the OGC at HHS and the current state of Congressional politics.

Quite honestly, I think it is going to be very difficult for all of the contemplated reforms to go through given the influence that various stake holders will be able to exert on HHS by placing some calls to Capital Hill.

Zachary M. Schrag (2011-08-30 21:06:13)

Other than DeGette, does anyone in Congress care about this?

Roberto Veloso (2011-08-31 13:24:47)

Although reforming the Common Rule doesn't have the same political implications as reforming healthcare last year, there's no reason to believe Pharma wouldn't exercise the same amount of muscle here, on a pro-rated basis.

"The Pharmaceutical Research and Manufacturers of America spent $22 million and deployed an army of no fewer than 52 lobbyists" in 2010. http://money.cnn.com/2011/03/25/news/economy/health _care _lobbying/index.htm

Also Pharma has the ear of the White House (http://hcrenewal.blogspot.com/2011/08/why-cultivate-weldons-confi dence-ceo.html) as Pharma is viewed as one of the parts of the economy that has the potential for creating new jobs.

Zachary M. Schrag (2011-08-31 14:08:50)
I would think the pharmaceutical industry would welcome such reforms as the streamlining of multi-site studies and the harmonization of federal guidance.

Roberto Veloso (2011-08-31 17:46:18)
"I would think the pharmaceutical industry would welcome such reforms as the streamlining of multi-site studies and the harmonization of federal guidance."
. . . and that's about it. No real improvements to protect human research subjects. At least that's my fear.

6.8.17 The Years Spin By (2011-08-30 23:54)

In his presentation to the Presidential Commission for the Study of Bioethical Issues today, Ezekiel Emanuel showed some textual slides that were visible during the live webcast but do not show up–at least on my browsers–when I replay the recording.
One of these slides featured a timeline of events leading to the current system of human subjects protections. That timeline featured two common errors.
First, Emanuel dated the Belmont Report to 1979. You will see this date a lot: on the [1]NIH website in a blurb for [2]Belmont Revisited, and–until I fixed it just now–on the [3]Wikipedia entry, .
But read the [4]report itself, and there's the date, 30 September 1978, at the top of each of the four transmission letters. The report even has a DHEW publication number, 78-0012, indicating the year in which it was published.
True, the report appeared in the [5]Federal Register on 18 April 1979. But dating the Belmont Report to April 1979 is like dating the Declaration of Independence to August 1776, because [6]that's when it was engrossed. We don't launch fireworks on August 2.
Second, Emanuel suggested that 45 CFR 46 was first promulgated in 1981. In fact, the first version of 45 CFR 46 was promulgated on [7]30 May 1974.
These errors are of little consequence by themselves. But I would like to think that an acquaintance with the history of IRB policy–an acquaintance complete enough that getting these dates right becomes second nature–would help today's policymakers gauge the probable outcomes of the various proposals on the table.

1. http://ohsr.od.nih.gov/guidelines/belmont.html
2. http://www.press.georgetown.edu/book/georgetown/belmont-revisited
3. http://en.wikipedia.org/wiki/Belmont_Report
4. http://videocast.nih.gov/pdf/ohrp_belmont_report.pdf
5. http://www.hhs.gov/ohrp/archive/documents/19790418.pdf
6. http://www.ourdocuments.gov/doc.php?flash=true&doc=2
7. http://www.hhs.gov/ohrp/archive/documents/19740530.pdf

6.8.18 ANPRM Comment Period Extended to October 26 (2011-08-31 14:14)

The Department of Health and Human Services has extended the comment period for the ANPRM to October 26. HHS has posted a [1]preliminary announcement, and the official announcement is planned for the September 1 Federal Register.

1. http://www.ofr.gov/OFRUpload/OFRData/2011-22341_PI.pdf

6.8.19 Does the ANPRM's Appeals Provision Address IRB Incompetence? (2011-08-31 21:40)

A correspondent suggests that the ANPRM fails to address the problem of incompetent IRBs, such as IRBs that lack the expertise necessary to do their work or otherwise fail to meet all the requirements of the existing Common Rule. I am inclined to disagree.

First, though the [1]ANPRM's problem statement is too diplomatic to state that IRBs are doing a poor job, the ANPRM cites some scholarship reporting serious flaws in the system.

One striking example is the three citations to Lee A. Green, Julie C. Lowery, Christine P. Kowalski, and Leon Wyszewianski, "[2]Impact of Institutional Review Board Practice Variation on Observational Health Services Research," Health Services Research 41 (February 2006): 214–230. Apparently frustrated by the 4,680 hours of staff time it took to win IRB approval for a multisite study of physician practices, the researchers decided to study their own notes to figure out what had sucked up the equivalent of more than two years of work. They found all sorts of IRB-generated problems and concluded that "several features of the IRB system as currently configured impose costly burdens of administrative activity and delay on observational health services research studies, and paradoxically decrease protection of human subjects." Just by citing such studies, the ANPRM recognizes IRB fallibility to a greater degree than other official documents I've seen.

Second, the ANPRM's questions 27 through 29 at least raise the possibility that IRBs are making serious errors. Question 27 asks if IRBs remember that they "should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks that fall within the purview of its responsibility." In other words, it acknowledges that IRBs may frequently overlook some of the protections for research built into the regulations.

Question 29 asks if IRBs that act in ways not specified by the regulations be required to say that they are doing so "in furtherance of increased transparency." Here again, the implication is that IRBs are acting in ways not intended by the framers of the regulation, and either failing to notice that they are doing so, or not bothering to explain their actions.

Most dramatically, Question 28 raises the possibility of a mandatory appeal mechanism. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research specifically rejected such a provision, arguing that "[3]an IRB should have the final word at its institution regarding the ethical acceptability of proposed research involving human subjects." Though the Commission had heard accounts of what Robert Levine later called "remarkably stupid behavior by IRBs," ([4]PRIM &R Through the Years, 32), its members ultimately decided that maintaining IRB authority was more important than protecting researcher rights. Since then, groups like the AAUP have pointed to the "[5]unchecked power granted to IRBs" as a contributor to IRB malfunction.

I would like to suggest, then, that the ANPRM contains a more radical critique of the IRB system than one would get from reading its [6]problem statement alone. I encourage those who want significant change to answer Question 28 and call for an appeal mechanism as an important step toward addressing IRB incompetence.

1. http://www.institutionalreviewblog.com/2011/08/anprms-problem-statement-helpful-but.html
2. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681539
3. http://videocast.nih.gov/pdf/ohrp_institutional_review_boards.pdf
4. http://www.primr.org/resourcecenter.aspx?id=268
5. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm
6. http://www.institutionalreviewblog.com/2011/08/anprms-problem-statement-helpful-but.html

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6.9 September

6.9.1 Website Covers Boston College Oral History Subpoena (2011-09-03 21:41)

An anonymous comment on my post, [1]DOJ: "There Is No Academic Privilege", alerts me to [2]Boston College Subpoena News, described as a "website following Boston College's motion to quash the DoJ subpoena." The site

does not credit its authors, but it seems to have useful information.

1. http://www.institutionalreviewblog.com/2011/07/doj-there-is-no-academic-privilege.html
2. http://bostoncollegesubpoena.wordpress.com/

6.9.2 Canadian Tortoise Beats American Hare (2011-09-06 11:00)

In the United States, human subjects regulations remained unchanged for twenty years, and almost unchanged for thirty. Then, in July, federal regulators proposed dramatic changes but gave citizens only sixty days to respond. When [1]scholarly and professional organizations complained, that period was [2]extended to a leisurely ninety days. Once that period closes, scholars may need to wait additional decades for such a chance to shape the regulations under which they must work.

Meanwhile, the Canadian Interagency Advisory Panel on Research Ethics has released its [3]first responses to written requests for interpretation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), only eight months after the release of that document. Whereas [4]Americans must wait years for regulators to respond to their concerns, Canadians are promised contact with a policy analyst within 48 hours and, as we have seen, may get formal interpretations within months. If the past is a guide, they can expect amendments to the TCPS every few years (the first edition was amended three times) and perhaps another full revision after twelve.

The protection of research participants should be subject to constant improvement. We will not get sensible rules from decades of inaction interrupted by brief spasms of debate.

1. http://www.institutionalreviewblog.com/2011/08/anprm-organizations-seek-longer-comment.html
2. http://www.institutionalreviewblog.com/2011/08/anprm-comment-period-extended-to.html
3. http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/Default/
4. http://www.institutionalreviewblog.com/2011/01/three-years-inaction-at-ohrp.html

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6.9.3 Circuit Court Affirms Right to Record Videos in Public (2011-09-07 10:05)

As noted by the [1]New York Times, a recent First Circuit decision in [2]Glik v. Cunniffe affirms the First Amendment right to make video recordings in public places.

The appellee, Simon Glik, had a particularly strong case because he was filming police officers making an arrest. As the court noted in its August 25 decision, "Gathering information about government officials in a form that can readily be disseminated to others serves a cardinal First Amendment interest in protecting and promoting 'the free discussion of governmental affairs.'"

Moreover, even had Glik been affiliated with a university, his actions did not constitute human-subjects research under the current regulatory definition, since he did not voluntarily interact with the officers he was filming. (They interacted with him by arresting him on bogus charges, but I would hope no IRB would hold that against him.)

Still, it is worth considering the significance of the court's more general statement that the First Amendment protects the gathering of information as well as its dissemination:

> It is firmly established that the First Amendment's aegis extends further than the text's proscription on laws "abridging the freedom of speech, or of the press," and encompasses a range of conduct related to the gathering and dissemination of information. As the Supreme Court has observed, "the First Amendment goes beyond protection of the press and the self-expression of individuals to prohibit government from limiting the stock of information from which members of the public may draw." First Nat'l Bank v. Bellotti, 435 U.S. 765, 783 (1978); see also Stanley v. Georgia, 394 U.S. 557, 564 (1969) ("It is . . .

well established that the Constitution protects the right to receive information and ideas."). An important corollary to this interest in protecting the stock of public information is that "[t]here is an undoubted right to gather news 'from any source by means within the law.'" Houchins v. KQED, Inc., 438 U.S. 1, 11 (1978) (quoting Branzburg v. Hayes, 408 U.S. 665, 681-82 (1972)).

At the very least, such statements complicate claims that "[3]human-subjects research is a privilege and not a right."

1. http://www.nytimes.com/2011/09/02/opinion/a-vital-liberty.html
2. http://www.ca1.uscourts.gov/pdf.opinions/10-1764P-01A.pdf
3. http://books.google.com/books?id=ZVByC6VVsl0C&pg=PA17e#v=onepage&q&f=false

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6.9.4 Boellstorff Warns of ANPRM Ethics Creep (2011-09-11 20:41)

[1]Occupational Health & Safety alerts me to a [2]comment on the ANPRM posted on September 1 by Tom Boellstorff, Professor of Anthropology, University of California, Irvine, and Editor-in-Chief, American Anthropologist.
Boellstorff welcomes the idea of the Excused category and the ANPRM's deemphasis of written consent forms, which, he says, "are often hard to understand and designed more to protect home institutions from liability than truly inform those being studied." He also believes that social scientists may be able to address concerns about data security.
On the other hand, Boellstorff worries that two of the ANRPM's proposals could lead to the same kind of ethics creep we have seen with the current Common Rule.
First, he warns of the ANPRM's handling of "'vulnerable' populations." He writes,

> The proposed revisions retain the concept of "vulnerable" populations, but without ever providing a clear definition of what vulnerability might entail. As it stands, the examples provided of vulnerable populations are "children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons." There are at least two issues here. First, social science researchers have long noted that we have a real dearth of quality research on children and prison populations due to the very high barriers IRBs often place on conducting research on such populations, even when it is only informational risk that is at issue. In other words, the notion of "vulnerable" needs to be recalibrated in light of research that carries only informational risk. Often, research on children or prisoners should qualify for Excused status. Second, the notion of "economically or educationally disadvantaged persons" is so broad so as to include a majority of the world's population under its scope. The mere fact of being disadvantaged does not mean someone is "vulnerable" with respect to social science research that carries only informational risk. It is crucial that the ANPRM be revised to reflect this fact. The notion of "competent" may be more useful, though at present it is limited to "adults who would be able to provide 'legally effective informed consent."

Second, Boellstorff worries that ANPRM's Question 16, which envisions stricter scrutiny of "emotionally charged" topics, would hinder legitimate research about sexuality.

> My concern is that while it is "sexual abuse" that is named, there is a real danger that this could be taken to mark all research on sexuality as "emotionally charged." Any abuse in theory can be emotionally charged. Marking out sexual abuse (and physical abuse more generally) as emotionally charged can contribute to the singling out of sexuality research as ethically suspect, which is counterproductive for encouraging careful work on this important topic.

I concur with Boellstorff's points and admire the brevity and clarity of his comments.
As of September 9, the [3]ANPRM docket on regulations.gov contained 185 public submissions. I hope to post about more of them soon.

1. http://ohsonline.com/articles/2011/09/08/commenters-debating-changes-in-human-subjects-research-rules.aspx?admgarea=news
2. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0179
3. http://www.regulations.gov/#!docketDetail;dct=PS;rpp=10;po=0;D=HHS-OPHS-2011-0005

6.9.5 Professional Geographer Focuses on IRBs (2011-09-21 16:32)

The [1]Professional Geographer has posted a six-item special section on "Protecting Human Subjects Across the Geographic Research Process," edited by Patricia L. Price.
Do I have time to write about each of these as we enter the last stretch of the ANPRM comment period? I do not!
As a placeholder, then, I offer the table of contents:
Focus: Protecting Human Subjects Across the Geographic Research Process (Guest Editor: Patricia L. Price)
Introduction: Protecting Human Subjects Across the Geographic Research Process
Patricia L. Price
DOI:10.1080/00330124.2011.596780
Subjectivity, Power, and the IRB
Deborah G. Martin & Joshua Inwood
DOI:10.1080/00330124.2011.596781
Bridging Guidelines and Practice: Toward a Grounded Care Ethics in Youth Participatory Action Research
Amy Ritterbusch
DOI:10.1080/00330124.2011.596783
IRBs as Asset for Ethics Education in Geography
Dan Trudeau
DOI:10.1080/00330124.2011.596786
Geography, Me, and the IRB: From Roadblock to Resource
Patricia L. Price
DOI:10.1080/00330124.2011.596789
Institutional Review for Research in the Social Sciences from the Federal Perspective
Scott M. Freundschuh
DOI:10.1080/00330124.2011.596791

1. http://www.tandfonline.com/action/showAxaArticles?journalCode=rtpg20

6.9.6 Would ANPRM's Audits Require Massive Record-Keeping? (2011-09-23 14:39)

Part of the ANPRM's proposal for a new category of Excused research is an audit regime for projects that researchers declare eligible for Excusal. An observer asks whether this requirement would impose inappropriate burdens on researchers. I am hopeful that it would not, but commenters on the ANPRM should be aware of this possibility as they answer question 21.
The ANPRM explains:

> We are considering a mechanism to track Excused research, and to audit only a small but appropriate portion of such research, because it would still be subject to other regulatory protections, such as the proposed data security and information protection standards and certain consent requirements. In addition, such a mechanism to track and audit Excused research will also enable institutions to assure that the research does indeed meet the criteria for inclusion in the Excused category. (That is all that an audit would in most cases involve: a brief review of the registration form, similar to what many institutions currently do when they determine whether a study is exempt.) Key to this would be a requirement that researchers register their study with an institutional office by completing a brief form. This would make the institution aware of the research and identify the study's principal investigator. In addition the institution could choose to review some of the submissions at the time they are filed (and we contemplate that this would only be done in a relatively small percentage of the filings) and if deemed appropriate, require that the study be sent for expedited review or, in exceptionally rare cases, convened IRB review.
> The proposed auditing requirement is intended to encourage institutions to use the regulatory flexibility proposed for the Excused category of research. Rather than maintaining many institutions' current practice of routinely requiring that research that meets the current exemption categories undergo some type of review before it is permitted to proceed, the proposed auditing requirement would provide institutions with information needed to assess their compliance with the new Excused category without unnecessarily subjecting all such research to either prospective review, or even routine review sometime after the study is begun.

Writing on the [1]IRB Forum, Dr. John H. Noble Jr. warns that such an audit mechnanism could impose new burdens:

> Maybe I can offer some insight about conducting audits from efforts of the government auditors I worked with in the 1970s-1980s. Far too often the auditors conclude that an audit cannot be completed because of lack of needed records. Ironically, the proposed new Common Rule requiring random retrospective audits of exempt studies, unless accompanied by very specific record-keeping requirements for the various kinds of research that might be considered "exempt," as well as the noted institutional uncertainty and concern about "regulations, laws, obligations and risks," seems likely to add to the burden of PIs, the research institutions, sponsors, and IRBs. Will the lack of a specific document or record create an "audit exception" that is deemed blameworthy? That said, in my experience the common reason that organizations were able to walk away from a government audit as "not susceptible to audit for lack of needed records" was to avoid disclosure of illegalities. What happens when the prosecution lacks the evidence to prosecute? Check out what penalties can be imposed for lack of adequate record-keeping. For a start, see, for example: http://pcaobus.org/Standards/Auditing/Pages/Auditing _Standard _3 _Appendix _A.aspx and http://www.picpa.org/Content/AreasOfInterest/EmployeeBenefitPlans .aspx and http://www.irs.gov/businesses/article/0,,id=183208,00.html and http://en.wikipedia.org/wiki/Health _Insurance _Portability _and _Accountability _Act .
> Yummy, I see adoption of such a rule as guaranteeing full-employment for lawyers and auditors who will flock to help the thousands of research institutions that exempt certain studies as SOP. I would also add statisticians, who will have to design adequate size samples of the exempt studies in order to satisfy the audit requirements in this regard. Some of us government retirees with program evaluation and audit experience may well be drawn out of retirement to fill the demand for expertise to implement the proposed new Common Rule–if it is serious about moving in this direction. It is important to keep in mind that when audits and auditors become part of regulatory equation, it is only a matter of time before government audit standards will be evoked or modified to encompass the new activity. Be careful of what you pray for!!!

I am hopeful that the human-research audit regime need not be nearly as elaborate as the financial and health analogies Dr. Noble offers. It could instead resemble the retrospective audits now used in cases of alleged plagiarism, fabrication,

and falsification. Researchers are not subject to "very specific record-keeping requirements" beyond general scholarly norms that they retain enough notes and other materials that they can answer probing questions about their research. This system is not perfect (consider the debate over [2]Michael Bellesiles's soggy notepads), but I think it suffices.
Moreover, I would think that in most cases, an audit could be conducted using solely published materials. That is, if you declare that your research is Excused because you are only talking to people, and then you publish an article about the LSD you gave them, that would be a problem.
Still, given the history of IRB regulations so far, it would be a mistake to ignore Dr. Noble's nightmare. I recommend that replies to question 21 suggest that the auditing system not impose any new record-keeping requirements. And I agree that the proposal for "random selection" is odd. Why not limit audits to cases in which institutions have reason to suspect noncompliance as is now the case with plagiarism, fabrication, and falsification?
[Note: In deference to the [3]IRB Forum's policy I secured Dr. Noble's permission to quote his posting.]

1. http://www.irbforum.org/
2. http://hnn.us/articles/742.html
3. http://www.irbforum.org/help/phil.php

6.9.7 ANPRM Question 25: Read the Statute (2011-09-26 09:53)

It is September 26, the original comment deadline for the ANPRM, and the beginning of the final 30 days of the extended comment period. Here I offer my latest draft comments on the crucial Question 25. (This is adapted from my [1]August 5 post.)

Question 25. Are there certain fields of study whose usual methods of inquiry were not intended to or should not be covered by the Common Rule (such as classics, history, languages, literature, and journalism) because they do not create generalizable knowledge and may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule? If so, what are those fields, and how should those methods of inquiry be identified? Should the Common Rule be revised to explicitly state that those activities are not subject to its requirements?

Answer: The Common Rule should cover only biomedical and behavioral research. It should be rewritten to exclude explicitly the social sciences, humanities, and journalism.

General comments on the scope of the Common Rule

For those interested in academic freedom, the most important questions in the ANPRM are those gathered as **Question 25**. I am heartened that OSTP and HHS have posed these vital questions, and I reply that the Common Rule should cover only the biomedical and behavioral research that Congress has authorized HHS to regulate.

Statutory authority covers only biomedical and behavioral research

As the ANPRM notes, the Common Rule draws its statutory authority primarily from 42 USC 289, which calls for the establishments of IRBs "to review biomedical and behavioral research involving human subjects."

The ANPRM also cites 42 USC 300v, which established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Section 300v(a)(1) of that title calls for membership in the commission to be split among three groups: (A) "individuals who are distinguished in biomedical or behavioral research," (B) " individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care," and (C) "individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs."

Thus, federal law distinguishes between "biomedical or behavioral research" on the one hand and "the social sciences, the humanities, health administration, government, and public affairs" on the other. As the deputy general counsel of

the Department of Health, Education, and Welfare put it in 1979, "if Congress had wished . . . to cover all human subjects research, rather than just biomedical and behavioral, it could have done so."[2][1]

The Common Rule should reflect the underlying statutes and apply only to biomedical and behavioral research.

The Common Rule should cover only research methods that have proven risky

The ANPRM notes that "While physical risks generally are the greatest concern in biomedical research, social and behavioral studies rarely pose physical risk but may pose psychological or informational risks. Some have argued that, particularly given the paucity of information suggesting significant risks to subjects in certain types of survey and interview-based research, the current system over-regulates such research." I agree with the latter assessment.

Both the statute and the regulations were designed to address concerns raised in the 1973 Senate hearings. As the secretary of HEW explained in 1976,

The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 USC 289 1-3 (added by Pub. L. 93-348) . . .

The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psycho-surgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devises; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study; the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human in vitro fertilization . . .[3][2]

The hearings did not address the risks of survey, observation, and interview-based research. Nor has the experience subsequent decades shown that this kind of research is particularly risky. One can find exceptions, but these are rare. Stuart Plattner put it well in 2006. "In all the years I was responsible for human-subjects issues at NSF, I never learned of one case in which a respondent was actually harmed from participation in anthropological research." He concluded, "although the possibility of harm to participants in ethnographic research is real, the probability of harm is very low."[4][3]

As the ANPRM notes, "Over-regulating social and behavioral research in general may serve to distract attention from attempts to identify those social and behavioral research studies that do pose threats to the welfare of subjects and thus do merit significant oversight."

Different scholarly disciplines adhere to different ethical codes

The U.S. IRB system was designed by experts in the ethics of medical and psychological experimentation. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote the Belmont Report without any regard to the ethical codes developed by journalists or scholars in the social sciences and the humanities, and it is a poor fit for their work. Its insistence on the equitable selection of subjects is simply irrelevant when a researcher chooses people based on their unique characteristics. More significantly, instructions to "do no harm" cannot apply to investigative journalism and other forms of critical inquiry. IRBs have consistently proven themselves unable to make this distinction.[5][4]

The new "excused" category may not work for research in which real names are the norm

When institutions do impose IRB authority on oral history and other research in which participants are generally identified, they can generally rule it exempt under the current Common Rule. But this category may disappear under the present proposal.

If that happens, this kind of research would be an awkward fit for the new "excused" category, which emphasizes privacy. While the new category rules "allow subjects to authorize researchers to disclose the subjects' identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition," its clear emphasis is on preserving the confidentiality of information. The present Common Rule does not require anonymity, but its emphasis on confidentiality has led IRBs to impose inappropriate demands

on researchers, such as requiring oral historians to anonymize their narrators or destroy recordings and transcripts. If, as is likely, institutions determined that real-name research was not eligible for the new excused category, IRBs would find themselves reviewing research the ANPRM considers only a distraction.

Alternatively, institutions allow real-name research to proceed under the excused category. But if that were the case, then historians, journalists, and folkorists would find themselves submitting forms that said only that they did not intend to follow most of the provisions of the excused category. This would be nothing but a waste of time and paper.

Non-generalizability has proven an unreliable tool

ANPRM's Question 25 hints that regulators are considering letting journalists, historians and other humanists off the hook by declaring their work to be non-generalizable, and therefore not subject to regulation under the Common Rule.

The advantage of this approach is that it has something of a track record. The idea that "journalism, history, biography, philosophy" generally fall outside of the regulatory definition of research because they are not generalizable dates back at least to the 1999 report of the Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council, which argued that

a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the definite purpose of contributing to generalizable knowledge. Research can include a wide variety of activities including: experiments, observational studies, surveys, tests, and recordings designed to contribute to generalizable knowledge. It generally does not include such operational activities as: medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, program evaluation, fiscal or program audits, journalism, history, biography, philosophy, "fact-finding" inquiries such as criminal, civil and congressional investigations, intelligence gathering, and simple data collection or data collection for other purposes. However, some of these activities may include or constitute research in the specific circumstance where there is clear advance intent to contribute to generalizable knowledge with a formal scientific protocol.[6][5]

In 2003, OHRP ruled that "most oral history interviewing projects are not subject to the requirements" of the regulation "primarily on the grounds that oral history interviews, in general, are not designed to contribute to 'generalizable knowledge.'"[7][6] Most of the university policies excluding oral history from IRB jurisdiction do so on the grounds that it is not generalizable.

The ANPRM seems to suggest that the 1999 position might be "explicitly" written into the Common Rule, thus locking it in place and giving historians and narrators the freedom to converse without seeking official permission. For example, the Common Rule could be amended to read

For purposes of this policy, research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. This policy does not cover such operational activities as: medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, program evaluation, fiscal or program audits, journalism, history, biography, philosophy, "fact-finding" inquiries such as criminal, civil and congressional investigations, intelligence gathering, and simple data collection or data collection for other purposes.

If this were to happen, it could be a boon for scholars, research participants, and administrators alike. So the obvious response would be for historians and others to reply, "Why, yes, now that you mention it, we do not create generalizable knowledge!"

Yet this would leave problems.

For one thing, non-generalizability has proven an unreliable tool. OHRP has muddied the waters, apparently contending–for example–that "Open ended interviews are conducted with surviving Negro League Baseball players in

order to create an archive for future research" would constitute generalizable research because "the creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research."[8][7]

This conflicts with OHRP's earlier determination that "oral history interviews, in general, are not designed to contribute to 'generalizable knowledge." If generalizable means that some future researcher might conceivably use the information, then nothing is non-generalizable. Do not daily newspapers; criminal, civil and congressional investigations; and disease monitoring all create an archive for future research?

Moreover, as Robert Townsend of the American Historical Association has noted,

The argument [that oral history is not generalizable] prompted some derision from outside the field, from academics who interpreted the phrase to say simply "history is not research." (As a case in point, the vice president for research at my own university, after a fairly contentious meeting on the subject, wished me well on my "non-research dissertation.")

We also received a number of complaints from within the discipline. Some historians argue that history does contribute generalizable knowledge, even if it bears little resemblance to the scientific definition of the word. And faculty members at history of medicine departments and in the social science side of history warned that this position undermined both their institutional standing and their ability to obtain grants. They made it clear that however finely worded, stating that history did not constitute research in even the most bureaucratic terms could have some real financial costs to the discipline.[9][8]

More fundamentally, no one can be sure what generalizable means. It is left undefined in the Common Rule. The Belmont Report version is longer, but hardly more helpful:

The term 'research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

This goes some way to distinguish research from diagnosis of an individual patient–the main goal of that section of the Belmont Report–but I am not even sure of that; I would hope that an MRI operator diagnosing a patient has an objective and a set of procedures designed to reach that objective.

Nor does it distinguish science from journalism, which regularly permits conclusions to be drawn and expresses statements of relationships.

Conversely, qualitative social scientists debate whether their work is generalizable. So "generalizable" covers research that the National Commission did not want covered and leaves uncovered research that the Commission did seek to regulate.

Serious observers have noted the problem. Tom Beauchamp recently complained that "generalizable knowledge," like other terms, "can be understood in several ways."[10][9] Rena Lederman has found that "the regulatory definition did little to resolve the very ambiguities within medical practice for which it was designed. Heroic efforts of clarification can be found in works that interpret the Common Rule for IRBs. Nevertheless, to this day it continues to be a frequent topic of debate in IRB circles."[11][10] And in 2008, David Strauss of the Secretary's Advisory Committee on Human Research Protections complained that "we shouldn't be reviewing research that we don't think needs to be reviewed because some folks 30 years ago, at the end of a long, hot day, decided to use the word 'generalizable' . . . We have to have language that makes sense to us."[12][11]

The Common Rule can be rewritten to exclude the research that should not be subject to oversight

I can imagine various ways to align the Common Rule with the statutes and the known risks. One would be to exclude particular types of research from the scope of the regulation.

In 1979, twelve scholarly and educational organizations offered the following formula:

These regulations do not apply to research using legally competent subjects that involves neither deceit nor intrusion upon the subject's person nor denial or withholding of accustomed or necessary resources.[13][12]

In 2006, the American Association of University Professors offered similar proposal:

Research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, [shall] be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.[14][13]

Either one of these would achieve the ANPRM's goal of "facilitating valuable research and reducing burden, delay, and ambiguity for investigators." There should also be a provision for community research that might involve children or adults who are not legally competent. For example, an anthropologist living in a community should not trigger IRB review simply because he or she occasionally speaks to a child.

The regulatory definition must change

In addition, the regulatory definition must change. The Common Rule currently claims to regulate "research" even though it has no statutory authority to do so. It should be rewritten to emphasize its applicability only to biomedical and behavioral research.

For example, in place of the current definition of research, it could present a definition of biomedical and behavioral research:

Biomedical and behavioral research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge about the structure and function of the human mind and body. It does not include research about specific individuals, social groups, or organizations.

Alternatively, we could borrow language about "health information" from 46 CFR 160.103 and insert it in the Common Rule:

For purposes of this policy, research means biomedical and behavioral research.

Biomedical and behavioral research means an investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge by systematically collecting health information. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Health information through intervention or interaction with the individual, or

(2) Identifiable private health information.

Health information means any information, whether oral or recorded in any form or medium relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. It does not include incidental information about an individual's health, such as the mention of a past illness in the course of an interview about a broad range of subjects.

Either of these definitions would achieve many of the objectives of the ANPRM and bring the regulations into compliance with the underlying statute.

I do not expect that this definition will resolve all cases; every definition has a core and hazier penumbra.[15][14] I therefore urge the establishment of a federal body that will offer guidance on the hard cases after consulting the scholarly societies whose members will be affected.

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[27][12] J. W. Peltason, "Comment on the Proposed Regulations from Higher Education and Professional Social Science Associations," *IRB: Ethics and Human Research* 2 (February 1980), 10

[28][13] “AAUP: Research on Human Subjects: Academic Freedom and the Institutional Review Board”, 2006, http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm.

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Anonymous (2011-09-26 20:57:19)
Could you clarify the difference between behavioral science and social science?

Zachary M. Schrag (2011-10-05 10:47:25)
Thanks for this question. I have responded with a new post: [1]What is Behavioral Research?

1. http://www.institutionalreviewblog.com/2011/10/what-is-behavioral-research.html

6.9.8 ANPRM Comments: Oral Historians Call for Exclusion from Common Rule (2011-09-26 23:55)

Of the [1]253 public submissions filed in response to the ANPRM as of 26 September 2011, 17 showed up in a search for the term "oral history."
One, submitted by Nancy M. P. King, JD, and Ana S. Iltis, PhD of the Wake Forest University Center for Bioethics, Health, and Society, calls for IRB jurisdiction over oral history and journalism. No First-Amendment champions they.
Another, from [2]Julie Ozier, Assistant Director, Institutional Review Board, Vanderbilt University, briefly answers Question 25, "Yes, oral history since again the projects are ill defined (by design) and it take[s] a willing participant to provide their 'story.'"
The remaining 15 come from historians who have been burned by IRBs and want a way out. Just two of them, Kathryn Edgerton-Tarpley and Alan Lessoff, see merit in the proposed Excused category; the rest want nothing at all to do with IRB regulations.
Edgerton-Tarpley wins the prize for best horror story, in which she relates how the San Diego State IRB proved more censorious than the Chinese government. Runner-ups are the reports submitted by James Williams and Kristin Hoganson about the chilling effects on student work .
Here are the comments, in order of their posting:

Blake Slonecker, Waldorf College, August 15

I am a historian who studies social activism in the 1960s and 1970s. As a result, oral history is a vital component of my source base. The IRB process–both in graduate school and at my first academic position–has been a continual thorn in my side, without providing any of my interview subjects with additional protections. In fact, very often the IRB paperwork has made subjects far less inclined to participate in the study, despite minimal risks. Eliminating the IRB process for oral histories that meet certain basic criteria would be a boon not only to me and my colleagues, but

to our interview subjects as well. Thank you for your consideration.

Thomas Scott, Kennesaw State University, August 15

I would like to argue that oral history should not be covered by the Common Rule and therefore should not be subject to IRB supervision. Oral history differs from research in scientific fields in a number of important ways. Rather than conducting anonymous surveys for the purpose of generating statistical data, oral historians concentrate on individual memories and ask narrators to sign a release, giving the copyright for the interview to the interviewer or to the library, archive, museum, or other organization that will house the interview. While medical and psychological examiners for obvious reasons need to protect the privacy of their subjects, oral historians in all but the most sensitive cases must be able to cite the names of the people they interview and when and where the interview was conducted. Otherwise, their research will have little credibility with other historians. While scientific researchers typically work from a script and ask all subjects the same questions, oral historians are trained to start with a minimal number of open-ended questions, listen to what the interviewee says, and then follow-up with unscripted questions designed to elicit more detail or to pursue a line of inquiry that was unanticipated before the interview began. I have headed an oral history project at Kennesaw State University since 1978, and it seems to me that the most important information I have gathered has come from unscripted follow-up questions after interviewees expressed opinions and provided information that were interesting, relevant, and unexpected. For several decades the Oral History Association has published a statement on "Principles and Best Practices." The OHA guidelines say a great deal about ethical behavior and protecting interviewees from possible harm. In my own project, I have always returned edited transcripts to the interviewees to give them a chance to rethink and correct what they have said before I open the interview to the public. Following the OHA guidelines, I have always called to their attention any part of the interview that could possibly be libelous or could in any way cause them harm. While oral history is clearly a form of research, it is very different from scientific research and should not be subject to the same requirements that are needed in other fields.

Nan Mullenneaux, Duke University, August 15

I was so pleased to learn that Research Protections that govern oral history research may be streamilined. I fully support the American Historical Association's ideas for separating oral history from other more dangerous research involving human subjects., but maintaining its status as "research" to allow for financial support. As a professor, I have many students interested in oral history but put off by the complex paperwork and seemingly inappropriate instructions. I support restrictions that demand sensitivity, responsibility, and accountability, but not those that hamper rigorous investigation. Thank-you.

Robert Luckett, Jackson State University, August 15

As a historian, I am writing to ask that the application of completely inappropriate rules and criteria to historical research be reconsidered, particularly through what has constituted a growing, intrusive IRB process that discourages the pursuit of oral history. I ask that HHS consider the complete exclusion of certain forms of research such as oral histories from the "Common Rule" governing human-subject research.

Gabrielle Spiegel, Johns Hopkins University, August 15

I would like to argue that historians should be exempted from having to procure IRB approval when doing Oral history research. The goals of oral history research are often fundamentally at odds with the procedures and particular forms of protection of human subjects required for IRB approval of research. Notably, it is often the name of a person and his or her specific relation to a past historical event that makes their testimony valuable. Having to suppress such facts therefore vitiates the force , authority and authenticity of the material collected in interviews. Although this is not invariably the case, it is true enough of the time to make IRB approval a hindrance to well-conducted and reported historical research on contemporary topics, in which the existence of living witnesses provides valuable information which cannot be procured in other ways. I strongly urge the IRB to consider exempting historical work from its review

procedures and protocols, which are designed for scientitic, not humanistic research. I write as a past President of the American Historical Association who worked closely with oral historians to try to amend the regulations governing their activities.

Kathryn Edgerton-Tarpley, San Diego State, August 16

I am writing to you to express my strong support for the current proposal to re-evaluate the rules governing human-subject research. As a professor of modern Chinese history, oral history is an important part of my research on Chinese responses to and cultural constructions of famines and floods. I also supervise M.A. students who have tried to conduct oral history in China. Having been through the IRB process at my university in 2008, and having tried (unsuccessfully) to help an M.A. student negotiate the process last year (2010), I can say from experience that the policies and procedures of the IRB create significant and wholly unnecessary hurdles to conducting good oral history research.
The IRB wanted detailed information about who I would interview in China, and prior approval of the questions I would ask each interviewee. Anyone who has conducted oral history, however, knows that the historian often learns of new interviewees as he/she conducts his/her work, and that the freedom to ask new questions based on information an interviewee has raised is absolutely crucial. This meant that the questions I actually asked interviewees in China often differed significantly from those the IRB had approved before I began my work. The demand that I have interviewees fill out written consent forms also proved quite off-putting to many of my Chinese respondents. In sum, the demands of the IRB bear little resemblance to the actual process of conducting good oral history research, in China or elsewhere.
While my proposal did eventually receive IRB approval, my M.A. student's proposal was rejected so many times that she eventually gave up her plan to conduct oral history research in China. My student had met with several visiting professors from one of my university's sister universities in China, and had arranged to travel to that Chinese university to interview Chinese women there about their view of China's One-Child policy. The IRB repeatedly rejected her list of questions, even though her supervising professors had approved them, and demanded more information and tighter parameters than were possible for my student to provide before she arrived in China. Because my student wanted to interview well-educated adult women about a widely-known policy, her project posed minimal risk. However, the IRB proved so slow and so unreasonable that the entire spring semester and summer passed without a resolution, and in the end my student had to cancel her trip to China and rely on text-based sources alone. In short, the intrusion of overzealous IRB oversight into a very low-risk project robbed this M.A. student of an important, exciting opportunity to conduct oral history in China and include current Chinese voices in her thesis.
In conclusion, it is time for the HHS to stop extending to oral history rules that were established to protect human subjects from dangerous medical and psychological experiments. There is no need for such intrusive oversight of projects that simply ask consenting adults to talk about their life experiences. Adult interviewees can easily choose not to answer questions that make them uncomfortable or that might in some way bring them harm. I thus urge the HHS to recommend a new category, "Excused" to cover research that poses "no more than minimal risk," involves only "competent adults," and includes reasonable "data security and protection standards."

Anna Krome-Lukens, PhD Candidate, History, University of North Carolina at Chapel Hill, August 16

As both a research assistant for UNC's Southern Oral History Program and a historian with many colleagues who use oral history in their research, I'd like to submit my opinion that oral history interviews should be exempt from IRB requirements. While IRB guidelines certainly have a valuable function in the health and social sciences, they often require things of oral historians that are impossible, given the methods of our discipline. For example, IRB regulations often require researchers to submit a list of interview questions as part of the pre-research approval process. This procedure is anathema to oral historians, who prepare assiduously for each interview but never know where the interviewee's recollections will take them. Regulation of oral history is best left to the ethical standards of the discipline; there is no reason for Institutional Review Boards to be involved.

James Williams, Albert Gore Research Center, Middle Tennessee State University, August 16

As a professional historian and practitioner of oral history for more than twenty years, I urge the Department of Health

and Human Services to exempt the vast majority of oral history projects and interviews from Institutional Review Board oversight. Oral historians instead should fall under the regulations and standards promulgated by the Oral History Association and adopted by many professional historical organizations. The archive that I direct conducts one of the largest oral history projects in Tennessee. We participate in the Veterans Oral History Project (Library of Congress) and have completed oral history project for the National Park Service. Students under my supervision conduct oral history interviews for their undergraduate and graduate courses. We provide a valuable historical service to various publics by conducting these projects that, frankly, have been slowed down, impeded, and reduced in scope by the requirement to submit each and every interview and project to our IRB. As 99 % of our interviewees do not come from vulnerable populations, to force regulations for that vast majority for the sake of the very occasional project that potentially could deal with a vulnerable population is a great example of administrative overreach. The federal government's interest in oral history should be negligible. I find it ironic that I can conduct oral history projects as a contractor for federal agencies who do not feel bound by HHS regulations on oral history (as they have their own policies and protocols, which are entirely less burdensome than HHS's). However, to conduct an interview on my own campus–only because of fear of the loss of federal funding–triggers hours of needless work on my part and on the part of the IRB members to rubber stamp a project. It is time once and for all for common sense to prevail, for HHS to listen to the history professionals, and to state clearly that its protections do not apply to oral history projects.

David K. Robinson, Professor of History Truman State University, August 23

Oral History projects have been unduly burdened by Institutional Review protocols that really have nothing to do with oral history. For this reason I want to support a letter, to this effect, that was sent to the Office of Human Research Protections, back in 2007. Please find that letter at the following link: http://www.historians.org/press/OralHistoryExclusionLetter.pdf I will quote only the conclusions: We believe that "oral history" should therefore be removed from category 7 and explicitly exempted from IRB review. Given our research into the way these policies are infringing on historical research that poses minimal risk of harm, we side with the recent recommendation from the American Association of University Professors, that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."2 However well meaning and well intentioned the original decision to include oral history in Category 7, in practice, the application of these rules to oral history are not appropriate and fundamentally impede and abridge scholarly work in our discipline. The proposed changes to category 5 seem to increase the likelihood that the harm being done to current members of our profession will be extended to future generations, as the simple gathering and use of such materials will become more circumscribed and difficult. Thank you for giving me this opportunity to support our efforts to clarify this policy.

Simson Garfinkel, August 29

Regarding question 25, I have been troubled by the inconsistent application of the Common Rule to many fields not originally envisioned. The ANPRM mentions history, language, literature and journalism: these are all problem areas. As a practicing journalist I have frequently noted that I do not require IRB approval to do federally funded journalism but I do require IRB approval to do federally funded scientific interviews. I have seen problems in ethnography and anthropology as well: few IRB's are willing to approve a multi-year protocol that say, essentially, "I'm going to live with the natives, talk to them, take notes on what they say, and publish a book in 5-10 years." Yet this is the basis of both many journalistic and ethnographic endeavors. Today the only way to work such efforts is to argue that it is not scientific research. This has caused problems for political scientists and ethnographers, who maintain (rightly or wrongly) that they are engaged in scientific research.

Efforts to extend the Common Rule to journalism are particularly troublesome, both because of First Amendment issues, and because journalism seems to violate the "Beneficence" principle of the Belmont Report. That is, it is rarely in the interest of a politician or a business leader to speak with a journalist!

Likewise, I am troubled by the longstanding application of the Common Rule to oral history projects, as these projects

are essentially journalistic in nature. The common rule should be revised to explicitly state that history, oral histories, language, literature, journalism, and ethnography are not subject to its requirements, especially when experimenters in these areas employ unstructured interviews that use journalistic methodology. Yet I have seen many oral history projects encounter IRB problems. I personally offered tapes of many oral histories that I had collected in the 1980s and early 1990s to an oral history project and had my efforts rebuffed because I did not have IRB approval when I performed the interviews.

Alan Lessoff, Professor of History, Illinois State University, September 6

I would like to add my voice to those professional historians who are calling for implementation of something like an "excused" category to apply to most oral history. I say this as a current departmental IRB representative and someone with long experience in other capacities with the issue. The research of my professional colleague, Zachary Schrag, documents what many of us have long known: that there has never been a persuasive rationale for the extension of IRB oversight to oral history or similar forms of social science and humanities research. Also, as Schrag likewise explains and as many of us have experienced directly, the overall structure, emphases, and priorities of the IRB system make the system a poor fit for the types of ethical issues that oral historians face most of the time. One could provide many, many examples gathered over the years to support this position. At my university, colleagues who run the IRB and the adminstrators who manage it are generally sympathetic to the problem and work to carry out their duties in a constructive way. But understandably, their priorities are psychological and educational research, crucial at our university. Historians submitting protocols continually face irrational amounts of frankly irrelevant work to conform to the guidelines. Unlike Schrag, I do not believe that history should be removed from human subjects protection regulations altogether. Our colleagues in other departments have a legitimate interest in monitoring the ethical character of our research. But only some sorts of oral history research–for example medical history, criminal-justice history, and some forms of family or social-welfare history–truly conform to the intention and procedures of the IRB system. The contemplated "excused" category provides a middle ground, since it requires historians to document that they are following appropropriate ethical practices, but only in relevant cases would a protocol be necessary.

Kristin Hoganson, University of Illinois, Urbana-Champaign, September 15

My field is the 19th century, so I do not apply for IRB approval for my own work. But I have found that including History as an IRB field has a chilling effect on teaching. My students can no longer interview friends, neighbors, relatives, etc. about their service in World War II or Vietnam. They can no longer ask grandma or grandpa questions with the intention of using their answers to add an oral history component to their research papers. I have advised a student in the McNair Program (aimed at encouraging underrepresented students to become college professors) who used up most of the time he should have spent doing his research trying to get IRB approval. I have other students change their research topics so as to avoid the IRB process. Why can journalism students call me up for comments without IRB approval but my students cannot ask anybody questions? This seems like a freedom of speech violation. When I worked with my McNair student to get IRB approval, I was directed to websites full of information about medical experiments. This is completely irrelevant to what we Historians do. Like journalism students, we ask people questions, which they can choose to answer or not. My students have no power of coercion. Indeed, pre IRB days, they used to report that older people loved to have an audience for their stories. I think oral history, like journalism, should be exempt because the line between them is a blurry one indeed.

Harold Cook, Brown University, September 21

I am acutely aware of how the regulations on human subject research, when applied to oral history research, can handicap research and the presentation of research. I urge you to think carefully about whether the regulation of human subjects research, which should of course apply to biological research, also applies to research that is non-intervensionist, without even touch involved. Research that involves no biological intervention should be free of the regulations that apply to human subjects research. Thank you.

Troy Reeves, University of Wisconsin-Madison Libraries, September 23

As the head of a campus oral history program, I submit my comments with the hope that they can lead to a world on campuses around the country where oral history projects are as best exempted from the current IRB review or at least current IRBs are given specific language to fast track oral history projects with as minimal review as possible. As the current system stands, IRB can delay or stifle the collection of history on campus. I do not or will not argue that people doing oral history on campus need some type of guidance, oversight, or support. But this can be done using tools, such as the Best Standards and General Principles of the Oral History Association, or putting humanists on IRBs to add to the board a voice that understands and can argue for the difference in oral history or similar type interviewing that the interviews that should fall under IRB review. It can also be done by changing the language to either place oral history and similar type interviewing outside the IRB bounds.

