Zachary M. Schrag

Institutional Review Blog

August 2012 – January 2017

This document contains all text appearing on the Institutional Review Blog, http://www.institutionalreviewblog.com/, from 31 August 2012 (the first entry after the previous archive) through the end of January 2017. 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.

Readers are encouraged to cite individual blog entries, e.g., Zachary M. Schrag, "Smithsonian Frees Oral History, Journalism, and Folklore," Institutional Review Blog, 30 July 2010, http://www.institutionalreviewblog.com/2010/07/smithsonian-frees-oral-history.html

www.institutionalreviewblog.com

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Institutional Review Blog: Archival Edition (2012-08-31 08:44)

For some time, I have been meaning to create an archival backup of this blog, not dependent on Google's whims. With the help of [1]BlogBooker and the [2]Mason Archival Repository Service, I have posted a PDF of [3]all the entries and comments on this blog from its launch in December 2006 through the start of this week. The compilation and individual entries can be downloaded under a [4]Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported License.

1. http://www.blogbooker.com/
2. http://digilib.gmu.edu:8080/dspace/
3. http://digilib.gmu.edu:8080/dspace/handle/1920/7916
4. http://creativecommons.org/licenses/by-nc-nd/3.0/

1.2 September

REB Member: Make Review Process Educative, Not Regulatory (2012-09-01 08:35)

Dominique Rivière, an education researcher at the University of Toronto, reports that REB service left her somewhat less critical of the ethics-review process, but she still calls for significant reform.

[Dominique Rivière, "Looking from the Outside/In: Re-thinking Research Ethics Review." Journal of Academic Ethics 9, no. 3 (2011): 193–204. DOI: [1]10.1007/s10805-011-9139-y]

Rivière has had her share of ethics-committee frustrations. In the spring of 2007, she and colleauges submitted an ethics protocol that they expected would take 3-6 weeks to be approved. Instead, the prcocess took six months, leaving Rivière "with a decidedly critical view of the purpose and functioning of the institutional ethics review process." (194)

The next year, Rivière herself joined the REB, and, she reports,

> my perspective on research ethics review has changed ... somewhat. I'm not nearly as critical of the process as I had been when I was outside it: I now understand that the REB's requests for more information and documentation were so that they could make a well-informed decision about our protocol, not so that they could contain and constrain our project to fit a research model with which they were more familiar—and, therefore, more comfortable. Moreover, I've come to realize that many of the questions asked by the REB are exactly the questions that researchers should be already asking of themselves: for example, is the nature of the intended research relationship to the participants is one of "power over" (e.g. teacher-student)?; are their intended methods supported by the project's rationale?; is community consent desired

> or required before the research can begin?; is participant compensation appropriate (e.g. if so, in what form(s)? If not, why not?). As I reflect on the experience of seeking ethics approval for our multi-sited study, however, I realized that what was troublesome to me—though I couldn't articulate it in this way at the time—was that I felt the research ethics office wasn't asking the kinds of questions that the research team should have already been asking of ourselves: the kinds of questions that would help us to frame ethically the decisions that, as critical, social justice-oriented researchers, we would have to make "in the field." (195)

In particular, Rivière questions the standardized consent process imposed by REBs on all manner of research; she argues that "this particular process of consent does not fully let participants know what they are agreeing to . . ."

She proposes a more open-ended review process.

> What if research ethics review encouraged researchers to outline an ongoing "trust process", in addition to a consent process? That is, what if researchers were asked to outline those "public actions of the body" we would perform in order to earn participants' trust? What if we had to outline how we might mediate trust and credibility in face-to-face interactions with our research participants? This might help to create a productive tension between receiving ethics approval and being an ethical researcher: first, researchers would be attempting to articulate the ethical issues of their work as they understand them; and, second, researchers would then be able to inform their institutions' ethics review boards about those issues, thus making the review process educative, rather than regulatory. (202)

She concludes,

> I am advocating for the research ethics review process to support researchers differently as they reflect on the ethical dilemmas, tensions and issues that are specific to the nature and context of the research they are conducting, by deliberately troubling their assumed understandings of "informed consent", instead of expecting them to twist, bend, and otherwise reshape their research such that it conforms to an a priori set of definitions. (203)

That sounds nice, and it resembles some of the suggestions found in Martin Tolich and [2]Maureen H. Fitzgerald, "If Ethics Committees Were Designed For Ethnography," Journal of Empirical Research on Human Research Ethics 1 (2006): 71-78. But I would have liked Rivière to consider whether the structure of ethics committees and offices dictates their approach to ethics review.

First, there is the question of expertise. A committee drawn from across the university will lack deep [3]expertise on many of the proposasl before it. I think this explains some of the reliance on a priori definitions.

Second, Rivière hints that it was not the REB but the "research ethics office" that was responsible for much of the delay of her initial project and for asking the wrong questions. Does the rise of IRB and REB staff lead to inappropriate demands on researchers?

Third, and most significantly, Rivière suggests a dichonomy between the educative and the regulatory, but she does not ask whether moving from the latter to the former will need structural changes. Sociologists [4]Carol Heimer and JuLeigh Petty have argued–persuasively, I think–that the "bureaucratized research ethics" Rivière dislikes is a product of government policies, organizational interests, and professional self-interest. Unless IRBs and REBs are stripped of some of their coercive power, I wonder if we can expect any serious changes.

1. http://dx.doi.org/10.1007/s10805-011-9139-y
2. http://www.institutionalreviewblog.com/2008/03/maureen-fitzgeralds-ethics-project.html
3. http://www.institutionalreviewblog.com/search/label/expertise
4. http://www.institutionalreviewblog.com/2011/01/sociologists-find-irbs-serve.html

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AAUP Posts New IRB Report (2012-09-04 19:46)

The American Association of University Professors has posted "[1]Regulation of Research on Human Subjects: Academic Freedom and the Institutional Review Board," a report prepared by a subcommittee of the Committee A on Academic Freedom and Tenure. I served on that subcommittee, which was chaired by Professor Judith Jarvis Thomson of MIT.

The [2]AAUP press release explains,

> In July 2011, the federal government took what may be the first step toward the most substantial change in the regulations since 1981, issuing an advance notice of proposed rulemaking, or ANPRM. More than 1,100 individuals and associations have submitted formal comments.
>
> The AAUP report notes that “out of respect for liberty, it is normally expected that government regulation of behavior will consist in listing what is forbidden, all else being permitted.” The report goes on to suggest ways in which the regulations could be rewritten along these lines.

The Association welcomes comments on the report through September 28.

1. http://www.aaup.org/AAUP/comm/rep/A/irb.htm
2. http://www.aaup.org/AAUP/newsroom/2012PRs/irb.htm

Can an IRB Ban a Researcher? (2012-09-07 10:22)

In July, [1]the Sacramento Bee reported that the University of California, Davis, had ordered two doctors–J. Paul Muizelaar and Dr. Rudolph J. Schrot–"to halt all human research activity ’except as necessary to protect the safety and welfare of research participants.’" Schrot told the Bee that "To be banned from clinical research makes a career in academic medicine challenging, to say the least."

The Common Rule ([2]45 CFR 46.113) empowers IRBs to "suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects," but it does not explicitly empower them to ban a researcher from all research.

Curious about this case, I submitted a public records request to the university and received a copy of the [3]attachments to the letter sent by the university to the FDA, including–on page 134 of the PDF–a copy of the 14 October 2011 letter in which the UC Davis IRB office told the two doctors to "immediately cease and desist from any research activity in studies for which you serve as Principal Investigator or co-Principal Investigator" (emphasis in original) and to "cease participation on any human research activity" for which they were co-investigators. The letter did not

limit itself to the research described in 45 CFR 46.113, nor did it offer citation to federal or university regulations giving it the authority to make these demands.

Perhaps I am unfamiliar with some federal or university regulation or guidance empowering an IRB to ban a researcher from all human subjects research. If so, the UC Davis IRB missed an opportunity to educate me. If no such regulation exists, the IRB may have exceeded its authority in imposing this penalty. What we need is a [4]culture of legality in which IRBs explain their actions.

Meanwhile, the [5]Bee reports that the federal government is investigating the case an one of possibly improper patient care, not research misconduct.

1. http://www.sacbee.com/2012/07/22/4648415/2-uc-davis-neurosurgeons-accused.html
2. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.113
3. http://zacharyschrag.files.wordpress.com/2011/06/attachments-to-fda-letter-00056090.pdf
4. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html
5. http://www.sacbee.com/2012/09/06/4791800/federal-agency-probes-deaths-of.html

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Anonymous (2012-09-07 12:02:05)
An institution doesn't need a regulation in order to demand that an employee cease an activity, not least one that threatens the integrity and funding of institution.

Zachary M. Schrag (2012-09-07 12:50:54)
Yes, it really does, if it's committed to academic freedom and the rule of law. And the IRB is not the institution. A committee is only empowered to carry out the duties granted to it by the institution's governing board.

Anonymous (2012-09-07 14:06:37)
Academic freedom to experiment on people with terminal illnesses with disregard of the IRB, FDA, and so on? With all freedoms come responsibilities. They blew it.

True, "the IRB is not the institution". But if you really think that the letter telling them to cease all research wasn't written without the knowledge and approval of the university's GC and senior leadership, I have bridge in Brooklyn I can offer you at a great price.

Zachary M. Schrag (2012-09-07 14:17:45)
The UC Davis leadership and GC [1]couldn't control the police department. Why assume that the IRB chairs weren't going rogue as well?

1. http://www.theatlantic.com/politics/archive/2012/04/reports-reveal-two-new-scandals-in-the-pepper-spraying-at-uc-davis/256058/

OHRP Calls for 2013 SACHRP Nominations Without Announcing 2012 Appointments

(2012-09-09 19:56)

OHRP is [1]calling for nominations to fill two SACHRP positions that will open in 2013.

OHRP has not, to my knowledge, announced the new members for 2012, including replacements for two members whose terms expired in July.

How is the public to suggest appropriate names for 2013 when we do not know what qualifications the 2012 appointments will bring to the committee?

1. http://www.gpo.gov/fdsys/pkg/FR-2012-09-07/html/2012-22103.htm

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I Review van den Hoonaard, The Seduction of Ethics (2012-09-12 12:43)

Contemporary Sociology has published my review of Will C. van den Hoonaard's Seduction of Ethics, which I term "a powerful, combined-arms assault on the system of ethics review of the social sciences."

[Zachary M. Schrag, review of The Seduction of Ethics: Transforming the Social Sciences by Will C. van den Hoonaard, Contemporary Sociology: A Journal of Reviews 41, no. 5 (September 2012): 678–679, doi:[1]10.1177/0094306112457769oo.]

1. http://dx.doi.org/10.1177/0094306112457769oo

Could Guidance and Feedback Replace Rote Compliance? (2012-09-16 18:59)

Murray Dyck and Gary Allen, both of Griffith University in Australia, argue that "the review process should be an advisory and collegial one—not one that focuses on compliance, enforcement and gatekeeping."

[Murray Dyck and Gary Allen. "Is Mandatory Research Ethics Reviewing Ethical?" Journal of Medical Ethics (August 3, 2012), DOI: [1]10.1136/medethics-2011-100274.]

Dyck and Allen find that "mandatory IRB review procedures would not themselves reach the ethical standard expected of researchers."

- "Respect for Persons: Mandatory review is a clear failure to show respect for persons (researchers) because it presupposes that researchers cannot be trusted to design and implement research that respects the rights of participants unless researchers are made accountable to an IRB to do so (even though IRB procedures also presuppose the ethical integrity of the applications for ethical approval) . . .
- "Merit and Integrity: Mandatory multiple reviews of multisite research indicate that IRBs do not trust the merit and integrity of other IRBs and their failure to accept the judgment of other IRBs shows disrespect for other IRBs' members." . . .
- "Justice: IRBs often place what, at face value, is an unfair burden on researchers." . . .
- "Beneficence: . . . Although there is minimal empirical evidence that the oversight provided by IRBs is effective in protecting research participants from human rights abuse, there is clear evidence that IRB reviews impose tangible costs on society that greatly exceed even the costs in time and money that are expended in complying with IRB procedures."

Yet Dyck and Allen are not opposed to ethics review; they are opposed only to mandatory ethics review, and they suggest replacing it with a system of guidance and persuasion.

> Instead of promoting rote compliance with inflexible and universal rules, the role of an IRB should be to facilitate and resource the reflective practice of researchers. A simple, but significant, shift would be to move ethical review from approving a proposed project to providing guidance and feedback on submitted projects. An IRB may play a useful role in identifying ethical issues and suggesting how to deal with them, but otherwise, responsibility for research ethics needs to return to the researchers who use the feedback they receive in a reflective and project-appropriate way. Rather than policing compliance with standards that can have limited usefulness for some methods, participant populations and contexts, such an advisory review would aim to assist researchers in reflecting on the specific ethical challenges of their research.

Crucially, they argue, "There should be resources available to assist researchers during the planning, conduct, analysis and reporting of results. Institutions should establish networks of research ethics advisors—colleagues who can be approached for advice and support."

This is exactly what is missing from the current system: a network of people and published material to which researchers can turn for insight on their specific challenges. Mandatory review goes hand in hand with [2]mortifyingly stupid ethics training. An IRB focused on advice and support might be more likely to lure researchers with [3]guidance relevant to their particular projects.

1. http://dx.doi.org/10.1136/medethics-2011-100274
2. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
3. http://www.institutionalreviewblog.com/2008/04/michael-rowe-on-situational-ethics.html

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Fredericton to Host Summit on Research-Ethics Review Alternatives (2012-09-17 19:55)

Will C. van den Hoonaard, author of [1]The Seduction of Ethics, is organizing a conference to be held next month in Fredericton, New Brunswick, entitled "Ethics Rupture: An Invitational Summit about Alternatives to Research-Ethics Review."

[2]

The [3]conference site explains:

> Many scholars in the social sciences and humanities have noted the inadequacy of the current formal system of research-ethics review to fairly offer ethical consideration in light of their research needs. The formal system of ethics review has placed the social sciences (and some of the humanities research) in a precarious situation. The bio-medical conceptions of research on which the system relies is not up to the task to give discipline-appropriate advice to other fields.

> The time has come to convene an international summit to find alternative means to underscore the ethical approaches in social-science and humanities research. Alternative means would also stem the tide of the homogenization of the social sciences and the humanities and the pauperization of their methodologies brought on today by research-ethics regimes.
>
> The Ethics Rupture summit is a convocation of outstanding thinkers from a half-dozen countries who have substantially contributed to debates on these issues and who already have thought and written about viable alternatives. Because supporters of the prevailing formal research-ethics regimes are already given much air-time on official agendas, listservs, and policy conferences, the Summit aims at creating an environment that where thinkers can freely express new ideas without the distractions of having the presence of advocates of current formal ethics-review systems.

I plan to present a paper entitled, "Ethical Pluralism: Scholarly Societies and the Regulation of Research Ethics."

[18 September 2012: Edited to link to a more complete site.]

1. http://www.institutionalreviewblog.com/2012/09/i-review-van-den-hoonaard-seduction-of.html
2. http://wp.stu.ca/ethicsrupture/wp-content/uploads/2012/07/cropped-ethics_header-01.jpg
3. http://wp.stu.ca/ethicsrupture/

U of Illinois Launches Ethics CORE (2012-09-21 10:49)

The University of Illinois at Urbana-Champaign has officially launched Ethics CORE ([1]NationalEthicsCenter.org), an online resource for education in research ethics.

The [2]press release explains:

> (URBANA, Ill.) – The University of Illinois at Urbana-Champaign has announced the formal launch of an interactive online resource to help researchers and professionals in the sciences, engineering and mathematics incorporate ethical practices into their professional lives.
>
> Ethics CORE (NationalEthicsCenter.org), funded by the National Science Foundation, gathers and disseminates ethics resources, including educational curricula and online courses, reference materials, scholarly and research literature and resources available for use in Responsible Conduct of Research (RCR) education required by NSF and other funders of research. In addition, the site's interactive community offers a place where users can publish and share scholarship, discuss ethics-related issues for professionals and researchers and develop and share new course offerings.
>
> "From the outset, our goal has been to create a dynamic, one-stop environment where people can collaborate and discuss ethical questions and issues that arise on a daily basis," said C. K. Gunsalus, director of the National Center for Professional & Research Ethics, which has developed Ethics CORE. NCPRE is part of the University of Illinois' Coordinated Science Laboratory.
>
> "Ethics CORE aims to help people seamlessly integrate ethics into their daily behavior by providing a toolbox of resources to meet their varied needs," she said
>
> Ethics CORE resources available for open use include:

• 5,400 full-text articles and reports
• 250,000 peer-reviewed journal articles
• A full-text search capability for more than 45 professional society codes of ethics
• More than 250 catalogued and indexed RCR instructional and support materials sites with drill-down limit and search capabilities

A beta version of the site, which launched in 2011, has already attracted nearly 900 registered users from across the world.

Users are encouraged to share resources that they have developed, and researchers from around the country have contributed everything from videos to role-acting activities. An additional 300 people at a range of institutions are taking specialized RCR courses developed at the University of Washington. In addition, instructors at Arizona State University and Rochester Institute of Technology have taught a multi-institution suite of courses on sustainability ethics using custom multi-user games and simulation exercises that have all been deposited on the Ethics CORE site.

1. http://NationalEthicsCenter.org/
2. http://engineering.illinois.edu/news/2012/09/20/university-illinois-launches-online-ethics-resource-researchers-professionals

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Schrag Responds to Responses to Schrag (2012-09-25 11:23)

The [1]June 2012 issue of Research Ethics features four responses to my December 2011 essay, "[2]The Case Against Ethics Review in the Social Sciences." Three scholars based in Canada wrote a joint response, while three in Britain wrote individual replies. I am grateful to all of the respondents for their attention, kind words, and challenging critiques.

- Nicholls, Stuart G., Jamie Brehaut, and Raphae Saginur. “Social Science and Ethics Review: A Question of Practice Not Principle.” Research Ethics 8, no. 2 (June 2012): 71–78. [3]doi:10.1177/1747016112445435
- Hedgecoe, Adam. “The Problems of Presumed Isomorphism and the Ethics Review of Social Science: A Response to Schrag.” Research Ethics 8, no. 2 (June 2012): 79–86. [4]doi:10.1177/1747016112445437
- Jennings, Sean. “Response to Schrag: What Are Ethics Committees for Anyway? A Defence of Social Science Research Ethics Review.” Research Ethics 8, no. 2 (June 2012): 87–96. [5]doi:10.1177/1747016112445423
- Bond, Tim. “Ethical Imperialism or Ethical Mindfulness? Rethinking Ethical Review for Social Sciences.” Research Ethics 8, no. 2 (June 2012): 97–112. [6]doi:10.1177/1747016112445423

Since the responses overlap somewhat in their themes, I think it best for me to respond to them collectively.

Benefits

In my essay, I argued that "ethics review has few success stories." Two respondents reply by asserting that there are success stories; I just don’t know about them. Sean Jennings claims that "anyone who has worked with ethics

committees for any length of time has reason to believe that while there are many very good and ethical researchers, there are also a number who are just blind to significant ethical questions that their work gives rise to." And Tim Bond writes that "each year the review process [at the University of Bristol] has discovered and prevented a small number of potential situations in which participants were vulnerable to significant harm."

Neither respondent offers examples of such flawed proposals. I would suggest that this opacity is in itself a great flaw in the present system, for it prevents the kind of discussion of research ethics advocated by Stuart Nicholls, Jamie Brehaut, and Raphae Saginur, and instead leads ethics committees and resarchers to talk past each other. Somewhere out there, ethics committee members are shaking their heads over the researcher so blind to ethical questions that she didn't know you need signed consent forms from every barista who serves you coffee. If ethics committees rely on the "if you only knew" defense, they will never have such misguided beliefs challenged.

They will also fail to persuade researchers and critics like me of the need for ethics review. If Jennings and Bond were to write up in detail some of the cases in which ethics review prevented a flawed social science project from proceeding, they would have a much better chance of persuading me of the system's benefits, and they would provide researchers at large a chance to think through the ethics of similar projects before they ever face a committee. [7]Alexander Halavais has offered suggestions along these lines.

In the absence of evidence of ethics review's ability to protect people from harm, two responses offer alternative justifications. Nicholls et al. propose that ethics committees can serve as peer review bodies, denying funding and publication to "poorly conducted" research. They do not explain why these decisions should be made by interdisciplinary committees that may have no representatives from the researcher's discipline, rather than the disciplinary groups–funding panels, scholarly conferences and journals, and the like–that have peformed these functions for a century or so.

Bond suggests another justification for mandatory ethics review: he directs his committee to ask, "what is ethically required to ensure public trust in, and willingness to participate in, social science research"?

I am intrigued by this idea, but it raises many questions. Why does Bond think that the public is apt to distrust social scientists and refuse to participate in social science research? Why does he think ethics review builds that trust? As Bond himself notes, "Seeking written consent in cultural contexts where oral transactions are the accepted norm may actively communicate mistrust and alarm participants." Thus, some ethics review decisions work against the goal he sets for ethics review.

We could also test Bond's claims by comparing various regimes over time and space. Did the public trust social scientists more after ethics review was imposed in various countries? Did it trust them less in the United States after social science won broad exemptions in 1981, and more after review became stricter in the 1990s? Are people in countries without ethics review of the social science—e.g., France and Germany—less trustful? Obviously these are empirical questions, and again, I suggest the burden of proof is on the defenders of ethics review.

Finaly, how far is Bond willing to go with this argument? Would he require ethics review for marketers and, especially, journalists? We know that [8]some journalists abuse the public trust, but I know that Americans, at least, would consider mandatory ethics review of journalism an unconstitutional burden on the freedom of the press.

[9]David Hyman has argued that "there is no empirical evidence that IRBs have any benefit whatsoever." I disagree, for I have read many (well, several) accounts by researchers who, like Bond, are grateful to ethics committees for the guidance they offered. But those accounts are much harder to find than are stories of research damaged by inappopriate requirements. The evidence of an overall benefit from ethics review is thin, and the respondents have done little to bulk it up.

Costs

Just as they emphasizes the purported benefits of ethics review, the responses downplay the costs by labelling my arguments as merely pragmatic, not principled. Nicholls et al. argue that "it is not a principle that social science research should not undergo ethical review, but rather that the current process of ethical review can be inappropriate for some social science studies." Similiarly, Jennings argues that "Even if we grant that there are problems with the way that ethics review works in practice for social science, we can maintain that the appropriate response would be to improve the system of review, rather than scrap the system entirely."

I take this to mean that with enough time, money, and effort, ethics review of the social sciences could work a good deal better than it does now. I suppose I agree, and in that sense, my objections are indeed pragmatic rather than principled. But I don't think that distinction is as important as Jennings and Nicholls et al. charge.

I offer, as a comparison, the Constellation Program, a proposal to develop spacecraft that could send six-astronaut teams to the moon. In 2009, the [10]Review of U.S. Human Spaceflight Plans Committee concluded that while such a mission was possible, pursuing it would require the abandonment of more compelling projects, and that "if resources are not available to match established goals, new goals need to be adopted." This was not a rejection of Constellation on principle—a moon mission required no physical impossibilities, and it would achieve desirable results—but its pragmatic reasoning convinced the Obama administration to [11]scrap Constellation entirely. (Congress later revived portions.)

Similarly, with enough resources, ethics committees could perhaps be trained to review social sciences proposals with the same sensitivity that Nicholls et al. say they bring to cluster randomized trials. For example, [12]Philip Rubin and Joan Sieber have suggested that "each department [could] nominate to the IRB those of its members who have extensive and up-to-date methodological expertise and research experience. In turn, those members could assist faculty who teach methodology to include critical curriculum at the intersection of ethics and methodology. For this service, they should be compensated with release time from teaching and recognition in promotion decisions." I have no doubt that this would reduce the problems with ethics committees, but it would also require a substantial shift of resources away from both teaching and research, the primary functions of a university. Since governments and universities are unlikely to support this shift, new goals need to be adopted.

Exemplars

Nicholls et al. caution against "throwing the baby out with the bathwater." Having recently made a similar argument in the course of [13]defending scholarly editing, I am sympathetic to this stance. But in the case of ethics review of the social sciences, it can be awfully hard to find the baby.

In accusing me of "assumed isomorphism," Adam Hedgecoe suggests two, competing answers to this problem. At one level, he suggests that my critique applies only to "one, specific, jurisdiction (i.e. the US IRB system)." That is, the United States has the bathwater, and everyone else has the baby.

Hedgecoe acknowledges that I provided examples of dirty bathwater from Canada, the United Kingdom, and Australia, but thinks five are too few. How many are enough?

As Hedgecoe knows from reading The Seduction of Ethics, Will van den Hoonaard has compiled plenty of horror stories from Canada. Robert Dingwall is probably the best source for British versions, and Hedgecoe's compatriots, Bond and Jennings, had no trouble recognizing the British variants of the problems I outlined. For example, Hedgecoe seems to think that "institutional protection" is a mission unique to U.S. IRBs. He may want to consult Bond, whose ethics committee is charged with protecting not only research participants and academic freedom, but also "[14]the reputation of the University [of Bristol] as a centre for properly conducted, high quality research."

For Australia, I have noted works by [15]Robert Cribb, [16]Greg Bamber and Jennifer Sappey, and [17]Anthony Langlois, as well as Australia's [18]National Statement on Ethical Conduct in Human Research.

Finally, since Hedgecoe thinks that we should trust ethnographic observations of ethics committees at work, I would refer him to the findings of [19]
Maureen H. Fitzgerald, Paul A. Phillips, and Elisa Yule, who observed "29 ethics committee meetings in five countries (13 in Australia, 2 in Canada, 3 in New Zealand, 4 in the United Kingdom, and 7 in the United States)" and interviewed "213 people (79 in Australia, 52 in Canada, 16 in New Zealand, 15 in the United Kingdom, and 51 in the United States) from a total of 37 cities or metropolitan areas." They found that

> Despite the fact that the ethics review process in each of the countries involved is based on different sets of regulations or guidelines and laws, our observations suggest that the actual meetings and the narratives within them are similar enough in this case to deal with our body of data as one body of data. Thus, although there are differences across countries and committees, we focus here on a remarkable commonality, the narratives involved. When asked by some committee members after the meetings how they compared to other committees, we often joked that if we could modify the accents of the people involved and a few of the acronyms and terms, people probably could not tell in which country the meeting occurred.

Elsewhere, [20]Fitzgerald and Martin Tolich have written 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."

Thus, Hedgecoe is quite right that my critique follows other scholars in regarding the differences among Anglophone counties as less striking than the similarities. But the isomorphism is observed, not assumed. The bathwater, while filthiest in the United States, is everywhere.

Hedgecoe's second answer is to find a baby within the British bath; he claims that National Health Service (NHS) RECs are "capable of reviewing qualitative social science in a reasonable and supportive manner." He is correct that I found his article an [21]unpersuasive rebuttal of the work of [22]Sue Richardson and Miriam McMullan, who noted sociologists' complaints about the same committees. Perhaps a longer account of his observations would yield examples of serious ethical lapses set right by an NHS committee.

I do share Hedgecoe's wish to find working variants of the ethics review system. Maybe [23]Macquarie University. Maybe [24]Macalester College. But these are at best islands of sanity in a sea of madness. Perhaps my final challenge to my readers should have been to find me an institution whose researchers in the social sciences and humanities broadly agree that the ethics review system is doing more good than harm, and where few scholars are outraged by the mistreatment they have received.

Coercion

In the final sentence of my article, I referred to the "coercive nature of ethics review." More eloquently than I, Bond expresses this central problem. What he wants is

> not primarily a coercive relationship but one that is supported by reviewers modelling the ethical qualities they seek to foster in the researchers and working in dialogue with researchers in a timely fashion.

> Asking the right questions in Socratic style to promote the ethical development of researchers and their engagement with ethical issues that they face has many advantages. It acknowledges the characteristic ethical commitment of most social science researchers rather than undermines it. Listening to the responses to questions with sufficient humility to empathically engage with and demonstrate respect for the researchers, and especially their subjects, provides the best possible basis for constructive outcomes to ethical review.

Yet Bond recognizes that "the legal framework underpinning ethical review in some of the jurisdictions is so protective of the independence of the review process that it prevents any meaningful communication between applicant and reviewer during the research. This may be a further factor that accounts for some of Schrag's cases. Some systems of review appear to be inherently coercive by design."

I would put that last bit more strongly: almost all systems of review with which I am familiar appear to be inherently coercive by design. And it is ethics committees' reliance on coercion, rather than suasion, that is at the root of the problem, that robs committees of the "sufficient humility" to do their jobs.

[25]Murray Dyck and Gary Allen recently made this point well, when they called for moving "ethical review from approving a proposed project to providing guidance and feedback on submitted projects," that is, reducing ethics committees to advisory bodies. This is consistent with Bond's call for "greater emphasis on suitably thorough and wide-ranging ethics training, relatively limited review at the proposal stage but greater availability of ethical support as the research proceeds, rather than a high stakes review prior to starting the research."

I suppose, then, that my article was incompletely titled. It is mandatory ethics review that should be scrapped. If ethics committees want researchers' respect, let them earn it.

1. http://rea.sagepub.com/content/8/2.toc
2. http://sageinsight.wordpress.com/2012/07/10/the-case-against-ethics-review-in-the-social-sciences/
3. http://dx.doi.org/10.1177/1747016112445435
4. http://dx.doi.org/10.1177/1747016112445437
5. http://dx.doi.org/10.1177/1747016112445423
6. http://dx.doi.org/10.1177/1747016112445423
7. http://www.institutionalreviewblog.com/2011/12/halavais-calls-for-open-publication-of.html
8. http://www.pbs.org/wgbh/pages/frontline/murdochs-scandal/
9. http://www.law.northwestern.edu/lawreview/v101/n2/749/LR101n2Hyman.pdf
10. http://www.nasa.gov/offices/hsf/meetings/10_22_pressconference.html
11. http://www.nytimes.com/2010/10/01/science/space/01nasa.html
12. http://dx.doi.org/10.1525/jer.2006.1.4.1
13. http://theaporetic.com/?p=2776
14. http://www.bristol.ac.uk/red/research-governance/practice-training/researchethicspolicy.pdf
15. http://www.ncbi.nlm.nih.gov/pubmed/15685785
16. http://www.institutionalreviewblog.com/2007/02/australian.html
17. http://www.institutionalreviewblog.com/2011/05/australian-political-scientist-causing.html
18. http://www.nhmrc.gov.au/guidelines/publications/e72
19. http://dx.doi.org/10.1207/s15327019eb1604_7
20. http://dx.doi.org/10.1525/jer.2006.1.2.71
21. http://www.institutionalreviewblog.com/2009/07/defense-of-recs.html
22. http://soc.sagepub.com/content/41/6/1115.long
23. http://www.institutionalreviewblog.com/2007/08/macquaries-respect-for-expertise.html
24. http://www.institutionalreviewblog.com/2012/07/can-macalesters-divisional-review-work.html
25. http://www.institutionalreviewblog.com/2012/09/could-guidance-and-feedback-replace.html

PCM (2012-10-10 01:17:06)
Excellent thought-provoking post.

Adam Hedgecoe (2012-10-23 04:13:42)
Zachary, how does this work?:

“Hedgecoe seems to think that ‘institutional protection’ is a mission unique to U.S. IRBs”

even tho’ I explicitly say:

“the University REC system in the UK…does resemble the US IRB system in terms of institutional affiliations, and as a result we might expect institutional protection to play a role in these RECs’ decisions” (p.81).

Are you doing your ’misrepresenting other people to support your own position’ thing again?

a.h.

Zachary M. Schrag (2012-10-23 21:14:55)
Thanks for this comment.

I fear I was thrown off by the conditional phrasing of that sentence in your essay.

I gather from your comment that what you really meant is not that "we might expect institutional protection to play a role in these RECs’ decisions," but rather that "institutional protection plays a role in these RECs’ decisions." If so, I appreciate your recognition of this transnational isomorphism of university ethics committees.

Adam Hedgecoe (2012-10-24 06:12:57)
While the UK UREC sector is under-researched (not least of all because of isomorphic ’all UK RECs, UREC or NHS, are the same’ thinking) there is some data out there suggesting that yes, these committees do base some decisions on ’institutional protection’ ground. I made this point at the end of my 2008 _Sociology _ paper when I suggested that “it has largely escaped the notice of those commenting on the rise of ethics review in UK social science that British university RECs _are _ institutionally located, and there is already some preliminary anecdotal evidence that such committees are prepared to act against researchers investigating potentially controversial topics..."

I’m not convinced that this means that UK URECs are isomorphic with US university IRBs in all other characteristics, since for me that’s an empirical question (rather than an assumed item of faith).

Zachary M. Schrag (2012-10-24 22:24:48)
Thanks for this comment.

I agree that this would be an interesting area of research. Perhaps it could begin at your own Cardiff University, which, like Bristol, [1]instructs its REC to protect "the reputation of the University as a centre for properly conducted and high-quality research." Who came up with these instructions?

Institutional protection has its place. Scholars do represent not only themselves but also their profession and their institution when they go out into the world. But a concern for a university’s reputation can fade into a disregard for academic freedom, as in the appalling essay by Jonathan Moss that you so aptly quoted in your published comments on my piece. I would therefore prefer to see Cardiff and other universities instruct their ethics boards to protect their universities’ reputations as centers "for properly conducted and high-quality research and as bastions of academic freedom."

1. http://www.cardiff.ac.uk/racdv/ethics/urec/URECProcedures.doc

Adam Hedgecoe (2012-10-25 03:45:07)
Pointing at Cardiff regs. is a red herring, not least of all since I was not here when they were drawn up.

The sociologically interesting question is not "why does Cardiff has this in its REC regs" but rather "Why is this a common feature in a large number of UK Universities, and what processes have driven it." The answer (I'm working on a paper with Robert Dingwell on this at the moment)centres on the rise of 'new managerialism' in the UK HE sector in the past 20 years, and other broader institutional factors.

For me, the interesting question is structural rather than about individual organisations.

My own view on institutional protection is that it has NO place in the proper functioning of a body set up to protect human subjects. I accept that universities will act to restrict research on 'problematic' (i.e. embarrassing) research but they should be forced to do this openly - i.e. through management routes - thereby opening themselves up to clear criticism, rather than sneaking it in through RECs.

SACHRP Still Lacks Social Scientists (2012-09-29 21:31)

OHRP has announced new members of the Secretary's Advisory Committee on Human Research Protections (SACHRP):

- Chair Designate: Jeffrey R. Botkin, M.D., M.P.H., Professor of Pediatrics and Medical Ethics, Associate Vice President for Research, University of Utah. Term: October 15, 2012 - October 15, 2016
- Thomas Eissenberg, Ph.D., Professor, Department of Psychology and Institute for Drug and Alcohol Studies; Director, Clinical Behavioral Pharmacology Laboratory, Virginia Commonwealth University. Term: October 9, 2012 - October 9, 2016
- Owen Garrick, M.D., M.B.A., President and CEO, Bridge Clinical Research, Inc. Term: October 15, 2012 - October 15, 2016
- Pilar Ossorio, J.D., Ph.D., Associate Professor of Law and Bioethics, University of Wisconsin-Madison. Term: October 15, 2012 - October 15, 2016

[1]Eissenberg's PhD is in Experimental Psychology, and his "primary area of research is the behavioral pharmacology of drugs of abuse, focusing primarily on nicotine/tobacco." [2]Ossorio's PhD is in Microbiology and Immunology. So that's four new members with background in biomedical research of one kind or another, none whose primary interests are in non-medical research.

1. http://www.psychology.vcu.edu/people/eissenberg.shtml
2. http://www.law.wisc.edu/profiles/pnossorio@wisc.edu

1.3 October

Mark Israel Questions Lists of Vulnerabilities (2012-10-10 10:22)

Mark Israel, Winthrop Professor of Law at the University of Western Australia, sees problems with mandatory ethics review but doubts that they can be fixed by limiting such review to projects involving "specific vulnerable groups."

[Mark Israel, “Rolling Back the Bureaucracies of Ethics Review.” Journal of Medical Ethics (October 2, 2012), [1]DOI:10.1136/medethics-2012-100942.]

Israel’s essay responds to [2]Murray Dyck and Gary Allen, who hope to "move ethical review from approving a proposed project to providing guidance and feedback on submitted projects." Israel acknowledges the flaws in the present system, including, in his words, "the numbers of committees claiming jurisdiction of any particular piece of research are expanding and it is frequently left to the researcher to sort through competing and incompatible rulings; research ethics committees appear to be used as gatekeepers by their institutional hosts with the discourses of ethics deployed to make legitimate a far less laudable desire of avoiding external scrutiny; some of the more dubious research projects evade review either by concealing their true intent from committees or by falling outside the jurisdiction of review bodies."

Israel does, however, take issue with the suggestion by Dyck and Allen that while ethics review should not be compulsory for most projects, "There may be cases where prior ethical review should be mandated, such as in the case of research with specific vulnerable groups (possibly including prisoners, refugees, persons not capable of providing consent, unborn foetuses, and dispossessed cultural groups) and specific areas of research (including work intended to expose illegal behaviour) . . ." Israel notes that while policies in Canada, the United Kingdom, and the United States all rely on such lists, "the issue of powerlessness is relative and points to the unequal relationship among researchers, research participants and various other stakeholders. This cannot be captured by a list."

This is indeed true, but it can support an argument for greater or diminished ethics-committee jurisdiction. Israel seems to think that the blurry edges of vulnerability argue for sweeping most research into mandatory review. I see them as a challenge to the wisdom of empowering inexpert review bodies rather than researchers to decide who is vulnerable to what kinds of research.

As an example of the problem of letting committees decide who is vulnerable and what is dangerous, I would note the striking comments posted to this blog by medical anthropologist [3]Kimberly Sue:

> One major concern was that my questions might increase the risk of cravings (for drugs)– one of those questions [the IRB] 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 . . .
>
> I researched the question about craving by talking to a woman who is advising my project, who is many years in recovery from opiates. She scoffed at the notion that my questions would cause drug cravings more than what she encounters every day in the world. Just the thought of the upcoming weekend, seeing someone’s protruding vein on an arm, passing by a sign on a freeway where she had once bought drugs–all of these can cause cravings. Having a cravings, of course, does not necessarily mean someone will go out and use. It’s patronizing and out of touch with reality for the people on the

IRB to think that my research questions are a significant risk for increased drug use.

1. http://dx.doi.org/10.1136/medethics-2012-100942
2. http://www.institutionalreviewblog.com/2012/09/could-guidance-and-feedback-replace.html
3. http://www.institutionalreviewblog.com/2012/08/irbs-impeded-harvard-dissertation-on.html

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IRB Demands and Forbids that Survey Researchers Collect E-Mail Addresses (2012-10-23 22:50)

Andrew Gelman revisits IRB nightmares at [1]Statistical Modeling, Causal Inference, and Social Science.

He links to [2]Andrew Perrin's lament:

> I just got back a response from our IRB asking for changes to a protocol for my semiannual telephone poll of NC voters. Note the "semiannual" – essentially the same poll, with the same protocol, is submitted twice a year. And twice a year, like clockwork, the ethics cops at the IRB take a break from deciding whether or not radioactive isotopes can be administered to prison populations to cure restless-leg syndrome to dream up some fancy new way in which participating in an automated telephone poll might cause harm.
>
> Last year, it was that people needed an email address to contact if they had questions about their rights as "subjects." This year — it was that if they were to take advantage of said email address, then we would have their email address, which could cause a breach of confidentiality.
>
> These people are nuts. Grr.

Gelman then adds another story.

> Recently a high school student contacted me about a research project he has, involving online surveys. He had some interesting ideas and it looked like a great project. But it might never get done. Why? His high school has no IRB. But he can't do it through the Columbia IRB because he's not a Columbia student (and it's his project, not mine, so it doesn't help that I work here.)

Gelman concludes, "Bottom line: Everybody's afraid of getting sued. That's the problem with living in a country that's run by lawyers."

Two points. First, it's not clear to me why the high school student would have any trouble. If he's not receiving federal funds and doesn't live in a state with crazy unconstitutional laws like Virginia's, who's to stop him from running his surveys?

Second, I think Gelman is wrong to blame IRB troubles on lawyers. The regulations were written by medical

researchers who ignored the objections of lawyers (notably HEW Deputy General Counsel Peter Hamilton) and thus failed to adhere to statutory limits. To fix them, we may need more lawyers, not fewer.

1. http://andrewgelman.com/2012/10/irb-nightmares/
2. http://scatter.wordpress.com/2012/09/07/aaup-new-report-on-irbs-and-academic-freedom/#comment-14040

I Review Stark, Behind Closed Doors (2012-10-25 08:57)

The American Journal of Sociology has published my review of Laura Stark's Behind Closed Doors. I describe it as an "illuminating account of how ethics review really works," but note that "Stark's reluctance to condemn [IRB] behavior sets her apart from other observers of IRBs in action" and that it is "a stretch for Stark to claim that today's IRBs use 'a decision-making model that stabilized in the 1950s and 1960s.'"

[Zachary M. Schrag, Review of Behind Closed Doors: IRBs and the Making of Ethical Research by Laura Stark. Chicago: University of Chicago Press, 2012. Pp. Viii+229. $85.00 (cloth); $27.50 (paper)." American Journal of Sociology 118, no. 2 (September 2012): 494–496. [1]www.jstor.org/stable/10.1086/664671]

For my comments on Stark's dissertation, on which the book is based, see "[2]How IRBs Decide–Badly: A Comment on Laura Stark's 'Morality in Science.'"

1. http://www.jstor.org/stable/10.1086/664671
2. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html

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One Year Since ANPRM Comment Deadline (2012-10-26 16:20)

Today marks the first anniversary of the deadline for comments on the ANPRM. The federal government received [1]more than 1100 comments in response to its proposals and queries. I have heard nothing official, and only vague and contradictory rumors, about what progress, if any, has taken place in the past year.

Meanwhile, I am attending Will C. van den Hoonaard's [2]Ethics Rupture conference, and I am delighted to meet in person so many people with whom I have corresponded and whose work I have read. But I am saddened to hear Canadian scholars' frustration that the revision of the TCPS has not done more to allow them to conduct research according to the ethical and methodological standards of their disciplines.

1. http://www.regulations.gov/#!docketDetail;D=HHS-OPHS-2011-0005
2. http://wp.stu.ca/ethicsrupture/

New Zealand Offers Voluntary Ethics Review—for Some (2012-10-27 14:32)

At the Ethics Rupture conference, Martin Tolich described his work as convenor of the [1]New Zealand Ethics Committee, described on its site as "a national ethics advisory committee, based in Dunedin, serving any researcher not eligible for health or institutional ethics review."

Tolich listed several innovations, the boldest of which is the voluntary nature of the review. "No researcher is mandated to submit his or her proposal to NZEC," the site explains."It is a voluntary service and fees are based on

[2]koha." If the committee wants to attract proposals, it will have to persuade researchers of its wisdom, rather than threatening them with penalties.

New Zealand researchers affiliated with health institutions or universities are still stuck with mandatory review. But it will be fascinating to see what ethics review looks like when it is no longer mandatory.

1. http://www.nzethics.com/
2. http://www.otago.ac.nz/administration/policies/otago003233.html

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Farewell, Fredericton! (2012-10-29 16:46)

I made it home from the Ethics Rupture conference in time to defend my basement against Hurricane Sandy.

It was delightful to meet so many scholars–several of whom have been cited in this blog over the years–with such deep knowledge of the problems of ethics review and creative ideas for improving it.

The conference was recorded, and a podcast should appear before too long. Also, we hope to publish a conference volume. As time permits, I will blog some of the things I learned there.

I thank all those who organized and hosted the conference, especially Will van den Hoonaard.

U of Sheffield REC Suspended Professor for Discussing Research (2012-10-29 16:47)

The Times Higher Education reports that in 2010, the director of research in the University of Sheffield Management School told Professor Stuart Macdonald to suspend his research, even though the professor had done nothing but mention another professor's research during a "discussion on research ethics and integrity."

[Paul Jump, "[1]Found guilty until proven innocent over unapproved research claims," Times Higher Education, 25 October 2012.]

The story reports, "Fifteen days later, [Macdonald] received an email from the chair of the research ethics committee, Richard Jenkins, saying a 'misunderstanding' had occurred, although he was offered no apology or further explanation."

Macdonald filed a formal complaint about his treatment by the REC, but it was dismissed.

The case echoes the experience of [2]Bernadette McCauley, who also received an order to suspend all research from an ethics committee that had no idea of what it was doing.

1. http://www.timeshighereducation.co.uk/story.asp?sectioncode=26&storycode=421600
2. http://www.historians.org/perspectives/issues/2006/0602/0602new2.cfm

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Health Researchers Learn that Ethics Review Really Is Creepy (2012-10-30 10:07)

Three Canadian scholars with backgrounds in various approaches to health research and bioethics find that, contrary to their expectations, many REB members and staffers believe that "ethics creep" is real. The authors have collected

interesting thoughts from REB staff and members, but the authors' analysis and their own proposals for reform are unclear.

[Adrian Guta, Stephanie A. Nixon, and Mike G. Wilson, "Resisting the Seduction of 'Ethics Creep': Using Foucault to Surface Complexity and Contradiction in Research Ethics Review," Social Science & Medicine available online 25 September 2012, DOI: [1]10.1016/j.socscimed.2012.09.019.]

Misunderstanding the Critique

The article begins with a discussion of the scholarly literature surrounding ethics review. Guta et al. have assembled an impressive bibliography, and they acknowledge social scientists' widespread dissatisfaction, but they don't fully understand the critique.

For one thing, they misdate by decades the beginnings of scholars' complaints. For example, they write, "the concept of ethics creep has been linked to the erosion of academic freedom. This claim was first advanced by Haggerty (2004) . . . ." Haggerty's article is great, but back in 1966, the Society for the Study of Social Problems warned that [2]"the power vested in such committees could be used to encroach upon academic freedom," and ever since social scientists have voiced similar concerns.

Second, Guta et al. don't seem to understand the concept of critical inquiry. "Do we not have a shared interest in promoting research that does not harm (in the broadest sense) participants?" they ask. No, we don't, or at least, that's not all we have. As TCPS2 explains, "some research, involving critical assessments of public, political or corporate institutions and associated public figures, for example, may be legitimately critical and/or opposed to the welfare of those individuals in a position of power, and may cause them some harm."

Third, Guta et al. think that ethics review is comparable to peer review, noting "We are aware of the many documented examples of thoughtless and ineffective ethics reviews, along with other less discussed, but equally ineffective academic processes such as grant reviews and manuscript reviews." Later, they assert that "ethics review is similar to funding review, and we would add many other forms of 'examination' on which the academe is based" and that "many researchers will end up sitting on an REB/IRB at some point."

Such statements ignore important differences that have been well articulated by critics. For example, Charles Bosk, whom they cite, has described ethics review as "[3]faux peer review" on the grounds that key decisions are made not by peer researchers, but by professional staff. Nor do they address the disciplinary imbalances among researchers who do serve on ethics committees, a point raise by Will van den Hoonaard in The Seduction of Ethics.

Based on these incomplete understandings of scholarship they cite, Guta et al. seem to have begun their research thinking that critiques of ethics review are overstated. They decided to ask "how ethics creep is experienced from the perspective of REB/IRB members and staff . . ."

A Taste of Ethics Creep

In trying to investigate the issue, Guta et al. got a taste of the obstacles ethics review can impose:

> We identified 18 REB/IRBs to sample and, of those, we successfully recruited from a total of 24 participants from 7 of them (with 1 participants recruited per REB/IRB). Of the original 18 REB/IRBs, one declined outright stating lack of interest, another said they do not review the type of research we were

> interested in and so were ineligible, a third required us to first go through an ethics review at their home institution and then declined to participate after we had received ethics approval, and a fourth told us we would have to add a researcher from their institution as a co-investigator, which we declined.

Despite these obstacles, the authors were able to interview 24 REB members, staffers, and "other key informants working in ethics policy reform" about "their experiences reviewing protocols that used a community-engaged approach," though they found people more eager to speak "about how their REB/IRB reviews research in general."

Some had good things to say about what they are doing, or at least about what they would like to do. As one board member put it, "One of our goals is to build capacity in our community. That is something we're looking for. Are you going to be hiring anybody in the community to do this work with you? Are you going to be training anybody? We see it as positive, something we're looking for."

But the researchers also heard about the system's flaws. "To the research team's surprise," they write, REB members and staffers acknolwedged the existence of "ethics creep." Staffers complained that "I think the focus is really shifted from ethics to risk management" and "I spend all of my time enforcing compliance which is not what I thought I was hired to do." Another noted, "The ethics creep is always there. I think we try to fix it on a regular basis, always having discussions about, are we going too far on this, taking the pulse, you know . . ."

Board members concede that researchers find them inaccessible, and that electronic submission can make things worse, both by limiting the amount researchers can write and raising the false expectation of quick turnaround. Staffers and members agree that audits from above reduces their flexibility. They feel they lack time to do their job, and that if they manage to voice a concern, they will be chastised for "slowing down production of this research [and] preventing this university from obtaining its funding." Yet they cannot imagine an alternative.

Guta et al. conclude that ethics creep is real, and that it is driven by multiple factors, including

> the growing needs of researchers who keep presenting REB/IRBs with new methods and designs, and by institutional strategies that increasingly rely on research funding dollars. There is a simultaneous growing and retreating of ethics review as it expands into new terrain while losing control of its traditional domain. While ethics review may be asking more of researchers working in communities, the pressures of compliance monitoring may be resulting in a system too overburdened to ask basic questions about risk and harm (Lidz et al., 2012). This leaves many REB/IRBs struggling to manage growing expectations from researchers in the face of budget and staffing cuts, while at the same time being required to meet regulatory requirements imposed from outside the academy. This tension serves to create an adversarial relationship between researchers and REB/IRBs who are both struggling to stay afloat in the wake of changes to university cultures and expectations.

Unclear Alternatives

Despite these findings, they go on to belittle the complaints of researchers:

> While we are confident in our assertion, we struggle to make sense of why this has become such a divisive issue in the academy. We are reminded that ethics review is similar to funding review (Hedgecoe, 2008, 880), and we would add many other forms of 'examination' on which the academe is based. Yet, there

> has been far less concern raised over these issues. Borrowing language from van der Hoonaard (2001) and Fitzgerald (2005), we ask; has ethics creep itself become a “moral panic”?

Rather than answer that question with the evidence they have assembled, Guta et al. present critics of ethics review as privileged professors who, if they don’t like restrictions on their research, should abandon their precious attachment to facts:

> We question whether ethics creep has become a repressive hypothesis which belies the complexity of the phenomenon it purports to explain, and, if so, who benefits? When researchers raise claims of censorship from REB/IRBs, they mean restrictions on their freedom to speak in particular ways; that is, to speak through the authoritative voice of empirical evidence, which is greatly privileged within the neoliberal system that promotes evidence-based medicine, education, and policy. There is little stopping academics from sharing their views through formats that do not require ethics review (e.g., commentaries, theoretical work), but the voice of the funded empiricist has become the dominant voice in the Canadian academy.

Guta et. al (who themselves received funding from the Canadian Institutes of Health Research) conclude with a condemnation of "well-intentioned" attempts "to replace one form of governance with another, while continuing to stoke the furnace that fuels the academic industrial complex." Instead, they "encourage greater discussion about how to (re)imagine the ethical researcher in today’s academic industrial complex." If there is a difference in those two approaches, I was unable to discern it.

The essay is heavy in Foucauldian jargon, and I may have missed some theoretical niceties while listening for that "authoritative voice of empirical evidence."

1. http://dx.doi.org/10.1016/j.socscimed.2012.09.019
2. http://www.jstor.org/stable/799157
3. http://www.institutionalreviewblog.com/2008/08/reform-or-revolution-comment-on-bosk.html

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College Freshmen Don’t Mind Research Use of Public Facebook Profiles (2012-10-30 10:21)

An interdisciplinary team of researchers "investigated publicly available Facebook profiles of freshmen undergraduate students within one large state university Facebook network" and invited 188 of those freshmen to be interviewed for a health study. At the end of the interview, they told the freshmen that they had been selected using their public Facebook profiles. "Participant responses included endorsement (19.7 %), fine (36.4 %), neutral (28.8 %), uneasy (9.1 %), and concerned (6.1 %)." The researchers acknowledge that 6 percent minority but conclude that "publicly available Facebook profiles of older adolescents are viewed as public spaces by both the adolescents themselves as well as the legal system."

[Moreno, Megan A., Alison Grant, Lauren Kacvinsky, Peter Moreno, and Michael Fleming. “Older Adolescents’ Views Regarding Participation in Facebook Research.” Journal of Adolescent Health 51, no. 5 (November 2012): 439–444. [1]doi:10.1016/j.jadohealth.2012.02.001]

1. http://dx.doi.org/10.1016/j.jadohealth.2012.02.001

1.4 November

What Has OHRP Told Huron It Hasn't Told Me? (2012-11-02 08:21)

The Huron Consulting Group is advertising a free webinar on November 7 entitled "[1]OHRP Regulatory Interpretations That You Need To Know, But Have Never Been Told." The press release explains:

> The Health and Human Services (HHS) human subjects regulations aren't always clear-cut and often times Institutional Review Boards (IRBs) and researchers struggle with how to interpret them. During this webinar, the presenters will share the knowledge Huron has gained through communications with Office for Human Research Protections (OHRP) about topics such as:
>
> - How to handle "protocol exceptions for a single subject"
> - When an unanticipated problem involving risks to subjects or others does not have to be reported to OHRP
> - Whether the IRB has to require the submission of the names of all study staff on a research study
> - When Subpart C does not apply to a subject who becomes incarcerated

I am troubled by the premise of this webinar: that OHRP has passed on important information to a private consulting firm without posting it for public use. For some topics, this may be puffery by Huron. For example, OHRP has issued public guidance on "[2]What happens if a human subject becomes a prisoner during the course of a research study?" But I don't know of similar guidance on topics like "protocol exceptions for a single subject." If OHRP has in fact made such regulatory interpretations, why aren't they on its website?

1. http://eon.businesswire.com/news/eon/20120914005057/en/huron/pharmaceutical/medical-device
2. http://answers.hhs.gov/ohrp/questions/7243

Is Boston College Still Clueless about Oral History? (2012-11-05 15:54)

H-Oralhist is running a thread of responses to an oral historian who is seeking IRB approval. [1]One response came from Jillian Maxey, a Ph.D. candidate in Comparative Theology at Boston College.

She writes,

> I am working through my IRB proposal right now. I am interviewing key scholars in my field and will be identifying them by name in my dissertation. One person to whom I spoke who serves on the IRB balked at this at first. When I insisted that it was necessary she gave me some tips for articulating the need to the IRB. I'm just wondering if anyone has experience with this or knows of any oral history publications that name participants that I could use to backup my proposal.

Can it be that a year and a half into an [2]international legal controversy involving oral history recordings stored at Boston College, its IRB still doesn't know that oral historians identify their narrators by name? If so, that's all the more reason to think that [3]IRB oversight is not the right response to the Boston College case.

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=1211&week=a&msg=CEPhUXMiGx8%2BnO0KyUxO3Q&user=&pw=
2. http://bostoncollegesubpoena.wordpress.com/
3. http://www.boston.com/bostonglobe/editorial_opinion/letters/articles/2011/05/31/board_oversight_is_no_safeguard/

Meyer: "IRB Review Has Only One Step" (2012-11-26 09:17)

Writing on Bill of Health, the blog of the Petrie-Flom Center, Michelle Meyer argues that while human subjects "regulations in theory establish three risk-based tiers of review — human subjects research (HSR) otherwise subject to IRB review that the regulations nevertheless exempt; HSR that is eligible for expedited review; and HSR that requires review by a fully convened IRB (everything else) — in practice, the first two tiers tend to collapse into the third. In this sense, and now I borrow from Matthew Stephenson and Adrian Vermeule, IRB review has only one step."

[Meyer, Michelle. "Exempt Research & Expedited IRB Review: Curb Your Enthusiasm |." Bill of Health, October 22, 2012. [1]https://blogs.law.harvard.edu/billofhealth/2012/10/22/exempt-human-subjects-research-expedited-irb-review-curb-your-enthusiasm/]

I think this implies that even projects that are not federally funded, that don't meet the regulatory definition of human subjects research, or that fit one of the exemption categories are apt to go to full board review.

While it's easy enough to find [2]examples of projects that suffered more scrutiny than required by the regulations, I would note that the exempt and expedited categories remain large. For example, the [3]University of Michigan reports that only 11 percent of projects brought to the Health Sciences and Behavioral Sciences Institutional Review Boards required full review. (Table 4)

1. https://blogs.law.harvard.edu/billofhealth/2012/10/22/exempt-human-subjects-research-expedited-irb-review-curb-your-enthusiasm
2. http://www.institutionalreviewblog.com/2012/07/irb-sought-to-monitor-interviews-with.html
3. http://ur.umich.edu/1011/Jun20_11/2437-report-on-investigator

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Tolich Launches TEAR: The Ethics Application Repository (2012-11-27 14:39)

Professor Martin Tolich of the University of Otago (New Zealand) has launched [1]TEAR: The Ethics Application Repository.

The site explains:

> TEAR is long overdue. Few novice IRB (ethics committee) applications are approved on their first reading leading to multiple resubmissions delaying the commencement of research. Novices forced to reinvent the ethics wheel from scratch, creates, at best, a fear of dealing with the processes around ethics

> rather than engaging in thinking about ethical principles. At worst, many supervisors get students to avoid IRB review and conduct secondary analysis. The latter students fail to learn how to think ethically. What they do learn is ethical cynicism: IRBs are to be avoided if possible.
>
> TEAR sets out to break this cycle of fear and avoidance facilitating better relationships between researchers and their IRBs in the short and long term. Current practice sees IRBs as a singular compliance moment in a linear process. TEAR promotes a new role for IRBs: they can become part of an iterative ethics review cycle but only if the IRB approval process is less daunting.
>
> TEAR does not promote a filling in the boxes mentality when seeking approval from an IRB . . . TEAR's goal is to facilitate sound ethical practice by allowing novice researchers to read how scholars have described the pathways used to protect their research subjects from harm. For example, guidelines on how to research children found on IRB webpages are useful only up to a point. TEAR believes that reading multiple examples of best practice can promote best practice for novice researchers allowing them to compare and contrast their project with donated exemplars.

This strikes me as a promising implementation of an idea floated by [2]Alex Halavais and others.

1. http://tear.otago.ac.nz/
2. http://www.institutionalreviewblog.com/2011/12/halavais-calls-for-open-publication-of.html

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Autoethnographer Finds REB Review Intimidating (2012-11-28 08:40)

Lee Murray describes getting REB approval for her doctoral research at the University of Saskatchewan. Though she was able to devise a proposal that passed the committee "without taking away from what I want to accomplish," she was left feeling she "would not want to make the journey again."

[Lee Murray, Debbie Pushor, and Pat Renihan. "Reflections on the Ethics-Approval Process." Qualitative Inquiry 18, no. 1 (January 2012): 43–54. [1]doi:10.1177/1077800411427845.]

Murray's plan was to "describe, explore and analyze my own personal and professional experiences and perceptions as a mother, clinical nurse specialist, and advocate for children with developmental disabilities." (This from her [2]archived application at TEAR.) As if "children" and "developmental disabilities" were not by themselves sufficiently bright red flags, Murray planned to write about the experiences of her own developmentally disabled son, who suffered sexual abuse.

Knowing that the REB could kill her project, Murray dreaded each step of the process:

> I feel stressed but not anxious. My heart should be beating at 200/min but it's not. I feel uptight but have no signs of helpful adrenaline surging through my veins. Maybe I am just too tired. Maybe, on days like today, I doubt myself and what I am doing. Maybe the pain of my experience is too much with all these difficulties layered on top. It would be much easier to give up and surrender. Maybe it is the realization that I won't surrender that keeps me going.

> I comment to Debbie how surreal this moment feels and she concurs. At this moment, I don't know how to think, feel, or act. It seems like I am just going through the motions, yet in a few minutes, I will be required to defend my proposal to a group of people who may not understand the complexities of autoethnography and the resulting ethical issues.

Compared to other horror stories, Murray's depicts a fairly benign committee that seemed willing to learn. Still, she suggests that the power of the REB is itself a problem:

> There is currently a sense, perhaps more perceived than real, but a palpable sense that the REB is a gatekeeper for what research will be done. How can we reposition REBs, instead, to assume a role as supportive and facilitative of research, particularly research that involves sensitive stories and vulnerable populations?

1. http://dx.doi.org/10.1177/1077800411427845
2. http://tear.otago.ac.nz:8080/jspui/handle/123456789/60

Palys and Lowman on Boston College: "Be Suspicious of Universities" (2012-11-28 13:07)

Ted Palys and John Lowman of the School of Criminology at Simon Fraser University provide a helpful overview of the Boston College Belfast Project oral history legal case while condeming Boston College's actions before and after the arrival of the subpoena. Though the article is marred by an incomplete understanding of U.S. human subjects regulations, it makes a strong case that universities need to practice "ethical and legal due diligence" before promising confidentiality to research participants.

[Ted Palys and John Lowman. "Defending Research Confidentiality 'To the Extent the Law Allows:' Lessons From the Boston College Subpoenas." Journal of Academic Ethics 10, no. 4 (2012): 271–297. [1]doi:10.1007/s10805-012-9172-5.]

Palys and Lowman trace the history of the Belfast Project from its conception in 1999/2000 up through about September 2012. Building on [2]earlier work they have done concerning researchers' and universities' duty to fight subpoenas, they maintain that by prioritizing legal obedience over ethical obligation, "Boston College has provided an example that will be cited for years to come of how not to protect research participants to the extent American law allows." Moreover, they argue, "In the absence of statute-based protections for research participants, a privilege for research confidentiality is something that the academy has to fight for, with researchers and the institutions they work for leading the charge." For now, they counsel, "one of the other lessons learned from the Boston College subpoenas is to be suspicious of universities."

Though I agree with the general thrust of the article, I am unpersuaded by its claim that "independent ethics oversight should have been the institutional order of the day." Palys and Lowman mock a statement by a Boston College spokesman that the Belfast Project did not fit "the federal definition of research"; they suggest that because "the project met professional standards" it must count as "research." But U.S. officials have long held that [3]all manner of professional investigations don't meet the regulatory definition of research. (Much more on this in *[4]Ethical Imperialism*, 145-159.)

Nor am I persuaded by the article's suggestion that IRB review would have prevented the misunderstanding at the heart of the case. As I noted last year, [5]IRBs are unreliable protectors of subject confidentiality. And as I recently noted, [6]Boston College's IRB seems pretty clueless, even today.

1. http://dx.doi.org/10.1007/s10805-012-9172-5
2. http://www.institutionalreviewblog.com/2009/03/canadian-criminologists-decry-tcps.html
3. http://www.jstor.org/stable/3564451
4. http://books.google.com/books?id=nSv83XkNq3gC&dq=schrag+%22ethical+imperialism%22&source=gbs_navlinks_s
5. http://www.institutionalreviewblog.com/2011/06/us-and-british-governments-subpoena.html
6. http://www.institutionalreviewblog.com/2012/11/is-boston-college-stil-clueless-about.html

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What Is This Thing Called Research? (2012-11-28 20:45)

I have posted the paper I prepared for the May 2012 Petrie-Flom conference as "What is this Thing Called Research? (May 7, 2012), [1]http://ssrn.com/abstract=2182297.

A shorter version will appear in a book to be published by the MIT Press, tentatively entitled The Future of Human Subjects Research Regulation.

Here is the abstract:

Since the 1950s, policymakers and researchers in the United States and abroad have labored to distinguish those activities that require some level of prior approval from other forms of human interaction and information exchange. In 1978, Albert Jonsen—a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research—expressed this problem well, when he said of a draft of the Belmont Report that "There is nothing in here that tells us why we are about to make a great big step which we have made from the beginning. Namely, why ought the thing that we are calling research be subject to what we call review?" Nearly half a century since the first federal requirements for IRB review, that question remains unanswered.

The ANPRM makes only a gesture at this crucial problem, asking, in Question 25, if there are "certain fields of study whose usual methods of inquiry were not intended to or should not be covered by the Common Rule . . . 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." But the generalizability of knowledge is only one of several criteria that have been advanced to distinguish research that should and should not be covered by regulations, and—I would argue—it is the least helpful. This paper seeks to explore more widely some of the efforts that have been made to distinguish activities that should be vetted by one or more reviewers prior to their initiation from those that should not. As we reconsider the regulatory system in the wake of the ANPRM, we should ask why we think some activities need review and craft definitions that include those and nothing more.

1. http://ssrn.com/abstract=2182297

1.5 December

Marakowitz Reviews Ethical Imperialism (2012-12-01 21:53)

Ellen Marakowitz, a lecturer in the Department of Anthropology at Columbia University and a member of the Columbia IRB, reviews Ethical Imperialism for Academe, the magazine of the American Association of University Professors. She finds it "a well-documented history of the impact of institutional review boards on social science research in the United States," but wishes I had paid more attention to IRBs' potential to help researchers "think critically about their practices, including potential risks to subjects."

[Ellen Marakowitz, "[1]Regulated Research" (Review of Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009 by Zachary M. Schrag), Academe November-December 2012.]

1. http://www.aaup.org/AAUP/pubsres/academe/2012/ND/BR/irbs.htm

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Anonymous (2012-12-03 13:43:19)
Interesting thought, but I think it is IRBs' responsibility to promote their (unmet) 'potential to help researchers "think critically about their practices, including potential risks to subjects"' - rather than historians'.

NIH Policy Makes Interviewing Children Easier (2012-12-05 14:38)

Susan Ridgely, assistant professor of religious studies at the University of Wisconsin at Oshkosh, finds that IRBs can cause trouble for qualitative researchers who want to talk with children, but that IRB review has some benefits. Moreover, since the NIH started calling for children to be included in medical studies, she is finding it easier to get IRB permission to speak to children.

[Susan B. Ridgely, "[1]Doing Ethnography with Child Consultants: Making the IRB Process Work." Journal of American Folklore 125, no. 3 (2012): 474–485.]

The Bad News

Since 1996, Ridgely has been talking with children about their religious practices. She describes elements of her IRB experience in terms familiar to many frustrated qualitative researchers:

- "Since each IRB has its own interpretation about how to meet the federal requirements, what might be approved by one board may be rejected by another."
- IRBs require researchers to complete training "focused . . . on a series of exploitative medical experiments, [which] can be off-putting for those of us in the humanities."
- "The process for translating an interactive research plan into language that the review board will find acceptable can be arduous . . ."
- "The approval committee . . . prefers yes and no answers to existential questions."

- "The IRB goal in the process was less child-centered than my own: they wanted to ensure that I had made my research clear to children, therefore meeting the institution's legal obligations."

The Good News

Yet Ridgely finds that some IRB requirements have helped her think through the ethical consequences of her research design:

- "I realized that my belief in the parity of children's and adults' ability to understand the consequences of participating in research (when the research and the consequences are clearly discussed) failed to account for the real power imbalances with which children must continually contend. The IRB process forced me to grapple more directly with this power differential."

- "As I wrote short answers to each of the application's inquiries . . . I found it useful to have to process my own motivations for working with children and assess my abilities to make my study safe and free from coercion."

- "Even though many children wanted their real names to be in a book, my IRB protocol helped me to understand that these children might not be able to foresee the longterm consequences of their participation." [Ridgely is ambivalent about this one, noting that "scholars working with teens and children involved in youth advocacy have argued persuasively that insisting on pseudonyms is paternalistic and further marginalizes children."]

Biomedical Ethics to the Rescue?

The biggest surprise in the article is Ridgely's finding that evolving standards in biomedicine, which so often mean stricter rules for social scientists, can benefit them as well. In her case, the NIH's call for children to be included in research created "an opening for scholars in the humanities to find ways to bring children's social experiences into the purview of adults." New NIH standards "can be used to demonstrate that work in the humanities, as well as the sciences, can no longer be excluded because of vague concerns over children's vulnerability," though Ridgely notes that "I do not mean to suggest that the process is simple."

1. http://www.jstor.org/stable/10.5406/jamerfolk.125.498.0474

Expedited Review Reaches the Institutional Review Blog (2012-12-12 20:26)

Today this blog is six years old. Proud as I am of its reception and impact, I find it increasingly difficult to comment on all relevant items while fulfilling my other professional responsibilities.

In the hope of reducing burden, delay, and ambiguity for myself and my readers, I plan to note briefly some items I come across, offering only a line or two of commentary rather than the more thorough analysis I have aimed for in many of my entries.

If this goes well I may adopt this format for the bulk of items I mention. I hope this will allow me to bring readers' attention to otherwise disparate items in less time than I have spent in the past.

Northeastern U. IRB Makes Sex Research Untenable (2012-12-13 06:19)

Carey Noland, associate professor of communcation studies at Northeastern University, complains that "many IRBs . . . seem to have difficulty accurately assessing the potential harm involved with qualitative research on sex."

[Carey M. Noland, "Institutional Barriers to Research on Sensitive Topics: Case of Sex Communication Research Among University Students." Journal of Research Practice 8, no. 1 (November 24, 2012): Article M2, [1]http://jrp.icaap.org/index.php/jrp/article/view/332/262]

Noland writes,

> As a sex researcher, like many other sex researchers, I am continuously denied approval or asked to compromise my research process so radically that the original study becomes untenable. While I fully acknowledge that the IRB is an important entity and that research subjects ought to be protected, I contend that when it comes to sensitive topics, many IRBs err on the side of caution, to the detriment of research quality.

She is particularly frustrated that the IRB blocks her students' proposals as well:

> I often encourage the students to choose research topics in my area of expertise (communication about sex) for obvious reasons: it is easier for me to mentor them in the project if I have expertise in the area. In the ten years I have been doing this, whenever the class proposed doing anything related to sexual relationships, the protocol would go to the full IRB review process and rarely pass. Each time the IRB recommended that, rather than have qualitative interviews performed by peer interviewers (i.e., the students), we should consider an anonymous quantitative survey. It is important to note that none of the proposed projects asked students about their sexual behaviors, rather the questions were entirely focused on communication about sex (e.g., Whom do you talk to about sex? Do you talk about safe sex?).

Both Noland's own research and her teaching have suffered:

> On one occasion, I met with the Vice-Provost of Research to discuss the IRB to argue that the research project on sex that I proposed should be exempt according to federal guidelines; he agreed after looking at the protocol and said he would talk to the IRB. After six months of negotiating with the IRB, I dropped the study. In the past few years we have done the most innocuous research in my capstone courses; for example, this semester we are doing a project on communication about nutrition. The limitations imposed by the IRB are unnecessarily depriving students of the experience of conducting in-depth interviews as part of a qualitative research process.

Noland concedes that some people may find being asked about sex more stressful than answering other questions, based on a survey she administered to Northeastern students. Yet it seems that she asked students about what topics they

thought might be stressful in a hypothetical survey, rather than asking them about surveys they had already taken. I'd be interested to learn if the responses would differ if the question were posed retrospectively rather than prospectively.

1. http://jrp.icaap.org/index.php/jrp/article/view/332/262

Prisoners Find Interview Research Rewarding (2012-12-14 10:39)

A team of researchers finds that prisoners who participated in interview research "reported some intangible benefits and no harms or negative consequences. They also reported the interviews as being a positive and rewarding experience and uniformly said that they had not been subject to coercive persuasion."

[Heith Copes, Andy Hochstetler, and Anastasia Brown. "Inmates' Perceptions of the Benefits and Harm of Prison Interviews." Field Methods (November 21, 2012). doi: [1]10.1177/1525822X12465798. h/t [2]Dan T. A. Eisenberg]

Back in May, I mentioned [3]the impressive work by Michael McDonald, Susan Cox, and Anne Townsend, who conduct follow-up interviews with research participants in the hope of assembling empirical evidence about the impact of research as a basis for future research decisions. In this article, Copes, Hochstetler, and Brown adopt this approach. A few days after forty Alabama prisoners participated in interviews about their perceptions of parole revocation, Copes interviewed them about their experience of being interviewed.

The prisoners' responses suggest that IRBs and researchers do need to respect respondents' desire for confidentiality. As one prisoner put it, "I might want to tell you something, but I might not want to tell someone else, because I know you ain't gonna say nothing of what I got to say."

But the researchers found no evidence to support IRBs' common worries that prisoners might expect their participation to lead to leniency, that they would be confused about the difference between researchers and correctional officials, and that talking itself would cause emotional trauma. As the researchers put it,

> Another potential source of harm that can come from consenting to an interview is emotional discomfort emerging from reliving painful experiences. It is possible that asking the imprisoned to discuss painful events and times may trigger anxiety, self-doubt, and/or depression. To assess this, we asked all participants if they experienced negative emotions after the interview. None said they did. As shown in the previous section, participants said that they felt better after the interview.

All told, the prisoners reported that participating in research had been empowering. IRBs that are thinking about blocking prisoners' access to researchers may want to remember one's statement:

> I kinda had a better feeling just going back to the dorm. Just to know that somebody cared enough to come check things out. You kinda lost down here. Free world people don't come see you. These people in here ain't gonna give you no information on nothing except we got you.

1. http://dx.doi.org/doi:10.1177/1525822X12465798
2. http://www.dtae.net/
3. http://www.institutionalreviewblog.com/2012/05/against-armchair-ethics-some.html

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Muara Pos (2013-03-11 07:09:37)
I want to translate some of your works into my own language "Indonesian" Would you mind?

Zachary M. Schrag (2013-03-14 13:10:06)
Sure, that would be fine. And thank you for asking.

Law Professor Decries, Ponders IRB Variability (2012-12-17 14:23)

Christopher Robertson, associate professor at the James E. Rogers College of Law, University of Arizona, laments the variation in IRB policies and practices from one institution to another and sees it as an opportunity for research.

[Christopher Robertson, "Variability in Local IRB Regulation: A Gold Mine for Future Research," Bill of Health, November 24, 2012. [1]http://blogs.law.harvard.edu/billofhealth/2012/11/24/variability-in-lo cal-irb-regulation-a-gold-mine-for-future-research.]

Robertson opens with an all-too-common tale of inconsistency between institutions:

> When I moved to the University of Arizona, I quickly discovered something that I'll politely call "heterogeneity" in Institutional Review Board's (IRB) policies and practices. All of a sudden, some of the rather vanilla human subjects research practices I had been doing for years, with IRB approval, were now forbidden. Turns out that I had been exerting "undue influence" on human subjects all along by — wait for it — telling them how much I proposed to pay them. (Good thing there is no IRB jail for miscreants like me.)