Samuel Martland, September 26

Please put new human-subject research rules in place that are appropriate for the ethical practice of oral history. That means allowing open-ended oral history interviews, allowing historians to identify interviewees (subjects) who agree to be identified, and generally operating on the assumption that interviews and conversations have minimal risk. It is, frankly, silly that some IRBs have barred historians from undertaking the kinds of interviews that reporters, historical society members, and kids in high school do routinely without IRB review, and which practically no one has ever said are risky. I have never done oral history myself, since I am a nineteenth-century specialist, but I know that good historical research requires following the thread of the evidence and asking further questions. Sometimes I also wonder whether chatting with another historian is "human subject research," and then I realize the absurdity of the situation. As a historian, I am most familiar with the plight of oral historians before IRBs, but I think the new rules should also extend to literary scholars talking to authors, political scientists interviewing political leaders, linguists getting samples of dialects, and pretty much any other research about people that has no reasonable chance of being any more harmful than any other day-to-day conversation. I don't think it's productive to say that oral history isn't covered because it does not produce generalizable results. The rules should be based on what the researcher is asking the human subjects to do, or what kind of information s/he's asking them to reveal, not on what the final product of the research will look like.

1. http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=HHS-OPHS-2011-0005

2. http://www.mc.vanderbilt.edu/irb/contact/

6.9.9 Tuchman Reviews Ethical Imperialism (2011-09-29 15:27)

Gaye Tuchman, author of [1]Wannabe U: Inside the Corporate University, reviews Ethical Imperialism for Contemporary Sociology: A Journal of Reviews.
[Gaye Tuchman, "Review of Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009," Contemporary Sociology: A Journal of Reviews 40, no. 5 (2011): 617 -619.]
As a sociologist, Tuchman enjoyed the sections dealing with the history of her discipline. "It is a real treat," she writes, "to read how Ithiel DeSola Pool, James Davis, Albert Reiss, Howard Becker, Edna Bonacich and Jack Katz all more or less agreed that the regulations harm social science."
Tuchman apparently disagrees with Donald Bersoff's sense that [2]"Schrag, as an academic historian, has an axe to grind." She writes,

> this scholarly book does not read like the result of anger. Rather, it is the dry and thoroughly researched story of how IRBs came to be, how they came to adopt rules designed for medical, biological,

and psychological researchers and then to apply them to the social sciences, how those rules became institutionalized, and how the rules protect universities rather than the people who serve as subjects and informants in social science research.

Tuchman herself finds that

> IRB regulations and especially their application to social science are examples of an accountability regime, a politics of surveillance, control, and market management that disguises itself as the value-neutral and scientific administration of individuals and organizations that increasingly dominate American higher education. At colleges and universities, the accountability regime is itself redolent of neoliberalism, an approach to socio-economic policy that lauds the efficiency of private enterprise, promotes the effectiveness of managerial oversight by fostering individual and institutional accountability, and seeks to increase the role of the private sector in determining the political and economic priorities of the state. IRBs are just one piece of the new higher-education complex that has been mandating missions statements and strategic plans, encouraging profit from (copyrighted) research, assessing teaching practices, fiddling with faculty governance, and expanding the (largely powerless) contingent labor force.
> IRBs protect universities, not researchers, not the subjects or informants whom social scientists observe and interview. At my own university, I can think of graduate-student projects that (I believe) the IRB killed, because the research would have made the university look bad.

1. http://www.press.uchicago.edu/presssite/metadata.epl?mode=synopsis&bookkey=342121
2. http://www.institutionalreviewblog.com/2011/05/bersoff-reviews-ethical-imperialism.html

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6.10 October

6.10.1 AHA Warns of ANPRM's HIPAA Proposals (2011-10-03 14:04)

Rob Townsend of the American Historical Association warns of the ANPRM's idea of subjecting a broad range of data to protections bassed on the provisions of the Health Insurance Portability and Accountability Act (HIPAA). If this proposal is implemented carelessly, historians could find themselves barred from some archival research.
[1]"Could History Become an Information Risk'?," AHA Today, 28 September 2011.

> If these new restrictions were implemented in a uniform way to encompass all research subject to IRB review, they could extend even to archival research and effectively make those restrictions permanent. For a number of years now, former AHA Council member Linda Shopes has been warning that the rules could lead to regulations on archival research "simply because they deal with the activities of human beings." The new proposal makes that possibility quite explicit, by encompassing "researchers' use of pre-existing data (i.e. data that were previously collected for purposes other than the currently proposed research study)" and insists that a researcher acquire "written consent" if he or she "obtains information that identifies the subjects." The proposal is not clear about whether consent agreements obtained by the original interviewer or host archive would be adequate for subsequent research, but the general tendency in these regulations to seek "one size fits all" solutions makes this deeply worrisome.

The post encourages AHA members to submit comments in response to the ANPRM. "At the very least, the regulations should allow for some sort of sunset provision—similar to those for U.S. census data—to assure that someday historians will be able to make use of the information collected in the present."

1. http://blog.historians.org/articles/1424/could-history-become-an-information-risk

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6.10.2 What is Behavioral Research? (2011-10-05 10:46)

An anonymous comment on an [1]earlier post asks, "Could you clarify the difference between behavioral science and social science?"
Robert Veatch stated the basic problem in his 1973 testimony to the House Subcommittee on Public Health and Environment:

> If the proposal before us is an act for the protection of human subjects of biomedical and behavioral research, it is crucial to have a clear understanding of what constitutes "behavioral research." I note that in the definitions (sec. 1213) the term is nowhere defined. It may have two meanings. To many social scientists it will have a rather limited meaning–research in behaviorist psychology–while to the layman it may mean more broadly any research to study human behavior including all social scientific investigation. It is my hope that the intent of the bill is to use the latter meaning. If not, the act may be considerably less inclusive in application than the present HEW guidelines, which clearly are meant to apply to all social scientific research (in which subjects are 'at risk). To leave such ambiguity is a tragedy.
> [U.S. House of Representatives, Biomedical Research Ethics and the Protection of Human Research Subjects: Hearings before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce (93d Cong., 1st sess., 1973), 240]

Veatch was right about the tragic ambiguity of the statute. But I do not think he was right about the laymen's understanding of behavioral research, at least if laymen are to include congressmen and senators. As [2]the secretary of HEW noted in 1976, "The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 U.S.C. 289l-3 (added by Pub. L. No. 93-343) . . ."
Congress took almost no testimony about social science (e.g., it did not invite Laud Humphreys to testify), and nothing resembling testimony about the humanities. It did take testimony about behavioral control, and available evidence suggests that it was to oversee that kind of research that the word "behavioral" was included in the statute.
(Much more on this in [3]Ethical Imperialism.)
If we are to align the regulations to the wording and intent of the statute, we have two choices. 1. Define behavioral by method (e.g., intervention, not interaction.) 2. Define behavioral by subject matter (designed to study mental and physical health, not social conditions.) Either could lead to improvements.

1. http://www.institutionalreviewblog.com/2011/09/anprm-question-25-read-statute.html
2. http://www.hhs.gov/ohrp/archive/documents/19760624.pdf
3. http://jhupbooks.press.jhu.edu/ecom/MasterServlet/GetItemDetailsHandler?iN=9780801894909&qty=1&source=2&viewMode=3&loggedIN=false&JavaScript=y

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6.10.3 Compliance Administrator Wants ANPRM to Address Subparts (2011-10-10 16:17)

Writing for PRIM &R's blog, amp &rsand, [1]Wendy Tate, assistant director of process improvement and compliance at the University of Arizona, complains that the ANPRM fails to address the subparts of 45 CFR 46.

[Wendy Tate, "[2]What's Missing in the ANPRM?," amp &rsand, 5 October 2011.]
Tate points to [3]Subpart B, which imposes special restrictions on research involving pregnant women. She writes,

> Subpart B is a good discussion point for understanding how important it is for the subparts to be included in the ANPRM discussion. Having been a pregnant woman myself and speaking to other women who have been pregnant, there are very few times in a pregnancy when a woman is vulnerable. These times generally center around labor and delivery. Pregnant women make decisions every day that can affect their unborn children. These decisions range from what to eat and drink, to taking prenatal vitamins, to long distance travel, to choosing medical care. Research needs to be done in this population.
> The FDA has stated that excluding pregnant women from clinical trials is unethical. Revision or removal of subpart B will go a long way toward harmonizing regulations and gathering important information on how drugs work in women, as well as to avoid the discriminatory status of being a "woman of childbearing potential." It seems to me that combining necessary changes to the subparts with the ANPRM review process would be the most expeditious way to accomplish this.

So far, so good.
[4]Subpart C could also use rethinking, since it was written with biomedical research in mind but has been used to [5]block important social research requiring interviews of prisoners.
[6]Subpart D could also use reconsideration. It limits research on children, defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." But what jurisdictions specify the legal age for being interviewed, surveyed, or observed? This confusion between patient and subject disrupts important research on adolescents.
Canada has made progress on these fronts. Article 4.3 of the 2010 TCPS states that "Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding." And Article 4.4 states that "Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage." The TCPS does not offer similar language about prisoners, but neither does it suggest restrictions as strict as those of Subpart C.

1. http://primr.blogspot.com/2010/11/meet-prim-blog-squad-wendy-tate.html
2. http://primr.blogspot.com/2011/10/whats-missing-in-anprm.html
3. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
4. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
5. http://www.institutionalreviewblog.com/2007/05/scott-atran-research-police-how.html
6. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd

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6.10.4 AAUP Posts ANPRM Comments (2011-10-13 23:55)

The American Association of University Professors has posted [1]a reply to the ANPRM. I am proud to have contributed to this document.

1. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0371

6.10.5 AHA Posts ANPRM Talking Points (2011-10-18 10:10)

The American Historical Association (AHA) has issued a set of "talking points" to "invite comments and concerns from members as we craft our response, and as a guide to historians and related specialists looking to craft their own

response to the federal proposal."
Robert B. Townsend, "[1]Oral History and Information Risk: A Response to the Federal Proposal," AHA Today, 17 October 2011.
The main argument is for "the full exclusion of oral history from IRB oversight," rather than its incorporation into the proposed "Excused" category. In addition, the talking points warn that new proposals for the use of existing data could set "an impossibly high bar for the future use of archival or public use data sources will seriously inhibit our understanding of the past, including future projects that would hold scientists accountable for their misuse of research subjects (such as the recent study exposing U.S. research practices in Guatemala in the 1940s) . . ."
The AHA has not yet drafted a formal comment, which will, I hope, translate these broad points into responses to specific questions in the ANPRM. But historians can use the talking points to alert regulators to the key issues involved.

1. http://blog.historians.org/news/1439/oral-history-and-information-risk-a-response-to-the-federal-proposal

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6.10.6 OHA Endorses AHA ANPRM Talking Points (2011-10-19 10:51)

The Oral History Association Council [1]has endorsed the talking points on the ANRPM posted earlier by the American Historical Association, and it is encouraging its members to submit an abbreviated version of them as a formal comment to HHS.
h/t: [2]Rob Townsend.

1. http://www.oralhistory.org/2011/10/18/oral-history-and-information-risk-a-response-to-the-federal-proposal/
2. http://twitter.com/#!/RBTatAHA

6.10.7 Rohde Reviews Ethical Imperialism (2011-10-21 08:36)

Joy Rohde, assistant professor of history at Trinity University, reviews Ethical Imperialism for the Journal of American History and finds it "a valuable contribution to the history of federal science policy and a useful critique of a system ill-suited to the uses to which it is being put."
[Joy Rohde, Review of Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009, by Zachary M. Schrag, Journal of American History 98 (2011): 600, doi: [1]10.1093/jahist/jar274.]
Rohde writes,

> Schrag's evidence leaves no doubt. Federal commissions repeatedly failed to recognize important distinctions between the methods and subjects of biomedical and psychological research and those of the social sciences. In some cases, like that of the Belmont Report (1978), policy makers failed to seek appropriate outside advice from qualified researchers. In others, such as that of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974–1978), policy makers listened to input from social scientists, yet inexplicably wrote rules that papered over difficult disciplinary and ethical distinctions.

Rohde does find that "Schrag's evidence also indicates that social scientists' plight might be, in part, their own doing. Social scientists have repeatedly failed to reach consensus within their own disciplines about the ethical limits of

methods such as deception, the ethical threats posed by certain forms of research sponsorship, and the abilities of their own professional associations to serve as ethics police forces."
This is a good description of the 1990s, but in the 1960s and 1970s, social scientists achieved a remarkable consensus about IRBs. Here's hoping the 2010s will reprise those earlier efforts.

1. http://dx.doi.org/10.1093/jahist/jar274

6.10.8 Anthropologists' ANPRM Comments Call for Free Inquiry (2011-10-22 21:33)

The [1]American Anthropological Association has posted comments on the ANPRM to the regulations.gov website. Composed by AAA Committee on Ethics member Lise Dobrin and former Committee chair Rena Lederman, the 23-page document is stunningly eloquent and thorough in its indictment of the present IRB system and the shortcomings of the ANPRM. And it offers two bold and constructive suggestions that could point the way to a true reform.

The comment is organized in the haphazardly ordered sequence of the ANPRM's questions. Here, I extract some major features.

Critiques of the Status Quo

Taken together, the comment's descriptions of the status quo present a bleak picture.

Even though their modes of planning differ from the experimental designs that IRBs expect, folklorists, interpretive sociocultural anthropologists and the like consider what they do to be research (in their respective disciplinary senses), present it as such to their IRBs, and are therefore advised by IRBs to submit applications. However, when they do so, their protocols are evaluated as 'poorly designed': as bad research, rather than simply not 'research' (in the present regulatory sense).

Anthropologists preparing to engage in participant observation routinely experience review of their protocols by board members who lack expertise in the standard methods anthropologists employ . . . This situation has demoralized individual researchers and encouraged widespread cynicism about the value of regulatory oversight.

Our colleagues have reported that many rounds of requests for clarifications and changes can be as discouraging as outright disapproval.

> While we were preparing these comments, one anthropologist mentioned to us that she was forced to model her consent documents for classroom observations and interviews on forms designed for medical interventions such as intubation. Her IRB prevented her from adjusting her consent forms—using language that would be clear and pragmatically appropriate for the study population—to facilitate truly informed consent. We must recognize that foreign participants can be baffled and overwhelmed by procedures that Americans take for granted, such as 'initialing' a line.

The comment is particularly effective in its insistence that "the vagueness of the key regulatory definitions is a key cause of the relentless expansion in the workload of IRBs." It offers several examples of unhelpfully vague language, both in the current regulations and the ANPRM:

"The current definition of 'minimal risk' (45 CFR 46.102(i)) is ambiguous and the examples provided are not (and cannot be) comprehensively helpful."

"'Psychological' risk is a slippery, inherently subjective concept. As such, it is likely to become a fresh source of uncertainty and cautious reviewing, thereby undermining the point of this proposed rulemaking."

"Our expertise in cross-cultural research further leads us to view as fruitless efforts to specify across-the-board 'types of questions' or topics (e.g., sexuality) as inherently 'greater than minimal risk'. . . the ANPRM's effort to predetermine offensive or risky topics is inherently flawed."

"The term 'related methodologies' is inadequate: the proposed rulemaking offers no principled approach to creating that grouping or interpreting that phrase."

"[Question 23] asks about the circumstances under which it should be permissible to waive consent for research involving 'existing data and biospecimens.' We find the phrasing of this question extremely troubling as it reveals a lack of distinction between the very general concept of 'data' with the very specific notion of 'biospecimens'. So long as the framing of ethical regulations continues to take for granted a model of research in which 'biospecimens' are the prototypical form of 'data', there is no hope of achieving a reasonable, efficacious regulatory system."

> If our concern is to identify 'risks' to human research participants, then generalizable/not- generalizable is not a useful diagnostic for distinguishing reviewable from not-reviewable research. Literary scholars and historians write biographies that transform private individuals into public figures and shape their reputations (not infrequently for the worse) whereas survey researchers typically anonymize their respondents since their research questions concern social trends and mass phenomena. Nevertheless, survey researchers, but not biographers, have been made subject to the Common Rule. Clearly, 'generalizability' has not proved a helpful resource for comparing the relative risks of these activities.

Existing lists include activities familiar to marketing researchers (e.g., taste-testing) but regularly omit mention of activities familiar to linguists, anthropologists, and others (e.g., conversation analysis, elicitation of grammaticality judgments, participant observation). The 'human subject protection' rationale for these omissions is obscure: one suspects that they may simply be unfamiliar to the list authors.

Second, such lists are confusing to researchers and IRBs because different disciplines use methodological terms (e.g., 'interview') differently. Additionally, as the ANPRM itself notes, because research methodologies are dynamic, any enumeration of techniques is likely to need endless adjustment. The ANPRM indirectly acknowledges this problem when it ends its lists with the phrase 'and [other] similar procedures.'

> The definition of 'human subject' makes quite explicit reference to biomedicine ('venipuncture' and 'medical records'). Indeed, the term is drawn from biomedical and experimental science usage, where 'subjects' are understood to respond to stimuli introduced and controlled by experimenters. However, most social and humanities research construes human participants as more proactively engaged (in various particular senses) in the research process: as open-ended interview 'respondents', oral history 'narrators', or ethnographic 'informants', 'consultants', and 'interlocutors'. Consequently, 'human subject' imports misleading connotations into IRB evaluations of social and humanistic research (introducing inaccurate study design expectations concerning 'subject selection' and the like).

Skepticism of HIPAA

The comment emphasizes that the use of HIPAA standards—'which were designed for dealing with health information'—are most definitely not 'appropriate for use in all types of research studies, including social and behavioral research'.

A Radical Redefinition

The comment's boldest proposal is to redefine the scope of the regulation:

Whereas the Common Rule currently applies to 'research; involving 'human subjects' (45 CFR 46.102d, f), we recommend that a revised Common Rule apply only to the following two kinds of work:

1. Biomedical and other study procedures involving risks of physical harm to human participants: that is, more specifically, harm defined in 76 FR 44515 II(A) as "characterized by short term or long term damage to the body such as pain, bruising, infection, worsening current disease states, long-term symptoms, or even death."

2. Human experimentation and other methodologies whose results depend for their validity on limiting or controlling the information available to research subjects: that is, study designs reliant either on the passive withholding of information concerning what the study is about or on the active provision of misinformation: e.g., the use of placebos in biomedical clinical trials; the use of confederates in behavioral research concerning competition, conformity and the like; and the deceptive presentation of fictional narratives as actual news reports in social research concerning public opinion.

The comment later clarifies that "we recommend adopting a more precise definition of what is being regulated (human experimentation and study procedures involving physical risks to participants). Doing so would obviate the need for listing 'Excused' activities in the first place."

On the one hand, this would be a radical reduction in IRB authority; IRBs would be left with no power over researchers using surveys, interviews, and observation, power they have claimed since the first policies of the 1960s.

On the other hand, this is a very conservative proposal, in that it would restrict the regulatory power to the statutes on which it claims to be based.

The comment notes that it is proposing a "default-out reviewing strategy," in which activities could proceed unless they hit one of the triggers in the new definition, as opposed to the "current strategy [which] defines the object of IRB review relatively generally and then labors to identify and enumerate specific methodologies or types of study eligible for 'exemption' or 'expediting.'" Indeed. In [2]1981, HHS explicitly rejected the "suggestion that the regulations should define what is covered rather than list specific exemptions if research were exempted from coverage unless it met the criteria proposed by the commentators" lest "other categories of research involving significant risk . . . would be inadvertently exempted from coverage." This was a terrible mistake, and the AAA rightly condemns it.

The comment particularly wants participant observation, "sociocultural anthropologyPs distinctive research method," excused from IRB review.

I was puzzled by the combination of the comment's call to narrow the regulatory definition of research and its apparent expectation that there would still be some regulatory oversight over some social research. Thus, the response to question 15 imagines "obviat[ing] the need for listing 'Excused' activities in the first place," while the response to question 19 "strongly support[s] the idea that researchers who are engaged in 'excused' research adhere to a 'brief (i.e. no more than one week) waiting period' before commencing with their project."

I wonder if this apparent contradiction is the result of the ANPRM's format, which more or less forces respondents to argue in the alternative.

A Proposal for a Social and Humanistic Commission

The comment's second major suggestion is

the creation of a commission constituted specifically of social scientists (e.g., sociologists and the like), humanistic social researchers (e.g., cultural anthropologists and the like), and humanists (e.g., historians, legal scholars, and the like). Rather than adapting strategies developed to protect biomedical information–which are fundamentally incompatible with core intellectual and ethical commitments of humanistic social studies–this commission would be tasked with developing alternative guidance appropriate for their fields.

As the anthropologists note, such a commission is already functioning in Canada, where the Social Sciences and Humanities Research Council helps shape the Tri-Council Policy Statement and its interpretations. Like the call for a meaningful definition of research, this proposal is a bold assertion of what should be common sense. The anthropologists suggest the Association for Practical and Professional Ethics and the Consortium of Social Science Organizations as organizations that should have a greater role in shaping rules.

Again, I see some tension in this proposal between the comment's wish for more expert review and its defense of "the existing local model of IRB process." The comment rightly "attribute[s] the phenomenon of 'mission creep' in some part to the fact that institutions labor under the anxiety of federal audits. This contributes to an adversarial atmosphere in which it is only rational for boards and IRB administrators to emphasize bureaucratic documentation over situationally appropriate ethical decision-making." Yet its complaints about "variable interpretations by IRBs" could hint at problems with the local model itself.

Similarly, in response to question 9, the comment states that "We view a 'systematic, empirical assessment of the levels of risk' as impractical." Yet in just the previous section, a reply to question 8, the comment cites a National Academy of Science report to argue that "every exposure to [ionizing] radiation produces a corresponding increase in cancer risk." So there's an example of a practical, empirical assessment of the level of risk.

I am the last person to suggest an uncritical mapping of such a medical finding onto non-medical fields, but I still think some empirical evidence about nonmedical research can help guide rulemakers and local IRBs. For example, it seems that experience has shown that [3]people who study universities should not count on being able to disguise the identity of their research sites (especially when they study their home institutions), and that [4]interviews with survivors of trauma pose little risk of causing further trauma.

Respect for Historians

Though naturally emphasizing the concerns of anthropologists, the AAA comment goes out of its way to stress both the value of historical research and the dangers the ANPRM's muddier ideas pose. For example,

Taken literally, the wording of this question is directly applicable to historiography, which accords special credibility to the study of records collected (often by interactions with persons) for purposes unrelated to that of the investigator. To require consent in such a case 'based on the likelihood of identifying the research subject' would cause IRB (or HIPAA Privacy Board) workloads to rise dramatically and historical scholarship to grind to a halt.

I expect historians to make this point, but for anthropologists to do so is an act of gallantry.

An Endorsement of Freedom

In several sections, the AAA raises a value often missing in discussions of human subjects regulation: "the rights of citizens in a free society, researchers and participants alike."

My favorite expression of this value–and my favorite passage of all in the comment–comes in response to question 27, which asks about the risks that IRBs should consider. The anthropologists respond:

The research world is rife with projects whose results bore, interest, annoy, please, anger, or enlighten research participants (just as they do fellow researchers). This world is not generically the people's enemy. On the contrary, those of us working in US colleges,

universities, news media, and research institutions have inherited traditions of free inquiry whose continuation is vital to this country's political, economic and social life. It would be deeply ironic if a regulatory system put in place to protect human beings were transformed into a device focused on restricting their power to know the world.

I have in the past been quite [5]critical of anthropologists' approach to the IRB debate, in large part because of what I understood as their failure to accept that safeguarding freedom will inevitably bore, annoy, anger or [6]otherwise harm some people being studied. The AAA's response to the ANPRM changes that. It strikes me as not only a much-needed set of comments on the proposals immediately before us, but also as a welcome assertion of anthropologists' rights and responsibilities in the pursuit of knowledge.

1. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0431
2. http://www.hhs.gov/ohrp/archive/documents/19810126.pdf
3. http://www.institutionalreviewblog.com/2011/01/uconn-irb-encouraged-failed-effort-at.html
4. http://www.institutionalreviewblog.com/2008/03/trauma-based-research-is-less-risky.html
5. http://www.institutionalreviewblog.com/2007/03/my-problem-with-anthropologists.html
6. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-ii-aaa-ethics.html

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6.10.9 (2011-10-22 21:45)

The [1]American Anthropological Association has posted comments on the ANPRM to the regulations.gov website. Composed by AAA Committee on Ethics member Lise Dobrin and former Committee chair Rena Lederman, the 23-page document is stunningly eloquent and thorough in its indictment of the present IRB system and the shortcomings of the ANPRM. And it offers two bold and constructive suggestions that could point the way to a true reform.
The comment is organized in the haphazardly ordered sequence of the ANPRM's questions. Here, I extract some major features.

Critiques of the Status Quo

Taken together, the comment's descriptions of the status quo present a bleak picture.

- " Even though their modes of planning differ from the experimental designs that IRBs expect, folklorists, interpretive sociocultural anthropologists and the like consider what they do to be research (in their respective disciplinary senses), present it as such to their IRBs, and are therefore advised by IRBs to submit applications. However, when they do so, their protocols are evaluated as 'poorly designed': as bad research, rather than simply not 'research' (in the present regulatory sense)."
- " Anthropologists preparing to engage in participant observation routinely experience review of their protocols by board members who lack expertise in the standard methods anthropologists employ . . . This situation has demoralized individual researchers and encouraged widespread cynicism about the value of regulatory oversight."
- "Our colleagues have reported that many rounds of requests for clarifications and changes can be as discouraging as outright disapproval."
- "While we were preparing these comments, one anthropologist mentioned to us that she was forced to model her consent documents for classroom observations and interviews on forms designed for medical interventions such as intubation. Her IRB prevented her from adjusting her consent forms—using language that would be clear and

pragmatically appropriate for the study population—to facilitate truly informed consent. We must recognize that foreign participants can be baffled and overwhelmed by procedures that Americans take for granted, such as 'initialing' a line."

Attacks on Muddled Language

The comment is particularly effective in its insistence that "the vagueness of the key regulatory definitions is a key cause of the relentless expansion in the workload of IRBs." It offers several examples of unhelpfully vague language, both in the current regulations and the ANPRM:

- "The current definition of 'minimal risk' (45 CFR 46.102(i)) is ambiguous and the examples provided are not (and cannot be) comprehensively helpful."
- "'Psychological' risk is a slippery, inherently subjective concept. As such, it is likely to become a fresh source of uncertainty and cautious reviewing, thereby undermining the point of this proposed rulemaking."
- "Our expertise in cross-cultural research further leads us to view as fruitless efforts to specify across-the-board 'types of questions' or topics (e.g., sexuality) as inherently 'greater than minimal risk'. . . the ANPRM's effort to predetermine offensive or risky topics is inherently flawed."
- "The term 'related methodologies' is inadequate: the proposed rulemaking offers no principled approach to creating that grouping or interpreting that phrase."
- "[Question 23] asks about the circumstances under which it should be permissible to waive consent for research involving 'existing data and biospecimens.' We find the phrasing of this question extremely troubling as it reveals a lack of distinction between the very general concept of 'data' with the very specific notion of 'biospecimens'. So long as the framing of ethical regulations continues to take for granted a model of research in which 'biospecimens' are the prototypical form of 'data', there is no hope of achieving a reasonable, efficacious regulatory system."
- "If our concern is to identify 'risks' to human research participants, then generalizable/not- generalizable is not a useful diagnostic for distinguishing reviewable from not-reviewable research. Literary scholars and historians write biographies that transform private individuals into public figures and shape their reputations (not infrequently for the worse) whereas survey researchers typically anonymize their respondents since their research questions concern social trends and mass phenomena. Nevertheless, survey researchers, but not biographers, have been made subject to the Common Rule. Clearly, 'generalizability' has not proved a helpful resource for comparing the relative risks of these activities."
- "Existing lists include activities familiar to marketing researchers (e.g., taste-testing) but regularly omit mention of activities familiar to linguists, anthropologists, and others (e.g., conversation analysis, elicitation of grammaticality judgments, participant observation). The 'human subject protection' rationale for these omissions is obscure: one suspects that they may simply be unfamiliar to the list authors. Second, such lists are confusing to researchers and IRBs because different disciplines use methodological terms (e.g., 'interview') differently. Additionally, as the ANPRM itself notes, because research methodologies are dynamic, any enumeration of techniques is likely to need endless adjustment. The ANPRM indirectly acknowledges this problem when it ends its lists with the phrase 'and [other] similar procedures.'"
- "The definition of 'human subject' makes quite explicit reference to biomedicine ('venipuncture' and 'medical records'). Indeed, the term is drawn from biomedical and experimental science usage, where 'subjects' are understood to respond to stimuli introduced and controlled by experimenters. However, most social and humanities research construes human participants as more proactively engaged (in various particular senses) in

the research process: as open-ended interview 'respondents', oral history 'narrators', or ethnographic 'informants', 'consultants', and 'interlocutors'. Consequently, 'human subject' imports misleading connotations into IRB evaluations of social and humanistic research (introducing inaccurate study design expectations concerning 'subject selection' and the like). "

Skepticism of HIPAA

The comment emphasizes that the use of HIPAA standards—'which were designed for dealing with health information'—are most definitely not 'appropriate for use in all types of research studies, including social and behavioral research'.

A Radical Redefinition

The comment's boldest proposal is to redefine the scope of the regulation:

> Whereas the Common Rule currently applies to 'research; involving 'human subjects' (45 CFR 46.102d, f), we recommend that a revised Common Rule apply only to the following two kinds of work:
> 1. Biomedical and other study procedures involving risks of physical harm to human participants: that is, more specifically, harm defined in 76 FR 44515 II(A) as "characterized by short term or long term damage to the body such as pain, bruising, infection, worsening current disease states, long-term symptoms, or even death."
> 2. Human experimentation and other methodologies whose results depend for their validity on limiting or controlling the information available to research subjects: that is, study designs reliant either on the passive withholding of information concerning what the study is about or on the active provision of misinformation: e.g., the use of placebos in biomedical clinical trials; the use of confederates in behavioral research concerning competition, conformity and the like; and the deceptive presentation of fictional narratives as actual news reports in social research concerning public opinion."

The comment later clarifies that "we recommend adopting a more precise definition of what is being regulated (human experimentation and study procedures involving physical risks to participants). Doing so would obviate the need for listing 'Excused' activities in the first place."
On the one hand, this would be a radical reduction in IRB authority; IRBs would be left with no power over researchers using surveys, interviews, and observation, power they have claimed since the first policies of the 1960s.
On the other hand, this is a very conservative proposal, in that it would restrict the regulatory power to the statutes on which it claims to be based.
The comment notes that it is proposing a "default-out reviewing strategy," in which activities could proceed unless they hit one of the triggers in the new definition, as opposed to the "current strategy [which] defines the object of IRB review relatively generally and then labors to identify and enumerate specific methodologies or types of study eligible for 'exemption' or 'expediting.'" Indeed. In [2]1981, HHS explicitly rejected the "suggestion that the regulations should define what is covered rather than list specific exemptions if research were exempted from coverage unless it met the criteria proposed by the commentators" lest "other categories of research involving significant risk . . . would be inadvertently exempted from coverage." This was a terrible mistake, and the AAA rightly condemns it.
The comment particularly wants participant observation, "sociocultural anthropologyPs distinctive research method," excused from IRB review.
I was puzzled by the combination of the comment's call to narrow the regulatory definition of research and its apparent expectation that there would still be some regulatory oversight over some social research. Thus, the response to question 15 imagines "obviat[ing] the need for listing 'Excused' activities in the first place," while the response to question 19 "strongly support[s] the idea that researchers who are engaged in 'excused' research adhere to a 'brief (i.e. no more than one week) waiting period' before commencing with their project."

I wonder if this apparent contradiction is the result of the ANPRM's format, which more or less forces respondents to argue in the alternative.

A Proposal for a Social and Humanistic Commission

The comment's second major suggestion is

> the creation of a commission constituted specifically of social scientists (e.g., sociologists and the like), humanistic social researchers (e.g., cultural anthropologists and the like), and humanists (e.g., historians, legal scholars, and the like). Rather than adapting strategies developed to protect biomedical information–which are fundamentally incompatible with core intellectual and ethical commitments of humanistic social studies–this commission would be tasked with developing alternative guidance appropriate for their fields."

As the anthropologists note, such a commission is already functioning in Canada, where the Social Sciences and Humanities Research Council helps shape the Tri-Council Policy Statement and its interpretations. Like the call for a meaningful definition of research, this proposal is a bold assertion of what should be common sense. The anthropologists suggest the Association for Practical and Professional Ethics and the Consortium of Social Science Organizations as organizations that should have a greater role in shaping rules.

Again, I see some tension in this proposal between the comment's wish for more expert review and its defense of "the existing local model of IRB process." The comment rightly "attribute[s] the phenomenon of 'mission creep' in some part to the fact that institutions labor under the anxiety of federal audits. This contributes to an adversarial atmosphere in which it is only rational for boards and IRB administrators to emphasize bureaucratic documentation over situationally appropriate ethical decision-making." Yet its complaints about "variable interpretations by IRBs" could hint at problems with the local model itself.

Similarly, in response to question 9, the comment states that "We view a 'systematic, empirical assessment of the levels of risk' as impractical." Yet in just the previous section, a reply to question 8, the comment cites a National Academy of Science report to argue that "every exposure to [ionizing] radiation produces a corresponding increase in cancer risk." So there's an example of a practical, empirical assessment of the level of risk.

I am the last person to suggest an uncritical mapping of such a medical finding onto non-medical fields, but I still think some empirical evidence about nonmedical research can help guide rulemakers and local IRBs. For example, it seems that experience has shown that [3]people who study universities should not count on being able to disguise the identity of their research sites (especially when they study their home institutions), and that [4]interviews with survivors of trauma pose little risk of causing further trauma.

Respect for Historians

Though naturally emphasizing the concerns of anthropologists, the AAA comment goes out of its way to stress both the value of historical research and the dangers the ANPRM's muddier ideas pose. For example,

> Taken literally, the wording of this question is directly applicable to historiography, which accords special credibility to the study of records collected (often by interactions with persons) for purposes unrelated to that of the investigator. To require consent in such a case 'based on the likelihood of identifying the research subject' would cause IRB (or HIPAA Privacy Board) workloads to rise dramatically and historical scholarship to grind to a halt."

I expect historians to make this point, but for anthropologists to do so is an act of gallantry.

An Endorsement of Freedom

In several sections, the AAA raises a value often missing in discussions of human subjects regulation: "the rights of citizens in a free society, researchers and participants alike."
My favorite expression of this value–and my favorite passage of all in the comment–comes in response to question 27, which asks about the risks that IRBs should consider. The anthropologists respond:

> The research world is rife with projects whose results bore, interest, annoy, please, anger, or enlighten research participants (just as they do fellow researchers). This world is not generically the people's enemy. On the contrary, those of us working in US colleges,
> universities, news media, and research institutions have inherited traditions of free inquiry whose continuation is vital to this country's political, economic and social life. It would be deeply ironic if a regulatory system put in place to protect human beings were transformed into a device focused on restricting their power to know the world.

I have in the past been quite [5]critical of anthropologists' approach to the IRB debate, in large part because of what I understood as their failure to accept that safeguarding freedom will inevitably bore, annoy, anger or [6]otherwise harm some people being studied. The AAA's response to the ANPRM changes that. It strikes me as not only a much-needed set of comments on the proposals immediately before us, but also as a welcome assertion of anthropologists' rights and responsibilities in the pursuit of knowledge.

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6. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-ii-aaa-ethics.html

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6.10.10 In ANPRM Comments, Anthropologists Champion Free Inquiry (2011-10-23 13:48)

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The comment is organized in the haphazardly ordered sequence of the ANPRM's questions. Here, I extract some major features.

Critiques of the Status Quo

Taken together, the comment's descriptions of the status quo present a bleak picture.

- "Even though their modes of planning differ from the experimental designs that IRBs expect, folklorists, interpretive sociocultural anthropologists and the like consider what they do to be research (in their respective disciplinary senses), present it as such to their IRBs, and are therefore advised by IRBs to submit applications.

However, when they do so, their protocols are evaluated as 'poorly designed': as bad research, rather than simply not 'research' (in the present regulatory sense)."

- "Anthropologists preparing to engage in participant observation routinely experience review of their protocols by board members who lack expertise in the standard methods anthropologists employ . . . This situation has demoralized individual researchers and encouraged widespread cynicism about the value of regulatory oversight."

- "Our colleagues have reported that many rounds of requests for clarifications and changes can be as discouraging as outright disapproval."

- "While we were preparing these comments, one anthropologist mentioned to us that she was forced to model her consent documents for classroom observations and interviews on forms designed for medical interventions such as intubation. Her IRB prevented her from adjusting her consent forms—using language that would be clear and pragmatically appropriate for the study population—to facilitate truly informed consent. We must recognize that foreign participants can be baffled and overwhelmed by procedures that Americans take for granted, such as 'initialing' a line."

Attacks on Muddled Language

The comment is particularly effective in its insistence that "the vagueness of the key regulatory definitions is a key cause of the relentless expansion in the workload of IRBs." It offers several examples of unhelpfully vague language, both in the current regulations and the ANPRM:

- "The current definition of 'minimal risk' (45 CFR 46.102(i)) is ambiguous and the examples provided are not (and cannot be) comprehensively helpful."

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- "[Question 23] asks about the circumstances under which it should be permissible to waive consent for research involving 'existing data and biospecimens.' We find the phrasing of this question extremely troubling as it reveals a lack of distinction between the very general concept of 'data' with the very specific notion of 'biospecimens'. So long as the framing of ethical regulations continues to take for granted a model of research in which 'biospecimens' are the prototypical form of 'data', there is no hope of achieving a reasonable, efficacious regulatory system."

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On the one hand, this would be a radical reduction in IRB authority; IRBs would be left with no power over researchers using surveys, interviews, and observation, power they have claimed since the first policies of the 1960s.
On the other hand, this is a very conservative proposal, in that it would restrict the regulatory power to the statutes on which it claims to be based.
The comment notes that it is proposing a "default-out reviewing strategy," in which activities could proceed unless

they hit one of the triggers in the new definition, as opposed to the "current strategy [which] defines the object of IRB review relatively generally and then labors to identify and enumerate specific methodologies or types of study eligible for 'exemption' or 'expediting.'" Indeed. In [2]1981, HHS explicitly rejected the "suggestion that the regulations should define what is covered rather than list specific exemptions if research were exempted from coverage unless it met the criteria proposed by the commentators" lest "other categories of research involving significant risk . . . would be inadvertently exempted from coverage." This was a terrible mistake, and the AAA rightly condemns it.

The comment particularly wants participant observation, "sociocultural anthropology's distinctive research method," excused from IRB review.

I was puzzled by the combination of the comment's call to narrow the regulatory definition of research and its apparent expectation that there would still be some regulatory oversight over some social research. Thus, the response to question 15 imagines "obviat[ing] the need for listing 'Excused' activities in the first place," while the response to question 19 "strongly support[s] the idea that researchers who are engaged in 'excused' research adhere to a 'brief (i.e. no more than one week) waiting period' before commencing with their project."

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The comment's second major suggestion is

> the creation of a commission constituted specifically of social scientists (e.g., sociologists and the like), humanistic social researchers (e.g., cultural anthropologists and the like), and humanists (e.g., historians, legal scholars, and the like). Rather than adapting strategies developed to protect biomedical information–which are fundamentally incompatible with core intellectual and ethical commitments of humanistic social studies–this commission would be tasked with developing alternative guidance appropriate for their fields.

As the anthropologists note, such a commission is already functioning in Canada, where the Social Sciences and Humanities Research Council helps shape the Tri-Council Policy Statement and its interpretations. Like the call for a meaningful definition of research, this proposal is a bold assertion of what should be common sense. The anthropologists suggest the Association for Practical and Professional Ethics and the Consortium of Social Science Organizations as organizations that should have a greater role in shaping rules.

Again, I see some tension in this proposal between the comment's wish for more expert review and its defense of "the existing local model of IRB process." The comment rightly "attribute[s] the phenomenon of 'mission creep' in some part to the fact that institutions labor under the anxiety of federal audits. This contributes to an adversarial atmosphere in which it is only rational for boards and IRB administrators to emphasize bureaucratic documentation over situationally appropriate ethical decision-making." Yet its complaints about "variable interpretations by IRBs" could hint at problems with the local model itself.

Similarly, in response to question 9, the comment states that "We view a 'systematic, empirical assessment of the levels of risk' as impractical." Yet in just the previous section, a reply to question 8, the comment cites a National Academy of Science report to argue that "every exposure to [ionizing] radiation produces a corresponding increase in cancer risk." So there's an example of a practical, empirical assessment of the level of risk.

I am the last person to suggest an uncritical mapping of such a medical finding onto non-medical fields, but I still think some empirical evidence about nonmedical research can help guide rulemakers and local IRBs. For example, it seems that experience has shown that [3]people who study universities should not count on being able to disguise the identity of their research sites (especially when they study their home institutions), and that [4]interviews with survivors of trauma pose little risk of causing further trauma.

Respect for Historians

Though naturally emphasizing the concerns of anthropologists, the AAA comment goes out of its way to stress both the value of historical research and the dangers the ANPRM's muddier ideas pose. For example,

> Taken literally, the wording of this question is directly applicable to historiography, which accords special credibility to the study of records collected (often by interactions with persons) for purposes unrelated to that of the investigator. To require consent in such a case 'based on the likelihood of identifying the research subject' would cause IRB (or HIPAA Privacy Board) workloads to rise dramatically and historical scholarship to grind to a halt."

I expect historians to make this point, but for anthropologists to do so is an act of collegial generosity.

An Endorsement of Freedom

In several sections, the AAA raises a value often missing in discussions of human subjects regulation: "the rights of citizens in a free society, researchers and participants alike."
My favorite expression of this value–and my favorite passage of all in the comment–comes in response to question 27, which asks about the risks that IRBs should consider. The anthropologists respond:

> The research world is rife with projects whose results bore, interest, annoy, please, anger, or enlighten research participants (just as they do fellow researchers). This world is not generically the people's enemy. On the contrary, those of us working in US colleges, universities, news media, and research institutions have inherited traditions of free inquiry whose continuation is vital to this country's political, economic and social life. It would be deeply ironic if a regulatory system put in place to protect human beings were transformed into a device focused on restricting their power to know the world.

I have in the past been quite [5]critical of anthropologists' approach to the IRB debate, in large part because of what I understood as their failure to accept that safeguarding freedom will inevitably bore, annoy, anger or [6]otherwise harm some people being studied. The AAA's response to the ANPRM changes that. It strikes me as not only a much-needed set of comments on the proposals immediately before us, but also as a welcome assertion of anthropologists' rights and responsibilities in the pursuit of knowledge.

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5. http://www.institutionalreviewblog.com/2007/03/my-problem-with-anthropologists.html
6. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-ii-aaa-ethics.html

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6.10.11 New York Times: Menikoff Promises Not to Restrict Public Information (2011-10-24 11:28)

Today's New York Times reports on historians' and social scientists' hopes and concerns about the ANPRM, especially the prospect of deregulating oral history while restricting the reuse of social science data.
[Patricia Cohen, "[1]Questioning Privacy Protections in Research," New York Times, 24 October 2011.]
The story quotes three historians–Linda Shopes, Alice Kessler-Harris, and your humble blogger–all expressing hope

that the ANPRM will lead to the end of IRB oversight of oral history and concern that privacy rules based on HIPAA will restrict archival research. It also cites the public responses posted by the [2]American Anthropological Association and the [3]American Association of University Professors.
In response to such concerns,

> Jerry Menikoff, director of the federal Office for Human Research Protections, which oversees the Common Rule, cautions that any alarm is premature, saying that federal officials do not intend to pose tougher restrictions on information that is already public. "If the technical rules end up doing that, we'll try to come up with a result that's appropriate," he said.

The article ends with Menikoff's sentiments:

> Dr. Menikoff said, "We want to hear all these comments." But he maintained that when the final language is published, critics may find themselves saying, "Wow, this is reasonable stuff."

I'm only a cockeyed optimist, but I think that is entirely possible.

1. http://www.nytimes.com/2011/10/24/arts/rules-meant-to-protect-human-research-subjects-cause-concern.html
2. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html
3. http://www.institutionalreviewblog.com/2011/10/aaup-posts-anprm-comments.html

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6.10.12 My Comments on the ANPRM (2011-10-25 16:32)

In addition to having assisted with the comments submitted by the American Association of University Professors and the American Historical Association, today I submitted the following comments on the ANPRM. The [1]PDF version may be easier to read.

25 October 2011
Jerry Menikoff, MD, JD
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Dear Dr. Menikoff:
Thank you for the opportunity to comment on the advance notice of proposed rulemaking, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" (docket ID number HHS–OPHS–2011–0005). I am grateful to all of the ANPRM's creators for taking this first step toward a much needed reform of the present system of research regulation.
I write these comments as the author of "How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965-1991," Journal of Policy History 21 (2009): 3-37, and Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009 (Baltimore: Johns Hopkins University Press, 2010), both of which were graciously cited in the ANPRM. I also edited the 2011 special issue of the Journal of Policy History on human subjects research, which featured Susan Reverby's influential article on the Public Health Service experiments in Guatemala. And since 2006, I have edited the Institutional Review Blog, http://www.institutionalreviewblog.com.

I contributed to the response to the ANPRM submitted earlier by the American Association of University Professors, and I was consulted by the authors of the response submitted by the American Historical Association. I endorse those two responses wholeheartedly.
In addition to the comments in those documents, I wish to offer the attached observations, which reflect only my views and may not represent those of the AAUP, AHA, George Mason University, or any other institution.
Sincerely,
Zachary M. Schrag, PhD
Associate Professor of History

Zachary M. Schrag
Associate Professor
Department of History and Art History
George Mason University Comments on advance notice of proposed rulemaking,
"Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators"

25 October 2011

Question 4. IRBs Need Help Assessing Risk

Question 4: Should the regulations be changed to indicate that IRBs should only consider "reasonably foreseeable risks or discomforts"?

A. I support this change and suggest adding the word "significant" to describe the risks that may be considered. Comments

The ANPRM acknowledges that "it is not clear that . . . [IRB] members have appropriate expertise regarding data protections." That is true, but it is not clear that IRB members have appropriate expertise regarding physical risk, psychological risk, the benefits of particular restrictions, or any of the other factors that they would need to do their appointed tasks.

The ANPRM notes that when identical proposals are submitted to multiple IRBs, researchers can expect "widely differing outcomes regarding the level of review required." But that is just a small part of the problem. Given identical proposals, IRBs will disagree about a great many things.[2][1] This is not just a problem for multi-site studies; it is also an indicator that IRBs are making many or most of their decisions based on guesswork. That is, if the same proposal given to three IRBs comes back with three wildly different demands for changes, at some level it means that two of the three have offered bad advice. In extreme cases, a committee may applaud part of an application as "eloquent and well-grounded in the literature," only to fault the same section when the same application is reviewed after revisions.[3][2]

Jay Katz pointed to the basic problem back in 1973:

The review committees work in isolation from one another, and no mechanisms have been established for disseminating whatever knowledge is gained from their individual experiences. Thus, each committee is condemned to repeat the process of finding its own answers. This is not only an overwhelming, unnecessary and unproductive assignment, but also one which most review committees are neither prepared nor willing to assume.[4][3]

This statement is as true today as it was then.

To remedy this problem, I call for regulations and guidance that require IRBs to use available empirical evidence when making decisions. I concur with the 1999 recommendation of the Working Group of the Human Subjects

Research Subcommittee of the National Science and Technology Council: "In determining whether there might be a reasonable risk or damage related to divulging the sensitive information, etc., it is not enough that there be merely some hypothetical possible risk that can be construed. Rather, the risks resulting from disclosure must be readily appreciable and significant."[5][4]

Regardless of the specific adjectives and adverbs used, any regulation should be accompanied by guidance recommending that IRBs base their decisions on empirical evidence. If a researcher can show that a given method is in regular use, and an IRB cannot show that the method regularly abuses research participants, the research should proceed.[6][5]

IRBs should also document the reasons for their decisions, something they seem to be doing now at a low rate.[7][6]

The University of Texas's 2009 report, "Trust, Integrity, and Responsibility in the Conduct of Human Subjects Research," encourages IRBs to act based on "evidencebased research" and "empirical studies." The federal government should do the same.

Finally, I recommend the establishment of a national clearinghouse to disseminate the empirical findings of researchers and IRBs.

Question 25. The Common Rule Should Cover Only Biomedical and Behavioral Research

Question 25. Are there certain fields of study whose usual methods of inquiry were not intended to or should not be covered by the Common Rule (such as classics, history, languages, literature, and journalism) because they do not create generalizable knowledge and may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule? If so, what are those fields, and how should those methods of inquiry be identified? Should the Common Rule be revised to explicitly state that those activities are not subject to its requirements?

Answer: The Common Rule currently claims to regulate all "research" even though it has no statutory authority to do so. It is this over-reaching that diminishes protections for research subjects while imposing burden, delay, and ambiguity on investigators. The Common Rule should be rewritten to emphasize its applicability only to biomedical and behavioral research.

I therefore endorse the proposal made by the American Anthropological Association, in its comments on the ANPRM, to limit the Common Rule to the oversight of two kinds of work:

1. Biomedical and other study procedures involving risks of physical harm to human participants: that is, more specifically, harm defined in 76 FR 44515 II(A) as "characterized by short term or long term damage to the body such as pain, bruising, infection, worsening current disease states, long-term symptoms, or even death."

2. Human experimentation and other methodologies whose results depend for their validity on limiting or controlling the information available to research subjects: that is, study designs reliant either on the passive withholding of information concerning what the study is about or on the active provision of misinformation: e.g., the use of placebos in biomedical clinical trials; the use of confederates in behavioral research concerning competition, conformity and the like; and the deceptive presentation of fictional narratives as actual news reports in social research concerning public opinion.[8][7]

This definition would achieve many of the objectives of the ANPRM and bring the regulations into compliance with the underlying statute and the intent of Congress.

Statutory authority covers only biomedical and behavioral research

As the ANPRM notes, the Common Rule draws its statutory authority primarily from 42 USC 289, which calls for the establishments of IRBs "to review biomedical and behavioral research involving human subjects."

The ANPRM also cites 42 USC 300v, which established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Section 300v(a)(1) of that title calls for membership in the commission to be split among three groups: (A) "individuals who are distinguished in biomedical or behavioral

research," (B) " individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care," and (C) "individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs."

Thus, federal law distinguishes between "biomedical or behavioral research" on the one hand and "the social sciences, the humanities, health administration, government, and public affairs" on the other, and it covers only the former categories. As the deputy general counsel of the Department of Health, Education, and Welfare put it in 1979, "if Congress had wished . . . to cover all human subjects research, rather than just biomedical and behavioral, it could have done so."[9][8]

The Common Rule should reflect the underlying statutes and apply only to biomedical and behavioral research.

The Common Rule should cover only research methods that have proven risky

The ANPRM notes that "While physical risks generally are the greatest concern in biomedical research, social and behavioral studies rarely pose physical risk but may pose psychological or informational risks. Some have argued that, particularly given the paucity of information suggesting significant risks to subjects in certain types of survey and interview-based research, the current system over-regulates such research." I agree with the latter assessment.

Both the statute and the regulations were designed to address concerns raised in the 1973 Senate hearings. As the secretary of HEW explained in 1976,

The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 of the Public Health Service Act, 42 USC 289 1-3 (added by Pub. L. 93-348) . . .

The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psycho-surgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devises; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study; the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human in vitro fertilization . . .[10][9]

The hearings did not address the risks of survey, observation, and interview-based research. Nor has the experience subsequent decades shown that this kind of research is particularly risky. One can find exceptions, but these are rare. Stuart Plattner put it well in 2006. "In all the years I was responsible for human-subjects issues at NSF, I never learned of one case in which a respondent was actually harmed from participation in anthropological research." He concluded, "although the possibility of harm to participants in ethnographic research is real, the probability of harm is very low."[11][10]

As the ANPRM notes, "Over-regulating social and behavioral research in general may serve to distract attention from attempts to identify those social and behavioral research studies that do pose threats to the welfare of subjects and thus do merit significant oversight."

Different scholarly disciplines adhere to different ethical codes

The U.S. IRB system was designed by experts in the ethics of medical and psychological experimentation. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote the Belmont Report without any regard to the ethical codes developed by journalists or scholars in the social sciences and the humanities, and it is a poor fit for their work. Its insistence on the equitable selection of subjects is simply irrelevant when a researcher chooses people based on their unique characteristics. More significantly, instructions to "do no harm" cannot apply to investigative journalism and other forms of critical inquiry. IRBs have consistently proven themselves unable to make this distinction.[12][11]

The new "excused" category may not work for research in which real names are the norm

When institutions do impose IRB authority on oral history and other research in which participants are generally identified, they can generally rule it exempt under the current Common Rule. But this category may disappear under the present proposal.

If that happens, this kind of research would be an awkward fit for the new "excused" category, which emphasizes privacy. While the new category rules "allow subjects to authorize researchers to disclose the subjects' identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition," its clear emphasis is on preserving the confidentiality of information. The present Common Rule does not require anonymity, but its emphasis on confidentiality has led IRBs to impose inappropriate demands on researchers, such as requiring oral historians to anonymize their narrators or destroy recordings and transcripts. If, as is likely, institutions determined that real-name research was not eligible for the new excused category, IRBs would find themselves reviewing research the ANPRM considers only a distraction.

Alternatively, institutions allow real-name research to proceed under the excused category. But if that were the case, then historians, journalists, and folkorists would find themselves submitting forms that said only that they did not intend to follow most of the provisions of the excused category. This would be nothing but a waste of time and paper.

non-generalizability has proven an unreliable tool

ANPRM's Question 25 hints that regulators are considering letting journalists, historians and other humanists off the hook by declaring their work to be non-generalizable, and therefore not subject to regulation under the Common Rule.

Yet non-generalizability has proven an unreliable tool. OHRP has muddied the waters, apparently contending—for example—that "Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research" would constitute generalizable research because "the creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research."[13][12]

This conflicts with OHRP's earlier determination that "oral history interviews, in general, are not designed to contribute to generalizable knowledge." If generalizable means that some future researcher might conceivably use the information, then nothing is non-generalizable. Do not daily newspapers; criminal, civil and congressional investigations; and disease monitoring all create an archive for future research?

Moreover, as Robert Townsend of the American Historical Association has noted,

The argument [that oral history is not generalizable] prompted some derision from outside the field, from academics who interpreted the phrase to say simply "history is not research." (As a case in point, the vice president for research at my own university, after a fairly contentious meeting on the subject, wished me well on my "non-research dissertation.")

We also received a number of complaints from within the discipline. Some historians argue that history does contribute generalizable knowledge, even if it bears little resemblance to the scientific definition of the word. And faculty members at history of medicine departments and in the social science side of history warned that this position undermined both their institutional standing and their ability to obtain grants. They made it clear that however finely worded, stating that history did not constitute research in even the most bureaucratic terms could have some real financial costs to the discipline.[14][13]

More fundamentally, no one can be sure what generalizable means. It is left undefined in the Common Rule. The Belmont Report version is longer, but hardly more helpful:

The term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

This goes some way to distinguish research from diagnosis of an individual patient—the main goal of that section of the Belmont Report—but I am not even sure of that; I would hope that an MRI operator diagnosing a patient has an objective and a set of procedures designed to reach that objective.

Nor does it distinguish science from journalism, which regularly permits conclusions to be drawn and expresses statements of relationships.

Conversely, qualitative social scientists debate whether their work is generalizable. So "generalizable" covers research that the National Commission did not want covered and leaves uncovered research that the Commission did seek to regulate.

Serious observers have noted the problem. Tom Beauchamp recently complained that "generalizable knowledge," like other terms, "can be understood in several ways."[15][14] Rena Lederman has found that "the regulatory definition did little to resolve the very ambiguities within medical practice for which it was designed. Heroic efforts of clarification can be found in works that interpret the Common Rule for IRBs. Nevertheless, to this day it continues to be a frequent topic of debate in IRB circles."[16][15] And in 2008, David Strauss of the Secretary's Advisory Committee on Human Research Protections complained that "we shouldn't be reviewing research that we don't think needs to be reviewed because some folks 30 years ago, at the end of a long, hot day, decided to use the word 'generalizable' . . . We have to have language that makes sense to us."[17][16]

The American Anthropological Association's proposal makes sense.

Questions 68 and 69. The federal government should monitor both the costs and benefits of IRB review

Question 68: With regard to data reported to the Federal government:
a. Should the number of research participants in Federally funded human subjects research be reported (either to funding agencies or to a central authority)? If so, how?

Answer. I agree with the ANPRM's intent "not to expand the information that has to be reported." Qualitative researchers should not be expected to produce quantitative data. That is, for a researcher whose results already depend on careful counts, it is relatively easy to report figures to federal regulators. But an ethnographer who attends mass events should not be expected to guess how many people he or she observed. Nor should an interviewer have to tabulate how many people he or she interviewed in a given year. **b.** What additional data, not currently being collected, about participants in human subjects research should be systematically collected in order to provide an empirically-based assessment of the risks of particular areas of research or of human subjects research more globally?

Answer. These questions seem to envision collecting only data on adverse events and unanticipated problems that come about as a result of research. What about adverse events and unanticipated problems that result from IRB review? In order to know if the system is working well, we must measure its costs as well as its benefits. Thus, the government should establish a formal mechanism for registering researcher and participant complaints about inappropriate restrictions and requirements. **Question 69**: There are a variety of possible ways to support an empiric approach to optimizing human subjects protections. Toward that end, is it desirable to have all data on adverse events and unanticipated problems collected in a central database accessible by all pertinent Federal agencies?

Answer. The most recent comprehensive data on the IRB system as a whole come from the mid-1970s survey conducted for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. If new data are collected, they should be analyzed and presented in a form accessible to the general public as well as federal agencies.

Questions 9 and 73: Both the Belmont Report and the Common Rule require constant interpretation and periodic revision

Question 9: How frequently should a mandatory review and update of the list of research activities that can qualify for expedited review take place? Should the list be revised once a year, every two years, or less frequently?

A.Not only the expedited-review list be reviewed at least every three or four years, but so should the entire regulation. And the regulation should be overhauled every twelve years in the light of experience. **Question 73**: To what extent do the existing differences in guidance on research protections from different agencies either facilitate or inhibit the conduct of research domestically and internationally? What are the most important such differences influencing the

conduct of research?

A.The National Science Foundation and the Agency for International Development have posted interpretations that discourage overregulation of classroom activities, oral history, journalism, and other endeavors.[18][17] This shows the value of reducing OHRP's role as the sole lead agency for the interpretation of the Common Rule. Instead, agencies that sponsor non-health research should have a greater voice.

Comments

The ANPRM contemplates creating "a standing Federal panel" to review and update the list of research activities that can qualify for expedited review.

This is far too modest a proposal. In fact, a standing federal panel should be empowered to offer guidance on all elements of the regulations and to revise the regulations themselves periodically. Moreover, the Belmont Report should be retired and replaced with a statement on research ethics that can be updated to reflect current thinking and experience.

No ethical or legal statement can address all future cases, so a sound regulatory system will provide for interpretation and revision. Congress understood this need when it called for a National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research that would "review periodically changes in the scope, purpose, and types of biomedical and behavioral research being conducted and the impact such changes have on the policies, regulations, and other requirements of the Secretary for the protection of human subjects of such research."[19][18] Similarly, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research did its work expecting that it would be constantly revised and interpreted. As commissioner Albert Jonsen has written

my colleagues and I fully anticipated that an Ethical Advisory Board (EAB) would he established as a standing agency within the Department of Health and Human Services. We had so recommended in almost all of our reports. We expected that such a Board could be the living oracle of Belmont's principles. Just as our Constitution requires a Supreme Court to interpret its majestically open-ended phrases, and, if I may allude to my own Catholic tradition, as the Bible requires a living Magisterium to interpret its mystic and metaphoric message, so does Belmont, a much more modest document than Constitution or Bible, require a constantly moving and creative interpretation and application.[20][19]

Congress abolished the National Advisory Council in 1978. Since then, there have been various federal bodies charged with reviewing the protection of human subjects. But these have been largely ineffectual. For one thing, they have lacked the power to issue guidance. Under the current system, SACHRP can make recommendations to OHRP, but only OHRP can issue the guidance. This creates a bottleneck.

In some cases, federal regulators have explicitly refused to offer clear decisions about murky regulatory language. In 2003, for example, Dr. Carome of OHRP issued guidance about the applicability of the Common Rule to oral history that left both historians and university administrators unsure how to proceed. Pressed to clarify his stance, he stated that OHRP was too busy to do so.[21][20]

What little guidance the federal government has provided often takes the form of quasi-official statements that are not binding on institutions and therefore have little effect. For example, in 1999, a Working Group of the Human Subjects Research Subcommittee of the National Science and Technology Council offered some sound advice on interpreting the Common Rule. But the guidance came with the warning that it had been prepared by "a working group of individuals who attend the Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council. The document does not necessarily represent the position of any of their respective agencies."[22][21] Similarly, the National Science Foundation website presents some sensible interpretations in its "Frequently Asked Questions and Vignettes: Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research."[23][22] However, their force is undercut by the disclaimer that "These notes represent the personal opinion of the Human Subjects Research Officer and do not supersede the official documents referred to."[24][23]

What we need is a permanent federal body with the power to issue prompt, clear, official guidance. It must be more representative than the current bodies such as SACHRP or the Presidential Commission for the Study of Bioethical

Issues. In 2003, the National Research Council's Panel on Institutional Review Boards, Surveys, and Social Science Research concluded that "Any committee or commission established to provide advice to the federal government on human research participant protection policy should represent the full spectrum of disciplines that conduct research involving human participants."[25][24] Neither the presidential commission nor SACHRP approach this standard.

The Canadian Panel on Research Ethics offers a promising model. Because its members are appointed by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC), the panel is more representative than its U.S. counterparts. And it has shown itself to be responsive to the concerns of researchers. The second edition of its Tri-Council Policy Statement, released in 2010, offers sensible guidance on organizational research, Internet research, and qualitative research—topics that U.S. bodies have scarcely addressed. Better still, it has promised ongoing interpretation of the regulations, the first of which appeared in August 2011.[26][25] Australia likewise expects its guidelines be "reviewed at least every five years."[27][26]

I therefore recommend that the United States emulate the best features of the Canadian system of regulation: representation by all parties, regular updates to both regulations and ethical standards (every three to five years), and full-scale reconsideration at intervals of no more than twelve years. To this end, I endorse the American Anthropological Association's call for

the creation of a commission constituted specifically of social scientists (e.g., sociologists and the like), humanistic social researchers (e.g., cultural anthropologists and the like), and humanists (e.g., historians, legal scholars, and the like). Rather than adapting strategies developed to protect biomedical information—which are fundamentally incompatible with core intellectual and ethical commitments of humanistic social studies—this commission would be tasked with developing alternative guidance appropriate for their fields.

The ANPRM notes that "although the regulations have been amended over the years, they have not kept pace with the evolving human research enterprise." I expect the next decades to witness equally dramatic changes, so I suggest a mechanism for periodic revision of the regulations. While it is true that the ANPRM "offers a rare opportunity for needed modernization," there is no reason for opportunities to remain rare.[28][27]

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41. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref13
42. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref14
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44. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref16
45. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref17
46. http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp
47. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref18
48. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref19
49. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref20
50. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref21

51. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref22
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56. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html#_ftnref27

6.10.13 In ANPRM Comments, American Historical Association Calls for Oral History Deregulation (2011-10-25 16:37)

As reported on [1]AHA Today, the [2]American Historical Association has submitted its ANPRM comments, with clear opposition to IRB oversight of oral history and the imposition of medical privacy rules to history research.

1. http://blog.historians.org/news/1451/aha-reiterates-stance-on-oral-history-review-and-cautions-on-extension-of-privacy-rules
2. http://blog.historians.org/file_download/43

6.10.14 Blogged Down (2011-10-28 15:55)

The ANPRM comment period has now closed, with (as of this writing) [1]1099 public submissions at the regulations.gov website. A taxing number!
I imagine the bulk of these will concern biomedical research issues beyond the scope of this blog. Even so, extracting some of the most significant comments about the social sciences and humanities is going to be a lot of work, and I apologize in advance for what I expect to be some pretty scrappy blogging for the rest of the year.

1. http://www.regulations.gov/#!docketDetail;dct=PS;rpp=10;po=0;D=HHS-OPHS-2011-0005

6.10.15 Is PRIM&R "Unaware" of Historians' Complaints? (2011-10-28 15:57)

[1]PRIM &R has posted its ANPRM comments.
There are a number of interesting points, but let's start with the response to Question 25, about the possible exclusion of "certain fields of study" from the Common Rule.
Executive director Joan Rachlin writes,

> Regarding the ANPRM's question about whether the Common Rule should be revised to explicitly state that certain activities that have traditionally not been viewed as research (classics, history, languages, literature, and journalism, e.g.) are not covered (Q. 25), PRIM &R is unaware that the failure to exclude these fields from the Common Rule has ever been a problem for scholars in classics, or literature, etc., and therefore questions whether such a provision is even worth considering. That said, PRIM &R suggests that determinations regarding what is and is not subject to IRB review should be made on the basis of the specific research activity in question, and not on the basis of an investigator's scholarly discipline. This would address some current inconsistencies regarding what type of inquiry gets reviewed.

"Classics, or literature, etc.?"
What's up with the "etc."? Has Rachlin not heard the complaints from historians, linguists, and journalists? Or has she heard the rumbling, but thinks that if she avoids writing "history," "language," or "journalism," those problems will go away?
History. It's the new [2]bear taboo.

1. http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/PRIMR_ANPRM_comments_10.26.11.pdf
2. http://cloudline.org/LinguisticArchaeology.html

6.11 November

6.11.1 PRIM&R: IRBs Don't Write Consent Forms (2011-11-03 20:01)

[1]PRIM &R's ANPRM comments make the helpful concession that "consent forms have become longer, more complicated, more 'legalistic,' and less useful as sources of information to potential subjects." But PRIM &R does not wish its members blamed for this trend, and claims that IRBs do not write consent forms. While this may be true in a technical sense, I believe it fails to acknowledge IRBs' share of responsibility for the problem.
Here's PRIM &R's version:

> IRBs neither interact with subjects nor write consent forms. Rather, consent forms are often written by sponsors and sometimes by investigators, who then present them to an IRB as part of its review of the research. IRBs work with what is submitted to them, so we strongly urge that OHRP remind sponsors and investigators that they have an obligation to create clear and understandable consent forms prior to submitting them to IRBs for review, and that they are the entities that actually design and conduct research which makes them primarily responsible for protecting human subjects. As discussed below, we recognize that consent forms have become increasingly legalistic documents designed to protect institutions and sponsors rather than to protect human subjects. This is not, though, a problem created by IRBs, and often there is little an IRB can do to correct this in the face of institutional and sponsor pressure.

I think this would surprise [2]Lee A. Green, Julie C. Lowery, Christine P. Kowalski, and Leon Wyszewianski:

> Most IRBs returned applications for revision, requiring changes to consent procedures, study protocols, and forms. Especially in the beginning of the study, this feedback was often helpful in refining the protocol and clarifying the consent form. However, revisions continued to be requested at an undiminished rate even late in the recruitment phase of the study, when the study protocols and consent forms had been refined through revisions at multiple previous centers. At least one resubmission was required at 76 percent (31 of 41) of the sites, and three or more (up to six) resubmissions were needed to secure IRB approval from 15 percent (6 of 41) of the sites. The types of revisions required by the sites were categorized into editorial versus procedural revisions. Editorial revisions include changes in wording to the consent or clarifications in the protocol, while procedural revisions include changes in the actual procedures described in the protocol. All sites that requested revisions requested editorial revisions; indeed, nine sites each requested more than 10 editorial revisions apiece. Procedural revisions were required in only 12 percent (5 of 41) of the sites. Of the five procedural revisions requested, three were requests to eliminate the consent form and use a cover letter instead. No discernible patterns in the specifics of the

editorial revisions emerged; they comprised a wide range of requests for deleting or adding sentences or paragraphs, phrasing, tense, and word choice.

Or [3]Jim Vander Putten:

You can imagine my surprise when several of the IRBs rejected the proposals on the basis of an inconsistent array of style issues, such as consent forms not cumulatively paginated (e.g., 1 of 3, 2 of 3, etc) and either written or not written in the past tense. The time delays associated with revision and re-submission of these IRB proposals (some of which were rejected a second time) were measured in months, and would have been even longer had we been required to complete each institution's responsible conduct of research training program. These delays began a chain reaction of subsequent delays in data collection, research conference proposal submissions and presentations, and manuscript submissions for publication consideration. For untenured faculty, these delays can present formidable obstacles to meeting institutional expectations for scholarly productivity leading to tenure and promotion.

Or the various [4]communication scholars who described their experiences in 2005:

We once submitted an informed consent form that had previously been approved. It was virtually identical to the previous one except for minor wording and title changes. The IRB came back with eleven major changes required before it could be approved . . .
We had intentionally prepared a very clear, concise, non-academic script and consent form for the subjects explaining the study's nature, goals, procedures, etc. However, the IRB did not approve of the script or consent form we prepared because they said that these respondents would include some illiterate or marginally educated individuals. They assumed the factory workers were not educated enough to read and understand our forms. Even though we informed the IRB that all employees at this factory were required to have a minimum of a high school diploma for employment, the IRB provided us with a script and consent form they created. Their materials were clearly written by a committee of academics; longer sentences, more polysyllabic words, more complex sentence structures. We were very surprised that they preferred their form over our own. While the IRB's goal may have been to protect human subjects from harm, we did not see how their more complex script and consent form helped accomplish this objective.

Or, for that matter, [5]AAHRPP:

IRBs are too rigid in consent document development, often using the precise wording in the 45 CFR 46.116 required elements of informed consent. In fact, many use even the exact order of the elements as written in 45 CFR 46.116. Guidance about elements that are optional, elements that are more important than others, or formatting sections would be helpful to the research community.

I would be curious to know what evidence PRIM &R has that "institutional and sponsor pressure" is behind this.

1. http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/PRIMR_ANPRM_comments_10.26.11.pdf
2. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681539/

3. http://www.institutionalreviewblog.com/2009/11/former-irb-chair-decries-inconsistency.html
4. http://www.tandfonline.com/doi/abs/10.1080/00909880500149361
5. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0354

6.11.2 Harvard Law School to Sponsor ANPRM Conference (2011-11-04 11:39)

Michelle Meyer of the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School kindly alerted me to a conference on the ANPRM planned for May 18 and 19, 2012. The following comes from the official announcement.

Conference Announcement and Call for Proposals: The Future of Human Subjects Research Regulation

The Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School is pleased to announce plans for our annual conference, this year entitled: "The Future of Human Subjects Research Regulation" The one and a half day event will take place Friday, May 18 and Saturday May 19, 2012 at Harvard Law School in Cambridge, Massachusetts.

Conference Description

The U.S. Department of Health and Human Services recently released an Advanced Notice of Proposed Rulemaking (ANPRM), titled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," which proposes to substantially amend the Common Rule for the first time in twenty years. This development, as well as attention by the Presidential Commission for the Study of Bioethical Issues, suggests we are at a moment when the regulation of human subjects research is ripe for re-thinking. This conference is meant to gather leading experts from the U.S. and across the globe to assist in that rethinking.

For further information on the call and for application requirements and deadlines, please see [1]http://www.law.harvard.edu/programs/petrie-flom/events/confer ences/humansubjects/hsrconfcall.pdf

Proposals are due November 25.

1. http://www.law.harvard.edu/programs/petrie-flom/events/conferences/humansubjects/hsrconfcall.pdf

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Anonymous (2011-11-05 18:28:06)

The time is now to press for a proposed rule that eliminates totally and completely regulation of the social sciences and humanities. The Obama Administration is trying to show its bona fides in deregulation. Eliminating current censorship and torture by IRBs could save tens of millions of hours and billions of dollars a year in wasted "paperwork" and "information collection" costs that are currently illegally imposed in violation of the Paperwork Reduction Act and the First Amendment. The man in charge is Cass Sunstein, head of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget, and a former University of Chicago professor. It is time for him to earn his pay. The woman in charge is Kathleen Sibelius, Secretary of HHS. We do NOT want to wait until next spring for a conference on the ANPRM, we want a proposed rule (NPRM) this winter, aimed at eliminating IRB review of riskless social and humanities research and at preventing IRBs from even reviewing whether such research is exempt or "excluded." Send Sunstein and Sibelius a message, and enlist thinktank and other external support. Remember that the current rule actually says that 99 percent of all social science is excluded, and doesn't even bother to discuss history and the humanities, which were not ever regarded as human experimentation that even needed to be excluded. The current rule does not give IRBs any authority to review exempt research, let alone to decide whether or not it is exempt. This is a problem that can easily be solved, if only the Administration will face it frontally. The time for academic discussion is over. The time for action is now.

6.11.3 PRIM&R: Efficiency Is Not an Ethical Value (2011-11-08 11:17)

Before moving on to other subjects, I wish to note one last passage in the [1]PRIM &R response to the ANPRM:

> The stated purpose of issuing this ANPRM is to make the process of human subjects protection more efficient. We fully recognize the potential benefits of accomplishing this goal. But we also want to note that efficiency itself is not a moral imperative or even an ethical value; human subjects protection should not be compromised by a desire for increased efficiency, a view we believe OHRP shares.

Really?
Is there no ethical problem when [2]bright, curious undergraduates are forbidden from seeking answers to their questions? When [3]a researcher abandons a project after months of inaction by the IRB? Or finds that [4]by the time she gets approval, she has missed the chance to do her research? When [5]IRB inefficiency delays medical research that can save lives?
I had thought that PRIM &R recognized justice as an ethical value. And justice delayed is justice denied.

1. http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/PRIMR_ANPRM_comments_10.26.11.pdf
2. http://www.institutionalreviewblog.com/2009/11/princeton-irb-delays-student-research.html
3. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
4. http://www.institutionalreviewblog.com/2007/05/even-best-irb-can-antagonize.html
5. http://www.institutionalreviewblog.com/2011/04/costs-of-ethical-review-part-ii.html

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6.11.4 AAUP and Me (2011-11-13 19:52)

I earlier mentioned that [1]I helped draft the AAUP comments in response to the ANPRM. I am pleased to report that I have since joined the AAUP's Subcommittee on Academic Freedom and the Institutional Review Board, which since 1981 has sought to keep IRB oversight within reasonable bounds.

1. http://www.institutionalreviewblog.com/2011/10/aaup-posts-anprm-comments.html

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6.11.5 Radio Show to Feature Menikoff, Hudson, and Me (2011-11-17 14:04)

On Monday (November 21) at 1pm, WAMU's Kojo Nnamdi Show will air "[1]Rethinking the 'Common Rule': The Ethics of Research with Human Subjects." Jerry Menikoff of OHRP, Kathy Hudson of NIH, and I will discuss the ANPRM.
The show airs in Washington on 88.5 FM and is [2]streamed online.

1. http://thekojonnamdishow.org/shows/2011-11-21/rethinking-common-rule-ethics-research-human-subjects
2. http://thekojonnamdishow.org/audio-player

6.11.6 Kojo Nnamdi Show on Common Rule Now Online (2011-11-22 13:26)

Yesterday I had the pleasure of joining Jerry Menikoff of OHRP and Kathy Hudson of NIH on an episode of the Kojo Nnamdi Show entitled, "[1]Rethinking the "Common Rule": The Ethics of Research with Human Subjects." We received many thoughtful, informed comments and questions.
I don't think any of us said anything that will surprise those who have followed the ANPRM debate closely, but I was pleased to hear Dr. Hudson concede that "The level to which current IRB protections actually protect participants is a somewhat understudied area. And I would hope that as we put these new rules in place that we can actually try to measure how effective they are in protecting participants in research."
In other words, after 45 years of imposing IRB review on researchers, we might begin asking if it does any good.
The audio recording and a transcript are now online at the link above.

1. http://thekojonnamdishow.org/shows/2011-11-21/rethinking-common-rule-ethics-research-human-subjects

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6.11.7 Criminologists: IRB Demands Threatened Confidentiality (2011-11-23 09:48)

Two professors of criminal justice–Mitch Librett of Bridgewater State College and Dina Perrone of California State University at Long Beach–describe IRB demands that endangered research participants. They suggest that "the oversight element and informed consent requirement of IRBs may in fact represent the greatest threat to the well-being of participants, which is contrary to the mission, purpose and objective of IRBs."
[Mitch Librett and Dina Perrone, "Apples and Oranges: Ethnography and the IRB," Qualitative Research 10 (2010): 729-747, [1]DOI: 10.1177/1468794110380548.]

IRB Demanded that Boss Be Informed

At the heart of the article of the article are the authors' accounts of IRB interference in their own criminal justice research.
The first concerns Librett's dissertation research, which he began while still a serving police officer. Librett wanted to interview five serving officers about the effects of undercover work, including "work-related psychological disorders [especially post-traumatic stress disorder (PTSD)], or any other difficulties (i.e., alcohol or other substance abuse)." (Brackets in original.) Since the disclosure of some of these effects could get a police officer fired or even prosecuted, Librett wanted to offer his narrators "an absolutely ironclad guarantee that any revelations would never be traceable to an identifiable person." Thus, he planned to interview them outside of their work settings and to avoid publishing any information that could identify them or even their agencies.
Librett describes the resulting exchange with the IRB:

> IRB: You've presented a very persuasive argument. However we are unable to approve your request. We absolutely must have letters of cooperation from the agencies involved, there's too much liability involved here.
> M.L: But sir, if I ask for official participation from the agencies, then the participants' identities might be compromised. We are talking about very small agencies here, and it wouldn't take an intimate knowledge of quantum physics for a police chief to figure out which undercover officer I was interviewing – when there is only one in the department.
> IRB: Well, we just can't approve it without official permission.

Librett eventually settled for interviewing two retired police officers at significant cost to his research. He preferred to sacrifice his findings rather than accede to an IRB demand that would have put his narrators at risk.

IRB Demanded that Researcher Disclose Names and Tapes

Perrone had less trouble getting initial approval for her study of "club drug" users, but she was frustrated by her IRB's demand that she get signed consent forms. As she and her narrators understood, such consent forms posed more threat than protection, since they would create a document stating, in effect, that the signer used illegal drugs.

[Yes, I know that [2]45 CFR 46.117 allows IRBs to "waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds . . . that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality." The problem here is that Perrone's IRB didn't understand that, and the rule itself [3]requires the investigator to offer subjects forms that will endanger them.]

Perrone got around this by giving each informant the "option to sign any name she/he chose." How this process boosted trust or protected subjects is anyone's guess.

Perrone's IRB more seriously threatened her subjects when it investigated her research as part of an audit of randomly selected projects.

As part of the audit, the IRB demanded "the keys linking the pseudonyms the participants had chosen to their biographical information" and "an actual audiotaped recording of an interview session held with informants." Both demands raised the chances that the narrators' illegal drug use would become known in ways that hurt them, and forced Perrone to violate the promises she had made to them. Still, she gave in.

> Perrone was perplexed and stressed that she had assured her participants that no one would listen to the tapes but her. Therefore, the IRB's 'audit' violated the trust participants had in Perrone, and breached confidentiality. The auditors stressed that as members of the IRB, they have the legal authority to listen to the tape. Perrone conceded, however there was not much choice here. As in all cases, refusal to comply with requests from IRB results in cancellation of projects, failure to complete dissertations, and the resultant damage to careers. Perhaps more importantly, disinformation and grapevine anecdotal evidence may prevent some projects from ever being attempted in the first place.

Questioning the Model

Reflecting on such experiences, Librett and Perrone assert "a fundamental disconnect between what the typical Institutional (or Ethical) Review Board will perceive as essential to safeguard the rights of human subjects and critical ethnographers' interest in maintaining a high degree of trust and partnership with their research participants."

They note that ethnographic projects "are by definition open-ended and unpredictable as far as the sort of questions that will be asked, the activities that will take place in the field, and the direction of interview protocols" and that "Ethnographers are hardly psychic. They are unable to accurately predict possible events with any degree of certainty in the field. While psychologists or hard scientists are not psychic either, their research is often conducted in closed and controlled laboratory environments."

Because the course of research is so hard to predict, Librett and Perrone note that "the greatest potential for harm to participants in an ethnography is the release of the participants' true names and/or identifying information. Thus, the IRBs' focus on research plans is quite beside the point."

They do not say so explicitly, but a logical next step would be to replace prospective review of field research with "ethical proofreading" of manuscripts just prior to publication to make sure that they did not violate any promises of confidentiality. [See Carole Gaar Johnson, "Risks in the Publication of Fieldwork," in Joan E. Sieber, ed., [4]The Ethics of Social Research: Fieldwork, Regulation, and Publication (New York: Springer-Verlag, 1982).]

Additional Points

Librett and Perrone also pose some minor points, which perhaps could use elaboration. They write that "ethnographies may not fall within the definition of research, as it is currently defined in federal regulations. Ethnographies are by nature decidedly unsystematic. There is no testing and whatever knowledge is generated is heuristic. While ethnography

most certainly is science, in that it informs our understanding of significant phenomena, it is not systematic or generalizable; it lies beyond the realm of positivism." Given the history of the National Commission, which specifically mentioned anthropological research in its IRB report, it's bold to claim that ethnography does not fit the regulatory definition of research. But perhaps there is a case to be made.

The authors also claim that "if a legal authority – police or court – had asked for [tape-recordings of interviews] Perrone would have certainly been free to state that the records had been 'lost' (without consequence) . . ." A researcher who receives a subpoena for her recordings may indeed seek to quash the subpoena, but falsely claiming that the records had been lost, or destroying the records, could in fact have very unpleasant legal consequences.

1. http://dx.doi.org/10.1177/1468794110380548
2. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117
3. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-2-calcified.html
4. http://books.google.com/books?id=--AtAAAAIAAJ

Anonymous (2011-11-23 10:58:12)

Interesting. I do not see any evidence that the disconnect is "typical". You'd think researchers would know better than to generalize from their own personal experience and anecdote.

The requirements in the Librett case are clearly ridiculous and contrary to the requirement to minimize risk. The IRB seems to be more concerned about institutional risk.

However, Librett is wrong if he thought he could offer "an absolutely ironclad guarantee that any revelations would never be traceable to an identifiable person." Researchers should never make promises that might not hold up. You'd think a detective, whose job is to identify people who beleive they won't be identified, would no better. Better to describe for the subject the steps taken to greatly reduce the risk. Telling subjects that there is "no risk" is unethical.

In the Perrone case there should be no requirement for signed informed consent because this is covered, as noted, by 117(c)(1). I agree that requiring documentation be made available as an option is stupid but following the minimizing risk requirement elsewhere in the regs an IRB is more than justified in ignoring it. If there are conflicting requirements I think it is fair game for the reviewers have to make a sensible choice.

They allowed her to keep audio recordings and keep keys to the participants identities despite the legal risk? If they were doing their job they'd want to severely limit the collection of identifiable data and the time it could exist in an identifiable state. And if you collect this identifiable data that makes you ineligible for 117(c)(1). It states "the only record" linking is the consent form. If you want that documentation exemption you can't record other identifying data. That doesn't make any sense. I wonder if they required her to get a certificate of confidentiality? I'm skeptical about how effectiveness of CoCs but at least it's something. Perrone seems to be almost as clueless as she makes her IRB out to be. The part about the option of lying to the court shows really bad judgement.

If a breach of confidentiality creates significant risk, you want to severely limit any data that could be identifying including documented consent. You don't want audio recordings or keys files or anything like that. You want to create de-identified data that can't be re-linked without great difficulty or where there is significant doubt about the validity of the recreated links. If the only links are in the researcher's memory, then there is plenty of room for "I'm not sure who said what". Do enough interviews, and believe me, that's true.

So, where does this leave us? Sure there are IRBs who do a bad job, but there are researchers who need adult supervision.

Zachary M. Schrag (2011-11-23 14:45:38)

Thanks for these thoughtful comments. I should have mentioned that the authors do not merely "generalize from their own personal experience and anecdote"; they also cite a number of other publications noting similar problems with IRBs.

I agree that these two researchers could have used some guidance on the limits of confidentiality. Unfortunately, their IRBs seem to have lacked the expertise necessary to provide such guidance, and instead made matters worse. Nor is this surprising. As [1]Joan Sieber noted back in 2001, "There is now a literature of virtually hundreds of approaches to protecting privacy or assuring confidentiality. This literature is rarely sought out by IRBs, researchers, or teachers of research methods. Most are not even aware that it exists. . . ."

The coercive power of IRBs relieves them of the need to achieve and demonstrate true expertise while discrediting the idea of any kind of ethics review. Deregulating social science research might encourage individual researchers and departments to seek

out true expertise. See "[2]Michael Rowe on Situational Ethics."

1. http://www.institutionalreviewblog.com/2007/01/why-not-make-irb-review-voluntary.html
2. http://www.institutionalreviewblog.com/2008/04/michael-rowe-on-situational-ethics.html

Mitch Librett (2011-12-29 11:31:28)
My 'absolutely ironclad guarantee' represented my personal word, as a cop-to other cops-while I was a serving police officer. This section of the article referred to a grad school project that never was published- for that and other reasons (I promised the participants that I wouldn't ever publish what they gave me for one). Lessons learned! But in regarding the IRB, their demands were impossible to satisfy; there are many, many similar cases cited in this extensive literature.

Zachary M. Schrag (2011-12-29 17:05:04)
Thanks for this comment. As Boston College prepares to supply prosecutors with interview materials for which the narrators were promised confidentiality, I think all researchers must ask themselves if their "personal word" includes a promise to go to jail before complying with a subpoena.

6.11.8 Stark Reviews Ethical Imperialism (2011-11-25 14:11)

Laura Stark, assistant professor of sociology at Wesleyan University, reviews Ethical Imperialism for the American Journal of Sociology. She finds that the occasional "keen observation . . . is not harnessed to a broader analytic framework or explanatory apparatus."
[Laura Stark, [1]Review of Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009 by Zachary Schrag, American Journal of Sociology 117 (November 2011): 1019-1021.]
Stark apparently rejects my conclusion that "IRB review of the social sciences and the humanities was founded on ignorance, haste, and disrespect." Instead, she claims that

> research methods commonly used in the social sciences were included in the regulations because of contemporary concerns about social, legal, and financial risks—not only the (nonexistent) physical risks of sharing information with a social researcher. To understand how worries about nonphysical risks might have seemed legitimate to historical actors, readers should bring to the book a sense of broader political conversations at the time about civil rights, "privacy," and expert authority.

One can find some evidence to support such a thesis. For example, I report the 1967 recommendations of the Panel on Privacy in Behavioral Research, which supported the idea of institutional review out of concern with privacy. Yet that same panel concluded that

> because of its relative inflexibility, legislation cannot meet the challenge of the subtle and sensitive conflict of values under consideration, nor can it aid in the wise decision making by individuals which is required to assure optimum protection of subjects, together with the fullest effectiveness of research . . . Institutions differ in their internal structures and operating procedures, and no single rigid formula will work for all. (Ethical Imperialism, 36)

Of course, Congress and the executive agencies ignored this advice, passing legislation imposing rigid formulae. Most of my book is a narrative of such disconnects between the people genuine concerned with the issues that Stark notes and those who had the power to pass rules over the objections of the former group.

Stark and I may disagree most on our understanding of the power of individuals and groups to shape the law. Back in 2007, [2]I complained about Stark's use of the passive voice in describing the origins of the IRB system, and I am sorry to see her still relying on it: "research methods commonly used in the social sciences were included in the regulations because of contemporary concerns . . ." The active voice would have required her to explain who exactly was so concerned. Congress? The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research? NIH officials?

But Stark discounts the value of studying people, arguing that my "historical interpretations tend to be character assessments of individuals rather than reflections on how IRBs connected to broader social processes or how IRB debates fit into a wider political context." Indeed, I do study individuals, and small groups such as the National Commission. I do so in the belief that people, and not "broader social processes," write laws, regulations, and guidance. And I was unable to find anyone with the power to craft those rules who was also seriously interested in the problems of social science.

Stark also accuses me of crafting a narrative in support of a policy position, writing, "Schrag's concern is to justify the view that most social scientists' research should not be subject to the federal regulations."

As I explained in my preface,

> I approached this project with as open a mind as I could, abandoning some of my preconceptions as my research progressed. In particular, I began my investigations expecting to find that the officials who wrote today's human subjects regulations had wholly failed to consider the impact of their work on non-biomedical research, and I was repeatedly surprised to learn how frequently (if superficially) they debated the subject. I hope all those interested in the topic, regardless of their positions, will likewise let themselves be surprised by the facts in this account. (x)

Either Stark overlooked this passage, or she doesn't believe me.

1. http://ljstark.faculty.wesleyan.edu/files/2009/09/Review_AJS3.pdf
2. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html

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6.11.9 Health Researcher Complains of "Social Science Types" and HIPAA (2011-11-26 08:43)

Since I have frequently documented the complaints of social scientists who suffer from inappopriate conditions imposed by medically oriented IRBs, it seems fair to report a story going the other way, related on a [1]Scientific American blog by Judy Stone, MD:

> This past summer, I went to India to volunteer at a hospital and to try and help them with their self-identified problem with tuberculosis. There was considerable debate as to whether or not IRB approval was necessary—my infectious disease colleagues felt it was not, as it was part of a public health initiative and the "research" was no different than that conducted every day in public health departments. The social science types at the U.S. university I was working with all insisted we obtain IRB approval, a time-consuming and, in some settings, expensive process. (Many IRBs levy an administrative charge of $1-2,000 per study). And the folks in India could have cared less, nor did they understand the fuss, as there is next to no patient privacy in their crowded facility, nor was it culturally relevant. All they wanted was help caring for their patients.

Stone does not relate what happened next: whether she did, in fact, seek IRB approval, and–if so–what level review she received or what kinds of restrictions she faced.

Ultimately, Stone blames not the social science types but flaws in the regulations and laws, especially HIPAA, which she blames for "failing to provide any protection for clinical research subjects [while] increasing research costs and probably reducing participation . . ." She hopes "that reason will prevail, and the HIPAA rules will be eliminated for clinical research."

1. http://blogs.scientificamerican.com/guest-blog/2011/11/22/molecules-to-medicine-pharma-trumps-hipaa/

6.11.10 Claude Fischer: Zealous IRBs Can Derail Social Studies (2011-11-30 16:13)

Claude Fischer, professor of sociology at UC Berkeley, links IRB restrictions with the death of The Statistical Abstract of the United States and fears that they and other trends "combine to increasingly blind policymakers and the public to what is going on in America."
[Claude Fischer, "Stumbling in the Dark," Made in America (blog), 22 November 2011,
[1]http://madeinamericathebook.wordpress.com.]
Fischer writes that in addition to the cuts to census data collection and the National Science Foundation's behavioral science programs,

> Social research has been boxed in from another angle by what many scholars consider a too-obsessive concern about privacy. For example, my colleagues and I found that it extremely difficult if not impossible to obtain decades-old information about neighborhoods – for example, the proportion of the workers living in a particular census tract in 1960 who held professional jobs. The fear, baked into U.S. Census rules, is that with enough such general data we might be able to identify a particular person in a census report 50 years ago and find out, say, how much money he made.
> Social scientists on campuses have been struggling against zealous IRB's – university Institutional Review Boards — that must approve any research conducted by faculty on human subjects. Designed quite properly to prevent harm to subjects of studies, particularly subjects of medical treatments, the IRBs in many places have expanded their mission to closely supervising social science research. Some, for example, treat the posing of survey questions – say, asking respondents' opinions about social issues – or even the gathering of historical records as if they were in the same category as injecting people with drugs. This zealotry sets up great hurdles that delay or derail social studies. Doctoral students, in particular, can have careers crippled by these restrictions. (See statements by social science organizations here in 2001 and here in 2011.)
> (At one time here at Berkeley, the local IRB, according to some reports, entertained the idea of "social harm": research that might impugn a social group — for instance, showing that women get more emotional in some settings than men — ought to be stopped. That would pretty much stop social research altogether.)

Readers of [2]Ethical Imperialism will know that in 1972 Berkeley's IRB chair, Bernard Diamond, did indeed announce his intention to screen research that could threaten the reputations of social groups. Faculty protested this infringement on academic freedom, and the university reversed this policy in the spring of 1973.
Fischer suspects that today's "restrictions on social science may also reflect yet another attitude held by some, both left and right: the conviction that there is no need to gather the data, because they already know the answers." Indeed, IRB regulations and procedures do make more sense [3]if you believe that social science plays an unimportant role in a democracy.