As he explains,

> There seems to be variation in local policies, such as implementation guidelines and boilerplate informed consent language. Indeed, on a particular policy question that I am now studying, I have found an entire gamut, with some schools forbidding precisely what others mandate (and everything in between), with practically nobody in the normative literature arguing for either of those polar extremes.

He also notes more systematic studies of such variability, such as Lee A Green, Julie C Lowery, Christine P Kowalski, and Leon Wyszewianski. "Impact of Institutional Review Board Practice Variation on Observational Health Services Research." Health Services Research 41, no. 1 (February 2006): 214–230. doi:10.1111/j.1475-6773.2005.00458.x.

Rather than cursing the darkness, Robertson proposes to study the phenomenon, the way other researchers have studied local prosecutors' offices. "Somebody needs to do the same for IRB regulation — getting into the black box to figure out what, if anything, really explains all this variation in outcomes for identical cases. Are there in fact internal constraints?"

I agree that there's work to be done along these lines. I'd be particularly interested in comparisons between those IRB administrators who have and have not had extensive certification and contact with PRIM &R, which I think seeks to promote best practices across institutions.

1. http://blogs.law.harvard.edu/billofhealth/2012/11/24/variability-in-local-irb-regulation-a-gold-mine-for-future-research

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Dunn and Hunter Defend Mandatory Review (2012-12-23 16:59)

The Journal of Medical Ethics has published two responses to Murray Dyck and Gary Allen's August 2012 article, "Is Mandatory Research Ethics Reviewing Ethical?" The responses do little to grapple with what I take to be the article's major's proposal.

[Michael Dunn, "Getting the Justification for Research Ethics Review Right." Journal of Medical Ethics (October 31, 2012). doi:10.1136/medethics-2012-100943; David Hunter, "How Not to Argue Against Mandatory Ethics Review." Journal of Medical Ethics (December 12, 2012). doi:10.1136/medethics-2012-101074.]

[1]As I wrote in September, I understand Dyck and Allen to be arguing not for the abolition of ethics committees, but rather for a shift from compulsion to persuasion as committees' chief tool.

I am not sure that Dunn and Hunter share this understanding. While they offer challenges to some of Dyck and Allen's claims about the current workings of ethics committees, they say little about the suggestion that advisory committees might preserve the best features of mandatory ethics review while eliminating its abuses.

Dunn agrees that ethics committees can be flawed and calls, briefly, for "novel governance frameworks" to improve efficiency and accountability. If one follows his footnotes, one finds that he cites with approval [2]Sheehan's call for enhanced due process in ethics review. Yet Dunn believes that "any such approach would be diametrically opposed to the path laid out for us by Dyck and Allen." Why? It strikes me that stripping ethics committees of the power of compulsion is–like Sheehan's vague proposals–a move toward accountability.

Hunter asks, "Why would not responsible professionals want the input of an expert panel to help guide them to an ethically defensible decision about their research?" Well, Dyck and Allen ask the same thing, and suggest that the committees' power of coercion makes them lazy, so that they become inexpert panels. Their proposal would force panels to become expert if they wanted to shape research, rather than relying on the threat of sanctions.

Whether researchers are empowered to appeal decisions or vote with their feet, ethics committees must be brought to account.

1. http://www.institutionalreviewblog.com/2012/09/could-guidance-and-feedback-replace.html
2. http://dx.doi.org/10.1136/jme.2007.022574

Is Ethics Review Like a Building Permit? (2012-12-27 09:01)

In the course of his [1]response to Dyck and Allen, David Hunter also challenges claims by Whitney and Schneider that [2]ethics review costs lives by delaying research for months or years. I am unpersuaded by Hunter's claims.

Hunter writes,

> People often complain about the need for council approval for building projects because these approvals delay projects from being completed. Does this mean that council approval makes builders significantly less efficient? Well, unless they actually down tools until they have approval, no it does not; instead, what happens is that they work on another project until approval comes through. Hence it would be wrong to say that the need for council approval makes builders less efficient even if it does slow down specific building projects. It is likewise mistaken to think that regulation of this kind will mean less houses will be built in a specific time period; while specific houses may be delayed, overall the same amount of building work will go on.
>
> The same holds true for researchers: while they wait for research ethics approval they are not simply sitting around doing nothing having downed test tubes; instead, they will be working on other things including other research projects and new proposals. Hence while research ethics regulation might delay specific projects it does not dramatically decrease the amount of work that the researchers involved are doing. Insofar as their work is saving lives they will still be doing that regardless of the length of time the approval process takes. In other words, roughly the same quantity of research is being carried out even if specific research projects are delayed. Some researcher time will be taken up by filling in ethics forms, attending meetings and so on. However, much of this time will either be valuable work (by encouraging the researchers to think through the ethics of their project) or parasitic on existing work such as writing up a research protocol. While there is no doubt some delay here it is on a relatively small scale compared with the claims of Whitney and Schneider.

The second part of this argument–that filling out forms imposes delay "on a relatively small scale"–does not address accounts that [3]ethics approval alone can consume hundreds or thousands of person-hours and consumer up to half the funds of a research project. Nor does it address the claims by Roberts et al. that [4]"consent rituals" can delay urgent treatment, obscuring its effect.

More intriguing, though, is Hunter's comparison of scientific research to building construction. If you are waiting for a permit on one project, he asserts, you can work on another.

I have doubts about this analogy, which Hunter offers strictly as an armchair exercise, with no references to studies of the building industry. First of all, for large projects, increased regulation has indeed slowed down the overall pace of building. In writing [5]my first book, I interviewed engineers who told me that their work had become vastly more complex after the passage of the National Environment Policy Act, which required environmental impact statements for federally funded projects. These statements had ripple effects in time and money, since the transit authority or other organization could not simply go into suspended animation while awaiting approval. While I tend to think that environmental laws do necessary work balancing the costs and benefits of major projects, it's pretty clear that they make infrastructure harder to build.

Perhaps Hunter was thinking of smaller projects (he mentions houses) that face less regulation. If so, I find this version of the analogy doubtful. While cutting-edge architects may respond to one another's projects, for the most part, one house can proceed without reference to another. Hunter seems to imagine that scientific research teams can also run multiple, simultaneous projects on wholly independent schedules, so that delay in one will not hamper the others.

But I thought that scientific research is supposed to build on previous projects. Thus, creating knowledge is less like erecting buildings and more like breeding animals. The longer each generation takes to mature, the longer

until the breeder achieves the desired results. Three simulataneous research projects each taking three years will be less valuable than three projects that each takes one year, with each new project building on its predecessor.

1. http://www.institutionalreviewblog.com/2012/12/dunn-and-hunter-defend-mandatory-review.html
2. http://www.institutionalreviewblog.com/2011/04/costs-of-ethical-review-part-ii.html
3. http://www.institutionalreviewblog.com/2012/05/minimal-risk-approval-27-months-170000.html
4. http://www.institutionalreviewblog.com/2011/04/costs-of-ethical-review-part-ii.html
5. http://jhupbooks.press.jhu.edu/ecom/MasterServlet/GetItemDetailsHandler?iN=9780801882463&qty=1&viewMode=1&loggedIN=false&JavaScript=y

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BPiper (2012-12-27 09:38:10)
Hunter also ignores the problems encountered by graduate students who must obtain IRB approval before starting their masters or doctoral research. Those students don't have other research that they can work on while waiting, and this can make a difference in their lives. In our experience, for example, a distressing number of M.A. students in anthropology who would like to finish their degree in 2 or 3 semesters end up spending another semester because of IRB delays. At a private university that does not offer tuition support to masters level graduate students, this delay can be extremely expensive. Our doctoral students have it a little better, since their proposals are typically submitted for IRB approval at the same time that those proposals are submitted for external funding, and the IRB approval normally gets sorted out earlier, but we do have the occasional student who gets set back one or two semesters because of some red flag in their proposal – red flags that invariably (in my 30+ years of experience) turn out to be chimeras.

Zachary M. Schrag (2012-12-27 14:59:47)
Thanks for this comment. You are quite right that the IRB hammer falls hardest on graduate students.

Hunter may have been thinking specifically about the life-saving medical research discussed by Schneider and Whitney, not the social sciences. But even here, delaying graduate education in the way you describe may cost lives. As the [1]President's Council of Advisors on Science and Technology recently noted, "Overly long times to degree are costly, waste precious graduate education resources, and serve as a disincentive for attracting bright minds to STEM fields." Excessive IRB delays thus threaten the scientific enterprise at the graduate student level.

1. http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_future_research_enterprise_20121130.pdf

Sociologists Call for IRB Moratorium (2012-12-31 18:38)

To close out the year, I briefly note a piece that appeared online at the start of 2011, but which I came across only recently. Three sociologists call for a "moratorium on IRB review for social scientific audit research involving non-institutionalized, mentally competent adult subjects," but their reasons are unclear.

[Hessler, Richard M., D. J. Donnell-Watson, and John F. Galliher. "A Case for Limiting the Reach of Institutional Review Boards." *American Sociologist* 42, no. 1 (January 29, 2011): 145–152. [1]doi:10.1007/s12108-011-9122-5.]

The authors challenge two tenets of the IRB regime: nonmaleficence and informed consent.

First, they argue that the "do no harm" ideal of the Belmont Report may be misplaced for social science research. Offering the example of a researcher who testified against the prostitution business that had employed her as an accountant, they note that "the researcher's ethical principles might well include a commitment to blow the whistle on gross injustices discovered during fieldwork." Since this researcher completed her scholarly work without IRB surpervision, the authors must speculate that an IRB would oppose such whistle-blowing. But they are certainly correct that U.S. regulations currently lack a [2]provision for critical inquiry comparable to Canada's.

On the other hand, the authors muddy this argument by arguing that "It is ethical if the harm is contained as much as possible." So are they calling for true freedom to pursue knowledge, or must researchers (and perhaps overseers) make an effort to contain harm?

Second, the authors question the need for informed consent in all cases, arguing that "The right to have one's illegal actions protected from detection by requiring that researchers get informed consent gets trumped by social justice concerns of social and economic security of the prostitutes and the larger community in terms of tax revenues." Yet in the very next paragraph, they state that "Researchers should negotiate rights and obligations with the research subjects directly, like physicians and other service professionals do currently."

What is the difference between "requiring that researchers get informed consent" and demanding that they "negotiate rights and obligations with the research subjects directly"?

Galliher was clearer on these points in 1973. [John F. Galliher, "The Protection of Human Subjects: A Reexamination of the Professional Code of Ethics," *American Sociologist* 8 (August 1973): 93-100.]

1. http://dx.doi.org/10.1007/s12108-011-9122-5.
2. http://www.institutionalreviewblog.com/2009/01/canada-considers-new-tcps.html

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2. 2013

2.1 January

Should We Expect an NPRM in April? (2013-01-04 09:06)

The [1]Report on Research Compliance notes that the December 21 Current Regulatory Plan and the Unified Agenda of Regulatory and Deregulatory Actions projects a [2]Notice of Proposed Rulemaking (NPRM) in April 2013 as the next step in a revised Common Rule.

RRC also cautions that "federal agencies are notorious for missing specified dates," so I won't hold my breath.

1. http://www.reportonresearchcompliance.com/
2. http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201210&RIN=0937-AA02

Journal of Law, Medicine & Ethics Symposium Reexamines Research Ethics (2013-01-10 09:17)

The Winter 2012 issue of the Journal of Law, Medicine & Ethics features presented at a November 2011 Wake Forest University Center for Bioethics, Health, and Society presented a conference entitled "Research Ethics: Reexamining Key Concerns."

As the introduction to the symposium explains,

> This symposium contains papers prepared by presenters at that conference and in response to a call for papers addressing the three conference foci: the legacy of Tuskegee; innovation, commercialization, and the goals of biotechnology research; and rethinking the IRB's role. Conference presenters with papers in this symposium are Giselle Corbie-Smith, Rebecca Dresser, Steven Joffe, James Jones, Jonathan Kahn, Alex John London, and Jeremy Sugarman.

Here is the table of contents for the symposium. I will comment on relevant items as time allows. As of posting, the DOI's below are not working; I think this is a problem with the journal, not my HTML.

INTRODUCTION: Research Ethics: Reexamining Key Concerns (pages 865–866)
Nancy M. P. King and Ana S. Iltis
Article first published online: 3 JAN 2013 | DOI: [1]10.1111/j.1748-720X.2012.00715.x

Bad Blood Thirty Years Later: A Q &A with James H. Jones (pages 867–872)
James H. Jones and Nancy M. P. King
Article first published online: 3 JAN 2013 | DOI: [2]10.1111/j.1748-720X.2012.00716.x

The Troubling Persistence of Race in Pharmacogenomics (pages 873–885)

Jonathan Kahn
Article first published online: 3 JAN 2013 | DOI: [3]10.1111/j.1748-720X.2012.00717.x

Ethical Dimensions of Disparities in Depression Research and Treatment in the Pharmacogenomic Era (pages 886–903)
Lisa S. Parker and Valerie B. Satkoske
Article first published online: 3 JAN 2013 | DOI: [4]10.1111/j.1748-720X.2012.00718.x

Practical Steps to Community Engaged Research: From Inputs to Outcomes (pages 904–914)
Malika Roman Isler and Giselle Corbie-Smith
Article first published online: 3 JAN 2013 | DOI: [5]10.1111/j.1748-720X.2012.00719.x

Alive and Well: The Research Imperative (pages 915–921)
Rebecca Dresser
Article first published online: 3 JAN 2013 | DOI: [6]10.1111/j.1748-720X.2012.00720.x

Revolution or Reform in Human Subjects Research Oversight (pages 922–929)
Steven Joffe
Article first published online: 3 JAN 2013 | DOI: [7]10.1111/j.1748-720X.2012.00721.x

A Non-Paternalistic Model of Research Ethics and Oversight: Assessing the Benefits of Prospective Review (pages 930–944)
Alex John London
Article first published online: 3 JAN 2013 | DOI: [8]10.1111/j.1748-720X.2012.00722.x

Questions Concerning the Clinical Translation of Cell-Based Interventions under an Innovation Pathway (pages 945–950)
Jeremy Sugarman
Article first published online: 3 JAN 2013 | DOI: [9]10.1111/j.1748-720X.2012.00723.x

IRB Decision-Making with Imperfect Knowledge: A Framework for Evidence-Based Research Ethics Review (pages 951–969)
Emily E. Anderson and James M. DuBois
Article first published online: 3 JAN 2013 | DOI: [10]10.1111/j.1748-720X.2012.00724.x

In Plain Sight: A Solution to a Fundamental Challenge in Human Research (pages 970–989)
Lois Shepherd and Margaret Foster Riley
Article first published online: 3 JAN 2013 | DOI: [11]10.1111/j.1748-720X.2012.00725.x

More Than Cheating: Deception, IRB Shopping, and the Normative Legitimacy of IRBs (pages 990–996)
Ryan Spellecy and Thomas May
Article first published online: 3 JAN 2013 | DOI: [12]10.1111/j.1748-720X.2012.00726.x

Rethinking Local Institutional Review Board (IRB) Review at State Health Departments: Implications for a Consolidated, Independent Public Health IRB (pages 997–1007)
David Perlman
Article first published online: 3 JAN 2013 | DOI: [13]10.1111/j.1748-720X.2012.00727.x

What Research Ethics Should Learn from Genomics and Society Research: Lessons from the ELSI Congress of 2011 (pages 1008–1024)

Gail E. Henderson, Eric T. Juengst, Nancy M. P. King, Kristine Kuczynski and Marsha Michie
Article first published online: 3 JAN 2013 | DOI: [14]10.1111/j.1748-720X.2012.00728.x

1. http://dx.doi.org/10.1111/j.1748-720X.2012.00715.x
2. http://dx.doi.org/10.1111/j.1748-720X.2012.00716.x
3. http://dx.doi.org/10.1111/j.1748-720X.2012.00717.x
4. http://dx.doi.org/10.1111/j.1748-720X.2012.00718.x
5. http://dx.doi.org/10.1111/j.1748-720X.2012.00719.x
6. http://dx.doi.org/10.1111/j.1748-720X.2012.00720.x
7. http://dx.doi.org/10.1111/j.1748-720X.2012.00721.x
8. http://dx.doi.org/10.1111/j.1748-720X.2012.00722.x
9. http://dx.doi.org/10.1111/j.1748-720X.2012.00723.x
10. http://dx.doi.org/10.1111/j.1748-720X.2012.00724.x
11. http://dx.doi.org/10.1111/j.1748-720X.2012.00725.x
12. http://dx.doi.org/10.1111/j.1748-720X.2012.00726.x
13. http://dx.doi.org/10.1111/j.1748-720X.2012.00727.x
14. http://dx.doi.org/10.1111/j.1748-720X.2012.00728.x

Bell and Salmon Warn of Dangerous Assumptions **(2013-01-14 09:13)**

Kirsten Bell and Amy Salmon, both of the University of British Columbia, warn that in trying to protect people they consider vulnerable, ethics committees ignore empirical evidence that some measures are counterproductive.

[Bell, Kirsten, and Amy Salmon. “Good Intentions and Dangerous Assumptions: Research Ethics Committees and Illicit Drug Use Research.” Research Ethics 8, no. 4 (December 2012): 191–199. doi:[1]10.1177/1747016112461731.]

The authors’ particular interest is studies of people who use illicit drugs. In an [2]earler article, they compared ethics committees’ assumptions about these people with the views of the people themselves. Women in focus groups told them that "assuming incapacity merely on the basis of someone’s status as a drug ’addict’ was stereotypical, simplistic, and discriminatory."

Here, Bell and Salmon compare ethics committee assumptions with published scholarship they found using database searches. Again, they find little empirical support for REC beliefs that drug users lack the ability to provide informed consent, are unduly influenced by financial incentives, or risk being "re-traumatized" by questions.

Though Bell and Salmon focus on research with drug users, they hint at a broader need for "[3]evidence-based research ethics." As the Belmont Report puts it,

> 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.

Bell and Salmon show RECs' failure to meet this standard for one brand of research, but I fear their findings apply to a much broader range of activities.

1. http://dx.doi.org/10.1177/1747016112461731
2. http://www.institutionalreviewblog.com/2012/05/research-participants-find-reb.html
3. http://dx.doi.org.mutex.gmu.edu/10.1016/j.drugalcdep.2006.06.011

Alan (2013-01-14 10:57:32)
Sensible risk analysis and response are easier to discuss than accomplish. For one, in general, people are really bad at gauging risks. Lots of people shove their children into cars every day without much thought but will worry about the risk of child abduction. Secondly, risks are the language of persuasion. Many risks are highly politicized. Health care? Lots of screening tests are marketed using fear, but many of the tests aren't very good and the the risk of unnecessary distress and treatment often out-weigh the purported benefits. FUD is everywhere. And third, the response to risk always involves a trade-off but people are much happier living in the fantasy land of "no risk". Either they deny the risk or no risk is too small.

This blog itself, although it makes some good points, hardly passes for a sober, evidence-based analysis of the IRB-related risks to research.

Zachary M. Schrag (2013-01-14 12:35:38)
Thanks for this comment. I fail to see how it responds to Bell and Salmon's suggestion that RECs read relevant scholarly literature before restricting research.

New Comment Policy (2013-01-14 12:45)

As I try to reduce the time I spend maintaining this blog, I will no longer publish comments that do not include the author's first and last names, and institutional affiliation as appropriate. I find that commenters who identify themselves post more helpful responses.

Armchairs vs. Evidence in the Journal of Law, Medicine & Ethics (2013-01-18 09:35)

Last week I [1]promised some comments on the Winter 2012 issue of the Journal of Law, Medicine & Ethics, which features a symposium entitled "[2]Research Ethics: Reexamining Key Concerns."

The contributions reinforced my sense that the IRB debate is in part a contest between [3]evidence-based approaches and armchair ethics.

The most armchair-bound piece seems to be Alex John London's "[4]A Non-Paternalistic Model of Research Ethics and Oversight: Assessing the Benefits of Prospective Review." Relying on such classic thought experiments as

Hardin’s "Tragedy of the Commons" and Akerlof’s "Market for ’Lemons,’" he claims that IRB review

> helps to provide a credible social assurance to the American people that social institutions, funded by their tax dollars and empowered to advance their health and well-being, work to: respect and affirm the moral equality of all community members; prevent the arbitrary exercise of social authority; and help to create a “market” in which the diverse stakeholders, often working to advance diverse ends, collaborate in a way that advances the common good.

Yet his analysis depends on unsupported claims like "If all researchers were ideally rational and knowledgeable . . . almost all protocols would be submitted in a form that would be acceptable with, at most, minor revisions. In this environment, IRBs would be able to quickly approve most protocols and their actual review would add little marginal value." In other words, he assumes that IRBs are competent at approving ethical proposals.

Such claims can be challenged using both armchair and empirical evidence. On the armchair side, London ignores the systems of incentives operating on IRBs ([5]above all, avoid federal suspension of research funds) which lead them to impose [6]onerous restrictions on innocuous protocols. If we were to take seriously the kind of economic modeling London offers, I suspect it would lead us to believe that IRB behavior fits models of rational ignorance, or possibly [7]rational irrationality. But I lack the incentive to investigate this fully.

London also ignores empirical works such as those of [8]Carl Elliott. London frets that bad studies will drain "the reservoir of public trust," but so do bad IRBs. Does London suppose that readers of [9]White Coat, Black Hat or Elliott’s [10]opinion pieces finish with warm, trusting feelings about medical research approved by IRBs?

Steven Joffe’s contribution, " [11]Revolution or Reform in Human Subjects Research Oversight," is also largely speculative. "What might the consequences of abandoning the requirement for prospective oversight of research be?" he asks. "Given the lack of relevant data, it is not possible to provide an evidence-based answer to this question."

But relevant data do exist, in the form of before-and-after comparisons of countries that have expanded or contracted review requirements, and comparisons among countries with different regulatory regimes. For example, I have argued that in the fourteen years following the revision of 45 CFR 46 (1981-1995), social scientists in the United States faced few IRB restrictions yet did not produce the wave of scandalous research that might be predicted by IRB advocates.

In "[12]More Than Cheating: Deception, IRB Shopping, and the Normative Legitimacy of IRBs," Ryan Spellecy and Thomas May present anlaysis more grounded in experience. They argue that "the current IRB system is flawed at a very fundamental level," basing this argument in part on the incentives operating on IRBs "to err on the side of not approving research," but also on [13]Abbot and Grady’s empirical work and on their own experience as IRB members. An IRB system this bad, they warn, teaches researchers to "ignore, avoid, or outright violate policies aimed at protecting research participants."

The loudest, clearest call for evidence-based reform is "[14]IRB Decision- Making with Imperfect Knowledge: A Framework for Evidence-Based Research Ethics Review" by Emily Anderson and James DuBois. They recommend five steps:

1. Translation of Uncertainty to an Answerable Question
2. Systematic Retrieval of the Best Available Evidence

3. Critical Appraisal of Evidence for Validity, Relevance, and Importance
4. Application of Evidence to Make a Decision
5. Evaluating Performance

They then offer examples of how this process might be applied. For instance, an IRB worried that paying heroin addicts to participate in interviews would use the money to buy drugs might review the empirical research on the subject and learn that "existing evidence, although limited, suggests that six $70 cash payments over the course of five years will not contribute to an increase in drug use." Yet they note that "the gap between empirical research on research ethics and the application of evidence to IRB review is still quite vast," and that for decisions to be based on evidence, "the culture of IRB review and decision-making must change."

1. http://www.institutionalreviewblog.com/2013/01/journal-of-law-medicine-ethics.html
2. http://onlinelibrary.wiley.com/doi/10.1111/jlme.2012.40.issue-4/issuetoc#group2
3. http://www.institutionalreviewblog.com/2012/05/against-armchair-ethics-some.html
4. http://dx.doi.org/10.1111/j.1748-720X.2012.00722.x
5. http://www.institutionalreviewblog.com/2012/05/berkeley-historian-defends-irb-review.html
6. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
7. http://econfaculty.gmu.edu/bcaplan/pdfs/rationalignorancevs.pdf
8. http://chronicle.com/blogs/brainstorm/when-medical-muckraking-fails/50767
9. http://www.beacon.org/productdetails.cfm?PC=2166
10. http://www.nytimes.com/2011/07/29/opinion/useless-pharmaceutical-studies-real-harm.html?_r=2&
11. http://dx.doi.org/10.1111/j.1748-720X.2012.00721.x
12. http://dx.doi.org/10.1111/j.1748-720X.2012.00726.x
13. http://www.jstor.org/stable/10.1525/jer.2011.6.1.3
14. http://dx.doi.org/10.1111/j.1748-720X.2012.00724.x

British Government Denies Conducting Research (2013-01-25 07:19)

I have reported in the past on [1]the ability of U.S. federal officials to avoid IRB review of their work by asserting that they are not conducting research, even as university scholars doing the same kind of work face sanctions if they proceed without IRB approval.

It turns out that British officials take similar positions:

> Having considered these guidance notes, their definitions of social research and the report in question, I can confirm that I do not consider ‘Listening to Troubled Families’ as being within the definition of Government social research and thus the scope of the guidance. My rationale for this is that this report falls more properly within the description ‘dipstick/informal information gathering’.
>
> (Reply from Jane Todorovic, Head of Profession for the Government Social Research (GSR) service at DCLG, 3 October 2012)

[“Policy Based on Unethical Research.” Poverty and Social Exclusion. Accessed January 25, 2013. [2]http://www.poverty.ac.uk/news-and-views/articles/policy-built-unethical- research. h/t Robert Dingwall]

1. http://www.institutionalreviewblog.com/2007/01/generalizable-revisited.html
2. http://www.poverty.ac.uk/news-and-views/articles/policy-built-unethical-research

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2.2 February

Faden et al. Question Research-Treatment Distinction (2013-02-10 09:18)

Writing in a special report of the *Hastings Center Report*, a team of prominent ethicists and researchers "argue that conceptual, moral, and empirical problems surround the received view that we can and should draw sharp distinctions between clinical research and clinical practice." Yet they decline to detail the implications of any regulatory change for IRB review of medical research, much less research in the social sciences and humanities.

[Kass, Nancy E., Ruth R. Faden, Steven N. Goodman, Peter Pronovost, Sean Tunis, and Tom L. Beauchamp. "The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight." *Hastings Center Report* 43, no. s1 (2013): S4–S15. doi:[1]10.1002/hast.133. h/t Yashar Saghai]

Kass et al. note that the current distinction between research and practice dates to the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the 1970s. They suggest that it was a useful distinction at the time, but that developments over the decades have made it less so:

> The traditional definitions and descriptions of clinical research and clinical practice are becoming blurred as a model of health care emerges in which practice and learning are integrated, where a central goal of the health care system is to collect, aggregate, analyze, and learn from patient-level data, and where clinicians are expected to make evidence-based practice decisions guided by the general knowledge produced from structured learning. This emerging way of organizing health care did not prevail when federal regulations governing research involving human subjects were initially developed, but it increasingly does today.

What does this mean for IRB review? As other authors in the special report point out, Kass et al. "deliberately leave the role of independent oversight in a learning health care system un- specified." [Largent, Emily A., Franklin G. Miller, and Steven Joffe. "A Prescription for Ethical Learning." *Hastings Center Report* 43, no. s1 (2013): S28–S29. doi:[2]10.1002/hast.135.]

But Kass et al. do make a good case that deciding what requires prior approval based on a design to contribute to generalizable knowledge or its use of a "systematic investigation" is increasingly problematic even for the purpose for which it was originally designed.

1. http://dx.doi.org/10.1002/hast.133
2. http://dx.doi.org/10.1002/hast.135

Puglisi: ANPRM Is Stalled; Write Your Own Common Rule (2013-02-12 19:54)

Tom Puglisi, director of the Office of Research Oversight in the Department of Veterans Affairs and former director of human subject protections at OHRP, writes that the Common Rule needs reform but believes that the ANRPM is

"stalled." He offers the Veterans Health Administration's interpretation of the Common Rule as a partial fix, but he does not address the implications of letting agencies rewrite the Common Rule for their specific needs.

[Puglisi, Tom. "Reform Within the Common Rule?" *Hastings Center Report* 43, no. s1 (2013): S40–S42. doi:10.1002/hast.140.]

Puglisi writes that the ANPRM is more or less dead:

> Sadly, recent proposals to modify the Common Rule have become stalled, at least for the foreseeable future, if not permanently. Given the current political climate and the often divergent interests of the seventeen agencies that adhere to the rule, meaningful systemic modernization of the Common Rule is not likely to occur any time soon.

The article offers no explanation of this pessimism, though one can guess that Puglisi has been involved in internal federal discussions of the ANPRM process and has his reasons to doubt its progress.

In any case, Puglisi thinks we need to do the best we can with a flawed system of regulation and review:

> All the same, modernization of the Common Rule is desperately needed. Regulatory requirements have become so complicated that most researchers cannot fully understand or remember them, and thus cannot draw the connections between many of these requirements and the goal of protecting subjects. In my experience, all but a relative handful of research investigators embrace the need to protect human subjects from reasonably foreseeable risks of harm, understand the need to protect subjects' privacy and the confidentiality of subjects' data, and genuinely want to comply with regulatory requirements. However, these requirements are now so detailed that they frustrate investigators (and IRB members) and undermine the respect needed to foster compliance and ensure meaningful protections for human subjects.
>
> In addition, the IRB system has been stretched well beyond its limits. Poorly resourced and still largely dependent on the dedication of its volunteer members, IRBs are expected to do too much with too little. Regulatory requirements must be simplified so investigators can understand and respect them, and so IRBs can spend their valuable time and resources on activities that genuinely protect subjects. So how can the much-needed reform be accomplished, given current practical and political realities?
>
> In the short term, the agencies responsible for implementation of the Common Rule—particularly the Department of Health and Human Services and its Office for Human Research Protections—must be willing to develop practical guidance for implementing the current regulatory requirements in a way that promotes clarity and understanding and allocates human and fiscal resources based on the level of risk to subjects.

As an example, he offers the Veterans Health Administration Handbook 1058.05, "[1]Operations Activities That May Constitute Research," October 28, 2011.

That handbook offers the following definitions:

> a. Generalizable Knowledge. For purposes of this Handbook, generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research. Thus, systematic investigations designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field of study constitute research . .
>
> d. Research. Research is a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. Thus, for purposes of this Handbook, and in accordance with the definition of generalizable knowledge in subparagraph 4a, research may be defined as a systematic investigation designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study). NOTE: Research typically involves the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question to expand the knowledge base of a field of study.

I offer some observations.

First, the VHA definition of generalizable knowledge departs from what I would consider commonly understood meanings of "generalizable." For example, the findings of researchers investigating the recently exhumed bones of Richard III ("[2]a large skull fracture behind the left ear that was consistent with a crushing blow from a halberd") certainly expand the knowledge base of historians of the 15th century, but in what sense are they generalizable?

Second, the VHA definition of generalizable knowledge departs from the Belmont Report's hint at what that term means. Belmont states that " 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)." The VHA definition makes no mention of theories, principles, or statements of relationships.

Third, even as it ignores the second half of the passage of the Belmont Report quoted above, the VHA relies on the first part about testing hypotheses, something that does not appear in the regulatory definitions of research.

The VHA definitions track neither those of 45 CFR 46 nor those of the Belmont Report. They are, effectively, a new Common Rule, written by the VHA for its own purposes. And the VHA comes close to admitting this, stating that the definitions "are intended for use only within this Handbook."

I take this to mean that the VHA is willing to let other federal agencies make their own guesses about what the Common Rule might mean while it finds its own modus vivendi with the incomplete definitions in the regulations. That's not terribly different from the approach taken by USAID, which has posted [3]the unofficial guidance of a 1999 working group as its version of the Common Rule.

Such an approach might work for federal agencies and the research they directly support, since each agency could effectively write its own version of the Common Rule that makes sense for the kind of research (and non-research) it conducts. It won't do much for researchers at universities and other federally supported institutions who do not receive direct funding and thus may be left squabbling with their IRBs about which Common Rule to apply.

1. http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2456
2. http://www.nytimes.com/2013/02/05/world/europe/richard-the-third-bones.html
3. http://transition.usaid.gov/our_work/global_health/home/TechAreas/commrule.html

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Sarah Babb (2013-02-19 15:06:52)
Thanks for the post and the heads-up on the "stalling" of ANPRM! I'd be interested in hearing more about what's going on with ANPRM and why.
Sarah Babb, Boston College

Melora Norman (2013-02-20 00:51:48)
Thanks so much for your updates on this important subject. It's sad to think that a consensus on a more sensible and functional framework may be postponed indefinitely. If that is the case, journalism and history will surely continue to be impoverished while biomedical research continues to be unevenly reviewed.
-Melora @ Unity

Dreger Reviews Stark: It Is Lawyers All The Way Down (2013-02-20 09:07)

Alice Dreger reviews Laura Stark's Behind Closed Doors for the Journal of American History:

> Contrary to the self-aggrandizing story bioethicists like to tell about how IRBs arose out of concern for human subjects of research, Stark shows that, when you dig into this history, it is lawyers all the way down . . . She argues that IRB work was decentralized not to make it more ethical, but to protect the NIH from lawsuits. Stark convincingly concludes that IRBs today do not primarily enact ethical principles; they manage procedures.

[Dreger, Alice. "[1]Behind Closed Doors: IRBs and the Making of Ethical Research." Journal of American History 99, no. 4 (March 2013): 1328–1328. doi:10.1093/jahist/jas666.]

1. http://alicedreger.com/tidbits_files/Dreger%20JAH%20review%20Stark%20Behind%20Closed%20Doors.pdf

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Dingwall Links Ethics Review to University "Command and Control" (2013-02-23 13:44)

Robert Dingwall argues that ethics regulation is just one part of a corporate model that threatens innovative research in universities.

[Dingwall, Robert. "How Did We Ever Get into This Mess? The Rise of Ethical Regulation in the Social Sciences." *Studies in Qualitative Methodology* 12 (2012): 3–26. [1]doi:10.1108/S1042-3192(2012)0000012004.]

Dingwall identifies a key tension in social scientists' demands for greater freedom from ethics regulation. Scholars' claims for the social value of their research can become an argument for academic freedom or for more central control of their work.

On the one hand, social scientists may need to assert the value of their work beyond their own desire for freedom. "Professions are afforded autonomy because there is a societal benefit for this," he explains, "not simply because they have captured legislatures and obtained favourable legislation."

On the other hand, too great a claim for the societal benefit of research may lead to its narrowing:

> By the end of the century, research has changed into an activity done under contracts with specified processes and outcomes. In United Kingdom, and European Union, funding, it is the language of 'deliverables'. Researchers are expected to describe in advance what they expect to find and to be evaluated on that basis. This is a recipe for incremental rather than breakthrough science.

Dingwall thus presents ethics regulation as just one means by which university administrations assert control over their faculty, with dangerous effects:

> The historically decentralised nature of universities, with faculty grouped in small, relatively autonomous, production units in close proximity to their distinctive markets is an evolved solution to the challenge of innovation very much of the kind currently envisaged by leading management theorists. There is a certain paradox in that the strengthening of central control, by measures like ethical regulation, quality assurance, and research performance management is introducing the sort of corporate model that has clearly failed to sustain and profit from innovation. One of the most important arguments against ethical regulation may then relate to its place in a wider structure of command and control that is actually inimical to one of the most important institutional goals of a research-oriented university system – if universities cease to generate revolutionary science, what is the point of universities?

1. http://dx.doi.org/10.1108/S1042-3192(2012)0000012004

New Brunswick Declaration Seeks Respect for Researchers and Participants (2013-02-26 09:53)

Back in October, I participated in the [1]Ethics Rupture summit, hosted by the University of New Brunswick and St. Thomas University of Fredericton, New Brunswick.

One product of that conference is the [2]New Brunswick Declaration: A Declaration on Research Ethics, Integrity and Governance. It's only a page long and therefore hardly bears summarizing, but I would note its desire to "encourage regulators and administrators to nurture a regulatory culture that grants researchers the same level of respect that researchers should offer research participants." That shouldn't be a radical demand, but it is.

1. http://wp.stu.ca/ethicsrupture/
2. http://www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf

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George Mason University Adopts Shelton Definition, Solicits Faculty Advice (2013-02-27 10:53)

My own institution, George Mason University, has adopted two significant IRB reforms: clarifying the regulatory definition of research, and establishing a faculty advisory board to help shape IRB policies.

First, Mason's new page on the [1]Human Subjects Research Definition presents the guidance offered in James D. Shelton, "[2]How to Interpret the Federal Policy for the Protection of Human Subjects or 'Common Rule' (Part A)," IRB: Ethics and Human Research 21, no. 6 (November 1999): 6–9.

Developed by an unofficial working group of federal officials, the guidance explains 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 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.

The expectation that history and biography are generally not included in the definition of research will be particularly helpful to researchers in my Department of History and Art History.

Second, the university is in the process of establishing a Faculty Advisory Board for Policy Development (on which I will serve) "to enhance communication and provide opportunities for advice and feedback on proposed policies related to research integrity & assurance developed for the university by [Office of Research Integrity & Assurance], compliance committees, and other offices." That is, the IRB will now be able to consult with facutly when developing policies, rather than springing them as often unwelcome surprises.

These structural changes are just the most visible elements of an improved climate here at Mason. I hope other institutions will consider comparable moves.

1. http://oria.gmu.edu/research-with-humans-or-animals/institutional-review-board/human-subjects-policies-procedures-forms-and-instructions/human-subjects-research-definition/
2. http://dx.doi.org/10.2307/3564451

Lecture at Brigham Young University (2013-02-27 10:59)

On Thursday, February 28, I'll speak at Brigham Young University. The talk, "[1]Ignorance Is Strength: Pseudo-Expertise and the Regulation of Human Subjects Research," is an updated version of one I delivered at Virginia Tech in 2011.

1. http://www.facebook.com/events/304262313032597/

Journal Retracts Interview-Based Article for Lack of IRB Approval (2013-02-28 11:19)

[1]Retraction Watch reports that Social Science & Medicine has retracted an article based on interviews with Costa Rican healthcare providers, apparently because it did not receive the IRB approval it claimed.

["Social Sciences Paper Retracted for Lack of Ethical Approval." Retraction Watch, February 25, 2013. [2]http://retractionwatch.wordpress.com/201 3/02/25/social-sciences-paper-retracted-for-lack-of-ethical-approval/; Goldade, Kate, and Kolawole S. Okuyemi. "RETRACTED: Deservingness to State Health Services for South–South Migrants: A Preliminary Study of Costa Rican Providers' Views." Social Science & Medicine 74, no. 6 (March 2012): 882–886. doi:[3]10.1016/j.socscimed.2011.06.045.]

The details of the case are murky. The official retraction states that

> This article has been retracted at the request of the Editors-in-Chief.
>
> The article is based on work that was undertaken without obtaining prior informed consent to conduct human subjects research from the Author's institution. The scientific community takes a very strong view on any ethical infringement in the conduct of research and apologies are offered to readers of the journal that this was not brought to our attention prior to publication.

IRB aficionados know that one secures informed consent from one's subjects or participants, not one's institution. So whoever wrote the retraction notice appears unfamiliar with regulatory terminology.

To add to the puzzle, the authors of the piece seem to have been aware of IRB rules, for the article clearly states that "Ethical approval for the research was obtained from the Institutional Review Board at the University of Arizona," where Goldade earned her PhD. Retraction Watch explains that

> The editors of the journal tell us that while the notice says the retraction was their request, Goldade — whom we have not been able to reach for comment — asked for it first. We've asked the University of Arizona how the lack of IRB approval became clear, and will update with anything we learn.
>
> Goldade's co-author, Kola Okuyemie, who leads the University of Minnesota's program in health disparities, said through the university that he only interpreted the data and developed the manuscript, so did not have anything to do with the work related to the IRB approval.

Finally, while it's hard to read the article with the word "RETRACTED" pasted in big red letters across the text, nothing that I could find explained why this project would not be exempt from IRB review under [4]45 CFR 46.101(b)(2). The interviewers seem to have asked health care providers about their views of "state responsibility for non-citizens within its territory," with such question as "What services do you think that migrants deserve even if they are undocumented?"

Had the investigators sought information about health care providers' decision to offer more or less care than was legally permissible or required, I can see how the answers "could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation." But interviews with competent adults about their political beliefs should not trigger IRB jurisdiction.

1. http://retractionwatch.wordpress.com/2013/02/25/social-sciences-paper-retracted-for-lack-of-ethical-approval/

2. http://retractionwatch.wordpress.com/2013/02/25/social-sciences-paper-retracted-for-lack-of-ethical-approval
3. http://dx.doi.org/10.1016/j.socscimed.2011.06.045
4. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

Brian Borchers (2013-03-02 16:27:47)
I don't know anything about the political situation in Costa Rica, and I'm not making any statement about what might have happened in this case, but I can certainly imagine situations in which a regime was so repressive and/or xenophobic that it might take action against any of its citizens who responded to a survey on a politically sensitive topic. In that situation you would be creating a risk for your survey respondents, and there really would be a serious ethical issue to be considered.

At another level, it's a clear ethical violation to claim that IRB approval was obtained when it had not in fact been obtained. If I were the editor of the journal, I'd be comfortable defending the decision to retract the paper on that basis alone.

As an IRB member, I'd be very upset if someone claimed that our IRB had approved a proposal when we hadn't actually approved it.

Zachary M. Schrag (2013-03-02 16:37:40)
Thanks for this message.

Costa Rica is a stable democracy that in 2013 earned [1]Freedom House's highest scores for both political rights and civil liberties.

I agree that a false claim of IRB approval is grounds for retraction. But the facts as stated make me wonder if the explanation for the false statement might be a confusion between approval and exemption.

1. http://www.freedomhouse.org/report/freedom-world/freedom-world-2013

2.3 March

A Credible Social Assurance (2013-03-04 08:21)

I am reading [1]Alex John London's claims that IRBs help to "provide a 'credible social assurance' to the American people that social institutions, funded by their tax dollars and empowered to advance their health and well-being, work to: respect and affirm the moral equality of all community members; prevent the arbitrary exercise of social authority; and help create a 'market' in which the diverse stakeholders, often working to advance diverse ends, collaborate in a way that advances the common good."

I am reading [2]Carl Elliott's accounts of the difficulties he has faced trying to use the IRB system at a public university to achieve any accountability for the burying of a drug study after it did not deliver the results a drug company wanted.

And I am re-reading Allan Brandt's [3]Cigarette Century, which explains how tobacco companies reacted to early findings that cigarette smoking causes lung cancer. They promoted the use of filter tips, which didn't trap carcinogens but did turn brown as the cigarette burned. In 1966, Philip Morris executives noted that "the illusion of filtration is as important as the fact of filtration."

1. http://www.sciencecodex.com/reforming_us_research_ethics_alex_john_london_calls_for_system_that_works_for_all_stakeholders-107383

2. http://loathingbioethics.blogspot.com/2013/03/did-university-of-minnesota-destroy.html
3. http://www.cigarettecentury.com/

AAUP Publishes Final Report, Regulation of Research on Human Subjects: Academic Freedom and the Institutional Review Board (2013-03-05 14:40)

The American Association of University Professors has published the final version of [1]Regulation of Research on Human Subjects: Academic Freedom and the Institutional Review Board, prepared by a subcommittee (of which I am a member) of the Association's Committee A on Academic Freedom and Tenure.

The report explains,

> As things now stand, the IRB system assembles local committees whose members have no special competence in assessing research projects in the wide range of disciplines they are called on to assess, whose approval is required for an only minimally restricted range of research projects and who are invited to bring to bear in assessing them an only minimally restricted body of what they take to be information, who are only minimally restricted in the demands they may make on the researchers, and whose judgments about whether to permit the research to be carried out at all are, in most institutions, final. When one steps back from it, one can find oneself amazed that such an institution has developed on university campuses across the country.

1. http://www.aaup.org/report/regulation-research-human-subjects-academic-freedom-and-institutional-review-board

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Inside Higher Ed Reports on AAUP Recommendations (2013-03-06 08:44)

Inside Higher Ed presents the key points of the newly finalized AAUP report.

[Carl Straumsheim, "AAUP Recommends More Researcher Autonomy in IRB Reform," *Inside Higher Ed*, March 6, 2013. [1]http://www.insidehighered.com/news/2013/03/06/aaup-recommends-more-res earcher-autonomy-irb-reform.
]

1. http://www.insidehighered.com/news/2013/03/06/aaup-recommends-more-researcher-autonomy-irb-reform

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ANPRM Is Mostly Dead (2013-03-07 21:27)

The Chronicle of Higher Education reports that the regulatory reform process that began with the 2011 ANPRM "appears to be stuck, with little optimism for a way forward."

[Basken, Paul. “Federal Overhaul of Rules for Human Research Hits Impasse.” Chronicle of Higher Education, March 7, 2013, sec. Government. [1]http://chronicle.com/article/Overhaul-of-Rules-for-Human/137811/ (paywall)]

The article explains,

> After months of trying to reconcile the sometimes competing goals of making the rules both simpler and tougher, while engaging 17 different federal agencies affected by the Common Rule, participants are describing the process as stalemated.
>
> "I think it’s dead, pretty much," said E. Greg Koski, a former director of the human-research-protections office, reflecting assessments he’s heard from key players in the process.
>
> The office has a published timetable suggesting it will formally propose a new set of regulations next month. In a written statement, the current director of the Office for Human Research Protections, Jerry A. Menikoff, said he intended to keep trying.
>
> "This is, of course, a complicated undertaking, as was stated from the outset, and it takes time," Dr. Menikoff said.

In other words, [2]there’s a big difference between mostly dead and all dead. Mostly dead is slightly alive.

1. http://chronicle.com/article/Overhaul-of-Rules-for-Human/137811
2. http://www.imdb.com/title/tt0093779/quotes

National Academies Run Workshops on Common Rule Revisions (2013-03-13 11:51)

The National Academies are running workshops on "[1]Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences." I was unaware of the first two meetings in January, but I hope to attend the upcoming meetings on March 21 and 22.

The panel’s scope sounds promising:

> The work of the panel is intended to inform the current efforts of the federal government to update the Common Rule (45 CFR 46), last revised in 1991. The panel will consider such issues as the appropriateness of the Common Rule for different behavioral and social science research methods; the concept of information risk and its relationship to methods and mechanisms developed by the federal statistical community to protect confidentiality while providing access to research data; the concept and appropriate treatment of psychological risk for human research participants; appropriate classification of research projects by the level of scrutiny required by an institutional review board (IRB); revisions to the consent process to facilitate informed decisions by human research participants while minimizing barriers to participation; and training that can effectively instruct researchers, IRB members, and other administrators with a role in IRB processes.

I am concerned, however, by the composition of the 12-person committee, which seems heavy on quantitative and experimental approaches and concerns with health, and light on qualitative methods.

Based on their [2]NAS biographies, I count six doctorates in psychology, two in economics, and one each in social epidemiology and sociology, plus an MD and a JD. One of the economists (Weir) and the lawyer (Riley) specialize in health issues. Though Charles Plott's doctorate is in economics, he has an appointment in political science as well, so perhaps we can count that discipline as represented. But the committee has no anthropologists, communication scholars, folklorists, geographers, historians, journalists, or linguists, no one primarily interested in ethnography, interviewing, participant observation, or action research.

I am disappointed by this narrowness. The [3]National Academies' committee appointment process states that

> The committee must include experts with the specific expertise and experience needed to address the study's statement of task. One of the strengths of the National Academies is the tradition of bringing together recognized experts from diverse disciplines and backgrounds who might not otherwise collaborate. These diverse groups are encouraged to conceive new ways of thinking about a problem.

Moreover, the National Academies' own 2003 study, [4]Protecting Participants and Facilitating Social and Behavioral Sciences Research, recommended that "any committee or commission that is established to provide advice to the federal government on human research participant protection sould represent the full spectrum of disciplines that conduct research involving human participants."

I don't see how the composition of the present committee meets either goal. I realize that the National Academies post provisional committee lists for public comment, and I am sorry to have missed that phase.

1. http://www8.nationalacademies.org/cp/projectview.aspx?key=49500
2. http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49500
3. http://www8.nationalacademies.org/cp/information.aspx?key=Committee_Appointment
4. http://www.nap.edu/catalog.php?record_id=10638

Chris Lawrence (2013-03-13 13:36:17)
Fiske is at least pretty well-known in political psychology circles, and Groves as former director of ISR at Michigan certainly has experience with political science research through SRC and ICPSR (as would Weir to a lesser extent).

That said I do think the humanities and qualitative/interpretivist social sciences are underrepresented.

- Chris Lawrence, Middle Georgia State College

Tolich and Tumilty Explain TEAR **(2013-03-14 21:36)**

Martin Tolich and Emma Tumilty explain the origins and aims of The Ethics Application Repository (TEAR)

[Tolich, Martin, and Emma Tumilty. "Making Ethics Review a Learning Institution: The Ethics Application Repository Proof of Concept. Tear.otago.ac.nz." *Qualitative Research* (January 3, 2013). doi:[1]10.1177/1468794112468476.]

The problem, they note, was that IRBs are not set up to learn or to teach.

> Each month, IRB Chair Tolich saw applicants, especially novice researchers stumble through the IRB application process struggling with their clash of theory, methodology and ethical principles without much guidance. If ethics committees were a learning institution, they would have identified and posted common problems and their solutions and supplied templates of appropriate permissions for others to mirror. Examples of strategies used to ensure safety both in complex situations like data archiving or of vulnerable participants, as well as models of best practice for often occurring issues, could be identified and pooled as in data sharing initiatives. In lieu of these innovations, ethics committee members went on saying, as they do, 'when will researchers ever learn'. But how can they learn? Where are the resources? TEAR establishes a precedent.

The solution is TEAR, "an array of special collections of IRB applications that addressed specific topics that qualitative researchers see as ethical hotspots."

> TEAR's goal is to pool resources and facilitate sound ethical practice by allowing both novice researchers and their supervisors (who may be a novice on a specific topic) to read how scholars have previously thought through pathways less travelled allowing researchers to protect their research subjects from harm. Given the constantly shifting and developing nature of research and research ethics, as it explores the dynamic world around us, a sharing of knowledge and practice between IRBs and experienced and novice researchers can only be welcomed.

And the underlying values are respect for expertise and humility:

> Tolich who has 20 years of experience in graduate supervision, a decade of that spent on IRBs, is doubtful whether he could advise a graduate student wanting to research identity in chat rooms or Facebook in appropriate ethical pathways.

1. http://dx.doi.org/10.1177/1468794112468476

On Signing the Markingson Petition (2013-03-17 11:36)

By April 1942, the Pentagon was 40 percent over budget, partly because it had been enlarged since first approved, but mostly because the original estimate of $35 million had never been realistic. Lieutenant General Brehon Somervell delayed telling Congress, but in June he finally sent Colonel Leslie Groves to appear before a House Apppropriations subcommittee.

[1]Steve Vogel describes the appearance:

> No protest was raised at the increased size or cost. Instead, much of the hearing dealt with complaints that the floors of the Pentagon were dusty. "We can get rid of the dust inside the building, but we cannot get rid of the dust outside, and it keeps coming in," Groves explained.
>
> [Captain Clarence] Renshaw was incredulous; they had been dreading Congress's reaction to the overrun, and all the members cared about was the dust. "They listened to a $15 million deficit, and swallowed it without a comment," he afterward told George Holmes, Somervell's PR man. "When somebody said there was dust on the floors, they sent for me to come up and explain it."

Oversight committees can be at once nitpicking about small matters and inattentive to large concerns.

Not everyone gets this. Consider Carl Elliott, who has done heroic work bringing to light the case of Dan Markingson, who committed suicide while enrolled in a University of Minnesota trial of anti-psychotic drugs. Given his outrage over the university's treatment of Markingson, and over its conduct after Markingson's death, [2]Elliott can't understand why university president Eric Kaler would proclaim "a quest to 'free' our organization from unnecessary administrative burden—those that we impose on ourselves because we have a low tolerance for risk, or because we're afraid a misdeed of two decades ago will reappear again."

Elliott writes,

> the current problems at the university are not the result of any excessive regulatory burden. They are the result of industry-funded university investigators ignoring research regulations, repeatedly failing to meet their ethical obligations, and fearing no sanctions whatsoever. University officials have repeatedly defended this misconduct or looked the other way. To suggest that the university needs to "recalibrate its risk tolerance" is an insult to the research subjects who are being asked to bear those risks.

Well, some problems come from too little regulation, and some come from too much. This is [3]Alice Dreger's conclusion as she looks at the Markingson case and joins a [4]petition for the governor of Minneosta to investigate the case as potential research misconduct. Even as she does so, she notes that "many social scientists are quite reasonably fed up with the way in which IRBs have evolved to the point where they attempt to hyper-regulate our work, often forcing us to adhere to systems that make no sense for our disciplines."

She continues,

> I would argue that the mistreatment of social scientists and the failure to really police dangerous medical studies are two sides of the same coin: both cases show how IRBs and the OHRP are failing to focus on what really matters – the protection of human subjects in genuinely dangerous research.

While IRBs fret about dust on the floors, participants in medical trials die.

I worry about the consequences of the petition drive. In the past, the regulatory response to abuses by biomedical researchers has been to make life harder for social scientists. I can imagine the University of Minnesota responding to a state investigation not by cleaning up its lucrative drug trials but by making its [5]geographers jump

through more silly hoops.

But what is that compared to a chance for justice for Dan Markingson? I will sign the petition.

1. http://www.thepentagonhistory.com/
2. http://loathingbioethics.blogspot.com/2013/03/does-president-kaler-really-believe.html
3. http://alicedreger.com/worst.html
4. https://www.change.org/petitions/governor-mark-dayton-of-minnesota-investigate-psychiatric-research-misconduct-at-the-university-of-minnesota-2
5. http://www.institutionalreviewblog.com/2012/07/geographer-unnecessary-irb-delay.html

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National Academies Post Workshop Agenda (2013-03-20 15:30)

The National Academies has posted the agenda for their [1]Workshop on Proposed Revisions to the Common Rule in Relation to Behavioral and Social Sciences, to be held tomorrow and Friday in Washington, D.C.

I plan to attend and to post comments to this blog. If I can establish WiFi, I may also live tweet at [2]@IRBblog.

1. http://sites.nationalacademies.org/DBASSE/BBCSS/CurrentProjects/DBASSE_080452#.UUob31vEozN
2. https://twitter.com/IRBblog

Report from the National Academies Workshop (2013-03-25 13:06)

Last week I attended the [1]Revisions to the "Common Rule" in Relation to Behavioral and Social Sciences Workshop sponsored by the National Academies.

I live-tweeted the event on my @IRBblog account, and I have collected those tweets on [2]Storify.

What follows are what I consider some of the key messages from selected presenters. The statements following each name represent my summary of the remarks, not necessarily a quotation or paraphrase.

Connie Citro: Hey, We Did This Ten Years Ago

Connie Citro of the National Research Council was one of the editors of the 2003 report, [3]Protecting Participants and Facilitating Social and Behavioral Sciences Research. She explained the origins of that report; while the 2002 report on medical research, [4]Responsible Research: A Systems Approach to Protecting Research Participants, got funding from HHS, the National Research Council itself had to pay for the companion volume on social and behavioral science from its own funds. Citro suggested that the 2003 report could still guide policy, and she seemed miffed that the ANPRM paid so little attention to it. Social and behavior research, she argued, remain the neglected stepchild of human subjects regulation.

While I see flaws in the 2003 report (see Ethical Imperialism, 176-177), I agree that the ANPRM writers could have paid it more attention. And, [5]as I noted recently, I wish the National Academies had paid more attention to the report's recommendation that "any committee or commission that is established to provide advice to the federal government on human research participant protection sould represent the full spectrum of disciplines that conduct

research involving human participants."

Jeffery Rodamar: What, Me Worry?

Jeffery Rodamar of the Department of Education began with a quotation from Montaigne: "Nothing is so firmly believed as what is least known." But given what followed, he would have better started with Doctor Pangloss.

Rodamar's first major claim is that IRBs do not place a great burden on researchers. Looking at statistics on turnaround time, he noted that expedited reviews only take about a month from submission to final approvals, and full review takes, on average, a month and a half. Few studies are rejected outright.

Such analysis obscures a great deal. First, it does not consider the impact of these delays. For a multiyear drug study, a one month wait may not mean much. For a political scientist seeking to react to events, or a student hoping to get a project done during a one-semester research seminar, one month can be fatal. Nor would Rodamar's statistics pick up studies gutted by the requirements imposed by IRBs, studies withdrawn after the researcher abandoned hope, or studies never even attempted because the researcher knew it would be too difficult to get approval.

Rodamar then claimed that the University of Michigan survey showed that social scientists are not much more dissatisfied than medical researchers. I believe this to be a misreading of the data, [6]which did not break down researchers by discipline.

Finally, Rodamar offered a grab-bag of studies he considered harmful to participants. He did not argue that the harms of these could have been foreseen by IRBs, and he even threw in some long-range consequences that IRBs are forbidden to consider.

Brian Mustanski: IRBs Don't Speak for Our Participants

Brian Mustanski reiterated the lessons drawn from his powerful 2011 article, [7]"Ethical and Regulatory Issues with Conducting Sexuality Research with LGBT Adolescents: A Call to Action for a Scientifically Informed Approach."

He noted the divergence between IRBs demands and the lives of the people he studied. If an IRB tells participants that they might need psychological services, and that's not true, how is that informed consent? If participants report that being asked questions made them feel important, why does the IRB prohibit the researchers from telling that to other prospective participants? Why can't social researchers note that particpating may provide useful information to avoid HIV, if that is the case?

Charles Plott: Sometimes, There Really Is No Risk

Charles Plott of CalTech described lab experiments run by behavioral economists, political scientists, and others interested in decision making. This research has enormous consequences, since it can help policy makers devise efficient markets for things like airport landing rights, pollution permits, and radio spectrum licenses. And the most serious adverse impacts reported, among hundreds of thousands of participants, are things like being irritated by a question. To understand the risk of harm, he argued, you need to recognize when it doesn't exist.

Roxane Cohen Silver: IRBs Should Approve Generic Protocols

Silver, of the University of California Irvine, is a psychologist who studies random, unpredictable events, e.g., natural disaster, school shootings. Ideally, she wants research to start almost immediately, since people can't accurately

reconstruct their emotional experiences weeks or months after an event.

She has persuaded her IRB to approve a generic disaster protocol, which could allow her to get exempt or expedited approval within 24 hours of a request. As she described it, this is based on her IRB's knowledge that she and her team have been trained to do research with sensitivity, and to refer participants to help when appropriate.

Though Silver did not put it this way, the IRB has in effect gone from a protocol-review model to [8]a researcher-certification model, along the lines proposed by Greg Koski. And Silver seems to like this idea; she disapproves of the idea of researchers descending on a traumatized area (e.g., post-Katrina New Orleans) without adequate training.

Silver noted that the ANPRM's proposal to define trauma research as necessarily "emotionally charged" would impede scientific process; so would a 1-week waiting period.

George Alter: Regulations May Not Keep Pace with Technology

Alter, director of the Interuniversity Consortium for Political and Social Research (ICPSR), explained that since technology changes rapidly, it would be better for regulations to focus on risk, not specific technologies.

He also noted that the ICPSR is developing online training specific to data privacy. Could this be an alternative to the [9]mortifyingly stupid CITI Program?

Laura Stark: Alternative Models Can Address Local-Precedent Problem

Stark, author of [10]Behind Closed Doors noted that the ANPRM seeks to reduce variability among IRBs, a problem she attributes to their use of "local precedents" to decide cases. She presented some of the findings of her work; when she noted that IRBs often judge researchers' ethics based on grammatical errors and typographical mistakes, the audience giggled.

Stark noted three alternatives: study networks that allow centralized review; collegial review, such as the devolution of review to the department level; and the collection and dissemination of decisions and applications, e.g., Otago's [11]TEAR.

Stark described variability as a problem for multi-site studies. When I asked her if the fact that two IRBs on the opposite sides of a river could produce wildly different judgments on an identifical study might indicate that at least one of the IRBs was simply wrong about regulations, ethics, or both, she said no, any result can be explained by community attitudes.

Thomas Coates: No Clear Line Between Social and Medical

Coates, whose PhD is in psychology and who directs the UCLA Program in Global Health, argued that there no clear lines to be drawn among social, behavioral, and medical research in a project designed, for example, to ask why some people resist medical regimens prescribed for them. He stressed the importance of local knowledge; for example, asking about homosexuality will bring greater risks in countries where homosexuality is illegal.

Lois Brako: An Unchecked Box Can Do a Lot of Good

Brako, Assistant Vice President, Regulatory and Compliance Oversight at the University of Michigan, described a long list of measures her university has taken to reduce problems for investigators. An automated system tells them if

their research is free from review. Exemptions can be delivered within a day or two; expedited approval in about 14. Her office looks for types of research that deserves exemption, and gives 2-year approvals to reduce the workload of continuing review.

Some of this can be done within current regulations, but much of it only works for non-funded research. For example, current regulations specify elements of a consent process that are inapplicable to much social research. Inconsistent guidance from agencies is a big problem, and she thinks that some IRBs would benefit from OHRP telling them what they don't need to review.

[Editor's note: [12]OHRP has never been good at this.]

In the Q &A, NAS Committee Member Richard Nisbett, also of the U of Michigan, told everyone that Brako had really turned things around there; before her arrival, the IRB could debate semicolons vs. commas, take weeks to grant exemptions, and reject consent forms identical to ones it had earlier approved.

Neither Brake nor Nisbett addressed the survey's findings that researchers don't think the IRBs are good at explaining their actions, and that only 44 percent of researchers believed that the changes made to their projects improved the protection of participants.

Committee member Robert Levine stated that the National Commission had recommended that each institution be able to decide which procedures could be expedited, and only later did HHS regulators change that to a fixed, federal list. As I pointed out to him later, the National Commission in fact recommended that any list crafted by an institution would need federal approval.

Rena Lederman: Regulations Should Embrace Their Inner Clinician

Reiterating the ANPRM response she helped prepare for the American Anthropological Association, Rena Lederman of Princeton argued that biomedical assumptions are embedded in the Common Rule, and that minor tinkering cannot fix that.

Consent requirements assume a thin, contractual relationship with subjects, she argued, whereas ethnographers seek thick relationships, not with "subjects" but with hosts, interlocutors, neighbors, collaborators, and friends. They do not find IRBs to be a welcoming space, since IRBs don't understand that ethnographers work in heterogenous, dynamic communities different from our own.

Adapting IRB regs to social science and humanities would require a regulatory revolution, probably beyond the capacity of the National Academies committee. What is really needed is a commission made up of experts from disciplines not served by current system of oversight.

Cheryl Crawford Watson: Longer Consent Forms, Less Informed Consent

Watson, of the National Institute of Justice, noted that informed consent is serious business when asking people about their criminal behavior. But when IRBs insist on consent forms that discuss nonexistent possibilities of physical injury from surveys, or inapplicable alternative treatments, participants may miss the important information.

Richard Nisbett: People Can Die for Want of Research

Nisbett, of the University of Michigan, is a member of the NAS Committee. His comments were the most forceful

denunciation of IRB abuses.

Nisbett doesn't think that IRBs are effective at preventing unethical research by social sciences. Yes, people can name examples of inappropriate projects, but many of those have been approved by IRBs. IRBs can't teach people not to be stupid.

What they can do is block important research. Some of that research, even though not biomedical, can saves lives, if it teaches city planners how to prevent violent crime, or helps people avoid obesity. And some research, he believes, should never be reviewed. He noted history as an example. It is not enough for regulators to tell IRBs what to review, he argued. They must tell IRBs what not to review, with examples.

My Thoughts

I left the workshop with a few major observations.

First, most of the people attending seem to believe that the regulatory revision process is not as stalled as [13]Tom Puglisi believes. Maybe we won't get a Notice of Proposed Rulemaking this spring, but perhaps by the end of the year.

Second, I did not hear anyone express support for the ANPRM's proposal of using the HIPAA privacy rule to govern human subjects research. The consensus is that the rule would be overprotective in some areas, underprotective in others.

Third, money talks. One participant–I think it was Plott–noted that the committee and the panelists almost all come from major research universities, not smaller colleges and universities who may have trouble affording competent IRB staffs. I would add that most of the projects discussed were major, grant-funded quantitative studies. Who will speak for the [14]undergraduate?

The [15]workshop's agenda cautioned that "observers who draw conclusions about the committee's work based on today's discussions will be doing so prematurely." That's just as well, since I would not want to predict where the committee will go from here. The committee members heard from some who want only tinkering around the edges of the current system, some who want wholesale rethinking, and some who would like relatively bold reform (such as greatly expanded lists of exemptions) within the current system. I can't guess which will prove the most persuasive.

1. http://sites.nationalacademies.org/DBASSE/BBCSS/CurrentProjects/DBASSE_080452#Workshop
2. http://storify.com/IRBblog/nas-common-rule-workshop-march-2013?awesm=sfy.co_cG49&utm_medium=sfy.co-twitter&utm_campaign=&utm_source=t.co&utm_content=storify-pingback
3. http://www.nap.edu/openbook.php?isbn=0309088526
4. http://books.nap.edu/catalog.php?record_id=10508
5. http://www.institutionalreviewblog.com/2013/03/national-academies-run-workshops-on.html
6. http://www.institutionalreviewblog.com/2011/07/u-of-michigan-reports-some-progress.html
7. http://www.institutionalreviewblog.com/2011/05/sex-researcher-calls-for-evidence.html
8. http://www.institutionalreviewblog.com/2012/07/harvard-law-today-reports-on-anprm.html
9. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
10. http://www.institutionalreviewblog.com/2012/10/i-review-stark-behind-closed-doors.html
11. http://www.institutionalreviewblog.com/2013/03/tolich-and-tumilty-explain-tear.html
12. http://www.institutionalreviewblog.com/2010/12/menikoff-passes-buck.html
13. http://www.institutionalreviewblog.com/2013/02/puglisi-anprm-is-stalled-write-your-own.html
14. http://www.institutionalreviewblog.com/2009/11/brown-pledges-irb-reform.html
15. http://sites.nationalacademies.org/DBASSE/BBCSS/CurrentProjects/DBASSE_080452#Workshop

Rivera: Faculty Researchers Are Notoriously Poor Judges of Risks (2013-03-30 09:03)

Suzanne Rivera, Associate Vice President for Research at Case Western Reserve University and member of the Secretary's Advisory Committee on Human Research Protections, responds to the AAUP's IRB report by asserting that faculty are inept at making determinations of exemption. I question this claim.

[Rivera, Suzanne A. "Academic Freedom and Responsibility |." Bill of Health. Accessed March 28, 2013. [1]http://blogs.law.harvard.edu/billofhealt h/2013/03/24/academic-freedom-and-responsibility/. h/t Michelle Meyer]

I have posted the following comments on the blog where Rivera's statement appeared.

Dear Dr. Rivera,

Thank you for taking the time to comment on the AAUP's recent report, "[2]Regulation of Research on Human Subjects: Academic Freedom and the Institutional Review Board," which I helped prepare. As you note, the report recommends that researchers conducting some types of minimal-risk studies should be allowed to proceed without first getting approval from an IRB office or an IRB itself. This was the intention of at least some of the drafters of the current regulations, and in 2009 [3]OHRP affirmed that "the regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt."

This is not good enough for you, however. "Placing responsibility for exemption determinations entirely in the hands of researchers is a bad fix," you write. "Faculty researchers are notoriously poor judges of the risks posed by their studies. Ask anyone experienced in the IRB 'intake' process about how often studies posing more than minimal risk are submitted for verification of 'exempt' status and I can bet the number will not be insubstantial."

I imagine that you intended this last sentence as a rhetorical device. But why should it be? Your biography explains that you have "responsibility for oversight of the research enterprise" at Case Western Reserve University, so presumably you have ample opportunity to ask your staff how often faculty researchers underestimate the risk of their studies. Have you done so?

Specifically, I would like to know the following:

How many proposals in the social sciences and humanities (the major concern of the AAUP report) sought exempt status at Case Western in 2012?

Of these, how many did the IRB intake staff find to be non-exempt under the terms of the Common Rule?

How were these disagreements between researcher and staff distributed among the six categories and various subcategories of exemption in 45 CFR 46.101(b)? For example, did any faculty researcher mistakenly claim to be interviewing elected or appointed public officials or candidates for public office? Did any misunderstand the federal department-approval requirements of category 5?

When IRB staff and researchers disagree over a project's eligibility for exemption, how is this resolved? Do you assume that the IRB staff is always right? Or do you audit their work to guard against unnecessary escalation of review? Can researchers appeal the determination?

As a member of SACHRP, have you collected or sponsored any research to determine the frequency of inappropriate requests for exemption, and their breakdown by category, nationwide? Have you collected or sponsored any such

research about unnecessary escalation?

I know of only scant data on such questions. In 1998, [4]James Bell Associates reported that "According to chairs, about one-half or fewer protocols eligible for exemption were actually exempted from review, depending on research category." And while that study is rather old now, a [5]2010 report on the IRB process at my university found a similar figure: "of the nine protocols that were given an expedited review, five or 55 % could have been exempted from review." (I am glad to report that matters have improved since then.) Rather than finding that "faculty researchers are notoriously poor judges," these reports suggest that IRBs and their staffs can be the poor judges of exemption eligibility.

If you have "not insubstantial" numbers suggesting otherwise, I would be glad to consider them and discuss ways they could be used to reform the regulations. For example, if most of the disputes over exemption concentrate in one or two categories, then perhaps researchers could be allowed to determine their eligibility for other exemptions while regulators rewrote the confusing exemptions in clearer terms.

But if you lack numbers, perhaps we should discuss the terms of a bet.

1. http://blogs.law.harvard.edu/billofhealth/2013/03/24/academic-freedom-and-responsibility
2. http://www.aaup.org/report/regulation-research-human-subjects-academic-freedom-and-institutional-review-board
3. http://www.institutionalreviewblog.com/2009/10/ohrp-grudgingly-okays-self-exemption.html
4. http://www.hhs.gov/ohrp/archive/policy/hsp_final_rpt.pdf
5. http://research.gmu.edu/docs/HuronHSRB_FinalReport.pdf

2.4 April

REB Members Beg U of Ottawa to Defend Confidentiality (2013-04-10 12:20)

[1]IRB apologists sometimes argue that IRB review is necessary to ensure that universities will defend researchers and their participants from litigation. Boston College Subpoena News reminds us that ethics approval is no guarantee of such support.

["News of Interest: Canadian Academics Strongly Defend Research Confidentiality, Call for University Support of Researchers." Boston College Subpoena News, April 9, 2013. [2]http://bostoncollegesubpoena.wordpress.com/2013/04/09/news-of-interest-canadian-academics-strongly-defend-research-co nfidentiality-call-for-university-support-of-researchers/.]

Faculty members of two University of Ottawa REBs have petitioned the university administration on behalf of Professors Chris Bruckert and Colette Parent. They explain:

> The issue, as we understand it, concerns the Montreal Police department's efforts to seize confidential data collected in the context of a 2007 research study – in particular, an interview the researchers conducted with a Montreal sex worker. This study received approval by the university's Research Ethics Board on the explicit condition that the research participants' confidentiality would be protected. We are asking that the university immediately step forward to offer support to these professors including but not limited to their legal costs in defending the confidentiality of their research records.

> Professors Bruckert and Parent have petitioned the Superior Court of Quebec to ensure the confidentiality their research participant was promised in exchange for his participation in the research. The two professors, the Association of Professors at the University of Ottawa, and the Canadian Association of University Teachers (CAUT) have all requested support from the University of Ottawa for the professors' legal expenses. Despite these requests, the university has thus far refused to cover or contribute to the legal costs of defending research confidentiality.

1. http://www.institutionalreviewblog.com/2012/05/berkeley-historian-defends-irb-review.html
2. http://bostoncollegesubpoena.wordpress.com/2013/04/09/news-of-interest-canadian-academics-strongly-defend-research-confidentiality-call-for-university-support-of-researchers

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Federal Demonstration Parternship Pilots Exempt Wizard **(2013-04-11 09:53)**

In response to concern about [1]"Over-review of Exempt Research", the Federal Demonstration Partnership is testing an [2]Exempt Wizard, which would allow researchers to fill in a computer form and learn if their projects are exempt, rather than waiting for an IRB or IRB staff to make that determination.

Boston University, University of Michigan, Michigan State University, College of Charleston, Sacramento State, New York University, and the University of Washington are participating in the trial.

This sounds most promising.

1. http://sites.nationalacademies.org/PGA/fdp/PGA_061069
2. http://engage.washington.edu/site/MessageViewer?em_id=93201.0

Boston College Oral History Roundup **(2013-04-14 00:51)**

I rely on the exceptionally thorough [1]Boston College Subpoena News for updates on the efforts of the United Kingdom and United States governments to get access to oral history interviews of participants in Northern Ireland's Troubles, but I feel I should flag three items of special interest to readers of this blog.

Society of American Archivists Government Affairs Working Group Notes Debate About "Archival Privilege"

On February 11, the SAA GAWG posted a [2]Discussion of the Boston College/IRA Oral History Situation. This document claimed that

> The researchers, apparently acting in the belief that additional assurances of confidentiality made to the oral history subjects could be supported in case of legal action, made additional written promises to participants in the oral history project that went beyond those offered by Boston College, but project staff did not disclose to participants that these additional assurances were made on behalf of the project staff and did not represent the position of Boston College. These additional assurances apparently were founded in the researchers' belief in a legal theory of "archival privilege" previously rejected by a federal court.

The document also notes that

> The belief that there should be an archival privilege of confidentiality requires careful and thorough discussion within the archival profession. Although some members of the profession clearly believe that such a right should be asserted, others believe that asserting such a right could be interpreted as an unfortunate exercise in absolutism that would be detrimental to the broader public interest. At the very least, such a right would have to be nuanced carefully and placed into a context of mutual rights and responsibilities that others might legitimately assert for the availability and use of archival material under certain circumstances.

Ed Moloney Replies

On February 27, former project director [3]Ed Moloney replied to the SAA document. He disputed its account and blamed Boston College for drafting a donor agreement that could not withstand subpoena:

> Do you seriously think that a) we considered ourselves or were in any way competent to draw up a contract that would apply in a country where we did not live and whose laws we were unfamiliar with and b) do you think Boston College would allow a bunch of amateurs living 3,000 miles away who were ignorant of American contract law to draw up an agreement dealing with the ownership rights of such an archive, especially considering that its unique and singular nature would, with time, bestow upon it considerable value?
>
> The answer to both questions is an emphatic ‘No’, as common sense would tell you.

Lowman and Palys Lament Betrayal

In an article for the journal Research Ethics John Lowman and Ted Palys link the Boston College case to two cases in which United Kingdom universities failed to support researchers who wished to ask about illegal behavor. [“The Betrayal of Research Confidentiality in British Sociology.” *Research Ethics* (March 20, 2013). [4]doi:10.1177/1747016113481145.]

Lowman and Palys call on universities to support researchers’ willingness to "accept imprisonment" to preserve confidentiality.

No Good Choices

Taken together, these documents show the difficulty of conducting research about criminal behavior, past, present, or future. Warning participants that their words may be released under subpoena can kill a project. Had such a warning been included in the Belfast Project consent form, Moloney writes, "so many red lights would have flashed that the project would have been stillborn, certainly on our side of the Atlantic." And Lowman and Palys note a U.S. case in which

> the court held that, because research participants had been warned that a court might require the information, now that the court did require the information, it should be handed over, because this was precisely the limitation to confidentiality about which participants had been warned. Instead of buttressing a researchers' ethical commitment to confidentiality, a priori limitations could sabotage a researcher's ability to invoke privilege on the participants' behalf. Warning the participant that a court might order disclosure devolves into a form of caveat emptor dressed up as ethics, allowing the researcher to roll over without a fight, sacrificing participant rights at the altar of informed consent.

Lowman and Palys write that "The implications of the Law of the Land doctrine [instructing researchers to submit to legal requests for their confidential data] for sociology and criminology are truly disturbing. Already, the Belfast Project subpoenas have had a chilling effect on research." But the implications of their "ethics-first perspective" are pretty disturbing as well, since it would mean that only researchers willing to accept imprisonment could conduct the most sensitive research. Either way, we face the problem they identify: "How complete is our knowledge of society's underdogs and those with the most power when the only people who get to be heard are government-approved spokespersons and administrative hacks? There could be a huge price to pay if the state is able to turn researchers into informants."

Lowman and Palys seem more hopeful about the certificate-of-confidentiality model, but they note that certificates cover only "sensitive topics that fits under the mandate of the National Institutes of Health." The National Institute of Justice's [5]privacy certificates are a better fit, but it is hard to see how they could work for an oral history project, since they demand the eventual "removal of identifiers" or complete destruction of research records. And I haven't heard anything to suggest that legislatures, agencies, or courts are working to expand these kinds of regimes.

1. http://bostoncollegesubpoena.wordpress.com/
2. http://files.archivists.org/advocacy/BostonCollIRAOralHist_FINAL2.pdf
3. http://files.archivists.org/advocacy/Response_to_Background_Paper.pdf
4. http://dx.doi.org/10.1177/1747016113481145
5. http://www.nij.gov/nij/funding/humansubjects/privacy-certificate-guidance.htm

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What Can One University Do? **(2013-04-17 09:13)**

A few weeks ago, a correspondent asked me what reforms individual universities can implement while awaiting systemic, regulatory reform. It's an excellent question, so here's a roundup from material previously covered on the blog.

No university has adopted all of these measures, and at least one of these measures has not been adopted by any. But most of them are in place already, and there's no reason they can't spread.

1. Uncheck the box

Current regulations do not require institutions to apply federal regulatory standards to research not directly funded by one of the Common Rule agencies, so universities have the option to "uncheck the box" on their federal assurances to avoid making such pledges. In 2006, [1]Richard Shweder identified this unchecking as "a monumental (even if small) first step" toward defending academic freedom. While many universities have unchecked their boxes simply to avoid federal sanctions, rather than to free up research, some have in fact made life better for researchers and the participants in their projects.

2. Free oral history, journalism, and folklore

Several top research universities, including [2]Columbia, [3]Princeton, [4]Texas at Austin, [5]Michigan, [6]Notre Dame, [7]USC, and now [8]George Mason, have acted on OHRP's 2003 advice that oral history does not constitute generalizable research, and have stopped requiring oral historians to seek IRB review. So have several government agencies. Often, such policies also liberate other forms of interviewing in which attribution by full name is the norm, notably journalism and folklore.

3. Accept evolving research

A common complaint among ethnographers and other interview researchers is that IRBs expect researchers to form questions in advance, rather than asking questions about what they observe. The University of Pennsylvania has addressed this in its [9]policy on evolving research. Canada's TCPS2 takes a similar approach in its chapter on [10]qualitative research.

4. Allow alternative training

[11]Mortifyingly stupid CITI training can quickly destroy any goodwill a new researcher brings to the IRB process. Yet it is not required by the regulations. A university can still subscribe to CITI but offer researchers the opportunity to document in other ways that they are familiar with their responsibilities. Macquarie University has developed an [12]online training course for ethnographers, and Princeton has crafted a [13]research-ethics course for historians. Universities could allow researchers to complete such training in lieu of the CITI Program.

5. Offer alternatives to Belmont

[14]45 CFR 46.103(b)(1) requires institutions to submit "a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research," but gives them the choice of "an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself." The [15]last I checked, no U.S. university had meaningfully used this flexibility to do anything but pledge allegiance to the Belmont Report. But a university could embrace greater pluralism by recognizing alternatives to Belmont, such as the ethical codes crafted by scholarly societies.

6. Allow researchers to determine exemptions.

As I document in my book, the framers of the regulations expected researchers to be able to determine for themselves whether their research is exempt under 45 CFR 46.101(b). [16]OHRP has made clear that this remains permissible. Now, [17]several universities are testing a computer program that would make exemption determinations in respose to inputs from researchers. If the test goes well, this reform could be quite easy for other universities to implement.

7. Adopt evidence-based review

I was most impressed by the recent article, Anderson and DuBois. "[18]IRB Decision-Making with Imperfect Knowledge: A Framework for Evidence-Based Research Ethics Review," *Journal of Law, Medicine & Ethics* 40, no. 4 (2012): 951–969. This offers step-by-step instructions for an IRB that wants to base its decision on evidence, rather than gut reactions. The *[19]Journal of Empirical Research on Human Research Ethics* and [20]The Ethics Application Repository are good resources for such an approach.

8. Establish an appeals process

The AAUP's 2013 report, "[21]Regulation of Research on Human Subjects: Academic Freedom and the Insti-

tutional Review Board," notes that many responses to the ANPRM called for an appeals process, and the AAUP did so as well. Current regulations make an appeals process cumbersome, but the AAUP suggests features of a good appeals process, some of which could be implemented under current regulations.

9. Create an advisory board

Allowing IRBs and IRB offices to set policies about research, as well as reviewing specific proposals, can create a dangerous concentration of power. Several universities, most recently [22]Mason, have created faculty advisory boards, not to review cases or even hear appeals, but to offer guidance on such issues as when does a classroom project need review.

Universities with some kind of oversight include [23]Michigan State, [24]Ohio State, [25]UCLA, the [26]University of Michigan, and [27]Virginia Commonwealth. I have seen references to others as well, but they may be defunct.

10. Learn

I haven't read much of the [28]literature on organizational learning, but the basic idea is that experience should shape what organizations know and, better still, what they do.

Some university human research protections programs learn from experience. The University of Michigan seems particularly committed to continuously improving its program, sponoring [29]surveys of investigator experiences, and trying out new policies (including unchecking the box, freeing oral history, providing oversight of the IRB, and trying out new exemption procedures). Not all universities have the resources of Michigan, but all can resolve to look for opportunities to make things better.

1. http://medanthro.net/academic/docs/ShwederIRBcriticalreview.pdf
2. http://www.institutionalreviewblog.com/2007/12/columbia-university-grants-oral-history.html
3. http://www.institutionalreviewblog.com/2010/04/more-universities-deregulate-oral.html
4. http://www.institutionalreviewblog.com/2010/04/more-universities-deregulate-oral.html
5. http://www.hrpp.umich.edu/om/Part4.html
6. http://www.institutionalreviewblog.com/2011/03/notre-dame-frees-oral-history.html
7. http://www.institutionalreviewblog.com/2011/04/usc-frees-oral-history.html
8. http://www.institutionalreviewblog.com/2013/02/george-mason-university-adopts-shelton.html
9. http://www.institutionalreviewblog.com/2007/08/evolving-research.html
10. http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/
11. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
12. http://www.institutionalreviewblog.com/2009/04/macquaries-innovative-ethics-training.html
13. http://www.institutionalreviewblog.com/2011/04/princeton-offers-phd-students-serious.html
14. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.103
15. http://www.institutionalreviewblog.com/2008/07/dormant-right-to-ethical-self.html
16. http://www.institutionalreviewblog.com/2009/10/ohrp-grudgingly-okays-self-exemption.html
17. http://www.institutionalreviewblog.com/2013/04/federal-demonstration-parternship.html
18. http:dx.doi.org/10.1111/j.1748-720X.2012.00724.x
19. http://ucpressjournals.com/journal.php?j=jer

20. http://www.institutionalreviewblog.com/2013/03/tolich-and-tumilty-explain-tear.html
21. http://www.aaup.org/report/regulation-research-human-subjects-academic-freedom-and-institutional-review-board
22. http://www.institutionalreviewblog.com/2013/02/george-mason-university-adopts-shelton.html
23. http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/protection.htm
24. http://orrp.osu.edu/irb/about/IRBPolicyCommittee.cfm
25. http://www.senate.ucla.edu/news/documents/IRBchargeletter.pdf
26. http://www.hrpp.umich.edu/om/Part2.html
27. http://www.research.vcu.edu/irb/wpp/flash/IV-4.htm
28. http://dx.doi.org/10.1287/orsc.1100.0621
29. http://www.institutionalreviewblog.com/2011/07/u-of-michigan-reports-some-progress.html

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2.5 May

Mortifyingly Stupid CITI Training Kills Oral History Course (2013-05-03 07:22)

Writing on [1]H-Oral, Carl Kramer, the retired director of the Institute for Local and Oral History, Indiana University Southeast, reports that Indiana University's requirement of the [2]mortifyingly stupid CITI Program dissuaded him from requiring oral history students to conduct actual interviews:

> The issue is whether the training is relevant to oral history. Last year, I planned to have the students in my Oral History course at Indiana University Southeast interview baby boomers who grew up in a nearby former company town. The local library had conducted a similar project of the previous generation about 25 years earlier, and I thought it would be a great follow up. But meanwhile, Indiana University had adopted a national training program for human subjects research that was oriented toward biomedical and psychological standards, including units on dealing with pregnant women and fetuses, HIPPA, medically-oriented conflict of interest issues. It took me approximately seven hours to review the tutorial and take the exam. As an instructor who has conducted hundreds of interviews for many years, I concluded that if it took me that long to take an exam whose content was largely irrelevant to oral history, then I could not reasonably require my students to take it. So I ended up giving them the option of doing an interview or taking a final exam. The split was about 50-50, with the majority opting for the final exam. This was for an expedited review project through the IRB. I retired from the institute under which I taught the course, and I would never again teach a course that required such an irrelevant exam.

His comment comes in reply to a [3]posting by a Kent State graduate student who may lose grant funding because she relied on [4]OHRP's 2003 letter stating 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)."

1. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=1305&week=a&msg=hTEqx9oXO/Dnlee6V0ZEhA
2. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html
3. http://h-net.msu.edu/cgi-bin/logbrowse.pl?trx=vx&list=H-Oralhist&month=1304&week=e&msg=G8QAGcaWZXQuGTCNQ2tGPw
4. http://www.historians.org/press/IRBLetter.pdf

What Good Are Statements of Committee Approval? (2013-05-08 13:47)

Sara Jordan and Phillip Gray argue that public administration journals should follow medical journals' requirements "that all articles describe informed consent and ethics committee approval or why these were waived."

[Sara R. Jordan and Phillip W. Gray. "Reporting Ethics Committee Approval in Public Administration Research." *Science and Engineering Ethics* (April 2013): 1–21. Accessed May 6, 2013. [1]doi:10.1007/s11948-013-9436-5.]

Jordan and Gray find that less than three percent of public administration articles "report having obtained ethical clearance by the relevant committee at their institution," compared to 33 percent that report outside funding.

They find this troubling for two reasons. The first is that they crave the respect of other disciplines.

> If the reputation of an academic field rests on its appraisal by other scholars as conforming to the norms of good science, then evidence of insufficient attention to substance, methods, or ethics stand to damage the reputation of a field. Failing to report ethical clearances, consistently to report methods and participant numbers, and to report ethical considerations raises the possibility that researchers in public administration could be accused of questionable research practice.

The authors offer no examples of scholars from other field whose respect for public administration research has been diminished by the absence of ethics committee statements. Interdisciplinary respect and appreciation is a complex matter, involving everything from expectations of external funding to prose style. In the absence of evidence, I'm skeptical the absence or presence of committee approval plays an important part.

Second, Jordan and Gray note that "in the event that later researchers hope to replicate a study, information on the ethical considerations about the research could assist them to design their later study in ways that saves them time and hassle with their own ethics committees."

This strikes me as a stronger argument, but a brief line stating that a project was approved by an ethics committee would not be sufficient for a later researcher to design a follow-up study. Only if the researchers deposited their applications in a depository like [2]TEAR would others have the information they needed. Thoughtful essays about research ethics in fora such as the [3]Journal of Empirical Research on Human Research Ethics or [4]Ethics CORE would also be more helpful than boilerplate statements.

A better strategy, then, might be for researchers and journals to include references to fuller statements of their ethics reasoning, rather than equate committee approval with ethical action. Mere statements of approval are neither necessary nor sufficient for the goals articulated by Jordan and Gray.

1. http://dx.doi.org/10.1007/s11948-013-9436-5
2. http://www.institutionalreviewblog.com/2012/11/tolich-launches-tear-ethics-application.html
3. http://ucpressjournals.com/journal.php?j=jer
4. http://nationalethicscenter.org/

Sara Jordan (2013-05-28 03:13:01)
Dear Dr Schrag,
Thank you for your insights into our article. We agree with you that mentioning review may not be the best we can do. In other venues we discuss how a Social Science IRB may not be the best that could be done vis-a-vis social science researchers or

research participants in social sciences, either. In many ways, we agree with the premise of Ethical Imperialism– social scientists are wedged into a system that is ill-suited for us. However, we hope that you can agree that variability in ethical requirements for disciplines that wish to claim the mantle of science introduces problems for research ethics, responsible conduct of research, and outlining justifications for either separating the disciplines or enforcing the same rules upon them.
Of course, you'll recognize that the way that this article was framed and the venue in which it appears is a bit unusual for the topic. The hell of attempting to publish this in social science journals was a sincere shock. Incredulous responses such as "we're not a science like the IRB means, so we don't have to play by their rules; we're not poking people in the eyes with sticks like the doctors do" were the norm, not the exception. This from reviewers at journals with science in their title. Thus the problem: social and political scientists are a science when we stamp our little feet and demand we are (such as when we want NSF funding), and are not a science when we stamp our little feet and demand we aren't (because we don't like the rules). This defies logic.

We loved your book and assign pieces of it in classes.

Zachary M. Schrag (2013-05-28 09:04:03)
Thanks for these comments.

To hold that such broad terms as "science" can have multiple meanings depending on context is not a defiance of logic. That is why laws and regulations, including human subjects regulations, often include lists of definitions.

IRB Imposed Anonymity on Campus Politics Book (2013-05-31 08:20)

An unnamed IRB prevented two sociologists from identifying the sites of their research, reducing their book's scholarly impact.

[Amy J. Binder and Kate Wood, Becoming Right: How Campuses Shape Young Conservatives (Princeton University Press, 2012).]

Amy J. Binder and Kate Wood are the authors of [1]Becoming Right: How Campuses Shape Young Conservatives. The book is based largely on interviews with students at two universities, identified in the text as Western Flagship and Eastern Elite. The authors explain, "Although it was not our first choice to keep the institutitions anonymous, we did so as a necessary concession to the Institutional Review Board at Eastern Elite, whose administrators granted us approval to interview undergraduates on their campus only on the condition that the campus not be identified in our work." (14)

To their credit, Binder and Wood effectively disguised their sites. One reviewer [2]"strongly suspects" that Western Flagship is Berkeley, while [3]another is sure it's the University of Colorado-Boulder. Given that the authors deliberately blended details from multiple universities (14), the University of Washington is also plausible.

I would tend to think that the description of Eastern Elite's "mainstream student newspaper" as "a farm team for the Washington Post or the New York Times" (225) could only fit the Harvard Crimson, but it's possible that a few Yale Daily News alumni have made The Show.

In any case, the book was not instantly and definitively outed in the manner of [4]My Freshman Year or [5]Wannabe U.

But successful anonymization may be worse than failed efforts. As [6]Jordan Bloom notes, "This anonymity grates against the thesis of the book—that different schools breed different conservatives—which suggests that campus conservatism isn't easily reduced to 'Eastern' and 'Western' styles."

Indeed, think of all the information that had to be stripped away to satisfy the IRB:

- No direct quotations from student newspapers. (As the authors note, "in our Google age such a move could easily reveal the identify of the Eastern Elite campus.")
- No discussion of students' relationships with individual professors. The authors mention a positive review of a book by Harvard's C. Harvey Mansfield by a conservative student newspaper. They can't tell us whether that newspaper was the Harvard Salient, which [7]Mansfield has advised since its founding, a fact that would contextualize the review.
- No students identified by name. If Binder and Wood were at all lucky, they spoke to some of the ideological leaders of the next generation. But the Eastern Elite IRB has deprived future scholars of material on these figures.

Fortunately, journalists do not face such restrictions, and can, for the time being at least, publish articles in which [8]students and universities are named in full.

The real pity may be that Binder and Wood even consulted the Eastern Elite IRB, a decision they do not explain. [9]OHRP has made clear that under federal regulations, no IRB approval is needed from

> Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.
>
> Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom; or a business that permits investigators from another institution to recruit research subjects or to draw a blood sample at the work site for research purposes.

Such institutions–Eastern Elite among them–are not "engaged" in the research, so their IRBs lack jurisdiction under federal regulations. It would have been better for Binder and Wood not to have sought permission.

(Note: I can't recall who brought this book to my attention, so I apologize for the missing hat tip.)

1. http://press.princeton.edu/titles/9841.html"
2. http://www.mindingthecampus.com/originals/2013/01/a_liberal_view_of_becoming_rig.html
3. http://www.nas.org/articles/the_schools_of_becoming_right
4. http://www.nysun.com/new-york/on-the-trail-of-an-undercover-professor/18869/
5. http://www.insidehighered.com/news/2009/10/06/wannabe
6. http://www.theamericanconservative.com/articles/two-blind-sociologists-and-an-elephant-2/
7. http://www.thecrimson.com/article/2005/9/29/doordropped-some-salient-advice-who-needs/
8. http://www.nytimes.com/2003/05/25/magazine/25REPUBLICANS.html
9. http://www.hhs.gov/ohrp/policy/engage08.html

2.6 June

First Circuit Denies UK Access to Most Boston College Tapes (2013-06-03 21:52)

The US Court of Appeals for the First Circuit has ruled that Boston College need hand over only 11 of the 85 oral history interviews sought by United Kingdom investigators. The Boston Globe, Chronicle of Higher Education, and Inside Higher Ed see this as mostly a win for Boston College.

[Andersen, Travis. "[1]Major Victory for BC in Court Battle over Belfast Project." Boston Globe, June 1, 2013.]

More complete coverage can be found at [2]Boston College Subpoena News.

1. http://www.boston.com/metrodesk/2013/05/31/major-victory-for-court-battle-over-belfast-project/EsH1paM1g0lIs5dTSgWveO/story.html
2. http://bostoncollegesubpoena.wordpress.com/

SACHRP: Exempt Research May "Be Subject to IRB Review" (2013-06-11 08:10)

As reported by Erica Check Hayden in [1]Nature, at its March meeting, SACHRP endorsed "[2]Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations, with Revisions," prepared by Elizabeth Buchanan and Dean Gallant. The guidance offers some common sense, but it struggles with the legacy of the poorly drafted Common Rule. And it threatens to make matters worse by suggesting that some exempt research may "be subject to IRB review."

The basic question is when can a researcher use information she finds on a website. [3]Article 2.2 of Canada's TCPS2 offers a relatively straightforward answer:

> Research that is non-intrusive, and does not involve direct interaction between the researcher and individuals through the Internet, also does not require REB review. Cyber-material such as documents, records, performances, online archival materials or published third party interviews to which the public is given uncontrolled access on the Internet for which there is no expectation of privacy is considered to be publicly available information.

The Buchanan-Gallant report falls short of this clarity. As I read it, the report gives three competing answers.

1. IRBs lack jurisdiction

The report properly notes that if a researcher does not interact with a subject or access private information, she is not conducting human subjects research. Thus, "If individuals intentionally post or otherwise provide information on the Internet, such information should be considered public unless existing law and the privacy policies and/or terms of service of the entity/entities receiving or hosting the information indicate that the information should be considered 'private.'"

The report offers helpful examples of "purely public sites" for which no IRB review is necessary:

> (1) Sites containing information that, by law, is considered "public." In most cases information from these sites will be available without restriction, although access to the information may require payment of a fee. Many federal, state, and local government sites are included in this category: property tax records, birth and death records, real estate transactions, certain court records, voter registration and voting history records, etc.
> (2) News, entertainment, classified, and other information-based sites where information is posted for the purpose of sharing with the public.
> (3) Open access data repositories, where information has been legally obtained (with IRB approval if necessary) and is made available with minimal or no restriction.
> (4) Discussion fora that are freely accessible to any individual with Internet access, and do not involve terms of access or terms of service that would restrict research use of the information.

2. IRBs might have jurisdiction

Having made these statements, the report hedges:

> (b) A subject's own expectation of privacy is not always "reasonable." A subject may assume— perhaps in ignorance—that his or her information provided or available on the Internet is private, but the first part of the regulatory definition of "private information" specifies that the individual "can reasonably [sic] expect that no observation or recording is taking place." Information that is archived online has, ipso facto, been recorded. Can it ever be reasonable to expect otherwise, absent an explicit statement that no information will be recorded?
>
> (c) Despite (b) above, the Belmont principle of beneficence may support a more conservative approach. A subject who incorrectly assumed his/her identifiable information was private, or restricted only to a select group, might not have posted the information on some social networking site if s/he thought the information would be widely available, believing that the information could be embarrassing or damaging.

I can understand the report's caution here; there will inevitably be marginal cases about the reasonable expectation of privacy. TCPS2 offers the examples of "Internet chat rooms, and self-help groups with restricted membership." And data linkage further complicates matters. Hayden's Nature article gives the example of Andrew Gordon, a computer scientist at USC, who reads blogs by people who leave off their real name but can be easily identified "by using information from photographs that they post or by looking up the registrant of the blog's domain name." TCPS2 offers confusing guidance on such research; article 2.2 states that "data linkage of different sources of publicly available information" triggers REB review and cross-references article 5.7, which in turn states that if "the research relies exclusively on publicly available information," data linkage does not trigger review and cites article 2.2. Hmmm.

I am perplexed, however, by the Buchanan-Gallant invocation of beneficence to justify possible IRB jurisdiction. The question here is whether the person posting the information has consented to having that information used for research purposes, and the Belmont Report presents consent as an application of respect for persons, not beneficence.

To bring beneficence into consideration invites mischief; for example, what if we were talking about information published in an unambiguously public forum, such as the letters column of a newspaper? If an IRB is allowed to assert jurisdiction over such public information on the grounds that "the information could be embarrassing or damaging," then it has become a censorship board.

3. Exempt is sometimes not exempt

Immediately following the passage quoted above ("embarrassing or damaging"), the report continues:

> Should the investigator and the IRB consider the proposed research to be subject to IRB review, even if under existing regulations the research is exempt because the information is publicly available? Researchers and IRBs should consider the nature of the study and the sensitivity of identifiable data; more details about the study, and thoughtful institutional policy, taken in consideration with standard professional or disciplinary norms and practices, would help inform such decisions.

This is dreadful. If the research is exempt (or, more properly, not research with human subjects), it is not subject to IRB review, period. That doesn't stop a researcher from voluntarily seeking advice from IRB members or anyone else. But I hate to see SACHRP suggesting that exempt research is in any way "subject to IRB review." We need to keep these categories clear.

4. If the information could be damaging, IRBs do have jurisdiction

After apparently emphasizing the fact that reading people's public postings does not constitute research with human subjects, the report backs further away and hints the opposite:

> If an activity (textual, visual, auditory) is legally available to any Internet user without specific permission or authorization from the individual being observed, or from the entity controlling access to the information, the activity should be considered "public behavior." Examples include "comment" postings on news sites; posting on publicly available hosting sites such as YouTube® or Flickr®; postings on classified sites such as Craigslist®; and postings on unrestricted blog or wiki sites. Information posted on social networking sites such as Facebook®, LinkedIn®, Myspace®, or similar fora, and available without restriction to any authorized user of the site, should also be considered "public behavior," even though access to the website itself may be restricted to individuals who have established an account to use the site. Note that the mere fact of an activity being considered "public behavior" does not mean that observation of the activity should automatically be considered exempt from the requirement of IRB review. Per 45 CFR 46.101(b)(2), if the information is recorded in a way that permits identification of subjects, and if disclosure of the identifiable information could "reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation," then the research would not be exempt from IRB review.

To start with, the inclusion of registration symbols shows Buchanan and Gallant to be timid in their approach to law. Someone once told them that in some circumstances it is useful to put those symbols after trademarked names, and,

rather than bothering to learn the [4]actual rule, they have cluttered an important document.

More significantly, they have gotten caught in a trap set by the Common Rule: simple observation of public behavior is simultaneously not human subjects research (because, under 45 CFR 46.102, it involves neither interaction nor identifiable private information) and, under 45 CFR 46.101, human subjects research that is exempt from review only if it means one of two criteria: not recorded or not damaging.

OHRP's [5]2004 decision chart tried to sort this out. It shows that if an individual cannot "reasonably expect" that information will not be made public, "the research is not research involving human subjects, and 45 CFR 46 does not apply."

Despite this guidance, Buchanan and Gallant have chased the red herring of the exemption for public observation in 45 CFR 46.101(b)(2). As a result, they offer "Discussion fora that are freely accessible to any individual with Internet access" as not human subjects research, but "postings on unrestricted blog or wiki sites" as human subjects research that may not be exempt. This is contradictory.

5. By the way, "recorded" means "recorded by the investigator"

In addition to probing the limits of an expectation of privacy, the report addresses the Common Rule's ambiguity about when the recording of information invalidates an exemption.

The [6]45 CFR 46.101(b) exemptions twice address the recording of information.

Section (b)(2) exempts "of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless . . . information obtained is recorded in such a manner that human subjects can be identified" while section (b)(4) exempts "Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the 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)? I haven't found an explanation in my research, and apparently neither have Buchanan and Gallant. While they "believe the intent of [section (b)(2)] is "recorded by the investigator in such manner . . ." they note that "Confirmation of this interpretation would be helpful." I quite agree, but, as best I can tell, rather than offering such confirmation or seeking it from OHRP, SACRHP approved their report without addressing this concern.

Rather than disentangle the issues raised in the report, SACHRP has added to the clutter.

1. http://www.nature.com/news/guidance-issued-for-us-internet-research-1.12860
2. http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf
3. http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/
4. http://www.chicagomanualofstyle.org/qanda/data/faq/topics/RegisteredTrademarks/faq0002.html
5. http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
6. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

Trolling Isn't Human Subjects Research **(2013-06-12 08:12)**

The Chronicle of Higher Education reports that IRBs at both NYU and the University of New Mexico are investigating the conduct of Professor Geoffrey Miller, now notorious for a June 2 tweet warning "obese PhD applicants" that "if

you didn't have the willpower to stop eating carbs, you won't have the willpower to do a dissertation."

According to the Chronicle, Miller "explained his action to university officials in New Mexico by saying he had sent the Twitter message as part of a research project." (In proper troll-speak, one says "[1]social experiment.") But Miller also maintains that "IRB approval was not necessary under his own understanding of federal law."

[Basken, Paul. "In Reversal, NYU Investigates Professor Who Tweeted on Obese Ph.D. Students." The Chronicle of Higher Education, June 11, 2013.]

[2]Michelle Meyer may disagree, but I think Miller has a reasonable case here, were he to assert that he obtained neither "[3](1) Data through intervention or interaction with [a living] individual, or (2) Identifiable private information."

Certainly, [4]he got a lot of reactions to his posting, but he did not directly solicit responses from any group. This puts his message in the same category as a provocative essay published in a more traditional venue, such as [5]Daniel Callahan's earlier, longer work of fatshaming.

If every written work likely to spark reaction is to count as interaction with living individuals, IRBs would need to vet everything written by university faculty and students, except for those works guaranteed to be obscure and dull.

Whether Miller can be trusted to evaluate applications to UNM's PhD progam in psychology, and whether his statement is comparable to that of a university administrator "[6]who writes publicly against the very policies that her government employer charges her with creating, promoting, and enforcing," is another matter, thankfully beyond the scope of this blog.

Note 1. A correspondent notes that I earlier reported on Miller's [7]critique of IRB assumptions about trauma and sex surveys.

Note 2. I wrote my dissertation on coffee, but my college thesis was mostly Chips Ahoy.

1. http://www.urbandictionary.com/define.php?term=social%20experiment
2. https://twitter.com/MichelleNMeyer
3. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102
4. http://www.theatlanticwire.com/national/2013/06/how-twitter-schooled-nyu-professor-about-fat-shaming/65833/
5. http://onlinelibrary.wiley.com/doi/10.1002/hast.114/full
6. http://www.ca6.uscourts.gov/opinions.pdf/12a0408p-06.pdf
7. http://www.institutionalreviewblog.com/2012/06/sex-and-trauma-surveys-no-riskier-than.html

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Joshua Gutoff (2013-06-12 13:07:05)

It seems to me that Miller's description of his alleged "study" places it clearly within the purview of an IRB. By his own claim, he's doing something to provoke a response in others so that he can study that response. According to him, the content of the tweet did not represent information or opinions that he wanted to disseminate (as in an article), but was purely meant as a stimulus acting on unaware and unconsenting subjects for the purpose of generating data. How would this not require IRB approval?

Joshua Gutoff
Gratz College

Zachary M. Schrag (2013-06-13 08:18:20)
Thanks for this comment.

I haven't seen anything stating that Miller claimed to be "doing something to provoke a response in others so that he can study that response."

The UNM has said only that Miller stated that "[1]his comment on Twitter was part of a research project." That's sufficiently vague that he may be able to distinguish his actions from those covered by the Common Rule.

If you have seen a direct statement from Miller, please let me know.

More at "[2] Michelle Meyer: Miller Interacted, Intervened."

1. http://news.unm.edu/2013/06/unm-response-to-tweet-by-professor-geoffrey-miller/
2. http://www.institutionalreviewblog.com/2013/06/michelle-meyer-miller-interacted.html

Michelle Meyer (2013-06-13 21:06:14)
Hi Zach,

From UNM Psychology Department chairwoman Jane Ellen Smith's video response to Miller's tweet: "[Miller] claims that he's been sending out provocative tweets over a number of months now to measure people's reactions to them . . . ." (http://www.youtube.com/watch?feature=player _embedded &v=fmX _xlJ59Ks)

Zachary M. Schrag (2013-06-14 14:09:05)
I had watched the Smith video but missed the passage about "to measure people's reactions." If that's what Miller claims, it's a bad fact that indeed changes my view of this case. I guess I would amend the headline to "Trolling Isn't Human Subjects Research, But Miller Wasn't Just Trolling."

Also, is it just me, or is there something weird about UNM's combining an official, formal, written statement about the case with a video response? Since when do universities respond to charges of unethical behavior with YouTube videos?

Michelle Meyer (2013-06-14 16:34:02)
No, it's not just you. I'm not sure if the video response is necessarily a bad thing, exactly – like testimony from live witnesses, we get a much better sense of how seriously someone is taking a complaint than if we just read the boilerplate "we're investigating" letter the office of legal council or PR puts out. But I've certainly never seen anything like it before. And it went up so quickly, and with an oddly professional quality to it – almost like someone wanted to try out their new videography software.

Robert Levine: We Should Have Done a Careful Study of Social and Behavioral Research

(2013-06-12 08:37)

The June issue of the Journal of Clinical Research Best Practices features an interview with Robert Levine about his service as consultant to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Levine concedes that the commission did not sufficiently explore "sociology, anthropology, education and other vast areas of research."

[Mark Barnes, "Bob Levine on the Making of the Belmont Report," [1]Journal of Clinical Research Best Practices 9, no. 6 (June 2013). h/t Michelle Meyer]

As part of the interview, Levine explains why the Common Rule defines "research" in reference to design, rather than intent:

> In my initial draft of the definition of research, I said research refers to a class of activities intended to do certain things, to develop knowledge. Joe Brady argued that there is no such thing as intent. One of the tenets of behavioral psychology is that the only things that count are what you can observe and measure; Joe insisted that one could not observe intent. He and I had a friendly and collegial, but very forceful argument. I argued that, before you write a protocol, you should know what people intend to do. At the next meeting, Joe brought in reinforcements — Israel Goldiamond, a psychologist from Chicago, to help explain why intent should not be used because you could never measure intent. We compromised on the term, "design." You can measure the design. You can look at it. It's written out in a protocol. I said the protocol represents intent, but I lost the argument. I was a pretty good loser. "Design" is not all that bad.

More significantly for this blog, Levine concedes that both the Commission and Congress erred in their treatment of social research:

> In my opinion, we should have done a careful study of social and behavioral research. Congress caused this mistake when it told the Commission to distinguish research from the routine and accepted practice of medicine or behavioral therapy. You don't have to go very far to distinguish sociology from routine practice. Sociologists don't have "practices." Sociology, anthropology, education and other vast areas of research were left out. The Commission made some passing statements that have been interpreted as being relevant to social and behavioral research, but they did not look into it thoroughly.

This is similar to what he said in his [2]2004 interview by Bernard Schwetz.

What would really have been nice, however, would have been for Levine to have said these things in 1979, when federal regulations were being debated most forcefully. Instead, at that fall's PRIM &R conference, he claimed the opposite:

> If one takes more than a superficial look, one will find that this Commission was quite concerned with problems of social and behavioral scientists. For example, the Appendices to the Belmont Report contain several important papers by distinguished social scientists about ethical issues in their fields. In addition, the presence of social scientists on the staff of the Commission—particularly Brad Gray—kept the attention of the Commission focused on their problems. As it considered each recommendation it was forced to think, "What would be the implications of this recommendation if it were to be applied to social research?" [[3]PRIM &R through the years, 1974-2005, p. 33]

1. http://www.firstclinical.com/journal/2013/1306_Levine_Interview.pdf
2. http://www.hhs.gov/ohrp/archive/docs/InterviewLevine.doc
3. books?id=u50eAQAAMAAJ

Michelle Meyer: Miller Interacted, Intervened (2013-06-13 08:12)

[1]Michelle Meyer had more to say about [2]my comments on Geoffrey Miller's fatshaming troll-tweet than would fit in Blogger's comment box. I post her comments here, along with some responses.

Meyer's Comments

Hi Zach,

For your readers' convenience, here's what I said "re: latest in #matingmind flap":

> (1) I remain skeptical he intended this as research but intent is (alas) key under regs & he claims it was.
>
> (2) If he did intend to contribute to generalizable knowledge, his tweeps were hum subjects b/c involved interaction (& maybe intervention).
>
> (3) Only real loophole available to him is if his investigation wasn't "systematic," but most IRBs have low threshold for that (or ignore).
>
> (4) Lots of reasons to dislike research regs/IRB system, but this isn't an especially good case for deregulating "just talking" research.
>
> (5) Even if you think a study 2 test reactions 2 provocative tweets shouldn't be subject to IRB review, until regs change, they apply to all.
>
> (6) Real issue neither free speech nor hum subj rsch but: does his statement reflect bias that affects performance of his academic duties?
>
> (7) Lesson to academics trying to disown controversial statement: claiming "research" will only move you from the frying pan into the fire.
>
> (8) Oh yeah. Even if he thot his rsch was exempt, like most, NYU's IRB gets to decide when research is exempt or not [link omitted]

I stand by this analysis – which isn't to say that I disagree with you that Miller has "a case." As we know, IRBs come out differently on "studies" like this. If I wanted to argue that he obtained "data through intervention or interaction with" living human beings, I'd focus on interaction. He didn't merely passively post the tweet, sit back, and collect data about reactions, as you suggest; rather, he responded to at least one person who questioned what she understood to be his claim that obesity and IQ are inversely correlated (http://alturl.com/jwrju)

He also "unfollowed" at least one person who disputed his tweet (yours truly). This interaction was, presumably, also part of his study: Why react with sincere anger to someone who was provoked by a tweet which you issued...in order to provoke? (I await his refollow, now that the study is over.)

Alternatively, consider that his research involved "manipulations of the subject's environment." He claims that he issued "provocative" tweets over a few months in order to gauge responses. You might say that Twitter is already

rife with trolling, such that this couldn't possibly have altered that environment. There's something to that. We'd need to know more about his hypothesis and methods. But it's certainly plausible that he sought to ratchet up the level of provocativeness in his tweets until they sparked a reaction that was measurable even against Twitter's baseline of trolling and outrage. Not every asinine tweet goes viral, prompts Tumblrs, and makes national news, but after months of hard work, he managed to create one – for science! – that did.

Consider, also, the expectations of those following a tenured academic on Twitter rather than, say, a teenage boy. Arguably, such a "provocative" tweet manipulated the environment of *his* tweeps in a way that it might not have for a teenage boy's tweeps. Although Miller had been provocatively tweeting for months, note that he claims that all of those tweets were part of his study. So at some point he deliberately altered the environment of his tweeps by shifting from non-provocative to provocative tweets.

Finally, consider the ripple effects in that manipulated environment. I spent an hour going back and forth with one of his followers who insisted that I caused the tweet to go viral, "tattled" to his employer (I did not), and cost Miller his career (for the record, I don't think he should be fired and I fully support his right to make claims that are patently falsifiable with a single counter-example; I'd just like some oversight to ensure that his views about obese academics don't ruin *their* careers). If this was all good (deceptive) research fun, then I wish Miller would debrief his follower-subjects so that they can stop blaming others for reacting in exactly the ways Miller presumably hypothesized that they would react.

Some Responses from Schrag

Thanks for these comments, Michelle.

We agree the most about your point 6: "[The] real issue [is] neither free speech nor [human subjects research] but: does his statement reflect bias that affects performance of his academic duties?"

Assuming it does, what should his department do with a faculty member who may have violated the [3]American Psychological Association's standard against unfair discrimination? (The standard prohibits discrimination on the basis of disability, and the EEOC has maintained that [4]"severe obesity" is a disability. Moreover, I doubt that the authors of the ethical principles would be happy about any discrimination based on body weight.) Dare we apply the standard in [5]Dixon v. University of Toledo to a professor?

We also agree about the first part of your point 1. I too am "skeptical he intended this as research," and the University of New Mexico seems skeptical as well, noting, "[6]We are looking into the validity of this assertion." It strikes me as more likely that when Miller claimed to be conducting "research," he was using the term to mean, "[7]I am a troll."

I think you are mistaken to write, "intent is (alas) key under regs." Intent matters under 45 CFR 46.119, but the relevant section here is §46.102, which defines research by design, not intent. Thanks to [8]Robert Levine, we know exactly why this is so. So if Miller intended to conduct research, but failed to design a project "to develop or contribute to generalizable knowledge," he's clear.

You ably lay out the grounds for considering Miller's tweet and subsequent actions to constitute intervention or interaction, but I find them unpersuasive. I would be very unhappy were any IRB to find that any speech in a public forum constitutes "manipulations of the subject or the subject's environment"; if so, what speech is not?

And I would like to know if you can distinguish between Miller's provocation and that of Daniel Callahan. Callahan came in for his fair share of outraged attention in the [9]national press and on [10]Tumblr. He, too, has [11]engaged with his critics, albeit more professionally than Miller. Is this, too, sufficient interaction to trigger IRB

jurisdiction?

1. http://www.law.harvard.edu/programs/petrie-flom/fellowship/meyer.html
2. http://www.institutionalreviewblog.com/2013/06/trolling-isnt-human-subjects-research.html
3. http://www.apa.org/ethics/code/index.aspx?item=6
4. http://www.eeoc.gov/eeoc/newsroom/release/4-10-12a.cfm
5. http://www.ca6.uscourts.gov/opinions.pdf/12a0408p-06.pdf
6. http://news.unm.edu/2013/06/unm-response-to-tweet-by-professor-geoffrey-miller/
7. http://www.urbandictionary.com/define.php?term=social%20experiment
8. http://www.institutionalreviewblog.com/2013/06/robert-levine-we-should-have-done.html
9. http://www.huffingtonpost.com/2013/01/24/daniel-callahan-fat-shaming-curb-obesity_n_2543270.html
10. http://cypheroftyr.tumblr.com/post/41434729863/fat-shaming-may-curb-obesity-bioethicist-says
11. http://onlinelibrary.wiley.com/doi/10.1002/hast.171/full

Michelle Meyer (2013-06-13 19:13:43)
Hi Zach,

On the design/intent point, I acknowledge Bob Levine's history of the Commission, in which he says the staff eventually came to conclude that "intent should not be used because you could never measure intent. We compromised on the term, 'design.' You can measure the design." Although I'm sympathetic to his point about the difficulty of measuring intent, I am not inclined to rely on such "legislative history" of a bioethics commission in interpreting agency regulations that seem, to me, to say something a bit different, even if unwittingly.

I read § 102's definition of research–"a systematic investigation . . . designed to develop or contribute to generalizable knowledge"–to require both intent and design: both are necessary, and neither is sufficient, for an activity to constitute "research." To say that an investigation is "designed to" do X implies an agent who did the designing with that purpose (X) in mind. (See, e.g., intelligent design theory.) If § 102 had instead referred to "a systematic investigation . . . *capable of* developing or contributing to generalizable knowledge," that would be different. But, alas, it does not.

So, as you say, someone could intend to conduct research but be so inept at research design that her activity is insufficiently systematic to count as "research" for purposes of the Common Rule. But, conversely, I think that an actor who engages in a systematic activity whose fruits *could* contribute to generalizable knowledge but who lacks that intent (e.g., she takes a poll to satisfy her own curiosity) isn't conducting "research" for purposes of the regs. I don't think IRBs are often faced with a scenario in which design is divorced from intent in either of these ways. And in any case, Miller said he intended this to be research, and as I said originally, IRBs tend to have a low bar for what constitutes a sufficiently systematic investigation, so I doubt that he would escape IRB jurisdiction that way.

Instead, I'd think the more natural way for him to try to wriggle out of IRB jurisdiction would be to argue that no "human subjects" were involved in his research. On this point, you rightly press me to distinguish Miller (research) from Callahan (speech). This takes us back a bit to the first point, about intent.

Callahan didn't publish his essay *in order to* elicit, measure, learn from, and report others' reactions; his essay itself was the *result* of his (non-human subjects) research. Similarly, Internet trolls do what they do, I gather, to entertain themselves or to hurt others, but not to contribute to generalizable knowledge. Institutions engage in quality improvement or assurance activities in order to benefit themselves and/or their clients. And so on. Intent became legally relevant when Congress asked the Commission to distinguish between research and practice, and the Commission decided that the latter "refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success" (Belmont Report). You might subject someone to the exact same experimental procedure, with the same risk-benefit profile, but your intent in doing so – whether to try to help them or to produce generalizable knowledge – makes all the difference for how your activity is regulated: as research or as "innovative treatment." That's what I meant when I lamented that intent was central to which activities get regulated and which don't; we ought to focus more on activities' foreseeably harmful consequences, not actors' intent.

Zachary M. Schrag (2013-06-14 14:18:14)
In your [1]comment on my earlier post on Miller, you pointed me to evidence that Miller said he sought to "to measure people's reactions," which strikes me as a statement of both design and intent. I agree that this could distinguish Miller from Callahan.

Since design and intent seem to be aligned in this case, I would say it's not such a good opportunity after all to split these hairs. And if we are very lucky, before such a case comes along, the Common Rule will be revised with a clearer definition of what needs to be overseen.

1. http://www.institutionalreviewblog.com/2013/06/trolling-isnt-human-subjects-research.html

2.7 July

Oh, I've Heard of It (2013-07-08 22:37)

Placeholder for

Hamburger, Philip. "[1]The Censorship You've Never Heard Of." *Commentary*, July 2013.

h/t [2]Chris Shea.

1. http://www.commentarymagazine.com/article/the-censorship-youve-never-heard-of/
2. https://twitter.com/cshea4

Two More Biomedical Members for SACHRP (2013-07-12 11:34)

From the OHRP List:

> The Office for Human Research Protections (OHRP) would like to announce two new members who have been invited to join the Secretary's Advisory Committee on Human Research Protections (SACHRP). The invited members are:
>
> • James R. Anderson, Ph.D., Professor of Biostatistics and the Associate Dean for Research at the University of Nebraska Medical Center College of Public Health; and
>
> • Stephen J. Rosenfeld. M.D., M.B.A., Chairperson of Quorum Review IRB
>
> OHRP would like to thank all applicants, and notes that the next SACHRP member solicitation will be published in the Federal Register in approximately six months.

2.8 August

Ignorance Is Strength: Lecture Video Online (2013-08-06 08:06)

I just noticed that Brigham Young University has posted a video of my February 2013 lecture, "Ignorance Is Strength: Pseudo-Expertise and the Regulation of Human Subjects Research." Many thanks to my hosts there and the producers of the video.

IFRAME: [1]//www.youtube.com/embed/9iYqx9ATFhM

1. file://www.youtube.com/embed/9iYqx9ATFhM

UNM, NYU: Miller's Fatshaming Tweet Wasn't Research (2013-08-06 19:51)

Two IRBs have concluded that Geoffrey Miller's June tweet about "obese PhD applicants" was not human subjects research.

A UNM statement explains,

> Miller at first claimed his tweet was part of a research project, but investigations by the Institutional Review Board at New York University where he was a visiting professor, and the IRB at UNM where he is a tenured professor, concluded that was not correct.

The statement also lists the terms of a censure by the university.

For background, see [1]Trolling Isn't Human Subjects Research and [2]Michelle Meyer: Miller Interacted, Intervened

1. http://www.institutionalreviewblog.com/2013/06/trolling-isnt-human-subjects-research.html
2. http://www.institutionalreviewblog.com/2013/06/michelle-meyer-miller-interacted.html

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Kevin Parson (2013-08-06 22:52:54)
Honestly, does anyone really believe that this tweet was part of a research project?

Zachary M. Schrag (2013-08-07 07:11:12)
I doubt it, but Miller's claim raised some mildly interesting issues about the definitional boundaries of human subjects research.

Hamburger: IRBs are Worse than McCarthyism (2013-08-12 19:06)

In a brief article in Commentary, Philip Hamburger summarizes his case against IRBs, made in much greater detail in his 2004 article, "The New Censorship: Institutional Review Boards," Supreme Court Review (2004): 271–354. In

this version, he argues that the regulation of human subjects research "is the most widespread and systematic assault on freedom of speech and the press in the nation's history. McCarthyism was more overtly political, but IRB licensing is more pervasive and methodical, and its consequences are far more lethal."

[Hamburger, Philip, "[1]The Censorship You've Never Heard Of." Commentary, July 2013, 21-26]

I appreciate Hamburger's bringing this issue to the attention of readers outside of universities, but such a brief article for a general readership necessarily simplifies and perhaps distorts some of the details. For example, Hamburger writes, "almost all HHS officials, other than the secretary of HHS, are protected by the HHS regulations on IRBs. So too are members of IRBs. As a result, empirical academic critiques of HHS decision-making, and even of the IRB licensing, are practically impossible."

I'm not sure where this is coming from. While the § 46.101(b)(3) exemption for research on public officials is vague, [2]SACHRP has noted that "university faculty, public school teachers, and police officers in general are not considered to be elected or appointed public officials, whereas mayors, governors, school superintendents, school board members, and police chiefs are considered to be elected or appointed public officials." If interviewing a school board member is exempt from review, I would imagine that a great number of HHS officials are likewise fair game, and I've never heard of an IRB denying a researcher's claim of exemption for such research. This is not to say that HHS decision-making is at all transparent (who drafted the ANPRM? Who is working on an NPRM? Is anyone?), but I don't see IRB regs themselves as the obstacle.

Hamburger concludes his essay with the obversvation that the First Amendment guarantees freedom of speech and of the press; "All that Americans need is a judge who is willing to enforce the Constitution." While judicial review might challenge the IRB regime, I wish Hamburger had mentioned the ANPRM and the efforts–however obscure–by regulators to address the problems he has noted.

1. http://www.commentarymagazine.com/article/the-censorship-youve-never-heard-of/
2. http://www.hhs.gov/ohrp/sachrp/sachrpletter091808.html

2.9 September

UNC Stops Pretending that IRBs Understand Data Encryption (2013-09-17 08:10)

The Chronicle of Higher Education reports that the University of North Carolina at Chapel Hill and Harvard are asking their IT departments, rather than their IRBs, to design data security protocols for human subjects researchers.

[Voosen, Paul. "Researchers Struggle to Secure Data in an Insecure Age." Chronicle of Higher Education, September 13, 2013. http://chronicle.com/article/Researchers-Struggle-to-Secure/141591/. (gated)]

As the Chronicle explains,

> Rather than trying to evaluate the data security of each experiment coming across the transom—[the University of North Carolina at Chapel Hill] has some 4,500 active studies at one time—[IRBs] now instead ask a few questions: Are you collecting protected health information? Genetic code? Surveys on illegal activity, substance abuse, or sexual behavior?

> The boards plug those answers into a formula that generates a security threat level for the study. Given these parameters, the IRB then says, you have a Level 3 study. Go see your designated IT contact to establish proper security.
>
> "At the end of the process," [Daniel K. Nelson, director of UNC's Office of Human Research Ethics] said, "rather than the investigator telling us what they're going to do, and us pretending we know how many bytes of encryption are up to standard, we flipped it."
>
> Harvard has adopted a similar system.

The Chronicle describes this shift by reporting that UNC "had to stop trusting the researchers." Given Nelson's acknowledgment that the IRB and research-ethics office had been "pretending" to dictate appropriate procedures, the article could just as well have reported that the university had to stop trusting IRBs.

As I argued in my Brigham Young University lecture, IRBs are composed of pseudo-experts. The UNC model of referring researchers to real experts marks a significant shift. Though the Chronicle article covers only data security, the same model could apply to the whole range of research risks.

Gontcharov Reviews van den Hoonaard **(2013-09-30 12:34)**

Igor Gontcharov, a fellow participant in last year's Ethics Rupture conference, reviews Will van den Hoonaard's Seduction of Ethics and explains its relation to the conference's "New Brunswick Declaration."

[Igor Gontcharov, "Methodological Crisis in the Social Sciences: The New Brunswick Declaration as a New Paradigm in Research Ethics Governance?" Transnational Legal Theory 4, no. 1 (2013): 146–156. doi:10.5235/20414005.4.1.146.]

As I noted in [1]my own review, The Seduction of Ethics is a pessimistic book, and Gontcharov agrees. "The question," he writes, "is no longer that of an alternative ethics review for the social sciences, but that of possible alternatives to ethics review." And he doesn't see that coming any time soon:

> The problem no longer lies in the necessity of substantiating the claims of and problematising such phenomena as ethics creep or ethical imperialism. The regulatory capture has already occurred, and it is time to identify effective strategies to decolonise social scholarship. Since it has proven difficult to challenge the regulatory capture of the social sciences by offering historical and conceptual arguments, it is necessary to redraw the line of critique and let the data showing how ethics review affects the production of new knowledge speak for itself. Impact studies of ethics review are especially important, since there have been no unequivocal signs indicating that the calls for evidence-based regulation of ethics have been received by the regulators.

I'm not sure that's fair, at least for the United States. The 2011 ANRPM cites a fair number of empirical studies, and then uses them to justify a proposed reduction in multiple reviews and greater empowment of researchers to determine

what projects need review. True, it has been close to two years since the comment period closed, and we haven't heard anything public from U.S. regulators. But at least we know they are listening.

1. http://csx.sagepub.com/content/41/5/678.full

2.10 November

Interview by Washington Monthly - Ten Miles Square (2013-11-01 21:55)

Rachel Cohen interviewed me for *Ten Miles Square*, a *Washington Monthly* blog.

I guess in this case the ten miles square still includes Arlington.

Cohen, Rachel. "What Are Institutional Review Boards and Why Should We Care? An Interview with Zach Schrag." *The Washington Monthly - Ten Miles Square*, November 1, 2013. [1]http://www.washingtonmonthly.com/ten-miles-square/2013/11/what _are _institutional _review047608.php?

1. http://www.washingtonmonthly.com/ten-miles-square/2013/11/what_are_institutional_review047608.php?

2.11 December

Emmerich on Schrag, Stark, and van den Hoonaard (2013-12-10 15:32)

Nathan Emmerich of Queen's University, UK, reviews Ethical Imperialism, Behind Closed Doors, and The Seduction of Ethics for Research Ethics.

[Emmerich, Nathan. "Between the Accountable and the Auditable: Ethics and Ethical Governance in the Social Sciences." Research Ethics 9, no. 4 (December 2013): 175–186. [1]doi:10.1177/1747016113510654.]

Emmerich is particularly frustrated by the lack of accountability of research ethics committees:

"The review process renders research accountable whilst, at the same time, erasing any trace of its own accountability (Stark: 73) or, we might say, its own status as an ethical endeavour . . .

"How systems of governance should themselves be held responsible − to researchers, to research participants, and to society as a whole − remains uninterrogated by applied ethical thinking."

1. http://dx.doi.org/10.1177/1747016113510654

CU-Boulder Tells Faculty to Consult IRB Before Teaching (2013-12-16 16:04)

A spokesman for the University of Colorado at Boulder has recommended that university faculty consult the IRB before teaching.

The comment concerns sociology professor Patti Adler's announcement that she plans to retire early rather than risk being fired for classroom teaching that might make students uncomfortable.

[Scott Jaschik, "Tenured Professor at Boulder Says She Is Being Forced out over Lecture on Prostitution," *Inside Higher Ed*, December 16, 2013. [1]http://www.insidehighered.com/news/2013/12/16/tenured-professor-boulder-says-she-being-forced-out-over-lecture-prostitution.]

In an e-mail interview with Inside Higher Ed, university spokesman Mark J. Miller wrote,

> In all cases involving people in research or teaching, whether controversial or not, we want to insist on best practices to ensure full regulatory compliance. In some cases, this could involve review from our Institutional Review Board, which is responsible for regulatory compliance involving human subjects.

Since the teaching in question did not involve human subjects research, I suppose faculty are left to guess when they should consult the IRB.

This is not Boulder's first clash between sociologists and the IRB. In the 1970s, university sociologists Edward Rose and Howard Higman accused the IRB of censorship. (*Ethical Imperialism*, 48-50). And in the 1990s, an IRB administrator told Adler's students that they could not use information gathered through informal conversations. [Patricia A. Adler and Peter Adler , "Do University Lawyers and the Police Define Research Values?," in *Walking the Tightrope: Ethical Issues for Qualitative Researchers*, ed. Will C. van den Hoonaard (Toronto: University of Toronto Press, 2002)]

It is not clear whether the IRB is involved in the current controversy, or whether Miller's statement merely reflects his own misunderstanding of human subjects regulations.

And to their credit, IRB members (though not necessarily from CU-Boulder) have distanced themselves from Miller's position. In the lead comment on the Inside Higher Ed piece, one writes, "As having served as a long-time IRB member, I resent having an IRB used as a 'fall-guy' to harass or threaten a faculty member."

1. http://www.insidehighered.com/news/2013/12/16/tenured-professor-boulder-says-she-being-forced-out-over-lecture-prostitution

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CU-Boulder Retracts IRB Claim (2013-12-17 07:17)

The Chronicle of Higher Education reports that Mark Miller, the University of Colorado at Boulder spokesman who had earlier suggested that professors should consult the IRB before teaching controversial subjects, has retracted that suggestion.

[Peter Schmidt, "U. of Colorado's Response to a Gritty Lecture Worries Sociologists," Chronicle of Higher Education, December 17, 2013. [1]http://chronicle.com/article/U-of-Colorados-Response-to-a/143653/. (gated)]

According to the Chronicle:

> Mark K. Miller, a university spokesman, initially responded to questions raised by Ms. Adler's treatment by suggesting that it might have been best for her to run her skit plans by an institutional review board.
>
> He clarified on Monday that Steven R. Leigh, dean of the university's College of Arts and Sciences, had raised the question of whether it might be appropriate for a review board to pass judgment on such an activity, but the university recognizes that such boards are established to oversee human-subjects research, not teaching.

Instead, the university will rely on the claim that the use of offensive words and references to violence in a classroom constitute a hostile work environment:

> The skit was performed this fall largely as it had been in past semesters, but the audience was slightly different in that it included representatives of the university's Office of Discrimination and Harassment.
>
> In a December 10 memorandum to Ms. Adler, Llen Pomeroy, that office's manager, pointed out three aspects of the performance that were later discussed with Ms. Adler as problematic: a student playing the role of a straight male streetwalker repeatedly used the term "faggot," a student playing a pimp made joking references to how he beats women, and a student portrayed a Latvian "slave whore" in a manner that might have offended students from that nation or other parts of Eastern Europe.
>
> The letter from Ms. Pomeroy acknowledged that her office had not formally investigated the performance because no one had formally complained about it, and that "this is the first time concerns have been raised to our office about your class or the prostitution skit."

1. http://chronicle.com/article/U-of-Colorados-Response-to-a/143653

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3. 2014

3.1 January

Happy New Year, National Academy of Sciences! (2014-01-07 08:50)

As longtime readers of this blog will know, I used to begin each year by [1]mocking OHRP for failing to issue "a lot of examples and will give more guidance on how to make the decision on what is research and what is not" by the end of 2007, as promised by a former director. That trope got a bit old after a few years, and I didn't recycle it in 2013.

I will note that [2]the National Academy of Sciences pledged to issue a summary of its March 2013 workshop "in summer 2013" and that "the study report will be issued in early winter 2013."

Anyone seen either of those?

1. http://www.institutionalreviewblog.com/2012/01/happy-new-year-ohrp.html
2. http://sites.nationalacademies.org/DBASSE/BBCSS/CurrentProjects/DBASSE_080452

National Research Council Issues IRB Report (2014-01-10 10:02)

The National Research Council has issued its [1]long awaited report, Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences.

[National Research Council. Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences. [2]Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences. Washington, D.C.: The National Academies Press, 2014.]

The report is an impressive work of scholarship by an able team of experts, constituted as the catchily-named Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences.

The committee membership has been tweaked since early 2013, when [3]I noted a lack of "anthropologists, communication scholars, folklorists, geographers, historians, journalists, or linguists, no one primarily interested in ethnography, interviewing, participant observation, or action research." [4]On May 31, 2013, Rena Lederman joined the committee, along with three other members. While I still wish the committee had brought in a fuller range of disciplines, Lederman alone brought to the committee a wealth of expertise in anthropology, ethnography, interviewing, and observation whose presence can be detected in the final report.

Rather than trying to get all my thoughts down in one long post, I'll address various elements of the report over the next few days. Watch this space.

See also coverage by the [5]Chronicle of Higher Education (gated) and [6]Inside Higher Ed.

1. http://www.institutionalreviewblog.com/2014/01/happy-new-year-national-academy-of.html
2. http://www.nap.edu/catalog.php?record_id=18614

3. http://www.institutionalreviewblog.com/2013/03/national-academies-run-workshops-on.html
4. http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49500
5. http://chronicle.com/article/National-Research-Council/143939/
6. http://www.insidehighered.com/news/2014/01/10/new-report-calls-reform-federal-rules-governing-human-subject-research

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NRC Report: Liberate Oral History (2014-01-11 17:54)

For historians, the most exciting passage in the [1]new National Research Council report—the passage that had me cheering out loud—is the recommendation that the Common Rule be amended to explicitly exclude historical interviews, as well as other forms of information gathering that do not constitute "human-subjects research specifically in the biomedical, behavioral, and social sciences."

Here's the [2]relevant passage in full:

> The framework for this chapter's recommendations follows from the fundamental point that the Common Rule was intended to apply to human-subjects research specifically in the biomedical, behavioral, and social sciences. From that perspective, the Common Rule does not apply to scientific research that does not meet the definition of human-subjects research. Also, it does not apply to scholarly or investigative activities that are not conventionally considered to be scientific research, even if they involve interaction with people.
>
> Recommendation 2.2: HHS should revise the Federal Regulations to clarify that many forms of scholarship that are widely labeled "research" should be considered as "not human- subjects research" because they are not covered by the intent or spirit of the term "human-subjects research" (see Box 2-3).
>
> Guidance Recommended: OHRP should provide guidance offering examples of forms of scholarship that conventionally fall outside of the definition of human-subjects research, which could help researchers and IRBs in determining whether research activities would be considered as not human-subjects research. For example, historians or nonfiction writers speaking to sources about particular events, or organizations collecting information about preferred benefits packages or studying internal process improvement (that is, self-study) are not engaged in human-subjects research, and such activities are not intended to be covered by 45 C.F.R. § 46.
>
> Box 2-3.
>
> Scholarship outside the definition of human-subjects research
>
> 1. Interviews with individuals for the purpose of establishing a historical record or supplementing extant historical records (e.g., biographical scholarship)
>
> 2. Personal observation and note taking preparatory to composition (e.g., fiction writing, memoir, and related creative or expressive writing) (p. 32)

Unfortunately, the report does not specifically address journalism and folklore, which could have been easily added to this list.

It's worth noting the justification for this recommendation: "the Common Rule was intended to apply to human-subjects research specifically in the biomedical, behavioral, and social sciences." Thus, the NRC committee has avoided any hairsplitting about generalizability, and has instead adopted an originalist stance, opposing the ever-widening scope of the Common Rule.

The report could have taken this analysis further by noting that the statute on which the Common Rule is allegedly based, the National Research Act of 1974, covers only biomedical and behavioral, not social research.

If we were really serious about the intent of the law, we would [3]restrict regulations to the scope authorized by Congress.

1. http://www.nap.edu/catalog.php?record_id=18614
2. http://www.nap.edu/openbook.php?record_id=18614&page=31
3. http://www.institutionalreviewblog.com/2011/09/anprm-question-25-read-statute.html

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NRC Report: Assess Risk Empirically (2014-01-12 09:21)

One theme running throughout the NRC report is the need to replace the [1]worthless gut reactions decried by Ezekiel Emanuel with a system that would base its judgments on the latest empirical evidence. But the report does not present a clear set of reforms that would effect this change without scrapping the current system of local IRB review.

Inexpert, Subjective Judgments

The NRC report notes the problem of subjective assessment of protocols:

> To avoid subjectivity and enhance continuity within and across institutions, IRBs could draw on established scientific and professional knowledge in their determination of the probability and magnitude of research harms in daily life and in routine medical, psychological, or educational examinations, tests, or procedures of the general population. However, care is needed to avoid confusing evidence-based probability estimates with the subjective possibility that harms and discomforts of high magnitude are likely to be produced by the research. For example, IRBs could consider adopting procedures that appropriately balance the probability and magnitude of research harms, in order to avoid subjectively judging research as having a greater than minimal risk in cases where there is a very small probability that the research may produce harm of high magnitude or where there is a high probability that research may produce harms or discomfort of small magnitude.
>
> Research Needed: To build a stronger evidence base, research is needed for identifying the probability and magnitude of harms and discomfort in daily life and the nature of age- indexed, routine medical, psychological, or educational examinations, tests, or procedures of the general population. In addition research is needed to examine appropriate algorithms for determining whether the calculus of probability and magnitude of harms and discomfort meets minimal-risk criteria . . .

> There may be little awareness by IRBs and investigators of the growing body of published empirical evidence describing participant perspectives on research risks and benefits of social and behavioral research, as well as biomedical research. (49)

The report goes on to note "an abundance of investigator reports of survey studies for research on sexuality, drug use, and other health-relevant behaviors in which IRBs have created barriers to research implementation based on the empirically unsupported claim that surveys or interviews on such topics may harm participants by encouraging them to engage in the behaviors being studied." (50)

And, "research is needed to properly address nonphysical risks of research and the methods that create them, rather than having IRBs rely on anecdote or moving to make drastic changes based on efficiency." (62)

(Is the concern about reliance on anecdotes a reference to [2]Laura Stark's "local precedents"?)

While accurately diagnosing the problems of subjectivity and inconsistency, the report offers little on how IRBs might be induced to base their decisions on evidence. The Belmont Report, now 35 years old, already calls for the "systematic, nonarbitrary analysis of risks and benefits," but—as NRC committee member Celia Fisher and others have documented-—[3]that hasn't stopped IRBs from acting idiosyncratically and arbitrarily. How does the NRC panel hope to change this?

Possible Incremental Reforms

The report hints at a few possibilities. Some of these could certainly help more conscientious boards, but it's not clear how they could address the worst IRB abuses.

1. More research about the effects of participation in research.

The report recommends that "Research is needed to study the effects of social and behavioral science research on research participants so that evidence-based assessments of "known and foreseeable" risk are more feasible. In particular, research is needed to properly address nonphysical risks of research and the methods that create them, rather than having IRBs rely on anecdote or moving to make drastic changes based on efficiency. Research is also needed on the effectiveness of confidentiality strategies in reducing risks of physical, social, economic, and legal harm." (62) Obviously, this would all be for the good. But how to get IRBs to read the research?

2. More guidance from OHRP.

Many passages in the report (e.g, 48, 61) suggest the need for more guidance from OHRP on various issues. That said, the recommendations mostly call for guidance on interpreting the regulations, not on protecting research participants. And the report obliquely notes OHRP's record of not responding promptly to previous calls for guidance (28).

3. An appeals process.

The report recommends that the "IRB process should allow appeals for review by an authoritative committee. This committee may exist either within the institution or within an outside agency." But it does not explain why this is needed or, more importantly, what effect the committee expects an appeals process would have. Do the members think that an IRB that was regularly overruled might begin to change its ways?

Bolder Alternatives

The most intriguing ideas come not in a discussion of human subjects research in general but rather in the discussions of more specific investigations.

First, the report suggests the development of "an institutional or organizational entity such as a national center to define and certify the levels of information risk of different types of studies and corresponding data protection plans to ensure risks are minimized." (92)

Second, it suggests alternative boards to review "quality assurance/ improvement (QA/QI) in the field of healthcare care and investigations into the nature, causes, and effectiveness of responses to natural disasters."

"Why, the report asks, "is IRB review not suitable in these fields? Studies in the field of QA/QI are characterized by frequent changes in the interventions utilized in the healthcare setting. IRBs, in general, lack the expertise to assess the methods employed to evaluate these interventions. Moreover, if each of these changes in the interventions must be reviewed at a convened meeting of the IRB, it would take much too much time to go through the technical IRB process of approval of amendments." (109)

The report then suggests a different form of committee for these other sorts of investigation:

> While procedural alternatives to IRB oversight are discussed elsewhere in this report, two suggestions related to the examples above are considered here. First, a committee could be established that was made up of experts in QA/QI as well as experts in the cognate medical specialties, ethicists, patient advocates, and persons who have no connection with the institution apart from membership on the committee . . . Second, studies of the nature, causes, and effectiveness of responses to natural disasters could be overseen by similarly constructed committees. (109)

Why should a national center only investigate data protection, as opposed to research risks in general? And when the committee states that IRBs lack the expertise to evaluate QA/QI, is it suggesting that IRBs possess the expertise to review all the many methods used in human subjects research? If so, where's the evidence for that? Or that the IRB process is nimble enough to keep up with the research process?

And given that existing [4]federal requirements for IRB expertise have been ineffective, what new rules could ensure a higher level of expertise for QA/QI and disaster research? If we can create new, independent boards of experts, might not human subjects research benefit from the same arrangement?

In short, if we can construct expert review of data research and QI by establishing regional or national bodies, why not extend that model to all research, and get rid of local IRB review?

To its credit, the NRC report does not assume that IRBs do more good than harm. (18) But I don't see a full discussion of "procedural alternatives to IRB oversight" for all the forms of research now covered by the Common Rule.

1. http://www.institutionalreviewblog.com/2011/08/emanuel-anprm-will-end-reliance-on.html
2. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
3. http://www.srcd.org/sites/default/files/spr_27-1.pdf
4. http://www.institutionalreviewblog.com/2007/02/in-search-of-expertise.html

NRC Report: Where's the Freedom? (2014-01-14 10:53)

My biggest disappointment with the [1]new NRC report is its silence on the question of academic and personal freedom.

Social scientists have warned of the dangers to freedom of ethics regulation since at least 1967, when political scientist Alfred de Grazia explained,

> It is easy to foresee that the federal government may both promote a number of intrusions upon privacy and liberty in this regard and also impose onerous restrictions of all types on the use of research funds, in the name of defending liberty. This is a formidable bureaucratic problem that may be inevitable and permanent. The long chain of command and line of communications from the subject through the research organization through all the agencies of government including the police and justice agents may end up in a depressing tangle in which neither individual right nor free research is helped.
>
> [U.S. Congress, House Committee on Government Operations, Research and Technical Programs Subcommittee, *The Use of Social Research in Federal Domestic Programs: Part III—The Relation of Private Social Scientists to Federal Programs on National Social Problems* (90th Cong., 1st. sess., 1967), 75.]

For nearly half a century, scholars have expressed similar concerns, right up to March 2013, when the American Association of University Professors (AAUP) published [2]a report which I helped draft, a successor to earlier reports published in 1981 and 2006.

Canada has shown that the freedom of inquiry can be woven into a human subjects research policy, finding that

> In order to maximize the benefits of research, researchers must have academic freedom. Academic freedom includes freedom of inquiry, the right to disseminate the results of that inquiry, freedom to challenge conventional thought, freedom to express one's opinion about the institution, its administration or the system in which one works, and freedom from institutional censorship. ([3]TCPS2, chapter 1)

Indeed, Rena Lederman, a member of the NRC committee, herself co-authored [4]a comment on the ANPRM that championed free inquiry:

> 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 found none of this sentiment in the new NRC report. The term "freedom" appears only once, as a reference to giving "IRBs the freedom to be flexible without diminishing human subjects protection, while being supportive of researchers." (69)

Even when it cites champions of academic freedom, the report ignores this concern. [5]Philip Hamburger's

2007 essay, terming IRB censorship an "outrageous assault on [the First] Amendment," is cited only as a criticism of "an immense bureaucracy engaged excessively in correcting minor flaws in research protocols." And the only mention of the AAUP is its recommendation that universities "uncheck the box."

Instead, the committee questions IRB jurisdiction on purely instrumental grounds. It "strives to balance respect for the individual persons whose consent to participate makes research possible and respect for the social benefits that productive research communities make possible," then enumerates those social benefits as "Lives, Health, Environment, Improved Ways of Life," such as reduced energy consumption and treatment for substance abuse. (10, 16-17)

That's all very well and good, but narrowing the benefits of research to such instrumental ends puts the NRC in league with those who would [6]strip universities of those activities that do not produce the most outside funding and the highest-paid graduates.

Freedom is a scholarly enterprise. Freedom is an ethical value. Freedom is a social benefit.

1. http://www.nap.edu/catalog.php?record_id=18614
2. http://www.aaup.org/report/regulation-research-human-subjects-academic-freedom-and-institutional-review-board
3. http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/
4. http://www.aaup.org/report/regulation-research-human-subjects-academic-freedom-and-institutional-review-board
5. http://www.law.northwestern.edu/lawreview/v101/n2/405/LR101n2Hamburger.pdf
6. http://www.insidehighered.com/news/2011/10/12/florida_governor_challenges_idea_of_non_stem_degrees

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University of Utah Plans Symposium on IRB Policy (2014-01-16 15:08)

On March 20 and 21, the University of Utah Political Science Department will host a symposium, [1]Field Research and US Institutional Review Board Policy.

I will give the keynote address, "'The Freedoms We are Committed to Protect': Political Science, Academic Freedom, and Institutional Review Boards in Historical Perspective."

1. http://poli-sci.utah.edu/2014-research-symposium.php

Caught Between an IRB and the Provost (2014-01-17 12:58)

The UNC-Chapel Hill IRB has suspended research on student-athlete literacy after former learning specialist Mary Willingham of UNC-Chapel Hill complied with her provost's demands for the data.

[Kane, Dan. "[1]UNC Board Suspends Whistle-Blower's Research on Literacy Level of Athletes." News & Observer, January 16, 2014]

The News & Observer reports:

The research, publicized on CNN last week, helped kick up more concerns about the academic fraud scandal at UNC-Chapel Hill that involved dozens of lecture-style classes that never met. Willingham, a former learning specialist with the tutoring program for athletes, blew the whistle on those classes to The News & Observer in 2011. Athletes made up nearly half of the enrollments in those classes.

But university officials disputed the findings and sought to see the data. This week, Willingham turned over data to Provost Jim Dean, who said he wanted to see it to determine how she arrived at her findings. Willingham said at the time that she had not wanted to turn over the data for fear she would violate research regulations.

Willingham couldn't be reached Thursday night after the research suspension was announced. Her co-investigator on the research project, Richard Southall, said he didn't know when the university was saying that the violation occurred.

"My question is, 'Did that violation occur when the data was forwarded on to the provost?' " said Southall, director of the College Sports Research Institute at the University of South Carolina.

Dean said in a statement that was not the case.

"Ms. Willingham had said a number of times that she had identified data, and in fact had shared some pieces of it ... in connection with earlier investigations," Dean said. "The (review board) had decided to look into her case before she finally turned the data set over to me."

He added that Willingham "did not have the authority to use identifiable data because to do so would have required (review board) ... approval, which she did not have."

Southall said Willingham's research could resume after she has met with the board to explain what happened and what steps she will take to protect her data. He anticipated that could take a few weeks.

1. http://www.newsobserver.com/2014/01/16/3538799/uncs-folt-questions-literacy-findings.html

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Theresa Defino (2014-01-18 09:34:43)
I believe they are claiming it was AFTER. She may not have had IRB approval but may also have not really needed it...you know that story!