1. http://madeinamericathebook.wordpress.com/2011/11/22/stumbling-in-the-dark/
2. http://books.google.com/books?id=nSv83XkNq3gC&lpg=PR12&ots=iWZqAnWRjf&dq=schrag%20%22ethical%

20imperialism%22&pg=PA45#v=onepage&q=a%20group%20may%20be%20derograted&f=false
3. http://www.institutionalreviewblog.com/2007/08/james-weinsteins-anti-intellectualism.html

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6.12 December

6.12.1 Special Issue of Qualitative Sociology: "Ethics Beyond the IRB." (2011-12-07 15:24)

I have just learned that the September 2011 issue of Qualitative Sociology is a special issue on the topic, "Ethics Beyond the IRB." It may be some time before I can address this issue in depth, but meanwhile here is the table of contents.
Qualitative Sociology
Volume 34, Number 3 / September 2011
[1]Special Issue: Ethics Beyond the IRB
Guest Editors: Kathleen Blee and Ashley Currier

- Kathleen M. Blee and Ashley Currier, "Ethics Beyond the IRB: An Introductory Essay," 401-413.
- Rachel L. Einwohner, "Ethical Considerations on the Use of Archived Testimonies in Holocaust Research: Beyond the IRB Exemption," 415-430.
- Bernadette Barton, "My Auto/Ethnographic Dilemma: Who Owns the Story?", 431-445.
- Gloria González-López, "Mindful Ethics: Comments on Informant-Centered Practices in Sociological Research," 447-461
- Ashley Currier, "Representing Gender and Sexual Dissidence in Southern Africa," 463-481.
- Leila J. Rupp and Verta Taylor, "Going Back and Giving Back: The Ethics of Staying in the Field," 483-496.
- Melissa Swauger, "Afterword: The Ethics of Risk, Power, and Representation," 497-502.

1. http://www.springerlink.com/content/0162-0436/34/3/

6.12.2 This Time, Vote as If Your Whole Research Agenda Depended on It (2011-12-08 10:00)

Alice Kessler-Harris, president of the Organization of American Historians (OAH), devotes her column in the November OAH Outlook to the question of "Historians and the Institutional Review Board."
Naturally, much of the piece introduces the IRB controversy to those historians who may not be familiar with it:

> For several chaotic years, IRBs have exercised what, in my view, seems like unwarranted influence over the research agendas of historians. Resentful professors have been asked to tell IRBs who they want to interview and why. Assistant professors who have not asked for prior permission have been told they cannot publish articles on which they have worked for years. Graduate students have been told to alter the questions they want to ask. In an illustration of the treacherous slippery slope, IRBs–claiming "information risk"–have suggested that archivists require researchers who want to access transcripts of interviews and data sets to acquire IRB clearance first.

Kessler-Harris frames this warning in an interesting way, noting that when the ANPRM was released this summer, the OAH Executive Board was able to "make its voice heard" by consulting with other historians' organizations and submitting a formal response. She then uses these actions to stress the importance of member participation:

> So why should you vote in this year's OAH election? Because next year, your elected board will be called upon to take anther equally important step. If you want to be sure that you will have an active and engaged executive board to represent your interests, look for your ballot and vote when it arrives.

I am still working my way through the ANPRM comments, but I suspect that many organizations took a similar approach, relying on existing ethics committees or executive boards to speak for the members. This approach balanced the wish to represent a broad membership with the need to act during the brief window for comment–originally 60 days, extended to 90. So I think Kessler-Harris is quite right to use the ANPRM as an example of the need for elected representatives within a scholarly discipline.

6.12.3 Bush Official: Ask IRB Before Speaking in Public Park (2011-12-08 13:06)

Diane Auer Jones, U.S. assistant secretary of postsecondary education in the George W. Bush administration, believes that professors should seek IRB permission before giving political speeches in public parks.

Since October, Andrew Ross, Professor of Social and Cultural Analysis at New York University, has been [1]floating the idea that indebted students and graduates might sign a pledge not to make further payments on their loans once one million debtors had signed.

Jones is currently vice president for external and regulatory affairs for the Career Education Corporation, [2]whose business model apparently consists of persuading students to take out government-backed loans by exaggerating their job prospects on graduation. Angered by Ross's ideas, [3]she wrote in her blog on the Chronicle of Higher Education website that "it is time for NYU to take action to silence Andrew Ross." She included a link to [4]a video of Ross speaking in Washington Square Park, near the NYU campus.

When [5]Ross (a member of the AAUP's Committee A on Academic Freedom) replied that his views are protected by academic freedom, [6]Jones dismissed the idea. "If Dr. Ross wishes for his call to default on student loans to be covered under the umbrella of academic freedom," she wrote, "then I would ask to see the written consent he received from his IRB to engage students in this experiment in cultural studies."

Jones's post reveals her to be as ignorant of the regulations governing human subjects research as she is contemptuous of academic freedom. She claims that "Academics–or at least the agencies that fund their work–do not believe that the right of academic freedom trumps the rights of individuals who may be harmed, either directly or indirectly, by the scholarly pursuit of knowledge, no matter how well intentioned that research might be."

In fact, [7]45 CFR 46.111 specifically instructs IRBs not to consider "possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility," thus disregarding the indirect harms of the pursuit of knowledge. And I doubt that even [8]the country's worst IRB office would consider Ross's speech in a public park to be research under the Common Rule.

Still, it's noteworthy that when Jones sought a weapon with which to silence a professor, the first rhetorical cudgel at hand was the IRB.

[h/t: [9]Roberto Veloso]

Note. Jones's second post may contain the seeds of a stronger argument when she asks, "does [Ross's] academic freedom free him from financial obligation for the damage he is inflicting?" That seems to suggest she thinks Ross liable for tortious interference in the contract between debtor and lender. I don't know if that's a good argument, but it's got to be better than the human-subjects claim.

1. http://chronicle.com/article/Protesters-Plan-a-National/129810/
2. http://www.cbsnews.com/stories/2005/01/31/60minutes/main670479.shtml
3. http://chronicle.com/blogs/brainstorm/academic-freedom-or-educational-malpractice/41815
4. http://www.youtube.com/watch?v=rFFgjJc9hPM
5. http://chronicle.com/blogs/brainstorm/dr-andrew-ross-responds/41861
6. http://chronicle.com/blogs/brainstorm/with-privilege-comes-responsibility/41870
7. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111
8. http://www.institutionalreviewblog.com/2008/04/do-ucla-researchers-have-permission-to.html
9. http://twitter.com/#!/roberto_veloso

6.12.4 Blogday (2011-12-13 13:32)

Yesterday marked the [1]fifth birthday of the Institutional Review Blog.
Not long after starting the Blog, I explained my intentions to [2]Inside Higher Ed:

> Schrag said that the problems with IRBs will probably remain for some time. "I think the regulations themselves are poorly drafted, with terms that are not well defined, and I anticipate problems until they are amended," he said. "Perhaps until then, I'm going to have to keep up the blog."

With the ANPRM out, I am closer to retirement as blogger than I dared to hope five years ago.

1. http://www.institutionalreviewblog.com/2006/12/introduction.html
2. http://www.insidehighered.com/news/2007/01/19/irb

Dylan (2011-12-15 12:44:53)
I just discovered this blog the other day, and have been fascinated by several postings already. I am a staff member in a University IRB support office and a Certified IRB Professional (CIP). Because we are a primarily social/behavioral research institution, we tend to be more a more generous IRB than many of those described in this blog. Nevertheless, problems (such as delays) remain.
I've often heard historians argue that IRBs and IRB offices often do not understand the nature of historical research. While I believe this is true, I also believe that many of these same IRBs do not understand the flexibility that is built into the Regulations to accommodate this kind of research. In fact, it may be more accurate to say that there is a failure of nerve on the part of IRBs to exercise this flexibility even when they do understand it.
I often fear that any change in the Regulations will result in less flexibility.
Anyway, those are just some quick thoughts for you... I'm enjoying this blog :)

Zachary M. Schrag (2011-12-15 12:54:22)
Thanks for this comment, and welcome to the blog. I hope that it will give a different perspective from what you might get from, say, PRIM &R.
As you will read, I am skeptical of the "flexibility" argument, since it is the vagueness of the current regulations that encourages much IRB abuse. See [1]Less Flexibility, More Freedom from 2009.

1. http://www.institutionalreviewblog.com/2009/02/less-flexibility-more-freedom.html

6.12.5 Halavais Calls for "Open Publication of IRB Protocols or Ethics Reflections" (2011-12-15 11:58)

In an essay in Nature and on his blog, Alexander Halavais, president of the Association of Internet Researchers, calls for funders to require "the open publication of IRB protocols or ethics reflections."
[Alexander Halavais, "Social Science: Open Up Online Research," Nature 480 (8 December 2011): 174–175, [1]doi:10.1038/480174a; Alexander Halavais, "[2]IRBs and Clean Secrets, A Thaumaturgical Compendium, 8 December 2011.]

The Problem: Secrecy

In his Nature essay, Halavais details the problems that Internet researchers face when submitting protocols to inexpert boards.

> High levels of scrutiny are clearly necessary for a drug trial. But scrutinizing whether gamers would be traumatized by being asked questions about dressing up as characters for conventions — to take an example from my students' research — is an issue best addressed by the researchers, who have had much more exposure to the participants and the culture being examined.
> For those who research online interactions, it can be especially frustrating to have a board filled with members who have never used Facebook or played World of Warcraft. Although IRBs can, and sometimes do, bring in experts who can address the context of the research more directly, this happens more rarely than it should . . .
> The decisions of IRBs seem to be idiosyncratic and, by extension, capricious, especially when multi-site research is approved by several boards, yet held up by others. In the case of a colleague, each of two review boards insisted on having the other approve a protocol first.

Looking for the source of IRB caprice, he finds it in IRB secrecy:

> The greatest problem faced by the ethics system is secrecy. Review boards must make decisions with limited access to previous cases. Their decisions are rarely available to other IRBs or to researchers who could make productive use of their precedents — particularly in new areas of research such as online social science, in which review boards tend to have little experience and would therefore benefit most from the experience of others.

This, of course, has been a problem since at least 1973, when [3]Jay Katz testified that "The review committees work in isolation from one another, and no mechanisms have been established for disseminating whatever knowledge is gained from their individual experiences."

The Solution: Transparency

Katz's proposed remedy was "the publication of the important [IRB] decisions rendered at the local and national level. This would radically change the current uninformed and secretive climate which pervades research decisionmaking. At present, decisionmaking remains divorced from pertinent prior decisions of other committees or from scholarly and public evaluation and criticism." He wanted Congress to establish this system, with a permanent National Human Investigation Board at its apex.
[Jay Katz, testimony, U.S. Senate, Quality of Health Care—Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, Part 3 (93d Cong., 1st sess., 1973), 1053.]

Halavais, too, wants research ethics to be made transparent, but he doesn't count on Congress or IRBs to lead the way. As he notes in Nature, "The IRB system is conservative by design; we must look elsewhere for change."
So instead of seeking the publication of IRB decisions (the outputs), Halavais wants the publication of researcher applications (the inputs). And, he blogs, even "if you don't have to have IRB approval, I think funders should still require you to talk about the ethical considerations of your research, and journals should require you to publish this online when you do not have an IRB-approved protocol to provide." He elaborates (in Nature):

> Most government funding agencies and private foundations prominently promote open data sharing and collaboration. Were they to make the open publication of IRB protocols or ethics reflections a requirement for receiving funding, it would provide a crack in an otherwise too-secretive process. Many journals expect social-science research to have been inspected by an IRB before submission; a few even require authors to sign a statement of IRB approval. None requires that the approved protocol be provided to the journal or published. They should. Although some information would need to be redacted from such documents — including anything that might violate the privacy of participants or of the researchers — they would open a new window on ethics considerations.

Some Questions

I applaud Halavais for this bold reimagining of a system of research ethics, and I hope he will flesh out some needed details.
1. Is boilerplate OK?
Halavais wants researchers to "talk about the ethical considerations of your research," but he doesn't explain what that would look like. As [4]Rena Lederman noted in 2007, neuroscientists using an fMRI machine

> developed a standard set of very detailed responses to the IRB questionnaire (e.g., about what subjects will experience, the safety risks they will face, and the measures that will be taken to minimize those risks). The only parts of the questionnaire that are individualized—apart from the researchers' names, ranks, and contact information—are the brief project descriptions (what they are looking for this time and what they hope to learn from the data). Generally, since the basic responses are all, by now, familiar to our IRB, the main ethical dilemma faced in discussing fMRI protocols concerns the possibility that a pathology might show up in a brain scan and the consequent question of whether and how the researchers ought to inform subjects.

Lederman used this model to write "standardized descriptions of anthropological research," noting, for example, the inappropriateness of consent forms. She then posted this for others to use. Would such standardized descriptions satisfy Halavais?
(Side note. In the comments section to Lederman's post, one researcher reports trying out Lederman's application and being told by the IRB to get written consent anyway.)
2. Is an approved protocol the same as an ethical reflection?
[5]L. L. Wynn surveyed ethnographers and found that "32 percent of the respondents actually believed that the [committee-required] modifications were 'detrimental to the welfare of the informants or research participants.'" If an IRB forces a researcher to change her plans in ways that endanger research participants, it seems unfair to require that researcher to publish the flawed protocol unless it is accompanied by a disclaimer.
Now, that could lead to some interesting results if researchers routinely declared, in writing, that they thought their IRBs were endangering research participants. But I wonder if Halavais intends to put researchers in so awkard a spot.
3. Why keep the IRB?

In a throwaway line in his Nature piece, Halavais writes, "The solution is not to do away with the IRB, but rather to make amendments that render its dysfunctions less acute."
Why?
In sketching a requirement for public declarations of ethics, Halavais envisions a complex system that brings researchers, funders, journals, and readers into dialogue about research ethics, without necessarily involving IRBs. If such a system gets off the ground, why would we want to maintain a system of "idiosyncratic and, by extension, capricious" review by ignorant IRBs?
Just because the IRB system has been around a long time is no reason to assume it should persist.

1. http://dx.doi.org/10.1038/480174a
2. http://alex.halavais.net/irbs-clean-secrets
3. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
4. http://savageminds.org/2007/04/02/educate-your-irb-a-boilerplate-experiment/
5. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=7974987&fulltextType=RA&fileId=S0898030610000333

6.12.6 Veterans Denied Chance to Comment on Foreign Policy (2011-12-15 12:52)

In a comment on [1]Alex Halavais's blog post on IRBs, [2]Wynn W. Gadkar-Wilcox of Western Connecticut State University relates a horror story:

> I will never forget a case from several years ago in which we were asked to approve a study that asked veterans of the wars in Iraq and Afghanistan their opinion of the foreign policy of the Bush administration, and the study was denied because of fears that the question might trigger PTSD. Ridiculous. If that study triggers post-traumatic stress, then vets should never be allowed to take history or political science courses.

We need to remember that this kind of IRB abuse diminishes not only the freedom of researchers, but also the freedom of participants–in this case veterans denied the chance to comment on national policy–and of all who can benefit from research.
Gadkar-Wilcox, who identifies himself as "a long-time member of an IRB," also notes that "sometimes IRB's do important work, such as when they prevent (in one case I remember) the distribution of a non-anonymous survey to students that asked them to reveal potentially illegal conduct. In general, though, there is plenty of overregulation."

1. http://alex.halavais.net/irbs-clean-secrets
2. http://people.wcsu.edu/wilcoxw/

6.12.7 Presidential Commission Prescribes Medical Ethics for Everyone (2011-12-16 09:25)

The Presidential Commission for the Study of Bioethical Issues has released a 200-page report, Moral Science: Protecting Participants in Human Subjects Research. Continuing a decades-old tradition, the report treats medical experimentation as the model for all research with human beings, ignoring the rights and responsibilities of researchers in other fields.
[Presidential Commission for the Study of Bioethical Issues, [1]Moral Science: Protecting Participants in Human Subjects Research, December 2011]
The report is a response to President Obama's November 2010 request for "a thorough review of human subjects protection to determine if federal regulations and international standards adequately guard the health and well-being of

participants in scientific studies supported by the federal government."
At the time of that charge, [2]I warned,

> the commission lacks the full range of expertise to review all the federal regulations and international standards that govern human subjects protection. Since the 1960s, committees and commissions composed of medical researchers, psychological researchers, and bioethicists have advised regulators and presidents about human subjects protections without adequately consulting researchers in the social sciences and humanities, who then find themselves subject to rules they were not allowed to shape.

Unfortunately, the report continues this trend.
The Commission claims to have made "attempts to understand the full range of human subjects research conducted or supported by the federal government." (44) But the Commission seems to have been only dimly aware that not all "human subjects research" is medical experimentation.
One passage refers to "Early stage translational research [that] serves to test physiological effects or biological functions of new drugs and medical interventions but is not necessarily designed to benefit subjects " and to "Research in other fields, including housing, social work, and criminology . . ."(19) Ah, yes. The social sciences as Other. A few pages later we get a reference to "Research beyond public health and medicine, in social science and related fields, [that] can involve thousands of research subjects through increasingly accessible survey tools and methodologies that expand experimental rigor." (21) Again with the "experimental rigor."
When the Commission tried to imagine "Non-Clinical Human Subjects Research," it came up with three examples all dealing with health in some way: a HUD study of obesity and diabetes, a DOE study of long-term health impacts from the atomic bombing of Japan, and a DOJ study of the safety of stun guns. (38, Table 2.2).
And several portions of the report suggest that the authors were thinking only about medical research. For example, the report claims that the Common Rule and FDA regulations "extend to most, although not all, research conducted in the United States and nearly all research funded with public monies outside of the country." (32) But these regulations do not cover the vast machinery of marketing surveys conducted every day by private corporations, much less the identifiable private information collected by every supermarket with a loyalty card program. If you understand what human subjects research is under present definitions, you know that the bulk of human subjects research conducted in the United States is not regulated. Nor should it be, if it only involves asking questions of adults.
The consequence of this misunderstanding is a failure to understand that different research enterprises involve different ethical principles. In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's [3]Belmont Report ignored warnings that medical ethics were not appropriate for all fields. Today's Commission still wants to shove everyone into the Belmont box:

> Medical research that poses risk of physical injury rightly raises more concerns than does routine social survey research, for example. Nonetheless, the same ethical principles govern all of these activities, and serve as enduring guideposts that must not be ignored. (3)

Naturally, if you believe that all ethics is medical ethics, why not make humanities majors study bioethics in college?

> Recommendation 7: Expand Ethics Discourse and Education
> To ensure the ethical design and conduct of human subjects research, universities, professional societies, licensing bodies, and journals should adopt more effective ways of integrating a lively understanding of personal responsibility into professional research practice. Rigorous courses in bioethics and human subjects research at the undergraduate as well as graduate and professional levels should be developed and expanded to include ongoing engagement and case reviews for investigators at all levels of experience. (22)

Moreover, Recommendation 13 wants the federal government to "require that all federal agencies conducting human subjects research adopt human subjects regulations that are consistent with the ethical requirements of the Common Rule." (102) Unless "human subjects research" is redefined, this could sweep into a flawed system researchers who are sponsored by non-signatory executive agencies, like the National Endowment for the Humanities, and perhaps even legislative agencies like the Library of Congress.
Medical ethics for everyone!
The irony here is that by ignorning ethical complexity, the Commission threatens to diminish rather than enhance "a lively understanding of personal responsibility."
The only really hopeful note in the report is its section on the ANPRM. The Commission "generally supports the objectives of the ANPRM and the goal of better protecting human subjects while reducing burden, delay, and ambiguity for investigators," and it has even learned from the ANPRM that "many social and behavioral scientists have argued that their research is over-regulated in the current system." (97) But no one on the Commission seems to have grasped the ANPRM's message that some research "may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule."

1. http://bioethics.gov/cms/node/558
2. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5107&blogid=140
3. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4999&blogid=140

PCM (2011-12-17 08:17:06)
Clearly you can't retire yet.
I bought and starting reading your book last night. Very good stuff.
I can only encourage every other social science researcher to buy and read this (unfortunately) essential book.

6.12.8 Judge Demands Boston College Oral Histories (2011-12-17 17:19)

Judge William G. Young has ruled that Boston College must turn over oral history recordings and materials to him so he can decide whether to share them with U.S. prosecutors.
The [1]full ruling and other coverage can be found at [2]Boston College Subpoena News. The [3]Boston Globe also covers the story.

1. http://bostoncollegesubpoena.wordpress.com/court-documents/young-ruling/
2. http://bostoncollegesubpoena.wordpress.com/
3. http://bostonglobe.com/metro/2011/12/17/judge-rejects-boston-college-request-quash-order-turn-over-ira-recordings/o0PHuhrMjfiDhoS99mtVnL/story.html

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6.12.9 IRB Thinks Overweight People Are Less Capable of Giving Informed Consent (2011-12-20 10:11)

Since it concerns a medical study, this is a little off-topic for this blog, but a recent essay tells us something about the paternalist mindset of IRBs and their reliance on guesswork.
[Jerry Rabow, "[1]An IRB Public Member's Education," Journal of Clinical Research Best Practices 7 (December 2011). h/t [2]Roberto Veloso]
Writing in the Journal of Clinical Research Best Practices, Jerry Rabow–a retired lawyer and non-affiliated, non-scientist member of the IRB at the Cedars-Sinai Medical Center in Beverly Hills–boasts of persuading his IRB to reject "a clinical study to evaluate the effectiveness of a new procedure for bariatric (weight loss) surgery."

Rabow believes that overweight people are more vulnerable to disappointment and less capable of making informed decisions than are other adults considering experimental surgery:

> Participants would be drawn from a psychologically vulnerable population (seriously overweight individuals who had tried and failed other methods of weight loss, such as diet, exercise and counseling). Assuming that the placebo effect and eating regimen would not secure long-term weight loss for the control group, individuals randomized to the sham surgery might experience stress and disillusionment from yet another personal "failure" — the inability once again to lose weight despite attempting to adhere to the prescribed eating regimen.
> Low self-esteem of the participants could also make them especially vulnerable during the consent process, due to societal views that are often openly critical of people who are seriously overweight (based, I believe, on the erroneous view that all obesity is a consequence of ignorance or lack of willpower). Taken together with the participants' past failed attempts to lose weight, these special vulnerabilities to psychological pressure to solve their obesity problems raise the question as to whether their signature on any ICF [Informed Consent Form] could be relied upon as signifying truly voluntary informed consent, at least in the absence of special consent procedures.

Rabow does not explain how he arrived at his understanding of overweight adults' capacity to make decisions or what "special consent procedures" he thinks necessary when recruiting them to a study.

1. http://www.firstclinical.com/journal/2011/1112_Public_IRB_Member.pdf
2. http://twitter.com/#!/roberto_veloso

6.12.10 AAA Draft Code: "Easily Remembered" or Overly Simplistic? (2011-12-28 11:13)

The American Anthropological Association (AAA) has released a [1]draft code of ethics, the latest step in a revision process that began in late 2008, as well as a [2]Final Report of The Task Force for Comprehensive Ethics Review. An Executive Board subcommittee is taking comments until January 30, 2012, at [3]ethicsfeedback@aaanet.org.
As a non-anthropologist who respects disciplinary differences, I don't mean to tell anthropologists what to do, and I do not plan to submit a comment to the subcommittee. But I can point out that while the two documents represent an impressive effort, the draft code does not reflect all the concerns of some anthropologists who have thought seriously about ethical obligations.
The draft code lists "core principles . . . expressed as concise statements which can be easily remembered for use by anthropologists in their everyday professional lives."
The principles are

1. Do no harm
2. Be open and honest regarding your work
3. Obtain informed consent and necessary permissions
4. Balance competing ethical obligations due collaborators and affected parties
5. Make your results accessible
6. Protect and preserve your records
7. Maintain respectful and ethical professional relationships

Let's take a look at them.

Do No Harm

As I noted last year, when this principle was first proposed [4]several scholars raised objections while others supported it.
The Task Force report acknowledges this debate:

> Past codes specifically stated that anthropologists owe their primary ethical obligation to the people they study. While the members of the Task Force were sympathetic to this view, it became increasingly clear that it reflected a cherished anthropological value rather than an actual principle of ethical practice. Anthropologists "studying up," studying those in power, do not owe a greater ethical obligation to powerful individuals than to those vulnerable to that power. Nor is that value equally applicable to all kinds of anthropologists without either broad exclusions or special pleading (e.g., archaeologists, paleoanthropologists). While acknowledging the problematic nature of this previous principle, the Task Force nevertheless did discuss concerns that its removal weakens what had traditionally been perceived to be clear guidance for anthropologists caught in conflicting positions between the needs of research participants, sponsors, and other populations. We wish to note that this was a difficult issue for the Task Force, and we were never able to reach unanimity.
>
> The new code does place responsibility for one's actions squarely on the anthropologist, however. It requires her/him to consider the impacts of the work and its potential to cause harm. The Task Force is keenly aware that the Do No Harm principle is also complex and problematic, yet we feel this more directly and immediately addresses the ethical imperative informing the older "primary responsibility" statement, while recognizing that anthropologists study all kinds of individuals and institutions, some of whom do not necessarily command our primary allegiance or obligation. As was the case with the 1998 revisions to the Code, this topic demanded much energy and emotion. We think the intense investment in this discussion – as we witnessed it among ourselves and in the wider membership through comments left on the blog – is a strength of our Association, and we assume attention to and investment in this topic will continue among our members for the foreseeable future.

I see no such complexity in the draft code itself. Can an anthropologist studying "those in power" ethically expose their wrongdoing? The report seems to say yes, but the draft code says no.
Nor do I see that draft code's blunt language as consistent with the [5]AAA's response to the regulatory proposals of this summer:

> The research world is rife with projects whose results bore, interest, annoy, please, anger, or enlighten research participants (just as they do fellow researchers). This world is not generically the people's enemy. On the contrary, those of us working in US colleges, universities, news media, and research institutions have inherited traditions of free inquiry whose continuation is vital to this country's political, economic and social life. It would be deeply ironic if a regulatory system put in place to protect human beings were transformed into a device focused on restricting their power to know the world.

The draft code's explanatory section on "Do No Harm" does note that "Anthropologists may choose to move beyond research to a position of advocacy." But I don't think advocacy and critical inquiry are the same thing. One can enter and leave a research project without becoming an advocate, yet still bore, interest, annoy, please, anger, or enlighten research participants.

Be open and honest regarding your work

The clear intent here is to discourage, in the task force report's terms, "clandestine research in which informed consent could not possibly, by design or context, be adequately and fairly given." In other words, no spying for the CIA.
It is not clear if the code considers the duty to be open and honest regarding one's work to extend to, for example, oppressive governments. As Brian du Toit wrote in 1980,

> There are persons who feel that certain kinds of research have to be conducted in a clandestine manner, and that unethical behavior is somehow excusable. Such research might involve subversive groups, the American Communist Party, the Ku Klux Klan, and depending on your philosophical persuasions, even the Pentagon. Pierre van den Berghe says of his research in South Africa that "from the outset I decided that I should have no scruples in deceiving the government. . ." Does informed consent become arguable when a social scientist studies groups or organizations who are by his/her evaluations dishonorable, anti-social, or morally outrageous? Should a researcher be ethical when studying superordinatates? Through whose definition are these moral evaluations reached? [Brian M. du Toit,"Ethics, Informed Consent, and Fieldwork," Journal of Anthropological Research 36 (Autumn 1980): 274-286, [6]JSTOR.]

Du Toit concluded that "the social scientist is obliged to represent the true nature of his study, to clarify aims and methodology to those to be studied, to treat them and the information gathered with dignity, and to produce protection or support promised to those studied." I think this means that he considered van den Berghe's deception of the South African government unethical, though it's not clear from the essay.
In any case, I cannot find in either the draft code or the task force report any guidance on the question of deceiving authoritarian governments or subversive groups.

Obtain informed consent and necessary permissions

The draft code is somewhat nuanced, explaning, for example, that

> The informed consent process is necessarily dynamic, continuous and reflexive. Anthropologists should initiate this process as a part of project design and continue through implementation as an on-going dialogue and negotiation with research participants. Informed consent does not necessarily imply or require a particular written or signed form. It is the quality of the consent, not its format, which is relevant.

In 1996, Murray Wax disparaged the "dogma of informed consent" on the grounds that

> "Informed consent is meaningful when a specific procedure is then to be administered at a specific time to a specific (powerless) research subject. However, in much ethnographic research, the researcher is not about to administer a specific procedure, but is initiating a long-term and open-ended social process among a group which typically possesses major powers in its own right. Because the social process will be jointly constructed by the investigator and the numerous and varied members of the host community, its outcomes are unknown, although the fieldworker's desired goal is recognition as a fellow human being and so allowing a form of membership and participation. [Murray L, Wax, "Reply to Herrera," Human Organization 55 (1996): 238]

The AAA draft code defines "informed consent" to resemble more the process described by Wax than the terms of the Belmont Report. But in doing so, I wonder if it risks confusion when anthropologists and IRBs find themselves using one term with two different meanings, as may also prove the case with "do no harm."
Moreover, the code fails to address some of the questions posed by du Toit back in 1980. Du Toit posed several questions about consent by children; when can a parent speak for a child when deciding to offer an object or photograph to a researcher? At what age can a child consent? As children reach maturity, can they change their minds about a study? I'm guessing I know the answer here: it depends on the context. As the AAA response to the ANPRM so nicely put it,

> even reference to "children" and the like only make sense in light of particular conditions and local cultural conditions. The Common Rule specification of "vulnerable populations" may make sense in most situations in the US, but may not make sense in other settings where social categories may differ (e.g., where the relevant distinction may be ritually initiated vs. uninitiated boys).

I am less certain what the draft code would suggest about the duty of getting consent from superordinates. Du Toit asked, "If a person's behavior is public, such as that of an office manager, company director, or police chief, but this person refuses consent for a study of that office, is the researcher at liberty to expose that person by name? Is the researcher exposing the public role, or also entering into the private realm of that official?" I see no answers in the draft code.

Balance competing ethical obligations due collaborators and affected parties

The gloss on this principle reads in part, that

> Anthropologists have an obligation to distinguish the different kinds of interdependencies and collaborations their work involves, and to consider the real and potential ethical dimensions of these diverse and sometimes contradictory relationships, which may be different in character or change over time. When conflicts between ethical standards or expectations arise, anthropologists need to make explicit their ethical obligations, and develop an ethical approach in consultation with those concerned. Anthropologists must balance these competing ethical obligations while recognizing their obligation to avoid harm to those they study. Anthropologists should not agree to conditions which inappropriately change the purpose, focus, or intended outcomes of their research, nor should they mislead sponsors or collaborators about the nature of the work or its outcomes. Anthropologists remain individually responsible for making ethical decisions.

This passage is particularly hard to to understand without context or examples.
I was struck by the acknowledgment that anthropologists may need to recognize "differing ethical frameworks of collaborators representing other disciplines or areas of practice." I think this means they should not be surprised when [7]other scholars fail to share their outrage about cooperation with the U.S. military.

Make your results accessible

This one seems relatively clear. While less absolute than the "do no harm" principle, it sets up the sharing of research findings–especially with research participants–as the norm, but admits exceptions "such as where participants have been fully informed and have freely agreed to limited dissemination."
This section notes that "Proprietary, classified or other research with limited distribution raises complex ethical questions." It's not clear if this includes publication in professional journals that are open only to paying subscribers and institutions. The AAA has shown leadership on this front, [8]making its publications available free or at reduced prices

to underresourced institutions around the world. But neither the code or the task force report mention such initiatives explicitly, so I just don't know how far this principle goes.

Protect and preserve your records

Like the previous principle, this one states a norm ("the interests of preservation ordinarily outweigh the potential benefits of destroying materials for preserving confidentiality") but also points to legitimate exceptions to that norm. It takes a similar approach to the ownership of the anthropologist's records. Normally, they belong to the anthropologist; but other arrangements may be appropriate.

Maintain respectful and ethical professional relationships

This section applies not to human subjects research per se, but to professional obligations not to "plagiarize, nor fabricate or falsify evidence," and to acknowledge the contributions of others, including students.

Final Thoughts

In sum, the draft code strikes me as uneven. Some sections appropriately acknowledge that rules have exceptions, but the earlier passages fail to allow for the possibility that scholars have the right, and even the duty, to hold people accountable for their public behavior, and to evade unjust restrictions on liberty.
The code also leaves me pessimistic about the value of codes in general. A set of principles followed by some paragraphs of explanation for each is better than just a bare list. But I am inclined to agree with [9]Patty Gray's comment that

> the circumstances of anthropological research done for corporate or marketing purposes is going to involve a slightly different set of ethical issues than anthropological research done for the purpose of discovering new knowledge about human beings and their lived experience, and sharing that knowledge in venues such as teaching, scholarly publications and academic conferences, popular communication (non-academic writing, public lectures, etc.). If you try to mix together these rather different "flavours", you are just going to get a mess that no one can swallow. I would rather see you serve them all up with their own individual integrity and let their nuances show through.

I am therefore more excited by the task force recommendation that

> The AAA should produce and periodically update a publication of case studies of ethical dilemmas anthropological researchers, teachers and practitioners might face, suitable for use in graduate training, post-doctorate training, and continuing education.

This was the approach taken by the American Psychological Association in its 1973 Ethical Principles in the Conduct of Research with Human Participants, and by the AAA in its 1987 [10]Handbook on Ethical Issues in Anthropology. (Not mentioned in the task force report; I wonder if they knew about it.) More recently, the [11]Macquarie University ethics training module has taken this case-study approach.
These documents are easier to understand, and more likely to provoke reflection, than the abstractions in the code. Moreover, since the code clearly responds to specific controversies (notably over Human Terrain Systems) without naming them, a document presenting case studies would be more transparent than the ones here. I would go so far as to say that a collection of case studies should have preceded the development of more abstract guidelines, so that

everyone would know what was at stake.

Note 1. In addition to stating the principles, the draft code notes that "The American Anthropological Association does not adjudicate assertions of unethical behavior, and these principles are intended to foster discussion, guide anthropologists in making responsible decisions, and educate." That is not to say that it will never again seek to do so; the task force recommends "that if the Executive Board wishes to pursue an adjudicative code as a possibility, it should appoint a committee to consider this matter only after the EB has determined if it is in a position to make a financial and philosophical commitment to this process."

Note 2. The AAA has a lousy server. This blog post was delayed by multiple periods in which I could not access the two main documents and their supporting materials. This problem was aggravated by the decision to post each section's bibliography as a separate PDF file. Make your results accessible, indeed!

1. http://www.aaanet.org/coe/2011/preamble_and_principles_9_10_11.pdf
2. http://www.aaanet.org/cmtes/ethics/upload/AAA-ETF-Final-Report.pdf
3. mailto:ethicsfeedback@aaanet.org
4. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-ii-aaa-ethics.html
5. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html
6. http://www.jstor.org/stable/3629524
7. http://culturematters.wordpress.com/2008/07/30/the-disciplinary-terrain-of-objections-to-hts/
8. http://blog.aaanet.org/2009/09/14/broad-access-to-aaa-journals/
9. http://blog.aaanet.org/ethics-task-force/ethics-task-force-fourth-draft-principle/
10. http://www.aaanet.org/committees/ethics/toc.htm
11. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html

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Anonymous (2012-02-01 11:20:59)

Daniel Lende points out that the AAA is being less than consistent in executing the principle of making results accessible with their recent stand on public access to scholarly work.

http://blogs.plos.org/neuroanthropology/2012/01/31/american-anthropo logical-association-takes-public-stand-against-open-access/

Zachary M. Schrag (2012-02-03 15:20:52)

Thanks for this comment.

I share some of Mr. Davis's fears that [1]open access could wreck valuable editorial systems. But I also share your puzzlement at his failure to mention the AAA's principled commitment to the dissemination of knowledge or that commitment's manifestation: the [2]AnthroSource Philanthropic Initiative.

1. http://theaporetic.com/?p=2776
2. http://www.aaanet.org/issues/AAA-Gives-Back.cfm

Chapter 7

2012

7.1 January

7.1.1 Happy New Year, OHRP! (2012-01-01 10:59)

I started [1]2009, [2]2010, and [3]2011 with complaints that OHRP had failed to act on two reform initiatives it had undertaken in 2007.
In February 2007, [4]Bernard Schwetz promised that by the end of 2007, OHRP would issue new guidelines that would give a lot of examples and will give more guidance on how to make the decision on what is research and what is not." And in October 2007, OHRP [5]formally requested "written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the Federal Register on November 9, 1998 (63 FR 60364)."
OHRP has yet to issue Schwetz's promised examples and guidance, or to amend the expedited review list. But July's ANPRM goes so far toward honoring both of these promises that I can say with full voice, Happy New Year, OHRP! I look forward to a cooperative and productive 2012.

1. http://www.institutionalreviewblog.com/2009/01/happy-new-year-ohrp.html
2. http://www.institutionalreviewblog.com/2010/01/two-years-inaction-at-ohrp.html
3. http://www.institutionalreviewblog.com/2011/01/three-years-inaction-at-ohrp.html
4. http://www.institutionalreviewblog.com/2009/01/happy-new-year-ohrp.html
5. http://www.hhs.gov/ohrp/documents/20071026.htm

7.1.2 Does Moral Science Think the System is Working? (2012-01-02 10:24)

I am struggling to understand an apparent contradiction in the Presidential Commission's report, [1]Moral Science. On page 42, we learn that

> The current U.S. system provides substantial protections for the health, rights, and welfare of research subjects and, in general, serves to "protect people from harm or unethical treatment" when they volunteer to participate as subjects in scientific studies supported by the federal government.

But on page 55, the report concedes that

> There remains a dearth of knowledge about the actual efficacy of human subjects protections. Given this, the Commission recommends that the federal government support an expanded operational research agenda to study the effectiveness of human subjects protections.

If there is a dearth of knowledge about the actual efficacy of human subjects protections, how could the Commission conclude that the current system serves to protect people from harm or unethical treatment?
And if there is a dearth of knowledge about the actual efficacy of human subjects protections, why does the Commission recommend that the federal government "require that all federal agencies conducting human subjects research adopt human subjects regulations that are consistent with the ethical requirements of the Common Rule"?

1. http://bioethics.gov/cms/node/558

7.1.3 The Ethical Imperialism of Moral Science (2012-01-04 12:36)

I have posted extended comments about Moral Science as
Zachary M. Schrag, "[1]The Ethical Imperialism of Moral Science," Bioethics Forum, 4 January 2012.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5673&blogid=140

7.1.4 Washington Post Confuses "Research," "Experiment," and "Medical Experiment" (2012-01-09 10:24)

On January 1, the Washington Post ran an editorial, "[1]Medical Experiments on Humans," claiming that "in 2010, the federal government funded 55,000 experiments worldwide on human subjects" and citing "[2]Moral Science."
But "Moral Science" does not make that claim. Rather, it states that "The federal government supported more than 55,000 human subjects research projects around the globe in fiscal year 2010, mostly in medical and health-related research, but also in other fields such as education and engineering." It does not break the 55,000 figure into experimental and non-experimental approaches.
The editorial shows some awareness of the complexity of human subjects research, noting that many people "take part in projects fueled by federal dollars that focus on social science and education research." But the editorial's headline, "Medical Experiments," does not match the data in the body of the editorial. As we proceed with regulatory reform, I hope editorial boards will learn to read and write more carefully.

1. http://www.washingtonpost.com/opinions/medical-experiments-on-humans/2011/12/16/gIQAHSHzUP_story.html
2. http://bioethics.gov/cms/node/558

7.1.5 Anthropologist: IRBs Create "the Worst of Possible Worlds" (2012-01-11 11:36)

[1]Jonathan Stillo, a PhD candidate in medical anthropology at the CUNY Graduate Center, writes with great sensitivity of the ethical challenges he faced while studying mortally ill patients at a tuberculosis sanatorium in Romania. He suggests that IRB review was at best an irrelevance and at worst a hindrance to his efforts at ethical research.
[Jonathan Stillo, "[2]The Trobriand Islanders Never Friended Malinowski on Facebook," 30 November 2011, CAC.OPHONY, and "[3]Research Ethics in Impossibly Unethical Situations," CAC.OPHONY, 21 December 2011.

Another hat tip to the indefatigable [4]Roberto Veloso. I realize the IRB angle on this may be the least interesting part of Stillo's story, but this is the blog I have.]

The background is this: Stillo "spent over two years studying TB and much of that was spent talking to dying people and sometimes even holding their hands while they died. The field site was amazing—visually stunning, but tragic. It was a place of abandonment where many patients would go to die, not just of TB, but also of its complicating factors: poverty and hopelessness."

Doing this research meant getting close to people suffering from pain, despair, and even the guilt that they had infected loved ones with an incurable disease. Eventually, he won their trust by talking to them about their lives, something doctors were unwilling to do.

Stillo's IRB impeded this process. As he explains,

> Part of my initial problem was I didn't know how to ask the patients to let me interview and survey them. Following my IRB protocol, I showed them my stamped informed consent, a full page of Romanian legalese with talk of risks and benefits. I would read sections out loud and the more "informed" the patients became the more uncomfortable they became. This level of formality does not exist in most aspects of their lives. They could not understand that if I only wanted to talk with them, why I needed such involved paperwork with multiple signatures, dates and stamps. In fact, when I submitted my original protocol to the Romanian medical ethics board, I was laughed at and told that this research did not need approval because it was not "clinical".
>
> What did patients care about? That I would protect their identities and that the process was voluntary. Everything else, including talk of risks and benefits, names and numbers of people to contact, made them uncomfortable. They just wanted my assurance that I would maintain their confidentiality by not publishing their names. Many patients did not even have an expectation of privacy and did not feel qualified to make the decision as to whether or not they should participate in my research. They did not want to hear about protocols. Rather, they wanted someone that they trusted to tell them it was ok and that they could trust me. A document from my IRB could not accomplish this, only someone else vouching for me could . . .
>
> Ultimately consent, at least in my research site, has little to do with my protocols and institutional approvals. For the patients informed consent is not something I read out loud to them, it is earned over the course of months through drinking coffee, staring off the balcony and exchanging stories of our families. It is something I take seriously not because of the IRB, but because I know that the people sharing their lives with me trust me on a personal level. I owe it to them to behave in a way that is ethically appropriate and respects their humanity and dignity. I think at this point we have a system of ethics approval which is designed by clinicians and enforced by lawyers for the protection of hospital and university endowments in a litigious society. It is the worst of possible worlds and despite best intentions 20 years from now, future researchers will read of all of the unethical research that took place even in this age of IRBs.

In short, the IRB forced Stillo to adopt an approach that made dying people uncomfortable. Only when he abandoned that approach could he bring them comfort instead.

Comments on the two posts report similar problems. Ben Spatz, commenting on the first post writes,

> I've always been confused by IRB guidelines for reasons exactly like these. In fact, this confusion is part of why I don't do the kind of research that requires IRB protocol. I can't imagine developing meaningful relationships with people while being bound to this kind of strict and highly limited interpretation of ethics. It's like an institutionalized codification and reduction of what it means to have an ethical relationship with another human being.

"Hillary," writing on the second post, agrees:

> Like you, I've found that the lengthy IRB consent form I need to pass across the desk often has the opposite effect from what is intended. Rather than instilling my interviewee with trust someone is indeed supervising, and that clear boundaries have been demarcated, it instead heightens awareness to a place of suspicion that hadn't been there before. "I thought this was just an interview about this neighborhood in the 70s?" Suddenly they're wary of being trapped– very different from your TB patients, but similarly besides the point of what I am trying to do/create. "What am I signing away my rights to? Are you trying to 'catch' me saying something about gentrification (or affordable housing or artists or local politics) that will soon come back to bite me?"
> While I would never ignore the historical need for safeguards that attempt to root out flatly unethical behavior in the name of "research," you've highlighted the many ways in which the current IRB protocols can miss the mark. And for certain projects, it can turn a normal discussion– in which questions should be freely raised by either party– into a three-party conversation, with the anonymous IRB as the unknown quantity.

Wrapping it up, Stillo comes to the same place:

> What I would hope for is a less formalized process and a more discipline centered discussion of the ethical ramifications and possible challenges of a proposed research project beforehand–maybe this could be something that ones dissertation committee would do. Something like this might enable an actual conversation about ethical matters and rather than the present IRB structure which encourages researchers to "pass" it in order to get grants, publish etc. In practice, I just don't see the IRB as productive–it does not help us think through our research and find ways to make it more ethical for the participants, rather it is punitive. You can be punished for stepping outside of your approved protocol, but it is not as if the IRB is assisting you to produce more effective, humane protocols- rather, they are just giving a thumbs up or thumbs down (I know, because after getting resistance on some points in my own protocol, I asked the IRB if they would like to suggest a way to do this so that it fit within their definition of ethical–apparently this is not the way things work, but if the IRB is the sole possessor of institutional ethics, then why not involve it in the creative process rather than simply in the destruction of protocols that are deemed unethical?)
> Ultimately, I think that ethical review is something that we can do better. I think the process has been hijacked by business people, lawyers and clinicians and all of this has little to do with the research that is happening in the social sciences and humanities. Hilary, your experience with participants becoming more suspicious once they saw your consent forms mirrors my own. This level of formality raises suspicion, it did for me at the sanatorium and I can see how it would in your research too. This is a tough balance, obviously the participants need to know their rights, but the consent forms, especially as they tend to be written make everything sound so much more perilous than it actually is. I wonder how useful it even is to have these fancy consents if they are going to be presented by someone like me who boils it down to "the most important thing is that I will keep your identity confidential and that this is voluntary and you don't have to answer any questions you don't want to." How that gets turned into a full page of risks and benefits i still don't understand…

NOTE: Stillo does believe that "There is definitely a role for ethics reviews, especially in fields such as medicine where lives are at stake." But I wonder if this belief is based on serious investigation or the CITI Program indoctrination he received. One sign of an incomplete understanding of medical history is his captioning of a photograph, "Tuskegee

syphilis study doctor injects subject with placebo." As Susan Reverby notes in [5]Examining Tuskegee, p. 288, the rubber tubing on the subject's arm indicates that blood is being drawn.

1. http://blsci.baruch.cuny.edu/members/jstillo/
2. http://cac.ophony.org/2011/11/30/the-trobriand-islanders-never-friended-malinowski-on-facebook/
3. http://cac.ophony.org/2011/12/21/research-ethics-in-impossibly-unethical-situations/
4. https://twitter.com/#!/roberto_veloso
5. http://books.google.com/books?id=DXHsFL-agEUC&lpg=PP1&dq=%22examining%20tuskegee%22&pg=PA288#v=snippet&q=rubber%20tubing&f=false

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Anonymous (2012-01-11 12:18:00)
What are the details of this research that disqualify it from a §46.101(2)(b)(2) exemption?

Zachary M. Schrag (2012-01-11 12:28:12)
Good question. I think the answer is that CUNY doesn't believe that exempt means exempt.
[1]CUNY policy dictates that only IRB chairs or members can determine a project to be exempt, and that "The individual making the determination of exemption has the authority to require additional protections for subjects in keeping with the guidelines of the Belmont Report, even though the research falls within an exempt category."
In other words, the IRB will do whatever it pleases.

1. http://www.baruch.cuny.edu/irb/documents/CUNYREGS.pdf

7.1.6 NIH Pledges $1 Million for Research on IRB Regulations (2012-01-12 11:10)

A January 10 [1]HHS press release notes that "the National Institutes of Health is committing $1 million to support research that will be used to evaluate the impact of the revisions to the HHS regulations governing human subject research that are currently being considered. Assessing the impact of the revisions that are ultimately implemented will be critical to the development of an evidence-based approach to ensuring the effectiveness of human research subject protections."
You have my attention.
h/t: [2]Theresa Defino.

1. http://www.hhs.gov/news/press/2012pres/01/20120110a.html
2. http://www.reportonresearchcompliance.com/

Louise Nelson Dyble (2012-01-31 08:32:43)
So, is your application pending?

7.1.7 SBS White Paper Calls for Drastic Reform (2012-01-16 23:12)

Weighing in at 72 pages, the "Social and Behavioral Science White Paper" is the most detailed response to the ANPRM from scholars in the social sciences. The paper presents a grim picture of the state of IRB review and is generally supportive of the ANPRM's goal of reform. But it offers detailed, helpful warnings about the potential effects of the proposed "excused" category and the adoption of HIPAA as a model for confidentiality requirements. Though it shies away from the toughest questions about the IRB system, it is a good expression of the frustrations felt by so many researchers in the social sciences and humanities.
[American Educational Research Association et al., "[1]Social and Behavioral Science White Paper on Advanced

Notice for Proposed Rulemaking (ANPRM), Federal Register 44512-531 (July 26, 2011); ID Docket HHS-OPHS-2011-0005," 26 October 2011.]

Authorship

The response bears an impressive pedgriee. It was drafted by Felice J. Levine–who has been involved with IRB issues for over a decade–Richard O. Lempert, and Paula R. Skedsvold, and endorsed by almost two dozen scholarly and professional organizations:

- American Educational Research Association
- Federation of Associations in Behavioral and Brain Sciences
- Consortium of Social Science Associations
- American Political Science Association
- American Sociological Association
- Association of Psychological Science
- Association of Population Centers
- Cognitive Science Society
- Council of Professional Associations on Federal Statistics
- Human Factors and Ergonomics Society
- Inter-university Consortium for Political and Social Research
- Law and Society Association
- National Academy of Neuropsychology
- National Communication Association
- NORC
- Population Association of America
- Social Science History Association
- Society for Behavioral Neuroendocrinology
- Society for Computers in Psychology
- Society of Experimental Social Psychology
- Society for Industrial and Organizational Psychology
- Society for Judgment and Decision Making

While it's not clear exactly how much input these organizations had in the final document, it may be that some of them pushed for the White Paper's critical stance. For example, a [2]column in the American Sociological Association's newsletter mentions the role of Harry Perlstadt in prodding the ASA to respond to the ANPRM. Some of the key concerns voiced in the White Paper resemble some of [3]Perlstadt's own comments.
In any case, I trust regulators will take seriously such a long response from so large a group of organizations. Certainly I do, and I remark on the following features.

Criticisms of the Status Quo

Spread throughout the White Paper are suggestions that the current Common Rule has serious flaws.

- The regulations are vague The regulations are hard to understand. The White Paper finds that the exemption for studies of educational practices "been administered with ambiguity, uncertainty and inconsistency regarding the activities that are not covered by 45CFR46." Similarly, the White Paper blames the regulations for encouraging IRBs to overestimate risk:

  > There is considerable ambiguity in the discussion of psychological risk in 45CFR46 creating a danger that IRBs will misjudge the nature of possible psychological harms and overestimate their likely magnitudes and risks. The result will be unneeded reviews and unnecessary regulation of important but low risk SBS research. Among the negative psychological risks labeled "psychological harms" that human subjects may experience are such emotions as boredom, worry, frustration, annoyance, stress, upset, guilt, and loss of self confidence. These may be minor in magnitude or transitory and may even stimulate new levels of personal insight or self awareness.

  Even the definition of human subjects research is flawed:

  > We suggest that rather than focus on what does or does not contribute to generalizable knowledge (which in fields of science and scholarship can be a rather insulting task) or making judgments based solely on the disciplinary identification of researchers, it would be wiser to define the categories of research activities that 45CFR46 should cover adhering to the explicit definition of human subjects, as is relied on in exemptions 46.101(b)(2), (b)(3), and (b)(4), for example.

- IRBs base decisions on unrealistic assessments of risk The White Paper repeatedly warns against allowing IRBs to base decisions on improbable risks, suggesting that its authors understand that IRBs now do this routinely. The paper calls for regulations that will judge risk and harm "not in the abstract or by envisioned worst case scenarios" and suggests that "unlikely deviant cases should not drive decision making."

  Such vivid imagination also infects consent requirements:

  > One of the primary factors contributing to the length and complexity of informed consent forms is the perceived need for institutions (through their IRBs) to require researchers to identify and mention every conceivable risk to human subjects, however remote. We assume institutional concerns with federal regulatory compliance and liability issues drive this requirement. However, in doing so, human subjects are presented with mounds of information that aid neither in comprehending their role in the research effort nor in assessing the risks and benefits associated with participation.

- IRBs impose unnecessary levels of scrutiny The White Paper finds that IRBs are overregulating research. Exempt studies have been "beset by delays," and studies that should be expedited suffer "regulatory creep to full review . . . given the all too common migration to full review by IRBs over time." It also hints that IRBs are currently overstepping their mission to protect human subjects. In a strongly worded reply to Question 27, the White Paper states,

> Consideration of other factors can limit research that needs to be done and chill the freedom of inquiry that scientists need to advance knowledge. We are concerned that factors other than human subjects protection not creep into the work of IRBs. It is of paramount importance that other considerations do not color the work or judgment of IRBs and that policy considerations do not interfere with academic freedom and the pursuit of knowledge. In addition, we urge emphasizing the core principle, perhaps with examples, to make its intention inescapably clear.

- The regulations encourage inappropriate requirements for informed consent The White Paper finds that

  > Current regulations as well as the proposed changes continue to assume a one-dimensional mental model of written consent at one point in time. In general, the informed consent process could benefit from more research (e.g., what do human subjects want to know, what do they comprehend, what kinds of information are most relevant to making a decision about participation) so that any changes to the regulations are evidence-based.

- Overregulation has a price Finally, the White Paper notes that these problems impose a high price:

  > the burdens to IRBs and to researchers are major and costly impediments to socially valuable research and that much of the impulse for this long overdue review is a sense of the need to divest IRBs of regulatory obligations that distract them from focusing on research that involves more than minimal risk.

- Overregulation is a systemic problem All told, "SBS researchers . . . often encounter IRBs that look only to guidance developed with biomedical research in mind even when the guidance is poorly suited to the proposed SBS research." Rather than dismiss such IRB failures as anomalies, the White Paper sees them as the result of systemic pressures to overregulate. It warns of "the drift toward hyper-regulation" and blames the system itself, noting, "A conservative bias is natural in a system that threatens to penalize insufficient scrutiny but that does not sanction unwarranted review." For example, it notes that OHRP's suggestion that researchers not be allowed to determine if their projects are exempt has created the "danger of a slippery slope of hyper-regulation and decisions that do not reflect legislative intent but instead the risk-aversion of IRBs." The result is that "Institutional practices surrounding human subjects regulations are increasingly driven by regulatory and legal liability concerns, rather than concerns for the welfare of human subjects."

Concerns about the "Excused" Category

The White Paper warns that moving from "exempt" to "excused" could make things worse, not better.

> Our concern is with the functional abandonment of an exempt category for research activities that are best left as uncovered by 45CFR46. To relocate activities as excused that have previously been classified as exempt from 45CFR46 and then to introduce new requirements they must meet is potentially a step backwards. The logic that led to the original creation of the exempt category for activities that fall outside of the province of 45CFR46 is principled and compelling. Whether the current categories and classifications of exempt are all the right choices is not the issue. The point here is that to shift activities that have been determined to be outside of the purview of 45CFR46 so that they now fall within it may, no matter how limited the requirements for excused research, place new burdens on work that as a matter of policy or principle should be outside of the scope of human subjects research.

I don't know if I would go so far as to say the current exemptions are based on "logic," but the [4]1981 Federal Register announcement did present them as a means to "clarify coverage questions, significantly reduce the work load of IRBs, and thus allows IRBs to concentrate on the review of research which involves a greater degree of risk to subjects."

Concerns about Confidentiality Rules and HIPAA

The White Paper sees in the ANPRM's proposed confidentiality regime "a new set of informed consent requirements about prior human subjects that are not based on empirical study but on potentially misleading if not erroneous, assumption about the likely intentions of human subjects and their wishes in agreeing to participate in research."
It complains that the ANPRM "does not build on the expertise or decades of guidance and experience in considering the relationship between consent, data protection, and appropriate data access and use," and warns that its proposal to require fresh consent for new uses of data "could have a devastating effect on much SBS and other large sample research where contacting subjects for additional consent will often be difficult, never complete, and not practically possible if in the interest of subject privacy identifiers and contact information was not originally collected or, if collected, retained in the data set."
And it is particularly scornful of the ANPRM's proposal to base human subjects requirements on HIPAA, which it dissects in detail, concluding that "Privacy acts like FERPA or HIPPA [sic] have their place for protecting administrative record systems under their aegis, but they fall short as guidance for preparing, storing, protecting data or stipulating conditions for public access or restricted data use. "Indeed, "Absent instances of serious harms associated with survey interviews or other means of data collection, we see no need to require standardized means of data security and information protection at the data gathering phase. We urge strongly against further consideration of this additional burden with no obvious benefit."

Recommendations based on the ANRPM

The White Paper addresses the problems it identifies with the following solutions:

- To fix hyper-protection, require empirical evidence The White Paper responds to Question 4 with the suggestion that

  > regulations should be changed to make clear that IRBs should only consider "reasonably foreseeable risks or discomforts." The proposed language properly emphasizes that although IRBs should evaluate the likelihood that harms might be more than minimal, they should not speculate about every possible harm. If harm is not reasonably foreseeable (likely), then the probability of that harm is minimal. As emphasized earlier in this white paper, the language should speak of "harm" in the same way it speaks of "discomfort" rather than use the word "risk." It is the possibility of harm and not risk that must be foreseeable. If, for example, the risk of harm is one in 10 million, the risk is reasonably foreseeable, but it would be unreasonable to foresee harm.

  One way to deploy such evidence would be the the collection of "Documents based on materials appropriate to similar studies or previously approved for use in similar expedited research—whether approved at the same institution or not—[which] should qualify as acceptable templates for expedited studies." (cf. [5]Alexander Halavais's recent suggestions.) The White Paper also argues that "Risks should not be considered greater than minimal simply because deception is involved" and that "Absent a sufficient research base, the rules should not presume that any particular study feature creates more than minimal non-physical risks." If a procedure does make it onto the list for expedited review, it should not be removed "except where a clear pattern of harm has developed." Similarly, "The vague language of 'emotionally charged' is unsatisfactory because topics that elicit no strong emotional reaction from most persons will be emotionally charged for some."

- To fix informed consent, reduce the regulatory requirements The White Paper recommends that non-clinical researchers not be burdened with irrelevant requirements that they tell participants about "appropriate alternative procedures or treatments," that the research is experimental, and that injuries will be compensated. More generally, it calls for "research on comprehension and modes of inviting consent." I think the White Paper could have gone a little further here, also dropping the requirement that researchers disclose "reasonably foreseeable risks

and benefits." I don't think commercial or political researchers offer such information, which in many social science projects will be "none."

- To fix regulatory creep, require due process protections The White Paper enthuses about the ANPRM's suggestion that IRBs be required to provide written justification every time they impose more scrutiny than is required by the regulations. It suggests that if an IRB wants to deny excused status to a proposal, "it should be incumbent on the reviewer to state specifically in writing what aspect of a registration document leads to doubt a project's excused status and to refrain from review where it finds none." It also

  > strongly support[s] the requirement of an appeals process. The consequences of an IRB's denying or substantially limiting how research can proceed could be severe, affecting those who might reap the benefits of the research, the immediate interests of the researcher, and the interests of institution or society over the longer run. When consequences are great, the fallibility of judges suggests the desirability of an appeals mechanism.

  By contrast, the White Paper calls for regulators to trust researchers: "Researchers can for the most part be trusted to make fair initial assessments so long as they must register their studies and know they risk being audited."

- Base confidentiality requirements on research The White Paper recommends rather than use HIPAA as a starting place, the regulations should encourage institutions to develop standards based on "National Research Council reports, in the ethics codes of professional associations, and in the practices employed by entities like the ICPSR which are responsible for storing and disseminating SBS data varying in sensitivity." And it suggests that "in almost all cases pre-existing data, whether collected for research or non-research purposes, should be reusable without consent as long as risks to human subjects are minimal and sufficient confidentiality protections are in place."

Recommendations Beyond the ANPRM

Some of the White Paper's most intriguing suggestions concern matters not raised directly by the ANPRM.
Some suggest that the current exemptions are too narrow. For example, the White Paper suggests that the current [6]45 CFR 46.101(b)(3)(i) exemption for research on "elected or appointed public officials or candidates for public office" be not only preserved but expanded to cover "any person who has public figure status." And it calls for projects to be excused from review

> where access to a location or to subjects is given by a person entitled to give access to a research setting and where the data will be collected by observation or by other methods that themselves qualify as excused so long as the data collected will not be linked to named persons. A business might, for example, provide a researcher access to observe and analyze how plant architecture affects worker interactions, or a police department may allow researchers to ride in police cars to observe exchanges between police and citizens.

The White Paper also envisions an ongoing, inclusive process of policy formation more like Canada's. The paper supports the creation of a panel to review the expedited review list every two years, and urges "strongly that SBS sciences be visibly present on that panel because of the preponderance of research in SBS fields that are appropriate for expedited review."
More generally, it calls for SBS researchers to be represented in policy-making bodies. It hopes that "An interagency committee under OSTP would facilitate communication and planning across agencies as new issues arise and ensure that the focus is not predominately biomedical." It calls for a National Research Council committee to "examine what types of research activities are appropriately exempt and how these determinations should be made going forward," and asks that if an adverse-event reporting system is developed, the "creators of such a system to include non-DHHS

agency representatives and SBS researchers in the development so that concerns may be addresses at the outset. Similarly, attempts to standardize forms should involve agencies who have signed on to the Common Rule and a wide range of research approaches, including SBS research."

Some Silences and a Departure

Taken together, the White Paper offers some stinging critiques of the current regulations and the ANPRM's proposals, while applauding some of the ANPRM's bolder proposals. It is worth noting, however, the degree to which the White Paper fails to examine some basic assumptions underlying today's IRB system.

First, the White Paper pays homage to the Belmont Report, noting that "our aim is to foster revisions to the Common Rule that are consistent with the principles set forth in the Belmont Report in 1979." Yet it calls for the abandonment of two of the three Belmont "applications" for minimal risk research, stating that a weighing of risks against benefits and a determination that subjects be equitably selected are unnecessary for such research. If major chunks of the Belmont Report are inapplicable to so much research, why keep that report as the basis of ethics governance? Why not start fresh?

Second, the White Paper suggests that the regulations be revised to abandon the distinction between research that is designed to produce generalizable knowledge, but it does not propose a clear alternative definition of human subjects research. This runs the risk of expanding the reach of the Common Rule, which the White Paper clearly does not want.

Third, the White Paper fails to note just how drastically the current regulations fall short of its standards for sound policy. The White Paper wants rules that are based on "a clear pattern of harm," "are evidence-based," and "reflect legislative intent." It concludes that "any decision to expand the Common Rule be evidence-based, and that research be funded to provide needed evidence."

Yet it ignores the fact that the requirements for IRB review of research in the humanities and social sciences have never met any of these standards. If the authors of the White Paper believe that "absent instances of serious harms" research should not be restricted, why not call for the wholesale liberation of the social sciences? If they believe that the Common Rule should only be expanded based on evidence proceeding from funded research, why not apply that criterion retroactively to the existing regulations?

Finally, buried in the paper is the claim that "IRBs are experts in research ethics, but seldom are experts in data security and data protection." While the emphasis in that sentence is clearly on the second half, it is a pity that the authors did not scrutinize the first. The White Paper tells us that IRBs impose inappropriate consent requirements, base decisions in improbable estimates of risk, get distracted by concerns other than the protection of research subjects, and "chill the freedom of inquiry." How, then, do they conclude that "IRBs are experts in research ethics"? Given that IRBs have shown themselves so inept, why does the White Paper believe that "research that poses greater than minimal risk should be reviewed by a fully convened IRB and that 45CFR46 should not be changed in that regard"?

Though it shies away from asking if there is any reason to think the IRB system is worth preserving, the White Paper represents a substantial departure from more accommodationist writings by some of the individuals and organizations it represents. In 2008, for example, two of the White Paper's lead authors–Felice J. Levine and Paula R. Skedsvold–believed that "[7]significant regulatory reform [was] not likely." Accordingly, they offered what I considered fairly [8]tame suggestions for reform based on the premise that "creative use of the flexibility within the current system might resolve some of the pressing concerns of social and behavioral science investigators while ensuring adequate oversight of research involving human participants." Now, with regulatory reform at least on the table, it is delightful to learn that they have so many proposals for dramatic changes in the regulations.

1. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-1102
2. http://w.www2.asanet.org/footnotes/dec11/vp_1211.html
3. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0323

4. http://www.hhs.gov/ohrp/archive/documents/19810126.pdf
5. http://www.institutionalreviewblog.com/2011/12/halavais-calls-for-open-publication-of.html
6. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/ht07w581-body.tex.lynx.html
7. http://www.blogger.com/comment.g?blogID=52577829256555451 9&postID=4693306898310512811
8. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html

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7.1.8 Survey: 28% of Linguists Report Inappropriate IRB Demands (2012-01-18 10:34)

The response to the ANPRM from the Linguistic Society of America led me to an interesting article describing the result of an international survey of linguists about their encounters with ethics review. Though the author of the article claims that "in general, ethics regulation appears to be working," her data suggest that IRB review exacts a heavy cost in time and knowledge with little clear benefit.
[Claire Bowern, "[1]Fieldwork and the IRB: A Snapshot," Language 86 (December 2010): 897-905 | DOI: 10.1353/lan.2010.0048]
Bowern surveyed "approximately 100 linguistic fieldworkers" in several countries (about half in the U.S. and Canada) about their responses to human subjects review.
She finds:

> for the most part, the regulation of field linguistic research is working, and the problems are concentrated in just a few (though complex) areas. These primarily involve informed consent and its documentation, and provisions for anonymity. A rare but worrying problem is that some ethics boards are requiring the destruction of primary research materials.

More specifically, when asked whether they had changed their research as a result of IRB review, 71 percent of those responding had not, and many of those who had made only minor modifications. Yet some number (Bowern does not say how many) had curtailed or abandoned a project because of IRB review.
Moreover, though 57 of 79 responders reported no methodological conflicts,

> Of the remaining twenty-two responses, nine mentioned problems with written consent forms. Some were required to use forms that in their view were too technical, or that exaggerated the risks to which participants would be exposed. Others were required to gain 'informed consent' in writing even when working with nonliterate research participants, and as a result both researcher and research participants felt that the consent process created an atmosphere of intimidation. One researcher mentioned having been reprimanded for submitting a consent form signed with an 'X'.
> The other most common problem involved the use of standardized questions. As mentioned above, several respondents reported that their IRB required them to clear all research questions in advance, which was incompatible with the emergent research method the researcher wished to use.
> Others mentioned problems with IRBs requiring the destruction of primary data on an endangered language, and one mentioned an issue involving the secondary use of data. Two mentioned that their protocols had initially been rejected because of their IRB's incorrect assumptions about the cultural background of research participants (for example, one person reported that their IRB had assumed that all speakers of nonstandard US English are African American, and therefore that the research was targeting a particular ethnic group). A few mentioned the area of payment (that an IRB required payment to research participants in cash (and recorded by receipt), which offended local customs). Another respondent gave the example of an ethics board requiring responses to be anonymous in language description where the consultants had expressed a wish to be identified and acknowledged for their work on their language.

> Finally, a few people stated that the IRB process had made them more conscious of their ethical responsibilities toward research participants and their communities.

Moreover, several respondents had shied away from interviewing children and teenagers for fear of additional IRB requirements, though doing so could have helped document language shift among speakers of endangered languages. And some had destroyed materials to meet IRB demands, despite an ethical duty to preserve such materials for future researchers.
Bowern puts her findings in rosy terms:

> In general, the review process appears to be working, in that more than two thirds of the respondents were seeking approval, gaining it with a minimum of protocol revision, conducting their research, and not reporting problems even when given the opportunity to do so anonymously. The majority of respondents were not required to alter their protocols; a few were asked to make minor changes, which did not affect the results and probably led to a better experience for the participants. Problems are confined to a few areas. This suggests that the 'social science victim narrative', as Stark (2007:785) has called the idea that social scientists are ill-served by IRBs, is not as prevalent in linguistics as we might have imagined from anecdotal reports.

Bowern apparently did not ask researchers if IRB changes protected participants, so she is guessing when she writes that those changes "probably led to a better experience for the participants." To the contrary, only "a few" respondents said the "the IRB process had made them more conscious of their ethical responsibilities toward research participants and their communities." Bowern does not compare the number of researchers with this response to the number who reported that participants felt intimidated by the consent process.
More significantly, saying "more than two thirds" faced only minor problems is the same as saying "more than a quarter" (22 of 79 respondents) had their work significantly disrupted by IRB meddling. I hope that not all linguists share Bowern's tolerance of a system that so commonly intimidates participants and diminishes knowledge.

1. http://muse.jhu.edu/journals/language/v086/86.4.bowern.html

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Claire Bowern (2012-01-18 16:03:21)
Your summary of my article is quite misleading. The point is that the vast majority of the problems were clearly concentrated in two or three quite specific areas: 1) mandated data destruction; 2) inappropriately legalistic consent forms; and 3) written consent forms for working with participants who do not read and write. Part of the purpose of the article was to give linguists (particularly fieldworkers) resources to quote when preparing IRB applications so that it's clear that (1) is a totally inappropriate way to treat linguistic data; and that (2) and (3) are harmful to research participants.
The number of people who curtailed or abandoned projects because of IRB review was 3/94 - and two of those were curtailed because they assumed that it would be too much trouble to fill out the paperwork for working with children. But given that their protocols were already classed as non-exempt, there's no indication that this assumption was correct.
Many of the revisions were protocol clarification questions. A number of researchers also reported that their IRB did not require further modification to protocols once procedures had been clarified (I cannot recall how many mentioned this but I can check the original responses if you really want to know).
If I was tolerant of a system that intimidates participants and diminishes knowledge, I wouldn't be taking time out of my other research activities to help linguists deal with their IRBs. Showing that the clear majority of linguists following standard protocols for linguistic field research get their protocols approved is very useful: it provides linguists working with IRBs who don't do that with a way to show who's out of step, along with information about why field linguists work the way they do and how it protects research participants.

Zachary M. Schrag (2012-01-18 16:07:36)
I agree that your findings are very useful, and I hope that linguists will use them to show that IRBs are out of step. Our disagreement is whether a system that fails 28 % of the time is "working."

7.1.9 Li and Brown Continue Negotiations (2012-01-23 12:01)

A [1]correspondent asks for an update in the case of[2] Jin Li, the Brown professor who sued her university after its IRB restricted her research.
I checked [3]Public Access to Court Electronic Records (PACER) and found that on January 13, the parties jointly asked for an extension of the discovery deadline, telling the court "that they continue to negotiate a settlement of the claims. Due to the efforts made negotiating a settlement, only minimal discovery has been propounded so far. As such, if the parties are unable to settle, then the parties will need time to complete formal discovery."
I have posted the motion and other key documents on my [4]IRB Documents page.

1. http://www.blogger.com/comment.g?blogID=52577829256555 4519&postID=1831228027562346847
2. http://www.institutionalreviewblog.com/2011/03/professor-sues-brown-university-over.html
3. http://www.pacer.gov/
4. http://zacharyschrag.com/irbs/irb-documents/

Shirley Isbill (2012-01-23 21:15:49)
Jin Li's chief complaint was that the Brown IRB would not let her use her research data.
IRBs do not have the authority to prevent the use of research data.
Brown did not comment on this in their answer to her complaint. Brown did admit that the IRB prevented Jin Li from using her research data.

7.1.10 Wednesday Talk at the U. of Michigan (2012-01-29 23:15)

I will speak about my work on IRBs on Wednesday afternoon at the University of Michigan's [1]Center for Bioethics and Social Sciences in Medicine.

1. http://cbssm.org/center_updates#dr-zachary-schrag-to-give-a-talk-february-1

7.2 February

7.2.1 Educator: Ethics Requirements Do Not Respect Ethnographic Participants (2012-02-01 14:06)

Kristen H. Perry, assistant professor of elementary literacy at the University of Kentucky College of Education, draws on her experience with refugees to argue that "Existing ethical guidelines may be inappropriate for the research designs qualitative researchers use and the communities they study, in part because they are based on positivistic, biomedical research paradigms."
[Kristen H. Perry, "Ethics,Vulnerability, and Speakers of Other Languages: How University IRBs (Do Not) Speak to Research Involving Refugee Participants," Qualitative Inquiry 17 (2011): 899–912, DOI:[1] 10.1177/1077800411425006]
A returned Peace Corps volunteer, Perry sought to build on her experience in Africa by working with orphaned Sudanese youth in the United States. She describes her experience:

> As an emerging researcher, I at first was quite naive about research ethics; without much critical thought, I accepted the ethical requirements set out by federal regulations and as applied by my institution. However, when one Sudanese youth refused to participate in my first study—simply because I was required to change his name, when he wanted to be identified—I began to question the appropriateness of ethical guidelines for research that are regularized and codified through university IRBs. While ostensibly protecting the rights of research participants, the ethics requirements (or, at the very least, the ways in which they were interpreted by IRB officials) did not seem to truly respect the rights of ethnographic participants or to account for the situated contexts in which qualitative research occurs.
> A number of subsequent experiences (including being told by an IRB official that research involving refugees is inherently unethical) encouraged me to more critically examine the discourses surrounding research ethics, particularly with respect to the inclusion of refugees and other marginalized participants in research.

To determine if such unhelpful IRB practices were widespread, Perry analyzed IRB requirements at 32 research-intensive institutions. She found that " a strong orientation toward medical and experimental models of research" affects even those universities that have separate "nonmedical" IRBs. Yale's Social, Behavioral, and Educational IRB defines "vulnerability" in medical terms: "Examples of individuals who may have impaired consent capacity include women in active labor, individuals who have suffered a stroke or other acute and severe illness, individuals under the influence of drugs or alcohol, individuals experiencing considerable pain, individuals under extreme emotional distress (e.g., learning of a newly diagnosed life threatening or terminal illness for self or loved one, anticipating imminent major surgery), and individuals suffering from cognitive disorders or mental disorders." Similar language appeared on websites at the University of Kentucky, the University of Iowa, and the University of Illinois.
The problem with such frameworks, Perry argues, is that they "inappropriately conflate[] vulnerability with incompetence," rather than putting the onus on researchers to help people make those decisions. For example, "the participant's ability to make an informed decision does not rest on whether or not he or she speaks English but rather on whether or not the researcher has presented the information in a language that is accessible to her. A non–English-speaking participant could meaningfully engage in the process and make an informed decision if the researcher were fluent in the participant's preferred language, or if a qualified translator were present."
Perry hints that she would like to do away with IRB review of social science, but laments that "Current policy and guidelines are . . . probably a reality that will not go away, at least not in the foreseeable future."
In lieu of wholesale reform, she recommends that we rethink the concept of vulnerability:

> If vulnerability is a product of an interaction between participant, context, and research design, rather than an inherent characteristic, then checklists of certain types of participants are not an appropriate way for IRBs to evaluate the potential vulnerability of those included in research. Instead of assuming that all humans have the potential to be vulnerable, checklists imply that a person either is or is not vulnerable and that this state can be determined according to some predetermined characteristic such as sex, race, age, or language. If all human participants are potentially vulnerable, a more appropriate assessment of vulnerability would be a qualitative description of all of the potential research participants targeted by the study, the ways in which those participants may be vulnerable, and what the researcher(s) will do to address and mitigate those potential vulnerabilities.

Missing from Perry's analysis is an estimate of the additional burdens her recommendations would impose on researchers and IRBs alike. For example, she advocates "Requiring all researchers, regardless of potential participants or research design, to describe the cultural and linguistic contexts for their research, instead of only requiring this for participants who are perceived to be 'Other' than the mainstream." That would certainly put immigrants on a more level footing with native English speakers, but it would also massively increase researcher workloads.

1. http://dx.doi.org/10.1177/1077800411425006

7.2.2 Biographer Decries IRB Assumptions (2012-02-06 14:36)

Craig Howes, professor of English and director of the Center for Biographical Research at the University of Hawai'i, Manoa, acknowledges the ethical challenges of biographical writing but seems to doubt that IRB review is the appropriate tool for handling them.
[Craig Howes, "Asking Permission to Write: Human Subject Research," Profession (2011): 98-106, DOI: [1]10.1632/prof.2011.2011.1.98. h/t Steve Burt.]
Howes begins by warning that "A specter is stalking language and literature departments: the specter of human subject research. Or maybe not." As he elaborates, university policies leave biographers guessing about whether they need to submit projects for approval:

> No institution worried about litigation will let its researchers decide unilaterally whether their research is exempt. The result? Many of us apply to the IRB for an official ruling that we don't need to apply for. This Catch-22 can lead to confusion. At least one university IRB simply refused to accept any human subject research requests from the English department, though this policy was later rewritten by an arts, law, and science research ethics board. Conversely, some researchers refuse to seek IRB approval on ethical grounds, claiming that permission can lead researchers to believe that anything is fine, as long as they don't violate the protocols.

Moreover, interest by IRBs in biography is just part of a broader set of liability concerns:

> Pressures from beyond IRBs and the academy are also pushing language and literature departments toward interactions with human sources. On the advice of their legal departments, some publishers are requiring written confirmation from individuals, and not just sources, mentioned in a book that they won't sue. Some granting agencies are demanding evidence that applicants have positive working relationships with the families of life narrative subjects. My center coproduces a television documentary series called Biography Hawai'i, and these programs are expensive, so we're always applying to private and government funding sources. One of our requests was recently turned down because we had not documented sufficiently the family's willingness to have such a documentary made. The good news is that we got letters of support, received the grant, and completed the program (Biography Hawai'i). Researchers might however be interested to know that our subject died in 1896. (If you're thinking about applying for grants to work on Paul Verlaine or Harriet Beecher Stowe, they died that year too.)

And Howes sees some value to this scrutiny:

> The demand that we ask permission can be beneficial to us as researchers if it prods us into rethinking some of our fundamental methodological assumptions. Reporters, biographers, and researchers who work with human subjects are fond of representing themselves as scholar adventurers, literary detectives, or even big-game hunters. Track down your elusive prey, use your cleverness and powerful will to extract the valuable secret, then take it home. In this model, the human subject is a place, and many cultural

> studies and indigenous research theorists have argued that this activity is inherently exploitive, even imperialist. A comment made at a colloquium at my university many years ago by the writer Susan Sheehan should give us pause. When asked what was the most challenging part of working with her subjects, she answered, “Knowing that you’re forming a relationship that will last the rest of your life.”

But not all biographers take this view. As Howes reports, Nancy Kriplen, the biographer of John D. MacArthur, wants people to see her as a a reporter. "I don’t want them to be seduced into thinking that I have become their best friend for life.”
And Howes stops short of calling for IRBs to review biography, since the regulations remain wedded "the assumption that subjects will be guaranteed anonymity and that the interviews will be destroyed after the relevant information has been extracted . . . the IRB assumption is still problematic, because for most humanities interviews granting anonymity and destroying the tapes and transcripts would make the whole exercise pointless." The problem is not that federal regulations require such destruction. It is bad enough that they take anonymity and the destruction of recordings as the norm and the creation of a historical record as deviant from that norm.
I think that Howes isn’t far from [2]the position I took in 2007 and which I still hold: learning about the ethical practices of other disciplines can help scholars think about their own ethical duties. But when governments and institutions impose foreign practices on researchers, they breed resistance and cynicism.

1. http://dx.doi.org/10.1632/prof.2011.2011.1.98
2. http://historians.org/Perspectives/issues/2007/0703/0703vie3.cfm

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7.2.3 "Informed Consent Is 20 Pages of Nothing" (2012-02-08 09:09)

Nature reporter Daniel Cressy writes that

> Informing clinical-trial participants of the risks they face is a cornerstone of modern medical research, and it is enshrined as a human right in international codes of ethics. But an influential group of ethicists and medical researchers warned at a meeting in Brussels last week that the process has become a box-ticking exercise focused more on offering legal protection to a trial’s organizer than actually protecting patients.

[Daniel Cressey, "Informed Consent on Trial," Nature 482, 16 (2 February 2012) [1]doi:10.1038/482016a]
Ethicists are particularly alarmed by the steady growth in the length of consent forms.

> In many cases “the informed consent is 20 pages of nothing,” says Harry Bleiberg, an oncologist formerly at the Jules Bordet Institute in Brussels who is now a medical consultant for the pharmaceutical industry.

While consent forms have grown longer, it is not clear that they were ever anything other than "a box-ticking exercise focused more on offering legal protection to a trial’s organizer than actually protecting patients." Perhaps Cressey wrote "has become a box-ticking exercise" when he meant "remains a box-ticking exercise."

1. http:dx.doi.org/10.1038/482016a

7.2.4 Inside Higher Ed Interviews Stark (2012-02-08 09:24)

Laura Stark speaks about her new book, Behind Closed Doors, with Inside Higher Ed.
[Mitch Smith, "[1]Behind Closed Doors," Inside Higher Ed, 8 February 2012.]
Stark explains, "It would seem that fairness is not the only criteria used in IRB evaluations."

1. http://www.insidehighered.com/news/2012/02/08/author-provides-inside-look-irbs

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7.2.5 VA IRB is "Kafkaesque and Dickensian" (2012-02-10 09:54)

Writing in Bioethics Forum, a team of interview researchers describe the Veterans Administration IRB process as "Kafkaesque and Dickensian."
[Jenny E. Ostergren, Marguerite E. Robinson, Molly J. Dingel, Bradley Partridge, Barbara A. Koenig, "[1]Kafkaesque and Dickensian: The Human Subjects Protection Maze," Bioethics Forum, 9 February 2012.]
They explain:

> In a multisite study we conducted interviews at addiction treatment programs to explore patients' views about an emerging genetic understanding of addiction. We thought the IRB review process at the Veteran's Administration Medical Center included among our sites would be relatively straightforward; ours was a low-risk interview study with stringent procedures in place to protect participant confidentiality, and our protocol had been approved by IRBs at other sites without difficulty. We never anticipated that it would take a full year to gain IRB approval and that due to further delays resulting from institutional rules and policies we would be able to conduct only six of the 20 planned interviews . . .
> While special efforts to protect veterans and those with stigmatized disorders such as substance use are clearly important, the emphasis placed on the minute details of the process has created an endless labyrinth in which the main objective of providing protection for research participants is lost.

With Dickens scholars arguing–on the bicentennial of his birth–that [2]Dickens's novels did not lead to policy reforms, let's hope that the IRB world finds its [3]Upton Sinclair.

1. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5728&blogid=140
2. http://www.bbc.co.uk/news/magazine-16907648
3. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1653522/

Anonymous (2012-02-10 10:23:39)
The VA has lots of IRBs. Our organization had a project involving the VA a few years ago and I don't remember anyone going through the sort of agony described here. The whole process was unremarkable.
As someone who has done multi-site research, I would agree that the process of obtaining approval from lots of sites is onerous (and necessarily so). But in my experience there's a lot of variation between sites. Some IRBs are well run and easy to work with; others are a nightmare.

Zachary M. Schrag (2012-02-10 14:28:38)
Thanks for this comment. If competence is the norm and nightmares the exception, an appeals process (as envisioned by the ANPRM) might provide an effective remedy.

7.2.6 Talk at NIH (2012-02-13 14:12)

On March 5 I will speak to the Bioethics Interest Group at the National Institutes of Health on the topic "[1]Blunder at Belmont: The 1970s Origins of IRB Mission Creep."
Those familiar with my first book may appreciate the irony of my speaking in the [2]William H. Natcher Building.

1. http://sigs.nih.gov/bioethics/Pages/Meetings.aspx
2. http://books.google.com/books?id=vDQI-02wki0C&lpg=PA137&vq=natcher&pg=PA122#v=snippet&q=natcher&f=false

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7.2.7 Moskos Plugs Ethical Imperialism (2012-02-17 07:38)

Peter Moskos gives a [1]a kind mention to Ethical Imperialism on his blog.
Moskos has nicer things to say about [2]flogging than about IRB review.

1. http://www.copinthehood.com/2012/02/ethical-imperialism.html
2. http://defenseofflogging.com/

7.2.8 IRBs Misunderstand Researchers' Complaints (2012-02-28 09:54)

A study of IRB chairs, members, and staff finds that they understand that researchers regard them as powerful actors, "Yet IRBs may misperceive PI complaints."
[Robert Klitzman, "The Ethics Police?: IRBs' Views Concerning Their Power," PLoS ONE 6 (2011): e28773. [1]doi:10.1371/journal.pone.0028773. h/t [2]Roberto Veloso]
Robert Klitzman, Associate Professor of Clinical Psychiatry at Columbia University, "conducted in-depth telephone interviews of 2 hours each with 46 [IRB] chairs, directors, administrators, and members" from 34 institutions, drawn from a list of the top 240 institutions by NIH funding. He took a Grounded Theory approach to identify "categories of recurrent themes and issues" among the interviews.
Klitzman's respondents did understand that researchers would not want a process that is biased against particular researchers, and that they care around turnaournd time. What they don't seem to understand is researchers' wish for what Malcolm Feeley and Jack Katz have called a "[3]culture of legality." As Klitzman puts it:

> IRBs appear to try to justify their power, arguing that it helps PIs and human subjects, though that claim may not be based on empirical evidence, and may actually cause harms that the IRB may not sufficiently acknowledge or weigh, delaying or impeding valuable research . . .
> Much of IRB work occurs behind closed doors, which can aggravate these tensions. Minutes are not publicly accessible, but arguably attempts should be make these available, at least in part, to whatever degree may be reasonable and possible. IRBs keep minutes private, along with all correspondence and decisions (except to the PI involved). Yet increasing transparency could potentially help improve perceptions of IRBs among PIs. Given concerns about proprietary information, redaction of details at any institution may be hard for certain studies, particularly those that are industry-funded. Yet transparency may not be as difficult for many other, non-industry funded protocols. IRBs could, for instance, post examples, with details redacted, of the types of concerns they have had about issues that arise in various protocols. Such an approach could yield many benefits. Yet IRBs may themselves prefer the lack of transparency, as it may reduce questions about their processes and decisions – which presumably is not the intended goal of the current practice of non- transparency. These interviews thus highlight key questions of how much lack of transparency is, or should be permitted.

In particular, he notes the significance of a lack of an appeals process.

> IRBs should realize that the absence of an appeals process gives them de facto considerable power. To ignore this fact can exacerbate tensions between IRBs and PIs, while increased acknowledgement of this perceived power can help IRBs facilitate interactions with PIs, and thus in the end best help protect human subjects.

Not only would an appeals process help researchers who feel wronged; it could also help IRBs that currently "cannot publicly respond if PIs vocally fault the committee within an institution." In a formal appeal, both sides could be heard. Indeed, a [4]comment on the article recounts an instance in which a PI and IRB submitted their disagreement to an independent IRB, which found that the IRB's concerns were justified.
Klitzman also notes IRBs' feelings of powerlessness in the face of federal regulations and enforcement actions. As he puts it, "PIs may also unfairly 'blame the messenger,' resisting federal regulations, exacerbating conflicts. Researchers should realize that IRBs, while subjectively implementing these regulations, are in fact also constrained in many ways by these policies, and fears of governmental audits, and generally appear to be trying their best." This finding nicely challenges the old line that IRBs need only take advantage of the regulations' "[5]flexibility." It's hard to be flexible with a cattle prod shoved into your back.
Klitzman cites several additional IRB articles he has in press; I will look forward to them.

1. http://dx.doi.org/10.1371/journal.pone.0028773
2. https://twitter.com/#!/roberto_veloso
3. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html
4. http://www.plosone.org/annotation/listThread.action?inReplyTo=info%3Adoi%2F10.1371%2Fannotation%2Fc65c9ac3-c1ed-4037-b479-d31d688ccc0a&root=info%3Adoi%2F10.1371%2Fannotation%2Fc65c9ac3-c1ed-4037-b479-d31d688ccc0a
5. http://www.institutionalreviewblog.com/search?q=flexibility&max-results=20&by-date=true

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7.3 March

7.3.1 Video of my Michigan Talk Now Online (2012-03-02 10:58)

The University of Michigan Center for Bioethics and Social Sciences has kindly posted a video recording of my February 1 talk:

IFRAME: [1]http://player.vimeo.com/video/36693842?title=0 &byline=0 &portrait=0

[2]Zachary Schrag talk, February 1, 2012 from [3]CBSSM Developers on [4]Vimeo. and the subsequent panel discussion, featuring Cleo Caldwell, Carl Schneider, and Alford Young, Jr.:

IFRAME: [5]http://player.vimeo.com/video/37246906?title=0 &byline=0 &portrait=0

[6]Ethical Imperialism: The Case Against IRB Review of the Social Sciences, 2/1/12 Panel Discussion from [7]CBSSM Developers on [8]Vimeo.

1. http://player.vimeo.com/video/36693842?title=0&byline=0&portrait=0
2. http://vimeo.com/36693842
3. http://vimeo.com/user7226566
4. http://vimeo.com/

5. http://player.vimeo.com/video/37246906?title=0&byline=0&portrait=0
6. http://vimeo.com/37246906
7. http://vimeo.com/user7226566
8. http://vimeo.com/

Thomas A. Becket (2012-03-13 16:01:13)
Please provide written names of panel participants. They are hard to understand on video.
Great session!

Zachary M. Schrag (2012-03-13 20:26:34)
Done, thanks.

7.3.2 REC Forbids Dissertations on Lap Dancing (2012-03-14 10:12)

Robert Dingwall fears that "research ethics is co-opted to infantilize students who are legally adults but treated as if they should never be allowed to risk a bad experience."
[Robert Dingwall, "[1]Better Drowned than Duffers…?," *social science space*, 19 February 2012.]
Dingwall compares a 1930 children's novel, which suggests that young people need some risk in their lives, to the case of

> two third-year undergraduates at an urban university who wanted to write dissertations about lap-dancing clubs. I have to confess that the fascination of students with the sex industry often baffles me and results in some assignments that can be quite unpleasant to mark. However, in the UK, lap-dancing bars and clubs goes on are commonly places open to anyone over 18. These young women could walk into these premises, spend the evening observing interactions and write a blog about them. They could not, however, use that material to write a dissertation because their research ethics committee would not approve the project 'in case something happened to them and the university was held responsible'.

Some precautions might be justified, he writes, but

> students surely have a right not to have their spirit of adventure stifled by institutional prissiness. If they are banned from taking everyday risks, how will they ever venture beyond what is safe and known? If universities cease to be places where unexpected, and possibly dangerous, things can happen, what is the point of universities? Are we just creating duffers?

1. http://www.socialsciencespace.com/2012/02/better-drowned-than-duffers%E2%80%A6/

7.3.3 Petrie-Flom Center Posts ANPRM Conference Program (2012-03-16 10:07)

The Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School has circulated the following announcement, concerning a conference at which I will speak. I am happy to post the announcement in full.

Annual Conference Announcement: The Future of Human Subjects Research Regulation

The Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School is pleased to announce plans for our annual conference, this year entitled: "The Future of Human Subjects Research Regulation." The one and a half day event will take place Friday, May 18 and Saturday May 19, 2012 at Harvard Law School in Cambridge, Massachusetts.

The U.S. Department of Health and Human Services recently released an Advanced Notice of Proposed Rulemaking (ANPRM), titled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," which proposes to substantially amend the Common Rule for the first time in twenty years. This development, as well as attention by the Presidential Commission for the Study of Bioethical Issues, suggests we are at a moment when the regulation of human subjects research is ripe for re-thinking. This conference will gather leading experts from the U.S. and across the globe to assist in that endeavor.

We have limited space, so attendance is by permission. To apply to attend please email a paragraph explaining your interest and background to Shannon Sayer at ssayer@law.harvard.edu.

[1]Click here for full conference schedule.

1. http://www.law.harvard.edu/programs/petrie-flom/events/conferences.html

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7.3.4 Hospital Blocks Access to 18th Century Records (2012-03-16 12:57)

Pennsylvania Hospital has refused a [1]graduate student's request to see 18th century medical records, citing HIPAA concerns.

[Melissa Dribben, [2]Health-record privacy impeding medical research," Philadelphia Inquirer, 13 March 2012. h/t [3]Michelle Meyer.]

The newspaper explains:

> Although [the hospital's archivist] was able to open admission records providing basic information - patients' sex, age, and suspected ailments - she could not allow access to detailed charts.
>
> In England, where Segesser also is conducting this research, she said, medical records are fair game 75 years after the patient's death.
>
> But in the United States, the privacy protection extends back forever.
>
> "This is a huge issue," said Howard Markel, director of the Center for the History of Medicine at the University of Michigan. "It's closing off some of the most intriguing avenues in the history of medicine research."

In related news, Connecticut has modified the state's Freedom of Information Act to block similar research there. It did so [4]without giving historians the chance to testify.