Theresa Defino (2014-01-18 09:37:27)
"Ms. Willingham had said a number of times that she had identified data, and in fact had shared some pieces of it ... in connection with earlier investigations," Dean said. "The (review board) had decided to look into her case before she finally turned the data set over to me."

He added that Willingham "did not have the authority to use identifiable data because to do so would have required (review board) ... approval, which she did not have."

Exemptions Don't Come to PRIM&R's Mind (2014-01-18 10:03)

In October, PRIM &R hosted a webinar on "Protecting Human Subjects in Qualitative Research: Ethical Considerations for IRBs and Researchers," hosted by Julie Simpson, director of research integrity services at the University of

New Hampshire.

A follow up question, [1]just posted the PRIM &R Blog, suggests that Simpson is unfamiliar with the Common Rule:

> AS: Under what circumstances might qualitative research not require IRB review?
> JS: None come to mind at this time. If the activity is research and it involves human subjects, then it needs IRB review.

Of course, [2]45 CFR 46.101 lists several circumstances in which human subjects research does not require IRB review, some of them–particularly (b)(2) and (b)(3)–of enormous importance to qualitative researchers.

To be sure, [3]OHRP is primarily responsible for discouraging institutions from recognizing the exemptions. But it is a pity to see PRIM &R spread such misinformation.

1. http://primr.blogspot.com/2014/01/keys-to-protecting-subjects-in.html
2. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101
3. http://www.institutionalreviewblog.com/2010/12/menikoff-passes-buck.html

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UNC Accuses Critics of Unauthorized Research (2014-01-21 09:15)

As [1]I noted briefly before, the UNC-Chapel Hill has accused Mary Willingham of violating human subjects rules in her study of the scholastic abilities of student athletes. Willingham has yet to offer a detailed account of her side of the story, and the university's account remains vague as well.

Was it human subjects research?

A January 17 university press release, "[2]UNC-Chapel Hill leaders share facts on Willingham dataset, findings," claims that Willingham departed from the plan she filed in 2008, which the IRB had determined not to constitute human-subjects research.

According to the press release,

> Every research university is required by the federal government to have a campus body, such as an IRB, to oversee human subjects research. UNC-Chapel Hill's IRB is an independent governing body comprised of faculty researchers, knowledgeable staff and community members. Willingham's analysis contradicted information she provided in her formal application to the federally regulated IRB in 2008. At that time, based on information she provided, the IRB determined that their oversight was not needed because 1) the data were represented as secondary (not collected directly from subjects) and 2) individuals could not be identified. De-identified means that the researchers themselves do not know the identities of subjects—not that the researchers do not disclose their subjects' identities as part of their work. As a result, the IRB allowed Willingham to proceed without direct IRB oversight. Willingham collected and

> retained identified data, as her public comments over the past two weeks have confirmed, and this was the basis of the IRB's decision to rescind its earlier determination.

[3]As noted by Inside Higher Ed, the press release does not specify which statements indicate access to identifiable data. Willingham's co-investigator, Richard Southall, last week said he [4]didn't know what UNC meant by the charge. [5]CNN Correspondent Sara Ganim notes that Willingham has not identified any students. (Ganim also accuses UNC of lying about CNN's requests for data.)

If UNC is so sure that Willinghham used identifiable data, why doesn't it share more facts to support that claim?

If so, was it exempt?

Making matters murkier, the press release uses the phrase, "federally regulated IRB," and includes the bullet point, "IRB Review Triggered by Federal Rules Regarding Use of Protected Data." But it UNC may be applying its own rules, not federal rules.

The provost, Jim Dean, told the News & Observer that Willingham "did not have the authority to use identifiable data because to do so would have required (review board) ... approval, which she did not have."

In fact, research with identifiable data may be exempt under 45 CFR 46.101(b)(4), so long as [6]the investigator records the information in such a manner that subjects cannot be identified either directly or indirectly through identifiers linked to the subjects. For example, if a researcher has access to complete records, but just takes notes on select, non-identifiable data, such as test scores.

At UNC, however, there is no such thing as exempt research. Rather, [7]all human subjects protocols must be reviewed by the IRB, which at most determine a project to be "exempt from continuing review."

It is possible, then, that Willingham's work was exempt under federal rules but not under UNC rules. If so, the press release's claim about "federal rules" may be misleading.

What rights do university faculty and staff possess?

Michelle Meyer makes the good point that [8]researchers shouldn't fib on their protocols, at least not most of the time. But nor should university administrations make unsubstantiated accusations about such lapses (or about [9]sexual harassment, [10]intimidation, etc.)

What, after all, is the value of a vague accusation of violating research ethics? It protects no research participants, provides no guidance for other researchers, yet affords the accused no more dignity than a clear explanation of how the IRB concluded that a researcher has broken her pledge. Both Willingham and the public deserve better.

1. http://www.institutionalreviewblog.com/2014/01/caught-between-irb-and-provost.html
2. https://uncnews.unc.edu/2014/01/17/unc-chapel-hill-leaders-share-facts-willingham-dataset-findings/
3. http://www.insidehighered.com/news/2014/01/20/u-north-carolina-shuts-down-whistle-blower-athletes
4. http://www.newsobserver.com/2014/01/16/3538799/uncs-folt-questions-literacy-findings.html
5. http://www.cnn.com/video/data/2.0/video/us/2014/01/17/lead-ganim-unc-athletes-literacy-willingham.cnn.html
6. http://www.hhs.gov/ohrp/policy/cdebiol.html
7. http://research.unc.edu/offices/human-research-ethics/researchers/faq/#whatirbrev

8. https://twitter.com/MichelleNMeyer/status/425416157567660032
9. http://www.dailycamera.com/cu-news/ci_24949191/cus-boulder-faculty-assembly-launches-review-patti-adler
10. http://www.insidehighered.com/news/2014/01/20/colorado-state-removes-email-account-professor-who-criticized-cuts

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Should IRBs Monitor Research Safety? (2014-01-24 12:16)

Susanne Bahn, Michelle Greenwood, and Harry Van Buren argue that "universities have a legal (and an ethical) duty of care for the safety of their employees and it is therefore reasonable to expect that all risks are identified, disclosed and adequately controlled" and that "highly risky research requires additional safeguards for the protection of the research subjects and researchers alike."

Their article offers scant details on what such safeguards might look like.

[Bahn, Susanne, Michelle Greenwood, and Harry J. Van Buren. "The Nexus of Employee Safety, Professional Integrity and Ethics: Applying Stakeholder Theory to University Researchers." Research in Ethical Issues in Organizations 9 (2013): 13–29. DOI: [1]10.1108/S1529-2096(2013)0000009007]

The article argues that

> Organisations such as universities have ethical obligations to their employees to reduce the harm associated with the employment relationship. Because research is such a significant part of what universities do, focusing on harm within the research environment is essential.
>
> After the risk of harm is assessed, the organisation has an obligation to disclose the existence of that harm to the researcher(s) based on its best knowledge and institutional expertise and allow the researchers to decide whether or not to assume it. Here the analogue is to informed consent given by research subjects. While no research or activity is risk free, part of any organisation's ethical responsibilities to stakeholders, including employees, is to assess, reduce and disclose the risk of harm in order to allow stakeholders to make decisions in their best interests.

The authors seem to think of the university as a sort of [2]toxic furniture factory, where a few engineers and managers can be expected to learn the dangers of all the chemicals used and then warn the workers who handle them.

But universities are communities of scholars pursuing a wide array of activities, each with its own goals and dangers. As the sorry history of IRBs has shown, assessing those dangers–to participants or researchers–is beyond the "best knowledge and institutional expertise" of any individual or committee.

While dangers to researchers are real, this article does not explain why we should expect ethics committees to understand those dangers better than the researchers themselves. Researchers would be better served by consulting [3]scholars who have done work similar to theirs, whether or not those scholars are affiliated with the same institution.

1. http://dx.doi.org/10.1108/S1529-2096(2013)0000009007
2. http://www.nytimes.com/2013/03/31/us/osha-emphasizes-safety-health-risks-fester.html
3. http://www.institutionalreviewblog.com/2008/04/michael-rowe-on-situational-ethics.html

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Quebec Court Shields Confidential Interview from Police (2014-01-25 13:58)

A Quebec court has quashed a search warrant for an interview given in confidence by accused killer Luka Magnotta to University of Ottawa researchers. The court agrees with the professors that "the public interest in protecting researcher-participant confidentiality in general, and in the specific circumstances of this case, clearly outweighs what minimal contribution, if any, the release of the seized items will make to the prosecution of the accused in the criminal proceeding." (2)

[[1]Parent c. R., 2014 QCCS 132. h/t Will C. van den Hoonaard]

In reaching this result, the court notes that

> The granting and maintenance of the promise of confidentiality to the participants as a condition of participation in the Research Project was an essential part of the SSHRC funding approval, the approval of the REB at the University of Ottawa, the training of the interviewers, the recruitment literature (recruitment flyer, recruitment letter) sent to potential participants, and the consent form signed by the interviewers for the participants. Without the promise of confidentiality and anonymity to participants, the Research project would not have been approved by the REB at the University of Ottawa, and could not have proceeded." (16)

So should we count this as a win for the REB system? It's not clear. Certainly the court needed evidence that the researchers were serious professionals whose relationship with secret sources "in the opinion of the community ought to be sedulously fostered." (20)

On the other hand, [2]the REB earlier proved unable to persuade the university to pay for the legal representation in this case. And the court seems willing to accept a broad range of evidence that researchers need confidentiality to conduct their valuable work. So perhaps an alternative ethics system, one not based on prior review, would have produced the same result.

For background on the case, see Cockburn, Neco. "[3]Magnotta Ruling Protects 'cornerstone' of Research: Profs." Ottawa Citizen, January 22, 2014.

1. http://www.jugements.qc.ca/php/decision.php?liste=74045948&doc=8C841AF15EDB722253890028D7D33DCC27683AF744B22FF950626727C3A43B16&page=1
2. http://www.institutionalreviewblog.com/2013/04/reb-members-beg-u-of-ottawa-to-defend.html
3. http://www.ottawacitizen.com/news/Magnotta+ruling+protects+cornerstone+research+profs/9418293/story.html

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Willingham Denies Misleading UNC IRB (2014-01-25 21:06)

Mary Willingham, accused by the University of North Carolina at Chapel Hill of diverging from the protocol she showed her IRB, states that the IRB always knew her plans.

[Wilson, Robin. "[1]Chapel Hill Researcher's Findings on Athletes' Literacy Bring a Backlash." Chronicle of Higher Education, January 24, 2014.]

The Chronicle of Higher Education reports,

> Daniel K. Nelson, director of the university's office of human-research ethics, who oversees the institutional review boards, issued a statement saying he had not been pressured by university administrators into requesting that Ms. Willingham seek IRB approval.
>
> He said it had simply become clear with the release of her research results that identifying details were in fact maintained in her data set. (Ms. Willingham has never publicly identified her research subjects.)
>
> But Ms. Willingham says that nothing has changed since she sought approval from the review board before her research began, and that reviewboard officials told her she didn't need it. Since she screened her student subjects over time, she says, she has had to keep track of their identities—something she says the IRB knew all along.

1. http://chronicle.com/article/Chapel-Hill-Researcher-s/144169

3.2 February

Belfast Project: No lawyers, few historians (and no IRB) (2014-02-22 22:14)

Discussions of the ill-fated Belfast Project at Boston College often frame the issue as what can happen to an oral history project in the absence of IRB oversight. But a recent account of the project in the Chronicle of Higher Education, as well as subsequent discussion, suggests that the real problem was a lack of involvement by lawyers and historians.

[McMurtrie, Beth. "[1]Secrets From Belfast." The Chronicle of Higher Education, January 26, 2014.]

No lawyers

The introduction to a [2]follow-up webcast on the Chronicle site exemplifies the framing of the controversy as one over IRBs:

> How is oral history different from other forms of scholarship? What obligations do oral historians and their colleges have, for example, if a subject reveals sensitive information? Who is allowed to hear these recordings and when? And should oral-history projects be vetted by institutional review boards?

But the webcast might better have asked, should oral-history projects be vetted by lawyers?

Here's what we learn from Beth McMurtrie's story:

In 2001, Robert O'Neill, head of the John J. Burns Library at Boston College, told researchers Anthony McIntyre and Ed Moloney, "I am working on the wording of the contract to be signed by the interview[ee], and I'll run this by [historian] Tom [Hachey] and university counsel." But, the article explains, "Mr. O'Neill never did check with a lawyer about the wording."

This may have been the step when the project went wrong. Indeed, the researchers see it that way. As researchers Ed Moloney, Anthony McIntyre, and Wilson McArthur put it in [3]follow-up statement:

> Following the disclosure in the current edition of the Chronicle of Higher Education that Boston College misled ourselves and the participants in the oral history project into believing that the donor contract or agreement for interviewees had been vetted by the college's legal advisers when it had not been, we are consulting our attorneys about the legal implications.

Let's be clear. It's not that the researchers or the university failed to recognize the need for legal advice. Rather, the university promised legal review and then failed to follow through.

In the webcast on the story, both Mary Marshall Clark, director of Columbia University's Center for Oral History Research, and Clifford M. Kuhn, executive director of the Oral History Association, stressed the importance of consulting lawyers, not ethicists, when making promises of confidentiality. As Clark put it, "IRB is not a legal board, it's an ethical board."

Ethics review occasionally offers legal advantage, as when the Quebec court considered it as a factor in quashing a subpoena. But recall that in that case, the University of Ottawa refused legal representation to the researchers, and that the [4]University of Arizona turned over data over the objection of its IRB. I suggest, then, that the problem at Boston College was not the absence of IRB review, but of legal review, which is quite a different thing.

Few historians

The article also shows the relatively small role played by professional historians and historical methods in the project.

- Anthony McIntyre, described in the article as "an independent historian," received his graduate training in political science. (McMurtrie's article doesn't mention this, but Wilson McArthur, who interviewed Loyalists, also has a degree in political science.)
- Thomas Hachey–the Boston College historian most involved in the project–states, "I don't think any pretense was made by any of us at the time that this was going to be following the template for official oral history."
- The project was mostly kept away from BC's history department and its Irish-studies program. And when Kevin O'Neill, an associate professor of history, was eventually consulted, he "wrote a memorandum saying that he was impressed by [the interviews'] potential value to historians, but was very concerned that the interviewer didn't appear to have much experience with oral-history methodology—asking leading questions, for example."

  Now, what O'Neill considers "[5]leading questions" sound a lot like the [6]two-sentence format used for decades by oral historians. At the risk of an ad hominem argument, I note that O'Neill is listed as a specialist on [7]pre-famine Ireland. What training does he have in oral history methods?

Perhaps knowing that no one involved had much if any training in oral history, Clark used her time on the webcast to repeatedly disavow the project as an oral history project, calling it journalism instead.

I don't know the exact basis for her distinction; it strikes me that a project aimed at developing an archive of interviews for future use is a lot more oral history than journalism. But this element of the story deserves more exploration.

What are the interests of third parties?

While McMurtrie's article is a helpful addition to our understanding of the Belfast Project, it leaves unanswered what I consider a key question: what would have happened if all the contracts had been honored, and the researchers had followed all the protocols suggested by Clark? What if, that is, all narrators had reviewed their interviews, and those interviews had remained sealed until the narrators' deaths?

The answer, it seems, is that the project would still have generated controversy, because the people most exposed by the interviews are not the narrators, but third parties they mentioned.

Here's a key passage from the article:

> Mr. Hughes gave a detailed account of the activities of the IRA's Belfast Brigade, of which he was a leader, including its role in the murder of Jean McConville. In December 1972 gunmen abducted the mother of 10 from her apartment in front of her children. Ms. McConville was never seen alive again. Mr. Hughes, who monitored the slum known as Divis Flats, where the McConville family lived, said she had been revealed as an informer for the British Army, was ordered killed, and her body buried. That order, he said, had come from Gerry Adams, his commanding officer.

Hughes died in 2008, so the interviewers broke no agreement by releasing his interviews after his death. Nor would the right of review stressed by Clark have kept Hughes from identifying Adams (who denies ever belonging to the IRA) as an IRA commander.

In his insightful take on the project, James Allison King, a doctoral student in information sciences, notes that Moloney claims inspiration from an earlier project conducted by the Irish Bureau of Military History.

[King, James Allison. "'Say Nothing': Silenced Records and the Boston College Subpoenas." Archives and Records (published online 31 January 2014): 1–15. [8]doi:10.1080/23257962.2013.859573.]

From 1947 to 1957, the Bureau compiled 1773 statements covering the Irish independence movement from 1913 to 1921. Rather than seal each interview until the narrator's death, the Bureau apparently sealed the entire project until 2003, by which point, one suspects, just about everyone mentioned in the interviews was dead. That some of the Belfast Project's interviews were published much more rapidly reflects not any misunderstanding between Boston College and the interviewers, nor the result of an unexpected subpoena. Rather, it was, at least in part, the decision of the interviewers that only the narrator had an interest in what he or she disclosed. But I haven't seen an explicit statement from Moloney or McIntyre to this effect.

Oral history, Clark argues, "is a field of ethics." I think she's right, and the field may need to say more about the Belfast Project than that it wasn't oral history.

1. http://chronicle.com/article/Secrets-from-Belfast/144059
2. http://chronicle.com/article/The-Belfast-Projects-Lessons/144249/?cid=pm&utm_source=pm&utm_medium=en
3. http://bostoncollegesubpoena.wordpress.com/2014/01/27/boston-college-project-director-and-researchers-statement/?utm_source=hootsuite&utm_campaign=hootsuite
4. http://www.institutionalreviewblog.com/2010/09/irb-is-no-substitute-for-shield-law.html"
5. http://bostoncollegesubpoena.wordpress.com/2014/02/06/confidential-2002-burns-belfast-project-report/
6. http://www.jstor.org/stable/3674957
7. http://www.bc.edu/schools/cas/history/faculty/alphabetical/oneill_kevin.html
8. http://dx.doi.org/10.1080/23257962.2013.859573

Ed Moloney (2014-02-24 10:29:15)
With reference to your penultimate paragraph, a little background on the issue of publication and emabargos ref the boston college project might be helpful.
at the outset this was a point of contention between ourselves in belfast and boston college and i do believe beth mcmurtrie made some reference to this in her article which you may have missed.
as the former director of the project my initial demand was to impose an embargo similar to that decreed by most european governments, which is no publication for thirty years.
we were told by BC that this would not be acceptable and that the college normally expected to be able to publish material or make it available within a decade.
the final agreement, to keep interviews embargoed until the death of the interviewee was something of a compromise.
even so, we believe that the college's decision to axe the project in 2006 stemmed directly from a refusal by ourselves to bend on the embargo issue.
in january 2006, tom hachey, who headed the project overall, phoned me and travelled to belfast to meet the researchers to ask if we would agree to approach the interviewees and ask them to alter the terms of the contract to allow publication while they were still alive. the college wanted bangs for its bucks, it seems. we refused and five months later the project was closed.
i hope this sheds some light on this question.
regards
ed moloney
former director
belfast project
boston college

Zachary M. Schrag (2014-02-24 11:20:05)
Thank you for this information.

The McMurtrie article makes no mention of a proposed thirty-year embargo for the interviews. And while I can't claim to have read all that has been written about the Belfast Project, this is the first I have heard of such a proposal.

3.3 March

Symposium: Field Research and US Institutional Review Board Policy (2014-03-02 13:35)

This month the Political Science Department, University of Utah, will host a symposium entitled, "[1]Field Research and US Institutional Review Board Policy." Sponsored by the Betty Glad Memorial Fund, the symposium will take place March 20 [8:45 am - 5:30 pm] and March 21 [9:00 am - 3:30 pm].

The description follows:

US Institutional Review Board (IRB) policy with respect to human subjects was created to protect human participants from harms caused by research. It institutionalizes three ethical principles: respect for persons, beneficence (do no harm), and a just distribution of the benefits and burdens of research. The federal policy has been shaped in light of research following an experimental design, a model that often does not fit the exigencies of field research. This symposium is intended to explore the ethical dimensions of social scientific field research, including those not envisioned in the federal policy.

Symposium Co-Directors
Peregrine Schwartz-Shea, Department of Political Science, University of Utah (psshea@poli-sci.utah.edu)
Dvora Yanow, Wageningen [NL] and Keele [UK] Universities (dvora.yanow@wur.nl)

Keynote speaker: Dr. Zachary Schrag, History and Art History, George Mason University

"'The Freedoms We Are Committed to Protect': Political Science, Academic Freedom, and Institutional Review Boards in Historical Perspective"

Historian Zachary Schrag is one of the leading scholars exploring US institutional review board policy with regard to the social sciences. Author of Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009 (2010), he has maintained a blog on the topic since 2006: http://www.institutionalreviewblog.com/.

The lead title of his keynote address, "The Freedoms We Are Committed to Protect," is a line from Ithiel de Sola Pool, a political scientist and founder of MIT's political science department, who played a key role in the history of IRB policy. Although Professor de Sola Pool died on March 11, 1984, his critiques of IRBs are still quite relevant to today's debates. The keynote address roughly marks the 30th anniversary of his death.

Panel and Roundtable Titles
Panel 1 Doing Undercover Research
Panel 2 Roundtable: Assessing Graduate Student Education in Research Ethics Across the Disciplines
Panel 3 Is IRB Policy Redefining the Meaning of Ethics in Field Research?
Panel 4 Regulating Researchers Who Study the State (Elected and appointed officials, public administrators, judges, ….)
Panel 5 Roundtable: Legal and Other Perspectives on IRBs—Regulatory Policy, Common Law, Academic Freedom and Documentary Film-Making
Panel 6 Roundtable: Looking Forward, Anticipating Change - Wrapping Up

Presenters

Lee Ann Fujii, Political Science, University of Toronto and Visiting Scholar at the Russell Sage Foundation
Samantha Majic, Political Science, John Jay College, City University of New York
Timothy Pachirat, Politics, New School for Social Research
Jacqueline Stevens, Political Science, Northwestern University, 2013-2014 Guggenheim Fellow

Panel and Roundtable Participants

Ed Buendia, Education, Culture and Society, University of Utah
Marianna di Paolo, Anthropology, University of Utah
John Francis, Political Science, University of Utah
Caren Frost, College of Social Work, University of Utah
Rick Green, Political Science, University of Utah

Samuel Handlin, Political Science, University of Utah
Claudio Holzner, Political Science, University of Utah
Daniel Levin, Political Science, University of Utah
Jenny Mackenzie, PhD., Documentary Film Maker
Dan McCool, Political Science, University of Utah
Ella Myers, Political Science, University of Utah
Lenora Olson, Public Health, University of Utah
Susan Olson, Law and Society Association, Executive Officer; Political Science (Emerita), University of Utah
Polly Wiessner, Anthropology, University of Utah
Jennifer Yim, Political Science (ABD), University of Utah

1. http://poli-sci.utah.edu/2014-research-symposium.php

David Wright: OASH "is secretive, autocratic and unaccountable." (2014-03-17 09:38)

David Wright has resigned as director of the Department of Health and Human Services' Office of Research Integrity. In his letter of resignation, obtained by Science Insider, Wright blames a dysfunctional Office of the Assistant Secretary for Health (OASH), which also houses OHRP.

[Kaiser, Joceyln. "[1]Top U.S. Scientific Misconduct Official Quits in Frustration With Bureaucracy." Science Insider, March 12, 2014.]

Science Insider posts Wright's February 25 resignation letter to Dr. Howard Koh, Assistant Secretary for Health. Wright explains:

> The organizational culture of OASH's immediate office is seriously flawed, in my opinion. The academic literature over the last twenty-five years on successful organizations highlights several characteristics: transparency, power-sharing or shared decision-making and accountability. If you invert these principles, you have an organization (OASH in this instance), which is secretive, autocratic and unaccountable.

He continues:

> The sociologist Max Weber observed in the early 20th century that while bureaucracy is in some instances an optimal organizational mode for a rationalized, industrial society, it has drawbacks. One is that public bureaucracies quit being about serving the public and focus instead on perpetuating themselves. This is exactly my experience with OASH. We spend exorbitant amounts of time in meetings and in generating repetitive and often meaningless data and reports to make our precinct of the bureaucracy look productive. None of this renders the slightest bit of assistance to ORI in handling allegations of misconduct or in promoting the responsible conduct of research. Instead, it sucks away time and resources that we might better use to meet our mission. Since I've been here I've been advised by my superiors that I had "to make my bosses look good." I've been admonished: "Dave, you are a visionary leader but what we need here are team players." Recently, I was advised that if I wanted to be happy in government service, I had to "lower my expectations." The one thing no one in OASH leadership has said to me in two years is 'how can we help ORI better serve the research community?' Not once.

And, he asks,

> Is OASH the proper home for a regulatory agency such as ORI? OASH is a collection of important public health offices that have agendas significantly different from the regulatory roles of ORI and OHRP. You've observed that OASH operates in an "intensely political environment." I agree and have observed that in this environment decisions are often made on the basis of political expediency and to obtain favorable "optics." There is often a lack of procedural rigor in this environment. I discovered recently, for example, that OASH operates a grievance procedure for employees that has no due process protections of any kind for respondents to those grievances. Indeed, there are no written rules or procedures for the OASH grievance process regarding the rights and responsibilities of respondents. By contrast, agencies such as ORI are bound by regulation to make principled decisions on the basis of clearly articulated procedures that protect the rights of all involved. Our decisions must be supported by the weight of factual evidence. ORI's decisions may be and frequently are tested in court. There are members of the press and the research community who don't believe ORI belongs in an agency such as OASH and I, reluctantly, have come to agree.

As Wright notes, OHRP is something of a sister office to ORI, a regulatory agency lost in a political division. The secrecy, inefficiency, low expectations, and lack of due process he observed at ORI could well explain some of the problems with the federal regulation of human subjects protections.

1. http://news.sciencemag.org/people-events/2014/03/top-u.s.-scientific-misconduct-official-quits-frustration-bureaucracy

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McCarthy's Mysterious Mythmaking (2014-03-19 09:06)

PRIM &R has launched "[1]People & Perspectives (P &P)," described as a "digital story-telling library." The site features a blurb by Joan Rachlin, PRIM &R's soon-to-retire executive director, who calls it "[2]an enduring and dynamic record of our historical antecedents, how and when we come together."

But is anyone going to vet the accuracy of stories posted on the site?

That question is raised by a 4-minute clip (taken from a much longer November 2013 interview) with Charlie McCarthy, director of the Office for Protection from Research Risks from 1978 to 1992.

I have not watched the full interview (not transcribed, and therefore a chore). But the four minutes and 12 seconds on "[3]social-behavior research" is by itself a disturbing stew of faulty memory and misinformation.

IFRAME: [4]//www.youtube.com/embed/5ltL2do4w6E

Here are some of the key inaccuracies.

"Social science and behavioral science."

The segment begins (0:14) with McCarthy saying that "the [National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research] was well aware that the law called on them to issue statements and

guidance on social science and behavioral science."

McCarthy also made this claim in his [5]2004 interview with OHRP. It's still not true.

[6]Public Law 93-348, the National Research Act of 1974, is there for all to read, including Title II, Part A, which established the National Commission and enumerated its duties. The law calls upon the commission 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 (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.

The phrase, "biomedical and behavioral research," appears three times in that charge, as well as in the commission's own name. At no point does the law call on the commission to issue statements or guidance on social science.

"Extended another year"

McCarthy (0:31): "They anticipated that at the end of their four years they would be extended another year to do the social science."

The National Research Act [sec. 204(d)] authorized the commission for only 24 months. In October 1976, Congress bumped that up to 36 months, and in November 1977 to 42 months, for a final termination date of 1 November 1978.

Already by July 1977, Sen. Edward Kennedy had introduced legislation to replace the National Commission with a President's Commission, so at no point could the commissioners have had any reason to believe that the commission would last for more than four years. And while I can't say I read every word of the commission meeting transcripts, I never saw any suggestion that the commission would last past 1978.

[For a chronology, see Vikki A. Zegel, Biomedical Ethics: Human Experimentation (Congressional Research Service, 1978).]

"They were going to . . . hear some of the best social scientists in the country."

McCarthy (0:50): "They were going to . . . hear some of the best social scientists in the country. As it happened, when they completed four years, they were disbanded. I think it was not their intent to do that. But it is true that they did not have many social scientists. The issues of the day–that were publicly debated–were primarily medical. I think, by hindsight, they probably made a mistake by putting off the social science issues until the end. And then ran out of time. They were not continued for one more year as expected. That work never was completed."

It's quite true that the the issues of the day "were primarily medical," and that the commission "did not have many social scientists." (In fact, none of the commissioners were social scientists, as opposed to behavioral scientists,

though the National Research Act required it.)

But McCarthy is wrong to suggest that the commission never heard from social scientists. In the spring of 1977, the commission held hearings in Chicago, San Francisco, and Bethesda. Social scientists used these occasions to voice their displeasure with IRB review. For example, Hans Mauksch, executive officer of the American Sociological Association, argued, "Requiring a premature formulation of a specific research proposal has been a very important obstacle to qualitative research."

[Transcript of the public hearings of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 5, April 15, and May 3, 1977 on Institutional Review Boards (Bethesda, Maryland, 1977), 656.]

It's not that the commissioners failed to hear social scientists. They failed to listen.

"Three more reports"

McCarthy (1:48): "I think they had drafted, or at least planned to draft, three more reports on social science research. They never saw the light of day, and I don't know what they would have said."

Well, neither do I. And at no point in my research did I find a whisper of a suggestion that the commission planned a single report on social science research. Staff memos, yes. But no reports.

A professor from the University of Chicago, a meeting in New Mexico

McCarthy (2:02): "They did get some guidance. They had a professor from the University of Chicago, who represented the social sciences. He held one meeting in which–he chaired a meeting outside the commission meetings, just to gather opinions. I attended that meeting, and I think something might have come of it. He had eight or ten top social science researchers at that meeting, which was held down in New Mexico, by the way, but the commission supported it. As often happens, it was the Tower of Babel. They had so many opinions, many of which were well worth following up on. But since there was no follow-up meeting, I don't think very much came of it. There was an effort made, or at least initiated, but not followed through."

I can't guess whom McCarthy is thinking of with the University of Chicago reference. A social science professor from the University of Chicago? Too vague.

I do have a guess about the "New Mexico" conference.

As noted above, the National Commission did hold hearings in Chicago and San Francisco, but not in New Mexico. In 1979, Tom Beauchamp organized a conference at Georgetown University that eventually produced the volume, [7]Ethical Issues in Social Science Research. That's not near New Mexico either.

But in April 1983, [8]NIH sponsored a conference on the protection of human subjects in behavioral and social science research, hosted by the University of Texas at Dallas. McCarthy was there, and Texas is at least New Mexico-adjacent.

Could this be the conference McCarthy was thinking of? If so, he's talking about a conference held more than four years after the expiration of the National Commission.

Which leads us to the next clue:

"The Reagan years"

McCarthy (3:12): "I think it is a legitimate criticism of the commission, but I'm quite sure where the blame should lie. I certainly don't blame the commissioners. They had no control over how long they were going to stay in existence. I think it was more a matter of a change in politics. Consequently, in the Reagan years, I don't think that the commission was favored by the new administration. So the funding dried up, and the commission disbanded. And with it went the social science issues that might have been addressed but never actually were."

The reference to the Reagan years strongly suggests that McCarthy is mixing up the history of two commissions: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978) and the Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1978-1983).

Reagan did not take office until January 1981, so obviously he played no role in the National Commission's 1978 demise; that was the product of congressional action. The latter commission did indeed endure into the Reagan years. Albert Jonsen, who served on both commission, notes that Reagan appointed commissioners to the Presidential Commission who disagreed strongly with some of the Carter appointees, resulting in "decidedly bland" recommendations. (Jonsen, [9]Birth of Bioethics, 114-115)

A confusion between the two commissions may explain why McCarthy thought the Texas (a.k.a. New Mexico) conference took place during the operations of the National Commission. In fact, it convened just after the demise of the Presidential Commission in March 1983.

"Where the blame should lie"

McCarthy is not a young man, and he's speaking of events thirty or forty years in the past. So we should cut him some slack when he mixes up two commissions with some overlapping duties and membership.

But some of McCarthy's claims, particularly about the three phantom reports, don't make sense for either commission. And keep in mind that social scientists who dealt with McCarthy in the 1970s and 1980s didn't find him a reliable narrator even at the time. Moreover, McCarthy's misremembering here has a decided political slant: "I certainly don't blame the commissioners." This deflects blame from the National Commission onto the Reagan administration, allowing PRIM &R listeners to continue in the pleasant fantasy that the National Commission, even in its failures, was on the right track. No need, then, to question the divine wisdom of the sacred Belmont Report.

Which brings us to the question of how an interview like this should be presented.

Ideally, the interviewer would have prepared for the interview well enough to interrupt with a gentle, "Dr. McCarthy, might you be thinking of the Presidential Commission?" But that could have required PRIM &R to engage a historian to conduct its historical interviews. Instead, they asked Dave Borasky, an IRB administrator.

In the absence of such intervention during the interview itself, PRIM &R still could present the interview in a way that would correct McCarthy's misstatements. It could, for example, commission a historian to prepare an annotated transcript. Or, at the very least, it could refer website visitors to more scholarly histories of the commission.

Instead, PRIM &R has posted McCarthy's inaccurate narrative without any warning to viewers that much of what they are hearing is not the truth. Is this the sort of publicly responsible research PRIM &R wishes to promote?

1. http://www.peopleandperspectives.org/story/interview/mccarthy-4c
2. http://www.peopleandperspectives.org/about
3. http://www.peopleandperspectives.org/story/interview/mccarthy-4c
4. file://www.youtube.com/embed/5ltL2do4w6E
5. http://archive.hhs.gov/ohrp/docs/InterviewMcCarthy.doc
6. http://history.nih.gov/research/downloads/PL93-348.pdf
7. http://books.google.com/books?id=teh9AAAAIAAJ&source=gbs_navlinks_s
8. http://catalog.hathitrust.org/Record/000163394
9. http://global.oup.com/academic/product/the-birth-of-bioethics-9780195171471;jsessionid=B1982F38E4C8238FD2FE5A789CAC4296?cc=us&lang=en&

Simon Whitney (2014-03-19 19:01:08)
Thanks for this disturbing exposé. You are right to call it "faulty memory and misinformation."

It is no surprise, however. Will van den Hoonaard has pointed out that IRB scholars and supporters live in a bubble in which genuine academic debate is not only absent but unwelcome. "No critical self-reflection about the work and nature of ethics committees. Participants of both conferences lived in a bubble of compliance. Unlike academic conferences, there were no voices of dissent, nor were any expected." (*The Seduction of Ethics: Transforming the Social Sciences.* Toronto; Buffalo: University of Toronto Press, p. 285)

Readers who want to learn more about the sordid history of McCarthy's tenure at OPRR should check the meticulous re-construction you provide in *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009.* It is a shocking story of deceit and double-dealing by McCarthy and his federal colleagues.

Ethics, indeed.

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[1]Suffocated Science and Scholarship

1. http://suffocatedscience.com/

3.4 April

IRB Still Isn't Peer Review (2014-04-08 20:36)

A bit off-topic here (this is a health-related study), but here's an illustration of the benefits of IRB shopping.

[Cordner, Alissa, and Phil Brown. "Moments of Uncertainty: Ethical Considerations and Emerging Contaminants." *Sociological Forum* 28, no. 3 (September 2013): 469–94. [1]doi:10.1111/socf.12034.]

> Breast milk biomonitoring can be controversial because of concerns that the reporting-back of individual contamination levels may discourage breastfeeding (Morello-Frosch et al. 2009), thus potentially balancing identifiable benefits to science with uncertain benefits and harms to participants. Breastfeeding provides important health benefits compared to formula feeding, even when the milk contains chemicals (Hooper and She 2003; Jorissen 2007), but some academics and IRBs worry that a woman's knowledge

> of her body burden could impact her decision to breastfeed. Yet evidence supporting these fears is based on hypothetical situations described in survey research (Geraghty et al. 2008) or is anecdotal (Gross-Loh 2004). A recent study of women who shared their breast milk for a biomonitoring project found that while some women in this study stated they became more aware of chemical exposure and some made lifestyle changes, none of them chose to stop breastfeeding or to breastfeed for a shorter period of time because of their study results (Wu et al. 2009).
>
> As an example of this ethical concern around breast milk biomonitoring research, one scientist's IRB initially denied a research protocol that would have tested for chemicals in breast milk on the grounds that the scientific benefits of learning about breast milk contamination did not outweigh the potential risks to women learning about personal contamination. That researcher looked to existing sociological and public health research showing this fear to be unjustified, and eventually did receive approval through another IRB to conduct their research. The researcher's trajectory points to both the ethical conflicts researchers can have with institutions when designing novel research programs, and to the absence of consistent institutional ethical guidelines in such areas of research. Because different IRBs have vastly contradictory stances on such issues, the ethical choices are by no means clear. Thus researchers must be attuned to the many moments at which choices come up.

In peer review, this is standard practice: you get rejected at one journal, you try again elsewhere. For the most part, however, researchers have no way to work around an IRB that is basing its decisions on unjustified fears. I wonder how the researchers in this example did it.

1. http://dx.doi.org/10.1111/socf.12034

"The Freedoms We Are Committed to Protect" (2014-04-09 20:57)

The Hinckley Institute of Politics, University of Utah, has posted a videorecording of my lecture there last month.

"'The Freedoms We Are Committed to Protect': Political Science, Academic Freedom, and Institutional Review Boards in Historical Perspective." Keynote address, Symposium on Field Research and US Institutional Review Board Policy, University of Utah, March 2014. [1]http://youtu.be/uwIFyDgLklU

IFRAME: [2]//www.youtube.com/embed/uwIFyDgLklU

1. http://youtu.be/uwIFyDgLklU
2. file://www.youtube.com/embed/uwIFyDgLklU

3.5 May

Canada: When the Subpoena Comes, Universities Should Pay for Independent Legal Advice (2014-05-02 20:50)

In [1]guidance issued in April 2014, the Secretariat on Responsible Conduct of Research finds that "In situations where safeguarding participant information may involve resisting an attempt by legal means to compel disclosure of

confidential research information, TCPS 2 requires institutions to provide researchers with financial and other support to obtain independent legal advice or to ensure that such support is provided."

The announcement does not explicitly say so, but I imagine this is somehow a response to the University of Ottawa's earlier [2]refusal to pay the legal costs of researchers who faced a subpoena. On the other hand, the new guidance addresses only "legal advice," not representation.

1. http://ethics.gc.ca/eng/policy-politique/interpretations/privacy-privee/
2. http://www.institutionalreviewblog.com/2013/04/reb-members-beg-u-of-ottawa-to-defend.html

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3.6 June

TCPS Envy (2014-06-17 18:59)

How good is TCPS2, Canada's current framework of research regulation?

Martin Tolich, with co-authors, thinks it's pretty good. He suggests that at the very least, it can serve as a starting point for other countries interested in reforming their systems of research ethics oversight to make them more responsive to the concerns of social scientists and the people they study.

[Tolich, M, and BP Smith. "Evolving Ethics envy—New Zealand Sociologists Reading the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans." *Kōtuitui: New Zealand Journal of Social Sciences Online* 9, no. 1 (2014): 1–10. doi:[1]10.1080/1177083X.2013.867513; Hoonaard, Will C. van den, and Martin Tolich. "[2]The New Brunswick Declaration of Research Ethics: A Simple and Radical Perspective." *Canadian Journal of Sociology* 39, no. 1 (March 31, 2014): 87 – 98]

I too have written admiringly of TCPS2, noting, for example, that [3]
it embraces academic freedom as a value, even as U.S. researchers do not.

Tolich and Barry Poata Smith of New Zealand see TCPS2's chapter 9, on research with indigenous peoples, as superior to existing structures in New Zealand and advocate for "a variation on the Canadian model" to avoid "paralysis" of research.

In a separate article, Tolich and Will van den Hoonaard report on the 2012 Ethics Summit (which I attended) and note that "Chapter Ten of the TCPS 2 [on qualitative research] did not become the subject of much discussion despite the international acclaim it had received." They offer the excuse that "it was essential that delegates to this first summit establish the problem (and solution) on their own terms, rather than one 'made in Canada,'" but a greater problem may have been the lack of information about how TCPS2 was working in practice less than two years since its promulgation.

As TCPS2 matures, I would like to see more Canadian researchers' descriptions of work under the new regime. Is TCPS2 as good in practice as it looks on paper?

1. http://dx.doi.org/10.1080/1177083X.2013.867513
2. https://ejournals.library.ualberta.ca/index.php/CJS/article/view/21732/16267
3. http://www.institutionalreviewblog.com/2014/01/nrc-report-wheres-freedom.html

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A Bit of Historical Perspective on the Facebook Flap (2014-06-30 20:24)

IRBs and behavioral research are all over the news, as a result of a paper that manipulated the news feeds of 689,003 Facebook users.

[Kramer, Adam D. I., Jamie E. Guillory, and Jeffrey T. Hancock. "Experimental Evidence of Massive-Scale Emotional Contagion through Social Networks." *Proceedings of the National Academy of Sciences* 111, no. 24 (June 17, 2014): 8788–90. [1]doi:10.1073/pnas.1320040111.]

Michelle Meyer has posted a detailed analysis of the regulatory context, explaining multiple ways a project like this could have been approved. She concludes that "so long as we allow private entities freely to engage in these practices, we ought not unduly restrain academics trying to determine their effects."

[Meyer, Michelle N. "How an IRB Could Have Legitimately Approved the Facebook Experiment—and Why That May Be a Good Thing." *The Faculty Lounge*, June 29, 2014. [2]http://www.thefacultylounge.org/2014/06/how-an-irb-could-have-legitima tely-approved-the-facebook-experimentand-why-that-may-be-a-good-thing.html.]

I have little to add to Meyer's excellent post, except a bit of historical perspective. Psychological experiments—whether in the lab, in the field, or online—fall outside my main area of concern, but perhaps I can offer a few relevant points.

1. Psychological Field Experiments Have a Long History

Over at Slate, Katy Waldman [3]presents the Facebook experiment as a human rights violation, quoting James Grimmelmann, who in turn claims that [4]"informed consent [is] the ethical and legal standard for human subjects research."

If that were true, we'd need to reconsider not only Facebook's latest manipulation, but a line of research–social psychology field experiments–dating back roughly half a century, in which researchers put on some kind of a performance for unwitting subjects to see how they'd react.

In looking for examples from the 1970s (when the human subjects regulations were crafted), I came across this peach: Peter Suedfeld, Stephen Bochner, and Deanna Wnek. "Helper-Sufferer Similarity and a Specific Request for Help: Bystander Intervention During a Peace Demonstration." *Journal of Applied Social Psychology* 2, no. 1 (March 1972): 17–23. [5]doi:10.1111/j.1559-1816.1972.tb01260.x.

According to the abstract (why bother reading the article, we're doing Facebook today),

> Eighty randomly selected male participants in the April 1971 peace demonstration in Washington, D.C. were approached by a young women E who asked them to help her friend who was feeling ill. The "friend" was a young male E, in either conventional or "hip" clothing, who was displaying either a "Support Nixon" or a "Dump Nixon" sign. The dependent variable was a 5-point ordinal scale of cooperation with a series of specific requests, which ranged from going over to the distressed E to providing bus fare and help for both Es to leave the area and go home. All 80 Ss went to the E and 79 helped to some extent. There was more helping behavior in the morning than in the afternoon, when the program of activities had intensified; with Ss who were tested in the afternoon, the E displaying a "Support Nixon" sign attracted less helping behavior than the "Dump Nixon" condition. The dress manipulation (implicit attitudinal similarity) had no effect.

I doubt that Facebook's algorithms served up a more depressing news feed message than "Support Nixon."

2. Controversy Over Field Experiments Have a Long History

These kinds of research projects can't offer informed consent of the sort Grimmelmann believes is required by federal law. But federal law has never required informed consent in all human subjects research.

Members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research were at least somewhat aware of the ethical challenges of field experiments. In their December 1977 and January 1978 meetings, they discussed the problem. For example, in December 1977, staffer Bradford Gray told the commission,

> There is a lot of field experimentation in social psychology, where something is fit into a public place, and observations are made. It might be something that is put in a store window, or it might be a wallet left on the street, or it could be any number of things. It could be walking a person dressed in a particular way down the street and observing the response. There are all sorts of things like this that are done. There are whole journals that publish this stuff."

Commissioner Joseph Brady interjected, "testimony from [6]Alan [sic] Funt, it seems to me."

Perhaps as a result of this discussion, the Commission's 1978 [7]Institutional Review Boards: Report and Recommendations stated that

> An IRB may waive the informed consent requirement in [social science] 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. Nondisclosure must be essential to the methodological soundness of the research, and must be justified by the importance or scientific merit of the research. Further, the research must present no more than minimal risk and be unlikely to cause embarrassment to the subjects.

After some debate, this led, in 1981, to the the current provision [46.116(d)] allowing IRBs to waive informed consent requirements. (More on that provision in Meyer's post.)

This is not to say people have to like field experiments, or even that the American Psychological Association's Code of Conduct permits them. (See [8]Standard 8.05).

But critics of the Facebook experiment should at least be aware that we are talking about a mode of research that existed long before Facebook, and that federal ethics advisors and regulators specifically decided that it should proceed.

3. It's Nice to Hear from the IRB

When the news first hit, both Grimmelmann and Meyer were forced to guess about whether the paper had been reviewed by an IRB and, if so, how that IRB reached its decision to approve the study; the original article offered no

explanation of if or how it had gotten IRB approval.

That mystery has been cleared up a bit, with a [9]Cornell press release explaining that the Cornell IRB had concluded that the Cornell researchers were [10]"not engaged in human subjects research." But this was exceptional. Most IRBs do not publish their rulings in any form.

That's a pity. Back in 1973, Yale law professor Jay Katz, a leading expert on human experimentation, told Congress of "the current uninformed and secretive climate which pervades research decision-making. At present, decision-making remains divorced from pertinent prior decisions of other committees or from scholarly and public evaluation and criticism."

Katz insisted that important decisions needed to be published, so they could be read and discussed nationwide. "The result," he predicted, "would not only be better thought out decisions, but also a more complex system of controls which, in effect, [would take] into account much broader sources of information as to societal values . . . I regard such a development, analogous to the experience of the common law, as the best hope, for ultimately providing workable standards for the regulation of the human experimentation process."

If Congress had required the publication of important IRB decisions, all the folks now outraged about the Facebook paper would be able to read not only the brief press release about the reasoning of the Cornell IRB, but also the reasoning of other IRBs that have approved [11]even more annoying social experiments. Then we'd be having a more informed debate over the ethics of this kind of research.

1. http://dx.doi.org/10.1073/pnas.1320040111
2. http://www.thefacultylounge.org/2014/06/how-an-irb-could-have-legitimately-approved-the-facebook-experiment and-why-that-may-be-a-good-thing.html
3. http://www.slate.com/articles/health_and_science/science/2014/06/facebook_unethical_experiment_it_made_news _feeds_happier_or_sadder_to_manipulate.html
4. http://laboratorium.net/archive/2014/06/28/as_flies_to_wanton_boys
5. http://dx.doi.org/10.1111/j.1559-1816.1972.tb01260.x
6. https://www.candidcamera.com/cc2/cc2e.html
7. http://videocast.nih.gov/pdf/ohrp_institutional_review_boards.pdf
8. http://www.apa.org/ethics/code/index.aspx?item=11
9. http://mediarelations.cornell.edu/2014/06/30/media-statement-on-cornell-universitys-role-in-facebook-emotio nal-contagion-research/
10. http://www.hhs.gov/ohrp/policy/engage08.html
11. http://www.institutionalreviewblog.com/2010/05/researchers-deceive-thousands-of.html

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3.7 July

Computer Scientist: Informed Consent is the Wrong Metaphor (2014-07-08 16:17)

Michael Bernstein, assistant professor of computer science at Stanford and a former postdoctoral scholar on Facebook's Data Science team, argues that "Hammering ethical protocols designed for laboratory studies onto internet experimentation is fundamentally misguided."

[Bernstein, Michael. "The Destructive Silence of Social Computing Researchers." Medium, July 7, 2014. [1]https://medium.com/@msbernst/9155cdff659.]

Writing about the controversy over the recently published study of Facebook users' posts after their news feeds had been altered, Bernstein laments the degree to which the debate has been dominated by "communication scholars, sociologists, policy folks and other really smart researchers." (Oddly, he leaves bioethicists off of that list.) While acknowledging their "insightful analyses and critiques," he calls for social computing researchers to push back against those who take clinical medical trials to be the norm.

> Informed consent seems to be the crux of the issue. Should we require it? There are many forms: opting in for each study, a one-time "opt in to science!" button on each site, or advertisement recruiting. What about debriefing afterwards?
>
> Regardless of the moral imperatives, let me start by saying as a designer of social systems for research that any such requirement will have an incredibly chilling effect on social systems research. IRB protocols are not the norm in online browsing, and so users are extremely wary of them. Have you ever tried putting a consent form inline on your social site? I have, and I can tell you that it drives away a large proportion of interested people who would probably actually want to participate if the interface were different. It looks scary. It's opt-in, and defaults are powerful. Forget that it's there to protect people—it makes the entire site look like something underhanded is going on. "I just came to check out this site, I don't want to be agreeing to anything weird." It's the wrong metaphor for today.

Indeed, the lab experiment has been the wrong metaphor for other kinds of research since 1965.

The real problem, Bernstein suggests, is users' misunderstanding of the websites they use. "Thousands of online experiments are being run every day by product managers at Google, Facebook, Starbucks, Microsoft, and the Obama Campaign. Let's take a user-centered approach and understand what peoples' expectations are."

That's going to be an uphill climb, since it seems that peoples' expectations are rather confused. My favorite illustration so far is a Washington Post editorial:

> Users agree to terms and conditions when they join the social network. In-house experiments, called "A/B testing," are routine, too. They observe how users react to small changes in format and content, such as a bigger icon or a different shade of blue. The purpose is to improve user experience on the site.
>
> But this crossed an important line: Unlike typical A/B testing, Facebook tried to directly influence emotions, not behaviors. Its purpose was not to improve user experience but rather to publish a study.

So it's OK to manipulate people's behavior without their knowledge, but not their emotions? Why is that so, and how could one possibly tell the difference?

1. https://medium.com/@msbernst/9155cdff659

Those Noisy Voices from the Grave (2014-07-09 15:30)

This afternoon I had the pleasure of speaking on the Kojo Nnamdi Show about the Belfast Project (a.k.a. Boston College's Oral History Archive on the Troubles in Northern Ireland) and its impact on oral history. I didn't have a lot of time, but I tried to make the case for a shield law, analogous to the protections provided to health research and DOJ-sponsored criminal justice research.

["[1]Old Wounds & Oral History: The Aftermath of the Belfast Project," *Kojo Nnamdi Show*, July 7, 2014.]

While I'm on the subject, it has been more than three years since [2]the U.S. Attorney's office filed a subpoena for two tapes that were recorded as part of the project. The [3]Boston College Subpoena News (which is published anonymously but presents things from the perspective of researchers Anthony McIntyre and Ed Moloney) remains the best source for links to news reports and opinion pieces about the case. But here are some recent items of note.

- **Cullen, Kevin. "[4]In Belfast, The Shadows and the Gunmen," *Boston Globe*, July 6, 2014.**

  Cullen, who joined the Kojo show via telephone, explores the fallout from the case in Northern Ireland, where former IRA members and loyalists fear being arrested or shot.

- **Zittrain, Jonathan. "[5]BC's Belfast Project: Archives Are in Danger, but Technology Can Help," *Boston Globe*, June 8, 2014.** h/t Rebecca Tushnet.

  Proposes encryption methods to put interview recording and transcripts beyond the reach of subpoena.

  > Are we stuck with either having to destroy our secrets or leave them exposed to near-instant disclosure? It might be possible to split the difference: to develop an ecosystem of contingent cryptography for libraries, companies, governments, and citizens. Instead of using new technologies to preserve for ready discovery material that might in the past never have been stored, or deleting everything as soon as possible, we can develop systems that place sensitive information beyond reach until a specified amount of time has passed, or other conditions are met.

- **Marcus, Jon. "[6]Oral History: Where next after the Belfast Project?" *Times Higher Education*, 5 June 2014.** h/t Rob Townsend.

  Suggests that oral historians and archivists may end up doing their job better.

  > "There have been a lot of things written with headlines like, 'This is the end for oral history'," says Cliff Kuhn, associate professor of history at Georgia State University and executive director of the Oral History Association. "I do think the Boston College case afforded something of a wake-up call. I'm sure there are a number of repositories that have re-examined their protocols to make sure things are tighter. And that's a good thing."

1. http://thekojonnamdishow.org/shows/2014-07-09/old-wounds-oral-history-aftermath-belfast-project
2. http://www.institutionalreviewblog.com/2011/06/us-and-british-governments-subpoena.html
3. http://bostoncollegesubpoena.wordpress.com/
4. https://www.bostonglobe.com/news/world/2014/07/05/belfast-the-shadows-and-gunmen/D5yv4DdNIxaBXM12Tlr6PL/story.html
5. https://www.bostonglobe.com/opinion/2014/06/07/belfast-project-archives-are-danger-but-technology-can-help/r3NfgdOobGLbte5PnqkvGN/story.html
6. http://www.timeshighereducation.co.uk/features/oral-history-where-next-after-the-belfast-project/2013679.article

Microsoft Seeks Ethics Review Without Bottlenecks and Frustration (2014-07-11 07:03)

Duncan Watts of Microsoft Research announces Microsoft will soon launch "an ethics-review process for human-subject research designed explicitly for web-based research." Could such a process avoid the pitfalls of the IRB?

[Watts, Duncan J. "[1]Lessons Learned From the Facebook Study." *Chronicle of Higher Education Blogs: The Conversation*, July 9, 2014. h/t Rebecca Tushnet]

Here is the proposal:

> What we need is an ethics-review process for human-subject research designed explicitly for web-based research, in a way that works across the regulatory and institutional boundaries separating universities and companies. For the past two years, my colleagues at Microsoft Research have been designing precisely such a system, which is to be rolled out shortly.
>
> It is still a work in process, and many details are liable to change as we learn what works and what doesn't, but the core principle is one of peer review. Although we have an ethics board composed of experienced researchers (including me), the idea is not to have every proposal submitted to the board for review—a recipe for bottlenecks and frustration. Rather, it is to force researchers to engage in structured, critical discussions with educated peers, where everyone involved will be accountable for the outcome and hence will have strong incentives to take the review seriously. Unproblematic designs will be approved via an expedited process, while red flags will provoke a full review—a two-tier system modeled on existing IRBs.
>
> Aside from its inherent scalability, the peer-review approach also has the benefit of involving the entire research community in discussions about ethics. Rather than placing the burden of review on a small committee of experts, everyone will have to undergo some basic training and consider the ethical implications of their research. The goal is to create an educated community that, in subjecting all cases to diverse viewpoints, lets fewer errors slip through. And because the process is designed to run continuously, insights arising from novel cases will diffuse quickly.

So this would be like current university IRBs in having a multi-tier level of review, but unlike those IRBs in that it would involve "the entire research community in discussions about ethics," rather than "a small committee of experts."

Watts claims "experience with review procedures both at Columbia University as well as in corporate research labs (first at Yahoo! Research, where we implemented an IRB-like process, and now at Microsoft)," and he knows their limits: "Although progress has been made over that time, many university IRBs still have little experience with the mechanics of web-based research." So I think it would be better to characterize those IRBs not as small committees of experts, but small committees of non-experts, or, worse, [2]pseudo-experts. [That last clause added 1:35pm]

And Watt's proposal to diffuse insights sounds encouragingly close to the [3]National Research Council's suggestion to bring more empirical evidence into ethics deliberations.

But I wonder if Watts is sufficiently aware of the problems with existing IRBs. He makes the odd claim, "we have pretty good procedures for reviewing and approving psychology experiments done in university labs. We also have a pretty clear idea of how to handle survey research or ethnographic studies."

[4]No, we don't.

1. http://chronicle.com/blogs/conversation/2014/07/09/lessons-learned-from-the-facebook-study/
2. http://www.institutionalreviewblog.com/2013/08/ignorance-is-strength-lecture-video.html
3. http://www.institutionalreviewblog.com/2014/01/nrc-report-assess-risk-empirically.html
4. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html

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A Reply to Maxine Robertson **(2014-07-11 10:08)**

In an essay in Research Ethics, Maxine Robertson, Professor of Innovation and Organisation at Queen Mary University of London (QMUL), responds to my essay, "The case against ethics review in the social sciences," published in the same journal in 2011. I wish she had responded to more of the broader ethics-review critique and offered more details about ethics review at her own institution.

[Robertson, Maxine. "The Case for Ethics Review in the Social Sciences: Drawing from Practice at Queen Mary University of London." *Research Ethics* 10, no. 2 (June 2014): 69–76. doi:[1]10.1177/1747016113511177]

Is the United States unusually bad?

Robertson argues that I assume "that the somewhat draconian measures taken with respect to the ethical review of social science research in the US are applied equivalently elsewhere. This," she claims, "is not the case in the UK."

[2]Adam Hedgecoe made a similar claim in 2012, and [3]I addressed it in a subsequent blog entry. Robertson knows of my blog, but it is not clear she has read that entry, or any my many entries tagged "[4]United Kingdom.

Robertson does cite Martin Tolich and Maureen H. Fitzgerald. "If Ethics Committees Were Designed for Ethnography," *Journal of Empirical Research on Human Research Ethics* 1, no. 2 (June 2006): 71–78. doi:[5]10.1525/jer.2006.1.2.71, but she does not mention that their critique is based in part on "Fitzgerald's extensive study of ethics committees in five countries (Australia, Canada, New Zealand, United Kingdom, and United States)."

She also allows (in a footnote) that [6]British researcher Irena Grugulis endured "a very unfortunate experience," and that "a range of approaches are applied in the UK and elsewhere," some of which produce "evidence of silly practice." She does not ask what mechanisms might be responsible for such conduct, or how they might be reformed.

Care or Harm?

In my 2012 response to responses, I wrote, "Perhaps my final challenge to my readers should have been to find me an institution whose researchers in the social sciences and humanities broadly agree that the ethics review system is doing more good than harm, and where few scholars are outraged by the mistreatment they have received."

Though apparently not familiar with the posting, Robertson has taken up the challenge, offering her own institution, Queen Mary University of London (QMUL), where Robertson both conducts research and serves on the ethics committee. She does "not claim that the process and practices that have been developed at QMUL are typical in the UK," only that " all manner of social science and humanities research can be effectively and efficiently reviewed when the emphasis throughout is placed on affording care rather than avoiding harm."

I don't know what Robertson means by distinguishing between "affording care" and "avoiding harm." She

goes on to describe a multi-level screening process, designed to quickly approve "low risk" projects while imposing heavy scrutiny on "research [that] is considered to be very high risk, i.e. it is generally agreed across the committee that there is the potential for actual psychological or physical harm, either to participants and/or the researcher, or the university's reputation may be put at risk." Putting aside the question of whether the university's reputation deserves such protection, what is this but a system designed to avoid harm?

Nor do I understand how an emphasis on care could be squared with the UK's [7]Framework for Research Ethics, which states as one of its "key principles of ethical research," "Harm to research participants and researchers must be avoided in all instances," but does not use the language of affording care. Does Robertson advocate departing from the FRE?

(See "[8]Anxious Pessimism on UK's New Framework for Research Ethics."

The University's Reputation?

Robertson is aligned with the FRE in her wish that REC's protect not only research participants, but also research institutions. But she offers no examples of legitimate restrictions from an REC that would protect the latter but not the former. It sounds to me like an opportunity for an administrator to squelch politically unpopular research in the name of ethics.

No Silly Restrictions?

As for effective and efficient review, Robertson offers the following elaboration:

> I conducted short interviews with a number of academics and doctoral students in social sciences/humanities at QMUL in writing this response, and the overwhelming message was that by engaging in and with this process, they reflected extensively on both their research design and the roles/responsibilities they had as researchers. All of those with whom I discussed the process therefore viewed the experience as contributing to their professional development. In summary, Queen Mary's research ethics committee does not impose silly restrictions.

Some scholarship offers quantitative evidence (numbers); some offers qualitative evidence (stories, quotations). The above paragraph offers neither. Two paragraphs previously, Robertson notes that "in particular research contexts it might be more appropriate to offer participants a 'voice' and give participants the opportunity to make that decision for themselves, provided they are given a clear explanation of how their data are going to be used." This was one of those research contexts.

If things are so peachy at QMUL, why couldn't Robertson get some researchers not on the ethics committee to say so in public, to tell the stories of the ethics reviews that contributed to their professional development?

(And, by the way, did she get ethics approval for her short interviews? How did that go?)

For all I know, QMUL is a model of sensible ethics review. But I can't rely on Robertson's assertions, and she gives only hints at what might make QMUL different from other institutions.

It is interesting to learn, for example, that "Researchers are invited to attend meetings and will be asked to respond to any outstanding issues or points of clarification the committee has raised at the meeting. The decision-making process is thus characterized by debate and, in some instances, negotiation both within the committee and with the applicant." This could be an important improvement to processes elsewhere, and perhaps QMUL has other tips to offer ethics committees around the world. But the Council of Queen Mary University of London Statement of Research Ethics Policy doesn't even seem to be a public document. (Try the link at the [9]QMUL REC's website.)

What should we call this?

Finally, I will note that Robertson charges that "Schrag (perhaps not surprisingly given his own background) implies that most social science/humanities research adopts an ethnographic approach."

Robertson is quite right that my essay (and my work in general) is particularly concerned with interview and ethnographic research, though I don't know how that implies that I think such methods represent "most social science/humanities research." One can be particularly concerned with the safety of bicyclists without thinking them a majority of road users.

This is not so much a question of counting, as of categorization, one that I've wrestled with since the beginning of my work on ethics review. (See "[10]The Language of Exemption, from the first months of the blog.)

At this point, I find TCPS2's formulation, "[11]qualitative research," to be a useful antidote to such forms as [12]"Research in the Behavioral and Social Sciences," which led the National Academies of Sciences initially stack its committee with quantitative researchers.

On the other hand, Gunsalus was onto something when she wrote of "[13]two people talking" as a promising target of deregulation. Whether the results are to be reported qualitatively or quantitatively, prior restraint of conversations between consenting adults is a particularly severe problem.

1. http://dx.doi.org/10.1177/1747016113511177
2. http://dx.doi.org/10.1177/1747016112445437
3. http://www.institutionalreviewblog.com/2012/09/schrag-responds-to-responses-to-schrag.html
4. http://www.institutionalreviewblog.com/search/label/United%20Kingdom
5. http://dx.doi.org/10.1525/jer.2006.1.2.71
6. http://www.socialsciencespace.com/2011/01/research-ethics-and-james-bond/
7. http://www.esrc.ac.uk/_images/framework-for-research-ethics-09-12_tcm8-4586.pdf
8. http://www.institutionalreviewblog.com/2011/02/anxious-pessimism-on-uks-new-framework.html
9. http://www.arcs.qmul.ac.uk/research-degrees/research-degree-students/ethics/94438.html
10. http://www.institutionalreviewblog.com/2007/01/language-of-exemption.html
11. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10
12. http://www.institutionalreviewblog.com/2013/03/national-academies-run-workshops-on.html
13. http://gunsalus.net/assets/IllinoisWhitePaperMissionCreep.pdf

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New Book on Human Subjects Research Regulation **(2014-07-15 19:08)**

MIT Press has published *[1]Human Subjects Research Regulation: Perspectives on the Future*, eds. I. Glenn Cohen and Holly Fernandez Lynch.

The volume emerges from the May 2012 conference, "The Future of Human Subjects Regulation," sponsored

by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. (See [2]Against Armchair Ethics: Some Reflections from Petrie-Flom.)

My own contribution is a chapter entitled, "What Is This Thing Called Research?" I have a preliminary version online at [3]SSRN.

Though published three years after the ANPRM, the book has hit print before an NPRM. Pity.

1. https://mitpress.mit.edu/books/human-subjects-research-regulation
2. http://www.institutionalreviewblog.com/2012/05/against-armchair-ethics-some.html
3. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2182297

UCSD Frees Oral History and Journalism (2014-07-16 13:03)

The University of California, San Diego, has determined that most projects by historians and journalists need not be submitted to the IRB.

The announcement comes in the form of a "fact sheet," titled "[1]Oral History/Journalism Projects," which is itself undated but was [2]apparently released on 1 October 2013.

The fact sheet explains that most oral histories and journalistic projects do not meet the federal definition of human subjects research.

> Historians and journalists typically use collected information to explain past or current events but not to create theories, principles, or statements of relationships that are predictive of future events or that can be widely applied. Such activities would not be considered “generalizable knowledge.”
>
> Where, however, projects at UCSD are, in fact, designed to develop or contribute to "generalizable knowledge," such projects must be submitted to the HRPP. Upon submission, such projects may be granted exemption from IRB review, handled through the expedited review process, or reviewed by the full IRB, as appropriate.
>
> Oral history projects conducted by, or under the supervision of, UCSD faculty, staff or students should be conducted in accordance with the guidelines established by the Oral History Association for the ethical and professional practice of oral history.

This policy builds on [3]Columbia University’s pioneering policy of 2007, which also excludes oral history on the grounds that it lacks predictive value and therefore is not designed to produce generalizable knowledge. And, like Columbia, UCSD expects its historians to adhere to the Oral History Association guidelines. But whereas Columbia took more than four pages to explain its reasoning, UCSD has managed to boil its policy down to one page.

Bravo!

1. http://irb.ucsd.edu/History_Journalism.pdf
2. http://irb.ucsd.edu/factsheets.shtml
3. http://www.columbia.edu/cu/irb/policies/documents/OralHistoryPolicy.FINAL.012308.pdf

Most IRB Chairs Can’t Recognize Exempt Research or Non-Research **(2014-07-21 21:08)**

A study of criminal justice researchers’ knowledge of IRB rules has found that IRB chairs can’t agree on what makes a project exempt from review and think that IRB review is needed for public records. The authors of the study, one of whom is an IRB chair, seem not to realize the significance of these findings.

[Tartaro, Christine, and Marissa P. Levy. "Criminal Justice Professionals’ Knowledge of Institutional Review Boards (IRBs) and Compliance with IRB Protocol." *Journal of Criminal Justice Education* 25, no. 3 (2014): 321–41. doi:[1]10.1080/10511253.2014.902982.]

"Correct" Answers in Scare Quotes

Christine Tartaro and Marissa P. Levy, both professors of criminal justice at the Richard Stockton College of New Jersey, sought to learn what their fellow criminologists knew about IRB rules and procedures.

To do this, they devised seven hypothetical research scenarios and posed them in survey form to two groups. First, IRB chairs–from whom they got 164 responses–and second, to U.S.-based, academic members of the Academy of Criminal Justice Sciences (ACJS). Of the 1,174 potential respondents in the latter group, they received 323 from respondents who work at institutions with IRBs.

For reasons not well explained, the authors labeled the consensus view of the IRB chairs as the "correct" answer to a given scenario.

> The correct answers for the scenario responses were gained by reviewing each scenario with the Chair [i.e., Levy] and comparing her answers to those of a national survey of IRB Chairs which produced responses from 164 IRB Chairs. While we acknowledge that many of these answers are subject to interpretation, it is the IRB Chairs who ultimately decide the level of review required for each protocol based on his or her interpretation of the federal guidelines. As such, IRB Chairs’ interpretations of federal guidelines as applied to the research scenarios is the closest one can get to identifying "correct" answers. All IRB Chairs were given the same amount of information from which to draw their conclusions and determine "correct" answers. IRB Chairs were divided on the correct course of action for two of the seven research scenarios, so those scenarios were excluded for the current analysis.

The scare-quotes around "correct" and the exclusion of two scenarios show that the authors are at least somewhat aware that the disagreements among IRB chairs pose serious questions about the clarity of the scenarios and of the regulations themselves. Rather than label any response "correct," it might have been better to describe the chairs’ view as just that: the chairs’ view.

Unforuntately, the study authors do not indicate how the IRB chairs split on these cases. What constituted enough of a consensus for the authors to label an answer "correct"? And, more importantly, what can the IRB chairs’ responses tell us about the consistency of IRB rulings?

IRB Chairs Can’t Recognize Non-Research

Assuming that a "correct" label represents a fairly broad consensus among Levy and the IRB chairs surveyed, it is striking that members of this group can't recognize non-human subjects research when they see it.

Here are Tartaro and Levy's descriptions of scenarios four and five:

> For scenario four, "You want to give students a non-graded quiz at the beginning of the semester. At the end, you plan to give students the same quiz to see how much they learned. You aren't going to publish the results. How will you handle this?" Ninety-five percent correctly chose "proceed without IRB approval," 3 % believed it was necessary to apply for an exempt or expedited review and 2 % selected full IRB review. For scenario five, the instructor from the previous scenario planned to use the assessment data for a conference presentation or publication. The correct answer is to apply for an IRB exempt/expedited review, and 65 % of respondents chose that option. Sixteen percent believed that no IRB review was necessary, and 19 % were in favor of a full IRB review.

Let's compare that "correct answer" to OHRP's [2]2010 guidance on quality improvement:

> The intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. The regulatory definition under 45 CFR 46.102(d) is "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities.

So while OHRP does not think that publication triggers IRB review, Tartaro and Levy, the consensus of IRB chairs, and something like 84 percent of the researcher respondents all think that it does.

A starker case is scenario two:

> For scenario two, respondents were asked to imagine that, "You are seeking information from a local police department about the date and location of each report of a stolen car over a period of a year. You are not requesting any identifying information on the owner or car. How would you handle this study?" The appropriate course of action, according to IRB rules, is to apply for exempt or expedited status from the IRB, and 66 % answered this correctly. Twenty-seven percent responded that proceeding without IRB approval was appropriate, and 8 % thought that a full IRB review was necessary.

Folks, while [3]laws about police records vary by state, police blotters (including reports of stolen cars) are public records in most or all states. And even if they weren't, if you are collecting data that does not include identifiable private information about a living individual, you are not conducting human subjects research as defined by the Common Rule.

It's appalling that that 74 percent of the researchers surveyed didn't know this, and more appalling that Levy and her fellow IRB chairs did not.

IRB Chairs Can’t Recognize Exempt Research

It’s also distressing that the IRB chairs could not agree on what constitutes exempt research.

The description of the first scenario states that "IRB Chairs were widely in agreement that some level of IRB review was necessary, but they were split on the extent of that review." Tartaro and Levy do not report how the split broke down among those favoring exemption (which Tartaro and Levy regard as "some level of IRB review"), expedited review, or full review. Thus, Tartaro and Levy present as wide agreement what may in fact have been substantial disagreement.

For scenario two (the public records of stolen cars) Tartaro and Levy report that "The appropriate course of action, according to IRB rules, is to apply for exempt or expedited status from the IRB." So not only did IRB members fail to spot the non-human subjects research, but having mistaken it for human subjects research, they couldn’t agree on whether it was exempt.

The same goes for scenario five, the quality improvement ("The correct answer is to apply for an IRB exempt/expedited review"). In these three scenarios, the IRB chairs could not come to consensus on whether a given activity was exempt, forcing the Tartaro and Levy to accept both exempt and expedited as "correct" answers.

Then there were the two scenarios excluded from the study because "IRB Chairs were divided on the correct course of action." Tartaro and Levy do not state whether those scenarios involved intepreting IRB regulations.

So of the 4-6 IRB-related scenarios Tartaro and Levy began with, the IRB chairs were able to agree on only one: no IRB involvement is needed to quiz your students on how much they have learned in a semester. For the remaining five, they could not come to consensus on whether the project as described is exempt under the Common Rule.

Tartaro and Levy do not remark on this finding. Yet their results stand as a potential counterpoint to the claims of IRB apologists like [4]Suzanne Rivera, who thinks that researchers are incompetent to determine exemption. Are researchers poorer interpreters of 45 CFR 46.101 than the IRB chairs in this study?

Criminologists Disagree on Ethics

For reasons not explained, one of the five scenarios in the article presents a question of ethics, not of regulatory procedures.

> Scenario three involved the ethics of identifying research participants. Participants were asked to consider the following: "As you prepare to present findings at a conference, your colleague presents you with slides that she wants to use. On one of the slides, your colleague has a picture of an offender that she took during field observations ... How do you respond?" Ninety-three percent chose, "tell your colleague that including the photo would be unethical," while 7 % would have advised the colleague to include the photo in the presentation.

Tartaro and Levy present this finding without comment, not claiming that it involves the IRBs or offering a "correct" response from the IRB chairs. For my part, I would have to say that the scenario offers insufficient information to

give an answer.

The [5]ACJS code of ethics makes clear that "Confidential information provided by research participants should be treated as such by members of the Academy, even when this information enjoys no legal protection or privilege and legal force is applied." But it is not clear that the photograph in the scenario is confidential. Are we talking about a photograph taken in someone's living room? Or on a public sidewalk? If the latter, I would note that newspapers regularly feature photographs of people committing offenses, such as [6]the apparently illegal chokehold used by NYPD Officer Daniel Pantaleo against Eric Gardner last week. (See also the Gericault-esque photographs of unauthorized migration by [7]Meridith Kohut for the New York Times.)

Criminologists Change Wording, but Otherwise Follow Rules

In addition to asking about the hypothetical scenarios, Tartaro and Levy surveyed the researchers about their own practices. They found that 41 percent had, in the past three years, undertaken "activities against IRB rules," but they acknowledge that their survey mistakenly listed researching "public records or other data not involving human participants" as such an infraction. The 41 percent is therefore an overstatement.

A better figure may be the 27 percent who "made a minor change to the wording of a survey or consent form after IRB approval without reporting back to the IRB." This jibes with the finding that "Twenty-one percent indicated that researchers should be able to make a minor wording change to a previously approved survey or consent form without reporting it to the IRB."

Much smaller numbers (less than 5 percent) made substantial changes without consulting the IRB, conducted human subjects research before receiving approval or "purposefully left out information or was vague about an aspect of the study that you anticipated that the IRB would challenge." This last group (3.3 percent, or nine of the 245 respondents to that question) included a respondent who explained, "My IRB doesn't understand qualitative research that uses grounded theory." Unfortunately, the analsyis compares the responses given by researchers according to various attributes, e.g., has the researcher served on the IRB, it does not break down the replies by quantitative or qualitative research.

Why Blame the Researchers?