1. http://www.history.utoronto.ca/graduate/gsprofiles/segesser.html
2. http://articles.philly.com/2012-03-13/news/31160163_1_medical-research-medical-history-controls
3. http://articles.philly.com/2012-03-13/news/31160163_1_medical-research-medical-history-controls
4. http://www.ctlawtribune.com/getarticle.aspx?id=40489

Anonymous (2012-03-21 14:07:20)
You should know the the access that is already being granted violates HIPAA. Patient names are protected health information. Surprised this was allowed.
Theresa Defino
Editor
Report on Research Compliance
Contributing Writer
Report on Patient Privacy

Zachary M. Schrag (2012-03-21 14:58:32)
Thanks for this message.
I claim little expertise here, but I think the matter is more complex than that, since HIPAA does allow some access to researchers. See HHS, [1]Understanding HIPAA Privacy, and Susan C. Lawrence, "[2]Access Anxiety: HIPAA and Historical Research," Journal of the History of Medicine and Allied Sciences 62 (2007): 422-460.

1. http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/research.html
2. http://jhmas.oxfordjournals.org/cgi/content/abstract/62/4/422

Anonymous (2012-06-24 15:25:23)
As a nurse and citizen, I appreciate the HIPPA laws but not allowing access to medical records from the 18th century is bazarre, ludicrous, stupid, misguided, assinine . . . you get my drift.
It serves NO purpose. Who is enforcing this? It makes me angry, frustrated, sickened, embarrassed for our nation, and generally confused. I can't even grasp this idiocy! Who is putting up wiht this c–p!

7.3.5 Ball State Student Finds IRB Instructions "Impersonal, Dry, and Long" (2012-03-21 10:03)

Stephanie Hedge, a PhD Candidate at Ball State University in Rhetoric and Composition, describes how IRB requirements aggravated her difficulties in "persuading students to be my guinea pigs for a semester."
[Stephanie Hedge, "[1]Successfully Recruiting Research Participants," Inside Higher Ed, 20 March 2012.]
Hedge writes,

> The initial solicitation emails that I sent out, per IRB regulations, were dense, intimidating walls of text. They are impersonal, dry, and long. Small wonder, then, that few students bothered to click through to the survey itself, particularly given that the link is buried down at the bottom. During my classroom visits, I directed students to the survey instead of to me, adding an extra step to the process. My directions were too complicated, and mired in dense IRB language. However, once I began handing around a sheet for students to put their names and email addresses, students signed up in droves. Nothing fancy, just a simple sign up sheet.

Hedge does state that "there are lots of ways to work within your specific IRB rules and regulations to find support." Without the details of her project or the language required by her IRB, it's impossible to know how bad this case is. Still, Hedge's account raises the question of why any project in rhetoric and composition would require an intimidating wall of text.

1. http://www.insidehighered.com/blogs/gradhacker/successfully-recruiting-research-participants

7.4 April

7.4.1 Could Retrospective Review End Nitpicking? (2012-04-06 08:40)

Robert Klitzman and Paul Appelbaum, both of Columbia University, suggest that shifting research oversight to the retrospective review of a subset of projects, rather than prospective review of proposals, could reduce the "variability and subjectivity across IRBs" that now characterizes ethics review.
[Robert Klitzman and Paul S. Appelbaum, "To Protect Human Subjects, Review What Was Done, Not Proposed," Science 335 no. 6076 (30 March 2012): 1576-1577,
DOI: [1]10.1126/science.1217225.]
The authors deprecate the current system. They note that "IRBs often face difficulties defining, interpreting, and applying critical concepts embodied in the regulations and central to human subjects protection (e.g., 'justice' and 'autonomy')," and therefore produce inconsistent judgments on identical proposals. Worse still, IRBs are unaware of how useless much of their effort is. "Many IRBs feel they play a vital role in rewording consent forms, because researchers may downplay risks and overemphasize potential benefits," they note. "But IRBs 'wordsmithing' the contents differently produces inconsistent results." Nor should we expect anything else from a system based almost entirely on guesswork: "the inherently speculative nature of prospective review exacerbates variability and subjectivity across IRBs."
As an alternative, the authors propose a system of retrospective review, comparable to "audits of government-funded health-care programs (Medicare and Medicaid), accreditation of hospitals, Data Safety Monitoring Boards' assessment of patient safety and treatment efficacy data during clinical trials, federal and state tax collection audits, and the tort system." (They might have added existing mechanisms to handle allegations of plagiarism, fabrication, and falsification.) Such a system, they suggest, "would allow determinations based on evidence of what actually occurred, rather than fears of what might happen."
Retrospective review would also facilitate the introduction of due process guarantees now absent in the system. "Due process is so fundamental a right in modern democracies," they write, "that there seems little reason to deny it to researchers."
Klitzman and Appelbaum are pragmatists, noting that "We cannot simply turn the clock back to 1966, when prospective review was first introduced, and cast it aside." Instead, they propose initially shifting to retrospective review only for "certain minimal risk research," as proposed by the ANPRM. "If initial moves away from a strictly prospective model are successful," they suggest, "it may be possible to expand them progressively to studies that pose higher levels of risk."
I don't think I've ever seen so much empirical evidence and careful thinking about IRBs packaged in so brief an essay. While [2]I look forward to reading more from Dr. Klitzman, he has set himself a high standard.

1. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/dx.doi.org/10.1126/science.1217225
2. http://www.institutionalreviewblog.com/2012/02/irbs-misunderstand-researchers.html

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7.4.2 AAHRPP Organizations Check Fewer Boxes (2012-04-12 14:03)

The AAHRPP has reported that [1]only 29 percent of its accredited organizations (not counting VA facilities, which don't have the option to uncheck boxes) pledged to apply all parts of the Common Rule to research not directly sponsored by the federal government. However, 72 percent of organizations that left at least one box unchecked still "applied the DHHS regulations to all research regardless of funding source." Thus, for a great many organizations, unchecking a box or two remains a way to escape federal oversight without offering researchers any additional freedom.

1. http://advance.aahrpp.org/2012/03/checking-boxes-on-fwacurrent-trends.html

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7.4.3 An End to IRBs? (2012-04-12 14:16)

Ethics review is a big industry. As [1]Will van den Hoonaard has noted,

> In Canada alone, the business of academic ethics is a $35 million industry; when you include three other countries (United States, United Kingdom, and Australia), the industry amounts to some $500 million, with an inordinate amount of costs borne by cash-strapped universities. The reciprocal obligations, contradictions, and inherent permutations of such a large industry are nearly impossible to escape.

It may be hard to imagine such an industry disappearing overnight.
Yet I was struck by a possible analogue in the history of the population control movement, as described by historian Matthew Connelly in his book, Fatal Misconception: The Struggle to Control World Population (Harvard University Press, 2008).
Connelly [2]describes the fate of the population control movement in the late 1970s, after the 1974 World Population Conference and India had moved away from its recommendations:

> All of the most important international and nongovernmental organizations in the field entered a period of agonizing reappraisal. Facing staff and budget cuts, population controllers could only take bitter satisfaction in receiving confirmation that fertility rates had begun to fall in almost every region of the world. Together with unfulfilled predictions of global famine, it only made their work seem less urgent, and their excesses all the more unforgivable. Continuing debates about whether government programs were reducing fertility rates—in most places, it started without them—were becoming matters of merely academic interest.
> Some people working from the inside had always resisted the idea that they needed to plan other people's families. But there was too much invested in population control for these institutions to transform themselves overnight. In 1980, about $2 billion was being spent on population programs in poor countries, including some $490 million in international aid. For the most part, it was not pledged to promote gender equality or maternal health. With funding already down relative to inflation as well as other kinds of international aid, downplaying a long-standing commitment to reduce fertility might lead to further losses. Careers and reputations depended on the proposition that it remained both practical and urgent. The status quo was also buttressed by the ideological detritus of decades, which continued to attribute war, famine, disease, and degeneration to "overpopulation."'
> Those who genuinely wanted to empower people, and not control them, struggled to disentangle themselves from all of this. It was not obvious how to make a clean break—that is, how to stop coercion and advance a different agenda that could work in dozens of different countries. Hundreds of millions of people had come to depend on family planning programs, for all their faults, and many more were still left to their own devices. If this was not to be a self-serving exercise in exculpation, their needs had to come first.
> [Matthew Connelly, Fatal Misconception: The Struggle to Control World Population, pp. 327-328. Kindle Edition.]

And yet, he suggests, by 1994, "Population control as a global movement was no more." (p. 369).
Can we imagine a similar end to IRBs? A reassessment of basic assumptions, followed by a 15 or 20 year period in which funding is gradually reduced, and people whose careers and reputations depend on erroneous propositions find other work to do? In 2031, perhaps we will look back on the ANPRM as the beginning of the end.

1. http://books.google.com/books?id=pTDndT5NzA0C&lpg=PA288&vq=%24500%20million&pg=PA288#v=snippet&q=$500%20million&f=false

2. http://books.google.com/books?id=CwImmRvyyiEC&lpg=PP1&dq=Fatal%20Misconception&pg=PA327#v=onepage&q=all%20the%20most%20important&f=false

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7.4.4 Reverby Reviews Ethical Imperialism (2012-04-24 10:28)

Writing in the April American Historical Review, Susan Reverby very kindly reviews Ethical Imperialism:

> Schrag is not alone in his critiques of the IRB process, but this is the first historical account of the problems IRBs pose to the social sciences. Officials in the federal government are currently considering revisions to the decadesold Common Rule; Schrag's work has already begun to have an impact on their thinking, as evidenced by footnotes to his scholarship in their most recent report. This book ought to be required reading for those concerned about the political forces that make our work possible, and sometimes not possible at all.

[Susan M. Reverby, Review of Zachary M. Schrag, Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009, American Historical Review 117, No. 2 (April 2012), pp. 484-485, DOI: [1]10.1086/ahr.117.2.484a, [2]http://www.jstor.org/stable/10.1086/ahr.117.2.484a.]

1. http:dx.doi.org/10.1086/ahr.117.2.484a
2. http://www.jstor.org/stable/10.1086/ahr.117.2.484a

7.4.5 Beauchamp and Saghai on the Mystery of Generalizable Knowledge (2012-04-26 12:11)

Philosophers Tom L. Beauchamp and Yashar Saghai find that although never defined, "the criterion of generalizable knowledge . . . is the foundation stone of the [National] Commission's conceptual and moral scheme in Belmont and beyond.

[Tom Beauchamp and Yashar Saghai. "The Historical Foundations of the Research-Practice Distinction in Bioethics," Theoretical Medicine and Bioethics 33, no. 1 (2012): 45–56. DOI [1]10.1007/s11017-011-9207-8. h/t [2]Nathan Emmerich.]

Relying largely on the transcripts and draft materials of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (which employed Beauchamp on its staff), Beauchamp and Saghai argue that the commission excluded medical practice from IRB not because its members thought medicine didn't need oversight, but because it was obeying instructions from Congress "in a context that had political origins and political limits."

The article emphasizes the provision in the [3]National Research Act to consider "The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine." It attributes this provision to the Senate's interest in testimony by Jay Katz, the only Senate witness to have used the language of boundaries in his 1973 testimony.

This may be true on the Senate side, but the article doesn't explore the House hearings, in which the president of the Association of American Medical Colleges complained that "the proposed legislation does not delimit the activities of the commission in a manner whereby it would be clear that the ordinary practice of medicine is not subject to the jurisdiction of this commission." He offered the following:

> PROPOSED NEW LANGUAGE FOR SECTION 1202(b) (5)
>
> We would suggest that section 1202(b) (5), which concerns the duties of the Commission, be amended to read as follows:

> ... defining more precisely the boundary between biomedical and behavioral research involving human subjects and the accepted practice of medicine, provided that, in defining these boundaries, the Commission shall concern itself with organized research support by Federal funds, and shall not have jurisdiction over the ordinary practice of medicine;
> [U.S. House of Representatives, Biomedical Research Ethics and the Protection of Human Research Subjects: Hearings before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce (93d Cong., 1st sess., 1973), p. 204]

Since this language ("accepted practice of medicine") is somewhat closer to the language in the final statute, I suspect the AAMC was more influential than Katz.
Understanding the AAMC's role actually offers greater support for the article's claim that the commissioners crafted the Belmont Report partly in search of "political acceptability." The authors note Commissioner Robert Cooke's concern that the commission not offend "organized medicine." In other words, IRBs don't govern routine medicine because in 1973 doctors were invited to testify before Congress. Social scientists were not, and we all know what happened to them.
The article finds that the concept of generalizability is central to the IRB world even though no one knows what it means:

> The criterion of generalizable knowledge, once articulated, did not generate any substantial debate among commissioners as to its meaning or its ultimate adequacy with regard to various types of learning activities. The notion was not then, and has never since been, carefully analyzed in Commission deliberations, in federal regulations, or in the bioethics literature. This fact is striking inasmuch as generalizable knowledge is the cornerstone of the work of the National Commission and in federal regulations for the purpose of distinguishing research from practice. Nothing is more basic.

1. http://dx.doi.org/10.1007/s11017-011-9207-8
2. http://nathanemmerich.org.uk/
3. http://history.nih.gov/research/downloads/PL93-348.pdf

7.4.6 Li Abandons Suit, But Brown University Still Ponders IRB Reform (2012-04-27 20:53)

Though it no longer faces a faculty lawsuit, Brown University is considering an outside review of its troubled IRB.
As readers of this blog may remember, [1]Brown faculty have been complaining about the IRB since 2007, if not before.
In 2011, a Brown professor, Jin Li, took the highly unusual step of [2]suing the university because of IRB interference in her work. In March, Li abandoned that effort, her attorneys agreeing to a [3]dismissal with prejudice.
According to the Daily Herald, Brown faculty and administrators are discussing possible reforms, including an external review, broader disciplinary representation on the IRB, the creation of an additional IRB for non-biomedical human subject research, and "changing the charge of the IRB to make it not only a monitory board but also one that provides a more supportive and guiding role to research teams."
[Aparaajit Sriram, "[4]IRB Likely to Undergo Review," Brown Daily Herald, 26 April 2012.]
The article does not mention the possibility of an appeals process, the lack of which was one of Li's complaints.

1. http://www.institutionalreviewblog.com/2009/11/brown-pledges-irb-reform.html
2. http://www.institutionalreviewblog.com/2011/03/professor-sues-brown-university-over.html

3. http://zacharyschrag.files.wordpress.com/2011/06/li_v_brown-dismissal-3-23-121.pdf
4. http://www.browndailyherald.com/irb-likely-to-undergo-review-1.2736179#.T5oYbjKXTRc

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7.5 May

7.5.1 Qualitative Sociology Ventures Beyond the IRB (2012-05-03 11:44)

Back in December, as I was still dealing with a crush of ANPRM-related reading, I mentioned that the journal [1]Qualitative Sociology had published a special issue on "Ethics Beyond the IRB". I have finally found some time to read the intriguing essays it contains.
The issue emerged from an [2]October 2010 workshop at the University of Pittsburgh and features five articles as well as introductory and concluding essays.
Qualitative Sociology
Volume 34, Number 3 / September 2011
[3]Special Issue: Ethics Beyond the IRB
Guest Editors: Kathleen Blee and Ashley Currier

- Kathleen M. Blee and Ashley Currier, "Ethics Beyond the IRB: An Introductory Essay," 401-413.
- Rachel L. Einwohner, "Ethical Considerations on the Use of Archived Testimonies in Holocaust Research: Beyond the IRB Exemption," 415-430.
- Bernadette Barton, "My Auto/Ethnographic Dilemma: Who Owns the Story?", 431-445.
- Gloria González-López, "Mindful Ethics: Comments on Informant-Centered Practices in Sociological Research," 447-461
- Ashley Currier, "Representing Gender and Sexual Dissidence in Southern Africa," 463-481.
- Leila J. Rupp and Verta Taylor, "Going Back and Giving Back: The Ethics of Staying in the Field," 483-496.
- Melissa Swauger, "Afterword: The Ethics of Risk, Power, and Representation," 497-502.

Ethical Dilemmas

All of the contributors to the issue recognize that qualitative sociologists face serious ethical challenges as they go about their work, especially the challenge of being torn between their duty to report objective truths and the wish not to write ill of the people they study.
Einwohner, borrowing from [4]Janet Liebman Jacobs calles this the "double vision" of observer and participant. (417) Currier concurs, noting that "the injunction to report all findings may be untenable for qualitative researchers who study vulnerable populations. In some scenarios, another ethical principle may trump that of sincerity: that of the researcher's responsibility to her research participants. Ethical and political concerns may motivate researchers to suppress certain observations they have made about research participants." (463) She suggests that researchers may want to adopt "an ethical principle of not 'air[ing] dirty...laundry in public,'" (466) but she notes that this conflicts with "researchers' professional obligations [that] may require them to critique activists' strategic priorities." (470). Currier resolves this tension with a rule of "When in Doubt, Leave It Out," though her list of episodes and statements she discarded from her findings is so long that I begin to wonder if her readers got a true picture of the phenomena she was seeking to describe. It's one thing not to air dirty laundy, another to suggest that people don't soil their clothes.
A second, related dilemma concerns the blurring of roles when research subjects become friends and acquaintances,

and when friends and acquaintances become research subjects. How much can one reveal about people you encounter in your daily life, the very people who teach you most about the world? What do you owe to people you have studied, once you have moved on to other projects? What do you do when "every single encounter I personally have with anyone or any text is potentially data"? (442) There are no easy answers. Barton refrains from quoting from an offensive essay by a student, but notes that "I feel some ownership of the incident and the essay." (436) But she recounts another story in the belief that "it is extremely unlikely" that Kentucky lesbians will enounter their descriptions in "a sociological or feminist academic journal." (441) Given the reach of the Internet, I'm not sure I share her faith. Rupp and Taylor describe a relationship with their informants that would seem to be as good as it gets. The researchers and participants became true friends, sharing confidences, life events, and even meager book royalties over the course of more than a dozen years. But even this relationship was not without suspicion and hurt feelings.

Some of the ethical challenges reported by the authors strike me as a bit overblown. In particular, Einwohner frets about building a spreadsheet that required her to assign an ID number to Holocaust survivors, an act she found "reminiscent of similar records kept by the perpetrators of violence." (422) I think this may be an example of what Currier (following Laurel Richardson) calls "'[5]analysis-paralysis,' a condition in which ethical worries grip researchers so much that they cannot move beyond an ethical impasse." (466) In this case, perhaps Einwohner might have taken comfort in reflecting that the Israeli government assigns its citizens identification numbers that must be used for all manner of transactions.

Unhelpful IRBs

The introductory essay by Blee and Currier explains that IRB system as it now exists is only one of many ways we could imagine to promote research ethics, and it may not be a very good one. Prospective review can be a poor fit for much research, since "the evolving understanding of the field that is characteristic of qualitative studies may change what is studied and how it is studied, while IRB procedures assume the full scope of a research study and contacts with people can be anticipated in advance. Particularly troubling, qualitative scholars face complex ethical issues that are not addressed by the procedures and protocols of institutional reviews, which are mainly oriented to the possible negative impact of research on individual subjects." (402)

Likewise, the Belmont Report's reliance on principles–respect for persons, beneficence, and justice–may be less effective than approaches emphasizing the training of ethical researchers (virtue ethics), explorations of cases (casuistry), or social relationships (feminist ethics). (403) Since "the ethical quandaries researchers face are particular to their research projects," Blee and Currier are skeptical of "universal rules of research ethics." (407)

Finally, Blee and Currier suggest that the punitive nature of the current IRB system could trap researchers who find themselves in ethically ambiguous situations. They offer the example of a researcher in Rwanda who showed compassion for one woman, which in turn offended another woman whose husband had been killed by the first. The researcher did her best to make amends, but I shudder to think how a case like this would be treated by an adverse-event reporting system.

The articles in the body of the issue present examples of the way the present system may fail researchers and participants alike. Einwohner describes work with "publicly available archived data collected from Holocaust survivors." Curiously, she then reports needing IRB permission to revise her protocol once she decided–on ethical grounds–to use the survivors' names in her project. If this is really the case, then Einwohner's IRB erred in not telling her that it has no jurisdiction over publicly available information. (It also sounds as though Einwohner might want to consult some historians as she continues her research on the Holocaust. She writes that "my strong desire to restore these survivors' identity and humanity by using their real names conflicts with the standards of research practices . . ." (427) Whose standards is she talking about?)

Other authors seem timid in their relations with IRBs, and somewhat unfamiliar with the regulations that govern them. Barton writes of her ethical practices "in addition, of course, to complying with [IRB] protocols." (432). Why "of course"? González-López is generous in her belief that "the IRB process helps researchers think about ethical issues and concerns," though she provides no examples. (448)

The authors are more eloquent about the ways the IRB process can impede rather than promote ethical reflection. González-López writes,

> In the past, I immersed myself in the field with great excitement after I had naively "taken care of all" of potential ethical problems or concerns, mainly through the IRB. However, by using a grounded theory approach to focus on the process of research, I realized that most ethical questions emerge after IRB review, especially in studies of sensitive topics, such as emotional trauma and sexual and sexualized abuse. (450)

She also has more specific concerns:

- The "taken-for granted signed consent form" that "could jeopardize the safety of my research participants." (447-448). Of course, [6]45 CFR 46.117(c)(1) specifically anticipates such circumstances, and a better IRB might have pointed that out to González-López. Instead, she had to reinvent this particular wheel.
- The IRB's power to "silence youth (as well as other populations socially constructed as vulnerable by the IRB) [which] may represent an ethical challenge and frustration for feminist qualitative researchers who are actually interested in investigating and exposing injustice, and advocating for populations vulnerable to multiple oppressions." (457) González-López offers the example of a young woman who had traveled three or four hours through Mexico City traffic to have a chance to talk with her. This case is a reminder that [7]IRBs that imagine conversation about traumatic events to be risky in itself are likely to deny such people the chance to make their own decisions about whom to talk to.
- The IRB's failure to anticipate that an informant might sexually harass the researcher. (456) This is not the IRB's responsibility, but the IRB could have done a better job explaining its role to González-López.

In her concluding essay, Swauger echoes some of these concerns, noting that

> The IRB's commitment to fixed procedures and rules and its discourse about the vulnerability of certain populations inadvertently blocks the ability of scholars to represent girls' voices, and homogenizes youth subjects by assuming a shared familial experience, particularly that both biological parents are present and capable of consenting for their child. Too, by seeking to protect girls by empowering organizational gatekeepers and parents to make decisions on their behalf, the IRB gives more importance to parents and organizations than to young people. It does not treat youth subjects as social agents capable of making life decisions. (497)

Swauger is more explicit than other contributors about the tension between research ethics and IRB compliance: "Some [researchers] redesign their methodological approach. Others sneak around IRB regulations, stating, 'I'll just leave it out of the protocol and see if they say anything.' Many push forward with projects that are directly opposed to IRB policies." (498)

Next Steps

The special issue offers little in the way of concrete proposals for improvement. The introduction ends with a call for "continued discussion among scholars who confront complicated ethical issues in their fieldwork," rather than any kind of change to the IRB system. (410)
Swauger's proposal is similarly vague:

> As we busy ourselves satisfying the IRB and teaching our students to get through the process, that is, as we "orient [our] consciousness and actions in relation to institutional ethical oversight," we lose opportunities to acknowledge, discuss, and confront the real ethical issues we face in our research. We must move beyond our fear of, acquiescence to, and confrontation with IRBs toward a deeper understanding of the ethical conundrums that emerge in our work." (498)

That sounds lovely, but how can deep understanding emerge in a climate of fear, acquiescence, and confrontation? It seems to me that only reform of federal and university policies can bring this change.

1. http://www.institutionalreviewblog.com/2011/12/special-issue-of-qualitative-sociology.html
2. http://www.wstudies.pitt.edu/sites/default/files/10.9%20-%20Beyond%20the%20IRB.pdf
3. http://www.springerlink.com/content/0162-0436/34/3/
4. http://www.jstor.org/stable/4149434
5. http://books.google.com/books?id=m-SJICOCVTwC&lpg=SL3-PA21&ots=BDsRKdVgXj&dq=richardson%20fields%20of%20play&pg=SL3-PA94#v=onepage&q=analysis-paralysis&f=false
6. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117
7. http://www.institutionalreviewblog.com/2008/03/trauma-based-research-is-less-risky.html

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7.5.2 Dingwall: UK May Enact Research Integrity Rules With Little Scholarly Input (2012-05-08 20:46)

Writing on *social science space*, Robert Dingwall warns that the United Kingdom's Economic and Social Research Council seems to be crafting burdensome regulations on research integrity without defining the problem to be solved, considering the costs of regulation, or consulting scholarly associations:

> A document drops into my inbox that purports to be a draft Concordat between the major UK funders and university managements on research integrity. It seems that publication has already been set for July 2012, but someone belatedly thought that it might be a good idea to get disciplinary associations on board. The result is a six-week consultation period across two public holiday weekends and a university vacation. This does not encourage respect for the consideration that will be given to responses or the integrity of those who have thought this would be adequate.

He notes the precedent: human subjects regulations. "This process resembles the way in which the academic community was bounced into ethical regulation by the particular concerns of US biomedical sciences, and their indifference to anyone else's views, as documented by the recent work of Schrag and of Laura Stark."
[Robert Dingwall, "[1]Research Integrity in the UK – the Spawn of Satan?," social science space, 6 April 2012.]

1. http://www.socialsciencespace.com/2012/04/research-integrity-in-the-uk-%E2%80%93-the-spawn-of-satan/

7.5.3 Philosopher and IRB Chair Call for Repeal of IRB Exemptions (2012-05-10 15:04)

Writing in IRB: Ethics & Human Research, Mahesh Ananth and Michael Scheessele, both of Indiana University South Bend, argue against exempting all minimal-risk research from IRB review. They do so in terms that would require the repeal of the 45 CFR 46.101 exemptions, though it is not clear they understand the implications of their own argument.

[Mahesh Ananth and Michael R. Scheessele, "[1]Exempting All Minimal-Risk Research from IRB Review: Pruning or Poisoning the Regulatory Tree?" IRB: Ethics & Human Research 34, no. 2 (April 2012): 9–14.]

Ananth and Scheessele frame their essay as a response to Scott Kim, Peter Ubel, and Raymond De Vries, "Pruning the Regulatory Tree," Nature 457 (29 January 2009), 534-535. (For my own comments on that piece, see "[2]And the Bush Was Not Consumed.") In that piece, Kim, Ubel, and de Vries argued for exempting minimal-risk research from IRB review, on the grounds that "it is unethical to support a system that creates a significant financial, scientific, clinical and ethical burden with virtually no counterbalancing good."

Ananth and Scheessele seek to discredit this argument. First, they suggest "Kim and colleagues clearly do not adhere to a strict act-utilitarian position," and that "rule utilitarianism is not (or should not be) their overarching normative foundation. The overall implication of these arguments is that utilitarian considerations are not motivating the authors' defense in any substantive way." This is a non sequitur. To state that someone doesn't follow a principle strictly is not the same as saying the principle does not motivate them in any way. The Belmont Report, which Ananth and Scheessele like, is no more pure in its use or rejection of utilitarian arguments than is the Nature essay.

Ananth and Scheessele then struggle to find examples of minimal-risk research that merits IRB review. They offer the case of Henrietta Lacks, whose tissue was taken for study without her consent. As the authors concede, "this example differs from present-day tissue collection, storage, and research, where tissue may be voluntarily donated or obtained from medical waste and where the researcher may not be able to readily identify the individual from whom tissue was obtained." So this isn't much of an argument for IRB review.

The second case they raise is that of the Havasupai, who thought they were donating blood for a diabetes study, but were dismayed when that blood was used to study other subjects, including schizophrenia. For this example to support their argument, Ananth and Scheessele would need to show that IRBs presented with such cases flag ethical concerns more effectively than the researchers alone. Though the [3]destruction of the IRB records in that case makes it impossible to know exactly what happened, I have found nothing to suggest that the Arizona State University IRB spotted the issues that later proved so controversial.

Ananth and Scheessele offer no similar real-world examples for social research, but generalities:

> Consider sociobehavioral research, which tends to pose minimal risk. Would professors engaged in this type of research obtain informed consent from students who depend on them for a grade knowing that their research is not subject to IRB review? Moreover, sociobehavioral research has very diverse goals and methodologies and is by no means limited to participants from the population of college students. Sociobehavioral research includes ethnographic studies of certain populations, domestic or international; psychological laboratory research on cognition and perception; certain types of oral history; user evaluation of Web sites and software interfaces; mental health studies that may have both a treatment and a research component; and community activism studies that may include a research component intertwined with activism. This heterogeneous list of sociobehavioral research paradigms is by no means exhaustive. In each of these research paradigms there may be power dynamics between the researchers and the participants that raise issues about adequate voluntary informed consent. With no IRB review of these studies, it is unclear what oversight mechanism would be used to deter researchers from unduly inducing or coercing individuals to participate in their studies.

Ananth and Scheessele do not mention that many of these activities, as well as much research using "pathological specimens, or diagnostic specimens, are already exempt from IRB review under [4]45 CFR 46.101. In other words, they are objecting not to Kim's proposal, but the regulations as they have existed since 1981. If they really believe that IRB review is necessary "to deter researchers from unduly inducing or coercing individuals to participate in their studies" whenever "there may be power dynamics between the researchers and the participants that raise issues about adequate voluntary informed consent," they are effectively calling for a repeal of all of 45 CFR 46.101.

One can make a case for repealing some or all of the exemptions. Leslie Wolf, for example, has argued that "the current exceptions to IRB review for much research involving biological materials are no longer justified, fail to recognize

donors' continuing interest in their biological materials and the ways in which they are used, and unnecessarily remove such research from the protections afforded by IRB review." ["Biology and Genetics: Advancing Research on Stored Biological Materials: Reconciling Law, Ethics & Practice," 11 Minn. J.L. Sci. & Tech. 99 (2010)] The ANPRM has some proposals along these lines for genetic material.

The difference between these documents and the Ananth and Scheessele essay is that Wolf and the ANPRM authors understand the current regulations' scope and their grounding in a mix of principle and pragmatism. Ananth and Scheessele, by contrast, overlook the Common Rule's efforts to balance protection and freedom, and therefore exaggerate the differences between a proposal for reform and the status quo.

1. http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=5755
2. http://www.institutionalreviewblog.com/2009/01/and-bush-was-not-consumed.html
3. http://cnhp.montana.edu/conference/HartReport.pdf
4. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

Michael R. Scheessele (2012-05-16 15:52:00)

Zachary Schrag's assertion that "philosopher and IRB chair call for repeal of IRB exemptions" is incorrect. We make no such claim, and our argument from our recent IRB article does not imply such a claim, either.

Our article shows that Kim and colleagues appear to have committed a logical fallacy in assuming that what might be true of minimal-risk QI human subjects research would also be true of all minimal-risk human subjects research. As such, their argument for deregulating all minimal-risk human subjects research would be logically unsound.

We contend that the only way their argument can be saved is if:

1. they are utilitarians making an utilitarian argument, or
2. it can be demonstrated that what might be true of minimal-risk QI human subjects research would also be true of minimal-risk non-QI human subjects research.

In order to evaluate (1), we examined the comments of Kim et al. and concluded that "utilitarian considerations are not mo¬tivating the authors' defense in any substantive way." Schrag criticizes our conclusion, claiming:

"This is a non sequitur. To state that someone doesn't follow a principle strictly is not the same as saying the principle does not motivate them in any way."

Now, this sort of casual sentiment might hold sway in a history department, but in the domain of ethics, it does not pass muster. To adhere to a moral system at one's whim is not to adhere to the moral system. You do not get to be a utilitarian at your leisure or to a degree or only under certain circumstances. Either you are a utilitarian or you are not. Alternatively, if Schrag is suggesting that Kim et al. endorse some sort of pluralism or mixed account, it is not clear how this would reconcile with their argument. If this indeed is their position, then we anticipate clarification from Kim and colleagues on this point.

In order to evaluate (2), we considered the potential effects of deregulation on both QI and non-QI minimal-risk human subjects research with respect to the Belmont principles of "respect for persons", beneficence, and justice. We based our analysis on these principles from The Belmont Report because of its foundational relationship to the current regulations, not simply because we "like" Belmont, as Schrag suggests. It is from this analysis that Schrag seems to make the leap to the conclusion that we advocate repealing IRB exemptions. The difficulty for Schrag appears to come from the excerpt from our article that describes the various forms of sociobehavioral research that can be minimal-risk. Schrag states:

"Ananth and Scheessele do not mention that many of these activities, as well as much research using pathological specimens, or diagnostic specimens, are already exempt from IRB review under 45 CFR 46.101. In other words, they are objecting not to Kim's proposal, but the regulations as they have existed since 1981."

This criticism is superficial, however. In the Kim et al. article, it is clear that they are arguing for exemption of minimal-risk research that is not currently exempt. Our article is a critique of their argument; from this context it should be clear that we are referring to precisely that minimal-risk sociobehavioral research which is not currently exempt. Further, we explicitly state our support for using current exemptions:

"Although we concur that IRB review should not be disproportional to a study's risk level, we believe that the correct approach to "easing the regulatory burden" is in the proper application of the flexibility that already exists in the Common Rule—for example, recognition of current exemption categories, appropriate use of an expedited procedure, and appro¬priate use of the provision to waive documentation of informed consent."

Michael R. Scheessele and Mahesh Ananth

Zachary M. Schrag (2012-05-16 22:52:51)
Thanks for these comments.
The key statement may be your claim that "Either you are a utilitarian or you are not." This may not be true for anyone outside a philosophy department, and it is certainly not true for the collective bodies that make policy in a democracy. The National Commission included both utilitarians and non-utilitarians among its members, staff, and consultants, and the Belmont Report's provisions reflect its mixed heritage. (See [1]Belmont Revisited, especially the Beauchamp and Veatch essays, but really the whole thing.)
I would be fascinated to know what single ethical tradition could explain the particular activities that do or do not appear in 45 CFR 46.101 and the list of activities eligible for expedited review.
In the real world, sound policies are both pluralist and pragmatist. I see no reason to expect reform measures to be intellectually purer than the existing regulations, only more sensible.

1. http://press.georgetown.edu/book/georgetown/belmont-revisited

Michael R. Scheessele (2012-05-17 16:03:11)
This shifts the debate away from our original argument, though. Of course, the Belmont report is pluralistic in its scope, informed by ethical traditions perhaps as varied as the backgrounds of the Commission members who ironed it out. This is obvious.
Returning to our point, however, it is this:
"Kim and colleagues' claim that there is "virtually no counterbalancing good" in regulating minimal-risk human subjects research assumes that the consequences of not regulating QI and non-QI minimal-risk studies would be identical. As we have argued, though, this assumption is unwarranted. … Because the claim that the current regulatory system offers "virtually no counterbalancing good" is false, Kim and colleagues' argument is unsound. Thus, federal regulators should not explicitly exempt all minimal-risk research from IRB oversight, even if it turns out that some additional categories of research should be exempted."
[Mahesh Ananth and Michael R. Scheessele, "Exempting All Minimal-Risk Research from IRB Review: Pruning or Poisoning the Regulatory Tree?" IRB: Ethics & Human Research 34, no. 2 (2012): 9-14.]
We showed that there may be differential consequences in deregulating QI versus non-QI minimal-risk human subjects research. Given the controversial topic of IRB reform, we don't expect that everyone will agree with us. But let's assume for a moment that we have persuaded a supporter of Kim et al's position. If he or she were an utilitarian, he or she could reply by saying something like:
"Sure, you've shown differential effects in terms of the Belmont principles of 'respect for persons' and justice. I'm an utilitarian, though, and I only care about 'the greatest good for the greatest number'. Autonomy ('respect for persons') in particular is nothing more than sentimental Kantian hogwash."
The gist is that even when we have succeeded in making our main point (above), an utilitarian could casually dismiss our argument because the "counterbalancing good" for which we argue may be of little value to an utilitarian. That is why we had to go to the trouble of showing upfront that Kim et al. do not appear to be utilitarians making an utilitarian argument.
Michael R. Scheessele and Mahesh Ananth

Zachary M. Schrag (2012-05-20 21:51:38)
Thank you for these comments. Kim et al. cite material relating to both QI and non-QI minimal risk research. Your one counterexample is that of the research–begun more than 20 years ago–with the Havasupai blood samples. Given the destruction of records in that case, it is unclear if anyone involved considered it to be minimal-risk research.
I would suggest that the issues raised by that case would be better addressed by policies designed for genetic research, rather than continued review of all minimal risk research at the cost of tens or hundreds of millions of dollars each year, lost researcher time, and lost knowledge.

Michael R. Scheessele (2012-05-21 22:32:48)
If we had made a glaring oversight, such as entirely missing some significant and useful discussion of non-QI minimal risk

research in Kim et al.'s article, reviewers and/or the editor likely would have caught this oversight immediately. This is the advantage of the peer-review process in journal publication over that of blogging, where unchecked mischaracterizations and half-truths are probably not uncommon.

But most readers understand this. So, we simply encourage them to read both our article and the Kim et al. article, in order to make up their minds. If Dr. Schrag would like to publish his own article, in a peer-reviewed journal, which specifically criticizes our article, then we eagerly await the opportunity to read and to respond to that piece. Until then, best wishes…

Michael R. Scheessele and Mahesh Ananth

7.5.4 Community Researchers Flee the CITI (2012-05-11 09:43)

An article in the latest issue of the Journal of Empirical Research on Human Research Ethics finds that standard research ethics training programs–specifically the [1]mortifyingly stupid CITI Program–are inappropriate for Community-Engaged Research (CEnR).

[Anderson, E., S. Solomon, E. Heitman, J. Dubois, C. Fisher, R. Kost, M. Lawless, et al. "Research Ethics Education for Community-Engaged Research: A Review and Research Agenda." Journal of Empirical Research on Human Research Ethics 7, no. 2 (April 2012): 3, DOI: [2]10.1525/jer.2012.7.2.3]

The authors note that

> IRBs have been more apt to recognize consistent, one-size-fits-all training programs. While some may criticize these "packaged" educational products, they are effective at providing a low-cost, low-commitment, and highly efficient way to streamline and track the delivery of education to a large number of individuals, hence their popularity with academic institutions. The widespread use of the online Collaborative Institutional Training Initiative (CITI) Program has created the impression for many institutions that CITI is the required training program. [emphasis in original]

But the [3]mind-numbing and coercive CITI Program doesn't prepare researchers for community studies:

> In many settings, modifying curricula initially designed for academic researchers or graduate students is not always a viable or appropriate solution. Current standardized programs contain much information that is not directly relevant to CEnR studies (especially those that do not involve medical intervention), and many do not include practical information that people involved in the day-to-day work of community-based studies need to know in order to do their jobs well . For example, research ethics education may deliver the message that protecting participant confidentiality is important but not necessarily explain how to accomplish this when working in the community—literally on the streets and out of cars—and interacting with research participants who are part of their regular social networks. There is often a disconnect between how recruitment, informed consent, and data collection tools are developed for institutional review board (IRB) submission and how they are implemented in the field. Written research protocols tend to focus on the language in the consent form but omit details of the recruitment and informed consent process that are essential for those who will actually be doing that work. Community research partners are not always provided with adequate guidance regarding what to do once they get in the field, the specific challenges they may face, or tools for resolving dilemmas—for example, how to handle if a potential participant slams a door in their face, insists that they want to participate but will not take the time to read the consent form (or have it read to them), or appears to lie to meet inclusion criteria. [citations omitted.]

The authors conclude that "Research ethics education should be evidence-based both in terms of the topics covered and instructional methods employed." While their article focuses on community-engaged research, I would suggest it is equally applicable to just about every form of research, "especially those that do not involve medical intervention." We need more programs like the [4]ethnography training at Macquarie and the [5]history training at Princeton. One-size-fits-all may fit none.

1. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
2. http://dx.doi.org/10.1525/jer.2012.7.2.3
3. http://www.institutionalreviewblog.com/2011/08/citi-program-as-mind-numbing-coercive.html
4. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html
5. http://www.institutionalreviewblog.com/2011/04/princeton-offers-phd-students-serious.html

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7.5.5 Sieber and Tolich Lament "Medical Model" (2012-05-12 23:06)

The editors of the Journal of Empirical Research on Human Research Ethics call for researchers to stand up to their IRBs.
[Joan E. Sieber and Martin Tolich. "Research Ethics and Research Governance." Journal of Empirical Research on Human Research Ethics 7, no. 2 (April 2012): 1-2, DOI: [1]10.1525/jer.2012.7.2.1].
Sieber and Tolich distinguish between research ethics and research governance:

> Research ethics is aimed primarily at protecting human subjects. Research governance is an administrative process (typically within a university) which sets standards in research, defines mechanisms to deliver standards (e.g., IRBs, Conflict of Interest Committees, Responsible Conduct of Research Committees, Legal Counsel, Office of Sponsored Projects, Adverse Incident Monitors, ...), and oversees those who enforce the standards.

They lament research governance's ability to crowd out research ethics:

> Among other things, the regulations governing institutions and IRBs are based on a medical model of human research in which one observes or experiments on a medical condition, as opposed to research in which one interacts socially, often in a complex field setting. It takes considerable intellectual acumen to respond ethically and intelligently to such mismatches between well-intended regulations and the actual research setting. More than that, it takes knowledgeable researchers who are willing to serve within their institution's research governance structure and educate the members of the governance structure to understand that one size does not fit all.

[2]As I have noted before, such calls to "educate the members of the governance structure" overlook the power dynamics within institutions. The IRB system lacks accountability in the form of appeals processes or the requirement that IRBs justify their decisions with empirical evidence. In such a system, "knowledgeable researchers" lack the leverage needed to gain the attention of institutional officials.
I would suggest that this is an opportunity for the kind of empirical research the journal promotes. While it might be difficult to get people to speak frankly on the issue, one could study institutions that have significantly reformed their human research protections programs and ask what led to the change. My guess is that the most effective reformers are not researchers with the greatest intellectual acumen, but those whose record of securing external grants gives them the most clout among administrators.

1. http://dx.doi.org/10.1525/jer.2012.7.2.1
2. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html

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7.5.6 Research Participants Find REB Assumptions "Stereotypical, Simplistic, and Discriminatory" (2012-05-14 14:06)

While I'm catching up on my JERHRE reading, here's an important article from the December 2011 issue. An anthropologist and a public health researcher at the University of British Columbia have found that women who use drugs resent assumptions that they are unable to consent to participating in research, and they consider participation in such research to be an absolute right.
[Kirsten Bell and Amy Salmon, "What Women Who Use Drugs Have to Say About Ethical Research: Findings of an Exploratory Qualitative Study." Journal of Empirical Research on Human Research Ethics 6, no. 4 (December 1, 2011): 84-98, DOI: [1]10.1525/jer.2011.6.4.84.]
Bell and Salmon begin with previous findings that

> Clearly, research with drug users entails very real ethical issues that require careful consideration on the part of researchers and institutional review boards. In light of these issues, it is unsurprising that applications for institutional ethics approval submitted by addictions researchers often undergo intense scrutiny. However, anecdotal evidence suggests that review boards' zeal in their application of ethics guidelines to drug research is partially due to over-protectionist attitudes. Unfortunately, these attitudes are often formed without an adequate understanding of the realities of drug use and rely to some extent on prevailing stereotypes that depict drug users as selfish, irresponsible, and unable to make sound judgments.
> The limited available empirical research into drug users' understanding and experiences of research suggests that the concerns of institutional review board members about the capacity issues of drug users and the potential coerciveness of financial incentives are overstated. Ironically, concerns expressed in the name of protecting drug users may actually harm individuals by inhibiting research that is beneficial to them and their communities or disallowing study procedures that participants themselves endorse as ethical and respectful. (85. Citations omitted.)

Wanting to know how women in particular felt about this issue, Bell and Salmon designed an "exploratory focus group study conducted in Vancouver, Canada, in 2008 with women who use illicit drugs." (85) They found that

> Women were highly critical of assertions that drug users lacked the capacity to consent to research. A consistent message across the focus groups was that assuming incapacity merely on the basis of someone's status as a drug "addict" was stereotypical, simplistic, and discriminatory. Participants insisted that capacity was a highly individual phenomenon that needed to be determined on a case-by-case basis. However, differing opinions were expressed on whether it was appropriate for people who were acutely intoxicated to take part in research, some asserting that people who were "high" should be actively excluded and others suggesting that there were benefits to including such individuals. Interestingly, one idea that was commonly expressed (although not consistently endorsed) across all of the focus groups was that in principle exclusions of actively intoxicated individuals were discriminatory and potentially harmful. For some women, the right to take part in research was deemed to be absolute—and trumped the informed consent requirements articulated in standard bioethical guidelines. (91)

Bell and Salmon conclude that "the unquestioning transposition of ethical principles from clinical and biomedical research to social science research has led to inappropriate practices that may actually encourage less ethical practice," with a gracious citation to your humble blogger.

1. http://dx.doi.org/10.1525/jer.2011.6.4.84

7.5.7 Berkeley Historian Defends IRB Review of Oral History (2012-05-16 09:49)

Martin Meeker, a historian with the Regional Oral History Office (ROHO) at the University of California, Berkeley, argues that "Historians of the recent past, many of whom use interviews as a source, need to be more systematic about doing oral histories as a form of research [and] that cooperation with IRBs offers one way to do that." What he really means, I think, is that cooperation with IRBs may help historians get legal help from their universities.
[Martin Meeker, "The Berkeley Compromise: Oral History, Human Subjects, and the Meaning of 'Research,'" in [1]Doing Recent History: On Privacy, Copyright, Video Games, Institutional Review Boards, Activist Scholarship, and History That Talks Back, edited by Claire Bond Potter and Renee C. Romano (Athens: University of Georgia Press, 2012).]

"Virtually Indecipherable" Rules

Meeker begins his essay with a description of federal human subjects regulations, interwoven with account of the relationship between IRBs and oral historians up through 2004. He quite accurately notes that "with individual university IRBs responding to the statements of the OHA, AHA, and OHRP in thoroughly inconsistent ways, if they have engaged with the statements at all, who and what governs oral history practices is virtually indecipherable, and the future remains unclear at many institutions."
Meeker has had his own struggle deciphering those rules; though generally on target, his account is marred by some significant factual inaccuracies.
The Common Rule does not apply "to all federally funded research," only to the 18 agencies that have adopted it. This does not include the National Endowment for the Humanities or the Library of Congress, both of which sponsor oral history research. Nor, as Meeker claims, does the Common Rule "mandate that the entire scope of human-subjects research within an institution be reviewed by the IRB, not just the specific research that seeks or has received federal funding at any given time." While institutions have the option of requiring IRB review of research that is not directly funded, hundreds of universities, [2]including Berkeley, do not.
And Meeker unfairly disparages the arguments set forth by Linda Shopes and Don Ritchie, including their claim

> that federally mandated human-subject protections were "designed for scientific and social scientific research projects that use standard questionnaires with generally anonymous sources to produce quantitative information." Factually, this statement is untrue; logically, it is peculiar. Federal oversight was instituted to protect individual subjects who might suffer physically or emotionally because of research; uncontroversial standardized questionnaires have long been covered by expedited review. Moreover, the statement that protections are appropriate only for anonymous individuals completing questionnaires used to produce quantitative information is curious logic. If anonymous survey respondents were in need of protection, wouldn't named participants in a revealing life history interview need to be doubly protected?

Here Meeker has confused his is and his ought. Shopes and Ritchie accurately reported both the history and language of the regulations. Perhaps Congress and the National Commission should have designed rules to protect oral history participants, but that doesn't mean they did. It is a [3]matter of record that policy makers have applied IRB requirements to quantitative surveys since the 1960s, but only in the late 1990s did they start applying them to oral history. I quite agree that much of the IRB system is logically peculiar, but it is Meeker who has his facts wrong.

Most notably, Meeker overlooks the role of federal officials in encouraging and perpetuating the finding that oral history lies outside the scope of the Common Rule. He contemptuously refers to [4]a letter written on HHS stationery and signed by the OHRP associate director for regulatory affairs Michael Carome as an "OHA-AHA statement." And he ignores the fact that the reasoning set forth in that letter has been used by the [5]Army, [6]Smithsonian, NIH, and [7]OHRP itself to free federal oral history projects from IRB review.

Journalism as "Blatant Bias and Even Hyperbole"

Meeker realizes that he must grapple with the question of why IRB oversight is appropriate for oral history but not for other forms of interviewing, particularly journalism. He writes,

> Although I tend to agree that journalism should remain exempt from review, I do so because I see journalism as inherently dissimilar from oral history interviewing—a difference that is rooted in my belief that journalism is a public enterprise, while oral history interviewing is (or should be) a scholarly one. Whereas journalism seeks to inform or influence public opinion, scholarship seeks to create or influence knowledge. While most readers approach journalistic writing with a critical eye, aware of blatant bias and even hyperbole, people tend to approach peer-reviewed research with a critical eye but also with a belief that what they read is based to some degree on serious research and applies some version of the scientific method to the answering of a question, whether quantitative or qualitative.

This is a bizarre inversion of [8]the argument used by James Weinstein to justify IRB review of the social sciences. Both Weinstein and Meeker try to distinguish information that shapes public opinion from information that does not (good luck with that!). But whereas Weinstein is contemptuous of social science as unworthy of First Amendment protection, Meeker derides journalism, with its "blatant bias and even hyperbole," as unworthy of IRB review.

True, we seem to be entering a leaden age of journalism. A previously serious trade publication gives space to [9]a blogger who boasts, "it is not my job to read" the scholarship she criticizes. An innovative radio program subcontracts its investigative reporting to a performance artist, then [10]acts surprised when he fabricates part of the story. And soon the last Washington Post reporter left will be covering the buyouts of all the other reporters.

But can Meeker really believe that journalism does not seek "to create or influence knowledge"? Would he say that to the face of [11]Philip Pan, [12]Katherine Boo, or [13]Walter Isaacson? Or would he prefer to tell the [14]Pulitzer-winning investigators at ProPublica that their work is not "based to some degree on serious research"?

And, anyway, what does the reader's "critical eye" have to do with human subjects protection?

Lawsuits, Legal Issues, and Litigation

Institutional, rather than methodological, distinctions better explain what happened at Berkeley.

Meeker reports that "From the mid-1980s until 2005, then, ROHO operated under a partial 'hear no evil, see no evil, speak no evil' arrangement with UC Berkeley's Office for the Protection of Human Subjects" (OPHS), with no IRB oversight. Then there came a Pharaoh who knew not Joseph. A new OPHS director, Rebecca Armstrong, decided that she knew better than OHRP what the Common Rule means, and insisted that her office have jurisdiction over the ROHO.

"First and foremost," Meeker writes, "the OPHS wanted to ensure that it fulfilled its obligation to abide by DHHS regulations and thus protect UC Berkeley's eligibility to receive federal funds for research." Well, there's frankness. IRB job number 1 is to keep federal funds flowing.

Berkeley historians, Meeker writes, "agree with the sentiment expressed in the Illinois White Paper that we should 'discard the current one-size-fits-all" approach that relies so heavily on criteria and procedures developed for biomedical research." But he does not explain how what he terms the "Berkeley Compromise" does that. He states that "While the OPHS will review proposals, themes, and interview topics, interviewers are not expected to submit predetermined lists of interviewees (provided interviewees are not in high-risk categories) or explicit protocols (lists of questions)."

Beyond that, Meeker's essay is lacking detail about the compromise in action. Must ROHO historians complete the [15]mortifyingly stupid CITI Program? Who does these expedited reviews: someone with real expertise in interview research, or a [16]nutritionist? What do the reviewers do with those proposals, themes, and topics? Have they ever ruled that risks to subjects are not reasonable in relation to anticipated benefits, or that the selection of subjects is not equitable? Do individual projects get any kind of useful scrutiny, or is this just a device for regulatory compliance?
Instead of showing the value of IRB review itself, Meeker stresses the desirability of getting legal protection:

> First, like our colleagues in the OPHS, we wanted to protect our interviewees from a variety of factors, including, potentially, lawsuits and possible repercussions from having their personal opinions widely broadcast through a clear process of informed consent. Second, considering the potential legal issues, we wished to protect the interviewers and the office they represented, to the extent possible, from lawsuits.

He adds third and fourth points, but they describe only what the historians didn't want: interference with their work. So Meeker's essay really comes down to the argument that submitting to IRB jurisdiction is a way to purchase liability insurance.

> Undergoing IRB review alone would not be enough to ward off lawsuits. However, working closely with our IRB and abiding by its recommendations does, we think, provide a measure of protection in at least two ways: first, the OPHS is expert in litigation that emerges from research and thus can contribute their experience in this field to our projects; and, second, in the event that we are sued, the buck need not stop at the desk of the program's director, which is key when thinking about the long-term viability of an oral history program on an intensely political campus such as Berkeley.

In the wake of the Boston College case, oral historians should indeed think about what kind of legal–and political–coverage they need, and perhaps how best to pass the buck to someone else. But an IRB is not a general counsel's office, and people who talk to other people aren't the only [17]scholars who need legal protection from their universities. A university more committed to free inquiry would protect its scholars independently of whether their work follows procedures designed for medical experimentation.
As it stands, though, Berkeley has apparently told its ROHO that it will only get the legal coverage it needs if it completes paperwork that will protect the university from the arbitrary withdrawal of federal funds. If that's the case, I can't fault the ROHO for taking the deal.
But if the regulations are revised to make clear that oral history is not covered, I hope Berkeley will rethink its compromise. There's nothing wrong with Meeker and Armstrong sharing ideas on how best to design interview projects, but Meeker makes a poor case for subjecting oral history to the specific provisions of the Common Rule.

1. http://www.ugapress.org/index.php/books/doing_recent_history
2. http://www.institutionalreviewblog.com/2010/08/more-universities-uncheck-their-boxes.html
3. http://books.google.com/books?id=nSv83XkNq3gC&dq=schrag+%22ethical+imperialism%22&source=gbs_navlinks_s
4. http://grants.nih.gov/grants/policy/hs/Oral_History.pdf
5. http://www.institutionalreviewblog.com/2009/12/hooah.html
6. http://www.institutionalreviewblog.com/2010/07/smithsonian-frees-oral-history.html
7. http://www.institutionalreviewblog.com/2007/01/generalizable-revisited.html
8. http://www.institutionalreviewblog.com/2007/08/james-weinsteins-anti-intellectualism.html
9. http://chronicle.com/blogs/brainstorm/black-studies-part-2-a-response-to-critics/46401
10. http://www.thisamericanlife.org/radio-archives/episode/460/retraction
11. http://www.outofmaosshadow.com/
12. http://www.behindthebeautifulforevers.com/

13. http://books.simonandschuster.com/Steve-Jobs/Walter-Isaacson/9781451648553
14. http://www.pulitzer.org/citation/2011-National-Reporting
15. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
16. http://chronicle.com/article/Oral-History-Under-Review/6566
17. http://www.ucsusa.org/scientific_integrity/abuses_of_science/va-ag-timeline.html

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7.5.8 The Case against Ethics Review in the Social Sciences (2012-05-17 10:18)

Research Ethics has published my article, "The Case against Ethics Review in the Social Sciences." The article appeared in print in December 2011, but it has only recently appeared online.
[Zachary M. Schrag, "The Case against Ethics Review in the Social Sciences," Research Ethics 7 (December 2011): 120-131, [1]doi:10.1177/174701611100700402]
(As of 17 May 2012, the DOI is working, but one can find the article at [2]http://rea.sagepub.com/content/7/4/120.abstract.)
The article gathers many of the arguments made in the first five years of this blog.
As permitted by the Sage policy, I have posted an April 2011, pre-review draft at [3]http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2061633. I hope that readers with access to the published version will consult that instead.
Here is the abstract:
For decades, scholars in the social sciences and humanities have questioned the appropriateness and utility of prior review of their research by human subjects' ethics committees. This essay seeks to organize thematically some of their published complaints and to serve as a brief restatement of the major critiques of ethics review. In particular, it argues that 1) ethics committees impose silly restrictions, 2) ethics review is a solution in search of a problem, 3) ethics committees lack expertise, 4) ethics committees apply inappropriate principles, 5) ethics review harms the innocent, and 6) better options exist.

1. http://dx.doi.org/10.1177/174701611100700402
2. http://rea.sagepub.com/content/7/4/120.abstract
3. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2061633

7.5.9 Against Armchair Ethics: Some Reflections from Petrie-Flom (2012-05-21 21:25)

As followers of [1]my Twitter feed will know, I spent Friday and the first half of the Saturday at [2]The Future of Human Subjects Research Regulation, a conference sponsored by the [3]Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.
The conference organizers, led by Professor Glenn Cohen, did a magnifent job bringing together participants with varied views and backgrounds, and as a group we discussed ideas ranging from treating research subjects as workers to including adolescents on IRBs. Those who want the full story should be able to watch videos of the presentations before too long.
I was struck, however, by one recurring theme: the distinction between evidence-based approaches and armchair ethics.
Some examples:

- [4]Osagie Obasogie argued that the [5]Institute of Medicine's report on prison research is inferior to the [6]National Commission's 1976 report on the grounds that the National Commission members visited more prisons, while the IOM authors relied more on the writings of ethicists.

- [7]Ellen Wright Clayton argued that the ANPRM's proposals for biospecimen privacy–particularly the "standard, brief general consent form allowing for broad, future research"–would not adequately balance subjects' wishes and researchers' needs. Her strongest argument against such an approach was empirical: at Vanderbilt, 12 percent of clinical patients opt out of the [8]BioVU DNA databank, evidence that a more layered yet still workable system of choice is up and running. She thinks the risks of inappropriate reidentification of biobank samples much smaller than other privacy risks.

- Michael McDonald, Susan Cox, and Anne Townsend reported on the findings of their multi-year study in which they asked research subjects about their experiences and found that participants did not use ethics-committee terms like risks and benefits, but instead discussed the "impacts" of research, both positive and negative. (McDonald also referred conference participants to their website, [9]QI4 Research Ethics, which has survey tools for soliciting participant views.)

- Carol Weil noted that while the ANPRM frets about privacy, that's not the main concern of people with rare diseases. They want research on those diseases, and they want to share information when they think it will lead to better medicine.

The problem is that the current regulatory system is not set up to get empirical information into the hands of ethics boards, researchers, or subjects. McDonald declared himself "astounded" at the resistance to evidence-based ethics review, and he was clearly dismayed when Laura Stark told him that the only time the IRBs she observed soliciting participants' views was as a "punitive" action against a researcher. If you don't look at outcomes, McDonald noted, "there's no such thing as getting it right."

Cynical as I am, I am not astounded. If IRBs existed to give researchers the information they need to conduct ethical research, we wouldn't have the [10]mortifyingly stupid CITI Program. And if one understands the IRB's primary role as protecting an institution's "[11]eligibility to receive federal funds for research," then there's not much reason for IRBs to take the trouble to learn about how they [12]offend research participants.

Clayton and McDonald both want to preserve prospective oversight for social science research; I do not. They think it appropriate to deploy the coercive power of the state in an effort to improve research ethics; I consider coercion counterproductive except for avoiding true atrocities.

But I think we agree on more than might be apparent. We are not fans of the current system, we consider TCPS2 an advance over both TCPS1 and the Common Rule, and we would like to see additional reforms based on what we have learned over the decades.

If policy reform were an ongoing process, we could try easing up on review or abolishing it and see what happens. But since the proposed reforms, if they go through, may be the last in our lifetimes, the high stakes exaggerate differences of opinion.

1. http://www.twitter.com/zacharyschrag
2. http://www.law.harvard.edu/programs/petrie-flom/events/conferences/humansubjects/program.pdf
3. http://www.law.harvard.edu/programs/petrie-flom/index.html
4. http://uchastings.edu/faculty-administration/faculty/obasogie/index.html
5. http://iom.edu/Reports/2006/Ethical-Considerations-for-Research-Involving-Prisoners.aspx
6. http://videocast.nih.gov/pdf/ohrp_research_involving_prisoners.pdf
7. http://law.vanderbilt.edu/clayton
8. http://dbmi.mc.vanderbilt.edu/research/dnadatabank.html
9. http://www.researchethicssurvey.ca/
10. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
11. http://www.institutionalreviewblog.com/2012/05/berkeley-historian-defends-irb-review.html
12. http://www.institutionalreviewblog.com/2012/05/research-participants-find-reb.html

7.5.10 AAHRPP Claims IRBs Rarely Disapprove Research (2012-05-24 10:14)

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) notes that of the organizations it surveyed (it doesn't report how many or how they were selected) [1]63 percent "did not disapprove any protocols in the past year" and only "13.2 percent disapproved two or more percent." The AAHRPP uses these figures to argue that the "perception that IRBs disapprove a significant portion of research protocols submitted is not true."
I wonder whom they are accusing of holding this perception. Serious observers of IRBs know that a board need not formally reject a proposal to make it impossible for the researcher to proceed. Look at what happened at [2]Linda Thornton. Look at what happened to [3]Kathryn Edgerton-Tarpley's student. Or the [4]anonymous researcher who wanted to study how parents discipline their children. In these cases, researchers abandoned projects in the face of IRB intransigence, allowing the IRB to claim it had not disapproved the project.
I am therefore unsurprised by AAHRPP's figures. I am surprised that AAHRPP thinks that formal disapproval is a meaningful measure of the IRB suppression of research, and by its stooping to this straw man argument.

1. http://advance.aahrpp.org/2012/05/disapproval-of-research.html
2. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
3. http://www.institutionalreviewblog.com/2011/09/anprm-comments-oral-historians-call-for.html
4. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html

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7.5.11 Minimal Risk Approval: 27 months, $170,000 (2012-05-30 09:35)

A team of health services researchers found that getting approval for a minimal risk study took 27 months and consumed $170,000 in staff time.
[Laura A. Petersen, Kate Simpson, Richard SoRelle, Tracy Urech, and Supicha Sookanan Chitwood, "[1]How Variability in the Institutional Review Board Review Process Affects Minimal-Risk Multisite Health Services Research," Annals of Internal Medicine 156, no. 10 (May 15, 2012): 728–735. h/t [2]Human Subject News.]
Like the [3]Green, Lowery, Kowalski, and Wyszewianski article cited in the ANPRM, this article describes the fate of a health services research study. That is, rather than directly studying patients, the researchers wanted to learn about the behavior of physicians and other clinicians, specifically if financial incentives would affect their adherence to the guidelines for hypertension care.
Like Green et al., they hoped to use Veterans Affairs (VA) medical centers as a way of setting up a controlled trials. This required getting IRB approval from each site, so the investigators submitted proposals to 17 facilities.
The responses varied widely. Two sites allowed expedited review, though one of those rejected the study, as did two others. Fourteen sites approved the study and classified it as minimal risk.
Nevertheless,

> The total time spent in the IRB approval process before the study could be implemented, from initial submission to the first site to approval of the protocol modification at the final site, was 827 days, or more than 27 months. This is 21 months longer than we had proposed and 23 months longer than the time for which we had received a budget. Staff spent an estimated 6729 hours working on IRB- and R &D-related tasks, costing approximately $168,229 in salaries. This estimate does not include the salary for the PI or site PIs.

The delay meant that some physicians left their posts before the study could begin, and the study was skewed toward "more highly affiliated, urban sites that were treating more complex patients, potentially affecting the external validity (generalizability) of the study findings."

The authors concede that "Some variation in review may be appropriate because of local values in assessing human subjects' risks and benefits." But they note that

> many of the revisions requested by local IRBs, when compared with what was approved by the IRB of a multisite study's coordinating center, have been shown to add little in terms of local context or essential protections and usually make few, if any, substantive changes to the study protocol. Our experience confirms this finding. One underlying issue responsible for the type of local variation we had is that IRBs do not seem to agree on the limits of their sphere of human research protections and do not confine themselves to reviewing the ethical issues related to them. For example, 1 IRB required that we provide documentation of union approval and then asked whether we were providing any incentives to the institution itself.

The authors find that "the time and costs involved in the review process seem incongruous," and they conclude that "An overall review of the standards for research as planned by the Department of Health and Human Services is welcome."
In a [4]comment on the article, Adam Rose of the Bedford VA Medical Center describes a similar experience: "In the course of our one-year, $100,000 study grant, we spent over half of our funds on the process of securing approvals . . . The utility of all this extra work, in terms of protecting human research subjects, was questionable at best."
A [5]second comment, by Jeffrey Silverstein of Mount Sinai School of Medicine, wishes that the authors had distinguished between those changes (whether mandated by the IRBs or others) that they found justified and those they found misguided. Though the article leaves a strong impression that they researchers did not think that the delay and expense were appropriate, it would indeed be interesting to know if they found anything of value in the review process.

1. http://annals.org/content/156/10/728.abstract
2. https://twitter.com/#!/HumanSubjects
3. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681539/
4. http://annals.org/content/156/10/728.abstract/reply#annintmed_el_148243
5. http://annals.org/content/156/10/728.abstract/reply#annintmed_el_148243

Anonymous (2012-05-31 14:18:54)
Part of the IRB review process is the back and forth between study team and IRB. In this summary, there is no discussion of the time the PI took to respond to IRB issues. Often PI's will complain the approval took 6 months when they sat on IRB comments for 5 months. Perhaps the original article has data on study team turnaround times to IRB comments? if not, their conclusions are suspect...

Zachary M. Schrag (2012-05-31 14:30:04)
Thanks for this comment. Dr. Silverstein also notes the desirability of such data.
That said, the authors do offer some data on the [1]variability of approval times. Three sites approved the study in less than 50 days. If we take that as a baseline, we need to explain the variability among the other sites.

1. http://annals.org/content/156/10/728/F2.expansion.html

Dylan (2012-06-01 15:40:27)
Even if hard data did exist about how much time the ball was in the "PI's court" as opposed to the "IRB's court," would that significantly reduce the perceived severity of this case, or eliminate it as an excellent example of why the IRB system needs major improvement? I'm not convinced it would.
I believe the time it takes PIs to respond to IRB requests is directly related to the reasonableness and consistency of the IRB's demands. Of course, I have no evidence to back that up – only my experience as an IRB staffer communicating such demands to researchers.

Zachary M. Schrag (2012-06-01 15:52:21)
Thanks for this comment. My guess is that if the researchers were to provide a careful analysis of the causes of the delay, we'd learn something. For example, it would be interesting to know if all the IRBs involved met only on a monthly schedule, so that every modification took at least a month to be considered and sent back, or if some reviewers were willing to engage in a constant back-and-forth with the researchers. Maybe a follow-up article for Petersen et al.?

7.6 June

7.6.1 Ethics Committees as Foucauldian Shepherds (2012-06-06 10:04)

Three Norwegian researchers using a "Foucault-inspired analysis" charge that "ethics monitoring bodies can be conceived as executing a type of paternalistic power over vulnerable and marginalized groups, a practice which is virtually identical to the exercise of power that, according to their mandate, they should be protecting these groups against."
[Truls I Juritzen, Harald Grimen, and Kristin Heggen. "Protecting Vulnerable Research Participants: A Foucault-Inspired Analysis of Ethics Committees." Nursing Ethics 18, no. 5 (September 2011): 640–650, [1]doi: 10.1177/0969733011403807]
They elaborate:

> The ethics monitoring committees exercise not only a power targeting the party which is assumed to be powerful, i.e. the researcher, with the objective of protecting the party which is assumed to be vulnerable, i.e. the participant. In addition, they intervene to control and assess the participant's room for decision making, and in so doing they appear as the 'good shepherd' who will guide the vulnerable participants safely away from any forms of offense and abuse committed in the name of science. This represents a form of exercise of power, in the service of benevolence, so to speak, which is less visible than the hazards and powerful interventions represented by the researchers.
> This invalidation of large groups of persons who are deemed incompetent to provide consent entails a potential for larger transgressions than those a researcher will be able to commit. A researcher can commit offenses against individuals or even small groups of individuals. However, the exclusion of entire groups of participants (such as those who are deemed incompetent to provide consent) from research may imply that an offense has been committed against large groups whose life conditions thereby remain concealed because of lack of research. In this manner, this involves not only the vulnerable and marginalized who are excluded from being studied. In addition, this harms large groups of others, as unworthy and/or harmful practices that could have been revealed by means of research remain undetected and are thereby allowed to continue. The paradox of this situation is that the most vulnerable and exposed remain protected from research, and thereby from transparency and public scrutiny.
> We claim that if we restrict ourselves to focusing on the ethics committees' external view and in this manner regulate the obviously asymmetric relationship between the researcher and the participant, we render other essential positions and relationships of power invisible. What is rendered unclear or is not being thematized is how the administration of ethics can remain an unassailable position that conceals the power of the ethics committees and elucidates the power of other parties.

The piece is short on examples, but a good place to look for them is in reports of ethics-committee reviews of research on [2]sexuality.

1. http://dx.doi.org/10.1177/0969733011403807
2. http://www.institutionalreviewblog.com/search?q=sex

7.6.2 Sex and Trauma Surveys No Riskier Than Cognitive Tests (2012-06-07 10:01)

A team of psychologists has found that responding to survey questions about trauma and sex is no more stressful than completing "well-established cognitive tests."
[Elizabeth Yeater, Geoffrey Miller, Jenny Rinehart, and Erica Nason. "Trauma and Sex Surveys Meet Minimal Risk Standards Implications for Institutional Review Boards." Psychological Science (Published online before print May 22, 2012), [1]doi: 10.1177/0956797611435131. h/t [2]Michelle Meyer.]
The authors, all affiliated with the University of New Mexico's Department of Psychology, found that their IRB's fears about such reactions was leading it to impede research:

> The IRB at the University of New Mexico has expressed many concerns about the use of [college students] in research that is judged as exceeding minimal risk (e.g., trauma and sex surveys). The IRB's primary concern is that college students may experience extreme distress or be harmed as a result of participation. IRBs also have assumed that the risks involved in asking questions about such topics are greater than the risks for ostensibly more benign measures (e.g., cognitive test questions). Thus, such "sensitive" questions require special protection of participants and a full rather than expedited review. Such assumptions, though unsupported by data, have delayed and derailed research projects at the University of New Mexico and have dissuaded researchers from studying "sensitive" topics that allegedly present greater than minimal risk.

Though they could (and do) cite several studies showing that "participation in trauma research does not cause long-term harm," the authors could find few explicit comparisons between allegedly sensitive questions and other topics. So they administered questionnaires to 504 undergraduates and compared reactions to those concerning trauma and sex with those taking cognitive measures.
They report that

> The standard definition of minimal-risk research is that the probability and magnitude of harm or discomfort anticipated in the research are not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. Our first three findings show that the trauma and sex surveys were no more distressing than the routine psychological tests used in the cognitive condition. Furthermore, even the handful of participants indicating some negative emotions were no more than mildly distressed, so these surveys could be considered as posing minimal risk by that criterion. Our fourth finding shows that participating in the trauma-sex condition was less distressing than many stressors experienced in daily life, so it could be considered as presenting minimal risk by that standard. Our fifth finding shows that the trauma-sex condition was reasonably benign even for sexually victimized women, who might be expected to be especially vulnerable.

They therefore conclude that "many IRB committees have systematically underestimated the maturity and resilience of 21st-century adult research participants, such as college students."
These findings are consonant with other findings that [3]trauma-based research is less risky than imagined.
Missing from the article is an indication of whether the UNM IRB was already familiar with the previous literature on the issue. If so, will one more study, even one enrolling as large a population as this, make a difference? If not, what would it take to get IRBs to base their decisions on evidence?
Note: The article states that "participants were 504 undergraduate men and women recruited from the psychology subject pool at a large Southwestern U.S. university." Since all the researchers work at the University of New Mexico,

and the article seems designed to rebut assertions by the UNM IRB, how seriously are we to take this anonymizing?

1. http://dx.doi.org/10.1177/0956797611435131
2. http://www.law.harvard.edu/programs/petrie-flom/fellowship/meyer.html
3. http://www.institutionalreviewblog.com/2008/03/trauma-based-research-is-less-risky.html

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7.6.3 Study Finds IRBs Often Fail to Discuss Common Rule Criteria (2012-06-08 19:12)

The Common Rule [[1]45 CFR 46.111(a)] requires IRBs to determine that each protocol they approve satisfies seven requirements: risks are minimized, risks are reasonable, selection of subject is equitable, informed consent is sought, informed consent is documented, safety is monitored when appropriate, and privacy and confidentiality are protected when appropriate. A team of researchers has found that "the IRB made clear determinations on all relevant criteria for 20 of the 104 (19 %) protocols" they examined.
[Charles W. Lidz, Paul S. Appelbaum, Robert Arnold, Philip Candilis, William Gardner, Suzanne Myers, and Lorna Simon. "How Closely Do Institutional Review Boards Follow the Common Rule?" Academic Medicine 87 (July 2012), [2]doi: 10.1097/ACM.0b013e3182575e2e, post author corrections version, 22 May 2012]
The researchers observed and recorded the full-board deliberations of IRBs at ten academic medical centers as they discussed a total of 104 protocols. They compared their own judgment about which of the seven Common Rule criteria should have been discussed in the deliberations to their findings on whether the IRB did in fact discuss the relevant criteria.
The researchers found that IRBs were extremely likely to tinker with consent forms:

> In contrast to the other criteria, which sometimes were not discussed, IRBs routinely discussed informed consent. They approved unchanged consent forms for 5 of the 104 (5 %) protocols while recommending or requesting changes to 92 (88 %) others. In 5 (5 %) reviews, an IRB committee member criticized or suggested changes to the consent form, but no further action was taken. In the remaining 2 (2 %) reviews, the IRB made no mention of informed consent.

No other criteria came close to that frequency. As the researchers explain,

> We found that not all IRBs discussed all of the criteria mandated by the Common Rule. First, in over 20 % of the protocol reviews of studies that posed greater than minimal risk, IRBs did not consider whether the studies' risks were appropriately addressed in the application or whether those risks could be minimized. Second, IRBs did not compare the risks versus benefits in 57 % of the protocol reviews that had risks other than those to confidentiality. Third, the fact that IRBs did not consider equity in subject selection in 60 % of the applications that excluded categories of subjects suggests that they are not routinely determining whether the benefits and burdens of research are distributed evenly among populations. Finally, IRBs in only about 40 % of reviews of relevant protocols either approved or proposed revisions to plans to monitor data for potential safety issues, in 70 % made determinations with regard to confidentiality, and in 20 % did not address the protection of vulnerable populations. In summary, although we could not listen to the audio recordings of the meetings without appreciating the seriousness with which the reviewers took their responsibilities, we found that the IRBs frequently failed to discuss many of the human subjects protection criteria mandated by the Common Rule.

The authors recognize that this is not a surprising finding; pretty much [3]everyone outside of PRIM &R understands that IRBs spend a lot of their time editing consent forms, [4]often making them harder to read in the process.
But the study does offer useful evidence that the IRB system is not working as advertised. I suspect the IRBs in question simply lacked the time to consider thoroughly all seven criteria for each protocol they reviewed, so they dwelled on the easiest task—the consent form—rather than the more nebulous challenges. And in many cases, this may have been the correct ethical decision. In particular, IRBs only rarely (12 percent of relevant protocols) raised questions or requested changes concerning risk-benefit reasonability. For critics of IRB paternalism, this may be welcome news.
(Here, as elsewhere, I wish the team had also investigated IRBs at non-medical institutions. It would be fascinating to know if those IRBs were any more or less likely to deem a study's potential benefits too small.)
On the other hand, the IRBs may have failed in what many would consider their most important duty of minimizing risks in significantly risky protocols. The article notes that IRBs failed to discuss the risks of "a phase 1 oncology study of a new combination of approved chemotherapy agents and a placebo-controlled, phase 3 trial of a new treatment for a previously untreatable disorder, both of which posed significant risks."
Assuming we don't want to double the time and money already devoted to IRB review, one could imagine improving the system in two, complementary ways. Either reduce the number of criteria each IRB is expected to examine, or reduce the number of protocols reviewed by IRBs. The article claims that the ANPRM does not address "IRBs' failures to assess all required Common Rule criteria, that is, to perform a comprehensive protocol review." But the ANPRM's proposal to move the current mass of expedited protocols off the desks of individual IRB members might be a step toward giving them time to focus on the protocols that raise the greatest concern.

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111
2. http://dx.doi.org/10.1097/ACM.0b013e3182575e2e
3. http://www.institutionalreviewblog.com/2011/11/prim-irbs-dont-write-consent-forms.html
4. http://www.institutionalreviewblog.com/2007/08/study-finds-irbs-make-consent-forms.html

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Anonymous (2012-08-04 17:41:08)
I suspect that IRBs are under intense pressure to approve protocols expeditiously. In some instances IRB members are discouraged to present their view points or concerns during board meetings in order not to be a disservice to the investigators.

Zachary M. Schrag (2012-08-06 22:35:38)
Thanks for your comment. I am doubtful that fears about hindering investigators can explain the demands for revised consent forms in 88 percent of the protocols tracked by these authors.

7.6.4 "Community Members" Play Murky Roles (2012-06-09 20:57)

Robert Klitzman continues to publish findings from his 2007-2009 series of interviews with 46 IRB chairs, directors, administrators, and members. In an Academic Medicine article, he finds that IRBs' "community members" struggle because their "roles can be murky."
Robert Klitzman, "Institutional Review Board Community Members," Academic Medicine 87 (July 2012), [1]doi: 10.1097/ACM.0b013e3182578b54, post author corrections version, 22 May 2012.]
Klitzman notes that "prior research has suggested that [nonaffiliated and nonscientific IRB] members frequently feel unempowered and disrespected." [He doesn't provide citations to such research, but one can consult Patricia E. Bauer, "A Few Simple Truths about Your Community IRB Members," IRB: Ethics and Human Research 23 (January-February 2001), 7-8; or Eliesh O'Neil Lane, "[2]Decision-Making in the Human Subjects Review System" (PhD diss. Georgia Tech, 2005) for support.]
Klitzman finds some confirmation:

> One interviewee, a longtime IRB administrator, said, "I'm not a scientist or physician, so sometimes I

> think my questions are stupid." She did not feel looked down on but, rather, saw herself apart in a room of white men in white coats—not purposefully disrespected but at times intimidated. Several interviewees recognized that community members may feel similarly.

But his main finding is that many IRB chairs and members are perplexed by the regulatory requirement itself:

> In viewing, choosing, and engaging nonscientific and nonaffiliated members, academic medical center IRBs often struggle, and their practices vary widely. IRBs range from having these members review entire protocols to having them perform only limited roles (particularly reading consent forms) to being more pro forma. Nonetheless, a few interviewees described situations in which these members' input was very important.
> Quandaries emerge as to whether these individuals do, or should, represent anyone specifically and, if so, whom they should represent, how well they do so, and how IRBs assess that role. Revealingly, confusion exists concerning even their name—whether they are nonaffiliated, lay, or community members—underscoring the ambiguities of who these members are. IRBs seem to vary even in the degrees to which they are disturbed by the apparent lack of representativeness of these members to their communities and in how they interpret the intent of the regulations.

In fact, the [3]1974 Federal Register announcement promulgating 45 CFR 46 was pretty explicit about the regulations' intent:

> the requirement for nonemployee members on organizational committees is an essential protection against the development of insular or parochial committee attitudes . . . it assists in maintaining community contacts, and would augment the credibility of the committee's independent role in protection of the subject.

We know from [4]Laura Stark's work that IRBs remain insular and parochial, relying on their own "local precedents," rather than outside evidence, to shape their decisions. And [5]Klitzman himself has found that "particular aspects of institutional histories (e.g., past federal audits and "shutdowns" of research) and IRB chairs' and/or vocal members' personalities, idiosyncrasies, and abilities to anticipate all future logistical problems," rather than community attitudes, best explain IRB variability.
As for maintaining community contacts and augmenting credibility, Klitzman finds that the record is spotty. As one interviewee put it,

> There might be some better criteria about who our community members are. We have not had people like leaders of local churches, [nongovernmental organizations], or other social service agencies—something with a strong minority membership . . . . One long-term community member is a medical malpractice attorney. He's been a great member and contributed important things. But I don't think that's the idea of what a community member really is or brings. Another community member is a retired director of research at a few local institutions. During retirement, he's been on our IRBs and another institution's IRBs. He contributes a lot and brings a nice cross-fertilization from the other institution. But he's not what you think of as a community member. On the other hand, we've also had attorneys from the juvenile public defenders' office. They are very good and genuine advocates for people in their community.

"The fact that these members are often found in unsystematic ways, through happenstance, may be acceptable and perhaps inevitable," Klitzman argues. "But the lack of guidance concerning these issues is disturbing."

1. http://dx.doi.org/10.1097/ACM.0b013e3182578b54
2. http://hdl.handle.net/1853/6834
3. http://www.hhs.gov/ohrp/archive/documents/19740530.pdf
4. http://press.uchicago.edu/ucp/books/book/chicago/B/bo12182576.html
5. http://dx.doi.org/10.1080/21507716.2011.601284

7.6.5 Limited-Time Offer! Act Now! (2012-06-13 22:29)

SAGE has kindly made my article, "The Case against Ethics Review in the Social Sciences," free to access for a month. Download it while you can!
[Zachary M. Schrag, "The Case against Ethics Review in the Social Sciences," Research Ethics 7 (December 2011): 120-131, [1]doi:10.1177/174701611100700402]

1. http://dx.doi.org/10.1177/174701611100700402

7.6.6 I Hope You All Get Pox (2012-06-14 12:34)

This is a little off-topic for the blog, but to understand the IRB system, it helps to understand the history of the U.S. Public Health Service, and to understand the history of the U.S. Public Health Service, it helps to read Michael Willrich's *[1]Pox: An American History*, which I just finished reading and am very glad to plug.
The history of public health is a struggle between the desire for liberty and the desire for health, since many of the most effective public health measures–quarantine, health codes, compulsory vaccination, and perhaps bans on 20-ounce soft drinks–are also infringements of liberty. Willrich's account of smallpox at the turn of the twentieth century does a marvellous job at presenting both sides of this struggle. It explains laypeople's legitimate fears about the doctors and health officers who came to snatch them and their children, but also why those health officers took pride in their snatching. We may wonder who in today's IRB debate most resembles the arrogant vaccinators of a century ago: researchers seeking scientific progress, or ethics boards seeking to restrain them?

1. http://us.penguingroup.com/nf/Book/BookDisplay/0,,9781594202865,00.html

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Anonymous (2012-06-17 10:43:31)
Dear Zachary– Thank you for this review! Will definitely check it out. BTW, I'm helping someone with a survey about tree pests; you'll no doubt be pleased to know that we are working hard with an IRB to ensure that the privacy of this sensitive information will be heavily and permanently guarded! MRN in Maine

7.7 July

7.7.1 Emmerich Reviews Behind Closed Doors and Ethical Imperialism (2012-07-04 15:34)

Nathan Emmerich of Queen's University, Belfast, finds that Laura Stark's book and my own "together . . . illustrate the nature of ethics as an aspect of research governance fundamentally contributing to our understanding of the phenomena in a manner that goes beyond the relatively limited or restricted consideration offered by applied ethical analysis."

[Nathan Emmerich, [1]Review of Behind Closed Doors: IRBs and the Making of Ethical Research and Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009, Sociological Research Online 17, Issue 2 (May 2012).]
Emmerich detects what I agree is a difference between the two books' conclusions about the IRB system. "For me the question at stake when reading both authors," he writes, "is whether the contemporary American IRB is well suited to the ethical governance of biomedical, behavioral and social scientific research . . . One can interpret [Schrag] as thinking the IRB, at least in its current form, is not well suited to social scientific research. Stark however comes at this question more tangentially and whilst she is aware of some difficulties she does seem broadly in favor of the current arrangements."
But he also finds some agreement: "Both Schrag and Stark argue that, in the actual practices of the IRB . . . flexibility is conspicuous by its absence. Instead IRB's tend to develop relatively determinate and static positions on particular issues raised by research ethics that, once inaugurated, become generically applied across research proposals in a variety of disciplines."
Doubting that such generic application will produce good results, he calls for "disciplinary experts [to] engage with the contemporary bureaucratic institutionalization research ethics in higher education sector of the UK and the administrative tasks local to their own [Higher Education Institutions] and departments." I hope they heed his call.

1. http://www.socresonline.org.uk/17/2/reviews/7.html

7.7.2 Sociologists of Sexuality Voice IRB Complaints (2012-07-09 15:49)

Sociologist Janice Irvine finds that IRBs "play a significant but largely unnoticed role in the marginalization of sexuality research," and that "the IRB closet obstructs a broad production of sexual knowledge—not simply about identities and communities, but also about a range of sexual acts, desires, and attitudes."
[Janice M. Irvine, "Can't Ask, Can't Tell : How Insitutional Review Boards Keep Sex In The Closet," Contexts 2012 11: 28, [1]DOI: 10.1177/1536504212446457. The story has been picked up by the Chronicle of Higher Education: Dan Berrett, "[2]Review Boards Force Sex Research Into the Closet, Survey Suggests," Chronicle of Higher Education, 28 June 2012.]
Concerned that evidence of IRB suppression of research consisted mostly of haphazardly circulating anecdotes, in 2011, Irvine surveyed the 450 members of the American Sociological Association Section on Sexualities. Close to 40 percent responded, giving her an unsually clear look at IRBs' impact on one academic speciality.
The responses suggest widespread problems. Of those who had submitted sexuality-related proposals to an IRB, 45 percent reported difficulty getting approval, and "41 percent report that other sexuality researchers at their university had also had IRB difficulties." Some were merely slowed down, while others acceded to conditions that reduced the value of their research. For example, IRB demands that interview tapes be destroyed precludes longitudinal follow-ups, or use by future historians.
Individual professors reported abandoning research on alternative sexualities and counseling students to avoid lines of inquiry likely to spook an IRB.

> One junior scholar noted: "It's made [my research] actually very difficult. I'm facing tenure review right now and needing to explain, for example, why my book's not published yet. Well, I spent a year and a half getting IRB [approval]. It's definitely hindered my ability to do the actual research and then write up the results, spending so much time trying to get the approval, and then all of the torturous hurdles they put in front of me as well makes it more difficult." Another said, "By and large, the IRB is the most difficult process and insti- tution I encounter in my sexuality research. The word "sex" sets off a set of red flags that can double or triple the amount of red tape I have to go through to get approval for my research." IRBs can shape a field of knowledge and discourage researchers, sim- ply through following

their bureaucratic procedures.

Nor are IRBs a problem only for researchers; their paternalism helps silence sexual minorities.

> In an alarming twist, however, my respondents reported that IRBs routinely blocked research on adult sexual minorities, particularly LGBTQ communities, because of their alleged vulnerability. For instance, one respondent noted, “Demographic surveys could not include any identifying information. I was told that because the infor- mation I was collecting was “sensitive” (life histories of black gay men), this would prevent the unanticipated “outing” of participants. Somehow the sexual identity of my participants was construed as clandestine and shameful.”
> Another respondent reports, “They made me change the reporting of names to be completely anonymous even though almost all of my subjects WANTED to be identified in the study—it was a Pride organization whose entire goal was about being out and proud!!”

Irvine concludes with the central irony of the situation. IRBs rely on guesswork and prejudice about what it means for a subject to be vulnerable or a procedure to be harmful, such as when they forbid researchers to use the word "queer" to recruit participants who identify themselves as queer. The only way to combat such prejudice is to conduct research, the very research that the IRBs make so difficult.

1. http:dx.doi.org/10.1177/1536504212446457
2. file://localhost/mnt/ext/blogbooker/tmp/ht07w581/chronicle.com/article/Review-Boards-Force-Sex/132691/

7.7.3 Harvard Law Today Reports on ANPRM Conference (2012-07-10 08:30)

Harvard Law Today, published by Harvard Law School, reports on May’s conference on the ANPRM, held at the school’s Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics.
["[1]The Future of Human Subjects Research Regulation," Harvard Law Today, July 2012.]
The article highlights the plenary address by Greg Koski, former director of OHRP.

> Koski said regulation has been dominated by human-subject protectionism and an ethical-review system that has “devolved to regulatory compliance oversight.” The result, he said, is a system that is “inefficient and burdensome.” His recommendation, he said, was to replace the current system with one modeled after medical training and certification.
> He said: “If we were able to develop a paradigm of professionalism in human research, it would likely be every bit as effective, less costly, less burdensome and more efficient than the protectionist, compliance-focused system that we are now seeking to reform. I would argue that reform of our current system is perhaps not the most appropriate or even adequate approach to try to achieve the goals that we seek.”

1. http://www.law.harvard.edu/news/hltoday/2012-july/regulation.html

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7.7.4 First Circuit Rejects Belfast Project Historians' Appeal (2012-07-11 10:45)

On Friday, July 6, the First Circuit Court of Appeals rejected the effort by two oral historians to block the release of interviews of participants in Northern Ireland's Troubles, archived as the Belfast Project at Boston College's Burns Library.

Citing precedent, especially [1]Branzburg v. Hayes, 408 U.S. 665 (1972), the court majority found that "the choice to investigate criminal activity belongs to the government and is not subject to veto by academic researchers."

[[2]In re Request from United Kingdom, Nos. 11-2511, 12-1159, — F.3d —-, 2012 WL 2628046 (1st Cir. July 06, 2012)]

In a concurrence, Judge Juan Torruella is more sympathetic to the researchers, arguing that academic researchers are entitled to "a degree of protection" and possess "a cognizable interest under the First Amendment." However, he continues, "any such interest has been weighed and measured by the Supreme Court and found insufficient to overcome the government's paramount concerns in the present context."

The [3]Inside Higher Ed story by Scott Jaschik includes the IRB angle on this, noting that in April the Boston College (BC) chapter of the AAUP called for the creation of a university committee that would, among other tasks, "[4]investigate the extent to which the research methods and procedures were subject to institutional review and oversight."

Jaschik reports that "David Quigley, dean of arts and science at Boston College, wrote back that the college's legal counsel had determined that the project did not meet the definition of human subjects research that would require an institutional review board review and approval."

As the court notes, Boston College did provide review, just not from an IRB.

> Before the Project started, Robert K. O'Neill, the Director of the Burns Library, informed [project director Ed] Moloney that, although he had not yet conferred with counsel on the point, he could not guarantee that BC "would be in a position to refuse to turn over documents [from the Project] on a court order without being held in contempt."
>
> Against this background, the Project attempted to guard against unauthorized disclosure. The agreement between Moloney and BC directed him as Project Director to require interviewers and interviewees to sign a confidentiality agreement forbidding them from disclosing the existence or scope of the Project without the permission of BC. The agreement also required the use of a coding system to maintain the anonymity of interviewees and provided that only the Burns Librarian and Moloney would have access to the key identifying the interviewees. Although the interviews were originally going to be stored in Belfast, Northern Ireland, as well as Boston, the Project leadership ultimately decided that the interviews could only be safely stored in the United States. They were eventually stored in the "Treasure Room" of the Burns Library, with extremely limited access.
>
> The agreement between Moloney and BC requires that "[e]ach interviewee is to be given a contract guaranteeing to the extent American law allows the conditions of the interview and the conditions of its deposit at the Burns Library, including terms of an embargo period if it becomes necessary" (emphasis added). The agreement, in this clause, expressly acknowledged that its protections could be limited by American law. The agreement also directs that the Project adopt an "appropriate user model, such as Columbia University's Oral History Research Office Guidelines statement."

Yet, "the donation agreements do not contain the 'to the extent American law allows' language that is contained in the agreement between Moloney and BC."

[5]Moloney and BC blame each other for writing those faulty donation agreements. And Moloney and a fellow researcher claim the college told them "that BC had taken legal advice on this and the guarantee of confidentiality was iron clad; that there was no possible way this material could be accessed or used by anyone outside the terms of the donor agreement (i.e., death or consent)." But the fact remains that the college warned Moloney, in writing, about the limits of the guarantee it was offering, and Moloney signed a contract with that warning.

[Note to [6]The Heights: I admire your reporting, but the truckload of Flash content on your site threatens to crash my computer every time I try to read a story.]
Perhaps, then, the lesson is that oral historians need to work more closely with the lawyers at the institutions with which they are affiliated, e.g., by making sure the lawyers have a chance to review materials given to donors. But [7]we should not confuse expert review by lawyers with the inexpert review offered by IRBs, which may not include any historians or lawyers in their ranks.
For extensive, continuing coverage of this case, and links to coverage in other media, see [8]Boston College Subpoena News.

1. http://www.law.cornell.edu/supct/html/historics/USSC_CR_0408_0665_ZS.html
2. http://www.ca1.uscourts.gov/pdf.opinions/11-2511P-01A.pdf
3. http://www.insidehighered.com/news/2012/07/09/appeals-court-rejects-researchers-bid-protect-oral-history-confidentiality
4. http://bcaaup.org/?p=353
5. http://www.bcheights.com/news/researchers-weigh-in-on-belfast-project-legal-drama-1.2783367?pagereq=2
6. http://www.bcheights.com/
7. http://www.institutionalreviewblog.com/2012/05/berkeley-historian-defends-irb-review.html
8. http://bostoncollegesubpoena.wordpress.com/

7.7.5 SAGE Insight Posts "The Case Against Ethics Review" (2012-07-12 08:37)

My Research Ethics article, "The Case Against Ethics Review in the Social Sciences," has been posted on the [1]SAGE Insight blog. This means you can read it free. Thanks, SAGE!