Tartaro and Levy conclude that "the results of this study indicate that academic researchers in criminal justice lack a uniform understanding of IRB rules." They could just as well have concluded that IRB chairs lack a uniform understanding of IRB rules.

But really, the fault lies not with the researchers or the chairs, but with a set of poorly written rules, layered with contradictory guidance from federal officials, and desperately in need of revision. It has been nearly 20 years since [8]the Office for Protection from Research Risks decided that exempt projects were not really exempt. Until the regulations are rewritten, there may be no "correct" answers on what they mean.

1. http://dx.doi.org/10.1080/10511253.2014.902982
2. http://answers.hhs.gov/ohrp/questions/7286
3. http://www.rcfp.org/rcfp/orders/docs/POLICE.pdf
4. http://www.institutionalreviewblog.com/2013/03/rivera-faculty-researchers-are.html

5. CA8flszKG2-body.tex.lynx.html
6. http://www.nydailynews.com/new-york/nyc-crime/nypd-chokehold-staten-island-man-eric-garner-stripped-shield-gun-article-1.1873033
7. http://www.nytimes.com/2014/07/20/world/americas/on-southern-border-mexico-faces-crisis-of-its-own.html?module=Search&mabReward=relbias%3Aw%2C%7B%221%22%3A%22RI%3A10%22%7D#slideshow/100000003006741/100000003006747
8. http://www.institutionalreviewblog.com/2007/08/guidance-creep.html

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3.8 August

Bell: Ethnography Shouldn't Be Like Victorian Sex (2014-08-25 14:31)

Writing in American Anthropologist, Kirsten Bell argues that ethnography should not be seen as a violation to which an informant must consent, and "although the concept of informed consent has now been enshrined in the AAA Code of Ethics for more than 15 years, the reality is that it is not an appropriate standard with which to judge ethnographic fieldwork."

[Bell, Kirsten. "Resisting Commensurability: Against Informed Consent as an Anthropological Virtue." American Anthropologist, July 21, 2014, [1]doi:10.1111/aman.12122.]

The need for informed consent, Bell argues, is premised on the idea that research is "an intrinsically risky enterprise."

> Research is often quite explicitly configured as a violation or invasion: biomedical research violates the physical integrity of the body, and social science research violates the individual' s privacy. Thus, one textbook on ethical issues in behavioral research warns: "The central ethical issues in field research are likely to revolve around potential invasions of privacy." This constitution of research as a "violation" or "invasion" helps to explain why informed consent is deemed so central to contemporary conceptions of research ethics. After all, to consent is quite literally to acquiesce to being "done to." In this framing, research is a violation to which, like sex, one must willingly consent (but presumably not actively participate in, like the Victorian bride counseled to "lie back and think of England"). Informed consent to research participation, like conceptions of consent to sexual intercourse, is thus based on certain underlying assumptions about the nature of the protagonists in this encounter.

Bell would prefer a view of ethnography that acknowledges that "ethnographic research can proceed ethically in the absence of a mutually agreed-upon understanding of its aims and that this absence is to a certain extent unavoidable." She finds such acknowledgement not in recent versions of the American Anthropological Association's Statement on Ethics, but rather in its 1971 [2]Principles of Professional Responsibility, which state merely that "the aims of the investigation should be communicated as well as possible to the informant."

As Bell notes, the phrase, "as well as possible," concedes that the level of understanding implied by the standard of "informed consent" is likely impossible. Better to face that reality, she suggests, than trivialize ethics by holding ethnographers to an unreachable standard.

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Note. In her acknowledgements, Bell writes that her essay is in part an effort to explain her views to "Laura-Lee Balkwill, a policy analyst from Canada's Secretariat on Responsible Conduct of Research, who braved the den of frustrated social scientists at the [2012 Ethics Rupture] conference in an effort to try to understand our concerns." I second Bell's praise of Balkwill, whose thoughtful questions and gracious skepticism helped many of us to reexamine our assumptions and refine our arguments.

1. http://dx.doi.org/10.1111/aman.12122
2. http://www.aaanet.org/cmtes/ethics/AAA-Statements-on-Ethics.cfm

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You Can't Ask That (2014-08-27 20:53)

The *Washington Monthly*'s fall college issue features my essay on IRBs. Nothing that will surprise regular readers of this blog, but perhaps this will reach new readers.

[Schrag, Zachary M. "[1]You Can't Ask That." *Washington Monthly*, September/October 2014.]

1. http://www.washingtonmonthly.com/magazine/septemberoctober_2014/features/you_cant_ask_that051759.php?page=all

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PCM (2014-08-30 14:12:49)
I saw your piece in Wash Monthly. Even though I read your blog, it was still nice to see everything presented clearly and concisely. Well done!

3.9 September

IRBs and America's Worst Colleges (2014-09-23 21:09)

IFRAME: [1]http://www.ustream.tv/embed/recorded/53023052?v=3 &wmode=direct

[2]Broadcast live streaming video on Ustream

I talk about IRB's as part of the New America Foundation's "[3]America's Worst Colleges" event.

1. http://www.ustream.tv/embed/recorded/53023052?v=3&wmode=direct
2. http://www.ustream.tv/
3. http://www.edcentral.org/watch-live-americas-worst-colleges/

Briefly Noted: Whitney, Bell, Elliott (2014-09-28 20:23)

Lacking time for full comment, I briefly note the publication of these two important, critical essays. Citations omitted from the quoted passages.

The Shell Game

[Whitney, Simon N. "The Shell Game: How Institutional Review Boards Shuffle Words." *Journal of Translational Medicine* 12, no. 1 (August 14, 2014): 201. [1]doi:10.1186/1479-5876-12-201.]

> Popular IRB guides ignore . . . subtleties and mangle the standard definitions. One handbook claims that "coercion means that a person is to some degree forced, or at least strongly pushed, to do something that is not good for him or her to do. In discussions of research regulation the term 'undue influence' is often used to describe the concept of coercion". This manual thus expands the narrow concept of coercion to include persuasion.
>
> A second handbook agrees: "Coercion can be subtle: persuasion, argument, and personality can be used to compel an individual to act in a certain way.... Coercion—including all the subtle forms—has no place in research". There is, of course, no such thing as subtle coercion. A guide to IRB management and function claims that in recruitment for clinical trials, "the possibilities for misinforming or disinforming potential subjects abound" and "the possibilities for inadvertent, unintentional coercion, or undue influence are also high". Inadvertent or unintentional coercion is oxymoronic.
>
> With encouragement from these guides, IRBs reject the standard meaning of the word and use "coercion" to refer to any statement, however innocuous, that might encourage trial participation. Some IRBs believe, for instance, that it is coercive for a consent form to mention that a study is funded by the National Institutes of Health.

Censorship in the Name of Ethics

[Bell, Kirsten, and Denielle Elliott. "Censorship in the Name of Ethics: Critical Public Health Research in the Age of Human Subjects Regulation." *Critical Public Health* 24, no. 4 (September 3, 2014): 385–91. [2]doi:10.1080/09581596.2014.936727.]

> Although the extent of the problems continue to be debated, the last few years have witnessed a growing institutional awareness that change is indeed necessary. For example, in December 2010, Canada's Interagency Panel on Research Ethics released revised national human ethics research guidelines that aimed to be more social science 'friendly'. Similarly, the US Office of Human Research Protections is currently toying with the possibility of sweeping changes to its national regulations. The proposed framework specifically highlights the over-regulation of social and behavioral research and the 'unwarranted variability across institutions... in how the requirements are interpreted and implemented'. Under the proposed regulations, many types of social science and behavioral research with 'competent adults' would be exempt from review.
>
> However, somewhat ironically, just as those tasked with oversight have started to talk of scaling back research ethics regimes (or at least reining in their scope), elsewhere we see movement in entirely the opposite direction. Beyond the ways requirements for ethics review have become tied up with publication (and funding), an ever-expanding array of organizations have begun to develop their own procedures around ethics review. Although their impetus is typically a desire to ensure the research needs of the populations they serve are met, their proliferation illustrates the ways in which the existing

> problems have tended to produce more oversight and regulation rather than less. In many respects, this speaks to the self-perpetuating aspect of audit culture, whereby its rituals of verification create the very mistrust they are designed to dispel.

[2015-11-13. Edited to correct the link to the Bell-Elliott paper.]

1. http://dx.doi.org/10.1186/1479-5876-12-201
2. http://dx.doi.org/10.1080/09581596.2014.936727

3.10 October

Ethics Consultancies—A Non-Coercive Alternative to IRBs? (2014-10-29 22:18)

[1]For some time, I've thought that the real problem with IRBs may be the coercive power granted to them. This relieves them of the need to make arguments strong enough to persuade researchers, and in some cases leads them instead to make demands based weak or even wrongheaded thinking.

This week, *Nature* reports on an alternative (or supplementary) model, the ethics consultancy.

[Dolgin, Elie. "Human-Subjects Research: The Ethics Squad." *Nature* 514, no. 7523 (October 21, 2014): 418–20. doi:[2]10.1038/514418a.]

As reporter Elie Dolgin explains,

> Ethical dilemmas in research are nothing new; what is new is that scientists can go to formal ethics consultancies such as [Tomas] Silber's to get advice. Unlike the standard way that scientists receive ethical guidance, through institutional review boards (IRBs), these services offer non-binding counsel. And because they do not form part of the regulatory process, they can weigh in on a wider range of issues — from mundane matters of informed consent and study protocol to controversial topics such as the use of experimental Ebola treatments — and offer more creative solutions.

Technically, that's a non sequitur; there's no regulatory prohibition preventing IRBs from weighing in on controversial topics or offering creative solutions, only a bar to "consider[ing] possible long-range effects of applying knowledge gained in the research." In practice, the coercive nature of IRB review often makes researchers less receptive to IRB counsel and chokes off productive discussions.

1. http://www.institutionalreviewblog.com/2007/01/why-not-make-irb-review-voluntary.html
2. http://dx.doi.org/10.1038/514418a

University of Washington IRB Demanded Dangerous Consent Form (2014-10-30 17:15)

The recent *Nature* story on ethics consultancies includes an example of counterproductive interference by an intransigent IRB.

[Dolgin, Elie. "Human-Subjects Research: The Ethics Squad." *Nature* 514, no. 7523 (October 21, 2014): 418–20. doi:[1]10.1038/514418a.]

> Amy Hagopian, a global-health researcher at the University of Washington in Seattle, found herself turning to an ethics consultant for help with a study in Iraq to find out how many people had died as a result of the US-led conflict that began there in 2003. Her team needed to obtain informed consent from participants, but the researchers on the ground in Iraq were concerned that including the University of Washington's name on the consent forms — a requirement for IRB approval — would make it difficult to get the data they needed. "They feared that being associated with American institutions would get them killed", says Hagopian. "They dug in their heels and refused" to carry the form.
>
> Hagopian wanted to strip the university's name from the consent document, but the IRB insisted that it was an important part of informed consent, which is meant to protect participants, not the investigators. The impasse brought Hagopian and her team to [ethics consultant Benjamin] Wilfond. He concluded that it would be ethical to remove mention of the institution, for three main reasons: first, research subjects would also be placed at risk by signing a document linking them to the University of Washington; second, apart from the link to the United States, the research involved minimal risk to the participants; and third, the study would not happen unless the name of the institution was removed.
>
> The IRB eventually agreed with Wilfond. The researchers went ahead with the study and found that nearly half a million people had died from causes attributable to the Iraq war between 2003 and 2011 — a figure much greater than most previous estimates. "We couldn't have done this without him," Hagopian says of Wilfond.

Of course, PRIM &R claims that "[2]IRBs neither interact with subjects nor write consent forms."

1. http://dx.doi.org/10.1038/514418a
2. http://www.institutionalreviewblog.com/2011/11/prim-irbs-dont-write-consent-forms.html

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3.11 November

OHRP Claims to Be "Working Very Hard" on NPRM (2014-11-04 08:57)

Writing for the Chronicle of Higher Education, Christopher Shea notes that though two years passed between the 2012 [1]Future of Human Subjects Research Regulation conference at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the [2]publication of the conference volume in July 2014, the delay of the next step in regulatory reform–a notice of proposed rulemaking (NPRM)–means that the book remains timely.

[Shea, Christopher. "[3]New Rules for Human-Subject Research Are Delayed and Debated." Chronicle of Higher Education, November 3, 2014.]

One also hopes that it won't be timely forever. Shea writes,

> A spokesman for the Office for Human Research Protections, which is part of the Department of Health and Human Services, could not provide a timetable but told The Chronicle late last month, "I can assure you that this continues to be an HHS priority, and all the relevant parties are still working very hard on this."

Or, as they might have put it, "[4]We have top men working on it right now."

1. http://www.institutionalreviewblog.com/2012/05/against-armchair-ethics-some.html
2. http://www.institutionalreviewblog.com/2014/07/new-book-on-human-subjects-research.html
3. http://chronicle.com/article/New-Rules-for-Human-Subject/149767/
4. https://www.youtube.com/watch?v=yoy4_h7Pb3M

New Book on Research Confidentiality (2014-11-07 14:12)

Ted Palys and John Lowman have published Protecting Research Confidentiality: What Happens When Law and Ethics Collide.

[Palys, Ted, and John Lowman. [1]Protecting Research Confidentiality: What Happens When Law and Ethics Collide. Toronto: James Lorimer & Company, 2014.]

[2]Over the years, I've learned a great deal from these two scholars about the ethics and law of research confidentiality in the social sciences, and I look forward to reading this compendium of what they have learned from their studies and their own struggles with their university.

1. http://www.lorimer.ca/adults/Book/2703/Protecting-Research-Confidentiality.html
2. http://www.institutionalreviewblog.com/search?q=palys&max-results=20&by-date=true

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Internal E-Mails Suggest NPRM is Coming (2014-11-25 20:54)

According to an [1]open letter to HHS secretary Sylvia Mathews Burwell, Public Citizen obtained "very recent internal emails" among officials at the Office of Management and Budget and the Department of Health and Human Services, showing that the latter is actively working on a Notice of Proposed Rulemaking (NPRM) to revise the Common Rule.

[2]I'll write separately about the substantive issue raised by Public Citizen. For now, the news is that as of November 13, 2014, senior officials were actively working to write an NPRM.

[3]Well I, for one, am very interested to see what's going to happen next.

1. http://www.citizen.org/documents/2232.pdf
2. http://www.institutionalreviewblog.com/2014/11/was-ohrp-ever-independent-watchdog.html
3. http://www.imdb.com/title/tt0101669/quotes

Was OHRP Ever an Independent Watchdog? (2014-11-25 21:11)

Public Citizen is upset that NIH will get to write much of the NPRM. I don't understand why that matters.

As [1]Public Citizen's November 20 letter to HHS secretary Sylvia Mathews Burwell puts it,

> NIH has been assigned responsibility for revising the preamble of the NPRM. The preamble will be the longest and most important part of the NPRM, as it will contain sections describing, among other things: (a) the summary and analysis of the public comments on the ANPRM; (b) the government's response to those comments; (c) the resolution of key policy disagreements that were during the earlier drafting of the NPRM; (d) the proposed changes to the Common Rule; and (e) the rationale for making those changes, all of which ultimately will have a major impact on the actual final content of the proposed revised Common Rule regulatory text.

It continues, "We suspect that NIH orchestrated such involvement in a deliberate attempt to undermine OHRP's regulatory authority and to achieve changes to the Common Rule that it desires. This shift of authority from the regulator to the regulated is unacceptable."

I think this overstates the difference between NIH and OHRP.

Not mentioned in the Public Citizen letter is the fact that the existing Common Rule was also written by NIH, back in 1981, when the Office for Protection from Research Risks was part of NIH. So at worst, we'd be going from one set of NIH-drafted regs to another.

And while the Office for Human Research Protections has, since its creation in 2000, been separate from NIH, I don't know that it has ever taken the independent position imagined by the Public Citizen message. Consider, for example, the [2]September 28, 2000, statement by Greg Koski, OHRP's first director. He explains OHRP's mission as coordinating regulation and guidance across agencies, not of providing independent oversight of NIH or any other funding agency.

If anything, HHS created OHRP to be less confrontational than its NIH predecessor, following Gary Ellis's drastic enforcement actions of 1998-2000. Nor can Public Citizen point to a time when OHRP acted as an aggressive, independent watchdog; to the contrary, its letter bemoans what it considers OHRP's inaction on the SUPPORT study controversy.

I think of OHRP as an agency that has [3]passed the buck on IRB reform efforts, [4]focused on form rather than substance in overseeing institutions, [5]communicated its work in opaque "determination letters" that say little about the underlying ethical challenges, and has been slow to act on [6]SACHRP recommendations or public responses to Federal Register notices.

My question, then, is when was the golden age of OHRP to which Public Citizen would like to return? And if there was none, why does it matter who drafts the NPRM?

1. http://www.citizen.org/documents/2232.pdf
2. http://www.hhs.gov/asl/testify/t000928.html
3. http://www.institutionalreviewblog.com/2010/12/menikoff-passes-buck.html
4. http://www.institutionalreviewblog.com/2007/07/ohrp-reprimand-puts-forms-over.html
5. http://www.institutionalreviewblog.com/2010/03/twenty-six-percent-of-boxes-go.html
6. http://www.hhs.gov/ohrp/sachrp/mtgings/mtg10-08/present/carome.html

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3.12 December

Blog Day (2014-12-12 22:27)

[1]Eight years of the Institutional Review Blog.

As [2]Inside Higher Ed reported at the time

> 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."

Can't be soon enough.

1. http://www.institutionalreviewblog.com/2006/12/introduction.html
2. https://www.insidehighered.com/news/2007/01/19/irb

National Science Foundation Charged with "Non-Biomedical Science Perspective" (2014-12-26 10:19)

Rereading the e-mails mysteriously "obtained" by Public Citizen, I noticed that the White House has asked the National Science Foundation "to ensure that the 'non-biomedical perspective is covered" in the forthcoming Notice of Proposed Rulemaking (NPRM), revising the Common Rule. Moreover, NSF "will identify places in the current regulatory text and preamble where edits are necessary to make the NPRM consistent with the January 2014 National Academy of Sciences' report that evaluated the applicability of the ideas presented in the 2011 ANPRM to the social and behavioral sciences."

[Margo Schwab to Andrea Palm, "Annotated draft reg text for Common Rule," 29 October 2014, reproduced in Michael Carome, "[1]Letter to Secretary Burwell Re: Common Rule NPRM," November 20, 2014.]

This strikes me as hopeful news. The January 2014 report, [2]though lacking in some respects, makes some sound recommendations for reform. And the NSF, which played only a minor part in writing the 1981 and 1991 regulations, is given a greater role in this round. As the sponsor of a great deal of social science research, NSF is indeed better positioned to take on this role than HHS or any other Common Rule agency.

1. http://www.citizen.org/documents/2232.pdf
2. http://www.institutionalreviewblog.com/search/label/NAS

Canada Embraces Ethical Pluralism (2014-12-27 21:32)

The Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada have released [1]a new version of TCPS2. Though it is not a dramatic change from the 2010 edition, it serves a reinder of how much more nimble the Canadian system is compared to the rigid U.S. regulations.

I was particularly interested in the new acknowledgement that Research Ethics Boards (REBs) do not possess a monopoly on ethical judgment:

> "Activities outside the scope of research subject to REB review (see Articles 2.5 and 2.6), as defined in this Policy, may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB. These ethics resources may be based in professional or disciplinary associations, particularly where those associations have established best practices guidelines for such activities in their discipline."

Back in 2012, [2]I traveled to Canada to argue that "Scholarly associations know more about the ethics of particular forms of research than do national regulatory bodies," and should be more involved in articulating ethical standards and practices. Coincidence?

1. http://www.pre.ethics.gc.ca/eng/resources-ressources/news-nouvelles/nr-cp/2014-12-18/
2. http://www.jstor.org/stable/10.1525/jer.2013.8.1.3

Nursing Professors Want IRB Oversight of Interviews with Bereaved (2014-12-31 21:56)

Two professors of nursing warn that "Psychological harm is indeed a risk when interviewing individuals who may be in a fragile state and researchers should not have unfettered access to them." But they offer no evidence that IRBs offer appropriate protection without restricting legitimate research that may directly benefit the people being interviewed.

[Florczak, Kristine L., and Nancy M. Lockie. "IRB Reformation Is Unfettered Access the Answer?" *Nursing Science Quarterly* 28, no. 1 (January 2015): 13–17. [1]doi:10.1177/0894318414558621.]

Florczak and Lockie rely on the story of "Katie," as in this passage:

> Katie knew from conducting numerous interviews that they were not innocuous. Her participants frequently broke down and expressed myriad emotions from anger to fear but most often a profound overwhelming sadness. Dyregrov and colleagues (2011) added credence to Katie's assumption that interviews are other than insipid conversations. They said that bereavement interviews can unearth painful memories resulting in the participants becoming emotionally exhausted and distressed.

It is not clear from the essay if "Katie" is a pseudonym, a composite, or an entirely fictional creation.

Florczak and Lockie do cite Kari Madeleine Dyregrov, Gudrun Dieserud, Heidi Marie Hjelmeland, Melanie Straiton, Mette Lyberg Rasmussen, Birthe Loa Knizek, and Antoon Adrian Leenaars. "Meaning-Making Through Psychological Autopsy Interviews: The Value of Participating in Qualitative Research for Those Bereaved by Suicide," *Death Studies* 35, no. 8 (September 2011): 685–710. [2]doi:10.1080/07481187.2011.553310. And that study did indeed report that "Some bereaved cried or were upset when talking about their loss."

But Florczak and Lockie do not report Dyregrov et al.'s equally important findings that "very few people felt distressed when discussing the suicide and almost all of the participants felt no different or better than usual at the 4-week follow-up" and that "The majority of informants (62 %) responded with unambiguous, highly positive statements that were numerous, varied, and spontaneous." This led Dyregrov et al. to warn that "Too often ethical boards delay or stop research projects with vulnerable populations, influenced by presumed rather than empirically documented vulnerability."

Dyregrov et al. attribute the positive results to "the value of talking about the circumstances with a professional who has insight into the reasons and processes around suicides." This suggests that a credentialling system, rather than review of individual protocols, might better serve research participants.

1. http://dx.doi.org/10.1177/0894318414558621
2. http://dx.doi.org/10.1080/07481187.2011.553310

Horror Story Buffet **(2014-12-31 22:01)**

We end the year with two collections of IRB horror stories.

[Varma, R. “Questioning Professional Autonomy in Qualitative Inquiry.” *IEEE Technology and Society Magazine* 33, no. 4 (winter 2014): 57–64. [1]doi:10.1109/MTS.2014.2363983; Glenda Droogsma Musoba, Stacy A. Jacob, and Leslie J. Robinson, The Institutional Review Board (IRB) and Faculty: Does the IRB Challenge Faculty Professionalism in the Social Sciences? *Qualitative Report* 19 (2014), Article 101, 1-14, [2]http://www.nova.edu/ssss/QR/QR19/musoba101.pdf]

From Varma:

- "According to a researcher, the IRB did not understand why his research questions were not converted into a hypothesis to be easily tested. Additionally, the IRB was not in agreement with his need to conduct face-to-face interviews with human subjects. Alternatively, the IRB expressed that administering an anonymous survey could collect the same information."
- "The IRB told a researcher that the snowball sampling that he had proposed was similar to collecting data from friends. In his experience, purposive sampling, interviews, and small sample size do not generally fall in line with IRB approval standards. They tend to favor surveys with a large sample that is selected randomly."
- "The IRB took over eight months to approve an application to study the selection of majors in institutions of higher education."
- "In the study on teaching mathematics in a developing country . . . the IRB contested that subjects may feel bored or tired during interviews."
- "earlier informed consents were brief, approximately 100 to 200 words. Now they consist of . . . multiple headings [each with] a brief write up."
- "In a developing country [participants] became apprehensive in reading the statement about possible concerns about interview, and the idea that they could call/contact the person listed on the consent form, who was located in the United States. They considered this a physical burden on them due to about a 10-hour time difference between their country and the United States. Furthermore, this meant they were being asked to use their personal funds to make long-distance phone calls."

From Musoba, Jacob, and Robinson:

- An IRB insists that a researcher get a nearby college’s approval before administering a ten-minute survey to students in a course; the college blocks it, "citing the burden to students. However, a member of the institution’s committee shared with Andrea that the focus of the research committee’s discussion was the potential of the research findings reflecting negatively on the college."
- "The staff member told Sam to use a quantitative survey in lieu of the qualitative design submitted for approval. It took two firm rejections by Sam for the staff member to back down–one a simple no and the second an assertion of a faculty member’s authority to decide research methodology."

- "Virtually identical research projects were to be conducted at two different research sites . . . The research team saw the studies as parallel with the same survey instrument, distributed the same way, and identical “compensation processes,” yet the process that was approved in the first application was denied in the second because it was deemed coercive." (So much for Laura Stark’s "local precedents.")
- "A doctoral student was reprimanded for copying one sentence from the approved informed consent document into the approved recruitment letter at the request of the research site director. As a result, participants were given information about the study earlier as a result of the change, increasing their opportunity to be fully informed . . . The professor as principal investigator and the doctoral student were summoned for an emergency meeting and were reprimanded by IRB staff with threats that the doctoral student would not be able to use the data. The intentionally humbling nature of the interchange seemed disproportionate to the mistake."

While Varma notes that "IRBs are not functioning constructively," she does not propose specific remedies. Musoba, Jacob, and Robinson argue that "faculty committee members must take ownership of the review process or academic researchers must handle contact between the committee and researchers." They correctly note that greater faculty involvement need not be limited to membership on the IRB itself; researcher evaluations of IRB staff, for example, could signal areas needing improvement.

1. http://dx.doi.org/10.1109/MTS.2014.2363983
2. http://www.nova.edu/ssss/QR/QR19/musoba101.pdf

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4. 2015

4.1 January

Research Ethics Scales and Measures (2015-01-11 21:14)

Dr. Elizabeth Yuko kindly points me to Research Ethics Scales and Measures [1]http://researchethicsmeasures.org/, a website run by Fordham University's Center for Ethics Education.

The website features a bibliography of publications about empirical assessments of researchers' and participants' experiences with human subjects research. Many concern medical research, particularly dealing with HIV, but they may be of interest to social researchers as well.

For additional pieces on this theme, please search this blog for the tag "[2]empirical research."

1. http://researchethicsmeasures.org/
2. http://www.institutionalreviewblog.com/search/label/empirical%20research

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Library Administrator Mistakes FOIA Request for Human Subjects Research (2015-01-18 18:01)

[1]Sometime human-subjects alarmist Michael Zimmer sent requests for public documents to 30 public libraries. Though most librarians welcome requests for information, in the age of the Common Rule, you can't take anything for granted.

[Zimmer, Michael. "[2]New Project on Privacy and Cloud Computing in Public Libraries (and Some Aftermath)." MichaelZimmer.org, January 9, 2015. h/t Rebecca Tushnet]

Zimmer reports:

> One library administrator seemed to take some umbrage with my project and approach. That director emailed a larger list of library directors asking if anyone else had received my records request, noting that "There is no promise of anonymizing the data or offer to opt out of the study, which is a typically included in studies these days" and expressing surprise that my IRB would approve such a methodology. (I learned of this concern due to that director's email being forwarded to a privacy list hosted by the ALA that I'm a subscriber to.) I've since replied that this methodology doesn't involve human subjects, and follows common approaches to obtaining government information (such as the Fordham Center for Law and Information Policy's excellent research on privacy and cloud computing in public schools). I'll reach out to this director personally, and hopefully the concerns will be put to rest.

1. http://www.institutionalreviewblog.com/2011/07/alarmist-views-on-harvard-facebook.html
2. http://www.michaelzimmer.org/2015/01/09/new-project-on-privacy-and-cloud-computing-in-public-libraries-and-some-aftermath/.

Atran: IRBs Block Understanding of Terrorism (2015-01-23 11:44)

Interviewed by Nature, anthropologist Scott Atran reminds us that human subjects rules have impeded his efforts to understand the origins of violence like the attack on Charlie Hebdo.

[Reardon, Sara. “Looking for the Roots of Terrorism.” Nature, January 15, 2015. doi: [1]10.1038/nature.2015.16732. h/t Donald Pollock]

Atran explains:

> If you really want to do a scientific study with jihadis — I do it — you have to convince them to put down their guns, not talk to one another, and answer your questions. Some people, if you ask them if they would give up their belief in God if offered a certain amount of money, they will shoot you. So you can’t ask that question.
>
> It’s not just because it’s dangerous. It’s because human subjects reviews at universities and especially the [US] defence department won’t let this work be done. It’s not because it puts the researcher in danger, but because human subjects [research ethics] criteria have been set up to defend middle class university students. What are you going do with these kind of protocols when you talk to jihadis? Get them to sign it saying, “I appreciate that the Defense Department has funded this work,” and by the way if you have any complaints, call the human subjects secretary? This sounds ridiculous and nothing gets done, literally.
>
> Have you run into such difficulties with your fieldwork?
>
> As an example, I got permission, before the [three] Bali bombers [who carried out a set of simultaneous attacks in 2002] were executed, to interview them. They were going to be shot because they blew up 200 people. I couldn’t get human subjects approval because “you have to bring a lawyer, and besides we won’t allow anyone to interview prisoners.” I said why? “You can never be sure you’re not violating their right to speech.”

For more detail, see [2]Scott Atran, "Research Police – How a University IRB Thwarts Understanding of Terrorism".

1. http://dx.doi.org/10.1038/nature.2015.16732
2. http://www.institutionalreviewblog.com/2007/05/scott-atran-research-police-how.html

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4.2 March

University of Queensland Punishes Researchers, Won’t Say Why (2015-03-01 08:54)

The University of Queensland demoted a professor and blocked him and another researcher from publishing findings, based on charges that they had not obtained necessary ethics clearances. But the university will not explain its conduct.

[Jorge Branco. "[1]UQ Suppressed Bus Racism Study: Academics." Brisbane Times, February 27, 2015. Thanks to Michelle Meyer for tweeting this to my attention.]

A Study of Racial Discrimination

The Brisbane Times explains the initial study:

> In 2013, Dr Redzo Mujcic and Professor Paul Frijters, from the university's School of Economics, published an early working paper finding strong evidence of discrimination against black-skinned people on Brisbane buses.
>
> Their study, inspired by US civil rights figure Rosa Parks' experience of racial discrimination on a bus, saw 29 testers from different gender and ethnic groups asking bus drivers to let them on for free because their Go Cards were empty.
>
> The researchers found white testers were twice as likely to be given a free ride than black testers (72 % to 36 %), among a host of other findings relating to group theory.
>
> They proposed this was due to people being more likely to discriminate against those who were less like them, or not in their "in-group".

As Ian Ayres explains in the [2]New York Times, "This elegant experiment follows in a tradition of audit testing, in which social scientists have sent testers of different races to, for example, bargain over the price of new cars or old baseball cards. But the Australian study is the first, to my knowledge, to focus on discretionary accommodations."

Frijters had gained approval by the the university's department of economics. But after the research was complete, Senior Deputy Vice-Chancellor Deborah Terry told Frijters that he should have sought approval from a university ethics committee. The university demoted him to assistant professor, though he has been restored to his previous rank.

Australia's National Statement Allows This Sort of Thing

Multiple provisions of Australia's [3]National Statement on Ethical Conduct in Human Research allow for covert research and research designed to expose illegal behavior, as well as for department-level review.

The National Statement specifically states that

> Research that is intended to study or expose illegal activity or that is likely to discover it must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review. (emphasis added)

That sounds like this case. The study may be embarrassing to the bus company, but there's no way to show that individual bus drivers misbehaved.

Weighing in after the fact, bioethicist Dr Andrew Crowden says that "the research was more than low risk because it involved deception of participants (the bus drivers) and therefore should have been reviewed by the UQ HREC (Human Research Ethics Committee)." But Chapter 2.1 of, which deals with harms, does not define low risk in terms of deception or disclosure, so Crowden has his categories confused. Nor is clear that the students deceived the bus drivers. If they had boarded with truly exhausted cards, would that have obviated the need for ethics committee review?

(Crowden would be better off citing sections 2.3.6 and 2.3.7, which seem to state that only an HREC can waive the requirement of consent.)

The University of Queensland Refuses to Explain Its Decisions

To be sure, the university might be able to demonstrate that Mujcic and Frijters deliberately violated university policies. Or, as seems more likely, that they made a good-faith effort to follow confusing rules, which need to be clarified.

Instead, the university went silent. Frijters submitted a public interest disclosure, and, after waiting six months without a reply, went public with his story.

The Brisbane Times reports, "UQ vice-chancellor and president Professor Peter Hoj issued a statement saying the university was unable to comment because of the confidentiality of the investigation but was confident it had responded appropriately." Terry, the former UQ administrator who reprimanded Frijters, also declined to comment.

This is the real scandal. I have quoted Jack Katz before, and I will quote him again:

> 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.]

The University of Queensland has failed not only its researchers but also everyone who has an interest in research ethics and in the fair provision of public services. An ethics process without transparency is no ethics process at all.

1. http://www.brisbanetimes.com.au/queensland/uq-suppressed-bus-racism-study-academics-20150226-13q5lu.html
2. http://www.nytimes.com/2015/02/24/opinion/research-shows-white-privilege-is-real.html?_r=0
3. http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf

IRB Asked, USB or FireWire. Silly, but Is It Bullying? (2015-03-02 13:51)

Caleb Carr, assistant professor of communication at Illinois State University, argues that abusive IRBs are best thought of as bullies.

> Though IRBs are a legally required element of many higher education institutions and an important ethical part of all, their overextension of unchecked power is creating a hostile work environment for many social scientists, and calling them for what they are – systemic bullies – can empower administrators and faculties to finally respond to the increasing calls for IRB reform.

[Carr, Caleb T. “Spotlight on Ethics: Institutional Review Boards as Systemic Bullies.” Journal of Higher Education Policy and Management 37 (2015): 1–16. doi:[1]10.1080/1360080X.2014.991530.]

Drawing on the work of Dan Olweus, Carr defines bullying as "the infliction of repeated, unwanted harm towards an individual, often resulting in physical or emotional harm," consisting of "a prolonged behaviour rather than a single incident, such as when a target is subjected to regular harm rather than an isolated instance. Additionally, bullying behaviours are dependent on an imbalance of strength, either physical or asymmetrical power."

Carr has no trouble showing that IRBs enjoy asymmetrical power and sometimes use that power inflict harm on researchers. But I wonder about the element of repetition. As Carr notes in a personal horror story, IRBs are famously inconsistent:

> The author of this article once received a protocol review from IRB for a student’s master’s thesis research, requesting explication of the mode of data transfer between a voice recorder and a computer. Inquiry revealed the IRB reviewer wanted the data transfer detailed to the level of whether USB or FireWire would be used to connect the digital voice recorder and researcher’s computer. Though anecdotal, this capricious (previous and subsequent reviews did not request this level of specificity for data transfer) and unrelated (it was never addressed how transfer cable type affected human subjects’ safety or protections) review concern is qualitatively reflected in the experience of social science researchers, who increasingly report widely varying research protocol reviews from IRBs.

Can a system that arbitrarily demands such information once, and then never again, be guilty of the repeated, prolongued behavior that marks a bully?

1. http://dx.doi.org/10.1080/1360080X.2014.991530

QI Focus Groups: Ditch Generalizability Criterion (2015-03-11 09:58)

Focus groups of professionals engaged in quality improvement (QI) or comparative effectiveness research (CER) report that the Common Rule’s "generalizable knowledge" standard does not provide clear guidance.

[Whicher, Danielle, Nancy Kass, Yashar Saghai, Ruth Faden, Sean Tunis, and Peter Pronovost. “The Views of Quality Improvement Professionals and Comparative Effectiveness Researchers on Ethics, IRBs, and Oversight.” Journal of Empirical Research on Human Research Ethics, Published online before print, February 23, 2015, doi:[1]10.1177/1556264615571558.]

The focus groups

> generally concluded that intent to produce generalizable knowledge or the related intent to publish were not useful criteria for distinguishing what activities should be subject to IRB oversight. Although some participants stated their local IRBs relied on these criteria, most participants felt they were conceptually confusing and ethically inappropriate. Some stated it may be hard to know, early in an activity, whether the results will be worth publishing. Others mentioned it is conceptually hard to distinguish local learning from learning generalizable to other situations as generalizability is a matter of degree. Scholars similarly have argued that it is difficult to ascertain intent and that generalizability is not a binary concept, but falls along a spectrum. Indeed, some suggest eliminating the intent to produce generalizable knowledge criterion from determinations about oversight.
>
> Instead, many participants suggested that considering the risk of harm to participants in a QI or CER activity makes more sense when determining what should be subject to ethical oversight, a view consistent with recommendations in the literature. (Citations omitted.)

The article misstates the language of the Common Rule, which defines research not by whether it is intended to produce generalizable knowledge, but rather by whether it is "designed to develop or contribute to generalizable knowledge." (Emphasis added.) That said, I doubt this distinction would have made a difference to the focus groups participants.

1. http://dx.doi.org/10.1177/1556264615571558

NPRM Jumps White House Fence (2015-03-23 11:18)

[1]Report on Research Compliance has spotted a [2]notice on the Office of Information and Regulatory Affairs website suggesting that a proposed rule on "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" has reached OIRA and is awaiting [3]EO 12866 Regulatory Review.

Don’t ask me what this means in terms of a timetable, but it sounds as though the process is moving forward.

1. http://aishealth.com/newsletters/reportonresearchcompliance
2. http://www.reginfo.gov/public/do/eoDetails?rrid=124965
3. http://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

4.3 April

New Books on IRBs: Israel, Klitzman, Schneider (2015-04-28 14:13)

Within the past few months, Mark Israel has published a second edition of Research Ethics and Integrity for Social Scientists, and Robert Klitzman and Carl Schneider have published substantial new works on the IRB debate.

At some point I hope to find the time to review these in depth. For now, here's the bibliography:

Israel, Mark. [1]Research Ethics and Integrity for Social Scientists: Beyond Regulatory Compliance. Second Edition edition. London; Thousand Oaks, Calif.: SAGE Publications Ltd, 2014.

Klitzman, Robert. [2]The Ethics Police?: The Struggle to Make Human Research Safe. 1 edition. Oxford; New York: Oxford University Press, 2015.

Schneider, Carl E. [3]The Censor's Hand: The Misregulation of Human-Subject Research. Cambridge, Massachusetts: The MIT Press, 2015.

1. http://www.uk.sagepub.com/books/Book236950
2. https://global.oup.com/academic/product/the-ethics-police-9780199364602?cc=us&lang=en&
3. http://mitpress.mit.edu/books/censors-hand

4.4 May

OHRP Inaction Leaves IRBs Reliant on Gut Feelings (2015-05-06 08:08)

Theresa Defino's Report on Research Compliance describes an April 14 webcast by Robert Klitzman about his new book, The Ethics Police.

["[1]Books, Bioethics Panel Say OHRP Inaction Weakens Protection System, Thwarts Trials," Report on Research Compliance, May 2015.]

Most of the excerpts from Klitzman concern the way that OHRP silence hampers IRBs:

> When they reach out to OHRP for support, IRB officials reported getting nowhere. In the chapter titled, "Federal Agencies vs. Local IRBs," Klitzman wrote that one chair told him, "Many times when you call for advice, they essentially just read back the regulations."
>
> One recounted waiting two years to hear from OHRP on changes it had made. When federal officials respond, "they often refrain from doing so in writing, or say that the clarification does not apply more generally," Klitzman was told.

Without assurance that they are acting correctly, IRBs act arbitrarily:

> IRB chairs and members, according to Klitzman, "relied on gut feelings, intuition, the sniff test. People wanted to feel comfortable….They wanted peace of mind" about the studies they approved. Decisions were influenced by "pet peeves" and the "prudishness" of IRB members and chairs. Some IRBs are "user-friendly" or "pro-research," he said.

In truth, such arbitrariness serves neither researchers nor research participants. Defino quotes Alice Dreger's new book Galileo's Middle Finger, which argues that "in practice, protections for people who become subjects of medical research may be their weakest in decades."

The IRB system is premised on the notion that, at times, researchers and subjects have competing interests. Thanks to OHRP, they also have a common enemy.

1. http://aishealth.com/archive/nrrc0515-01

Montana Political Scientist: IRB Process Is "Cumbersome, Inadequate" for Political Research (2015-05-17 17:43)

The Montana Commissioner of Political Practices (COPP), Jonathan Motl, has determined "that there are sufficient facts to show that Stanford, Dartmouth and/or its researchers violated Montana campaign practice laws requiring registration, reporting and disclosure of independent expenditures" in October 2014, when they [1]mailed pre-election postcards to 102,780 registered voters. The postcards were part of an effort to see if certain claims about candidates' place on an ideological spectrum would affect voting patterns.

As part of the investigation, Motl engaged Carroll College political science professor Jeremy Johnson to determine whether the Stanford and Dartmouth researchers had violated IRB requirements. Johnson finds that they did, but also that the Dartmouth IRBs could have approved the studies without addressing the most serious ethical issues they raised. "The fundamental problem with the IRB process," he writes, "is the narrow focus on protecting the individual subject. Concerns about human subjects in the aggregate often do not even occur to researchers, faculty, and staff involved in the IRB."

[McCulloch v. Stanford and Dartmouth, Commissioner of Political Practices of the State of Montana, No. COPP 2014-CFP–046, [2]Decision Findind Sufficient Facts to Demonstrate a Violation of Montana's Campaign Practice Laws, 11 May 2015. h/t [3]Chris Lawrence.]

Motl's own findings misstates IRB regulations, claiming that "There is a process by which Universities and Colleges are supposed to review or vet Institutional studies that have an impact on human beings. This process, called the Institutional Review Board (lRB) process …" In fact, IRB jurisdiction is triggered not by "impact," but rather the obtaining of data through "intervention or interaction with the individual" or the collection of "identifiable private information," neither of which was clearly the case here. But apparently both Stanford and Dartmouth think the project should have been reviewed by IRB.

Johnson does not address the question of IRB jurisdiction at all, perhaps because he does not think it makes much difference if studies like this go through the IRB process or not. He notes that when the Dartmouth researchers presented a related study (involving New Hampshire voters), "the most appalling aspect for many voters, the intent to manipulate vote totals that could potentially change the outcome of an election, was absent as a consideration in the

process." Instead, "the questions posed by the Dartmouth IRB focused narrowly on individual human subjects, Many of the questions are appropriate for biomedical research but irrelevant for political study."

Johnson argues that the whole IRB system is not well suited to monitor research of this sort:

> The problem for political scientists is that this vetting process remains narrowly tethered to its original purpose rather than evolving to appropriately address related issues involving human subjects in additional fields of study now subsumed by the IRB regulations. The process as currently constituted is not useful for the research conducted by many political scientists. Many colleges such as Dartmouth use only one form across disciplines. The narrowness creates an unwieldy system that attempts to shoehorn the study of politics within the confines of how traditional scientists and those involved in biomedical research study human subjects. Most notably considerations of the community, institutions, and group activities are given short shrift. Philosophical perspectives vary; however, many value humanity in the aggregate as worthy of equal, or greater, consideration than on the level of the individual.
>
> For political scientists the IRB process too often is not a tool that spurs reflection and consideration about the implications of research using human subjects but rather becomes viewed as an irritant hindering inquiry. Too often the IRB process is simply 'red tape' stifling the ability of researchers to interview public figures and elites, undercuts the ability of students to make public presentation of research, and consumes time by making irrelevant demands upon researchers. The outcome can be counter-productive. Completing the approval process for the IRB may produce complacency and a false sense of security for researchers. They may reflect no further on ethical considerations because the IRB has given its imprimatur.
>
> Research is an essential academic undertaking and ought to be encouraged. I am not calling for reviews that consume even greater amounts of time. We need to be smarter and move away from the biomedical model when appropriate. I suggest colleges and universities need to revisit the report filed in 2000 by the American Association of Universities Professors on how to modify the IRB process for research for political science and related disciplines as a starting point for such discussions. The cumbersome system currently in place is inadequate for the task at hand.

Johnson concludes with a bold claim that political scientists, and maybe all academics, need to rethink the respect due to communities in the aggregate:

> The myopia demonstrated by the researchers, the Dartmouth IRB, and the Stanford University response is emblematic of how academics have fallen short in showing respect for the communities and institutions they study. We need to confront the challenge by acknowledging that human interactions in the aggregate are as worthy to protect as individual subjects.

Unfortunately, a broad demand that academics show respect communities and institutions can easily become a burden on academic freedom far worse than the existing system Johnson denounces. I hope political scientists troubled by this case will think of the least restrictive standards that might deter their colleagues from designing experiments that might influence votes by the thousands.

Alternatively, scholars and lawmakers might conclude that existing election law, as stated by Commissioner Motl, may suffice to deter future researchers from repeating this type of experiment.

1. http://chronicle.com/article/DartmouthStanford/149687/
2. http://politicalpractices.mt.gov/content/2recentdecisions/McCullochvStanfordandDartmouthFinalDecision
3. http://blog.lordsutch.com/archives/4362

Search Function Not Quite Working (2015-05-18 12:38)

[1]Google has broken the search box at the top of this page, so please use the "Search This Blog" box to the right instead. Thanks.

1. http://blogging.nitecruzr.net/2015/05/navbar-based-blog-search-and-custom.html

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Elliott Still Wants to Scrap IRBs (2015-05-27 07:08)

Writing in the New York Times about a series of scandals at the University of Minnesota, bioethicist Carl Elliott calls for the IRB system to be abandoned and replaced with "a full-blown regulatory system." This is essentially the [1]same argument he made in the New York Times in 2011, when the ANPRM was issued.

[Carl Elliott, "[2]The University of Minnesota's Medical Research Mess," New York Times, May 26, 2015.]

Elliott terms medical research "a global, multibillion-dollar business enterprise, powered by the pharmaceutical and medical-device industries," with the resources to give researchers "powerful financial incentives to do unethical things." (Since scholars in the social sciences and the humanities don't receive powerful financial incentives to do anything, I trust Elliott does not wish to include us in his regulatory proposal.)

Elliott elaborates:

> With so much money at stake in drug research, research subjects need a full-blown regulatory system. I.R.B.s should be replaced with oversight bodies that are fully independent — both financially and institutionally — of the research they are overseeing. These bodies must have the staffing and the authority to monitor research on the ground. And they must have the power to punish researchers who break the rules and institutions that cover up wrongdoing.

He analogizes to other industries:

> In what other potentially dangerous industry do we rely on an honor code to keep people safe? Imagine if inspectors never actually set foot in meatpacking plants or coal mines, but gave approvals based entirely on paperwork filled out by the owners.

I realize Elliott's question is rhetorical, but Carl Schneider's new book, [3]The Censor's Hand, gives one answer:

> Doctors must daily use unproved treatments, and patients often face choices much more numerous and dangerous than most research subjects. Doctors cause over 50,000 unnecessary deaths annually—incalculably more than research misconduct in all its history. Yet doctors are regulated by licenses and tort liability, not a Treatment Review Board.

Is Elliott proposing full-blown regulation for that multi-trillion-dollar industry?

1. http://www.institutionalreviewblog.com/2011/07/elliott-wants-to-scrap-irbs.html
2. http://www.nytimes.com/2015/05/26/opinion/the-university-of-minnesotas-medical-research-mess.html.
3. http://mitpress.mit.edu/books/censors-hand

A/B ≠ A&B (2015-05-27 12:10)

A/B testing is the comparison of two products by providing each, simultaneously, to two randomly selected groups. As [1]Michelle Meyer notes, the practice is less ethically suspect than a common alternative: imposing a new product on all of one's customers without first testing it.

A &B is an abbreviation for [2]assault and battery. Depending on the jurisdiction, the two may be a single crime or distinct crimes, but everywhere A &B is unlawful.

Law professor [3]James Grimmelmann has confused the two:

> Suppose that Professor Cranium at Stonewall University wants to find out whether people bleed when hit in the head with bricks, but doesn't want to bother with the pesky IRB and its concern for "safety" and "ethics." So Cranium calls up a friend at Brickbook, which actually throws the bricks at people, and the two of them write a paper together describing the results. Professor Cranium has successfully laundered his research through Brickbook, cutting his own IRB out of the loop. This, I submit, is Not Good.

IRBs for everyone, or you get hit with a brick. I suggest that this parade of horribles is missing its elephant. Blame the IACUC?

Anyway, thanks for the link.
ETA(2:18PM): I originally linked to the wrong Meyer paper. Of course, [4]that one's worth reading too.

1. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2605132
2. https://www.law.cornell.edu/wex/assault_and_battery
3. http://www.slate.com/articles/technology/future_tense/2015/05/facebook_emotion_contagion_study_tech_companies_need_irb_review.html
4. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2138624

4.5 June

Schneider: IRB System Is A Model of How to Regulate Badly (2015-06-03 15:49)

In an interview about his new book, [1]The Censor's Hand: The Misregulation of Human-Subject Research, law professor Carl Schneider charges that IRB abuses are inherent to the design of the system.

[Scott Jaschik, "[2]'The Censor's Hand'," Inside Higher Ed, June 3, 2015.]

Schneider expands:

> The problem is that the IRB system is so fundamentally misconceived that it is virtually a model of how to regulate badly. Good regulation is accountable, but IRBs are effectively answerable to nobody. Good regulation has clearly defined jurisdictional limits, but IRBs may intervene as they wish. Good regulation is guided by clear rules, but IRBs have little more than empty principles. Good regulation is disciplined by fair procedures, but IRBs can ignore every fundamental precept of due process. Good regulation is transparent, but IRBs need not even explain – much less justify – their decisions. Good regulation is staffed by experts, but IRB members cannot be competent in all the specialties they regulate. Good regulation has manageable workloads, but IRBs regulate more details of more research in more ways than they can review responsibly, and they have steadily broadened and intensified their hold over research.
>
> In short, the IRB system makes unreliable decisions because it is lawless and unaccountable, because its organization, procedures, membership and imperialism are so inappropriate. The problem is not regulation, it is bad regulation.

Schneider thinks that the misregulation of social science is particularly bad, but warns that IRBs sap medical progress as well. See [3]The Costs of Ethical Review, Part II.

1. https://mitpress.mit.edu/index.php?q=books/censors-hand
2. https://www.insidehighered.com/news/2015/06/03/author-discusses-new-book-flaws-institutional-review-boards
3. http://www.institutionalreviewblog.com/2011/04/costs-of-ethical-review-part-ii.html

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Earnest Member Reads the Belmont Report (2015-06-04 07:07)

My favorite portion of [1]The Censor's Hand is Schneider's invention of Earnest Member, a conscientious gentleman with good intentions but no ethical training until he is appointed to the IRB and handed copies of what Schneider terms the Sacred Texts.

Most Sacred, of course, is the Belmont Report, and here Schneider imagines Earnest Member trying to make sense of that document:

> The Belmont principles mean different things among and within fields. "Respect for persons" is a philosophers' term of art that can mean treating people as ends, not means. Does Earnest Member know that? He treats people and is treated as a means daily, and so much the better. Nor can the philosopher's special meaning practically be taught to the IRB members, IRB staff, and researchers. And even philosophers disagree about what respect for persons means. Some "suggest that respect incorporates considerations of well-being. Others suggest that concern for well-being lies within the purview of beneficence and nonmaleficence" and that the ambiguity about "well-being is one reason the principle of

> respect for persons is unhelpful." This must confuse Earnest Member, especially since there is "a sense in which both are correct."
>
> Thus the Report's method is not reason, it is ipse dixit. It does not explain why its principles were chosen, why they are right, what they mean, or how to infer rules from them. It just announces conclusions. For example, one of the "complementary expressions" of beneficence is "do no harm." But instead of explaining why, the Report says, "The Hippocratic maxim 'do no harm' has long been a fundamental principle of medical ethics. Claude Bernard extended it to" research. But Miller and Wertheimer rightly question how far "'do no harm' is operative even for medical care." It can only be "operative" with arduous interpretation, since much care inflicts harm to do good and/or risks doing more harm than good. And who was Bernard, why did he "extend" the rule to research, and why does he matter?

[2]And where was Nana?

1. https://mitpress.mit.edu/index.php?q=books/censors-hand
2. http://www.gutenberg.org/files/16/16-h/16-h.htm

Berkeley IRB: 1 + 1 = Undue Influence (2015-06-04 10:52)

In a series of four tweets, [1]Nicholas Christakis of Yale reports a horror story out of Berkeley:

- colleague's experience with Berkeley IRB: including both the following sentences in an appeal for a survey may result in undo influence.
- sayeth the IRB: so just pick one of 2 sentences "Your participation would mean a lot to me and help my research."
- sayeth the IRB: so just pick one: "Many of your neighbors are participating, and I'd like to hear your opinion, too."
- 100,000 people die from medical care yearly, none die from surveys, & our IRB's are wordsmithing to avoid undue influence?

1. https://twitter.com/NAChristakis

Why Notes Get Shredded (2015-06-06 10:10)

While Steven Lubet criticizes Alice Goffman for having "[1]shredded all of her field notes," Northern Ireland's Public Prosecution Service [2]prosecutes Ivor Bell based on an interview seized by subpoena.

How are those [3]shield laws coming, Josh?

1. http://newramblerreview.com/book-reviews/law/ethics-on-the-run
2. http://www.irishtimes.com/news/crime-and-law/ivor-bell-to-be-prosecuted-over-jean-mcconville-murder-1.2237386
3. http://www.politico.com/blogs/under-the-radar/2015/06/house-passes-reporters-shield-measure-again-208206.html

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Klitzman Wants "Case Law." As Did Katz, 42 Years Ago (2015-06-06 10:59)

In an opinion piece drawn from his new book, The Ethics Police?, Robert Klitzman calls for IRB transparency and respect for precedent. That is a good idea, and one that should have been implemented decades ago.

[Robert Klitzman, "[1]Who Polices the 'Ethics Police'?," CNN, May 26, 2015]

Here's Klitzman:

> Boards that remain closed to researchers should be more open. A body of "case law" should be built, based on documented precedents. Interpretations and applications of principles in specific cases should, as much as possible, be openly vetted.

As I've mentioned in [2]2008, [3]2010, [4]2011, and [5]2014, law professor Jay Katz understood this all back in 1973, before the enactment of the National Research Act and 45 CFR 46. As he testified to the Senate,

> 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 wanted IRBs to publish their decisions and base new decision on precedent. "The result," he predicted, "would not only be better thought out decisions, but also a more complex system of controls which, in effect, [would take] into account much broader sources of information as to societal values … I regard such a development, analogous to the experience of the common law, as the best hope, for ultimately providing workable standards for the regulation of the human experimentation process."

Had the Senate, or the National Commission, or OPRR heeded Katz, we would not have endured decades of overwhelming, unnecessary and unproductive IRB guesswork.

I have a full review of Klitzman's book in the works. Watch this space.

1. http://www.cnn.com/2015/05/26/opinions/klitzman-human-guinea-pigs/index.html
2. http://www.institutionalreviewblog.com/2008/06/music-educator-finds-irbs-inconsistent.html
3. http://www.institutionalreviewblog.com/2010/10/dreger-wants-to-scrap-irbs.html
4. http://www.institutionalreviewblog.com/2011/12/halavais-calls-for-open-publication-of.html
5. http://www.institutionalreviewblog.com/2014/06/a-bit-of-historical-perspective-on.html

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PRIM&R Meets with OIRA (2015-06-08 22:46)

Elisa Hurley, executive director of PRIM &R, reports that representatives of her organization met with officials from the federal Office of Information and Regulatory Affairs (OIRA) to discuss a potential notice of proposed rule making (NPRM).

[Elisa Hurley, "[1]PRIM &R Meets with OMB to Offer Input on Proposed Changes to the 'Common Rule,"' Ampersand, June 8, 2015.]

Recall that PRIM &R's comments on the 2011 ANPRM were [2]ignorant of the concerns of qualitative researchers, particularly historians, [3]misleading about the responsibility of IRBs for bad consent forms, and [4]contemptuous of the goal of efficiency.

I hope OIRA will hear from other parties as well.

1. http://primr.blogspot.com/2015/06/prim-meets-with-omb-to-offer-input-on.html
2. http://www.institutionalreviewblog.com/2011/10/is-prim-unaware-of-historians.html
3. http://www.institutionalreviewblog.com/search/label/PRIMR
4. http://www.institutionalreviewblog.com/2011/11/prim-efficiency-is-not-ethical-value.html

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Goffman's Tightrope (2015-06-19 08:56)

Two new articles add useful context to the debate about Alice Goffman's On the Run. Together, they show just how narrow a path Goffman was walking between privacy and verifiability, and between scholarship and good writing. I will address the IRB issues in a separate post.

[Jesse Singal, "[1]The Internet Accused Alice Goffman of Faking Details In Her Study of a Black Neighborhood. I Went to Philadelphia to Check," Science of Us, June 18, 2015.; Leon Neyfakh, "[2]The Ethics of Ethnography," Slate, June 18, 2015.]

Jesse Singal of Science of Us tracked down some of Goffman's Philadelphia informants, as well as Goffman herself. He finds that while Goffman's "lack of precision in language" muddied some portions of her book, she "conducted some amazing ethnographic research, and her book is almost entirely true, not to mention quite important."

Singal quotes Goffman's adviser, Mitchell Duneier, on the realtime fact-checking that accompanied Goffman's research.

> During Goffman's time at Princeton, he said, "There was a constant sending her back for more details, more facts, more interviews on a whole variety of different questions and issues" — sometimes, she would put folks from the neighborhood on speakerphone. A warrant officer from Philadelphia — a "brilliant one with vast knowledge" — also read a big chunk of Goffman's research, and Duneier got dinner with him twice to talk about her work. This officer corrected some things, but mostly endorsed Goffman's account, and Duneier is positive he read about the hospital arrests.

Meanwhile, Leon Neyfakh of Slate interviewed Goffman and several experts on ethnography, including Rena Lederman and Alice Dreger. (Your humble blogger is also quoted.)

Lederman offers a particularly helpful context. As Neyfakh paraphrases:

> She pointed out that we don't expect survey researchers—scholars who conduct studies on large sample populations and present quantitative generalizations based on a statistical analysis of data—to know or care about the names of the individuals they question to generate their findings. Why should ethnographers be held to a standard of naming names? Lederman suggested that it is ethnographers' interest in developing qualitative generalizations—general truths—from the study of specific individuals that makes them similar to scholars whose work is more unambiguously recognizable as science.

Dreger is more skeptical, arguing that "If you want people to read for the big picture, then what you should write is the big picture. You should write, 'These are the general things I observed, these are the patterns I observed,' and not present it in the form of exquisite individual portraits as if those are true."

The problem, of course, with such an approach is that it won't have anywhere near the impact of a book like On the Run. Sociologist Katherine Newman has done brilliant research on the working poor, and won many honors within academia. But she lacks the profile of journalist Barbara Ehrenreich, who writes on similar topics based on relatively superficial, impressionistic experiences.

Maybe the lesson is that Goffman needs to pick a lane. But that strikes me as a loss for everyone.

1. http://nymag.com/scienceofus/2015/06/i-fact-checked-alice-goffman-with-her-subjects.html

2. http://www.slate.com/articles/news_and_politics/crime/2015/06/alice_goffman_s_on_the_run_is_the_sociologist_to_blame_for_the_inconsistencies.single.html

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Chilling Effects **(2015-06-19 10:29)**

Leon Neyfakh's essay on Alice Goffman's methods illustrates the dangers of researchers' anticipating, rather than documenting, IRB restrictions on their work.

[Leon Neyfakh, "[1]The Ethics of Ethnography," Slate, June 18, 2015.]

The first example is Goffman herself. She earlier told the Chronicle of Higher Education, "In keeping with IRB requirements, I kept the field notes and the research materials for three years. After that time had passed, I disposed of them. I did this in an effort to protect the subjects of the study from legal action, public scrutiny, or any other undesirable result of the book's publication." [Marc Parry, "[2]Conflict Over Sociologist's Narrative Puts Spotlight on Ethnography," Chronicle of Higher Education, June 12, 2015.]

Now, Neyfakh reports that "According to [Rena] Lederman, who sits on the IRB at Princeton, no such demands are placed on researchers at the school." So it seems that Goffman anticipated or assumed what the IRB required, rather than requesting clear instructions.

The second example is that of University of Chicago sociologist Richard Taub. Neyfakh writes,

> Taub is among the ethnographers who would prefer not to anonymize their research to the extent IRBs oblige them to. He wanted to use actual place names in his 2006 book There Goes the Neighborhood, co-written with Harvard's William Julius Wilson, about four working- and lower-middle-class neighborhoods in Chicago, but decided not to because the authors knew the institutional review board at the University of Chicago wouldn't allow it.

I am troubled by that phrase: "the authors knew." How did they know what the IRB would do without submitting a formal proposal that would identify neighborhoods by name?

I would suggest that all researchers, from any discipline, submit the protocols they wish to follow and put the burden of rejecting them on the IRB. If the IRB accepts the proposal as submitted, so much the better. If the IRB demands inappropriate anonymity, then scholars at least have more evidence of IRB interference with research, of the sort that has contributed to calls for reform at the regulatory and university levels.

Challenging IRB assumptions can be harder than it sounds, especially for graduate students, who may see the provisions listed on a boilerplate IRB application as non-negotiable. But self-censorship or docile acquiescence removes a crucial step in the feedback loop.

In Goffman's case, any misunderstanding seems to have been inconsequential, in that Goffman wanted to destroy her notes with or without IRB demands. And in this, she may well have been following best practices for researchers of criminal behavior. As I've noted on Twitter, scholars receiving privacy certificates from the [3]National Institute of Justice must pledge that

> the security of research or statistical information will be protected by either:
>
> - the complete physical destruction of all copies of the materials or the identified portions of the materials after a three year required recipient retention period or as soon as authorized by law; or
> - the removal of identifiers from the data and separate maintenance of a name-code index in a secure location. If you choose to keep a name-code index, you must maintain procedures to secure such an index.

Since name codes for research not funded by NIJ would still be vulnerable to subpoena, Goffman's destruction of her notes may well have been the only ethical option. I don't know if she took the three-year retention period from the NIJ guidelines, but she's not alone in thinking that a reasonable compromise between accuracy and security.

One more comment on the IRB storyline of this saga. Neyfakh relates,

> Goffman's graduate school adviser, Mitchell Duneier, voiced a somewhat dissenting view about the inflexibility of IRBs when it comes to anonymity. "It's a case by case thing that IRBs decide," Duneier said, noting that he was able to use real names and places in two of his ethnographies, about street vendors in Greenwich Village and a restaurant in Chicago.

This is a rather different account of Duneier's IRB experiences than the one he related for Chris Shea's 2000 landmark article, "[4]Don't Talk to the Humans." In that version, Duneier did not even contact the University of Chicago IRB for his restaurant research, and "improvised" techniques that may not have fit his protocol for his Greenwich Village book.

Researchers serious about ethics must do what's right, whether that means going beyond the IRB or going around it.

1. http://www.slate.com/articles/news_and_politics/crime/2015/06/alice_goffman_s_on_the_run_is_the_sociologist_to_blame_for_the_inconsistencies.single.html
2. http://chronicle.com/article/Conflict-Over-Sociologists/230883/
3. http://www.nij.gov/funding/humansubjects/pages/privacy-certificate-guidance.aspx
4. http://linguafranca.mirror.theinfo.org/print/0009/humans.html

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Unknown (2015-06-25 08:16:12)
God knows I disagree with a lot of what you write, but you are spot on about this. It seems daft to blame IRBs for ordering data-destruction when they don't actually order it.

Mark Lacour made the same excuse I think, even though the 'evidence' he presented included a letter from the chair of his IRB complaining about how he had carried out his research without submitting to the IRB.

I guess IRBs are easy targets to hang blame on....

Adam Hedgecoe, Cardiff University

4.6 July

Exemption by the Numbers? (2015-07-05 08:46)

Two computer researchers describe a system at Microsoft Research designed to provide automatic approval for low-risk studies. Rather than follow the Common Rule's exemption model of requiring IRB review if any of a series of conditions is met, the Microsoft system assigns numerical values to aspects of a proposal that bear some risk to participants. Proposals with a low total get immediate approval from an Excel spreadsheet.

[Bowser, Anne, and Janice Y. Tsai. "[1]Supporting Ethical Web Research: A New Research Ethics Review." In Proceedings of the 24th International Conference on World Wide Web, 151–61. WWW '15. Republic and Canton of Geneva, Switzerland: International World Wide Web Conferences Steering Committee, 2015. doi:10.1145/2736277.2741654.]

The authors, Anne Bowser and Janice Tsai, reviewed 358 research papers and identified "124 cases where the ethics of a research study may be questionable." Of these 124, only 13 involved elements so dubious (e.g., conducting research not in accordance with a website's policy) that they themselves merited ethical scrutiny, while the remaining 111 "flags" are raised "when each of two questions are answered in a particular way." The authors don't give vivid examples, but the idea seems to be that sensitive questions alone might not merit review, nor would loose confidentiality protections. But sensitive questions combined with loose confidentiality protections demand attention.

It's an interesting concept, but not one that this paper describes in detail. For instance, here is the authors' description of evaluating their system:

> Nine participants from our Redmond lab submitted 10 distinct research proposals… . Of the 10 proposals submitted, five were approved through automated expedited review; three were approved through human expedited review; and, two were designated for full board review. Though a few usability issues were noted, the majority of authors characterized the system as easy to use. Additionally, most appreciated the use of logic to avoid answering unnecessary questions: the order "makes sense."

This sounds as though they learned more about interface design than whether the automated scoring system correctly sorted the ten proposals by degree of risk. The paper does not explain how closely the numerically scored system compares to the existing Common Rule exemptions or the judgment of researchers or ethicists, or how it would have scored such controversial studies as the Facebook mood experiment.

1. http://dl.acm.org/citation.cfm?id=2736277.2741654

British Universities See Ethics Committees as "Easy and Convenient" Censors (2015-07-27 11:00)

Adam Hedgecoe reports on two cases in which British university administrators turned to their university research ethics committees (URECs) not to protect the subjects of research, but to block controversial research they feared would tarnish the universities' reputations.

[Adam Hedgecoe, "Reputational Risk, Academic Freedom and Research Ethics Review," Sociology, June 25, 2015, doi:[1]10.1177/0038038515590756.]

No sex, please

The first case concerns a Kingston University undergraduate who wanted to explore "female students' decision to enter the sex industry." The project got preliminary approval from an REC subcommittee, which asked only that the researcher stay safe and keep interviewees anonymous, and even agreed not to review consent forms lest that step slow down the research.

For reasons not clear from the article (Hedgecoe is working with a limited set of documents extracted with a Freedom of Information request), the supervisor then requested full committee review. This committee forbad the student from interviewing any fellow Kingston students. And while Hedgecoe doesn't have a smoking gun showing that the ethics committee was primarily concerned about the university's reputation for driving its students into prostitution or other sex work, he comes close with an e-mail from the university publicity and press office to the student's supervisor:

> What worries me is that although I'm sure the research does highlight it [i.e. student sex work] as a problem globally as well as nationally, your research is based on a survey undertaken with [our] University students and it's the publicity surrounding that which concerns me. The story has hit the international press in India which, as you probably know, is a big market for [the University]. [Brackets in the Hedgecoe article.]

Stymied, the researchers fell back on asking students if they knew someone else engaged in sex work, a dodge that "[2]provided a conduit through the maze of research ethics committee requirements."

An "easy and convenient" censorship board

In the second case, Nottingham University administrators sought to use the ethics committee to punish its affiliates for reading or teaching The Al-Qaida Training Manual, a document available on the U.S. Department of Justice Website and, for a time, at the university library.

A vice chancellor wrote that "now that we have clarity on the nature of the Al Qaeda manual it would be reasonable to ask the question whether access went through the Ethics Committee in the School of Politics," and the registrar told a doctoral student that citing the manual in his dissertation was "a question for the research ethics committee." Then the Head of School asked an REC subcommittee to review a list of teaching materials prepared by Rod Thornton, a lecturer at the university.

One REC member had the integrity to refuse, writing, "I am not aware of anything in the remit of Ethics Committee that would warrant a procedure whereby its members become responsible for the approval of module handouts [reading lists]." But the other two members raised no such concerns, and the Head of School insisted that "Whilst the vast majority of matters that may require a view in regard to ethics will be research-related, there are cases (such as the present one) where other matters may legitimately fall within the remit of an ethics committee." Asked why, he explained, " I wanted to be in a position to protect [the] School against any adverse criticism and the ethics committee existed, was easy and convenient and could act in short time."

Stealthy restrictions on research

Though Hedgecoe has only these two stories documented by Freedom of Information requests, he suggests, quite plausibly, they are just the tip of the iceberg. He offers them as evidence "that URECs in the UK are quite capable of mirroring the behaviour of their US counterparts." URECs, he warns, "present a new, and largely unacknowledged, stealthy, mechanism through which management can restrict, not just what academics say to the press or on their blogs, but what research they do in the first place."

1. http://dx.doi.org/10.1177/0038038515590756
2. http://dx.doi.org/10.1080/03098770701625720

Community Researchers: IRBs Reinforce Power Differentials (2015-07-28 07:57)

Practitioners of community-based participatory research (CPBR) warn that standard IRB review can reinforce the power inequalities that CPBR hopes to mitigate.

[J. Cross, K. Pickering, and M. Hickey, "Community-Based Participatory Research, Ethics, and Institutional Review Boards: Untying a Gordian Knot," Critical Sociology, June 3, 2014, doi:[1]10.1177/0896920513512696; Bruce Pietrykowski, "Participatory Economic Research: Benefits and Challenges of Incorporating Participatory Research into Social Economics," Review of Social Economy, July 7, 2015, 1–21, doi:[2]10.1080/00346764.2015.1044841.]

Jennifer Cross, Kathleen Pickering, and Matthew Hickey, all of Colorado State University, warn that "Traditional research paradigms can reinforce existing power relationships by defining researchers as experts and community members as mere objects of study."

Bruce Pietrykowski gives an example of this practice. In the first CBPR study to go before his university's IRB, the IRB categorized community researchers as "subjects," in a way that student researchers doing the same work would not have been. This distinction, he writes, "positioned the community researchers as outsiders lacking equal standing to the academic researcher during this phase of the project." Eventually, Pietrykowski and his associates—within the university and without—were able to proceed, but it sounds as though the IRB was more hindrance than help.

Cross et al. imagine a wholly different role for IRBs. In their ideal world,

> the IRB would oversee the negotiated agreements between the researcher and the community, rather than simply imposing a universal, and potentially a culturally inappropriate, standard. The model also assumes that the IRB is not the final arbiter, but rather a participant in the dialogue, or a guardian of processes for designing, implementing, and interpreting ethical community-based research. The process of human subjects review would then become less an issue of regulation, and more an issue of relationship – which is one of the foundational principles of CBPR. We envision an IRB that manages an ethical pluralism with sensitivity to competing ethical obligations, rather than simply making and enforcing rules. [Citations omitted.]

That sounds lovely, but [3]IRBs are the creature of regulation, and their essence is to make and enforce rules. I'm not sure that Cross et al. understand that their proposal would require a rethinking of human subjects regulation even bolder than imagined by the ANPRM, or that they recall that, in the end, the Gordian Knot could never be untied. Alexander sliced it with his sword.

1. http://dx.doi.org/10.1177/0896920513512696
2. http://dx.doi.org/10.1080/00346764.2015.1044841
3. https://mitpress.mit.edu/books/censors-hand

IRBs Ignore South Africans' Concerns (2015-07-29 08:30)

Leslie London and Helen Macdonald, both of the University of Cape Town, complain that funding institutions in North America and Europe solicited their advice but then showed "little regard for local ethical practices in South Africa."

[Leslie London and Helen Macdonald, "[1]Transnational Excursions: The Ethics of Northern Anthropological Investigations Going South," ResearchGate, 2014.]

London and Macdonald discuss two cases in which northern-hemisphere researchers planned to research South Africa health care with little advance preparation. They do not claim that the approved projects endangered specific participants. Rather, they argue that

> there are concerns that enter into the ethical assessment of research other than the well-being of participants. These relate, for example, to the very choice of the research question, and the relative distribution of burdens and benefits. Further, in global health research power imbalances between researchers and their institutions often play out, particularly where southern colleagues are recruited to justify large multicentre collaborative grants. How to moderate such power relations has emerged as an important source of debate, spawning an entire literature on "International Health Research Ethics". Some of the issues relevant to this form of considering power relate to challenges such as data ownership, ownership and appreciation of intellectual capital, respect for local institutional systems and capacity building of local partners. [Citations omitted.]

The two studies, they feel, ignored these broader concerns. They describe one as "'parachute research' 'in which a foreign PhD student swans into a country to conduct a study and disappears after getting local informants to agree to share data that no-one else can provide to the researcher. Once shared, the researcher disappears with the knowledge, the experience and the intellectual capital."' The other, they argue, seemed to assume that "the natives sit around with not much to do, so a U.S. undergraduate can easily mop up this kind of research in eight weeks."

Because a U.S. IRB approved so impractical a study, London and Macdonald judge it to have been "extraordinarily naive." This strikes me as potentially unfair, since IRBs are not charged with judging the practicality of a protocol, only its likelihood of harming living individuals. So while it may have been naive of a funder or an adviser to approve an impractical plan, the IRB could well have been making decisions out of regard for its own jurisdictional limits.

More troubling is the charge that the U.S. IRB in this case reduced the researcher's ability to respond to local concerns. Macdonald asked that the U.S. IRB approve the study and delegate the necessary modifications to the University of Cape Town Anthropology Department, but the U.S. IRB refused. This put the student in the difficult position of trying to please both the local experts and an IRB at home that knew little about ethnography or South Africa.

London and Macdonald conclude that the real goal of the U.S. ethics process was "generating a paper trail which they might use to defend their institution in the event something were to go wrong."

1. http://www.researchgate.net/publication/273760295_Ethical_Quandaries_-_London_and_Macdonald

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Botkin Expects NPRM by October (2015-07-30 08:12)

At the tail end of the July SACHRP meeting (5 hours, 35 minutes into the [1]video) chair Jeffrey Botkin stated, "We're all anticipating the NPRM will be out before October. What that means is our business in October is likely to be the NPRM."

Clear your calendars, folks.

1. http://videocast.nih.gov/summary.asp?Live=16586&bhcp=1

4.7 August

Goffman Blames IRB, Again (2015-08-22 09:32)

Sociologist Alice Goffman claims that “IRB guidelines” prevent her from disclosing the location where she was interrogated by police.

[Paul Campos, “[1]Alice Goffman’s Implausible Ethnography,” Chronicle of Higher Education, August 21, 2015. (paywall)]

Goffman’s comments come in response to a lengthy critique of her book, On the Run: Fugitive Life in an American City, by Paul Campos, a professor of law at the University of Colorado at Boulder. Campos points to several passages, some of which have been flagged by other critics, that he is reluctant to believe without further documentation, documentation that Goffman has been unwilling to provide or is unable to because she destroyed her field notes.

The only mention of IRBs in the essay concerns this passage from Goffman’s book:

> [The police officers] take me up the stairs to the second floor, the Detective Unit. I sit in a little room for a while, and then two white cops come in, dark green cargo pants and big black combat boots, and big guns strapped onto their legs. They remove the guns, and put them on the table facing me.

Campos ran the claim by three Philadelphia police officers. They doubt the story, noting that “as a matter of basic security, all personnel are prohibited from bringing weapons into interrogation rooms, let alone placing guns on a table where they could be seized by a suspect.” Campos hints that Goffman may be confusing her experience with a scene in the movie Menace II Society. He then reports,

> When asked by email where she was interrogated, Goffman declined to provide this information on the grounds that doing so would be “stepping far outside the IRB guidelines for protecting the identities of human subjects.” Why an institutional review board would protect the identities of the officers who interrogated her, who were not her research subjects, is unclear.

Yes and no. I wouldn’t put such behavior past the [2]UCLA IRB, which once told an undergraduate that he couldn’t use information he’d gained from a casual conversation about the 1960s. But the proper response to such silliness is to challenge it, not surrender.

And I would be surprised to learn that the IRB at Princeton, where Goffman did her dissertation work, imposed such a restriction. Rena Lederman, a member of that IRB, is already on record stating that [3]Goffman has misstated IRB requirements there.

I suspect, then, that Goffman has decided on her own either that it would be unethical to identify the officers who violated police procedure in order to intimidate her, or that she does not wish to give them the opportunity to rebut her account. Either way, attributing that choice to “IRB guidelines” muddies understanding of what those guidelines do and do not say. Goffman’s readers deserve a clearer account of her ethical choices.

1. http://chronicle.com/article/Alice-Goffmans-Implausible-/232491/
2. http://www.sscnet.ucla.edu/soc/faculty/katz/pubs/UndergroundEthnographersDraft.pdf
3. http://www.institutionalreviewblog.com/2015/06/chilling-effects.html

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Gentle Regulation May Be More Effective (2015-08-25 08:44)

Law professor Samuel Bagenstos argues that recent Title IX excesses follow the pattern of IRB horror stories: the feds threaten drastic action, so university administrators hyper-regulate. He offers disability rights as an example of a less punitive regulatory effort that has produced good results.

[Samuel R. Bagenstos, "[1]What Went Wrong With Title IX?," Washington Monthly, October 2015.]

Bagenstos (my wife's first cousin) laments the incidents at Northwestern, where university administrations forced one professor to endure hours of questioning, and Lousiana State University, which fired a professor for using profanity in class. He also concurs with the Harvard Law faculty who warned that a proposed sexual misconduct policy lacked due-process protections. Yet he notes that "There is nothing in Title IX, its implementing regulations, or the recent government pronouncements that purports to require universities to do what the universities did in those cases." Rather, university administrations are acting on what they think they must do to avoid federal penalties. As he explains,

> To blame are two bureaucracies, one at the federal level, the other within individual colleges and universities, each emphasizing compliance over communication and common sense. Universities, perhaps stung by being called out on their prior inaction, overreached by allowing a class of professional campus administrators, insulated from the classroom, to pursue a maximally risk-averse strategy that went way beyond what the federal government was calling for and that put important values of academic freedom and fair process at risk on their campuses.

He notes the parallel with other forms of university regulation:

> Because compliance administrators do not come from the faculty, they are unlikely to fully appreciate the academic values of independent inquiry that challenges—often aggressively—the certitudes of students and others in the academic community. When that lack of grounding in academic values is combined with the tunnel vision that arises whenever an office is designed with the sole aim of maximizing compliance with a particular mandate, it is a prescription for a bureaucracy that prefers to sanitize the classroom, and override fair-process interests, in order to avoid any risk of being found to have violated the applicable regulations. A very similar dynamic has led institutional review boards to metastasize at American universities, as Zachary Schrag recently pointed out in these pages ("[2]You Can't Ask That," September/October 2014).

(Thanks for the cite, Sam.)

But not all regulatory efforts end so badly, and Bagenstos offers the more hopeful example of the Department of Justice's Disability Rights Section (DRS), charged with leading universities and other institutions into compliance with the Americans with Disabilities Act (ADA):

> Many of the DRS's staff—including its longtime career chief, John Wodatch—had experience working at the [Office of Civil Rights]. But they never allowed the work of the DRS to be dominated by individual, adversarial complaint processing. Rather, from the beginning the DRS focused on policy, training, and technical assistance to translate the broad and revolutionary promises of the ADA into digestible and achievable directives for implementation. Through extensive letter writing, presentations to industry groups, and a continuously updated technical assistance manual, the DRS let regulated entities know both what the new statute required and, crucially, what it did not require. And the communication was not one way. Rather, the DRS's directives were informed by extensive input from disability rights advocates and the regulated entities …
>
> Sometimes that meant requiring less, or going slower, than advocates urged. And that approach hardly avoided all fights over the ADA's requirements. But Wodatch and his staff had built up so much credibility on all sides of these fights that most knowledgeable observers, most of the time, regarded their compromises as Solomonic. The DRS's approach led to widespread voluntary compliance, particularly among large businesses and organizations.

Might that be a model for human subjects oversight?

1. http://www.washingtonmonthly.com/magazine/septemberoctober_2015/features/what_went_wrong_with_title_ix057187.php?page=all.
2. http://www.washingtonmonthly.com/magazine/septemberoctober_2014/features/you_cant_ask_that051759.php

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4.8 September

NPRM Proposes Freedom for Historians! (2015-09-02 22:08)

The long awaited [1]Notice of Proposed Rulemaking: Federal Policy for the Protection of Human Subjects, released today, suggests the complete deregulation of "oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected."

In the coming 90-day comment period, historians will need to insist that this remains an unqualified exclusion. Still, despite this last peril, we have much to celebrate.

"[2]Great joy in camp we are in View of the Ocian, this great Pacific Octean which we been So long anxious to See."

1. https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects
2. http://www.encyclopediavirginia.org/Journal_Entry_by_William_Clark_November_7_1805

Oral History Association (2015-09-03 08:40:51)
This is a great breakthrough, and a real tribute to the enormous work which lots of people have done for a long time. However, it is imperative now that individuals and professional associations weigh in during the public comment period.

Cliff Kuhn
Executive Director
Oral History Association

Schrag Reviews Klitzman, Ethics Police? **(2015-09-03 13:53)**

Just in time for the NPRM comment period, Society has published my review of Robert Klitzman's book, The Ethics Police?: The Struggle to Make Human Research Safe (New York: Oxford University Press, 2015). I note that "By offering the subjective worldview of IRB members, Klitzman shows how good intentions combine with ethical ineptitude to produce arbitrary decisions."

Per my agreement with Springer, what follows is the accepted manuscript of the review. The final publication is available at Springer via [1]http://dx.doi.org/10.1007/s12115–015–9935-x.

Robert Klitzman. The Ethics Police?: The Struggle to Make Human Research Safe. New York: Oxford University Press, 2015.

In theory, institutional review boards, or IRBs, constitute a thin red line between the rights and welfare of participants in research studies and their exploitation by researchers who, intoxicated by scientific curiosity and their own ambition, can easily forget that their actions can harm the people they study. Since the 1960s, federal rules have required an increasing number of scholarly studies to be reviewed by IRBs, which operate independently in universities and research hospitals across the United States. The hope is that they will dispassionately referee between the scientist and the subject.

In practice, IRBs have gained a reputation for impeding science without protecting anyone. "Almost every researcher I know," reports psychiatrist, bioethicist, and scholar Robert Klitzman, "has complained at some point, often vociferously, about an IRB having unnecessarily blocked or delayed his or her research." (6) Klitzman himself has been kicked around by IRBs; early in his career, he lost eight months of a twelve-month fellowship trying to get approval from an IRB that, in the end, found nothing of concern in his protocol. (8)
After decades of such encounters, most of them less disruptive, Klitzman asked why a system so disliked by researchers made sense to those who run it. After choosing institutions from a list of NIH grant recipients, he created a sample of 46 IRB chairs, directors, administrators, and members, identified by pseudonyms in the text. Klitzman interviewed each informant for an hour or two, then supplemented these interviews with surveys of additional IRB members and staff and with some focus groups. He did not interview any researchers not affiliated with the IRB, any federal officials, or research participants. He did not observe IRBs in action or study their minutes, communications with researchers, or other written records. (364)

Though Klitzman claims inspiration from anthropologist Clifford Geertz's call for "thick description," his interviews produce a fairly thin record. Indeed, Klitzman bravely includes criticism of his methodology by Douglas Diekema, a physician, professor of bioethics, and IRB chair, voiced in comments on a 2011 article in which Klitzman laid out some of his early findings. In that commentary, Diekema complained that

> To truly understand why different IRBs make disparate decisions will likely require an anthropologic methodology where trained observers embed themselves within IRBs in multiple institutions and evaluate the deliberations and decisions of those IRBs … We will need to go beyond surveys and interviews to a systematic evaluation of the actual work that IRBs do. (361)

Klitzman does not disagree; replying only that "many IRBs have consistently thwarted such efforts."
That may be true of "many IRBs," but other researchers—including Maureen Fitzgerald, Jan Jaeger, Charles Lidz,

Laura Stark, and Will van den Hoonard—have succeeded in getting permission to observe IRBs in action and have achieved useful findings as a result. Klitzman is wrong to blame IRBs for his own disinclination to observe IRBs at work, and for not drawing more from the work of those who have observed IRBs in action. Still, Klitzman's interviews and surveys have produced more useful information that Diekema suspects. By offering the subjective worldview of IRB members, Klitzman shows how good intentions combine with ethical ineptitude to produce arbitrary decisions.

Klitzman's main finding is that IRB members, however accomplished in their primary professional fields, have scant expertise in ethical reasoning and regulatory compliance. "Given the importance of the work they do," he writes, "and the potentially grave consequences of IRB lapses and oversights, the lack of preparedness for the work is especially striking. Both general members and chairs have been found to have little if any formal training in ethics." (36) They are equally lost when it comes to regulatory interpretation. "Committees," Klitzman notes, "may thus grope, 'smelling their way,' rather than using explicit rational formulas." (100) In that sense, they are not so much an "ethics police" as an ethics posse: a group of virtuous but untrained citizens, recruited off the street, given lethal weapons, and told to stop the bad guys.

Among these "well-meaning amateurs" (a phrase Klitzman approvingly borrows from bioethicist John Lantos), the most amateurish are the "community members," required by regulation to include at least one non-scientist and at least one person not affiliated with the institution conducting the research. But even the professionals who make up the bulk of IRB membership are unlikely to be expert in the particulars of the varied proposals that come before them. When a truly problematic case comes before an IRB member with real expert knowledge, it's by luck rather than design. One IRB reviewed a protocol that looked fine to everyone except a hematologist, who noted that the drug involved can cause bleeding and insisted on a monitoring plan. (151) Count that as a win, but, as Klitzman notes, only "happenstance" brought that protocol before a board with a hematologist. Had the same protocol come before a board with, say, an endocrinologist but no hematologist, then too bad for the bleeders.

More typical are the cases in which no one on the IRB knows what's at stake, and everyone must fall back on guesswork and panic. Olivia, an IRB chair, describes a sleep study whose participants would stay awake for 60 hours:

> The IRB thinks it must be terrible to stay up for 60 hours. The rectal thermometer probe is everybody's greatest concern, but participants say it's the thing they get used to most quickly. Our community member was beside herself because of the description of the actograph. It looks like a wristwatch, and measures movement. But the protocol made it sound like it was a significant risk. (154)

As Klitzman notes about this case, IRB fears may not be "realistic or reality-based." (154—his italics.)
Klitzman's informants report few attempts to learn more about the reality-based risks of research. A few have attended conferences hosted by IRBs' professional organization, Public Responsibility in Medicine and Research (PRIM &R), but these are expensive and not terribly informative. (62) Klitzman seems not to have asked about another potential source of enlightenment: the library. Consider, for instance, the question of compensating research participants, which, Klitzman's informants report, is a constant puzzle. If researchers pay participants too much, might they risk giving poor people the feeling they have no real choice but to join the study? But if researchers pay only a token amount, are they not asking those same participants to give up time and take trouble—and perhaps bear risks—without fair compensation? As it turns out, both ethicists and empirical researchers have studied this question, and they have answers. (91) But Klitzman, who has published some of his work in the Journal of Empirical Research on Human Research Ethics, seems not to have asked IRB members whether they ever consult that or other scholarly journals in ethics when making their decisions.

IRBs do occasionally try to get help interpreting the federal regulations that govern their conduct. Canadian research ethics boards (REBs) with such questions can get written, public interpretations from the Secretariat on Responsible

Conduct of Research, plus periodic updates to their nation's Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Americans have no such resource. When IRBs query the federal Office for Human Research Protections (OHRP), officials "essentially just read back the regulations" or offer "vague generalities." (185) Jeff, an IRB chair, complains, "I've found OHRP communications to social scientists to be dishonest." (184)

Cut off from any national discussion, IRBs turn inward. In her book Behind Closed Doors, sociologist Laura Stark claimed that IRBs are guided less by national scholarly debate than by "local precedents," so they are at least internally consistent. Klitzman finds some evidence for this view (149), but it is outweighed by the evidence of local inconsistency. As one IRB chair tells him, "Investigators may get quite different and inconsistent advice from the committee depending on what it feels like that day." (93) Louis, an IRB chair, notes that a board may approve the same consent form for seven years, then turn around and reject it as too technical. (134)

The only defense for such inconsistency is that IRBs are somehow attuned to the surrounding communities, and thus may make appropriately distinct decisions. But in his most consistent challenge to his informants' assertions, Klitzman notes that IRBs make little effort to ascertain what those communities think, and that inconsistency is better explained by internal dynamics. "IRBs even within the same community and institution often differ widely," depending in part on who attends a given meeting. (143, 157) One IRB member confesses, "I can look at something one day, and then the next day: what the heck was I thinking?" (146) IRBs act differ not because they are expert in local conditions but because their members "use 'gut feelings' and the 'sniff test,' not careful 'ethical analysis."' (166) Feelings and smells are fickle.

Though IRB members seem frustrated by what they don't know, and incapable of finding help, they don't let their ignorance stop them from deriding others' decisions or imposing significant changes on researchers. To the contrary, one of Klitzman's informants boasts of her IRB's rejection of a study design that other IRBs had approved. Cynthia, an IRB administrator, explains:

> The researcher wanted to have a national database where any parent would have to have their child's name entered before they would be eligible to go into a clinical trial. If you disagreed with putting your child's name into this national database, you were not allowed to enroll in any trials. I said 'You cannot take away people's right to enroll in a research study if they say 'I don't want to place my child's name in a national registry.' You've suddenly made registration an eligibility requirement." We were the only IRB that found issue with that—which amazes me. They thought it was not an IRB issue because it was a registry—not a research study. But isn't this an invasion of a parent's right to choice and confidentiality? They then rescinded it. A lot of institutions would have OK'd it. (152)

Cynthia thinks of herself as playing the Henry Fonda role in Twelve Angry Men, bravely standing up for the weak when no one else will. Less clear is why she thinks that way. What is so exploitative about asking a participant to join a registry? Why does Cynthia think subjects have a "right" to participate in one part of a study but not another? Does she understand the confidentiality procedures of disease registries? How did the investigators feel about the restriction? How did study participants? What scientific knowledge was lost? Would greater participation in the registry speed research about a serious childhood disease?

And even if we assume that Cynthia's IRB was right when everyone else was wrong, did it not have a duty to persuade the national research community that participants should not be required to join registries? Yet the IRB system includes no mechanism for such alleged ethical wisdom to be shared. For anyone concerned with the rights and welfare of research participants, this should be terrifying. But rather than pressing Cynthia with follow-up questions, or providing extensive analysis, Klitzman takes at face value Cynthia's claim to have "discover[ed] points not found

by other reviewers." Thicker description would have helped.

Klitzman claims that IRBs "grapple with decisions that involve profound philosophical, moral, and political dilemmas," and he offers some examples, mostly involving research abroad. (316, 351) But most of the episodes his informants report concern superficial minutiae. How many expected non-English speakers does it take to require a consent form to be translated? (127) Can "four weeks" be stretched to "four weeks and three days"? (331) What punishment to impose on a researcher who misplaced a videotape, found it, and confessed his crime? (284) In some cases, procedural concerns are significant; one IRB blocked further research funds until an investigator had cleaned up a filing system that threatened subject confidentiality. (278) But other IRB requirements seem to lack any ethical content. One administrator relates,

> Urban myths are out there—things that the committee has interpreted in the past that are not regulations but are just comfort levels. Our IRB says, "You should say 'fill out,' not 'complete,' a survey. 'Complete' is coercive." But that's not in the regulations. Our IRB also likes consent forms to be on institutional letterhead. (150)

Klitzman's own IRB required him to tell each potential interviewee for this book, "the alternative to participating is not to participate." (138) Another Tuskegee averted!

That a renowned Columbia University medical professor would accept such indignities is an indication of IRBs' power, and one of Klitzman's most surprising findings is how little IRB members understand how much power they wield. As he notes, "Local IRBs serve as their own police, judge, jury and Supreme Court." (72) Told by regulation that their job is to balance risks and benefit, they instead seek to eliminate risk, including the risk of "bad press." (75) And they can kill careers, banning researchers from doing research. "Researchers certainly recognize the power of these boards," Klitzman finds, "and for IRB members to deny it is philosophically and sociologically naïve." (356)

The weakest section of the book consists of the final two chapters, in which Klitzman ventures into the ongoing policy debates about IRBs. Here his own interviews with IRB members and staffers are of limited help, for, as he concedes, his informants "receive support—even if it is only part of their salary—for their work in the status quo, which they may therefore be invested in continuing." (339) Don't ask your barber if you need a haircut. And Klitzman mischaracterizes some proposals for reform. He claims, for instance, that the Obama administration's 2011 proposals would allow researchers to declare any project to be "minimal risk" and proceed without prior review. (19) In fact, the 2011 proposals suggest allowing this streamlined track only for "specified types of benign interventions," not just anything a researcher claims to be low-risk.

Klitzman himself is painfully ambivalent about the worth of the present system. "The authors of the regulations 40 years ago embarked on a grand experiment," he crows. "Now, almost a half century later, it is clear that they have succeeded in many ways." (323) Yet he also concedes that "boards frequently appear to try to justify their power, arguing that it helps researchers and human subjects. But no clear data exist to support that claim. At times, an IRB's power may actually delay or impede research, causing harm that the committee may insufficiently recognize or acknowledge." (268) He offers no reconciliation of these apparently contradictory statements.

Klitzman concludes his work with an quotation from Winston Churchill and the suggestion that the IRB system, like democracy, is "the worst system … except for all the others." (368) But whereas Churchill's listeners knew full well what other systems had been tried from time to time, Klitzman does not compare today's system to the less heavy-handed IRB system in place in the 1980s; or to ethics oversight regimes in continental Europe, which review much narrower ranges of research; or to Canada's system, which offers its boards considerably more advice, and gives

researchers the right to appeal.

And while Churchill spoke despairingly of other forms of government that "will be tried in this world of sin and woe," Klitzman believes that better alternatives to the present IRB system remain to be found. He calls for additional work "to examine to what degree, and how exactly, different models might operate." (335) He insists that "boards must somehow be encouraged and even incentivized to reduce … idiosyncratic differences," perhaps through the publication of their decisions. (167, 347) He repeatedly calls for OHRP or the Institute of Medicine to provide detailed guidance, something they have in the past failed to do. He hopes for some system of "checks and balances" to restrain IRB nitpicking. (140) He even endorses a "small scale" test of self-regulation by researchers conducing minimal risk studies. (346) Though he does so with more ambivalence than in his earlier writings, Klitzman is willing, at times, to imagine radically different structures.

"This is not," Klitzman tells his readers, "an 'anti-IRB' book." (30). Yet any critic of the current system will find in it plenty of evidence that drastic reform is needed. Indeed, in The Censor's Hand, the most anti-IRB book ever written, Carl Schneider repeatedly cites Klitzman's articles to illustrate some of IRBs' worst pathologies, and their members' foggiest thinking. It is harder to imagine any of Klitzman's readers taking comfort in learning that researchers, research participants, and science itself must rely on the good intentions of these groping, sniffing amateurs.

For further reading

Fitzgerald, Maureen H. "Punctuated Equilibrium, Moral Panics and the Ethics Review Process." Journal of Academic Ethics 2, no. 4 (2005): 315–38.

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Stark, Laura. Behind Closed Doors: IRBs and the Making of Ethical Research. Chicago: University of Chicago Press, 2011.

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1. http://dx.doi.org/10.1007/s12115-015-9935-x

NPRM: Freedom for Historians, If They Can Keep It (2015-09-04 07:19)

The notice of proposed rulemaking (NPRM) promises long-sought relief for historians, journalists, and biographers. For these groups, the goal will be to ensure that the proposed rules are enacted as currently written.

[This post has been cross-posted to the Petrie-Flom Center's Bill of Health, which is conducting an online [1]NPRM Symposium.]

11 September 2015: See update at the bottom of this post.

Organizations representing anthropologists, sociologists, political scientists, and other social scientists have largely tried to make peace with IRB regulations, often counseling members to submit to IRB review and serve on IRBs. Historians, by contrast, have been almost uniform in our opposition to regulation, and since 2000, we have argued that our work should not be subject to rules written for "generalizable research." In 2003, OHRP endorsed that position, but then [2]distanced itself at the first challenge from IRB offices.

Now, the NPRM promises to eliminate the ambiguity. As it explains, it

> outlines eleven specific types of activities that will be outside the scope of the regulations. These activities will therefore not have to satisfy any regulatory requirements, nor is it expected (unlike exempt research) that they will undergo any type of review process to determine this status. The exclusions will eliminate uncertainty regarding some activities that are not research, and identify some activities that arguably might be judged to be research, but whose contribution to public welfare is so imperative that they should proceed without having to satisfy the regulatory requirements. The exclusions also identify certain research activities that are sufficiently low- risk and nonintrusive that the protections provided by the regulations are an unnecessary use of time and resources, whereas the potential benefits of the research are substantial.

History makes this first set of exclusions, concerning the "some activities that are not research." As the NPRM explains,

> While the NPRM does not propose to modify the definition of "research", it does propose to explicitly exclude oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information or biospecimens is collected. In the kinds of activities referred to here, the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not to protect them from public scrutiny. Therefore, the protections afforded to individuals by the Common Rule seem unhelpful in furthering the aforementioned ethical goal in this context. Additionally, these fields of research have their own codes of ethics, according to which, for example, consent is obtained for oral histories. It is believed that because of these reasons, explicit exclusion of these activities from the scope of the Common Rule is appropriate.

The specific provision states that among those activities "deemed not to be research … for the purposes of this regulation" are "Oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected."

This is tremendous news. The reference to "public scrutiny" may be the first time U.S. regulators have acknowledged that ethical research may be, in the words of Canada's TCPS2, "[3]legitimately critical and/or opposed to the welfare of those who are the focus of the research, and may cause them some harm." And the reference to historians' "own codes of ethics" is a nice nod to the work of oral historians and others, some of it predating the Belmont Report.

The NPRM dilutes this understanding a few pages later, when it states that "All investigators performing excluded studies are expected to act in a way that is consistent with the principles outlined in the Belmont Report, even if the Common Rule does not impose requirements on excluded work." As I've noted, [4]the Belmont Report makes no acknowledgement of the goal of public scrutiny, and is thus a poor guide for historians and journalists. But Tom Beauchamp himself told me that "the principles outlined in the Belmont Report" are really just "headings," so I

suppose historians can find a way to live with them.

More worrisome are two questions that follow the section describing the exclusions:

> 12. Public comment is sought regarding whether some or all of these activities should be exemptions rather than exclusions.
>
> 13. Public comment is sought regarding whether these exclusions should be narrowed such that studies with the potential for psychological risk are not included. Are there certain topic areas of sensitive information that should not be covered by this exclusion? If so, please provide exemplary language to characterize such topic areas in a manner that would provide clarity for implementing the Rule.

Either one of these could nullify any progress. As the NPRM itself notes later, "Institutions, if they so choose, could continue to have [exempt] determinations made by an individual who is knowledgeable about the exemption categories and who has access to sufficient information to make an informed and reasonable determination." In other words, exempt could still mean non-exempt.

As for "psychological risk," the [5]SBS White Paper of 2011 noted that

> 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.

Thus, the concept of potential psychological risk is so fluid that an alarmist IRB staffer could easily decide that any oral history interview poses such risk.

Historians, journalists, and biographers need exclusion from human subjects regulations, with no ifs, ands, or buts. The language of exclusion, with no qualifier about psychological risk, should be adopted as it appears in the proposed rule.

UPDATE: 11 September 2015

Now that I've seen the formatted Federal Register version, I no longer think that the NPRM has posed specific questions about oral history.

Questions 9-15, which at first worried me, fall under NPRM section II.A.2.b: Exclusion of Activities That Are Low-Risk and Already Subject to Independent Controls. The history exclusions fall under II.A.2.a: Exclusion of Activities That Are Deemed Not Research. So people concerned about II.A.2.a need not answer questions 9-15, right?

1. http://blogs.law.harvard.edu/billofhealth/category/human-subjects-research/nprm-symposium/
2. https://chnm.gmu.edu/digitalhistory/links/cached/chapter6/6_23d_caution.htm
3. http://www.pre.ethics.gc.ca/eng/archives/revised-revisee/chapter2-chapitre2/
4. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=5673&blogid=140
5. http://www.institutionalreviewblog.com/2012/01/sbs-white-paper-calls-for-drastic.html

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NPRM: Escape for Many, Scant Relief for Those Left Behind (2015-09-11 08:17)

While the NPRM might do much to reduce the number of projects requiring IRB review, it would do little to improve the quality of review for those projects for which it is still required. This is a retreat from the more ambitious plans of the 2011 advance notice of proposed rulemaking.
[This post will be cross-posted to the Petrie-Flom Center's Bill of Health, which is conducting an online [1]NPRM Symposium.]

Fewer reviews

A great many of the proposals in the NPRM would reduce IRB jurisdiction and workload. These include:

- Exclusion of some types of studies, such as oral history.
- Changes to exemption procedures, to encourage alternatives to the present system, in which many institutions regard an exemption determination as a "[2]level of review."
- Allowing a single IRB to approve a multi-site study.
- Elimination of continuing review for most expedited studies.

That's all well and good. IRBs and IRB staffs are overworked, often spending much of their time completing paperwork for low-risk studies. Both researchers and reviewers deserve relief.

But what about those studies that still face full-board review?

Single IRB review, but no consistency

The NPRM offers no reforms to improve the quality of IRB decision-making, but it could make IRB arbitrariness harder to spot.

Right now, some of the best evidence that IRBs make arbitrary decisions comes when identical proposals are submitted to multiple IRBs. Occasionally this happens as part of a deliberate test, as when [3]Laura Stark asked eighteen IRB chairs how they would handle a proposal to study hiring discrimination, and got "very different" answers.

More commonly, we learn about inconsistency when actual researchers want to do work at multiple sites. By submitting identical proposals to multiple IRBs, they perform a natural experiment, and learn how inconsistent and arbitrary IRB decisions can be. A classic example, cited first the ANPRM and now the NPRM, is Green et al., which found [4]"Wide variation in standards applied to review and approval of IRB applications."

The NPRM addresses such studies by reducing the number of IRBs that must be consulted, but not by making the decision-making any better.

Imagine a weather station whose operator complains of having to check a hundred thermometers, which vary widely in the temperatures they report. Allowing the operator to check a single thermometer will greatly reduce his burden,

but it won't do anything to address the lack of reliable information from any of the instruments.

Public scrutiny of consent forms, but not IRB decisions

The NPRM suggests mandatory posting of consent forms for clinical trials, "so that anyone drafting a consent form will do so knowing that it will eventually be subject to public scrutiny." But it does not explain how the public will distinguish the poor consent forms drafted by researchers from those good ones [5]mangled in response to IRB demands. Will PRIM &R continue to claim that "[6]IRBs neither interact with subjects nor write consent forms?"

More significantly, the NPRM does not propose the publication of IRB decisions themselves, though [7]public scrutiny of these documents could do a great more to address the arbitrariness the NPRM is designed to combat.

More consistent guidance, but even less of it

Critics of the current system have noted how hard it is to get timely, reliable guidance out of the federal government. As Klitzman notes, a call to OHRP produces just "[8]vague generalities." SACHRP is occasionally better, sometimes offering specific advice on matters like [9]internet research. But [10]SACHRP, an HHS body, is primarily focused on medical research.

In an effort to promote consistency across agencies in the interpretation of the Common Rule, the NPRM would require "Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible."

But rather than establish a body representative of the various agencies promulgating the rules, and of the various disciplines subject to them, the budget section of the proposal suggests that it would be the job of "Three [OHRP] staff people at the GS–14 level to draft new guidance and revise old guidance."

This strikes me as a poor mechanism for providing the timely, consistent guidance researchers and IRBs need. A better choice would be to fund a widely representative expert body like Canada's [11]Panel on Research Ethics, and both empower and require it to provide prompt, written, public responses to IRB queries.

Revision of expedited categories, but not of the regulations

The NPRM promises that the list of activities deemed minimal risk will be updated "at least every 8 years." While that's lovely, it also suggests that the NPRM framers do not expect that the rest of the regulations will be regularly revised, or at least not more frequently than once a generation. And that's a big disappointment. Canada has shown the value of more frequent revision, with a wholesale revision after 12 years, and a [12]significant update after only four.

No centralized reporting

The ANPRM (question 69) suggested having "all data on adverse events and unanticipated problems collected in a central database accessible by all pertinent Federal agencies." Explaining the ANPRM to the Presidential Commission for the Study of Bioethical Issues, ANPRM architect Ezekiel Emanuel stressed his wish for "[13]a learning process that would be constant and dynamic to reflect actual risk, which I took to be a reference to the database plan.

The NPRM notes that most commentators opposed the central database as burdensome and impractical, and so the NPRM takes it off the table. OK, but in its absence, it offers no other means for IRBs to learn or any requirement that

they base their decisions on evidence.

No appeals

Finally, the NPRM fails to mention one of the key proposals of the ANPRM: “a requirement that every institution must provide an appropriate appeal mechanism.” [14]As I noted in 2011, this suggestion was the closest the ANPRM came to addressing the issue of IRB incompetence. Its omission from the NPRM is a severe disappointment.

Eliminating distractions isn’t enough

The NPRM argues that “cumbersome and outdated regulatory standards overwhelm and distract oversight bodies and other stakeholders from appropriately addressing the real risks and benefits of research.”

That is no doubt true, and reducing burdens is a necessary step toward better IRB decision-making. But it is not a sufficient step. We have [15]substantial documentation of IRB ineptitude, and [16]no corresponding evidence of IRB effectiveness. Even if the NPRM’s drafters were unwilling to question the core premises of the IRB system, could they not have taken some steps toward improving those reviews it will continue to generate?

1. http://blogs.law.harvard.edu/billofhealth/category/human-subjects-research/nprm-symposium/
2. http://uncw.edu/research/compliance/human.html
3. https://www.insidehighered.com/news/2012/02/08/author-provides-inside-look-irbs
4. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681539/
5. http://www.institutionalreviewblog.com/2014/10/university-of-washington-irb-demanded.html#more
6. http://www.institutionalreviewblog.com/2011/11/prim-irbs-dont-write-consent-forms.html
7. http://www.institutionalreviewblog.com/2015/06/klitzman-wants-case-law-as-did-katz-42.html
8. http://www.institutionalreviewblog.com/2015/09/schrag-reviews-klitzman-ethics-police.html
9. http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf
10. http://www.institutionalreviewblog.com/2011/06/sachrp-now-lacks-social-scientists.html
11. http://www.pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/
12. http://www.pre.ethics.gc.ca/eng/resources-ressources/news-nouvelles/nr-cp/2014-12-18/
13. http://www.institutionalreviewblog.com/2011/08/emanuel-anprm-will-end-reliance-on.html
14. http://www.institutionalreviewblog.com/2011/08/does-anprms-appeals-provision-address.html
15. http://www.institutionalreviewblog.com/2015/06/schneider-irb-system-is-model-of-how-to.html
16. http://www.institutionalreviewblog.com/2010/12/nih-bioethicist-grady-questions-irb.html

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NPRM. Statute? What Statute? **(2015-09-18 09:30)**

The NPRM cites [1]42 U.S.C. 289 as its statutory authority, but it does not seem to care much about following the language of the statute.

The statute applies to “biomedical or behavioral research involving human subjects,” and does not mention social science. The NPRM acknowledges that “some of the commenters [on the ANPRM] recommended that the definition of research be focused more explicitly by being limited to ‘biomedical and behavioral research,’ in accordance with the statutory provision underlying the Common Rule.” But it makes no effort to focus the definition or to explain why the drafters felt comfortable ignoring this part of the statute.

Similarly, the statute requires IRB review of research supported by a “grant, contract, or cooperative agreement under this chapter.” When the 1981 version of 45 CFR 46 was promulgated, the [2]Federal Register notice explained,

> 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. (8369)

Now, the 2015 reverses that interpretation and "proposes an extension that would ensure that clinical trials are covered by the Common Rule if conducted at an institution in the United States that receives federal support for non-exempt and non-excluded human subjects research, regardless of the funding source of the specific clinical trial." (53989)

The 2015 NPRM acknowledges that ANPRM comments "argued that such a change was an overreach of federal oversight and constituted an unfunded mandate." But it offers no legal analysis of why regulators feel comfortable overriding public concern and the legal reasoning of previous HHS counsel.

1. https://www.law.cornell.edu/uscode/text/42/289
2. http://archive.hhs.gov/ohrp/documents/19810126.pdf

Alarmist Claims about Public Administration Research (2015-09-20 21:02)

Two scholars from the University of South Africa claim that more than one in four articles they sampled in two journals of public administration involved "research of a more than minimal risk level." This claim appears to be based on a misunderstanding of U.S. regulations.

[Jacobus S. Wessels and Retha G. Visagie, "The Eligibility of Public Administration Research for Ethics Review: A Case Study of Two International Peer-Reviewed Journals," International Review of Administrative Sciences, September 3, 2015, 0020852315585949, doi:[1]10.1177/0020852315585949.]

The error appears in Table 2, on p. 11 of the article. The authors list the following categories of "potential benefit and risks of the data-collection methods or techniques used":

- Individual interviews as a data-collection method (greater than minimal risk)
- Group interviews as a data-collection method (greater than minimal risk)
- Observation as a data-collection method (no risk to greater than minimal risk)
- Conceptual research (no risk)

Apparently, Wessels and Visagie believe that under U.S. definitions, all individual and group interviews should be regarded as greater than minimal risk. This is not correct.

Though the authors claim to be following the categories established by the U.S. regulations (p. 12), they have not consulted OPRR's 1998 [2]Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure, a list of the most common forms of minimal risk research. This list specifically includes "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."

Wessels and Visagie sampled 70 journal articles and report, "nearly 18 (26 % of the total sample) of the articles reported on research of a more than minimal risk level." This figure, repeated four times, is undoubtedly an overestimate, since it includes all interview projects, regardless of risk.

To be sure, public administration researchers may occasionally wander into challenging ethical territory. For instance, Wessels and Visagie cite an article by Iranian scholar Behzad Mashali, who [3]asked government officials about their beliefs about corruption. In the United States, such a project would qualify as both exempt and minimal risk, but Iran [4]jails journalists without due process, so what might its government do to employees who speak, even abstractly, about corruption?

I don't know, but neither do Wessels and Visagie. Instead of doing careful analysis of the case studies they've identified, they have deployed a simple and erroneous criterion to produce a misleading claim.

1. http://dx.doi.org/10.1177/0020852315585949
2. http://www.hhs.gov/ohrp/policy/expedited98.html
3. http://dx.doi.org/10.1177/0020852312455991
4. http://freejasonandyegi.com/

Jacobus Wessels (2015-10-12 13:29:20)

The purpose of our article was not to analyse or interpret the US regulatory language at all, but to "report on research aimed at assessing why Public Administration research is eligible for research ethics review at all". Our conceptual framework was never intended to be a replication of the US regulatory language, but a deduction from our reading of the Belmont Report and several scholarly works related to the report and research ethics review, including our evolving institutional policy on research ethics. In conclusion, we do not agree that the "article relies on a misunderstanding of U.S. regulatory language". We developed three risk-associated categories (no involvement, indirect involvement and direct involvement) that are context-specific. We acknowledged as a limitation of this study that "a simplistic picture of research ethics risk is presented in the article" (see page 17). We also stated: "we are in the process of developing more refined risk categories for research in Public Administration in current research (see page 17).

It seems that your main concern is our equation of "more than minimal risk" to "direct involvement" as you perceive it as a misrepresentation of the meaning "more than minimal risk" as used in the US regulatory practice. We have deduced the risk categorisation used in this article from various discussions and interpretations of the principles as stated in the Belmont Report. In fact, we have developed for the purpose of this article only three risk categories founded on the notion of 'human participant involvement'. On p 12 of our article we explicitly state that for "the purpose of this study, 'minimal risk' refers to the probability that harm or inconvenience anticipated in the research is not greater in itself than that encountered in ordinary daily life (OHRP, 1993); 'more than minimal risk' refers to research with the potential to harm or create inconvenience for human subjects. We stated explicitly on page 12 of the article that the risk category – 'more than minimal risk' reflect a potential to harm or to create inconvenience to human subjects. For the purpose of this research we regarded direct involvement of human participants through qualitative or quantitative methods as having that potential. Consequently, the conceptual framework presented in Table 2 has been used for the quantitative content analysis. We have deliberately decided to use for the purpose of this study a broad risk categoris action based on the nature of involvement of human participants. In fact, our current research focus specifically on a refined risk

assessment framework as stated previously. We take notice of the practice in the countries such as the US and Canada. However, we do not regard these countries' official risk categories and the definitions of these categories as the final word in this regard.

As we categorised the use of secondary data (indirect involvement) as of minimal risk, it makes logically sense that direct involvement through interview- or survey-based research be classified as having the potential for more than minimal risk. It depends on the classification system

Considering the definitions in our risk classification system the 26 percentage figure was not an over statement and indicates a "potential' for more than minimal risk. In our discussion (on page 17) we acknowledged as a limitation of the study "the lack of information typically needed to determine the extent to which research procedures have met ethical principles …" We further acknowledged "our inability to assess the actual behaviour of researchers' through the methods used".
We never claimed that the findings indicated that real harm occurred during the research. The findings of case studies are contextual and a limitation of this type of research is that the findings are not generalizable.

Kobus Wessels and Retha Visagie
University of South Africa

TCPS Envy, Continued **(2015-09-24 07:46)**

Writing in the Journal of Academic Freedom, law student James Nichols presents Canada's TCPS2 as a model of balance "that promotes intuitive and promising research without sacrificing human integrity and protection." However, his conclusion is largely speculative, since we still lack studies of how the document is working in practice.

[James Nichols, "[1]The Canadian Model: A Potential Solution to Institutional Review Board Overreach," Journal of Academic Freedom 6 (2015)]

Nichols points up several attractive features of TCPS2, including its:

- status as "a living document that is constantly evolving with the help of scholars"
- embrace of academic freedom as a guiding principle
- detailed guidance about specific issues, including a whole chapter on qualitative research
- heightened requirement for REB expertise
- requirement of an appeals process.

All of this makes TCPS2 look great on paper, and the [2]object of envy to American scholars like me, as well as some in New Zealand.

On the other hand, Kirsten Bell, a medical anthropologist working in Canada was skeptical of TCPS2 at the 2012 Ethics Summit, and her skepticism remains in [3]her chapter in the forthcoming conference volume, Ethics Rupture.

Neither side offers empirical research on how REB practice has or has not changed in the nearly five years since the release of TCPS2. If anyone knows of such a study, I hope they will alert me.

1. http://www.aaup.org/reports-publications/journal-academic-freedom/volume-6-2015/institutional-review-boards-attack.

2. http://www.institutionalreviewblog.com/2014/06/tcps-envy.html

3. http://www.academia.edu/8998258/The_more_things_change_the_more_they_stay_the_same_the_TCPS2_and_the_institutional_ethical_oversight_of_social_science_research_in_Canada

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NPRM: Forgotten Folklore (2015-09-24 08:13)

The [1]NPRM proposes "to explicitly exclude oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information or biospecimens is collected." Not listed is another scholarly discipline that also focuses on specific individuals: folklore. Why?

Folklore projects can closely resemble oral history and journalism. [2]Jeffrey Cooper of the WIRB-Copernicus Group alerts me to the example of the Library of Congress American Folklife Center's [3]Inauguration 2009 Sermons and Orations Project, which collected "audio and video recordings of sermons and orations that comment on the significance of the inauguration of 2009." These were not oral history interviews, but the effort "to enhance the nation's historical record and preserve the voices of religious leaders and other orators for researchers and scholars of the future" sounds a lot like many oral history projects, and presumably the sermons and orations will be credited to the speakers, much like oral history interviews.

Moreover, folklorists recognize that IRB regulations fit them poorly for the same reason they fail historians. In its comments on the 2011 ANPRM, the American Folklore Society explained,

> Folklorists have historically studied marginalized or disempowered populations: minorities, women, workers, and rural people. Over our century and a half of disciplinary existence, we have learned to stop treating people as generic members of a social category or as passive "tradition-bearers." Individuals typically want credit for their knowledge, experience, and creativity. It would be absurd to strip individual identifiers from a study of Plácido Domingo's vocal technique or an intellectual history of the counterinsurgency strategy in the Iraq war. It is equally nonsensical to strip such identifiers from a study of gospel singers or grassroots activists: no intellectual sense can be made of their practices without the surrounding context. More importantly, to demand the suppression of individual identities denies these people the dignity and respect conferred on more powerful individuals.

Given this claim, the AFS erred in framing its ANPRM comment as an endorsement of the American Anthropological Association's comment. While [4]the AAA's statement was bold and principled, it did come from a group that traditionally obscures the identities of its informants by providing them with pseudonyms and blending details from several people into composites, thus treating them more "as generic members of a social category" than as individuals. If the AFS is serious about studying individuals, it should claim closer kinship to journalism, biography, and history than to anthropology.

Even without a clearer comment from the AFS, the authors of the NPRM could have figured this out. The sole reference to folklore in the document is [5]a reference to this blog, in which I noted a [6]2010 Smithsonian Institution policy that combined journalism, and the "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" as activities that did not require IRB review. In other words, the NPRM cites, indirectly, a document equating folklore to journalism and history, but fails to grant folklore the same treatment as those other fields.

This could be corrected with the addition of a single word to the final rule: insert "folklore" after "biography" in § _ _ _ _.101(b)(ii). Folklorists who focus on specific individuals deserve the same exclusion granted to historians, biographers, and journalists.

1. http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf
2. http://www.wcgclinical.com/about-us/our-people/
3. http://www.loc.gov/folklife/inaugural/
4. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html
5. http://www.institutionalreviewblog.com/2010/07/smithsonian-frees-oral-history.html
6. https://zacharyschrag.files.wordpress.com/2011/06/human-subjects-research-faqs.doc

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4.9 October

Virginia Universities Take on Virginia Human Subjects Law (2015-10-22 05:55)

Virignia universities, including the University of Virginia, Virginia Tech, and Virginia Commonwealth University, want to reform Virginia's human subjects laws, which in theory impose IRB requirements on all research in the state, even constitutionally protected speech like surveys conducted by news organizations and political polling firms.

[Derek Quizon, "[1]New UVa Rector Discourages Post-Vote Dissent, Use of Email," Richmond Times-Dispatch, August 17, 2015.]

The Richmond Times-Dispatch reported this in August. I had missed it, and I thank the [2]IRBNet Newsletter for alerting me. Since the NPRM was released after the story came out, I don't know how it affects the state-level initiative. Also, though not mentioned in the story, I am told that my home, George Mason University, is involved in the effort.

In any case, here's the relevant portion of the Times-Dispatch report:

> UVa joined institutions around the state, including Virginia Tech and Virginia Commonwealth University, in calling for simpler regulations for human research projects deemed "low-risk."
>
> The university follows a complex web of state and federal regulations for research involving human subjects, Sullivan said.
>
> "The administrative burden is greater because we're basically following two sets of rules," Sullivan said. Some of the regulations could be trimmed for research that do not put a subject's health or well-being at risk — surveys, for example, or testing a new teaching model in a public school. The federal regulations

> can’t be changed, so this would only apply to research that receives no federal funding.
>
> One suggested change to the language in state law would expand the types of research that require “written informed consent” from subjects to include research that “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.”
>
> Another expands the categories of projects that would be up for “expedited review” by each institution’s human-research review committee.
> Sullivan said the changes will allow state and university regulators to focus on complex, high-risk projects involving human subjects.
>
> “If you don’t want to complete a survey, you just discard it,” she said. “It’s not harming anybody.”

The Virginia law is mostly duplicative of federal efforts, and to the extent it is not, it may be unconstitutional. So I would prefer that the universities called for outright repeal.

1. http://www.richmond.com/news/virginia/article_2fc4fa74-fb51-5ee3-87d2-5e135643a65c.html
2. https://www.irbnet.org/release/index.html

Does PRIM&R Welcome History Exclusion? (2015-10-30 20:42)

In its response to the 2011 ANPRM, [1]PRIM &R denied that an exclusion for “certain fields of study” was “even worth considering.”

Now, in [2]comments on the NPRM, PRIM &R Executive Director Elisa Hurley writes, “some of the exclusions proposed in the NPRM will likely be widely welcomed, such as the explicit exclusion of journalism, oral history, biography, and historical scholarship activities.”

As [3]Ellen Bresler Rockmore reminds us, passive constructions (“will … be widely welcomed”) can disguise meaning, and that is the case here; is Hurley among those who will welcome the change?

I hope so. But in any case, PRIM &R seems to be finally acknowledging the grievances of historians and journalists and the need for reform.

1. http://www.institutionalreviewblog.com/2011/10/is-prim-unaware-of-historians.html
2. http://blog.primr.org/unpacking-the-nprm-a-new-category-of-exclusions/
3. http://www.nytimes.com/2015/10/22/opinion/how-texas-teaches-history.html

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4.10 November

Scoping Out the Common Rule (2015-11-03 20:07)

Thursday I’ll speak at a meeting to discuss "Revising and Expanding the Scope of the Common Rule," Evanston, IL.

[1]Join us live or on the web.

1. http://myemail.constantcontact.com/Special-Invitation-.html?soid=1117107086342&aid=6OsS266w3bU

Historians Love the NPRM (2015-11-04 23:38)

Fifteen scholarly organizations, including the American Council of Learned Societies, the American Historical Association, the American Political Science Association, the Oral History Association, and the Organization of American Historians, have signed a [1]letter endorsing the NPRM's proposed exclusion of "oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected."

The letter (whose authors kindly consulted me in its early stages) is unequivocal:

> We concur with this recommendation of full exclusion of such activities from IRB oversight. It reflects an appreciation that these activities should not be evaluated under frameworks originally designed with the sciences in mind. It recognizes the value and attributes of these forms of scholarship. It eliminates any ambiguity about review, regulation and enforcement, and thus removes an enormous and contentious burden for both scholars and IRBs.

Don't change a thing!

1. http://historycoalition.org/wp-content/uploads/2015/10/NCH-HHS-Human-Subjects-Proposed-Rule-10-30-15.pdf

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Does the NPRM Exclude or Exempt Ethnography? (2015-11-05 00:43)

Though I could not attend the October 20 Public Town Hall Meeting on the Federal Policy for the Protection of Human Subjects (Common Rule) Notice of Proposed Rulemaking (NPRM), I've now watched the whole thing on YouTube. Much of the day was spent discussing procedures for biospecimens, which is outside the scope of this blog. But I was interested to see Julia Gorey of OHRP reply to questions that had been sent in by two anthropologists, Lise Dobrin, co-author of the American Anthropological Association's 2011 comment on the ANPRM, and Edward Liebow, the AAA's executive director. Gorey frankly admitted OHRP's lack of expertise on ethnography but held out hope that ethnography may be exempt or even excluded under the NPRM's proposals.

In [1]Part 3 of the video recording, at minute 56, Gorey read's Dobin's question:

> DOBRIN (as ready by Gorey): The NPRM provides a list of activities that are excluded on the grounds that they do not count as research. These include journalism, history, and biography. Among the reasons given for exclusion of these fields is that they focus on particular individuals and they are generally carried out by practitioners of disciplines that have their own codes of ethics. On what grounds was this exclusion made?
>
> GOREY: The rationale here really hinges on the concept of generalizability. The line was what activities do or do not create generalizable knowledge. Ethnographic fieldwork, at least as we understand it, when

> we discussed it, generally involves drawing conclusions from groups or from communities, and not from individuals. However, no one from OHRP was willing to put forth themselves as an expert in the field of ethnography. So we would invite your comment on whether this or other fields of scholarship should be included in or outside of this exclusion.

The nasty thing about that last line is that in 2011, Dobrin already crafted a [2]thoroughly reasoned, eloquent comment on the ANPRM, in which the AAA called for IRB review to be restricted to biomedical research and experiments that depend on deception. In drafting the NPRM, OHRP and other agencies ignored this suggestion without explanation. So it's a bit insulting for Gorey to confess ignorance and then tell Dobrin to again spit into the wind.

Things get better at minute 59:35, when Gorey responds to Liebow:

> LIEBOW (as read by Gorey): The NPRM makes no mention of ethnographic field work, that is, interactive activities such as conversation, open-ended interviewing, collection of life histories, participant observation in everyday settings, by means of which investigators seek to understand social and cultural particularities. Where does ethnographic fieldwork fit in, in the categories of review?
>
> GOREY: This is a hard question to answer. It really depends on exactly what the activities are that are encompassed in that ethnographic fieldwork. There are certainly portions of it that could fit in the exclusion at 101.b.2.i. for research not involving interventions that also involve survey procedures, or interview procedures, or observations of public behavior. But it's also very likely that some of this research could be exempt under 101.e.1. [I think she must mean 104.e.1] for surveys or interviews if the subjects can be identified. Without knowing the specifics of really what's going on here, it's hard to be very granular in the response other to say there are different pigeonholes where the research could indeed fit.

If they dig deep enough in the NPRM's provisions, the anthropologists may find their freedom.

1. https://www.youtube.com/watch?v=YVFr-tK3hu8
2. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html

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More Balanced Instructions for IRB Members? (2015-11-08 16:29)

Simon Whitney, [1]critic of conventional handbooks for IRB members, is about to publish his own. Should be interesting.

[Simon N. Whitney, [2]Balanced Ethics Review: A Guide for Institutional Review Board Members, (Springer, 2015).]

1. http://www.institutionalreviewblog.com/2014/09/briefly-noted-whitney-bell-elliott.html
2. http://www.springer.com/us/book/9783319207049

Cliff Kuhn, 1952-2015 (2015-11-09 23:45)

I am sorry to learn of the death of [1]Clifford M. Kuhn, executive director of the Oral History Association. Among his many other contributions to the study of the past, Cliff was concerned with freeing oral historians from inappropriate regulation while championing ethical standards for their work. In recent weeks I had the pleasure to talk with him about our hopes for regulatory reform, and I deeply regret that those conversations cannot continue.

1. https://tropicsofmeta.wordpress.com/2015/11/09/atlanta-loses-its-greatest-listener-cliff-kuhn-1952-2015/

NPRM: Will Political Science Interviews Require Review? (2015-11-22 09:44)

What do we know about interview research under the NPRM?

Whatever its final provisions, the new Common Rule seems bound to be much harder to follow than, say, Canada's TCPS2. The proposed rule is full of cross references from one section to the next, and often to other documents, such as Subpart D or the Belmont Report. This makes it hard to figure out what it says about any given form of research.

Here's what I've been able to figure out about one form: interview research. My sense is that the NPRM proposes to eliminate IRB review for the vast majority of conversations between consenting adults, but it may unintentionally impose review on projects that do not merit it.

Excluded

The NPRM proposed rule would exclude:

1. "Oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected." [§ _.101(b)(1)(ii).]
2. Interviews with adults where the "information is recorded by the investigator in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects." [§ _.101(b)(2)(i)(A).]
3. Interviews with adults where "disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation." [§ _.101(b)(2)(i)(B).]

Note that § _.101(b)(2) excludes the second and third exclusions for subpart D, which governs research with children, which is why I've inserted "with adults." I wish the proposed rule relied less on difficult-to-follow cross references and more on plain English.

Earlier [1]I fretted that folklore had not gained an exclusion, but following [2]Julia Gorey's comments at the October 20 Town Hall, I am more optimistic that the vast majority of folklore projects would gain exclusion under § _.101(b)(2)(i)(B). Folklorists can correct me, but I wouldn't think that their projects would "reasonably place the subjects at risk of criminal or civil liability" etc. For instance, a project like the [3]Library of Congress American Folklife Center's Inauguration 2009 Sermons and Orations Project would be excluded from review.

Exempt

The proposed rule would exempt:

1. Interviews where "the information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects" and investigators "implement and maintain reasonable and appropriate safeguards as specified" by the Secretary of HHS. [§ _.104(e)(1); [§ _.105(a)]

In other words, if you promise confidentiality, you don't need IRB review, but you do need to take reasonable measures to keep that promise.

But what if you don't promise confidentiality?

What about public figures?

What about disciplines other than history and journalism, such as political science and law, that ask tough questions to be answered on the record? The NPRM scraps the special exemption for research on "elected or appointed public officials or candidates for public office" on the grounds that "it does not seem appropriate to single out this category of subjects for different treatment in this way." (80 FR 53951 {September 8, 2015 }). It neither offers the reasoning behind this conclusion, draws on 34 years of experience with the exemption, nor explains how interviews with public officials would be treated under the proposed rule. Would researchers need full IRB review to [4]interview members of Congress?

At the very least, the public official exemption should be preserved.

Better still would be an exclusion or exemption not only for public officials, but for all public figures. As [5]TCPS2 notes,

> Some research, involving critical assessments of public, political or corporate institutions and associated public figures, for example, may be legitimately critical and/or opposed to the welfare of those individuals in a position of power, and may cause them some harm. There may be a compelling public interest in this research. Therefore, it should not be blocked through the use of risk-benefit analysis. Such research should be carried out according to the professional standards of the relevant discipline(s) or field(s) of research.

What about public comment?

And what about requests for public comment, like the NPRM comment process itself? All Federal Register comments are now publicly posted, so they wouldn't be exempt. Could they be excluded under § _.101(b)(2)(i)(B)?

Perhaps the "reasonably" language is enough to exclude on-the-record interviews and requests for comment. But I would prefer to see specific exclusion for all on-the-record interviews with adults, whether concerning journalism, history, or any other subject. The federal government has no business policing these interactions.

1. http://www.institutionalreviewblog.com/2015/09/nprm-forgotten-folklore.html
2. http://www.institutionalreviewblog.com/2015/11/does-nprm-exclude-or-exempt-ethnography.html
3. http://www.loc.gov/folklife/inaugural/
4. http://dx.doi.org/10.1017/S0003055403000868
5. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

NPRM Comment Deadline Extended to January 6 (2015-11-24 19:34)

[1]OHRP has extended the deadline for NPRM comments until January 6, 2016. As a teacher with papers to grade, I applaud this extension.

1. http://www.hhs.gov/ohrp/newsroom/announcements/2015.html

4.11 December

My NPRM Response. Draft 1. (2015-12-07 14:45)

Though the deadline for commenting on the NPRM has been extended until January 6, I post here a draft of my comments in the hopes that they may help others craft theirs and send me feedback on mine.

Jerry Menikoff, M.D., J.D.

Office for Human Research Protections (OHRP)

Department of Health and Human Services

Dear Dr. Menikoff:

Thank you for the opportunity to comment on the September 8 notice of proposed rulemaking: Federal Policy for the Protection of Human Subjects, docket ID number HHS–OPHS–2015–0008.

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), and as the editor of the Institutional Review Blog, http://www.institutionalreviewblog.com, all of which were graciously cited in the NPRM.

Most recently, in November 2015, I participated as a panelist in the Chicago round of the workshops on "Revising and Expanding the Scope of the Common Rule," sponsored by the CTSA Consortium Coordinating Center (C4). I also offered assistance to the drafters of the comments on the NPRM submitted by the National Coalition for History, and I endorse those comments.

In addition, I wish to offer the attached observations, which reflect only my views and may not represent those of historians' organizations, George Mason University, or any other institution.

Comments on Notice of Proposed Rulemaking: Federal Policy for the Protection of Human Subjects

The proposed rule is designed "to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." So far as research in the social sciences and humanities is concerned, several of its provisions are likely to achieve these goals, so I applaud this effort and look forward to the final rule. However, I wish to draw attention to some of the limits of the proposals, particularly in the areas of due process protections, empirical research, and revision in the light of experience.

The Common Rule should be limited to the provisions of statutory law

- HHS and other regulatory agencies lack the authority to regulate research in the humanities and social sciences

The NPRM cites as its statutory authority 42 U.S.C. 289, which applies to "biomedical or behavioral research involving human subjects," and does not mention social science or research in the humanities. As the NPRM acknowledges, "some of the commenters [on the ANPRM] recommended that the definition of research be focused more explicitly by being limited to 'biomedical and behavioral research,' in accordance with the statutory provision underlying the Common Rule." But it makes no effort to focus the definition or to explain why the drafters felt comfortable ignoring this part of the statute.

The Common Rule should be restricted to the biomedical or behavioral research involving human subjects as provided for by the statute.

- HHS lacks statutory authority to regulate research not directly funded by the Public Health Service

42 U.S.C. 289 requires IRB review of research supported by a "grant, contract, or cooperative agreement under this chapter." When the 1981 version of 45 CFR 46 was promulgated, the Federal Register notice explained,

> 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. (46 FR 8369)

The NPRM reverses that interpretation and "proposes an extension that would ensure that clinical trials are covered by the Common Rule if conducted at an institution in the United States that receives federal support for non-exempt and non-excluded human subjects research, regardless of the funding source of the specific clinical trial." It acknowledges that ANPRM comments "argued that such a change was an overreach of federal oversight and constituted an unfunded mandate." But it offers no legal analysis of why regulators have rejected public concern and the legal reasoning of previous HHS counsel.

If HHS wishes to regulate clinical trials regardless of the funding source of the specific clinical trial, it should suggest that change to Congress. Under current law, HHS has no authority to impose this regulation.

The proposals for interview research are helpful but incomplete

- Oral history, journalism, biography, and historical scholarship should be excluded

The proposed rule would "explicitly exclude oral history, journalism, biography, and historical scholarship." This is a welcome change and addresses the concerns put forth by historians and journalists since the first imposition of IRB review on their work in the 1990s. I endorse the comments provided by the National Coalition for History:

> We concur with this recommendation of full exclusion of such activities from IRB oversight. It reflects an appreciation that these activities should not be evaluated under frameworks originally designed with the sciences in mind. It recognizes the value and attributes of these forms of scholarship. It eliminates any ambiguity about review, regulation and enforcement, and thus removes an enormous and contentious burden for both scholars and IRBs.

- Oral history, journalism, biography, and historical scholarship should not be subject to the Belmont Report

The NPRM states that "All investigators performing excluded studies are expected to act in a way that is consistent with the principles outlined in the Belmont Report, even if the Common Rule does not impose requirements on excluded work." This is inconsistent with the NPRM's acknowledgment that "these fields of research have their own codes of ethics." Historians, journalists, and biographers are not ethically obligated to do no harm to the people they study, so the Belmont Report is a poor guide for their work.

- Other on-the-record interviews should be excluded

Scholars in law, political science, folklore, and other fields also frequently "focus directly on the specific individuals" they study, and conduct interviews, correspondence, or other forms of interaction with these individuals. OHRP itself conducts such studies when it solicits public input on its proposals; all comments on the NPRM provide information about individuals obtained through interaction, yet they are not nor should be subject to IRB review.

When interviews and other interactions are on the record, with the expectation that participants' real names will be used in any resulting study, the federal government has no business regulating the exchange of information and ideas between consenting adults.

At its December 4 meeting, the Secretary's Advisory Committee on Human Research Protections discussed modifying this provision to exclude all scholarship that focus directly on specific individuals selected for their particular knowledge about a subject. I would welcome such a change.

- Rules on ethnography must be clarified

Neither the NPRM nor the proposed rule uses the term "ethnography," and it is unclear how the rule would affect that practice.

At the October 20 Public Town Hall Meeting, Julia Gorey responded to a written question from Edward Liebow of the American Anthropological Association by suggesting that a great deal of ethnography could be excluded under section 101.b.2.i. or exempt under 104.e.1. Yet this is presumably further qualified by the proposed § _ _ _ _.101(b)(2), which limits the exclusion's application to subpart D, i.e., research with children.

Ethnographers deserve more clarity. If provisions for ethnography are to be split among multiple parts of the rule, with further cross-references to Subpart D, OHRP should work with the American Anthropological Association, the American Sociological Association, and other scholarly organizations to craft a guidance document specifically for ethnographic research.

The Common Rule should increase the transparency of the review process

The NPRM proposes "public posting of consent forms … to increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the development of future consent forms." This is a step in the right direction, but it is too limited.

Rather than posting only final consent forms, the federal site should allow researchers to post their proposed consent forms, so that the public could see the kinds of changes demanded by IRBs.

Better still would be the collection and posting of proposals and IRB decisions. 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].

This is as true today as it was in 1973, despite repeated calls for IRBs to base their decisions on evidence and precedent, and a small pilot project by the University of Otago. (See Alexander Halavais, "Social Science: Open Up Online Research," Nature 480 (8 December 2011): 174–175,doi:10.1038/480174a; Robert Klitzman, "Who Polices the 'Ethics Police'?," CNN, May 26, 2015; Tolich, Martin, and Emma Tumilty. "Making Ethics Review a Learning Institution: The Ethics Application Repository Proof of Concept. Tear.otago.ac.nz." Qualitative Research (January 3, 2013). doi:10.1177/1468794112468476.)

The revision of the Common Rule offers an opportunity to increase transparency, enhance confidence in the research enterprise, and increase accountability by disseminating knowledge in the form proposed by Katz. This should not be limited to finalized consent forms.

The proposed rule should require appeal mechanisms

The 2011 ANPRM proposed "a requirement that every institution must provide an appropriate appeal mechanism." Such a provision could help provide transparency and accountability to the IRB process.

An appeals process is already included in Canada's TCPS2 (articles 6.18 and 6.19), and it was recommended by the National Research Council's 2014 report, _Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences (Recommendation 6.3).

The NPRM fails even to mention appeals, dismissing the NRC recommendation without reason. The final rule should restore the requirement for an appeals mechanism.

Common Rule agencies should sponsor ongoing empirical research and use it future regulatory revision

Questions 27 - 32 asks the public to speculate on the prospect of an “automated exemption decision tool.”

This should be a matter of empirical knowledge, not mere speculation. In October 2009, OHRP stated that “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… . 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.” ([1]https://web.archive.org/web/20091016101015/http://www.hhs.gov/ohrp/policy/exempt _res _det.html.) So we should have six years of data on the workings of these tools. We do not.

OHRP has failed to encourage institutions to experiment with such promising procedures or to fund studies about the effectiveness of various alternative systems. Rather than continuing to rely on guesswork, the Common Rule agencies should jointly sponsor empirical research to learn what does and does not work in ethics review. This concerns not only the exemption decision tool, but all manner of human subjects research oversight.

Explaining the ANPRM to the Presidential Commission for the Study of Bioethical Issues in August 2011, ANPRM architect Ezekiel Emanuel stressed his wish for a “risk-based review process” and “a learning process that would be constant and dynamic to reflect actual risk” rather than what he termed “gut reactions … which is worthless.” Whether through a provision in the new rule or another mechanism, Common Rule agencies should institute such a learning process.

Common Rule agencies should provide prompt, clear guidance in response to the questions about regulation

Question 73 asks, “Will the proposed language at § _ _.101(j) be effective in achieving greater harmonization of agency guidance, and if not, how should it be modified?”

HHS has failed its statutory responsibility to “establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.” (42 U.S. Code § 289)

While OHRP sporadically issues interpretations, these are few and insufficient. As Robert Klitzman has documented in his book, The Ethics Police?, when IRBs seek help from OHRP, officials there “essentially just read back the regulations” or offer “vague generalities.” (p. 185)

The proposed language offers little hope for a remedy. Indeed, by demanding consultation among so many federal agencies, it threatens to slow an already deficient guidance system.

By contrast, Canada’s Panel on Research Ethics offers relatively prompt, clear guidance in response to the questions it receives. The Common Rule agencies need to follow this model and establish an interagency panel, staffed with experts in all forms of regulated research, who can offer prompt, authoritative, precise guidance on matters of regulatory interpretation.

Common Rule agencies should release the next ANPRM within eight years

The NPRM promises that the list of activities deemed minimal risk will be updated “at least every 8 years.” While that’s helpful, it also suggests that the NPRM framers do not expect that the rest of the regulations will be regularly

revised, or at least not more frequently than once a generation.

That is a disappointment. Canada has shown the value of more frequent revision, with a wholesale revision after 12 years, and a significant update after only four. The United States should follow this model by collecting data on the workings of the new rule and planning an ANPRM eight years from the promulgation of the new rule, in order for revisions to take effect within 12 years of the new rule.

1. https://web.archive.org/web/20091016101015/http://www.hhs.gov/ohrp/policy/exempt_res_det.html

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Protecting He-Man Subjects (2015-12-09 22:57)

After frustrating encounters with IRBs concerning two research projects, sociologists [1]Liberty Walther Barnes and [2]Christin L. Munsch argue that "IRBs are gendered institutions in which members base their decisions on culturally dominant, normative images of women and men."

[Liberty Walther Barnes and Christin L. Munsch, "The Paradoxical Privilege of Men and Masculinity in Institutional Review Boards," Feminist Studies 41, no. 3 (2015): 594–622, [3]doi:10.15767/feministstudies.41.3.594.]

Barnes and Munsch set out to study men, not ethics reviewers. But, they report, their "research programs were perceived by IRBs to expose men's private failures, personal feelings, and vulnerabilities. By proposing such topics, we inadvertently conducted an ethno-methodological study of IRBs," with each IRB letter revealing the assumptions and anxieties of the members and staff of the eight IRBs to whom they submitted protocols.

Boys Don't Cry

Barnes wanted to understand the experience of male infertility through participant observation and interviews with members of an infertility education and advocacy organization. Similar work about women had flown through IRBs, but not this study, in large part because the IRB was worried that the men might cry during the interviews.

> During a telephone conversation with one IRB analyst, the first author learned that what she had initially listed as a study benefit—the opportunity for men to share their feelings about infertility—the IRB perceived as a risk. Per the analyst's instructions, the informed consent forms were revised to read: "Should you feel uncomfortable for any reason, I will immediately stop the interview. You will have the option to terminate the interview, and/or have any particular answer expunged from the record." This is fairly common verbiage for IRB consent forms. Additionally, however, the analyst advised the researcher to include instructions for managing discomfort, which should entail stopping the interview if a man began to cry, allowing him to regain composure, and then asking him if he would like to terminate the interview or continue. Later, after expanding the study to include five hospital clinics, an IRB analyst at one hospital amended the consent form to read: "The risks of the study may include loss of confidentiality, or feeling uncomfortable or embarrassed. There is a risk that some of the questions may make you feel emotional and may make you cry."
>
> Giving notice about what may or may not occur, stopping interviews, and giving subjects the opportunity to recant statements were required protocol steps intended to demonstrate respect for subjects' emotions and privacy. However, such attempts at "managing discomfort" simultaneously signaled to participants

> that they needed to manage their emotional expressions. By listing "feeling emotional" and "crying" as explicit risks of participation, the consent form conveyed to participants that these behaviors are undesirable and should be avoided. Asking upset participants if they wished to terminate the interview also served to socialize men to control their emotions and suggested that they should feel ashamed when they fail to do so. Such modifications perpetuate the norm that men should maintain composure; additionally, they illuminate the implicit norm that others share in the social responsibility of preventing men from humiliating themselves in front of others by sharing tender feelings. Incidentally, this requisite prescription for managing discomfort biased the data: the goal of the proposed research was to better understand how men emotionally and cognitively process their infertility, but the IRB restricted which emotions could be expressed by participants.

Barnes soldiered on, achieving an 80 percent response rate. Moreover,

> many men expressed gratitude for the opportunity to participate. No participants withdrew from the study or requested to have their data expunged from the record. Most participants were very genuine and forthcoming about their medical experiences. In fact, many participants felt reassured to learn they were not the "only guy" struggling with infertility. On two occasions, in accordance with the revised research protocol, the investigator stopped interviews because respondents began to cry. Both men requested that the interview continue: they had more they wanted to share.

Doctors Aren't Human

In addition to interviewing patients, Barnes wanted to "shadow urologists specializing in male infertility and observe their interactions with patients." Here, again, the IRBs rode to the defense of privilege.

> When the first author [Barnes] listed medical doctors as research subjects on applications to the biomedical IRB committees, she was repeatedly informed that "Doctors cannot be research subjects." In fact, IRB analysts explicitly stated that they could not imagine a circumstance in which a medical doctor could be a human research subject, nor did they believe one could study culture through ethnographic research in US hospitals. Consequently, in order to gain access to her field sites, the investigator was required to list the doctors she shadowed as the Principal Investigators of her study and herself as the Co-Principal Investigator. She was also required to remove any part of the research protocol that said she would observe or interview the male-infertility specialists she shadowed during the study, a group of prominently white, upperclass, middle-aged men. The doctors' protected status as lead researcher meant that she could not claim to critically evaluate what she observed or heard from them. She was effectively directed by IRBs not to examine clinical practices as cultural practices, but to accept clinical practices and doctors' actions and interactions as the indisputable normative standard for medical care and as scientific practices uninfluenced by culture. Medical doctors' elevated status above the critical lens of social scientists demonstrates how biomedical IRBs operate to protect masculine institutions and authorities.

Girlie Men Got No Reason to Live

Part of Barnes's trouble seemed to come from working with hospital IRBs that lacked any concept of ethnography. Munsch, by contrast, sought to conduct relatively standard psychological experiments, but she too ran into resistance.

Munich wanted to study "'gender identity threat' to examine how people behave when their status as a man or woman is called into question." She would ask undergraduates to complete a survey that would allegedly produce a "gender identity score," though the actual number the subject received was random. "After receiving the gender identity-confirming or disconfirming feedback, participants would then read vignettes about ethically questionable

situations, including instances of sexual violence, and were asked their opinions about the players in each. At the conclusion of the activity, participants would be fully debriefed and learn that their gender identity scores were randomly determined and not valid."

Though “virtually identical research” had already been approved by the IRB, the IRB feared that the subjects could become upset, or worse. The IRB wrote to Munsch that

> one potential concern relates to the baseline incidence of suicide on campus and the impact that such “gender confused” feedback might have on certain participants. Is anything known about the propensity to commit suicide in the target population whose gender identity has been threatened? In this regard, whether this study poses a larger than normal risk remains
> unclear.

Eventually the IRB approved the study, but only after insisting on so much debriefing that participants could not take it seriously:

> In order to garner IRB approval, the debriefing script was revised to reiterate a total of seven times that the gender identity score participants had received was invalid. While the intention of the IRB was to ensure that participants understood the deceptive nature of the study, this repetition conveyed to participants that femininity among men, and masculinity among women, is nonnormative and undesirable. The debriefing script continued, “Do you feel upset by the feedback we gave you on the gender identity survey?” The question implied that participants might, and perhaps should, feel upset, socializing participants to feel shame about personal associations with the opposite gender. Moreover, assuming some participants would be upset, the IRB required that the debriefing protocol include information for obtaining a referral to the university counseling and psychological services, indicating that participation in the study could be emotionally distressing for participants. Notably, throughout the duration of the study, no participants required a referral to counseling services.
>
> Not only do scripted interactions socialize women and men and reify gender stereotypes, they also disrupt experimenter rapport. A number of participants began to laugh or question the investigator (e.g., “Are you serious?”) in reaction to the lengthy and repetitive debriefing script. Because the interactions often became uncomfortable, the investigator began to explain, “I know this is repetitive, but I am required to read this to you.”

It’s Not Just the Sex. It’s the Gender

Other scholars, such as [4]Brian Mustanski, [5]Carey Noland, and [6]Janice Irvine have shown how prudish IRBs have inhibited research on sexuality, especially concerning sexual minorities.

Barnes and Munsch break new ground in their emphasis not on sexuality, but on masculinity, and the ways that IRB requirements reinforce traditional gender norms by depicting any departure from those norms as a risk of research. As Barnes and Munsch explain,

> The committees’ concerns regarding the “sensitive subject” matter and the potential to “upset” participants across each of our studies reflects IRB reviewers’ own assumptions that infertility and associations with femininity are traumatizing. Moreover, the committees’ requirements to revise the first author’s interview

> questions and for the second author to "behave normally" were admonitions not to acknowledge that infertility might be challenging or that feminine feedback might be embarrassing. Rather than allowing us to empirically examine men's feelings regarding infertility and the consequences of masculinity threat, IRB members prioritized what they believed to be their responsibility, as well as the responsibility of researchers: to validate and shore up feelings of masculinity in men.

1. http://libertybarnes.com/
2. http://sociology.uconn.edu/munsch-2/
3. http://dx.doi.org/10.15767/feministstudies.41.3.594
4. http://www.institutionalreviewblog.com/2011/05/sex-researcher-calls-for-evidence.html
5. http://www.institutionalreviewblog.com/2012/12/northeastern-u-irb-makes-sex-research.html
6. http://www.institutionalreviewblog.com/2012/07/sociologists-of-sexuality-voice-irb.html

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Blog Day (2015-12-12 11:22)

The Institutional Review Blog is [1]nine years old today. It continues its original mission of aggregating news and commentary about IRB review of research in the humanities and social sciences, such as [2]Wednesday's report of an article from Feminist Studies. And it has never been closer to its goal of [3]regulatory reform.