1. http://sageinsight.wordpress.com/2012/07/10/the-case-against-ethics-review-in-the-social-sciences/

7.7.6 IRB Chair: "Human Subjects Oversight Is Here to Stay" (2012-07-13 10:30)

Back in [1]September 2011, I noted that the Professional Geographer had posted a focus section on IRBs (it appeared in print in February 2012). At the time I was too busy reading and writing ANPRM responses to comment on the six items in the focus section, but with the luxury of summer I can now do so. Today, I start with the introduction.
Ironically, given its appearance at that moment of regulatory upheaval, the introduction to the focus section dismisses the possibility of regulatory reform.
[Patricia L. Price, "Introduction: Protecting Human Subjects Across the Geographic Research Process," Professional Geographer 64:1 (2012), 1-6, [2]DOI: 10.1080/00330124.2011.596780.]
The introduction is written by Patricia Price, professor of geography and chair of the university-wide IRB at Florida International University.
Price insists that she is not "an apologist for human subjects oversight," and she acknowledges the "disjunctures that exist between regulatory structures on the one hand and the actual practice of research on the other."
Yet Price is dismissive of IRB critiques.

> Much of the literature on human subjects protection from the social sciences and humanities, however, presents an oversimplified picture. Too often, discussion devolves into a one-sided forum in which

> researchers vent their frustration at the oversight of university administrators, particularly those whose power to delay or modify research is seen as uninformed, arbitrary, or inappropriately interfering with academic freedom . . .
> At an interpersonal level, too, some of the juiciest tales around consist of academic horror stories involving abusive administrators, murky guidelines, missed deadlines, and research plans gone terribly awry, all in the name of human subjects protection . . .
> Although these tales provide ample opportunity for peer bonding (and, I'll admit it, the sheer entertainment value of some of them is quite high), and although some of them undoubtedly contain more than a kernel of truth, we wish to take a more constructive approach. To put it bluntly, human subjects oversight is here to stay: Now what?

In other words, Price believes that documentation of IRB abuse and calls for structural relief are not constructive, apparently since she thinks that federal regulations are immutable.
The focus section emerged from presentations at the Association of American Geographers annual meeting in 2009. Obviously, neither then nor during the preparation of the journal issue could Price have known that the ANPRM was coming, but she did have access to proposals for structural reform, such as the 2005 [3]Illinois White Paper (which she cites in her own contribution to the Focus Section) and the [4]2006 AAUP report, not to mention the impressive revision process in Canada. And a broader understanding of the history of IRB policy would have told her that the assemblage of "academic horror stories" led to the establishment of the exemption procedures that she praises in her own article.
I would say that an "oversimplified picture" of the IRB debate is one that denies the achievements of generations of IRB critics and offers the unqualified claim that "human subjects oversight is here to stay."

1. http://www.institutionalreviewblog.com/2011/09/professional-geographer-focuses-on-irbs.html
2. http://dx.doi.org/10.1080/00330124.2011.596780
3. http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Resource_Center/Articles/11.%20Illinois%20Whitepaper.pdf
4. http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm

7.7.7 IRB Sought to Monitor Interviews with Elected Officials (2012-07-16 09:30)

The first article in the Professional Geographer special issue argues that the IRB system assumes that the researcher is a "powerful, knowing agent who assembles a scientific methodology that is always of potential harm to the researched," while subjects are always "less knowing" and vulnerable. As a result, scholars "face the presumption of guilt while seeking to prove innocence in the IRB process of application, negotiation, and usually, but not painlessly, final approval to conduct research."
[Deborah G. Martin and Joshua Inwood. "Subjectivity, Power, and the IRB," Professional Geographer 64, no. 1 (2012): 7–15, [1]DOI:10.1080/00330124.2011.596781.]
Deborah Martin and Joshua Inwood cite others' complaints about the IRB system, notably those published in the special issues of the Northwestern Law Review and ACME. They then contribute additional horror stories:

- A scholar "wanted to interview people about their participation in a public process of reconciliation many years after a violent racialized confrontation in their community." The people had all already testified publicly about the event, and some were elected officials. Yet the IRB required the scholar to meet with the university counsel who asked to review all manuscripts "to ensure that the research wasn't going to put anyone in jeopardy. It was apparent at this point that 'anyone.' referred primarily to the university." The authors note that "the scholar was

treated in tone and substance not as a peer but as a wayward underling (e.g., the lawyer repeatedly referred to the project as a dissertation, despite the scholar's status as a member of the faculty)." The scholar himself reported, "I was now at the mercy of the university and its bureaucracy to the point that I thought my whole research agenda was in jeopardy and that my short and altogether brief academic career might be coming to an abrupt end."

- "A scholar seeking to teach her graduate students about qualitative methods was required by her university's IRB to submit a protocol for approval, even though the 'research' was pilot studies simulating a research process." When the instructor complained, the IRB chair "explained that it was institutional policy to review classroom activities, primarily because of a concern about loss of funding if any research was not reviewed." Eventually, the scholar acquiesed and used the experience as "a 'teachable moment' about the overreaching of IRBs.

- "An IRB member who was disturbed by a research topic about terrorism contacted the student-researcher individually to discuss the research," even though the project had been approved. The authors argue that "The concern of the individual IRB member might in fact have been important, well-founded, and legitimate, but for a student to be asked to meet with a faculty person to justify his or her research beyond the requirements of the IRB seems to be an abuse of power," since such an encounter would easily be intimidating. Not all IRB interactions are this bad. The authors note the case of a student studying domestic violence whose research was held up because neither the student nor her advisors had considered that the student would be legally required to report any suspected child abuse. (Note: the validity of this concern depends on where the research took place; [2]eighteen states and Puerto Rico require any person who suspects child abuse or neglect to report to authorities, but the rest do not.)

Martin and Inwood credit the willingness of the IRB to meet face-to-face for a good outcome: "The student and her advisors had not considered the possibility and greatly appreciated the concern of the IRB and the willingness to engage openly with the student about how to make the research method work so that the research could proceed and be safe for everyone involved."
On the whole, however, Martin and Inwood warn that IRB review can be "highly patriarchal and demeaning to researchers," as well as to "those who were choosing to take part in this research project." Though they do not offer specific policy prescriptions, their essay makes a good case for paying attention to the power dynamics in the IRB process.

1. http://dx.doi.org/10.1080/00330124.2011.596781
2. http://www.childwelfare.gov/systemwide/laws_policies/statutes/manda.cfm

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7.7.8 Common Rule Is "Out of Place" on the Streets of Bogotá (2012-07-17 08:34)

In the second article in the Professional Geographer special issue, Amy Ritterbusch argues that "when lives are at risk, socially and politically responsible action in the field becomes the driving force of human subjects protection," but that "standard human subjects protection procedures often pull initial field relations in the opposite direction, establishing distance and difference between the researcher and research population through a temporally and spatially restrictive web of institutional categorizations and paperwork that predefine participants' identities and role in the research project."
She finds that "Although well intentioned, 45 CFR 46 is a bureaucratic discourse that positions youth in problematic ways and is out of place in the world of Bogotana street girls."
[Amy Ritterbusch, "Bridging Guidelines and Practice: Toward a Grounded Care Ethics in Youth Participatory Action Research," Professional Geographer 64, no. 1 (2012): 16–24, [1]DOI: 10.1080/00330124.2011.596783.]
Ritterbusch conducts participatory action research with female street youth in Bogotá, and she is frustrated by Common Rule requirements that can be irrelevant or even counterproductive.

Specifically, she complains that Common Rule requirements for consent (and children's assent) depends on unmerited assumptions that people are either children or adults, vulnerable or not, and that the giving of consent is a one-time event:

> I contend that to effectively convey the principles of consent, prospective participants must first recognize value in themselves. In the case of my field research, working with a population of sexually exploited youth whose sense of self-worth is severely debased required me to begin by working with street girls to recognize the value of their sexual health (by distributing and motivating the consistent use of condoms and lubricants and discussing safe practices), their potential to help others in the community (by identifying and exerting their rights to health and social services), and the value of their contribution to the research project both in their personal lives and for others in the streets. PAR with street girls, therefore, necessarily calls for a reframing of consent as a process stretched out over time and space and involving community activism and outreach. This in turn initiates the flow of action research and destabilizes the conventional subject–object structuring of fieldwork in general and human subjects procedures in particular. Furthermore, I suggest that the process of making an agreement on consent is in itself the initiation of reciprocity and mutuality, which underpin the entire research relationship . . .
> Obtaining consent does not just happen in one place or in one moment; rather, it happens over time and in multiple spaces through the enactment of care ethics and communicative research relations.

She also notes that protection can go both ways:

> On countless occasions the girls have protected me in their street spaces far more than I will ever be able to protect them from the violence and abuse of pimps, clients, or rival street gangs. Considering this, it might be presumptuous to write about the protection of human subjects when the girls have developed a much more effective system of protection, both for themselves and for me, than I can ever hope to offer them, entering their space as I do only with the ungrounded tools provided by formal human subjects protection protocols based in federal U.S. guidelines . . .
> Far better than the OHRP, the girls themselves know their safe spaces and places of refuge, and only they know which state authorities can be trusted and which officials will threaten their lives to collect a brothel pay-off.

Finally, she argues that the real ethics of her work is protecting her informants not from foreign ethnographers, but from the dangers they face every day:

> The reality, however, is that I will not always be literally there in the field. Therefore, I have worked with the girls to build networks of care in the streets that will continue to expand without my presence. Thus, for as long as I am in the field, I am working to construct sustainable structures of caring through collaboration with a local nonprofit organization (Fundación Social Fénix) to plan organized, embodied acts of reaching out to community actors and cultivating street-corner leadership.

Ritterbusch argues that "identifying the local specificities of human subjects protection in a society in which the law and human rights are often disregarded is not a process that can be standardized or operationalized from a handbook. Rather, it became a process of learning from the research population how to best protect their lives as well as my own . . ." She does not suggest how this insight might be encoded into federal policy, though the [2]radical redefinition of human subjects research proposed by the American Anthropological Association would be a good start.

1. http://dx.doi.org/10.1080/00330124.2011.596783
2. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html

Anonymous (2012-07-17 09:20:24)
Who did the IRB review in this case and were they qualified to conduct the review? given the description I doubt the regulations and OHRP guidance were being followed. There is very clear instructions on a local knowledge requirement and there a lot of flexibility for sensible decision-making tailored to local specifics.
OHRP own guidance is in agreement with the statement: "identifying the local specificities of human subjects protection in a society in which the law and human rights are often disregarded is not a process that can be standardized or operationalized from a handbook."
"45 CFR 46 is a bureaucratic discourse" to the extent IRBs choose to make it such.

Zachary M. Schrag (2012-07-17 09:28:42)
Certainly some IRBs are better than others. But in a case like this, the specific requirements of, say, [1]45 CFR 46.116 may be impediments rather than aids to ethical research.

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

Dylan (2012-07-17 11:44:36)
At several PRIM &R conferences and trainings, I've repeatedly heard this theme emphasized – that is, consent is an ongoing process, not a single event. So a fair number of IRB professionals are certainly aware of the concept and seem to support it. However, I've seen very little guidance from IRBs on how to actually make it happen – how to make consent an ongoing process while still meeting the requirements of the regulations. Those requirements seem to be most easily met when consent is treated as an event.

Zachary M. Schrag (2012-07-17 11:55:04)
Thanks for this comment. I think Ritterbusch would agree: IRB members and staff are well intentioned, but regulatory requirements lead them astray.
PRIM &R itself, however, refuses to take responsibility, instead [1]blaming the problem on sponsors and investigators.

1. http://www.institutionalreviewblog.com/2011/11/prim-irbs-dont-write-consent-forms.html

Anonymous (2012-07-18 09:38:11)
The local knowledge review requirement?
Also, IRBs have quite a lot of flexibility on consent or, in this case parental permission. You reference 46.116 but you should also be referencing 46.408 in this case. It may very well be the case given the description of the work that parental consent could have been waived in accordance with the regs in this case. And one could work on crafting an appropriate oral assent process. There's a lot of flexibility on that.
At the end of the day the priority here is to undertake work in an ethical manner not implement mindless bureaucracy. Yes, the regulations set constraints and situations do arise where those constraints don't make a lot of sense, but in most cases there is flexibility to craft a sensible ethical approach if the IRB is willing to work with the researcher. If you document how the regulations have been interpreted and explain why this is the most ethical course of action, what's the problem?
A lot of the problems you cite on this blog are research institution issues. I've been to conferences and listened to OHRP officials talk about the under-use of exemption for social science research. Most social science research could be (and I would argue) should be treated as exempt. That institutions choose to create bureaucratic controls above and beyond what the regulations require is their prerogative and suggests that reforming the regulations is unlikely to solve many of the issues of concern here.

Zachary M. Schrag (2012-07-18 10:29:21)
Thanks for this comment. Whether consent is written or oral, 45 CFR 46.116 still requires several steps that would be inappropriate for the kind of research described here.
For my views on OHRP's responsibility for IRB inflexibility, please see [1]Menikoff Passes the Buck, December 7, 2010.
And while PRIM &R's ANPRM comment goes too far to absolve IRBs of their share of the blame, it does correctly note OHRP's culpability:
"As far as we know, OHRP has never criticized any institution for using consent forms that are too long or complex. It would

be incorrect to blame IRBs for this problem as sponsors, institutional lawyers, risk managers, and other executives are primarily concerned with institutional protection rather than subject information. One way to reduce some of this apprehension about changing, clarifying, and shortening consent forms is for OHRP to clarify its minimum requirements for such forms as well as its enforcement methods for consent form inadequacies."

1. http://www.institutionalreviewblog.com/2010/12/menikoff-passes-buck.html

Anonymous (2012-07-19 11:49:32)

"Whether consent is written or oral, 45 CFR 46.116 still requires several steps that would be inappropriate for the kind of research described here."

I still don't see the problem with the regs in this instance based on the details you've provided.

The research subjects are street youth so presumably there are no parents or guardians from whom one could obtain consent/permission or the conditions may be such that the parental/guardian permission is "not a reasonable requirement" –§46.408(c). The regs do discuss substituting an "appropriate mechanism for protecting the children who will participate as subjects in the research". She mentions that she worked with a local non-profit agency that was serving these children–maybe someone at that group or identified by that group could have played that role. Also, under §46.408 the IRB is basically free to determine what's appropriate assent. The whole section is about IRB's making "appropriate judgements" rather that complying with a list of pre-determined requirements.

Zachary M. Schrag (2012-07-19 12:08:02)

Thanks for this comment. Other researchers have reported that [1]IRBs try to check off all the regulatory requirements by encouraging stilted, formalized consent procedures, whether written or oral, and my guess would be that Ritterbusch faced something like that. But you are correct that that is mere speculation. It would have been helpful for Ritterbusch to describe in more detail the conditions imposed by her IRB, as [2]recommended by Alexander Halavais.

1. http://www.institutionalreviewblog.com/2008/08/critiques-of-consent-forms.html
2. http://www.institutionalreviewblog.com/2011/12/halavais-calls-for-open-publication-of.html

7.7.9 Can Macalester's Divisional Review Work Elsewhere? (2012-07-18 08:01)

In his contribution to the Professional Geographer special issue, Dan Trudeau of Macalester College writes that "IRBs can be a pedagogical asset, particularly if institutional review practices cultivate the habits of mind and strategies necessary for engaged and reflexive research." The key, his article suggests, may be the devolution of review to specialized committees rather than the general-purpose IRBs that are the norm. But Trudeau does not stress the degree to which Macalester's sucess depends on its departure from federal standards.

[Dan Trudeau, "IRBs as Asset for Ethics Education in Geography," Professional Geographer 64, no. 1 (2012): 25-33, [1]DOI: 10.1080/00330124.2011.596786.]

Trudeau concedes that "obstructive interventions occur; litigious instrumentalism can guide the work of bureaucratic programs, including IRBs; and I am genuinely sympathetic to the translation problems that stem from the evaluation of interpretive research from a framework attuned to experimental science." But he insists that "these instances should not, however, be mistaken for necessary characteristics of IRBs."

As evidence, he points to Macalaster, where "faculty initiatives created several IRB subsidiaries, including one that considers research proposals from the social sciences only (the others consider research involving animals and psychological research)." In fact, [2]Macalester's IRB guidelines go further than this, stating that "Departments, divisions and interdisciplinary programs that regularly sponsor research involving human participants may form their own institutional review boards." (Macalaster also recognizes that oral history does not constitute human subjects research.)

Trudeau has chaired the Social Science Division of the Institutional Review Board (SSIRB), which "reviews research protocols that faculty members develop for courses that integrate social research into the curriculum" and "proposals that students develop for original research." It does not review proposals bearing greater than minimal risk, such as "Highly sensitive research involving vulnerable populations." Nor, as I understand Trudeau's article, does it review the

faculty's own research.
Trudeau praises the SSIRB for helping him teach research ethics.

> The capacity for [my undergraduate] course to offer enduring lessons about the practice of ethics in human geography research has been greatly enhanced through my interaction with the SSIRB. Submitting a protocol helped me develop and organize curriculum that gives explicit instruction on ethically responsible research conduct. Furthermore, and most important, the SSIRB gave supportive, critical feedback on developing procedures to ensure informed consent and confidentiality. For instance, the SSIRB suggested that I integrate into the course multiple instances for students to consider the research ethics implications of the multiple roles that they will have in their research sites. In practice, I have convened conversations with students about their perceptions of and approaches to their roles as volunteer and researcher. Such conversations have also provided a forum for students to raise additional ethical questions and think through the ethics in practice of the research. Specifically, these conversations have helped both students and me to anticipate potential conflicts or troubles that might arise when one is both volunteering and researching. It has also helped students work collaboratively to generate strategies that address the troubles that do arise, including how to represent research participants in ways that respect individual privacy as well as individuals' unique relationships with community organizations.

Trudeau notes that Macalester's "approach has emerged in an institution that explicitly focuses on undergraduate education. This approach is thus likely tenable for a select set of institutions." Indeed, the big question here may be what elements of the Macalester model can work at larger, more research-intensive institutions.
[3]I have long been interested in departmental review as an alternative to the general-purpose or social-behavioral IRBs that force qualitative and quantitative, experimental and observational, and field vs. lab researchers to pass judgment on research methods they do not understand. Trudeau's article suggests that there is real value to this approach.

Federal Regulations Are Barriers

But it is important to note that the SSIRB and Macalester's other specialized committees are not empowered to review high-risk or federally funded research. So they aren't really IRBs at all, if we take "IRB" to mean a committee that meets federal standards. And real IRBs can't function the way Macalester's committees do.

- Macalester allows departments to form their own ethics committees. Official IRBs can't allow this, since the Common Rule states that "[4]No IRB may consist entirely of members of one profession."
- Macalester's committees can be small, needing only [5]three faculty members. This likely facilitates scheduling, deliberations, and communication. Official IRBs must include five members, including non-scientist and non-affiliated members.
- Because they do not review federally funded research or meet federal membership requirements, Macalester's committees are not subject to OHRP audit. Thus, if they make a mistake, they do not risk a suspension of the entire college's federal research funding. I would suggest that this may be a big help in developing what Trudeau calls a "high-trust set of assumptions"; it's easier to trust a committee whose failure won't wreck the college.

While I am grateful to Trudeau for calling attention to Macalester's successes, I don't think he has shown that obstruction and inappropriate demands are not "necessary characteristics of IRBs." The good work done by Macalester's unofficial ethics committees reinforces rather than challenging the claim that official IRB pathologies are the product of federal regulations.

Thus, if the Common Rule is extended "to all research that is not Federally funded that is being conducted at a domestic institution that receives some Federal funding for research with human subjects from a Common Rule agency," as proposed by the ANPRM, the island of sanity that is Macalester's SSIRB may be swept away.

1. http://dx.doi.org/10.1080/00330124.2011.596786
2. http://www.macalester.edu/committees/irb/documents/IRB%20Guidelines%202009.pdf
3. http://www.institutionalreviewblog.com/2007/08/irbs-vs-departmental-review.html
4. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107
5. http://www.macalester.edu/committees/irb/ssirb/SSIRB%20Purpose%20Composition%20Activities.pdf

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nathan (2012-07-18 15:32:09)
I wonder if it is worth distinguishing between people who do something professionally and a profession? I don;t think it is necessary to think of social science, sociology or, even, history as a profession, in the sense that medicine, law or the clergy is, even if we think that these activities can be done professionally. Thus, that problem can be made to disappear.
Alternatively we might also draw the boundaries around academia per se rather than focus on particular disciplines. As a result the problem would then be largely insurmountable and therefore the required should be subject to greater scrutiny.
We might consider what the spirit of the requirement is, presumably the independence of ethical review through ensuring a diversity of reviewers, more explicitly link it to the lay membership, and rethink formal constitutional requirements from there.

Zachary M. Schrag (2012-07-19 10:28:47)
[1]Robert Klitzman has suggested that the community member requirements aren't meeting their goals, and Trudeau's essay suggests that committees without such members may work better. Unfortunately, federal policy has long insisted on single models of oversight, rather than comparing possible alternatives.

1. http://www.institutionalreviewblog.com/2012/06/community-members-play-murky-roles.html

7.7.10 IRB Chair Denies Being a Vampire (2012-07-19 10:20)

Patricia Price, a geographer and IRB chair at Florida International University, assures us that her board is not "a malevolent, vampirish entity."
[Patricia L. Price, "Geography, Me, and the IRB: From Roadblock to Resource," Professional Geographer 64, no. 1 (2012): 34-42, [1]DOI:10.1080/00330124.2011.596789]
Price understands that IRB horror stories emerge from real mismatches between the structure of IRBs and the reality of research. As a geographer, she highlights two mismatches grounded in space. First, she notes that the collection of locational data can threaten subjects' privacy, but that "few IRB chairs are knowledgeable enough about GIScience to make useful suggestions to researchers about how to treat such data." Therefore, "geographers, as well as others using GIScience techniques, must take it on themselves to educate IRBs about the best (i.e., most appropriate as well as methodologically sound) ways to utilize linked sociospatial data without compromising confidentiality."
Second, she notes that the standard IRB model more or less assumes that researchers, subjects, and IRBs will stay put during the course of a project, but that "as researchers, human subjects, and IRB members move about locationally and institutionally, consistency and continuity of human subjects protection oversight is difficult to maintain."
Rather than propose any structural solution, Price calls on researchers to trust their IRB chairs.

> Most IRBs (almost always the ones you do not hear about) are chaired by thoughtful scholar-administrators whose desire to facilitate research at the home institution is balanced by the nagging fear of that one-in-a-thousand protocols that has the potential to bring the university's research to an embarrassingly public halt as federal regulators audit everything. The best among us are interpretivists, as opposed to literalists, who attempt to work with, rather than against, our local circumstances and cultures. We

> recognize that ours is largely a deliberative task, rather than the strict application of clearly defined parameters. We strive to stack our boards with a diversity of fellow faculty known primarily for their equanimity. And most of our time is not spent on regulatory issues but rather on education and outreach, particularly with graduate students and new faculty. Human subjects protection is as much, if not more, a cultural rather than a technical issue.

Price offers no evidence for these claims. I have no reason to doubt that Price herself is a fine IRB chair, though if she's done any research into FIU researchers' attitudes toward their IRB, she doesn't cite it. For instance, her article mentions but does not engage with the [2]critiques articulated by Amy Ritterbusch in her essay, though [3]Ritterbusch is Price's advisee and presumably is complaining of the "standardized or operationalized" procedures demanded by Price's IRB.

More significantly, though, Price gives us no reason to think that enlightened chairs are the exception rather than the rule. She concedes that IRB chairs exchange "chilling tales of university-wide research shutdowns during a federal for-cause audit wherein the buck ultimately stops with the IRB chair." If only 20 percent of chairs run their IRBs with the intention of avoiding federal audits rather than protecting subjects, that would still be a national disaster.

Nor does Price discuss the role of IRB staff and related entities. For example, [4]her university requires all researchers, regardless of discipline, to complete either the NIH course in Protecting Human Research Participants or the [5]mortifyingly stupid CITI Program. Regardless of what happens to their protocols, [6]self-respecting researchers detest such mind-numbing, coercive, counterproductive McEthics.

Price ends by calling for researchers to serve on their IRBs, claiming that this will diminish "much miscommunication, misinformation, and ill will toward IRBs emanating from researchers conducting surveys, focus groups, oral and life histories, or utilizing other qualitative techniques that do not fall under the methodological umbrella of clinical trials and behavioral interventions."

Maybe she should tell that to researchers like [7]Rena Lederman, [8]Anthony Langlois, and [9]Dominique Rivière, whose service on ethics committees did not extinguish their skepticism about the whole process. [Note: I hope to post comments on Rivière's piece before too long.]

Then Price tells researchers to "Familiarize yourself with the regulations." That's a good suggestion only so long as the IRB and IRB staff promise to follow the regulations themselves. Keep in mind that PRIM &R argues "[10]that institutions should always be permitted to add additional protections to the minimal regulatory requirements as they see fit without special permission." So long as this is the case, a researcher who knows the regulations well may be all the more frustrated when the IRB imposes additional restrictions. What is a researcher familiar with regulations to do when [11]IRB offices demand review of obviously exempt research?

In sum, Price acknowledges that IRBs–especially their chairs–enjoy somewhat dictatorial powers, but she tells us that dictators can be relied on to work fairly in obscurity. Whether dealing with IRBs or vampires, I put my trust in sunshine.

1. http://dx.doi.org/10.1080/00330124.2011.596789
2. http://www.institutionalreviewblog.com/2012/07/common-rule-is-out-of-place-on-streets.html
3. http://gss.fiu.edu/people/amy-ritterbusch/
4. http://research.fiu.edu/compliance/humanResearch/humanTraining.html
5. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
6. http://www.institutionalreviewblog.com/2011/08/citi-program-as-mind-numbing-coercive.html
7. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html
8. http://www.institutionalreviewblog.com/2011/05/australian-political-scientist-causing.html
9. http://dx.doi.org/10.1007/s10805-011-9139-y
10. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0834
11. http://www.institutionalreviewblog.com/2009/12/grad-student-needed-80-irb-approvals.html

7.7.11 IRB Chair Denies Being a Vampire (2012-07-19 10:23)

Patricia Price, a geographer and IRB chair at Florida International University, assures us that her board is not "a malevolent, vampirish entity."
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Price ends by calling for researchers to serve on their IRBs, claiming that this will diminish "much miscommunication, misinformation, and ill will toward IRBs emanating from researchers conducting surveys, focus groups, oral and life histories, or utilizing other qualitative techniques that do not fall under the methodological umbrella of clinical trials and behavioral interventions."
Maybe she should tell that to researchers like [7]Rena Lederman, [8]Anthony Langlois, and [9]Dominique Rivière, whose service on ethics committees did not extinguish their skepticism about the whole process. [Note: I hope to post comments on Rivière's piece before too long.]

Then Price tells researchers to "Familiarize yourself with the regulations." That's a good suggestion only so long as the IRB and IRB staff promise to follow the regulations themselves. Keep in mind that PRIM &R argues "[10]that institutions should always be permitted to add additional protections to the minimal regulatory requirements as they see fit without special permission." So long as this is the case, a researcher who knows the regulations well may be all the more frustrated when the IRB imposes additional restrictions. What is a researcher familiar with regulations to do when [11]IRB offices demand review of obviously exempt research?

In sum, Price acknowledges that IRBs–especially their chairs–enjoy somewhat dictatorial powers, but she tells us that dictators can be relied on to work fairly in obscurity. Whether dealing with IRBs or vampires, I put my trust in sunshine.

1. http://dx.doi.org/10.1080/00330124.2011.596789
2. http://www.institutionalreviewblog.com/2012/07/common-rule-is-out-of-place-on-streets.html
3. http://gss.fiu.edu/people/amy-ritterbusch/
4. http://research.fiu.edu/compliance/humanResearch/humanTraining.html
5. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
6. http://www.institutionalreviewblog.com/2011/08/citi-program-as-mind-numbing-coercive.html
7. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html
8. http://www.institutionalreviewblog.com/2011/05/australian-political-scientist-causing.html
9. http://dx.doi.org/10.1007/s10805-011-9139-y
10. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0834
11. http://www.institutionalreviewblog.com/2009/12/grad-student-needed-80-irb-approvals.html

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7.7.12 Geographer: Unnecessary IRB Delay Threatens NSF Grants (2012-07-20 08:09)

In the fifth and final Professional Geographer essay, Scott M. Freundschuh, Professor of Geography at the University of New Mexico, notes that many IRBs "unnecessarily require research protocols to be reviewed by the full IRB, therefore impeding the progress of research projects." Rather than suggesting structural changes to the IRB system, he counsels geographers to work within existing rules.

[Scott M. Freundschuh, "Institutional Review for Research in the Social Sciences from the Federal Perspective," Professional Geographer 64, no. 1 (2012): 43-48, [1]DOI:10.1080/00330124.2011.596791]

Horror Stories

Freundschuh begins his articles with two encounters he himself had with IRBs. He does not present them as horror stories, but I will.

In the first, he planned to ask children, ages 3-5, to navigate a simple obstacle course. Some would have a map, while others–the controls–would not. The IRB fretted that the controls would not benefit from instruction in map reading, and demanded that all participants benefit equally.

Freundschuh does not record his reaction to this demand. I would note that every playground ever built is a monument to preschoolers' fondness for navigating obstacle courses, with or without a map, so perhaps the original proposal would, in fact, have benefited all participants. More significantly, I would suggest that if IRBs are really composed of expert researchers as they claim, they have better things to do with their time than overruling parents' judgments about what is best for their children in a case like this. The case reminds me of [2]a 2008 comment by Liz Bankert: "I've gone to IRBs all over the country. They are thoughtful, sincere, really intelligent groups. To have all this brainpower sucked into the vortex of minimal risk research is not efficient."

The second study, by one of Freundschuh's students, sought to ask participants to discuss how they perceived safety on a university campus. Predictably, "the IRB expressed concern that this study could potentially expose participants to great emotional stress if it inadvertently caused a subject to relive a violent crime." Again, Freundschuh does not explicitly pass judgment on the IRB's action, and it's not clear that he is familiar with the [3]research discrediting this

common IRB fear.

Ass-Covering

Freundschuh reports that one IRB (it's not clear where) has modified its requirements for consent forms in a way that seems designed to protect the university rather than research participants. As Freundschuh explains

> In more recent reviews of research protocols, I have had to modify language in informed consent forms that reflect this growing awareness of liability. For example, I've had to remove the statement "This research project has been reviewed and approved by the University," and I have had to add the words "without prejudice" at the end of the statement "[participants] can stop their participation in this study at any time." Neither of the preceding examples modified the risk to participants, but they do reflect the university's responsibility for the IRB review process.

I'm not sure what he means by that last comment. The university demands that researchers submit protocols for review and get the university's approval, but then forbids them from sharing this fact with research participants. This strikes me as reflecting the university's refusal to take responsibility for its process. And I would be interested to meet the research particpant for whom the addition of the words "without prejudice" clarified rather than obscured the terms of an agreement.

Five Hours of Tutorials

Freundschuh states that the University of Minnesota's now requires first time IRB applicants to complete an online training course that "takes approximately five hours to complete."
While he does not directy register his opinion of the relevance of these tutorials to his work, Freundschuh does call for "the development and implementation of an ethics curriculum for geography faculty and departments," ideally with the aid of the Association of American Geographers. Does this suggest that he found the current tutorials lacking?

Some Good News

The good news from Freundschuh is that exemption and expedited review is working somewhere. He states that expedited review "is much faster [than full-board review], sometimes taking only a day or two rather than months," and that "Studies that I have conducted that have been exempt have gained that status in a single day." Since this is not the case everywhere ([4]Sugarman et al. found that expedited review at medical centers "costs about the same as full protocol review"), it would have been helpful for Freundschuh to note which of institutions have achieved this standard.

A Call for Compliance

Freundschuh is aware that researchers are frustrated:

> Social and behavioral research that typically involves minimal risk to human participants has often, at the dismay of the researcher, had to undergo IRB processes that are designed to assess the greater physical risks associated with biomedical research. In most instances, this level of review is not necessary. For example, a study protocol that measures the effectiveness of a new chemotherapy treatment will necessarily require greater scrutiny and control than a study that interviews residents to learn their views about a newly planned highway. The impact of these more onerous review processes has raised the concern that these processes interfere unnecessarily with the progress of research, creating unnecessary burdens and delays. It is not uncommon for the processing of an NSF award to be held up while the PI waits for

her or his institution's IRB to complete its review of a proposal. There have been instances where program officers at NSF have had to inform IRBs that an award was in jeopardy because of the long wait for review of a research protocol that could have been exempt or expedited.

But Freundschuh's article shows no awareness of the longstanding critiques of the application of IRB review to the social sciences. In 1979, such critiques led the Association of American Geographers to join in [5]a call to bar the regulation of conversations between consenting adults. More recent critiques–such as those noted by [6]Martin and Inwood–have not yet produced comparable action. For example, the AAG seems not to have responded to the 2011 ANPRM. Contrary to [7]Price's claim that we have had enough complaints, perhaps geogrpahers need more.
Instead of exploring this possibility, Freundschuh tells geographers to study up on the Common Rule enough to challenge IRBs that lack the basic competence to distinguish an exempt protocol from one requiring full-board review. I hope geographers are bolder than that.

1. http://dx.doi.org/10.1080/00330124.2011.596791
2. http://www.institutionalreviewblog.com/2008/07/report-from-sachrp-part-1-systems-level.html
3. http://www.institutionalreviewblog.com/2008/03/trauma-based-research-is-less-risky.html
4. http://http//www.nejm.org/doi/full/10.1056/NEJM200504283521723
5. http://www.jstor.org/stable/3564447
6. http://www.institutionalreviewblog.com/2012/07/irb-sought-to-monitor-interviews-with.html
7. http://www.institutionalreviewblog.com/2012/07/irb-chair-human-subjects-oversight-is.html

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Dana (2012-07-29 16:03:43)
I appreciated the candor of the author and his observations. Each IRB must apply the federal regulations but as both Schrag and Fruendschuh note, individual IRB policies and procedures may impair research. I found the example of research with children to be interesting. It is true that IRBs should consider the benefits of the research. The key being the term "research". There is not a requirement that each participant directly benefit. In this example, the IRB in question seems to be overly conservative in the application of the term "benefit".
Researchers should be aware of the code of federal regulations and if appropriate question the decision or comments of the IRB (in a professional manner). I was part of a research team looking at the result of menu labeling on food choices. We planned to present participants with a regular menu, ask them to make selections. Then participants were given the same menu but with calorie and fact content for each item. Since the focus of the study was to examine how the presence of the nutrition information changed food selection, we were shocked when the IRB (medical academic institution) requested a rationale for not providing the menus randomly. Because I have IRB experience, I responded with a reminder of the purpose of the study and a request for clarification on how this request applied to the CFR and ethics of the study. The IRB agreed and did not require a revision.
It is the role of researchers and IRB reviewers to protect participants. IRBs should do this without imposing undue barriers which do not affect the ethics of the study or the safety of participants.

Zachary M. Schrag (2012-08-06 14:08:59)
Thanks for this comment. I fear that relatively few researchers have the knowledge or gumption to contest inappropriate demands as you did.

7.8 August

7.8.1 Elliott Decries IRB Opacity (2012-08-14 14:47)

Writing for the Chronicle of Higher Education's Brainstorm Blog, Carl Elliott argues that the "by any reasonable estimate [the IRB] oversight system has been a failure . . . yet so many people are professionally invested in the current oversight system that they cannot imagine replacing it, only tinkering with it." He particularly condemns the secrecy

of the system.
[Carl Elliott, “[1]When Medical Muckraking Fails” Chronicle of Higher Education, Brainstorm, August 2, 2012.]
Elliott argues that a system designed to oversee federally funded research is "no match for the power and influence of today’s globalized, multi-billion-dollar research industry." Moreover,

> Of the many flaws in the current oversight system, perhaps the most dangerous is its secrecy. IRB meetings are closed to the public, and their proceedings are confidential. Many IRB’s are private, for-profit businesses, and thus not even subject to federal or state Freedom of Information Act requests. Often it is difficult even to find out which IRB has approved a research study. In fact, the very existence of some research studies is secret; research sponsors are not required to register Phase I clinical trials on Clinicaltrials.gov, the federal registry. So if you are an investigative reporter and want to see a potentially troubling research protocol – what the consent form looks like, how much the subjects were paid, whether the investigators had any financial conflicts of interest, how risky the study is – chances are that you will be denied.
> The problem with an oversight system that is both unreliable and secretive is that the public has no idea what is happening beneath the surface. If there is no mechanism for making oversight failures public, and barriers are erected to prevent journalists from investigating, how can we judge whether the oversight system is working? How certain are we that there are not many more hidden abuses, waiting to be uncovered?

One potential comparison would be with our transportation system. When a civil aviation or other major transportation accident occurs, the [2]National Transportation Safety Board investigates and [3]makes public the results of those investigations. The process has not eliminated transportation accidents, but it allows transportation operators around the country to learn from each other’s mistakes, and for the public to hold them accountable.
A system of shared information can also put lapses in perspective. Elliott lists a dozen "widely reported episodes" from the past twenty years as examples of "scandals" in human subjects research. As the comments on the Chronicle site note, these not everyone regards these episodes with the same outrage as does Elliott, and–[4]according to the Presidential Commission for the Study of Bioethical Issues–these are a dozen cases among the tens of thousands of studies conducted annually. A better reporting system might leave us thinking that human subjects research is indeed like aviation. Any crash is bad, but the system as a whole is pretty safe.
Greg Koski, who served as the first director of OHRP, has suggested [5]using the aviation industry as a model for clinical research. Perhaps Elliott could join that effort.

1. http://chronicle.com/blogs/brainstorm/when-medical-muckraking-fails/50767
2. http://www.ntsb.gov/investigations/process.html
3. http://www.ntsb.gov/investigations/reports.html
4. http://bioethics.gov/cms/node/558
5. http://www.acresglobal.net/newsandevents.html

7.8.2 IRBs Impeded Harvard Dissertation on Addiction and Incarceration (2012-08-16 14:18)

Kimberly Sue, a medical anthropologist in Harvard’s MD/PhD program, reports that IRB review can seem "a hassle, a nuisance or a stumbling block, as we seek to enact a more relevant and engaged era of anthropology."
[Kimberly Sue "Are IRBs a Stumbling Block for an Engaged Anthropology?" Somatosphere, 9 August 2012, [1]http://somatosphere.net/2012/08/are-irbs-a-stumbling-block-fo r-an-engaged-anthropology.html . h/t Michelle Meyer]
Sue wants to study "the interstices of addiction and incarceration as they play out in the lives of women with opiate addiction here in Massachusetts as the ’War on Drugs’ rages on." She considered writing her dissertation about

South Africa, but "felt morally compelled to work here at home, in the epicenter of the world's mass incarceration phenomenon." Unfortunately, the IRB system designed to protect prisoners has discouraged the research that could better their lot.
Sue explains:

> With my IRBs (I have submitted several, to various institutions across the state in order to conduct my research), I have seen a wide-range of concerns related to vulnerability and to the special status of "prisoners." For example, I was told by one IRB that if someone in my study who was not incarcerated (a group of women in the community with histories of opiate addiction) became incarcerated, I would have to inform the IRB "before her participation continues, since we must then apply the regulations regarding research involving prisoners." Technical accounting aside, this woman's "vulnerability"—in practical terms, her education, power, resources, life history, social supports—was probably unchanged from the days, months, even years before she became physically incarcerated. What does the reporting of someone's changed status regarding incarceration to the IRB actually entail, practically speaking? Increased protections? More careful auditing? A greater awareness of the coercive potential of her continued participation in my study?
> I also encountered some of the more typical "fieldwork" concerns and lack of general understanding of ethnographic methods. In response to my attempt at being honest about the nature of ethnographic engagement—saying that I hoped to conduct participant observation with my key informants as they sought treatment upon release from prison—the IRB asked me to "provide documentation of permission from those sites" (such as halfway houses or drug treatment programs that a woman might seek out). I felt somehow at fault for not explaining the nature of anthropological inquiry in adequate language for a lay audience: that it, that this research was prospective, longitudinal research tailored to individual women, and that a big part of my research was by nature contingent and situational.

One IRB wanted Sue to exclude the sicker individuals she encountered, even though "As an anthropologist particularly interested in those left behind, those least able to negotiate the world in an outwardly cohesive manner and those most 'vulnerable' to the vagaries of social injustices, [Sue] wanted to include—if not prioritize—their participation." Another wanted Sue to deploy "motivational interviewing," a counseling technique inapporpirate to observational anthropology.
It is not clear from Sue's essay how insistently these IRBs meddled. She writes, "Many of my colleagues have heard me talk about returning to finish my last year of medical school because I have been so overwhelmed by the magnitude and effort required by the research approval process." Does this mean that the IRBs delayed her dissertation by a whole year? Or just that she took advantage of some flexibility on staging her joint degree?
What is clear is that while Sue is not ready to call for the abolition of IRBs, she wants significant change.

> We . . . must acknowledge the very real possibility that the over-protections of IRBs applied to "populations" here at home—as opposed to expedited or fairly cursory reviews of committees for work proposed abroad—could actually deter medical anthropologists from doing valuable work here at home. I think it is critical that we also be more honest and forthright about how IRBs can actually impede, slow down and alter our research (to be fair, they can potentially offer cross-disciplinary dialogue and helpful suggestions); more of us need to share openly the details of our experiences with IRBs in order to come up with practical techniques for advancing our collective research endeavors.

Digression: I've seen a lot of scholarly blogs and online journals over the past few years, and I can't recall any with

designs as elegant as Maarten Ottens's design for Somatosphere. I'm particularly impressed that one can display suggested citations for each post in five different systems, and they appear automatically in the beautifully formatted PDFs one can download. (On the other hand, I can't square the suggested "Chicago citation" with the [2]form for blog entries recommended by the Chicago Manual of Style, 16th. ed., sec. 14.246.)

1. http://somatosphere.net/2012/08/are-irbs-a-stumbling-block-for-an-engaged-anthropology.html
2. http://www.chicagomanualofstyle.org/tools_citationguide.html

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Anonymous (2012-08-22 13:21:37)
The IRB is at the mercy of the federal government as it is charged with seeing that the Code of Federal Regulations is upheld for federal funded research at its institution. The regulations for research with prisoners require a different composition of the IRB (the majority of the board may have no relationship to the prision and a prisoner or prision representative must serve on the Board), and additional duties of the IRB. Don't blame the IRB for asking for information if a study that did not include prisoners at the outset has some subjects who are incarcerated during the course of the study. This isn't an arbitrary IRB rule but a requirement that is necessary so that the IRB doesn't land in hot water with the feds.

Zachary M. Schrag (2012-08-22 14:35:53)
Thanks for this comment. Sue's essay discusses the "IRB apparatus," the "IRB process," and the "IRB system," which I take to mean the regulations and their implementation together. Her experiences may complicate [1]claims that existing regulations offer sufficient flexibility to facilitate ethical research.

1. http://hrpp.blogspot.com/2008/11/prim-thoughts.html

Kimberly Sue (2012-08-22 16:50:41)
I have no problem with federal regulations mandating IRBs to monitor research involving prisoners or people who might become prisoners, but I wonder what the implications are besides a hassle for the researcher. I doubt that increasing reporting from the research level on up has any practical ethical implications for fieldwork.
Update: still mired since a committee convened for their August meeting last week. One major concern was that my questions might increase the risk of cravings (for drugs)– one of those questions they expressed concern about was: "How do you feel on your drug of choice?" It's really a pretty basic, standard qualitative drug question. I was asked to explain why the question was necessary for my research (short answer–it's necessary for an anthropologist to try to understand the lived experience/subjectivities of drug users) and what steps I would take to minimize the risks that answering these questions could lead the subject to crave drugs.

Zachary M. Schrag (2012-08-22 17:17:10)
Many thanks for these comments and your original essay. IRBs have long been imagining that [1]asking about trauma leads to trauma. Does yours have any evidence that asking about drug use leads to drug use? Or is this another [2]bear taboo?

1. http://www.institutionalreviewblog.com/2008/03/trauma-based-research-is-less-risky.html
2. http://www.webcitation.org/5uKg2yviN

7.8.3 Public Health Scholars Question Bioethics Framework (2012-08-23 09:17)

Amy L. Fairchild and David Merritt Johns, both with the Center for the History and Ethics of Public Health, Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, find that bioethics is "the wrong framework of accountability for some domains of inquiry."
[Amy L. Fairchild and David Merritt Johns. "Beyond Bioethics: Reckoning With the Public Health Paradigm," American Journal of Public Health 102, no. 8 (August 2012): 1447–1450, [1]DOI: 10.2105/AJPH.2012.300661.]
Fairchild and Johns note three such domains. Public health surveillance depends on "universal reporting of names," not informed consent. Quality assurane puts the protection of populations above the rights of individuals. And history,

journalism, and other social science inquiry can have as its primary obligation "ensuring the public's right to know." They conclude,

> the time has come to recognize that social inquiry in areas like history, public health, and quality assurance requires an alternative framework of analysis. Yet we cannot let an obsession with rules allow us to overlook the fact that scientific research is guided by a number of different ethical frameworks that do not always agree. Bioethics asserts that individual rights such as privacy require protection; many other frameworks demand that we look past the individual and prioritize the common good.

Fairchild and Johns believe that the 2011 ANPRM "creates space to reckon with other ethical traditions and paradigms of accountability that might inform research regulation besides the reigning bioethical regime, which emphasizes autonomy and privacy." Perhaps, but it's a small space. [2]As I noted last year, attention to different ethical principles is buried in the ANPRM's Question 25. And, as Harry Perlstadt noted in a comment on that post, the ANPRM does not go nearly as far as the Canadian TCPS to embrace academic freedom as an ethical principle.
On the other hand, the ANPRM is at least more sensitive to these issues than is [3]Moral Science.

1. http://dx.doi.org/10.2105/AJPH.2012.300661
2. http://www.institutionalreviewblog.com/2011/08/anprms-problem-statement-helpful-but.html
3. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5673&blogid=140

BlogBook v0.4,
LaTeX 2$_\varepsilon$ & GNU/Linux.
http://www.blogbooker.com

Edited: August 27, 2012