1. http://www.institutionalreviewblog.com/2006/12/introduction.html
2. http://www.institutionalreviewblog.com/2015/12/protecting-he-man-subjects.html
3. http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html

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George Mason University Frees Oral History (2015-12-18 12:41)

George Mason University, my employer and my home, has issued a new [1]Standard Operating Procedure (SOP) on Histories and Journalism, modeled closely on the excellent policies at [2]Columbia and [3]University of California, San Diego.

The Mason procedure states:

> Many projects involving histories or journalism methods are not likely to meet the definition of "research" stated in the Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects at 45 CFR Part 46, Subpart A: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Projects that do not meet this definition do not need to be submitted to the IRB for review.
>
> Historians and journalists typically use collected information to explain past or current events but not to create theories, principles, or statements of relationships that are predictive of future events or that can be widely applied. Such activities would not be considered "generalizable knowledge."
>
> However, when projects at Mason are, in fact, designed to develop or contribute to generalizable knowledge, such projects must be submitted to ORIA. Upon submission, such projects may be granted exemption from IRB review, handled through the expedited review process, or reviewed by the full IRB,

as appropriate.

> Oral history projects conducted by, or under the supervision of, Mason faculty, staff or students should be conducted in accordance with the guidelines established by the Oral History Association Principles and Best Practices. Journalism projects conducted by, or under the supervision of, Mason faculty, staff or students should be conducted in accordance with the Society of Professional Journalists Code of Ethics. A flow chart and examples, intended to be helpful in this evaluation, are provided at the end of this SOP.

I do hope that revisions to the Common Rule will relieve individual universities of the need to write such policies. While we wait, however, I am grateful to the good people at Columbia and UCSD for pointing the way, and to all those at Mason who showed their commitment to [4]Freedom and Learning.

1. http://oria.gmu.edu/wp-content/uploads/2014/04/SOP_1.2.1-Histories-Case-Studies-Investigative-Journalism.pdf
2. http://www.institutionalreviewblog.com/2007/12/columbia-university-grants-oral-history.html
3. http://www.institutionalreviewblog.com/2014/07/ucsd-frees-oral-history-and-journalism.html
4. http://vision.gmu.edu/the-mason-vision/

In NPRM Comments, Historians Applaud Proposed Rule (2015-12-28 08:44)

In addition to the formal comments from the National Coalition for History, endorsed by other scholarly associations, individual historians have begun submitting comments on the notice of proposed rulemaking. Without exception, they endorse the proposal to free oral history from IRB review. The only opposition comes from a professor of education and psychology who seems to suggest that tribal governments should hold veto power over oral history research.

Here are some of the highlights, alphabetical by last name. I have edited some for brevity. Full comments can be found at [1]http://www.regulations.gov/ #!documentDetail;D=HHS-OPHS–2015–0008–0001

Anonymous Anonymous

“My mother is 77 years old and lives with me. Yet campus IRB required me to get their permission to talk to her about the project (which included asking her questions as I went through church records). If that doesn’t indicate the idiocy of requiring IRB approval for history research projects, I don’t know what does.”

Janice Brockley

"The requirements for IRB review at my university have been taken to include student research, even that conducted in undergraduate classes. To avoid the paperwork, I do not give my students oral history interview assignments, even simple ones like interviewing relatives about their experiences during historical events. Another faculty member has told me that she restricts her students to interviewing one another when training them in oral history techniques. Graduate students are reluctant to include oral history interviews in their thesis research due to the time constraints imposed by the requirement of applying to the IRB.

“For historical scholars like myself, the difficulty lies in translating our research and goals into the mindset of the IRB forms and regulations. I can’t explain my statistical models, not having any, and my research does not have specific, replicable social benefits. Further some of the requirements, like preserving records for a minimum of three

years can be counterproductive. If an interviewee changes their mind about an interview, this requirement prevents the interviewer from protecting their subject's privacy by destroying the recording. The required ethical training has limited application to the actual ethical dilemmas oral historians face. It also seems counterproductive to burden IRB boards, who, at least at my institution, are primarily scientists, with monitoring work that follows such a different paradigm, particularly given their heavy workload."

Erin Conlin

"As an oral history practitioner and instructor, I strongly recommend the Department of Health and Human Services exempt oral history from the IRB process. As a field we have developed a very strong code of ethics, including informed consent, which is a central tenet of the practice. The Oral History Association, the premiere national professional organization for oral historians, is committed to maintaining the highest standards and training new oral historians in those methodologies. Our "best practices" are widely respected, followed, and in line with traditional IRB requirements. Therefore, additional IRB certification is superfluous."

Melinda Gormley

"I would like to see the wording changed to phrasing along the lines of the following options.

"Oral history and journalistic interviews, biographical and historical scholarship, and other research activities that focus directly on the specific individuals about whom the information is collected.

"Activities that focus directly on the specific individuals about whom the information is collected such as oral history interviews, journalistic interviews, biographical scholarship, and historical scholarship."

Chris Green

"I have found the important goals and processes of the IRB, while crucial for their intended purpose, to miss the mark of the work being done with oral histories, as has been so well articulated time and time again. "

Jacquelyn Hall

"As the founding Director of the Southern Oral History Program at the University of North Carolina at Chapel Hill, I want to register my resounding approval of these revisions excluding oral history from review by institutional review boards."

Erin McCoy

"Abolishing the IRB requirements for Oral History projects would allow for more student research in the field, and would encourage humanities initiatives to be more creative and interesting. Of course, the OHA has recommendations and data regarding the preservation, documentation, and privacy rights for those participating in these projects, and I am fine with following them as opposed to the IRB process."

Todd Moye

"I have been a practicing oral historian for roughly twenty years. I have directed a university-based oral history program for the past ten, and I previously directed an oral history project as a historian for the National Park Service. In all of these roles–as a graduate student, public historian, federal employee, and academic administrator–I have relied on the Oral History Association's 'Principles and Best Practices,' which are applicable to the work of oral

historians in a way that human subject research protocols frankly are not. ”

Troy Reeves

“As a professional oral historian since 1999, including the last 8.5 years at a university with an Institutional Review Board. While I have submitted several of our projects (and advises others who have submitted theirs) to the IRB, I’ve felt it hampered doing oral history on campus more than helped it… . While I feel that IRBs have and do serve a valuable purpose on campuses, the humanities have never fit into the IRB’s focus.”

The dissenter: Apanakhi Buckley

The one dissenting comment comes from [2]Apanakhi Buckley of Heritage University. Not a historian, but rather an professor of education and psychology, Buckley writes that her IRB “is concerned about the protection of indigenous populations. While oral histories are usually benign, indigenous people have been vulnerable to historians and anthropologists taking their histories and using them without gaining tribal permission. Tribal group rights have been recognized in code (e.g. the Indian Child Welfare Act). Collecting oral histories may be tantamount to cultural appropriation, which constitutes more than minimal risk and yet may not be protected by the ethics of the bodies such as the Oral History Association.”

Buckley offers no examples of oral histories that “may be tantamount to cultural appropriation.” I can point her to occasions where university or tribal ethics boards in Canada and the United States [3]muted dissenting voices, [4]suppressed investigation of labor conditions, or [5]silenced indigenous voices entirely.

1. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2015-0008-0001
2. http://www.heritage.edu/FacultyStaff/CILTResourcesforFaculty/FacultyResearchScholarshipSeries/DrApanakhiBuckley.aspx
3. http://www.institutionalreviewblog.com/2007/01/nancy-janovicek-offers-canadian.html
4. http://www.institutionalreviewblog.com/2007/12/law-society-review-continued.html
5. http://www.institutionalreviewblog.com/2010/08/after-lawsuit-arizona-state-irb.html

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I Agree With PRIM&R on Something **(2015-12-28 14:16)**

PRIM &R has posted its [1]draft comments on the NPRM. I have found something to agree with.

PRIM &R writes:

> Over the past 25 years, the difficulty of getting all of the agencies to agree on the Common Rule was cited as the grounds for concluding that changing any provisions would require a Herculean effort. It may well be that revising the entire Common Rule at once is a task that can only be undertaken once in a generation.
>
> But if the current NPRM, issued four years after the ANPRM to revise the Common Rule (July 26, 2011), underlines how daunting a comprehensive revision can be, it also shows that the best, evidence-based revisions will not emerge from a process that tries to make all needed revisions at once. By perpetuating the view that regulations cannot be revised when needed, the current approach risks locking in place for another 25 years a number of provisions in the NPRM that even its most enthusiastic supporters admit

are flawed in important ways.

> Instead, we recommend that the relevant agencies pursue an issue-by-issue approach in which it is possible to "drill down" on an issue, to consider all the sections of the regulations where it arises and all the evidence that is available—and that is needed—to resolve it well. Further, the agencies should address each issue more openly, developing and relying upon evidence, and allowing consensus to emerge and revisions to be crafted that will work well for all stakeholders. This approach would not only produce better results, but would signal that, once adopted, any provision can be changed if it does not work as well as intended.

[2]Yes, indeed.

I don't go so far as to agree with PRIM &R that the proposed rule should be scrapped. Historians have already waited too long for their freedom. But even the best rules deserve reexamination more frequently than once every 25 or 35 years.

I would also note that [3]PRIM &R embodies the system's longstanding failure to consult "all stakeholders." If PRIM &R is serious about that phrase, it should endorse the [4]American Anthropological Association's call for "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) … tasked with developing alternative guidance appropriate for their fields."

1. http://www.primr.org/WorkArea/DownloadAsset.aspx?id=10166
2. http://www.institutionalreviewblog.com/2015/12/my-nprm-response-draft-1.html
3. http://www.institutionalreviewblog.com/2007/05/prim-public-responsibilities.html
4. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html

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PRIM&R and SACHRP Attack Social Science Exclusion (2015-12-31 16:12)

In their comments on the NPRM, SACHRP and PRIM &R oppose the proposed exclusion of "Research, not including interventions, that involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) uninfluenced by the investigators" (§ ll.101(b)(2)(i)); they want such research to be moved from the excluded to the exempt category. But they differ in what they think the consequences of such a move would be; SACHRP thinks that researchers would face low barriers, while PRIM &R sees a chance for its members to continue to exert more control than is authorized by regulations. Both groups fail to represent the researchers most likely to conduct these kinds of studies.

Fears of interview trauma

Since the exclusion would only apply to research with a low risk of privacy breach, either because the subjects could not be identified or because the information they share is not sensitive, PRIM &R and SACHRP attack it on the grounds that risks other than privacy are at stake.

[1]PRIM &R's draft comments explicitly worry that interviews are traumatic:

> Comprehensive ethics review of the sort envisioned in the Belmont Report requires thoughtful and experienced individuals to weigh the benefits and harms of each research project in terms of beneficence, justice, and respect for persons. Consider, for instance, a study in which college-aged victims of sexual trauma suffering from post-traumatic stress disorder are interviewed about their experience. Under the proposal at § _ _.101(b)(2)(i), this study may not be subject to the regulatory requirements of the Common Rule if the data are not recorded in an identifiable manner or if the researcher determines that disclosure of "responses outside the research would not reasonably place the subject at risk of criminal liability or be damaging to the subject's financial standing, employability, reputation, educational advancement, or reputation" [§ _ _.101(b)(2)(i)]. However, research only involving "interviews" often raises ethical questions beyond these privacy concerns, such as whether subjects will be recruited in a setting and in a manner that enables them to decline study involvement, whether subjects will receive sufficient information about the nature of research interview before being asked to make a decision to participate, whether the interviewers are appropriately trained to work with victims of sexual violence, whether there is a plan in place to address imminent risk associated with depression, substance use, or suicidal ideation if it emerges during the course of the interview, and whether the research is designed in a way that ensures its results will be useful.

[2]SACHRP's comments (inexplicably submitted anonymously to the HHS docket, and [3]not posted on SACHRP's website) are vaguer. In calling for "educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) uninfluenced by the investigators" to be moved from "excluded" to "exempt," SACHRP notes only that "there may be issues involved beyond privacy and confidentiality concerns."

The December 2015 SACHRP meeting, however, suggests that SACHRP too is fretting about people made to feel bad by talking. As David Forster explained the reasoning of the relevant subcommittee, "there's more risk involved in these types of research studies than just a confidentiality breach. There might be psychological harm, other types of harm that would not be considered under the application of the privacy act or HIPAA." ([4]SACHRP meeting, 4 December 2015, about 1:42).

These are not wholly fantastic concerns. As Michael McDonald, Susan Cox, and Anne Townsend note in their chapter, "[5]Toward human research protection that is evidence based and participant centered," interviews can leave participants sad or upset, even without any risk to their privacy.

There is scant evidence, however, that these risks are much greater than those encountered in daily life. As [6]Robert Dingwall notes, "Distress may be as easily provoked by a drama, a novel, a movie or a conversation overheard on a bus. A former colleague with a long and unsuccessful history of struggle with her own lack of fertility once told me how she was distressed every day by walking past the campus nursery and by the department's celebrations of new babies born to younger faculty members. This is recognized by the reform. Regulation is disproportionate when it does not add to a participant's own experiences of managing everyday psychological challenges."

Failure to consider the consequences

In calling for interviews to be "exempt," rather than excluded, SACHRP seems not to have considered the full impact of its recommendations. At the December meeting, SACHRP members, Nancy M. P. King in particular, seemed to believe that making an activity "exempt" would simply require a researcher to spend a few minutes online completing the determination tool. I doubt she has considered the conundrum this poses for [7]ethnographers, for whom all of life may be one rolling interview. Should they complete the determination tool each morning, before brushing their teeth?

PRIM &R at least offers a more realistic assessment of the difference between exclusion and exemption under the proposed rule. Excluded would mean exempt, while exempt might well continue to mean non-exempt. As [8]PRIM &R explains:

> Currently, research projects like [the hypothetical "study in which college-aged victims of sexual trauma suffering from post-traumatic stress disorder"] may be eligible for an exemption under 45 CFR 46.101(b)(2). At most institutions, this means that an experienced IRB staff person will review the study to determine whether it meets the exemption criteria and to weigh any other regulatory or ethical considerations that the research may raise. Through this process, many of the considerations outlined above, as well as those related to ensuring subject privacy, are evaluated and institutional oversight is established. If the reviewer determines that the research raises significant concerns, it may be subject to further consideration or oversight …
>
> PRIM &R … believes that, as is current practice, exempt research should be subject to some level of institutional review and oversight.

In other words, PRIM &R admits that IRB staff members, many of them certified by PRIM &R, are regularly subjecting exempt research "to further consideration or oversight," that is, to make it non-exempt, [9]delaying it for days, weeks, or months; [10]imposing heavy burdens, and [11]reducing participation. I can't say I'm surprised; in recent years, [12]PRIM &R has been generally dismissive of exemptions. But I'm not sure I've seen so bald a statement of its position that IRB staff should be able to demand oversight of projects that are eligible for exemption.

Unsurprisingly, PRIM &R offers no evidence that IRB staff or members are any good at training investigators or helping devise reasonable plans, and it ignores the harms of IRB review, such as [13]stunted research, [14]reinforced stereotypes, [15]exaggerated fears of interview trauma, and the [16]denial of opportunity to people who would benefit from conversation. PRIM &R claims to advocate "evidence-based revisions" to the regulations. But where is the evidence to support its own recommendations or current practices?

Ethical imperialism at work

Both sets of comments show the problem, now half a century old, of denying one set of researchers a voice in recommendations about their methods of research. HHS has repeatedly failed to appoint an ethnographer to SACHRP, so when a well-meaning bioethicist like King starts talking about exemption as if it were no barrier to research, there is no one in the room to point out to her the effect her recommendation would have on ethnography, participant observation, and the like, or to relate the horror stories that the existing system generates. And [17]PRIM &R's Public Policy Committee, which prepared the NPRM comments, of course does not include any qualitative social scientists or scholars in the humanities. [18]Because it's PRIM &R.

Robert Levine, who served as a consultant to the National Commission, has [19]lamented that that body had failed to consider the rights and responsibilities of social scientists. "Sociology, anthropology, education and other vast areas of research were left out," he told an interviewer. "The Commission made some passing statements that have been interpreted as being relevant to social and behavioral research, but they did not look into it thoroughly." Forty years later, as a member of the PRIM &R policy committee, he is making the same mistake.

1. http://www.primr.org/WorkArea/DownloadAsset.aspx?id=10166
2. http://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-0570&attachmentNumber=1&disposition=attachment&contentType=msw12
3. http://www.hhs.gov/ohrp/sachrp/commsec/index.html
4. http://videocast.nih.gov/summary.asp?Live=17710&bhcp=1

5. https://books.google.com/books?id=_oYIBAAAQBAJ&dq
6. http://www.socialsciencespace.com/2015/12/common-rule-revision-the-ethics-police-fight-back/
7. http://www.sscnet.ucla.edu/soc/faculty/katz/pubs/UndergroundEthnographersDraft.pdf
8. http://www.primr.org/WorkArea/DownloadAsset.aspx?id=10166
9. http://www.institutionalreviewblog.com/2011/07/u-of-michigan-reports-some-progress.html
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11. http://www.institutionalreviewblog.com/2010/03/irb-warns-that-opinions-may-vary.html
12. http://www.institutionalreviewblog.com/2014/01/exemptions-dont-come-to-prim-mind.html
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16. http://www.tandfonline.com/doi/abs/10.1080/07481187.2011.553310#.VoVj5pMrKas
17. http://www.primr.org/about/committees/
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NPRM: How to Exclude Journalism? (2015-12-31 16:21)

Few if any argue that journalists should be required to submit their work to IRB review. Some IRB apologists think [1]journalism is too important to bear restriction, while others consider it so full of "[2]blatant bias and even hyperbole" that it doesn't deserve the dignity of review. But all participants in the debate, at least in United States, seem uncomfortable with the idea of subjecting journalists to [3]prior restraint.

The question, as always, is how to draw the line between journalism and regulated forms of conversation. The NPRM's proposed rule attempts to do so with a specific exclusion for "Oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected." Will that suffice?

Neither the NPRM's language nor SACHRP's proposed replacement is quite right, so let me suggest an alternative.

In his [4]NPRM comments, Charles Seife, professor of journalism at NYU, fears that it will not. He writes,

> I believe that it is incorrect to modify or define "journalism" in such a manner. Much journalism does not "focus directly on the specific individuals about whom the information is collected." Journalists routinely gather information from and about individuals who are not the direct focus of our work. But the plain-language interpretation of the regulation as written would raise questions about whether, for example the following journalistic activities would be excluded from oversight:
>
> - Interviewing a whistleblower for a story about a corporation's malfeasance
> - Interviewing a editor for a story about a plagiarized paper that appeared in a scientific journal
> - Interviewing a scientist for a story about another scientist's work
> - Conducting a survey to gather opinions about a political race

- Analyzing government personnel records to determine how agency inspectors go about their jobs

In each case, the journalist would be gathering information from and about human subjects, yet the focus of the activity in each case is not upon the individuals about or from whom the information is collected.

The language of the final rule should make clear that journalism – without qualification – is excluded from the definition of research. Such an exclusion is the proper thing to do, ethically as well as legally.

OK, but how to exclude journalism without qualification? I see three basic options.

1. Eliminate IRBs entirely. Let's face it: [5]they don't work. Alas, this is not on the table.
2. Restrict the Common Rule to its statutory authority over "biomedical and behavioral research." This is Seife's preference, and it's a great idea. Unfortunately, it's not one the NPRM contemplates. To the contrary, [6]the NPRM's proposed rule would take us further from the statute.
3. Tinker with the proposed rule.

SACHRP recommends option 3. In its [7]comments, it proposes modifying the proposed rule to exclude:

Oral history, journalism, biography, historical, and other scholarship activities whose purpose is to collect and share evidence-based portrayals of specific individuals who have been selected as a result of the relevance of their personal experience to the phenomena being studied.

This is not quite right, since, as Seife points out, history and journalism interviews do not merely collect portrayals of the people being interviewed, but also other information known to specific individuals. A better exclusion would be for

Oral history, journalism, biography, historical, and other scholarship activities whose purpose is to collect and share information from specific individuals who have been selected as a result of the relevance of their personal experience to the phenomena being studied.

1. http://www.institutionalreviewblog.com/2007/08/james-weinsteins-anti-intellectualism.html
2. http://www.institutionalreviewblog.com/2012/05/berkeley-historian-defends-irb-review.html
3. https://www.rcfp.org/category/glossary-terms/prior-restraint-0
4. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2015-0008-0009
5. http://www.institutionalreviewblog.com/2015/09/schrag-reviews-klitzman-ethics-police.html
6. http://www.institutionalreviewblog.com/2015/09/nprm-statute-what-statute.html
7. http://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-0570&attachmentNumber=1&disposition=attachment&contentType=msw12

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5. 2016

5.1 January

My NPRM Comments (2016-01-01 12:15)

Perhaps 2016 will be the year when OHRP makes good on its [1]2007 promise to “give more guidance on how to make the decision on what is research and what is not,” in the form of a promulgated revision to the Common Rule. If so, Happy New Year, OHRP!

Wth these hopes, I have submitted my own comments on the NPRM. I have posted a [2]copy of the PDF I submitted, and below is a web version with links.

Zachary M. Schrag. Comments on Notice of Proposed Rulemaking: Federal Policy for the Protection of Human Subjects. 1 January 2016

The proposed rule is designed “to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.” So far as research in the social sciences and humanities is concerned, several of its provisions are likely to achieve these goals, so I applaud this effort and look forward to the final rule. However, I wish to draw attention to some of the limits of the proposals, particularly in the areas of due process protections, empirical research, and revision in light of experience.

The Common Rule should adhere to statutory law

- HHS and other regulatory agencies lack the authority to regulate research in the humanities and social sciences

The NPRM cites as its statutory authority [3]42 U.S.C. 289, which applies to “biomedical or behavioral research involving human subjects,” and does not mention social science or research in the humanities. As the NPRM acknowledges, “some of the commenters [on the ANPRM] recommended that the definition of research be focused more explicitly by being limited to ‘biomedical and behavioral research,’ in accordance with the statutory provision underlying the Common Rule.” But it makes no effort to focus the definition or to explain why the drafters felt comfortable ignoring this part of the statute.
The Common Rule should be restricted to biomedical or behavioral research involving human subjects as provided for by the statute.

- HHS lacks statutory authority to regulate research not directly funded by the Public Health Service

42 U.S.C. 289 requires IRB review of research supported by a “grant, contract, or cooperative agreement under this chapter.” When the 1981 version of 45 CFR 46 was promulgated, the Federal Register notice explained,

> 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. ([4]46 FR 8369)

In 1996, OPRR director Gary Ellis repeated this finding, telling the National Bioethics Advisory Commission, "It is not clear where the authority would come from to requiring institutions that receive money for this project to apply the rule to that project." ([5]National Bioethics Advisory Commission, transcript, inaugural meeting, 4 October 1996, p. 211.)

The NPRM "proposes an extension that would ensure that clinical trials are covered by the Common Rule if conducted at an institution in the United States that receives federal support for non-exempt and non-excluded human subjects research, regardless of the funding source of the specific clinical trial." It acknowledges that ANPRM comments "argued that such a change was an overreach of federal oversight and constituted an unfunded mandate." But it offers no legal analysis of why regulators have rejected public concern and the legal reasoning of previous HHS counsel. If HHS wishes to regulate clinical trials regardless of the funding source of the specific clinical trial, it should suggest that change to Congress. Under current law, HHS has no authority to impose this regulation.

The proposals for interview research are helpful but incomplete

- Oral history, journalism, biography, and historical scholarship should be excluded

The proposed rule would "explicitly exclude oral history, journalism, biography, and historical scholarship." This is a welcome change and addresses the concerns put forth by historians and journalists since the first imposition of IRB review on their work in the 1990s. I endorse the comments provided by the National Coalition for History:

> We concur with this recommendation of full exclusion of such activities from IRB oversight. It reflects an appreciation that these activities should not be evaluated under frameworks originally designed with the sciences in mind. It recognizes the value and attributes of these forms of scholarship. It eliminates any ambiguity about review, regulation and enforcement, and thus removes an enormous and contentious burden for both scholars and IRBs.

- Oral history, journalism, biography, and historical scholarship should not be subject to the Belmont Report

The NPRM states that "All investigators performing excluded studies are expected to act in a way that is consistent with the principles outlined in the Belmont Report, even if the Common Rule does not impose requirements on excluded work." This is inconsistent with the NPRM's acknowledgment that "these fields of research have their own codes of ethics." Historians, journalists, and biographers write critically about the people they study. Since the Belmont Report does not address such critical inquiry, it is a poor guide for their work.

- Other on-the-record interviews should be excluded

Scholars in law, political science, folklore, and other fields also frequently "focus directly on the specific individuals" they study, and conduct interviews, correspondence, or other forms of interaction with these individuals. OHRP itself conducts such studies when it solicits public input on its proposals; all comments on the NPRM provide information about individuals obtained through interaction, yet they are not nor should be subject to IRB review.

When interviews and other interactions are on the record, with the expectation that participants' real names will be used in any resulting study, the federal government has no business regulating the exchange of information and ideas between consenting adults.

In its NPRM comments, the Secretary's Advisory Committee on Human Research Protections suggests modifying this provision to exclude "Oral history, journalism, biography, historical, and other scholarship activities whose purpose is to collect and share evidence-based portrayals of specific individuals who have been selected as a result of the relevance of their personal experience to the phenomena being studied." This is not quite right, since, as Charles Seife points out in his comments, history and journalism interviews do not merely collect portrayals of the people being interviewed, but also other information known to specific individuals.

A better exclusion would be for :

> "Oral history, journalism, biography, historical, and other scholarship activities whose purpose is to collect and share information from specific individuals who have been selected as a result of the relevance of their personal experience to the phenomena being studied."

- Rules on ethnography must be clarified

Neither the NPRM nor the proposed rule uses the term "ethnography," and it is unclear how the rule would affect that practice.
At the October 20 Public Town Hall Meeting, Julia Gorey responded to a written question from Edward Liebow of the American Anthropological Association by suggesting that a great deal of ethnography could be excluded under section 101.b.2.i. or exempt under 104.e.1. Yet this is presumably further qualified by the proposed § _ _ _ _.101(b)(2), which limits the exclusion's application to subpart D, i.e., research with children. And SACHRP's recommendations, if followed, would further muddy the picture by making some of this work "exempt" rather than excluded.

Ethnographers deserve more clarity. If provisions for ethnography are to be split among multiple parts of the rule, with further cross-references to Subpart D, OHRP should work with the American Anthropological Association, the American Sociological Association, and other scholarly organizations to craft a guidance document specifically for ethnographic research.

- Low-risk conversations should be excluded, not exempt

PRIM &R and SACHRP have opposed the proposed exclusion of "Research, not including interventions, that involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) uninfluenced by the investigators" (§.101(b)(2)(i)). These forms of research should remain in the excluded category.

For twenty years, IRBs and IRB offices have interfered with exempt research, to the extent that "exempt" no longer means exempt, but rather has become a "type of IRB review." (University of Southern California OPRS Office for

the Protection of Research Subjects, "[6]Types of IRB Review.")

If the low-risk methods identified in (§.101(b)(2)(i)) are moved to the exempt category, scholars in the social sciences and humanities will continue to face undue burden, delay, and ambiguity, while IRBs and their staff will continue to be distracted by low-risk proposals to the detriment of attention to truly risky projects.

The Common Rule should increase the transparency of the review process

The NPRM proposes "public posting of consent forms … to increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the development of future consent forms." This is a step in the right direction, but it is too limited.

Rather than posting only final consent forms, the federal site should allow researchers to post their proposed consent forms, so that the public could see the kinds of changes demanded by IRBs.

Better still would be the collection and posting of proposals and IRB decisions. 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].

This is as true today as it was in 1973, despite repeated calls for IRBs to base their decisions on evidence and precedent, and a small pilot project by the University of Otago. (See Alexander Halavais, "[7]Social Science: Open Up Online Research," Nature 480 (8 December 2011): 174–175; Robert Klitzman, "[8]Who Polices the 'Ethics Police'?," CNN, May 26, 2015; Tolich, Martin, and Emma Tumilty. "[9]Making Ethics Review a Learning Institution: The Ethics Application Repository Proof of Concept. Tear.otago.ac.nz." Qualitative Research (January 3, 2013).)

The revision of the Common Rule offers an opportunity to increase transparency, enhance confidence in the research enterprise, and increase accountability by disseminating knowledge in the form proposed by Katz. This should not be limited to finalized consent forms.

The Common Rule should require appeal mechanisms

The 2011 ANPRM proposed "a requirement that every institution must provide an appropriate appeal mechanism." Such a provision could help provide transparency and accountability to the IRB process.

An appeals process is already included in Canada's TCPS2 (articles 6.18 and 6.19), and it was recommended by the National Research Council's 2014 report, Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences ([10]Recommendation 6.3).

The NPRM fails even to mention appeals, dismissing the NRC recommendation without reason. The final rule should restore the requirement for an appeals mechanism.

Common Rule agencies should sponsor ongoing empirical research and use it future regulatory revision

Questions 27 - 32 asks the public to speculate on the prospect of an “automated exemption decision tool.”

This should be a matter of empirical knowledge, not mere speculation. In [11]October 2009, OHRP stated that “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… . 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.” So we should have six years of data on the workings of these tools. We do not.

OHRP has failed to encourage institutions to experiment with such promising procedures or to fund studies about the effectiveness of various alternative systems. Rather than continuing to rely on guesswork, the Common Rule agencies should jointly sponsor empirical research to learn what does and does not work in ethics review. This concerns not only the exemption decision tool, but all manner of human subjects research oversight.

Explaining the ANPRM to the Presidential Commission for the Study of Bioethical Issues in August 2011, ANPRM architect Ezekiel Emanuel stressed his wish for a “risk-based review process” and “a learning process that would be constant and dynamic to reflect actual risk” rather than what he termed “gut reactions … which is worthless.” Whether through a provision in the new rule or another mechanism, Common Rule agencies should institute such a learning process.

Common Rule agencies should provide prompt, clear guidance in response to questions about regulation

Question 73 asks, “Will the proposed language at § _ _.101(j) be effective in achieving greater harmonization of agency guidance, and if not, how should it be modified?”

HHS has failed its statutory responsibility to “establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.” (42 U.S.C. 289) While OHRP sporadically issues interpretations, these are few and insufficient. As Robert Klitzman has documented in his book, The Ethics Police?, when IRBs seek help from OHRP, officials there “essentially just read back the regulations” or offer “vague generalities.” (p. 185) The proposed language offers little hope for a remedy. Indeed, by demanding consultation among so many federal agencies, it threatens to slow an already deficient guidance system.

By contrast, Canada’s Panel on Research Ethics offers relatively [12]prompt, clear guidance in response to the questions it receives . Unlike SACHRP, whose members know only biomedical and psychological research, the [13]panel is composed of “a wide spectrum of expertise and experience in the ethics of human research, such as research involving Aboriginal peoples, ethics and ethics review, research administration, research in the health, natural and social sciences, humanities and engineering, law, as well as a lay perspective.”

The Common Rule agencies need to follow this model and establish an interagency panel, staffed with experts in all forms of regulated research, who can offer prompt, authoritative, precise guidance on matters of regulatory interpretation.

Common Rule agencies should continuously revise the Common Rule

The NPRM promises that the list of activities deemed minimal risk will be updated "at least every 8 years." While that's helpful, it also suggests that the NPRM framers do not expect that the rest of the regulations will be regularly revised, or at least not more frequently than once a generation.

That is a disappointment. Canada has shown the value of more frequent revision, with a wholesale revision after 12 years, and a significant update after only four. The United States should follow this model by collecting data on the workings of the new rule and suggesting revisions in roughly four-year cycles. As PRIM &R notes in its draft comments, attempting to overhaul the regulations in their entirety impedes careful consideration of each part. It would be healthier to address one issue at a time, and build a system of continuous revision in light of experience.

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2. https://zacharyschrag.files.wordpress.com/2011/06/2016-01-01_zacharyschrag_nprm_comments.pdf
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Political Scientists Complain about Lost Exemption **(2016-01-17 11:03)**

Political scientists and law professors are protesting the proposed elimination of the current exemption for research about public officials and candidates for office. The drafters may have eliminated the exemption by mistake, thinking that such research was exempted by other provisions of the proposed rule, which turns out not to be the case.

OHRP can't explain why it cut the exemption

Since 1981, [1]45 CFR 46.101(b)(3)(i) has exempted "research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office." I was never able to nail down the exact origin of this exemption, but my best guess is that it was a response to the criticism leveled by political scientist Ithiel de Sola Pool, one of the leaders of the 1978–1981 social science campaign against IRB regulation.

The 2011 ANPRM proposed that "The existing six exemption categories would be retained as part of the new Excused category." (76 FR 44518). Since the ANPRM did not warn anyone that they might lose the public-official exemption, none of the 2011 ANPRM comments seems to have commented on its value.

The 2015 NPRM's proposed rule, however, does not include the exemption. As the NPRM states, "The rationale for this change in the proposed NPRM is that it does not seem appropriate to single out this category of subjects for different treatment in this way." (80 FR 53951) In other words, the drafters eliminated the exemption because they

wanted to eliminate the exemption.

Is so circular an explanation permissible under the Administrative Procedure Act? As Jason Schwartz and Richard Revesz note in their 2014 report, [2]Petitions for Rulemaking, "'bare conclusions,' such as simply asserting that existing rules are adequate, will be found 'not responsive': where a petition raises alternative regulatory options, it "merit[s] some brief explanation of why the agency did not find it desirable to consider those alternatives." But the NPRM was not a response to a petition, so I need some administrative law experts to weigh in.

OHRP officials offered a longer, but more tangled, rationale at the November 18 Town Hall in Philadelphia. As Peregrine Schwartz-Shea, Dvora Yanow, and Daniel Levin, note in their [3]NPRM comment, Julie Kaneshiro, Deputy Director, OHRP, thought that interviews with public officials could proceed under the proposed exclusion at § _ _ _ _.101.(b)(2)(i), while Ivor Pritchard, Senior Advisor to the Director, OHRP, thought they could go ahead as "activities that involve focusing on the specific individuals about whom one collects information," which presumably means § _ _ _ _.101.(b)(1)(ii). But, as Schwartz-Shea et al. note, the first applies only to research that could not reasonably damage the subjects' reputation, which is inappropriate for research that may hold public officials and candidates to account. And Pritchard's 101(b)(1)(ii) applies only to "oral history, journalism, biography, and historical scholarship activities," not research in law and political science.

In any event, political scientists are angry and increasingly organized, and [4]91 comments on the NPRM mentioned the public official exemption. I have not read them all, but a quick sampling suggests that most or all of them want to preserve the exemption.

At stake are interviews, not experiments

In her January 7 Vox article, "[5]The Obama Administration Is Quietly Trying to Make It Harder to Study Public Officials," Michelle Hackman claims that the current value of the exemption lies not in its easing of interviews, but rather because

> the newest wave of research, which involves using randomized field experiments to gauge politicians' behavior, relies heavily on the exemption.
>
> Take, for example, one recent study that tried to determine whether state legislators discriminate against their black constituents. The researchers sent state legislators emails from fake constituents, requesting help with registering to vote. The emails were identical but for the constituent's name, which the researchers varied to sound white (Jake Mueller) or black (DeShawn Jackson). They found that, on average, white legislators responded less often to the emails sent by constituents with black-sounding names. And black legislators did the exact opposite.
>
> Were that study conducted on private citizens, the researchers would probably have been required to ask for their prior consent, and politicians are unlikely to agree to participate in a study that measures how racist they are.

I'm not sure I buy this. For one thing, the current exemption covers tests, surveys, interviews, and observation. It's not clear that it covers deceptive experiments of the kind Hackman describes.

And for all of their faults, IRBs do seem to understand that they can and should waive the informed-consent requirement for this kind of "audit study." See, for instance, Katherine L. Milkman, Modupe Akinola, and Dolly

Chugh, “[6]What Happens Before? A Field Experiment Exploring How Pay and Representation Differentially Shape Bias on the Pathway Into Organizations” (2015) and Benjamin Edelman, Michael Luca, and Dan Svirsky, “[7]Racial Discrimination in the Sharing Economy: Evidence from a Field Experiment” (2016), neither of which involved public officials or candidates for office, and both of which got IRB approval.

So while eliminating the exemption is a bad idea, and the NPRM’s non-explanation might not satisfy the Administrative Procedure Act, I think what’s at stake are the same interviews that Pool fretted about in 1979.

Finally, I question Hackman’s evocation of Obama’s name in her headline. Both Kaneshiro and Pritchard have been at OHRP since the George W. Bush administration. If they are the ones behind the proposed elimination, why name Obama?

1. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101
2. https://www.acus.gov/report/petitions-rulemaking-final-report
3. http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2015-0008-1778
4. http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;s=%2522public%252Bofficials%2522;D=HHS-OPHS-2015-0008
5. http://www.vox.com/2016/1/7/10729338/academics-study-government-officials
6. http://www.apa.org/pubs/journals/releases/apl-0000022.pdf
7. http://www.benedelman.org/publications/airbnb-guest-discrimination-2016-01-06.pdf

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Advice on Scholarly Blogging **(2016-01-21 21:03)**

Alice Dreger is soliciting advice “[1]for a young scholar thinking of starting a blog.” My wife and I have each maintained blogs for several years, and here’s what we’ve come up with.

1. Set your goals.

A blog, like any other enterprise, benefits from a clear mission. Are you trying to draw attention to work you’ve done, or to work you’re doing? To exercise your writing muscles, to track developments in a particular field? One reason our blogs have lasted so long is that they have clear selection criteria. Rebecca blogs about the law of false advertising, and I blog about institutional review board oversight of the social sciences and humanities. Those topics are specific enough that we can keep track of major developments without being overwhelmed, yet broad enough that we have new material most weeks.

2. Keep it fresh

I’d say a good scholarly blog needs a posting at least once a month, preferably more. If you can’t manage that alone, consider joining or starting a group blog.

3. Put your name on it

Domain names, especially .com domains, are pretty cheap, and they give you the flexibility to move your blog later. As for the blog title, consider naming it at least partly after yourself. Most citations to the [2]Institutional Review Blog leave out its author. Putting your name in the title of the blog (e.g., “[3]Rebecca Tushnet’s 43(B)log),” gives you some hope of getting cited properly.

4. Consider wordpress.com

I've tried three different platforms. I started the Institutional Review Blog on Blogger in the hopes that using a Google product would increase my hits, but I'm frustrated by the lack of features, like the difficulty of posting a PDF. I also tried a WordPress installation on a hosting site, but that got hacked and made me sad. I've found [4]wordpress.com (which I use for [5]zacharyschrag.com and [6]HistoryProfessor.Org) to offer the features I need, robust security, and a low price (I pay $13 per year per site for domain mapping).

5. Don't allow anonymous comments

I've had mostly interesting exchanges on my blog with people willing to give their names, and mostly stupid conversations with people too cowardly to do so. At the outset, only post comments that arrive with full names and, if appropriate, affiliations.

6. Compose in Markdown

A colleague put me onto [7]nvALT, and I'm still lamenting all the tags I wrote by hand before I had it.

7. Use the <!–more–>– tag

If you write anything more than three paragraphs, put a <!–more–> tag after the lede. It will make it easier for people to see your posts, both browsing the blog and searching.

8. Archive your work

If it's a scholarly blog, it needs a scholarly home. In 2014, I used [8]BlogBooker to create a 568-page PDF of the first eight years of my blog and posted them to my [9]university's online repository. So when Blogger and I have both gone the way of Google Reader, it will still be someone's job to maintain in perpetuity my most ephemeral writings.

1. https://twitter.com/WetheHumanities/status/689990790119067648
2. http://www.institutionalreviewblog.com/
3. http://tushnet.blogspot.com/
4. https://wordpress.com/
5. http://zacharyschrag.com/
6. http://historyprofessor.org/
7. http://brettterpstra.com/projects/nvalt/
8. https://www.blogbooker.com/
9. http://digilib.gmu.edu/dspace/handle/1920/8642

5.2 February

Fifty Years of IRBs **(2016-02-08 09:47)**

As has been widely not reported, today marks the fiftieth anniversary the issuance of U.S. Public Health Service Policy and Procedure Order (PPO) #129, which mandated that each recipient of a PHS grant involving human beings secure prior review by "a committee of his institutional associates." From this document flowed all subsequent IRB policies, in the United States and in several other countries.

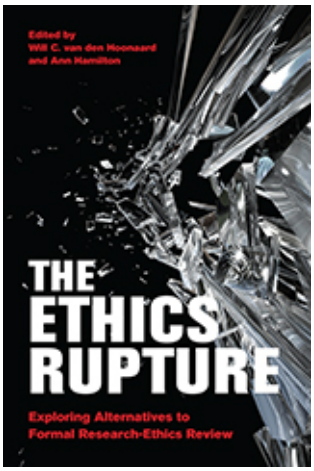
To honor the occasion, I have posted a [1]PDF of the order on [2]my page of IRB documents.

(Not really. A correspondent was looking for a copy, and I posted it for her.)

1. https://zacharyschrag.files.wordpress.com/2011/06/ppo129.pdf
2. http://zacharyschrag.com/irbs/irb-documents/

5.3 March

New Book: The Ethics Rupture (2016-03-19 15:48)



The University of Toronto Press has published [1]The Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review, edited by Will C. van den Hoonaard and Ann Hamilton. My chapter is entitled, "Ethical Pluralism: Scholarly Societies and the Regulation of Research Ethics."

The full contents are as follows:

INTRODUCTION

The Ethics Rupture Summit in the Context of Current Trends in Research-Ethics Review - Will C. van den Hoonaard and Ann Hamilton

I. STRAINS IN RESEARCH-ETHICS REVIEW PROCESSES

1. The Social Costs of Ethics Regulation - Robert Dingwall

2. Fieldwork Double-Bound in Human Research-Ethics Reviews: Disciplinary Competence, or Regulatory Compliance and the Muting of Disciplinary Values - Rena Lederman

FINAL THOUGHTS

So Where from Here? Finding Paths through the Bramble of Research-Ethics Review - Ann Hamilton and Will C. van den Hoonaard

APPENDIX

A. The New Brunswick Declaration: A Declaration on Research Ethics, Integrity, and Governance

1. http://www.utppublishing.com/The-Ethics-Rupture-Exploring-Alternatives-to-Formal-Research-Ethics-Review.html

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First, Do Some Harm, Part IV: Fake Submission to Fake Conference Yields Fake Charge of Misconduct **(2016-03-21 17:06)**

Professor Jim Vander Putten, [1]who spent six years as chair of the University of Arkansas Little Rock (UALR) IRB, is now charged with violating university rules by conducting research without that board's approval. The case highlights several problems with the current system, most notably its failure to provide standards for studies designed to expose misbehavior.

[Peter Schmidt, "[2]A Scholar's Sting of Education Conferences Stirs a Hornet's Nest," Chronicle of Higher Education, March 14, 2016, paywalled.]

Scamming the scammers

The Chronicle gives the basic facts of the study:

> Jim Vander Putten suspected that some education conferences accepted any study pitched by someone willing to pay a registration fee. He worried that the gatherings enabled scholars to pad their publishing records while tainting research in the field.
>
> To test his hypothesis, he sent fake research-paper summaries larded with unforgivable methodological errors to the organizers of 15 conferences he believed to have lax standards. All responded by offering to let him present his findings and to publish his papers as part of their proceedings.

Before proceeding with the study, Vander Putten spent 18 months trying to get approval from the UALR IRB, but it eventually ruled that, in the Chronicle's words, the proposal "had failed to assuage its concerns over issues such as potential harm to reviewers, whom conference organizers or people willing to investigate the review process might be able to identify." Rather than accept defeat, he turned to Solutions IRB, a commercial firm in Little Rock, which approved the study.

Issue 1: Can researchers choose their IRBs?

By seeking a second opinion on his proposal, Vander Putten engaged in what is called "IRB shopping." As Michelle Meyer notes in the story, this is rare among academics, because university policies usually require their affiliates to use university or other designated boards. And it's now going to be rarer, in that both UALR and Solutions IRB have changed their policies to block future researchers from repeating Vander Putten's gambit. [3]I myself would like to see more IRB shopping, not less, since it competition could require higher standards at university IRBs.

Issue 2: Should IRBs protect their institutions?

The Chronicle paraphrases a university administrator on the mission of an IRB:

> Scott L. Thomas, dean of Claremont Graduate University's School of Educational Studies and president of the Association for the Study of Higher Education, said it is a mistake to focus entirely on the question of whether a given study protected human subjects. University review boards, he said, function not just to protect human subjects, but to protect university interests and to verify that the research is insured. "There are liabilities and risks associated, for both the university and the researchers," he said.

[4]Federal law states that IRBs must be established "to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research," not to protect university interests. As Sanjay Srivastava [5]notes, it's a bit unusual for an administrator to be so blunt about the ways universities have repurposed the boards to protect themselves from embarrassment. [6]But not unprecedented. And everyone knows this is how things really work.

Issue 3: Should IRBs protect powerful malfeasors?

To me, the most interesting question is how the UALR IRB should have reviewed Vander Putten's proposal, given that it was largely designed to expose wrongdoing.

The Chronicle calls Vander Putten's project a "sting;" the fancier term "audit study" is often used to denote the submission of fake job applications, housing applications, and the like, to see if the people on the receiving end are playing by the rules. (Does "audit study" imply a controlled experiment, e.g., sending actors of different races to apply for the same apartment? I'm not sure.) This technique has a long history in social science and journalism.

Some IRBs have found a way to approve these kinds of studies. For example, the IRBs at Columbia and Penn approved the sending of [7]fake, urgent queries to university professors to see if prospective PhD students with names suggesting they are ethnic or racial minorities were less likely to get responses than those with names suggesting they were white men. And the IRB system itself has been the target of such a sting; in 2009, the Government Accountability Office used undercover tests to show that "[8]the IRB system is vulnerable to unethical manipulation."

But other IRBs have blocked research that could expose misbehavior, as when a team wanted to send San Francisco residents into stores to request loose cigarettes, and then record if the stores offered to make those illegal sales. The [9]UCSF IRB forbad that practice for unclear reasons. The Chronicle article does not provide any documents or statements from the UALR IRB, but I suspect they would provide the same muddled thinking as the UCSF IRB in the loosies case.

If so, it wouldn't be the individual IRB's fault; it would be the fault of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. At its January 1978 meeting, staffer Bradford Gray raised

this very issue. And, as it did whenever confronted with a challenging case of social science ethics, the commission failed to come to a resolution, and instead published the Belmont Report with its blanket statements about "do no harm."

[10]As I've noted before, in 2010 Canada's Panel on Research Ethics addressed this problem by declaring:

> Some research, involving critical assessments of public, political or corporate institutions and associated public figures, for example, may be legitimately critical and/or opposed to the welfare of those individuals in a position of power, and may cause them some harm. There may be a compelling public interest in this research. Therefore, it should not be blocked through the use of risk-benefit analysis. Such research should be carried out according to the professional standards of the relevant discipline(s) or field(s) of research.

The scammy conference organizers were in positions of power. Had the UALR IRB followed this guidance, Vander Putten could have conducted his research without fuss.

1. http://ualr.edu/edleadership/vander-putten/
2. http://chronicle.com/article/A-Scholar-s-Sting-of/235650?
3. http://www.institutionalreviewblog.com/2014/04/irb-still-isnt-peer-review.html
4. https://www.law.cornell.edu/uscode/text/42/289
5. https://twitter.com/hardsci/status/709460108690849793
6. http://www.institutionalreviewblog.com/2015/07/british-universities-see-ethics.html
7. http://www.institutionalreviewblog.com/2010/05/researchers-deceive-thousands-of.html
8. http://www.gao.gov/new.items/d09448t.pdf
9. http://www.institutionalreviewblog.com/2010/12/first-do-some-harm-part-iii-loosies-in.html
10. http://www.institutionalreviewblog.com/2015/11/nprm-will-political-science-interviews.html#more

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IRB Manager Laments "Unhappy Marriage" with Ethnography (2016-03-31 12:34)

Writing for Contexts, Abigail Cameron, an IRB manager for the Texas State Department of Health Services, laments that "IRBs and ethnographers often 'talk past each other' resulting in confusion, delays, and frustration—i.e., a very unhappy marriage." She rightly blames faulty federal regulations as the prime cause of this unhappiness, yet she downplays IRB misbehavior as a contributing factor.

[Abigail E. Cameron, "[1]The Unhappy Marriage of IRBs and Ethnography," Contexts, accessed March 24, 2016, h/t Rob Townsend.]

It's nice to have an IRB manager acknowledge that "Federal regulations were not written with ethnographic research in mind," and that "the details required by IRBs to assess risk to participants may not be known by the ethnographer until they have begun fieldwork." And Cameron even concedes that some "institutions review few ethnographic proposals regularly and/or do not have IRB members well-versed in qualitative methods."

That said, Cameron has her history wrong when she writes that "The unhappy marriage of IRBs and ethnography has existed since the Common Rule was published in 1991." She is off by a quarter century; sociologists have been unhappy with the marriage [2]since 1966.

More significant are Cameron's claims that "Most IRB committees working in university settings have seen their fair share of ethnographic proposals and have responded proactively to facilitate quality reviews. For instance, some IRBs may have subcommittees assigned to review ethnographies or a list of subject-matter experts to consult with."

Cameron offers no evidence or citation for these claims, and I tend to doubt them. Indeed, I have never heard of an IRB that has an ethnographic subcommittee. I do know that IRBs are frequently [3]groups of ignorant amateurs committed to avoiding any controversy, even at the expense of important, valid research.

Until Cameron acknowledges this, she won't understand why so many researchers reject her advice, "Don't sweep potentially problematic details under the rug!" When researchers are faced with an incompetent boards, "[4]we can't be to broad/honest in our thinking when filling out these forms."

1. https://contexts.org/blog/the-unhappy-marriage-of-irbs-and-ethnography/
2. https://books.google.com/books?id=nSv83XkNq3gC&lpg=PA32&ots=iYWvylVSfm&dq=%22dangers%20that%20some%20institutions%20may%20be%20over-zealous%22%20sykes&pg=PA32#v=onepage&q=%22dangers%20that%20some%20institutions%20may%20be%20over-zealous%22%20sykes&f=false
3. http://www.institutionalreviewblog.com/2014/12/horror-story-buffet.html
4. https://culturematters.wordpress.com/2009/04/29/embodied-ethics-oversight/

Cameron (2016-04-08 10:34:09)
Hi Zachary,

Thank you for your blog post about my article. Contexts asked me to write the article for the ethics series as a general interest piece rather than an academic submission with citations. I also did not have the space to take my brief review of the debate back very far in time. I certainly feel your pain. I can tell you that at NC State, we were fortunate to have excellent anthropologists serve as ethnography experts for our committee there many years ago. Many IRBs are not as fortunate. I have also been to many PRIM &R conferences where anthropologists have presented about their collaborations with IRBs. If you are interested, Laura Stark from Vanderbilt, has written a great book about IRBs, "Behind Closed Doors: IRBs and the Making of Ethical Research," that you might be interested in. There certainly needs to be more research on contemporary IRB committees and how they are implemented differently across institutions with attention to the review of qualitiative work. Best, Abby Cameron

Zachary M. Schrag (2016-04-13 13:38:20)
Thank you for this response. The NC State IRB webpage makes no mention of subcommittees, nor does Stark's book. I must question the accuracy of your claim that "some IRBs may have subcommittees assigned to review ethnographies."

Cameron (2016-04-13 14:30:27)
Hi Zachary,

NC State does not have their internal list of topic consultants published online, as is the case with many IRBs (many do not even post their minutes online, which I feel is essential for transparency). I was employed at NC State for several years and can refer you (privately) to the names of ethnographers used to consult on ethnographic projects. I have reached out to the IRB Forum (moderated by PRIM &R) to see if there is a public list of IRBs with subcommittees that I can provide you with. I have also posted a question on the subject on an IRB Facebook page to see if anyone is willing to share their subcommittee information. I will pass along my findings to you.

I can also assure you that there are published articles on the topic and that subcommittees are utilized. The Amdur and Bankert book is the "IRB Bible" for administrators and covers the use of subcommittees (chapter 3.7 in my ancient addition).

My short article in Contexts and my professional efforts (as a researcher and IRB administrator) have always been to improve the IRB experience for social/behavioral researchers and to offer constructive suggestions. I enjoy Laura Stark's book

because it provides a contemporary understanding of how IRB decisions are made. Unlike most critics of IRBs, Dr. Stark attends PRIM &R conferences and makes a committed effort to understand the perspective of both researchers and administrators.

I certainly understand the frustrations of researchers and wish there could be less animosity and more productive communication and collaborative work between committees and investigators. Thank you.

Abigail Cameron

Zachary M. Schrag (2016-04-13 15:02:50)
Thank you for your reply. The 2006 edition of [1]Institutional Review Board: Management and Function does mention subcommittees, but not for specific fields, such as ethnography.

Putting ethics review in the hands of specialists is a good idea, as [2]LL Wynn, an ethnographer, has argued. Some universities did deploy more specialized subcommittees in the early 1970s, only to face scolding from federal regulators. (See [3]Can We Patch This Flat Tire?.

The current system lacks provisions for review of ethnography by ethnographers.

1. https://books.google.com/books?id=ZVByC6VVsl0C&lpg=PA83&vq=subcommittee&pg=PA84#v=snippet&q=subcommittee&f=false
2. http://www.institutionalreviewblog.com/2016/04/wynn-calls-for-department-level-review.html
3. http://www.institutionalreviewblog.com/2008/07/can-we-patch-this-flat-tire.html

5.4 April

Oral Historians as Ethical Proofreaders (2016-04-07 08:12)

Kevin Bradley and Anisa Puri of the [1]Australian Generations Oral History Project explain that the ethical challenges they faced came after they had conducted the interviews.

[Kevin Bradley and Anisa Puri, "Creating an Oral History Archive: Digital Opportunities and Ethical Issues," Australian Historical Studies 47, no. 1 (2016): 75–91, [2]doi:10.1080/1031461X.2015.1122072.]

The project asked Australians from four generations "[3]about the interactions and overlaps between generations, and the ways in which class, gender, ethnicity, race and region inflect with and cut across age and generation." It elicited some frank responses on sensitive matters. As Bradley and Puri explain,

> The Australian Generations project required a process to ensure that potentially problematic material was identified and assessed before being made publicly available, especially online. We developed a 'traffic light system' to manage this issue when we realised how many interviews contained sensitive material. Unlike other oral history projects undertaken by the [National Library of Australia], the Australian Generations team did not fully anticipate the extent to which narratives about domestic and sexual abuse would appear in the interviews. The project adopted the key considerations used in the Forgotten Australians project to identify problematic material: namely, whether someone would be seriously offended or hurt by what was said and whether police would take action. In assessing contentious material, the project's

> attitude was shaped by the library's preference to err on the side of access, but to consider the risk in each instance.

In particular, project staff flagged content that, if made publicly available, "might be actionable for defamation or might cause harm to some other individual. Seven interviews were labelled red because they contained material about unreported sexual or domestic abuse where the perpetrator was identifiable and likely to still be alive." In such cases, "the entire interview will be closed until a certain date." Slightly less sensitive interviews can be studied in person at the National Library of Australia but will not be posted online, to reduce the chances of harm or misuse. Eventually, after everyone involved has the chance to die, the interviews will become unrestricted.

The essay only glancingly mentions IRBs/ethics committees, but it reinforces the claim that for these kinds of interviews, it is likely futile to try to anticipate in advance all the questions to be asked and all the answers that may be given. Thus, ethics committees' emphasis on prospective review of is misplaced.

Instead, the most serious deliberation must come at the stage between interview and publication. In 1982, Carole Gaar Johnson called this "ethical proofreading," and Bradley and Puri have shown themselves to be conscientious practitioners of the art.

[Carole Gaar Johnson, "Risks in the Publication of Fieldwork," in The Ethics of Social Research: Fieldwork, Regulation, and Publication, ed. Joan E. Sieber, (New York: Springer-Verlag, 1982), 87.]

1. http://artsonline.monash.edu.au/australian-generations/
2. http://dx.doi.org/10.1080/1031461X.2015.1122072
3. http://artsonline.monash.edu.au/australian-generations/

Wynn Calls for Department-Level Review of Student Research **(2016-04-11 11:51)**

L. L. Wynn, an anthropologist at Macquarie University and a member of that university's Human Research Ethics Committee, spoke to 40 teachers and administrators at 14 Australian universities. She finds that "opportunities for independent undergraduate human research are being eroded by expanding ethics bureaucracies" and that "the ethics review process [is] a significant obstacle to universities and teachers who wish to incorporate original human research into the curriculum." (7) She calls for the devolution of ethics review to individual departments.

[L. L. Wynn, "The Impact of Ethics Review on a Research-Led University Curriculum Results of a Qualitative Study in Australia," Journal of Empirical Research on Human Research Ethics, Published online before print, March 16, 2016, doi:[1]10.1177/1556264616636234.]

Wynn's informants tell her that ethics boards display "biomedical or clinical bias," that they delay student work by months, that they discourage bold questions about sexuality and mental health, and instead steer students into "much more generic, low-risk research that may actually not be all that interesting." (5)

As Wynn acknowledges, such complaints will be familiar to those who have read the existing literature on ethics review of the social sciences, including Wynn's own 2011 article, "[2]Ethnographers' Experiences of Institutional

Ethics Oversight: Results from a Quantitative and Qualitative Survey," which it was my privilege to edit.

Her chief contribution here is not documenting the problem, but forcefully advocating for a solution: departmental-level review. She writes than Australian university psychology department, which has such a practice, serves as "the single best-practice case that I identified during this research." (9) Because that department monitors only psychology, it can use simplified forms and offer quick review, averaging only three days. Yet the overall regime is robust, incorporating ethics training throughout the curriculum and achieving 100 percent participation by researchers, rather than the IRB evasion common elsewhere.

(Not cited in Wynn's article is Dan Trudeau, "[3]IRBs as Asset for Ethics Education in Geography," Professional Geographer 64, no. 1 (2012): 25–33, which also finds benefits in devolution. See "[4]Can Macalester's Divisional Review Work Elsewhere?")

Wynn concludes:

> The benefits of locating HREC review within departments are many. In addition to addressing researcher complaints that ethics committees do not understand their disciplinary methods, it would also decrease the workload of ethics secretariats, which are increasingly burdened as universities try to increase their research activity. It could dramatically improve the efficiency of the ethics review process. Smaller, more local committees are more flexible and can meet as often as needed. (9)

This will not solve all problems. Wynn concedes, "one potential negative to local review, however, is that it could lead to pressure to make all student research projects low-risk—thus, potentially, low-impact—to facilitate review." Still, it sounds a good deal more promising than the system now in place.

1. http://dx.doi.org/10.1177/1556264616636234
2. http://dx.doi.org/10.1017/S0898030610000333
3. http://dx.doi.org/10.1080/00330124.2011.596786
4. http://www.institutionalreviewblog.com/2012/07/can-macalesters-divisional-review-work.html

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The Cost of Ethical Review, Part III: Hindering HIV Prevention (2016-04-17 12:39)

Risk-averse IRBs are hindering potentially life-saving research, write Brian Mustanski and Celia Fisher. "Critical advances in HIV prevention among AMSM [adolescent men who have sex with men]," they note, "have been impeded by the failure of IRBs to apply federal regulations permitting adolescents to self-consent to research without parental involvement."

[Mustanski, B., & Fisher, C. B. (2016). HIV Rates Are Increasing in Gay/Bisexual Teens: IRB Barriers to Research Must Be Resolved to Bend the Curve. American Journal of Preventive Medicine, In Press. doi:[1]10.1016/j.amepre.2016.02.026.]

To understand how to stop HIV transmission among teens, Mustanski, Fisher, and other researchers need to be able to talk freely with those teens. And the teens are often willing to talk, so long as they don't need parental permission to do so. But most won't talk if the researchers must get permission from their parents, and the minority who are

willing to involve their parents are not representative of the larger group, thus skewing any sample and reducing the effectiveness of any intervention.

The IRBs that demand parental consent are ignoring expert guidance. More than ten years ago, Mustanski and Fisher note, the Secretary's Advisory Committee on Human Research Protections recommended that these kinds of studies be allowed to proceed without parental consultation. I wonder how many IRBs are even aware of such guidance; recall Klitzman's findings that [2]IRB fears may not be "realistic or reality-based."

In any case, these IRBs are jeopardizing the health and even the lives of America's youth. As Mustanski and Fisher conclude,

> IRB barriers to self-consent deprive AMSM of their right to participate in trials that will protect them from receiving developmentally untested, inappropriate, and unsafe interventions and is a clear case of scientific inequity driving health inequities. It is also an instance of losing sight of the forest for the trees. Study-by-study IRBs have sought to minimize risk to the institution and to AMSM participants by disapproving waivers of parental permission; in doing so, those individual decisions add up to a systemic injustice.

1. http://dx.doi.org/10.1016/j.amepre.2016.02.026
2. http://www.institutionalreviewblog.com/2015/09/schrag-reviews-klitzman-ethics-police.html

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U of Maryland Scapegoats IRB and Researcher for PR Foul Up (2016-04-28 09:17)

The University of Maryland has released a [1]report on the problematic December 2015 press release, which included unsubstantiated claims about the benefits of a sports drink based on chocolate milk. While the press release was indeed a disaster, the university report fails to hold to account the people most responsible. Instead, it makes matters worse by accusing the researcher and the IRB of transgressions they did not commit, and by recommending drastic changes that are unnecessary and burdensome.

Shielding the staff who wrote a bad press release

The university issued the press release on 22 December 2015. As reported by [2]Jesse Singal among others, the press release purported to summarize findings from a scientific study by kinesiologist Jae Shim, but the study had not been published, or even submitted for publication. The best the university could produce was a junky PowerPoint file that suggested serious methodological problems (no control group) and, notes Singal, "serious statistical red flags." As Singal writes, "What happened here happened only because the University of Maryland trampled upon very well-established norms about what it means to publish a press release about a 'study' on a dot-edu website."

The [3]untitled March 25, 2016, report on the incident was written by five professors: two psychologists, a geologist, a chemist, and a chemical engineer. The last, Denis Wirtz, is the vice provost for research at Johns Hopkins, while the rest are current or emeritus Maryland faculty.

Their report claims to offer "a detailed sequence of events beginning with the development of the proposal and ending with the release of the study results to the press." In fact, it obscures the identity of the individuals and offices responsible for the press release behind the passive voice:

> "By May 20, 2015, preparation for Press Release 1 was well underway …"

> "July 15, 2015. Press Release 1 was issued by MIPS. Before the Press Release was issued, MIPS had shared drafts and a request for comments with MIPS staff, Fluid Motion, Dr. Shim, the communications staff of the School of Public Health, the communications staff of the A. James Clark School of Engineering, and the UMD Central Communications Office. Several revisions of drafts were prepared based on feedback from individuals in all of these units."

Who had the idea to issue a press release? Who drafted it? The report castigates Professor Shim for the contents of the release, something that someone else wrote for him. Why not name the flack who did so? By concealing these details, the report obscures the parties most responsible for the fiasco and hinders future reforms.

Blaming the IRB—for what?

instead of focusing on the PR offices, the report seeks to impose blame on everyone, including the IRB.

According to the report,

> The IRB reviews of both Phase 1 and Phase 2 IRB protocols were expedited. Expedited Review means that they were reviewed by the Director of the IRB. IRB staff, and the Chair of the IRB, but no other IRB Board members even though Dr. Shim indicated on his application that he wanted a Full Board review. The IRB staff determined that expedited review was appropriate because the risk for participants was considered to be very low.

And you know what? The risk to participants was very low! Some dozens of teenaged and young adult athletes without food allergies were given a widely used food and put through some widely used tests, at least some of which they were taking already. Yes, we can quibble about whether all the actual procedures were fully described on the protocol, and what we mean by intervention. But nowhere does the report suggest that the study put any subjects at risk.

So while the IRB worked pretty much as advertised, the report recommends upending the system of expedited review:

> The IRB should review its current practice of expedited review and/or approval of a waiver of informed consent in cases in which the protocols involve an intervention with human subjects, even though the potential for harm is minimal, another entity will be collecting the data, the data are de-identified. and the PI is not directly involved with the subjects. Of particular importance is an assessment of the scientific merit of the proposal and whether the benefit gained is important enough to justify research on human subjects in general, but especially when the research involves un-consenting subjects and minors. This is an important issue both for projects involving service to industry and research designed to contribute to generalizable knowledge through publication in peer-reviewed journals and outlets.

The report makes no effort to imagine what restricting expedited review and waivers of consent would do to the thousands of other researchers at the university hoping to get their protocols cleared. While the federal government works to reduce the burden and delay associated with IRB review, the Maryland report seeks to increase them.

Redefining Conflict of Interest

The report is equally bizarre in its treatment of conflict of interest (COI).

As the report explains,

> the UMCPF [University of Maryland College Park Foundation] received the first of three gifts from the Allied Milk Foundation which, during the course of these projects, totaled $200,000. Officials of Allied Milk Foundation, who are also associated with Fluid Motion and FQF [the recovery drinks], authorized the gifts. The gifts provided unrestricted funding for the benefit of Dr. Shim's Neuromechanics Laboratory. Dr. Shim did not declare these gifts as a potential conflict of interest when he received them, when he submitted the Phase 2 application, nor in his applications to the IRB for continuing Phase 1 and Phase 2.

It continues:

> The committee has found a concerning lack of understanding of the basic principles of conflict of interest (COI) in research at all levels of the process among those we interviewed (MIPS, administration, and faculty). The PI. as well as several others, expressed less concern for, and were perhaps less attentive to. the potential of a research COI in part because they felt that this project was in support of small business which is highly encouraged by the state and actively promoted by the university. When asked by the committee to explain why he had not declared a COI regarding the funding from the Allied Milk Foundation, Dr. Shim stated that since the money had not gone directly to him, but had been given to UMCPF to support his research, he did not consider the funding a COI.

In other words, Shim didn't think he had a COI, and neither did anyone else the report authors interviewed. This might have been a hint that he had no COI.

He didn't. [4]University of Maryland Conflict of Interest policy, in place since 2003,

> The term "conflict of interest" denotes situations in which members of the University community are in a position to gain financial advantage or personal benefit (broadly construed) arising from their University positions, either through outside professional activities or through their research, administrative, or educational actions or decisions at the University.

Typically, a conflict of interest would mean that a researcher has outside financial interests that will be affected by the research. According to the [5]National Science Foundation, for instance, a significant financial interest does not include "salary, royalties or other remuneration from the applicant institution." Since Shim's only interested in the milk study seems to have been that it helped pay his university salary, I am not persuaded that he had a conflict of interest.

Rather than accept the commonly understood meaning of COI, the report authors seek to impose a new meaning, with any outside funding constituting a conflict. And they recommend imposing this meaning in the most burdensome way possible:

> Mandatory, in-person training on the principles of what constitutes a conflict of interest (COI) in research and why it must be disclosed should be required for all faculty, staff, and graduate students working on funded research or service projects, including those funded by MIPS, the Vice President for Research, or elsewhere.

To be sure, the chocolate milk press release was a disaster, but it was the fault of over-eager PR flacks trying to maximize profits for the corporate university. That is not excuse to punish thousands of student, staff, and faculty researchers by making them sit through mandatory in-person training, forcing an inexpert IRB to assess the scientific merit of their proposals, and taking away their chance at expedited IRB review.

This is how overregulation happens. Embarrassed by a single incident, a university overreacts and imposes burdens on researchers campuswide.

Bring on the [6]Bear Patrol!

1. http://umdrightnow.umd.edu/sites/umdrightnow.umd.edu/files/16-03-24-report-final.pdf
2. http://nymag.com/scienceofus/2016/01/chocolate-milk-concussion-scandal.html
3. http://umdrightnow.umd.edu/sites/umdrightnow.umd.edu/files/16-03-24-report-final.pdf
4. http://www.president.umd.edu/administration/policies/section-ii-faculty/ii-310a
5. http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_1/aag_4.jsp
6. https://en.wikipedia.org/wiki/Much_Apu_About_Nothing

University Research and Journalism: Distinctions Without Differences (2016-04-29 16:34)

Google Scholar belatedly alerts me a 2014 article in which two philosophers of education seek to distinguish investigative journalism from university-sponsored community research. They suggest it makes sense to require IRB oversight of the latter but not the former, but their arguments rest on factually doubtful claims of uncertain relevance, and they fail to show that IRB oversight makes sense for either type of research.

[Anne Newman and Ronald David Glass, “Comparing Ethical and Epistemic Standards for Investigative Journalists and Equity-Oriented Collaborative Community-Based Researchers: Why Working for a University Matters,” Journal of Higher Education 85, no. 3 (2014): 283–311, [1]doi:10.1353/jhe.2014.0013.]

As noted on this blog, many IRB apologists are sufficiently steeped in American traditions of freedom of the press to avoid calling for IRB oversight of journalism. Some, like [2]James Weinstein, try to distinguish the two by disparaging social science as focusing on "subjects not of public concern." Others, like [3]Martin Meeker, take the opposite stance, suggesting that journalism is too full of "blatant bias and even hyperbole" to be taken seriously.

Though they don't cite Meeker, Newman and Glass follow his line and attack Weinstein, arguing that equity-oriented collaborative community-based research (EOCCBR) does indeed address "policy issues that are undoubtedly matters of public concern (e.g., drinking water contamination, mentoring programs for parolees, civic engagement of low-income racialized youth)." How then, can they justify prior restraint?

Silly Claim 1: Reporters Don't Disclose Methodology

Newman and Glass's article is long and somewhat rambling, so I'm not sure how many distinctions they hope to draw between university research and journalism. I will choose two to illustrate their failure to offer evidence or to explain the relevance of their assumptions.

The first concerns methodology. They write,

> The institutional contexts in which journalists and researchers carry out their investigations and the epistemological aims that guide their studies shape how they employ seemingly similar methods. A key difference that results is the variance in the methodological transparency expected of them. Researchers must disclose how they collected their data and rigorously justify their decision in their publications; these methodological matters provide other researchers with crucial information for checking the soundness and validity of any claims made from the findings, so the methods and the transparency are both central elements of the research story being told. By contrast, journalists typically provide little, if any, methodological information in their reports, even leaving out explanations of how and why particular interviewees were selected. Readers generally do not consider replicating the investigation nor do they critically assess the knowledge claims against the proffered methods. Readers are simply to enter the story as presented and assume that appropriate individuals were consulted and the right events observed to illuminate the issues at hand. Researchers must wear their methodology on their sleeves, so to speak, while for reporters it remains hidden in the background, shared with editors but not with the reader. (295)

I guess Newman and Glass don't consider themselves researchers, because they disclose nothing about the methods that led them to this alleged finding. In contrast, since it's Pulitzer season, let's take a look at the purported obscurity of investigative journalists' methods:

> The Tampa Bay Times and Sarasota Herald-Tribune spent more than a year chronicling life in these institutions, interviewing patients and their families and examining thousands of pages of government records. Using police and hospital reports from across the state, reporters pieced together the first comprehensive list of injuries and violent attacks inside Florida's mental institutions.

and

Three reporters for the Tampa Bay Times and Sarasota Herald-Tribune spent more than a year investigating Florida's largest state mental hospitals.

Reporters interviewed dozens of current and former employees and crisscrossed the state to talk to mental patients and their families.

The newspapers collected "critical incident" reports from the state Department of Children and Families, which oversees the hospitals. But those reports provide an incomplete picture because they only track the most serious incidents. In addition, agency officials said they had lost reports for some hospitals in recent years.

To better chronicle conditions at the hospitals, reporters obtained public records on thousands of police calls made from mental hospitals across the state. They used the records to create a first-of-its kind database, representing the most comprehensive list of injuries and violent episodes ever created for Florida's mental institutions.

In calculating the number of incidents over time, the Times/Herald-Tribune discarded allegations that police dismissed as unfounded. In the case of South Florida State Hospital, however, that could not be determined because the Pembroke Pines Police Department was unable to provide copies of its reports.

When calculating budget cuts, the Times/Herald-Tribune used official figures published on the Florida Fiscal Portal, which include DCF's administrative costs.

and

In the name of patient privacy, the state has built a wall of secrecy around its mental hospitals, making it nearly impossible to track how they respond to abuse, neglect and carelessness by government workers. Over the past year, as the Times/Herald-Tribune investigated injuries at six of the state's primary mental institutions, officials repeatedly denied reporters information.

In some cases, they used their power to classify fatalities as natural or accidental even though employee mistakes or neglect contributed to the deaths.

In others, they cited a law that experts say was designed to crack down on abusers, but now protects them. When reporters asked for the names of hospital employees accused of abuse, state officials refused.

They said Florida Statute 415.107 — a law to protect the identity of victims and people who report abuse — also covers the names of abusers.

Like everyone else, mental patients have a legal right to keep their medical records private.

But hospitals also use those privacy laws to make it harder to get information about unscrupulous or inept employees.

Even parents can be denied information when their adult child is injured or killed in the state's care. (Leonora LaPeter Anton, Anthony Cormier, and Michael Braga, "[4]Insane. Invisible. In Danger," Tampa Bay Times and Sarasota Herald-Tribune, October 29, 2015.)

and

> The top administrator at each of Florida's six largest institutions declined to speak with the Times/Herald-Tribune.
> Doug McKenzie, who was being held at Treasure Coast, was one of the few current patients who agreed to be interviewed. Hospital officials approved the interview only after the newspapers' attorneys intervened.
>
> But soon after approving the visit, hospital staff encouraged him to cancel it, said McKenzie's mother, CJ. She said they offered him extra food and promised to transfer him to a less restrictive facility. The day before the scheduled interview, an assistant for hospital director George Gintoli emailed the reporter to say McKenzie had rescinded his invitation. The interview was cancelled.
>
> Three months later, McKenzie was transferred.
> "They really didn't want him talking to you guys," his mother said. "The guards would walk by and tell him: 'Enjoy your 15 minutes of fame, Doug.' His counselor was practically begging him not to talk."
>
> A spokeswoman for the company that runs Treasure Coast said his transfer was unrelated and denied that anyone encouraged McKenzie to cancel the interview.
>
> CJ McKenzie, who drove four hours every Sunday to see her son at Treasure Coast, believes that the mental hospitals don't want the public to hear from the patients they serve.
>
> "They don't want people like Doug telling you what really happens inside those places," she said.
>
> (Leonora LaPeter Anton, Anthony Cormier, and Michael Braga, "[5]Shrouded in Secrecy," Tampa Bay Times and Sarasota Herald-Tribune, November 2, 2015.)

Do Newman and Glass really believe that scholarly researchers offer that much transparency?

I realize that these examples were published after Newman and Glass wrote their essay, but you can find comparable statements in earlier investigative work in the [6]Pulitzer archive. You could also compare the investigative reporting cited by Newman and Glass, only there isn't any.

Silly Claim 2: Reporters Don't Work for Tax-Exempt Institutions

A similarly bizarre claim comes a few pages later:

> Another key distinction follows from how reporters and researchers conceive of their work in relation to the government and pressing social problems. investigative journalists and collaborative researchers share a strong commitment to identifying and diagnosing injustice. Yet the target of their concern is necessarily different due to their institutional commitments and norms. A key motivation for journalists' work is to guard against government abuses or to arouse public concern about an overlooked issue. University-based researchers, by contrast, must typically avoid direct political advocacy and commentary given the traditional notion of academic research as impartial and apolitical and given legal constraints on partisan political activities by 501(c)3 organizations. (300)

In fact, while 501(c)(3) status limits an organization's ability to participate in political campaigns or to lobby for legislation, it does nothing to restrict their ability to to "arouse public concern about an overlooked issue" or to engage in commentary. As the [7]IRS explains, "Organizations may … involve themselves in issues of public policy without the activity being considered as lobbying. For example, organizations may conduct educational meetings, prepare and distribute educational materials, or otherwise consider public policy issues in an educational manner without jeopardizing their tax-exempt status."

Newman and Glass might have figured this out had they read their own reference list, which is mostly composed of academic researchers hoping to arouse public concern about an overlooked issue: the overregulation of human subjects research. Heck, Newman herself is an employee of the [8]Leland Stanford Junior University, a tax-exempt institution under section 501(c)(3) of the Internal Revenue Code, and here she is writing about the subject.

For that matter, [9]many investigative journalism organizations enjoy 501(c)(3) status. This includes [10]ProPublica, another 2016 Pulitzer winner.

Some key distinction!

These alleged distinctions about methodological transparency and tax status are not merely non-existent; they are irrelevant. For what is the significance of methodological reporting or tax exemption to the freedom to ask questions without prior restraint? Newman and Glass never connect the dots.

One Possible Distinction

The profusion of inaccurate and silly non-distinctions distracts from the one potentially important distinction made by Newman and Glass: that reporters and community researchers have fundamentally different relationships with the people they interview.

> A notable difference remains in relation to the ethical obligations that engaged scholarship entails compared to investigative journalism. Journalists typically have limited and transactional connections to their interviewees and the extent of their relationship is generally directed at getting a story told and published: "The journalist's first obligation is to the public and the public's right to know and is not to the person or persons interviewed." Although some reporters establish long-term connections to sources on their beats, once investigative journalists tell a story, they usually move on to a new assignment. EOCCBR researchers, by contrast, often have ongoing and far more egalitarian and robust relationships with their partnering individuals and communities. this relational contrast becomes evident in the tensions that arise regarding who owns the data collected and who controls how community members and their concerns are represented in presentations and publications. concern for such tensions can only arise in the context of relationships of mutual respect and collaboration; for most journalists, these sorts of issues are moot given the transactional nature of their interactions. (302)

As Newman and Glass mention in that passage, [11]we can think of exceptions, but I am tentatively willing to accept this general distinction. What, then, are the implications?

Newman and Glass themselves note that the less transactional a relationship is, the worse IRBs are likely to muck it up:

> The mismatch between EOCCBR and standard IRB norms can actually thwart meaningful ethical review. For example, obtaining written, informed consent is a bedrock IRB ethical requirement. the standard

> consent process is transactional at a moment in time, and research "subjects" agree to participate only after being appraised of the predetermined and fixed "treatment" they will undergo. yet EOCCBR rests on an ongoing, negotiated, and collaborative relationship between researchers and community partners who codevelop the inquiry goals and process—and who may be both researcher and research subject. Additionally, the emergent nature of the research process may make it impossible in some cases to delineate at the outset the experiences a research participant might have. EOCCBR scholars also often work with communities that make decisions collectively (e.g., some tribal communities) or in contexts where group-level stigmas and potential harms are significant concerns (e.g., the HIV-positive community). in these contexts, the standard, individualistic consent process that focuses on individual harm does not necessarily ensure the ethical integrity of research (288).

and

> The ongoing nature of EOCCBR researchers' relationships with community partners, however, may warrant more strict assurance from researchers that they have a process for maintaining open communication, on equal terms, with community partners to address ethical issues and conflicts that may arise over time, particularly those that pertain to inequitable power in relation to race, gender, and class. monitoring these processes is clearly outside the scope of what an iRB can reasonably accomplish; this makes it all the more important to foster a research culture where ethical issues are prominent and integral to the assessment of academically sound work. this ethically sensitive research culture could be encouraged by requiring authors to make explicit in their publications how they have attended to the ethical issues their research raises, in the same way that they are now expected to make transparent their methodology. (307)

In other words, the real distinction between journalism and community-based research is that while IRBs are bad for journalists, they are even worse for community researchers. For both forms of research, other mechanisms, such as explicit discussions of research ethics in publications, would better serve researchers, readers, and citizens alike.

Newman and Glass conclude, "the IRB process, as flawed as it may be in the context of EOCCBR, is essential to ensuring that university-community collaborations can advance social justice, uphold academic standards, and respect community partners." (307)

Nothing in the article supports this conclusion.

1. http://dx.doi.org/10.1353/jhe.2014.0013
2. http://www.institutionalreviewblog.com/2007/08/james-weinsteins-anti-intellectualism.html
3. http://www.institutionalreviewblog.com/2012/05/berkeley-historian-defends-irb-review.html
4. http://tampabay.com/projects/2015/investigations/florida-mental-health-hospitals/cuts/.
5. http://www.tampabay.com/projects/2015/investigations/florida-mental-health-hospitals/secrecy/
6. http://archive.pulitzer.org/
7. https://www.irs.gov/Charities-&-Non-Profits/Lobbying
8. https://ogc.stanford.edu/stanford-legal-facts
9. http://www.dmlp.org/irs/applications
10. https://www.propublica.org/about/
11. http://alexkotlowitz.com/books/there-are-no-children-here

Political Scientists Consider "Local Control and Realities" and IRB Oversight (2016-04-29 16:57)

The April issue of PS: Political Science & Politics features several items about political science and IRBs. Here's a list; commentary will follow if I find the time.

- Dvora Yanow and Peregrine Schwartz-Shea, [1]Encountering Your IRB 2.0: What Political Scientists Need to Know
- Valerie Martinez-Ebers, [2]Introduction.
- Kenneth R. Mayer, [3]Working through the Unworkable? The View from Inside an Institutional Review Board.
- Kenneth J. Meier and M. Apolonia Calderon, [4]Goal Displacement and the Protection of Human Subjects: The View from Public Administration.
- Melissa R. Michelson, [5]The Risk of Over-Reliance on the Institutional Review Board: An Approved Project Is Not Always an Ethical Project.
- Brian R. Calfano, [6]"I" Does Not Mean Infallible: Pushing Back against Institutional Review Board Overreach.
- Lee Demetrius Walker, [7]National Science Foundation, Institutional Review Boards, and Political and Social Science.

1. http://dx.doi.org/10.1017/S1049096516000202
2. http://dx.doi.org/10.1017/S1049096516000214
3. http://dx.doi.org/10.1017/S1049096516000226
4. http://dx.doi.org/10.1017/S1049096516000238
5. http://dx.doi.org/10.1017/S104909651600024X
6. http://dx.doi.org/10.1017/S1049096516000251
7. http://dx.doi.org/10.1017/S1049096516000263

5.5 May

Yanow and Schwartz-Shea: IRBs Miss Their Targets (2016-05-06 13:50)

The first IRB related article in the [1]April 2016 issue of PS, and the only one not formally part of the symposium on IRBs, is Dvora Yanow and Peregrine Schwartz-Shea, "[2]Encountering Your IRB 2.0: What Political Scientists Need to Know." This essay is intended as an introduction to IRB issues for political scientists, and therefore presents material that will be familiar to readers of this blog.

In addition to this helpful introduction, Yanow and Schwartz-Shea make an interesting point about the scope of IRB review: on the one hand, it can be under inclusive, failing to cover serious ethical questions. On the other hand, mission creep continues apace, as universities impose restrictions not dictated by ethics or law.

[Dvora Yanow and Peregrine Schwartz-Shea, "Encountering Your IRB 2.0: What Political Scientists Need to Know," PS: Political Science & Politics 49, no. 02 (April 2016): 277–86, [3]doi:10.1017/S1049096516000202.]

The example of under-inclusiveness, also mentioned in Melissa Michelson's contribution to the issue, is the ill-fated 2014 postcard study, in which political scientists at Stanford University and Dartmouth College mailed tens of thousands of postcards to voters in Montana, California and New Hampshire, to see if they would influence voters. Each postcard bore an official state seal—likely confusing voters about the source—while the universities failed to disclose the expenditures as required by Montana law.

At the time, Montana asked Carroll College political science professor Jeremy Johnson to explore the controversy. Johnson concluded that the IRB "[4]process as currently constituted is not useful for the research conducted by many political scientists," including the postcard research. Now, Yanow and Schwartz-Shea concur, writing,

> the discipline's lack of attention to research ethics, possibly due to the expectation that IRBs will take over that discussion. In our view, this reliance is misplaced, given that IRBs largely focus on complying with the regulatory details of the federal policy, fostering a thin, compliance, or checklist ethics rather than a more substantive engagement with issues arising in the actual conduct of political scientific, sociological, and other field research.

The example of over-inclusiveness comes from the University of Northern Iowa. As Yanow and Schwartz-Shea note,

> the University of Northern Iowa IRB Manual states: "A letter of cooperation serves as documentation from the research site that the investigator has permission to conduct the research at that location. The letter typically must be from someone in authority at the organization, not a group counselor or teacher." In some cases, the permission must be included with the researcher's initial application; in other cases, the application may be assessed by the IRB without the permission, but it must be submitted later to obtain final approval.
>
> This is one example of current practice reaching beyond the scope of the initial policy document. The Belmont Report focuses on the consent of individual research participants; it does not require that researchers gain gatekeepers' approval to access research sites where the potential research participants are located (even if this is common practice in participant observer and ethnographic research, covert research excepted). Such requests for documented access to a community, organization, or other field site at the outset of a field research project are part of what critics call "mission creep" among IRBs. Requiring these requests further complicates already fraught processes of negotiating access to research settings, adding a level of formality that could, in some cases, forestall or prevent actual access.

Indeed, for this very reason, [5]Canada's TCPS2 specifically warns against requiring institutional permission:

> REBs should not prohibit research simply because the research is unpopular or looked upon with disfavour by a community or organization, in Canada or abroad. Similarly, REBs should not veto research on the grounds that the government in place or its agents have not given approval for the research project, or have expressed a dislike for the researchers.

1. http://www.institutionalreviewblog.com/2016/04/political-scientists-consider-local.html
2. http://dx.doi.org/10.1017/S1049096516000202
3. http://dx.doi.org/10.1017/S1049096516000202

4. http://www.institutionalreviewblog.com/2015/05/montana-political-scientist-irb-process.html
5. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/

IRB Chair: "Nobody Really Knows" If IRBs Do Any Good (2016-05-07 15:40)

A former chair of the University of Wisconsin-Madison Education and Social/Behavioral Science IRB guesses that IRB review "most likely" protects subjects from harm, but concedes that "nobody really knows." He also notes that it consumes tens of thousands of hours of work, mostly by researchers, at his university each year.

[Kenneth R. Mayer, "Working through the Unworkable? The View from Inside an Institutional Review Board," PS: Political Science & Politics 49, no. 02 (April 2016): 289–93, [1]doi:10.1017/S1049096516000226.]

Real Questions

Kenneth Mayer raises some significant methodological and ethical challenges facing social scientists. For instance,

> A PI proposed a study involving interviews with people who have been charged with a crime or are the target of a criminal investigation to discuss the activities that led to the charges or investigations. Should the IRB be concerned about the risk that participants could be subject to prosecution or hurt their ability to defend themselves if a district attorney demands the researcher's notes? Is informed consent sufficient to address these risks?

and

> How should we evaluate risks in a project that studies attitudes toward government in a country with an authoritarian regime? Can we rely on the proposition that people in those regimes understand the risks of criticizing their government and that those risks are therefore (in the Common Rule definition) "not greater in and of themselves than those ordinarily encountered in daily life" (45 CFR 102(j))?

Fake Answers

Unfortunately, Mayer's IRB was not able to give clear answers to such questions. Rather, it offered its best guess about what to do, while acknowledging that "another IRB, quite reasonably, may have come to different conclusions."

This practice marks Mayer and his colleagues as among those "[2]well-meaning amateurs" identified by John Lantos, whose idiosyncratic decisions endanger research participants and research alike. As Mayer concedes,

> The fact that the IRB process confronts ambiguities and competing standards is little comfort to researchers who believe their work is being delayed unnecessarily. If anything, this is a reason to clarify and address these ambiguities and tensions rather than to simply shrug our shoulders and say "it's complicated." A meaningful reform proposal would take far more space than available in this article, but if I were to offer one pragmatic suggestion for improving the IRB process, it would be to plead for better data. Even decades after the regulations have been in place, in social-science research we lack the most

> basic information about what we are doing and whether it actually does any good …
>
> Are we really protecting subjects from harm? Do all of the compliance and reporting requirements make a material contribution to the welfare of research subjects? Does the IRB process impede research that would improve society? My answers are most likely yes, no, and possibly, respectively. However, the real answer is "nobody really knows"—and there is little prospect of significant improvement until we do.

High Costs

Mayer does know that the process does harm, consuming vast amounts of time that could be better put to use:

> A "back-of-the-envelope" calculation provides a rough idea of the time costs involved in the process. It is a reasonable estimate that preparing and submitting a medium-complexity protocol for IRB review takes about 10 hours; more detailed projects take longer. Factor in another 2 to 5 hours responding to IRB questions even for an expedited protocol, and another approximate 10 hours for protocols that are deferred or require modifications. A conservative estimate is an average of 15 to 20 person-hours for each new protocol; however, complex protocols with multiple PIs or sites easily could be four or five times higher, which suggests about 12,000 to 16,000 hours annually of researcher time for initial submissions. Submitting materials for the protocols undergoing continuing review or involving changes each will take at least 1 to 2 hours—an additional 1,800 hours. IRB committee meetings and proposal reviews collectively add perhaps another 750 hours annually for the 14 non-staff IRB members; factor in another 10,000 hours annually for five full-time IRB staff. Allowing for additional consultation time, it is plausible that the UW spends annually, conservatively, at least 25,000 to 30,000 person-hours on the basics, with most of that burden falling on researchers. Unfortunately, we do not know the actual number because there is no mechanism for tracking how much time is spent on the process.

Outside Pressure

If we know that IRBs are doing harm, and can only guess if they are doing good, why continue? Mayer hints at the answer: outside pressure from the federal government and from accrediting institutions.

The 1998–2000 OPRR reign of terror is fresh in IRB memory. Mayer writes,

> What I told my frustrated colleagues is that they cannot use a "reasonable person" standard to judge the IRB process. They had to apply an "unreasonable bureaucrat" standard: that someone authorized to punish the university might question the IRB's work years later, perhaps after a serious adverse event that questions our entire process; who demands justification for each decision that the IRB has made; and who is not likely to give us the benefit of any doubts. When something goes wrong, the individual researcher is not the one who alone bears the cost. It is the institution and other researchers that face the most serious harm if the federal government imposes the nuclear option of shutting down all research.

In fact, [3]federal enforcement has dropped significantly in recent years, so a nuclear option seems unlikely. But with hundreds of millions of federal dollars at stake ($660 million in 2013–2014), I can understand why the University of Wisconsin keeps its [4]doomsday clock.

Mayer also alludes obliquely to "external review" which, he laments, imposes unnecessary burdens:

> During one external review, we faced pressure to require all foreign-language consent forms to be back-translated into English by independent professional translators. Such a rule, we were told, was necessary to ensure that consent forms contained what PIs claimed. The IRB Chair objected in the strongest terms, arguing that it would do nothing to protect subjects, would only serve to impose a monetary cost as a condition of submitting a protocol (it was understood that PIs would have to pay for it themselves), and that the UW trusted researchers to act ethically. The UW policy remains unchanged. Another review faulted us for returning too many protocols for minor changes that could be reviewed by a subcommittee of two IRB members rather than deferrals that had to go back to the full IRB, as well as for having too many unanimous votes. Still another review objected to the fact that some consent forms were signed in pencil rather than pen and wanted a requirement that all consent forms be signed in ink. Such a rule would do nothing but cause PIs to roll their eyes in exasperation.

Who were these nitpicking reviewers? Mayer doesn't say, but he does mention that Wisconsin-Madison is accredited by the Association for the Accreditation of Human Research Protection Programs.

1. http://dx.doi.org/10.1017/S1049096516000226
2. http://dx.doi.org/10.1001/archpediatrics.2009.225.
3. http://www.prweb.com/releases/2014/05/prweb11832519.htm
4. http://thebulletin.org/doomsday-dashboard

Texas A&M IRB Imposed Review for Surveys of Public Officials (2016-05-08 11:28)

In their contribution to the PS symposium, Kenneth Meiera and Apolonia Calderona complain of IRB interference in work that is clearly exempt or not even human subjects research.

[Kenneth J. Meier and M. Apolonia Calderon, "Goal Displacement and the Protection of Human Subjects: The View from Public Administration," PS: Political Science & Politics 49, no. 02 (April 2016): 294–98, [1]doi:10.1017/S1049096516000238.]

Meier and Calderon complain of two types of IRB overreach. First, the Texas A &M IRB is reviewing activities that are not human subjects research:

> Our surveys of school districts ([2]Meier and Rutherford 2014) are required to go through the Texas A &M IRB process. These surveys ask for public information: What is the process for selecting members to the board (e.g., election procedures), what is the racial composition of the board, the student enrollment, and the district administrative and teaching staff? The surveys are not confidential; school districts are identified so that these data can be merged with other public datasets for analysis. The question posed to our IRB was: "Who are the human subjects in this research and what risks do they incur that we should be prepared to mitigate"? The answer was the people who filled out the form are human subjects and they might be subject to retaliation if it were revealed how they filled it out. Insofar as we do not know exactly who fills out this form (it is likely a staff person designated to respond to information requests), the idea that an employee would be subject to retaliation for providing public information—information often posted on the district website—strikes us as an argument that is absurd on its face.

Though the Meier and Rutherford article (n. 6) states that "all data and documentation for the replication of this work can be found at http://perg.tamu.edu," I was unable to find the survey questions for that article on the [3]PERG

site. But if Meier and Calderon are accurate in their description of the project, it does sounds as though the IRB is reviewing work beyond its authority.

Second, Meier and Calderon are angry that the IRB insists on reviewing surveys of public officials:

> Public officials are specifically not covered by federal regulations for HSP [i.e., CFR § 46.101(b)3i]; clearly, this lack of coverage is consistent with the legislative history of HSP. The regulation states that research in which "the human subjects are elected or appointed public officials" are "exempt from this policy." No one believes that the purpose of the policy is to protect the Public Health Service employees who designed the Tuskegee and Guatemala syphilis studies. As students of bureaucracy, we teach that bureaucrats are public officials subject to different laws and regulations for no other reason than that they work for the government. We could contend that, at a minimum, any appointed officials in a policy-making position (e.g., school superintendents, university presidents, and agency heads) are public officials and, therefore, research on them is not covered by federal regulation. The Texas A &M IRB rejected this position and insists that surveys of such officials are subject to review and regulation.

Given [4]OHRP's explicit guidance that school superintendents are public officials for purposes of the Common Rule, Meier and Calderon have a good case here. Less clear is whether the [5]school principals they also survey count. OHRP has said that [6]superintendents are public officials but teachers are not, so where does that leave principals?

Meier and Calderon might have more patience with their IRB if it gave good, or at least consistent, advice. Instead,

> Our annual Texas Middle Managers Survey has the same research focus, design, and subjects every year because the goal is to study the management process over time. In every case in which we submitted the approved IRB application from the previous year, the IRB required additional changes. The variation both within and across universities prompts the question of how local IRBs implement national guidelines.

So much for [7]Stark's "local precedents."

Frustrated, Meier and Calderon turn to their training to explain otherwise baffling behavior:

> Goal displacement occurs when organizations lose sight of objectives (i.e., outcomes) and focus on procedures that may not be directly tied to achieving their goals. Goal displacement leads to suboptimization; that is, because IRBs maximize compliance with procedures, researchers spend more time on compliance procedures. Because human subjects' risks vary greatly across research areas, projects that pose little risk have a higher than optimal cost–benefit ratio. Even the IRB suffers from goal displacement based on the medical–legal model because it spends more time than it should on low-risk projects; as a result, it has less time available for high-risk projects. This misallocation of resources then increases the possibility of an adverse event affecting human subjects.

Actually, it's worse that that: IRB review may itself endanger research participants. As Meier and Calderon explain,

> Several years ago, the Project for Equity, Representation, and Governance conducted a study on Latino high school dropouts. The study began with a large quantitative study of school districts to determine

> how well they were performing relative to their resources and constraints. The second part of the study selected 10 districts based on regression diagnostics— five districts doing exceptionally well and five doing poorly—for in-depth study. We promised confidentiality to the districts in return for access. The Texas A &M IRB requested the district names; we refused. We are confident in our own confidentiality procedures; the ability of our IRB to protect confidentiality was unknown and its implementation problems did not inspire optimism concerning its ability to protect confidentiality… .
>
> [in footnote] After several rounds of negotiation and delays of months, the IRB agreed that if we provided a list of districts from which the 10 would be drawn, that would be sufficient. We provided a list of all 1,043 Texas school districts.

Reluctant to play such games forever, Meier and Calderon sketch out an alternative screening system in which the most intrusive research, involving the most vulnerable subjects, would get the most scrutiny. Of course, that is pretty much what was promised with the [8]promulgation of the 1981 regulations, the basis for today's Common Rule. And [9]it's terribly hard to know what intrusive, or risky, even means. So without specifying in painful detail that the IRB may not interfere with specific activities, it will be difficult to design a system that will defeat the "[10]one-way ratchet" of ever more burdensome oversight.

1. http://dx.doi.org/10.1017/S1049096516000238
2. http://dx.doi.org/10.1017/S0003055414000148
3. http://perg-tamu.com/
4. http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees-text-version/index.html
5. http://perg-tamu.com/documents/2015/7/2014%20Texas%20Principal%20Managment%20Final%20Summary%20Stats1.pdf
6. http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter/index.html
7. http://www.institutionalreviewblog.com/2008/01/how-irbs-decide-badly-comment-on-laura.html
8. https://wayback.archive-it.org/all/20160202182914/http://archive.hhs.gov/ohrp/documents/19810126.pdf
9. http://dx.doi.org/10.2139/ssrn.2138624
10. http://www.institutionalreviewblog.com/2008/12/burris-on-compliance-vs-conscience.html

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Call for Chapters: Virtue Ethics in the Conduct and Governance of Social Science Research **(2016-05-08 20:02)**

Nathan Emmerich has secured a contract for a 2017 book on Virtue Ethics in the Conduct and Governance of Social Science Research. He seeks additional contributors. See the [1]call for chapters.

1. http://nathanemmerich.org.uk/blog/call-for-chapters-virtue.html

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Can community partners replace IRBs for field experiments? **(2016-05-09 08:19)**

In her contribution to the PS symposium, Melissa Michelson argues that "real-world practitioners" will often know more about relevant ethics and law than will the members of an IRB.

[Melissa R. Michelson, "The Risk of Over-Reliance on the Institutional Review Board: An Approved Project Is Not Always an Ethical Project," PS: Political Science & Politics 49, no. 02 (April 2016): 299–303, doi:[1]10.1017/S104909651600024X.]

Michelson's essay is a commentary on the [2]Montana postcard fiasco, also mentioned by [3]Yanow and Schwartz-Shea. Michelson notes that a New Hampshire version of the experiment had been deemed exempt by the Dartmouth IRB, and that generally IRBs are the wrong tools to monitor such research.

> There were clear potential consequences that the researchers should have considered. Sending postcards to a large portion of the electorate in such a close race should have raised red flags about the possibility of altering the outcome of the election. Sending postcards with partisan information in a nonpartisan judicial race in a state that had recently endured dark-money scandals should have raised red flags about how the recipients of the mailers would react to outside money coming into their state. Sending postcards linked to elite out-of-state universities should have raised red flags about how the voters of Montana would react to being the guinea pigs in a research experiment.
>
> None of these concerns was likely to be revealed through the IRB process. IRB members are not likely to be experts in electoral law, and it is unreasonable to assume that they would have noted the possible illegal aspects of the experimental proposal. They were also unlikely to know much about Montana politics or that the size of the experiment raised the possibility of changing the outcome of the election.

Instead of relying on IRBs, Michelson advises that researchers (who know most about the proposed research) consult with experts.

> Seeking IRB approval should not be equated with a decision that a proposed experiment is ethical. Instead, researchers should start by asking themselves whether they are behaving ethically. As discussed previously, this can be difficult; our enthusiasm for our own ideas can blind us to possible risk and harm.
>
> Another route is for researchers to supplement their own internal check on the ethics of a [get-out-the-vote] experiment by involving partners. This may mean working with candidates, local election officials, or a local community organization. Involving actors who are not political scientists but rather real-world practitioners provides a different perspective and, usually, relevant expertise about legal constraints and possible unintended effects. Working with a partner in Montana, for example, might have helped the Stanford–Dartmouth team to better understand the local political context regarding dark money or led them to design postcards that did not break local laws. This type of pracademic [sic] work has other advantages as well. Of course, partnering with candidates and elected officials also can introduce disadvantages and ethical concerns, particularly if those partners have something to gain from the research. When possible, scholars should seek to partner with independent local actors, such as nonprofit and nonpartisan organizations.

In other words, rather than asking a group of non-experts assembled from the university and community, why not consult people who know something?

While Michelson generally seems to understand that "IRB procedures focus on possible harm to individuals, not election outcomes," she also writes that "Despite guidelines mandating avoidance of harm to society overall, the IRB process as interpreted at many institutions is solidly for the protection of individuals rather than broader populations."

What "guidelines"? The Common Rule ([4]§46.111) asks IRBs to consider only risks to subjects. It explicitly states that "the 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. http://dx.doi.org/10.1017/S104909651600024X
2. http://www.institutionalreviewblog.com/2015/05/montana-political-scientist-irb-process.html
3. http://www.institutionalreviewblog.com/2016/05/yanow-and-schwartz-shea-irbs-miss-their.html
4. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111

Concern that IRBs will hinder field experiments (2016-05-10 22:14)

In his PS contribution, Brian Calfano worries that the [1]Montana postcard fiasco will lead IRBs to impede political science field experiments, especially at teaching institutions.

[Brian R. Calfano, "'I' Does Not Mean Infallible: Pushing Back against Institutional Review Board Overreach," PS: Political Science & Politics 49, no. 02 (April 2016): 304–8, doi:[2]10.1017/S1049096516000251.]

Calfano writes,

> Field experiments are perhaps the most controversial of political science research methods, and my intention in this article is to encourage those at institutions where IRBs have proven hostile to the methodology. Although the Montana mailer controversy has made life difficult for scholars using field-based interventions, fallout may not be evenly distributed across institutions when sorted by type (e.g., R1s versus more teaching-oriented institutions). Although I am unaware of any available statistics on this issue, it is reasonable to assume that those at institutions where IRBs lack experience with field-experiment methodology (and, presumably, refuse to be educated) may be more likely to face a capricious denial of their research proposal. Given their increased classroom instruction and service responsibilities, IRB members at teaching institutions—on average—have less time and motivation to be familiar with cutting-edge research techniques versus those at research-intensive schools (exceptions notwithstanding). Unless these IRBs are willing to be educated on the method, a "perfect storm" of IRB ignorance and/or recalcitrance and the desire of newer faculty to make tenure and/or "move up" the institutional ladder means that bias against field experiments is likely to affect scholars at "teaching" institutions (i.e., liberal arts colleges and Master's-granting institutions) the most. This means field experiments may become an off-limits methodology for a large swath of political scientists whose IRBs are less aware of discipline-specific research trends, although there is no guarantee that IRBs at R1 institutions are always supportive of field-based interventions either. And, it is why simply allowing IRBs to pass unfair judgment on field experiments as if the "I" stands for "infallible" is intolerable.

As Calfano's repeated use of the terms "may" and "likely" indicate, he is speculating about possible future trends rather than reporting empirical findings.

I do question the assumption that IRBs at research institutions are less inclined to hamper research. It is equally plausible that IRBs at R1 institutions, like Mayer's [3]University of Wisconsin-Madison, are more likely to see their role as protecting the stream of research funding, and are therefore more risk averse, while teaching colleges, like [4]Macalester, allow for innovation.

1. http://www.institutionalreviewblog.com/2015/05/montana-political-scientist-irb-process.html
2. http://dx.doi.org/10.1017/S1049096516000251
3. http://www.institutionalreviewblog.com/2016/05/irb-chair-nobody-really-knows-if-irbs.html
4. http://www.institutionalreviewblog.com/2012/07/can-macalesters-divisional-review-work.html

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NSF Officer Misstates Belmont and Common Rule Standards (2016-05-11 09:35)

In the final contribution to the PS symposium, Lee Demetrius Walker, currently serving as program officer for the Political Science Program at the National Science Foundation, acknowledges the problems of applying a biomedical review system to social science. But he misstates the Belmont and Common Rule standards for assessing research.

[Lee Demetrius Walker, "National Science Foundation, Institutional Review Boards, and Political and Social Science," PS: Political Science & Politics 49, no. 02 (April 2016): 309–12, doi:[1]10.1017/S1049096516000263.]

Walker notes that

> On the one hand, IRB evaluations for experimental social science will be much like IRB evaluations for biomedical and behavioral sciences. In short, IRBs apply the Belmont principles to experimental social-science research with the same rigor as for biomedical and behavioral-science research.
>
> On the other hand, this extension of biomedical-level evaluation to experimental social science creates several problems: (1) the IRB review may be too severe because it is conducted by individuals who generally review more intrusive experimental research; (2) the IRB may assign social-science reviewers who are more comfortable with nonexperimental social-science methodologies; and/or (3) the IRB may extend the experimental protocols to social-science research that uses nonexperimental approaches. These problems may lead to delays that threaten completion of the research or to denial of proposed research because IRB reviewers are unfamiliar or uncomfortable with political science methods.

He calls on researchers to cooperate with their local IRBs, since "NSF program officers can neither waive the applicability of the Common Rule to research activities nor impose less oversight than the institution's IRB requires."

Walker unfortunately misstates the requirements of both the Belmont Report and the Common Rule. He writes,

> The fundamental principle of human-subjects protection is that people should not be involved in research without their informed consent and that subjects should not incur increased risk of harm from their research involvement.

In fact, while the [2]Belmont Report states that "in most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information," even this includes the qualifier, most," suggesting that some persons can be involved in research without their informed consent. This is made explicit in [3]§46.101 of the Common Rule, which exempts several categories of research from the standards of IRB review, including informed consent. Moreover, the Common Rule states that an institution's "statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of

human subjects of research … need not be applicable to any research exempted or waived under §46.101(b) or (i)."

As for risks, neither the Belmont Report nor the Common Rule demand that "subjects should not incur increased risk," since such a standard would make most research impossible. As the [4]Belmont Report explains, "Risk can perhaps never be entirely eliminated," and so it recommends merely that "Risks should be reduced to those necessary to achieve the research objective." This standard is encoded in [5]§46.111 of the Common Rule, which demands that "Risks to subjects are minimized" (not eliminated) and 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," not that they be zero.

The NSF has done good work explaining the application of the Common Rule to social science research, so it is disappointing that Walker, writing as the foundation's representative, has misinformed his readers about these important points.

1. http://dx.doi.org/10.1017/S1049096516000263
2. http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#xrespect
3. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101
4. http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#xassess
5. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111

NPRM Comments Focus on Biospecimens **(2016-05-12 11:00)**

The Council on Governmental Relations (COGR), with support from the Association of Public and Land-grant Universities (APLU), has reviewed and analyzed (they don't say "read") all 2,186 public comments submitted in response to the 2015 NPRM. The analysis suggests that the debate over biospecimens is crowding out discussion of other proposed reforms.

[Council on Governmental Relations, "[1]Analysis of Public Comments on the Common Rule NPRM," May 2016. h/t Michelle Meyer.]

Nearly 70 percent (1520 of 2186) of the comments "addressed one or more of the proposed changes detailed above involving non-identified biospecimens. Of these responses, 94 – 100 % of patients and members of the research community, including researchers, universities, medical centers and industry, opposed the changes" on the grounds that "the proposed changes will significantly reduce the availability of biospecimens for research, will have a significant negative impact on medical advances, and will adversely affect human health."

By contrast, only 15 percent of responses commented on the proposed mandate for single IRB review for multisite studies, and less than 10 percent commented on imposing the Common Rule regardless of funding source, security safeguards, and posting consent forms to a public website.

We don't know what percentage commented on [2]the stuff I care about, like interviews and ethnography. The COGR analysts did not code for that.

Once again, concerns about biomedical research dominate both the regulatory process and the public response to it. We've been on that path for [3]over 50 years; why stop now?

1. http://www.cogr.edu/COGR/files/ccLibraryFiles/Filename/000000000346/Analysis%20of%20Common%20Rule%20Comments.pdf
2. http://www.institutionalreviewblog.com/2016/01/my-nprm-comments.html
3. http://www.institutionalreviewblog.com/2016/02/fifty-years-of-irbs.html

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Medical researchers call for IRB clarity (2016-05-13 08:03)

Two medical researchers and a bioethicist, all affiliated with the UC Davis Center for Healthcare Policy and Research, call for IRBs to "reduce researchers' frustrations and foster greater trust" by offering "transparency and accountability around IRB decisions."

[Stephen G. Henry, Patrick S. Romano, and Mark Yarborough, "Building Trust Between Institutional Review Boards and Researchers," Journal of General Internal Medicine, May 2, 2016, 1–3, doi:[1]10.1007/s11606–016–3721–3.

Citing [2]Abbott and Grady, [3]Schneider, and [4]Stark, the authors lament that "Many IRBs deliberate in isolation and either lack access to or do not make use of sufficient scientific, clinical, or ethical expertise relevant to the protocols they review. Research shows that IRBs tend to adjudicate protocols in a disjointed, ad hoc manner rather than proactively developing and promulgating policies that they then apply to protocols that involve substantive ethical concerns in regulatory gray zones."

They call for IRBs and the institutions they serve to:

- "acknowledge [the broad discretion they possess] and then be willing to be held accountable for the manner in which they exercise it."
- "cite the specific sources that support their decisions, such as the Common Rule, written institutional policies, and/or IRB discretion."
- "specify whether decisions are driven by concerns for research participants or for institutions."
- "be explicit about the extent to which they used empirical evidence, if at all, to guide their decisions."
- establish "an organized appeals process … to mitigate the inherent power imbalance between researchers and IRBs."

"Widespread implementation of these recommendations," they hope, "will promote productive dialogue about research ethics within research institutions, and help to guard against the current prevailing focus on compliance. Implementation will also promote more consistent and defensible decisions from IRBs and greater trust between IRBs and researchers, both of which will strengthen public confidence in biomedical research."

Sounds good, but I must note that since 1981 IRBs have been required to write minutes that show "[5]the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." Henry et al. are asking IRBs to obey the regulations they have been flouting for 35 years.

1. http://dx.doi.org/10.1007/s11606-016-3721-3
2. http://dx.doi.org/10.1525/jer.2011.6.1.3

3. https://mitpress.mit.edu/books/censors-hand
4. http://press.uchicago.edu/ucp/books/book/chicago/B/bo12182576.html
5. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.115

Ethics of big data research are unsettled, and so are mechanisms (2016-05-23 11:34)

Sarah Zhang of WIRED uses the OKCupid data dump to explore the unsettled state of big data research ethics and mechanisms to promote them.

[Sarah Zhang, "[1]Scientists Are Just as Confused About the Ethics of Big-Data Research as You," WIRED, May 20, 2016.]

Everyone Zhang spoke to more or less agrees that while new forms of research raise new ethical questions, we haven't seen IRBs provide consistent, much less wise, answers:

- Your humble blogger: "The [IRB] structure was very much developed out of health agencies for experimental research."
- Kelsey Finch: "The IRB may make very different decisions based on who is on the board, what university it is, and what they're feeling that day."
- Michelle Meyer: "Someone needs to provide oversight, but the optimal body is unlikely to be an IRB, which usually lacks subject matter expertise in de-identification and re-identification techniques."

Unfortunately, researchers themselves aren't doing much better. Zhang notes that

> When Katie Shilton, an information technology research at the University of Maryland, interviewed 20 online data researchers, she found "significant disagreement" over issues like the ethics of ignoring Terms of Service and obtaining informed consent.

1. http://www.wired.com/2016/05/scientists-just-confused-ethics-big-data-research/.

CITI Program is not unique in its mortifying stupidity (2016-05-23 11:37)

Writing in Slate, L. V. Anderson condemns simplistic, online training programs that are supposed to encourage regulatory compliance, but really just suck up time and money without improving behavior.

[L. V. Anderson, "[1]Ethics Trainings Are Even Dumber Than You Think," Slate, May 19, 2016.]

Anderson writes,

> Regulators, managers, and employees are caught in a vicious cycle. Regulators pressure companies to implement training programs in hopes of reducing corporate crime and malfeasance. Executives implement training programs in hopes of protecting themselves against lawsuits and prosecution. Employees see through executives' motivations and ignore, or even rebel against, the lessons of the trainings.
>
> Although there's not much research one way or the other, the online nature of compliance courses probably exacerbates this vicious cycle.

Anderson does not specifically mention the [2]mortifyingly stupid CITI Program and its cousins in the IRB world, but everything she says applies to them.

1. http://www.slate.com/articles/business/the_ladder/2016/05/ethics_compliance_training_is_a_waste_of_time_here_s_why_you_have_to_do.html
2. http://www.institutionalreviewblog.com/2011/06/citi-program-as-mortifyingly-stupid.html

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Lawrence Hosman (2016-05-24 14:05:56)
I agree somewhat, but I think the Slate article is talking more about the sort of training my university has decided to require. It's from a group called Workplace Answers, and covers topics such as FERPA, Title IX, Clery Act, bullying, financial conflicts of interest, and so forth. We've been required to complete 9 modules so far this year. The CITI training is much less burdensome than the other courses I have gone through.

Zachary M. Schrag (2016-05-25 22:24:23)
Thanks for this comment.

The problem with the CITI Program is not that it's burdensome. Distinguishing the "correct" multiple choice answer from several obviously wrong ones is not hard, and if you happen to click wrong, you just do it again. The problem with the CITI Program is that it's mortifyingly stupid, and that's Anderson's complaint about these other programs as well.

As it happens, I just recently completed my university's sexual harassment training. If anything, it was slightly less mortifyingly stupid than the CITI Program, in that at least there's case law behind most of the answers.

5.6 June

Emmerich seeks case studies about social science ethics (2016-06-03 16:57)

Nathan Emmerich seeks case studies about social science ethics for the SAGE Research Method Cases.

The [1]Methodspace page explains:

> This special collection will be edited by Dr Nathan Emmerich (n.emmerich@qub.ac.uk). We are interested in cases that discuss substantive ethical issues or concern the process of securing ethical approval to conduct research. In both instances we seek accounts that will provide a description of 'what really happened' and offer lessons for those who are conducting similar research. These case studies will have significant pedagogical value whilst also engaging with current developments in the ethics of social science research. This includes the ESRC's recently revised Framework for Research Ethics (FRE) and the generic principals of research ethics recently adopted by the UK's Academy of Social Sciences.

> If you are interested in publishing your experiences, disseminating your thinking and to promoting your research, or would simply like to discuss the possibilities further, please contact Dr Nathan Emmerich, at: n.emmerich@qub.ac.uk

1. http://www.methodspace.com/resources/sage-research-method-cases/

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nathan (2016-06-06 17:58:01)
Thanks for posting this!

The Belmont Report was published in 1978, goddammit! (2016-06-04 08:15)

Bioethicists Barron Lerner and Arthur Caplan have published a nice essay about using history to make better decisions today. I will comment on their main points in a separate post, but I want to address separately the authors' repetition of a common error: the suggestion that the Belmont Report was published in 1979.

The Belmont Report was published in 1978, goddammit!

[Barron H. Lerner and Arthur L. Caplan, "Judging the Past: How History Should Inform Bioethics," Annals of Internal Medicine 164, no. 8 (April 19, 2016): 553–57, doi:[1]10.7326/M15–2642.

Here's the mistake as it appears in the essay:

> The public outcry over the revelations about the Tuskegee syphilis study was next, thanks to a 1972 newspaper exposé. This scandal led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which issued the famous Belmont Report in 1979 and the 3 following ethical principles designed to prevent future calamities: respect for persons, beneficence, and justice.

In fact, the National Commission did not issue any documents in 1979, for it went out of existence in October 1978:

PRESIDENT'S COMMISSION ON BIOETHICS

FRIDAY, AUGUST 4, 1978

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2123, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. ROGERS. The subcommittee will come to order, please.

This afternoon the Subcommittee on Health and the Environment is holding a legislative hearing on H.R. 13662, a bill to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The proposed Commission would succeed the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which goes out of existence on October 31, 1978.

The studies of the National Commission have been of great value to the Department of Health, Education, and Welfare and to Con-

A month prior to its disbandment, on 30 September 1978, the Commission had formally transmitted the report to the president and other officials:

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The identification of basic ethical principles that should underlie the conduct of research involving human subjects, and the development of guidelines to assure that such principles are followed, were topics of studies set forth in the Commission's mandate under Public Law 93-348. This mandate also directs the Commission to submit its report to the President, the Congress, and the Secretary of Health, Education, and Welfare.

Unlike most of the previous reports of the Commission, the Belmont Report does not make specific recommendations for administrative actions by the Secretary of Health, Education, and Welfare. Instead, it is our recommendation that the Belmont Report be adopted in its entirety as a statement of departmental policy on the conduct of research involving human subjects. Publication and dissemination of this policy will provide federal employees, members of Institutional Review Boards and scientific investigators with common points of reference for the analysis of ethical issues in human experimentation. While the principles cannot always be applied so as to resolve beyond dispute particular ethical problems, they provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

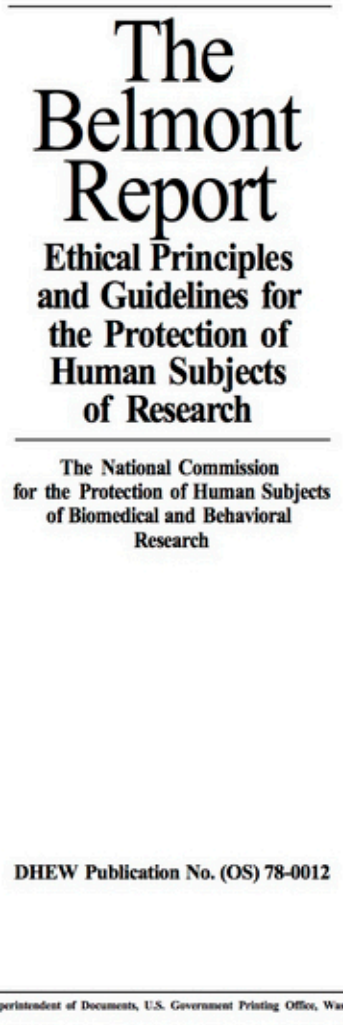
The Belmont Report is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center and the monthly Commission's deliberations that have been conducted over the nearly four years of our existence.

We appreciate the opportunity to have worked on this fundamental task in the protection of human research subjects.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

The Government Printing Office published the report, including the letters of transmittal, as DHEW Publication No. (OS) 78–0012:



The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

DHEW Publication No. (OS) 78-0012

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

What do you suppose that “78” stands for?

On 18 April 1979, nearly seven months after the transmittal, the Department of Health, Education, and Welfare published the Belmont Report in the [2]Federal Register and solicited public comment. And it has been reprinted in many places since.

If scholars wish to cite the Federal Register version for convenience, that’s fine, but they still need to indicate the original date of publication. [3]Here’s the APA style folks on the subject:

> If you are citing something that has been republished or reprinted, the entry in the reference list should

> use the date of the version you read. At the end, append the date of the original work or the source of the reprint (see Examples 21 and 26, pp. 203–204, for details on how to format the reference). In text, cite both dates: first the original version, then the version you read, separated by a slash (Freud, 1900/1953).

Freud died in 1939, so citing something he wrote to 1953 alone would be silly. As silly as saying that a commission that folded in 1978 issued a report in 1979.

[4]Citing Medicine, 2nd edition, which is the official style guide for the Annals of Internal Medicine is less clear, but it does give this example for a book first published in 1932 and reprinted in 1960:

> Herrick CJ. The thinking machine. 2nd ed. Chicago: University of Chicago Press; 1960, c1932. 372 p. (Chicago reprint series).

Citing that work to 1960 alone would mislead readers.

The gap between 1978 and 1979 is less substantial, but it still matters. DHEW issued draft regulations, based in part on the report, on 14 August 1979. Doing so just 10 months after the release of the report was hasty enough. Doing so just four months after (as those who cite the report to April 1979 are implying) would have been insane. History is more than names and dates, but names and dates do matter.

The Belmont Report was published in 1978, goddammit!

PS. The Lerner and Caplan essay includes another chronological howler:

> Students also learn about the efforts to address past abuses, such as the publication of the Belmont Report in 1979 and the establishment of institutional review boards by U.S. federal law in 1991.

[5]IRBs made it into U.S. federal law in 1974, and [6]by 1979 Caplan was falsely assuring us that their impact had been “miniscule.” His error here reminds us that eyewitnesses to history are not always the best witnesses to history.

1. http://dx.doi.org/10.7326/M15-2642
2. https://web.archive.org/web/20130618142422/http://www.hhs.gov/ohrp/archive/documents/19790418.pdf
3. http://blog.apastyle.org/apastyle/2010/01/the-generic-reference-when.html
4. http://www.ncbi.nlm.nih.gov/books/NBK7271/
5. https://www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg1233.pdf
6. http://www.nytimes.com/1979/12/27/archives/letters-hews-painless-way-to-review-human-research.html

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Mark Hakkarinen, M.A. (2016-06-06 09:04:30)
Nice detective work. I’ve checked and have corrected this archived page of the President’s Council on Bioethics listing former Bioethics Commissions and their published works to correctly note the Belmont Report as having been first published in 1978: https://bioethicsarchive.georgetown.edu/pcbe/reports/past _commissions/index.html

Bioethicists learn from history (2016-06-05 12:17)

Now that I’ve had [1]my rant about the Belmont Report’s year of publication, I can turn to the more substantive arguments of Barron Lerner and Arthur Caplan’s recent essay, “Judging the Past: How History Should Inform

Bioethics." These scholars wisely argue against simplistic condemnations of past behavior, yet they also reject the other extreme of attributing all past misbehavior to the age rather than the individual. By understanding what choices were open to actors in the past, we can better assess the morality of their actions and the choices that we ourselves face.

[Barron H. Lerner and Arthur L. Caplan, "Judging the Past: How History Should Inform Bioethics," Annals of Internal Medicine 164, no. 8 (April 19, 2016): 553–57, doi:[2]10.7326/M15–2642.

Lerner (who holds a PhD in history as well as an MD) and Caplan recite several of the usual human subjects horror stories: Nazis, Tuskegee, Willowbrook, Jewish Chronic Disease Hospital. ([3]Sanjay Srivastava will be glad to know that poor Stanley Milgram gets a pass this time.)

They offer a twist, however, in insisting that not all the perpetrators of these misdeeds were "monsters from an alien past." Rather, they draw on recent scholarship, including works by such eminent historians as Allan Brandt and Susan Reverby, to demand that we understand the context in which people acted immorally, including the crucial question of who supported or challenged the decisions now judged unethical.

They note, for instance, that "many students of bioethics may be surprised to learn that even though the Macon County [Alabama] Medical Society was predominantly African American by the late 1960s, it continued to approve the Tuskegee study. This reality, which raises issues of class, complicates explanations of the study that focus only on racism."

But complication is not exoneration.

> In promoting the historicizing of the past, we do not advocate moral relativism, in which past behaviors are merely excused because they occurred in an era with different values. For example, one might be tempted to explain away the behavior of the Tuskegee study investigators by noting that the study took place in the Jim Crow South, where racism was institutionalized. Historians would be unlikely to make such an argument, but they might ask the following contextual question: Why, in the case of the Tuskegee study, did otherwise progressive persons remain so backward when it came to the issue of race? Indeed, it is precisely the context that holds the key lesson for modern researchers and clinicians studying the moral failings of their predecessors.
>
> One way to help assess moral blame is to ask whether there were contemporaneous criticisms that should have alerted physicians to ethical problems. For example, even though the inventor of the lobotomy, Egas Moniz, won the Nobel Prize for his achievement, there were detractors. In 1947, for example, a Swedish psychiatrist labeled the operation "crude" and "hazardous." The neurologist Walter Freeman achieved renown in the mid–1940s for developing a less-invasive lobotomy, but he continued to do the operation into the 1960s on children with psychosis and healthy adolescents with "anxiety"—patients who were widely believed to be inappropriate candidates. This persistence, despite criticisms and other available options, surely deserves particular historical censure. In the case of the radiation experiments, some commentators at the time remarked that the experiments violated standards established by the Nuremburg Code, belying claims that the concept of informed consent was largely unknown. "It's not very long since we got through trying Germans for the exact same thing," wrote an official about a proposed study, adding that it had "a little of the Buchenwald touch." Researchers ignored these and other warnings, which arguably makes them more culpable than those whose behaviors were not challenged at the time.

Nicely put. Let's just also recall that certain regulators and bioethicists have ignored [4]timely warnings as well.

1. http://www.institutionalreviewblog.com/2016/06/the-belmont-report-was-published-in.html
2. http://dx.doi.org/10.7326/M15-2642
3. https://hardsci.wordpress.com/2011/07/06/citi-is-still-misrepresenting-milgrams-obedience-research/
4. http://www.nytimes.com/1979/12/16/archives/prior-restraint.html

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Strangers on a Train (2016-06-08 20:14)

In Patricia Highsmith's novel, Strangers on a Train (adapted for the screen by Alfred Hitchcock), a sociopath plans to get away with murder. Rather than kill his own nemesis and risk arrest, he will kill the troublesome wife of a stranger, and expect that stranger to reciprocate by killing his detested father. Since each man could arrange to be out of town at the time of his relative's murder, each alibi could be ironclad.

Ethnographers Staci Newmahr and Stacey Hannem think this is a good way to deal with the IRB. The idea might be stupid enough to work in some cases, but it is also a distraction from the hard work of regulatory reform.

[Staci Newmahr and Stacey Hannem, "Surrogate Ethnography Fieldwork, the Academy, and Resisting the IRB," Journal of Contemporary Ethnography, May 10, 2016, doi:[1]10.1177/0891241616646825.]

Newmahr and Hannem call their proposal "surrogate anthropology":

> ''Surrogate ethnography" is a methodology in which one ethnographer donates a story from her life to another ethnographer, who represents and analyzes that story, and in so doing, furthers our understanding of an aspect of society, culture, or social process.

In other words, one researcher tells a bunch of stories to another, who writes them up and, in return, tells her stories to the first researcher. Both get publications.

As a writing method, it may not be a bad idea. As Newmahr and Hannem put it,

> For those of us disinclined to write about ourselves, for whatever set of reasons or at whatever particular moments, surrogate ethnography provides an interloper; we can share our rich, reflective, and instructive stories without writing our own hearts onto the page.

Something like Byron Dobell telling Tom Wolfe just to [2]type out his notes from the car show. But is this a way to evade IRB scrutiny?

No systematic investigation here, officer!

Here's Newmahr and Hannem trying to explain why they think surrogate ethnography (SE) could evade IRB jurisdiction:

> There are no recording devices, no consent forms, and no interview guides: this is not a study, but two academic friends hanging out and swapping stories. Nor is it an interview (or a series of interviews), for as with any surrogacy, the "donor" must relinquish control of the process. The surrogate carries, and ultimately gives birth to, the tales from the field. Otherwise the pair (or triad or quad, etc.) is merely ghostwriting for the other. The point is not to sign their names to other researchers' stories and analyses. Rather they interpret, tell, and analyze the stories for themselves. True to ethnography proper, one person's story becomes the other's data. The difference in SE is that the (first) storyteller (the donor) is not a "human subject," but the site of a cultural text. Thus, a (would-be) ethnographer who witnesses a fight in a schoolyard, volunteers in a children's hospital, or whose brother competes in the Special Olympics can use her life as data.
>
> In short, SE means that we stay in the field. We keep personal diaries, we think our thoughts, we cultivate our relationships. We call ourselves field- workers. But we do not publish these stories ourselves. Instead, we tell someone else about them. We (probably) cannot provide our surrogates with our diaries, but we can talk about them … say, at a bar, at a conference.
>
> This situates SE as a kind of folklore, rather than social science. We are not studying the surrogate, only the oral history she provides, thereby, at least at this time, exempting it from human-subjects oversight. SE turns ethnography from a "data-gathering" project into a kind of narrative analysis. We recognize that this shift, like all methodologies, brings with it a set of challenges and important considerations. However, in order to provide (brief) illustrations of surrogate ethnography here, we cannot delve deeply into the method itself, nor explore the set of interesting methodological issues we encountered in the course of this project. Our aims here are to begin a conversation about its potential, via a case study of the method, and to continue the conversation about ethnography and IRBs.

Newmahr and Hannem do not cite or quote any regulations here, leaving us to guess why they think these activities would not qualify as research under U.S. or Canadian definitions. (Hannam teaches in Canada.) Clearly their proposal involves gathering data through interaction, so they can't escape scrutiny on that grounds. It's hardly worth asking whether surrogate ethnography is "[3]designed to develop or contribute to generalizable knowledge," since the U.S. regulatory concept of [4]generalizability is effectively meaningless.

Perhaps a more interesting question, then, is whether surrogate ethnography could avoid being counted as a "[5]systematic investigation" (the U.S. term) or "[6]disciplined inquiry and/or systematic investigation" (the Canadian version). Does it depend how long they stay at the bar?

As Newmahr and Hannem concede, the biggest problem with their argument is that some IRBs have asserted jurisdiction over even autoethnography. If you can't report your own life experience without asking permission, reporting the experiences of a colleague isn't going to be much better.

Playing at powerlessness

The essay includes two examples of surrogate ethnography: one concerning visitors to a prison, humiliated by the prison guards, the other about participation in sadomasochism. The latter story explains that "the bottom has agency, although she or he is playing at powerlessness." The same could be said for these ethnographers.

Newmahr and Hannem revel in their alleged powerlessness:

> When our flagship academic organizations step in on the side of IRBs (as ASA has; see Adler and Adler 2002), railing against IRB controls becomes even more daunting, if not entirely futile. Even the American Anthropological Association has abandoned the fight: "This means that the risks of harm must be considered in relation to the potential benefits of ethnographic research. This process should actively involve the researcher and the IRB, the researcher and participants, and finally the IRB, the researcher and stakeholders" (AAA 2006). We have seen an increase in journal editors and peer reviewers requesting that authors include the status and process of IRB reviews in their submitted manuscripts.
>
> Beyond the fundamental problem, that IRB mission creep directly challenges the very freedom of inquiry that many universities claim as their raison d'être, nearly everyone who has thought about it agrees that ethnography is uniquely affected by IRB regulations (see Adler and Adler 2002; Bosk and De Vries 2004). IRB translations of the federal mandates governing funded research are so grossly inapplicable to fieldwork that it becomes impossible to be fully compliant and honest, and still conduct (perfectly ethical) fieldwork.

I usually strip citations from quotations on this blog, but notice something about the ones here: while good articles, they are all over ten years old. Before TCPS2. Before the ANPRM. Before the NPRM. Particularly unfair is the treatment of the AAA, citing its 2006 statement but not its [7]marvelous 2011 attack on the current regime.

Neither Newmahr nor Hannem seem to have commented on either the ANPRM or the NPRM; I don't think comments on the draft TPCS2 are posted anywhere, but I can't find anything to suggest they commented on that either, or that they are at all aware of the efforts in both countries at reform. Nor do they seem to realize that blogs have authors. Meanwhile, some of us are working to make the rules better: in Canada already, and perhaps in the United States before too long.

I suggest, then, that Newmahr and Hannem are playing at powerlessness. Though they frame their essay as a "call to action," all they are really doing is sitting at the bar, shouting "Fuck the IRB!"

1. http://dx.doi.org/10.1177/0891241616646825
2. http://www.tomwolfe.com/KandyKoloredExcerpt.html
3. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102
4. http://dx.doi.org/10.2139/ssrn.2182297
5. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102
6. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#toc02-1a
7. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html

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Linguist condemns "moral depravity of ethics protocols" (2016-06-13 14:31)

George van Driem, Professor of Historical Linguistics at the University of Bern, minces no words in condemning the "moral depravity of ethics protocols." He argues that human subjects rules primarily serve to cover the asses of Western universities while hampering linguists in the field and insulting the people they encounter. Paraphrasing couldn't do justice to this marvelous essay, so enjoy the block quotations. Better still, read the whole thing.

[George van Driem, "Endangered Language Research and the Moral Depravity of Ethics Protocols," Language Documentation & Conservation 10 (2016): 243–252, [1]http://hdl.handle.net/10125/24693].

To illustrate the problem, Van Driem offers this horror story:

> One American researcher followed the dictates of the ethics protocol of the University of Oregon because the penalty for non-compliance for her would have been nothing less than to forfeit the right to earn a doctoral degree, even though, in the particular case in question, this involved just 400 Bhutanese 'ngütram, which at the time of the affair was less than US $10. The researcher was compelled to go back to a particular Bhutanese village and get a signature from a particular language informant on a receipt for this sum of money. The researcher in question did as she was told in good faith, and consequently the community ostracized her, shunning her on each subsequent visit because she had made them sign a legal document. The people of the language community later explained through intermediaries that they both felt insulted and were also genuinely afraid for having been made to sign a legal document, especially after all the assistance and hospitality which they had extended to the researcher. We are dealing with no less than a clash of cultures. Ethics protocols prescribe and require immoral, unseemly and outright rude behavior to be carried out by researchers in other societies with very different cultural norms. Yet how is it possible that these ethics protocols are so culturally insensitive?

He finds the answer in the experience of another researcher, who himself "was born and raised in Bhutan with all the cultural and moral sensibilities of a morally upright Bhutanese citizen."

> The Bhutanese researcher raised the issue that being compelled to sign a contract at all would be viewed by Bhutanese villagers as if they were not being treated in a civil fashion as human beings, whatever English label one might like to append to them as native speakers of their languages. The researcher objected that the feelings of the Bhutanese people should be taken into consideration. In response, one of the staff members of the Australian National University Ethics Division in a moment of candor told the Bhutanese researcher the following, as paraphrased by the researcher:
> "No, you don't understand. We care deeply about the people in Bhutan. We care not only about today's language community. We care even about the children and the grandchildren of these people, who might come to us one day and ask to see the written permission that their ancestors had granted us at Australian National University in order to be allowed to study their language." This admission was highly revealing because it alludes quite plainly to what institutions and bureaucracies are really after.

> When I once asked a solicitor in Geneva specialized in U.S. law what the abbreviation C.Y.A. stood for, he first suggested that I look it up on the internet because the metaphor was objectionable. He later explained to me that getting individuals to sign documents that could forestall subsequent litigation, in which people essentially waived certain rights, was referred to as a 'cover your ass.'

Van Driem reports some good news. First, the inanity has not reached Switzerland. He writes,

> I have twice been prompted by spokespersons of the Swiss National Science Foundation in Bern that language informants are speakers of languages and, as such, not deemed to be Versuchspersonen in the sense of experimental subjects of medical and biological experimentation. This commonsensical insight would evidently be a revelation to some ethics protocol enforcers in the Anglo-American world, where people who happen to speak a language, as most people do, become 'human subjects' once you ask them a question about their language.

Second, at least some people are benefiting from the Anglo-American system:

> A good number of industrious people in Nepal will be prepared to issue statements on official stationery which they will have especially printed for a foreigner asking for unusual services. In writing, these entrepreneurs will even be prepared formally to usurp the authority of speaking on behalf of an entire language community for the purposes of the paying client who must furnish this paperwork to, say, the National Science Foundation in Washington or the European Research Council in Brussels in order to receive funding and support for their research. The people issuing such paperwork are not guilty of wrongdoing. Toy passports and toy driving licenses are sold in children's stores and as a curiosity in some stationery shops in the West. Entrepreneurs merely accommodate the world of make-believe in which the foreign researcher is compelled to operate.

1. http://hdl.handle.net/10125/24693

5.7 July

The Ethical Imperialism of the NAS (2016-07-01 11:42)

The National Academies of Sciences, Engineering, and Medicine's Committee on Federal Research Regulations and Reporting Requirements has released the second part of its report, [1]Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century. The new part includes a chapter on "[2]Ethical, Legal, and Regulatory Framework for Human Subjects Research." While presenting valid critiques of the NRPM, the chapter ignores the voices of scholars in social sciences and the humanities. Its proposals are unlikely to be adopted, and if they were they would continue the half-century history of marginalizing those disciplines.

Yes, the NPRM has problems

The report identifies four main problems with the NPRM:

> Several provisions of the proposed regulations have been identified as problematic. These include: (1) proposed changes relating to the definition and handling of biospecimens; (2) how determinations are made regarding whether certain types of research may be excluded from administrative or institutional review board consideration; (3) inconsistencies amongst the proposed changes; and (4) an absence of specifics for key deliverables… .

> The omission of specifics on key tools and guidelines like the exemption determination tool, consent templates, and list of privacy safeguards is problematic; because the items are undefined at present, it is impossible to comment on their merit or utility prior to the issuance of the final rule. Furthermore, it is not possible to provide an accurate estimation of regulatory impact without a clear understanding of what compliance will involve.

All true.

But the NAS counterproposal is unrealistic

The report recommends

> that Congress authorize, and the President appoint, an independent, free-standing national commission modeled on the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. This commission was authorized by Congress under Public Law 95–622 in 1978, appointed by the President in 1979, and existed outside the structure of federal departments and agencies. The commission had a direct line-item appropriation from Congress, appointed its own staff, and set its own agenda.
>
> Congress should charge the proposed commission with examining and updating as necessary the ethical, legal, and institutional frameworks governing human subjects research. The commission should make recommendations to the President, Congress, and relevant federal agencies regarding how the basic ethical principles governing human subjects research should be applied to unresolved human research questions and novel human research contexts …

The report notes that Congress ignored a 2002 proposal from the Institute of Medicine "for a standing independent, multidisciplinary, nonpartisan expert Committee on Human Research Participant Protections." The report does not mention the [3]half dozen failed efforts by Glenn and DeGette to pass new human subjects legislation. There is little chance that Congress is going to do anything.

And even if Congress did act, that would take a couple of years, plus four or five years for the commission to run, then someone would have to translate its recommendation into a proposed rule, then the notice and comment, then the final rule. So really, the NAS is proposing a decade or more of the crappy status quo.

The NAS perpetuates ethical imperialism

The NAS chapter rests firmly in the half-century tradition of designing rules for biomedical research and imposing them on the social sciences and humanities.

It does acknowledge briefly that "the optimal application of regulations, developed primarily in the context of biomedical research, to the entire spectrum of sociobehavioral research has been contested for decades and remains unresolved," citing the National Research Council's 2014 [4]Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences and C. K. Gunsalus et al., "[5]Mission Creep in the IRB World." (2006). But it does not engage with social scientists' comments on the ANPRM or NPRM, instead relying on the biomedically oriented submissions from the Association of American Medical Colleges, the Council on Governmental Relations, the Association of American Universities and the Association of Public and Land-grant Universities, and PRIM &R.

Based on this narrow reading, the report proposes that its imagined commission would study:

- Research involving anonymous and de-identified human biospecimens;
- Research involving large datasets, for example, research with human genomic, transcriptomic, proteomic, or metabolomic data or associated DNA, RNA, and protein analyses and relevant integrated approaches;
- Research in which the interests of discrete and insular communities are at stake;
- Clinical studies conducted in emergency settings;
- Research involving adults with diminished decision-making capacities;
- Clinical trials where the unit of intervention is a cluster or group;

- Clinical studies comparing the effectiveness of different accepted interventions for a given disorder to determine whether one approach may be preferable to the other;
- Observational research involving large-scale databases;
- The appropriate boundaries of regulation of minimal-risk sociobehavioral research; and
- Research aimed at clinical innovation and quality assurance and improvement.

While history cannot predict future events, we know that such a commission would have few, if any, experts in the ethics of research in the social sciences and the humanities, and that little, if any, attention would be devoted to item 9 on that 10-point list.

In its [6]2011 comments on the ANPRM, the American Anthropological Association proposed

> 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.

Had the NAS committee considered that proposal and rejected it, at least it would have shown that it had done its homework. Instead, it has displayed the same contempt for the social sciences that has infected human subjects regulations from the start.

1. http://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory
2. http://www.nap.edu/read/21824/chapter/11
3. http://www.institutionalreviewblog.com/2009/05/degette-still-doesnt-get-it.html
4. http://www.nap.edu/catalog/18614/proposed-revisions-to-the-common-rule-for-the-protection-of-human-subjects-in-the-behavioral-and-social-sciences
5. http://dx.doi.org/10.1126/science.1121479
6. http://www.institutionalreviewblog.com/2011/10/in-anprm-comments-anthropologists.html

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5.8 August

Will TCPS2 Improvements Reach Researchers? (2016-08-08 17:59)

Canadian oral historian Nancy Janovicek applauds the ways that TCPS2 improves over TPCS's treatment of oral history, but she warns that historians still must devote time to bureaucratic strategy that might be better spent exploring ethics and interviewing narrators.

[Nancy Janovicek, ,"Oral History and Ethical Practice after TCPS2," in [1]The Canadian Oral History Reader, ed. Kristina R. Llewellyn, Alexander Freund, and Nolan Reilly (Montreal and Kingston: McGill-Queen's Press, 2015), 73–97.]

In 2003, Janovicek co-authored the Canadian Historical Association's comments on TCPS, and in [2]a 2006 article that became one of the first items mentioned on this blog, she warned that TCPS imposed anonymity on narrators who wished to be named, and that it suggested that Band Councils be allowed to censor indigenous narrators who might want to speak critically to historians. As she puts it in the new chapter,

> The original TCPS did not reflect historians' ethics and professional concerns. It presented new dilemmas and criteria based on the policy's emphasis on reducing harm, which had little to do with the moral issues that historians face in the field, REBs' strict interpretations of the policy made it difficult to pursue projects on sensitive issues and often ignored the methods that are practised by oral historians and which are proven measures for balancing the reputations of their informants with the requirements of the discipline. (79)

Canada proved more nimble than the United States in revising its guidelines, and the 2010 TCPS2 addressed Canadian historians' concerns. The revised policy, Janovicek explains, recognizes that "in oral history, anonymity is the exception," that "destroying evidence conflicts with what historians do," that overprotection is a problem, and that "the interpretation of the policy must not impede research on controversial subjects in First Nations, Inuit, and Metis communities." So far so good.

But such wisdom does not instantly filter down to local REBs, which for twelve years under TCPS were trained to restrict research. As Janovicek concludes,

> Unfortunately, after the implementation of the TCPS, historians were compelled to focus on bureaucracy; and since the introduction of TCPS2 this situation has not changed. Discussions among historians often turn to sharing strategies to ensure a successful application to the REB rather than examine deeper questions about balancing academic honesty with ethical considerations. Even though the revised policy incorporates many of the ethical issues that inform oral history practice, procedural questions continue to dominate historians' conversations about ethics and research. There is reason for concern. In informal conversations at conferences some graduate students have admitted that they avoid oral history because they are concerned that ethics administrators will delay their research and make it impossible for them to complete their graduate work in a timely manner. At a workshop on oral history practice that I attended at Concordia University in 2011, which dealt with the ongoing ethical negotiations that influence relationships between scholars and research participants, graduate students spoke about difficulties with REBs. This was an international conference. The similarities among the graduate students, who were working under ethics policies in different countries, underscore the continued need to monitor the implementation of ethics policy at the institutional level.
>
> Despite improvements in the policy, the apprehensive climate created by TCPS continues to inform how we think about ethics policy and how REBs implement the policy. It is the implementation of TCPS2 at the institutional level, rather than the policy itself, that creates barriers to research. Researchers should be able to use the policy to defend themselves from obstructive REBs and university administrations that are more concerned with legal liability than ethical responsibility. The TCPS2 clearly states that REBs "need independence in the decision-making process to … properly apply the core principles of [TCPS2] … to their ethics review of research projects." It advises against overprotection of research participants because it impedes justice, a core principle of the document. Academics should use the document to defend ethical research strategies. We need to be especially vigilant in defending graduate students whose research is scrutinized by research boards and advise them to use the policy to defend their research principles. Teaching ethics policy and practice is essential to mentorship in the field. (89)

1. http://www.mqup.ca/canadian-oral-history-reader--the-products-9780773544963.php
2. http://www.institutionalreviewblog.com/2007/01/nancy-janovicek-offers-canadian.html

"Vulnerable" participants may have the most to gain from talking (2016-08-11 10:30)

Seven qualitative researchers forcefully argue that IRBs mislead research participants when they demand consent forms stating that interview research has "no known benefits." In fact, people labeled "vulnerable" by IRBs often gain a great deal by participating in projects the IRBs deem "risky."

[Tara Opsal, Jennifer Wolgemuth, Jennifer Cross, Tanya Kaanta, Ellyn Dickmann, Soria Colomer, and Zeynep Erdil-Moody, "'There Are No Known Benefits …' Considering the Risk/Benefit Ratio of Qualitative Research," Qualitative Health Research 26, no. 8 (July 2016): 1137–50, [1]doi:10.1177/1049732315580109.]

The researchers describe six qualitative social science projects they conducted over the past decade, in several countries. Three of the six projects secured IRB approval without seriously difficulty, but the other three were hampered by IRB constraints. Kaanta's IRB demanded that she only interview inter-country Korean adoptees in places where she could find an on-call therapist in the event that her questions triggered "depression and emotional pain." Nor was she allowed to interview pregnant women. Dickmann faced such a hassle getting permission to interview high school resource officers that she gave up on seeking permission to interview their spouses. And Opsal only got permission to interview women leaving prison after "many IRB challenges."

The authors appreciate that the IRBs have the participants' best interests in mind, though perhaps this concern was mixed with "institutional risk mitigation and management." But they argue that the IRB conditions can have the perverse effect of denying a good experience to the very people they are meant to protect.

The fact is, people like being able to talk to a good listener. As they note,

> This was a major theme in Tanya's study of adoptees as a number of her participants spoke of these transformational impacts. Vanessa explained,
>
> > [Before participating] I did not realize how important a Korean identity was. I stifled my Asian-ness in an attempt to find acceptance from peers … I have made peace with my racial and ethnic identity. Thank you, Tanya, for an opportunity to participate in this study. Just verbalizing my experiences to you has brought about closure and healing to childhood issues I was previously unaware of. I'm happy being Asian. I'm happy having a white family. And, I'm happy I can finally say that.

Unfortunately, IRBs do a poor job predicting such outcomes:

> These examples provide evidence that there is an important difference in the way individuals who hold more marginalized ("risky") identities and those who do not experience the benefits across our project. The greater the IRB-defined risk of doing the research, the greater the quantity and quality of benefits expressed by the participants. There was not, however, a parallel finding in our themes centered on the risks individuals professed experiencing (or feared experiencing) by participating in the study. Specifically, we found no patterns of risk by research topic or population; in other words, not only were participants

> across our studies unlikely to identify experiencing risks because of their participation, but participants from vulnerable populations or sensitive topics were no more likely to identify risks.

Instead, IRBs' guesswork denies participants the right to make their own choices.

> IRBs tend to take a paternalistic approach to research participants and assume their inherent vulnerability, IRBs fail to empower them or their voices through the research process … When IRBs seek to "protect" individuals with marginalized identities or sensitive stories via a legal/risk framework and establish them as risky sites of examination, the entity simultaneously fails to see them as agents who actively negotiate a research space and use it to combat marginalization, take up space, and narrate their own stories … Through all of these actions, then, the IRB unintentionally becomes a part of a larger culture and structure that silences these individuals and, alongside other social actors and institutions, limits their agency.

The authors call for more evidence-based IRB decisions.

> Our first recommendation is that IRBs treat as real the evidence for benefits in qualitative research. We would like to see an end to the overly conservative, to the point of being false, assumption that there are "no known benefits" in qualitative interviews. Rather, participant consent forms should include an honest discussion of the benefits of participation.

Conversely, they need to stop imposing boilerplate protections on every project.

> An ethical research process is not, for example, providing suicide hotline numbers to every participant at the end of an interview, regardless of their needs. Instead, an ethical research process is one where the researcher is tuned into the needs of the participants, potential strengths and vulnerabilities that the population of focus brings to the table, and ways they can respond appropriately and effectively to each individual.

The authors do not deny that talking can cause harm, and that interviewers should be trained. But the present system is not working to distinguish real dangers from phantoms, and real protections from empty gestures.

In sum, the article is an eloquent contribution to previous calls for [2]human research protections based on empirical evidence rather than [3]gut feelings and urban myths.

1. http://dx.doi.org/10.1177/1049732315580109
2. http://www.institutionalreviewblog.com/2014/01/nrc-report-assess-risk-empirically.html
3. http://www.institutionalreviewblog.com/2015/09/schrag-reviews-klitzman-ethics-police.html

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5.9 September

A satisfied customer at American University (2016-09-06 10:27)

Patricia Aufderheide, University Professor of Communication Studies at American University, reports her satisfaction with the IRB at that institution. It's great to hear some good news, and Aufderheide's essay points to the importance

of having the right people in positions of power. But it also raises questions about how good and how replicable AU's experience is.

[Patricia Aufderheide, "[1]Does This Have to Go Through the IRB?," Chronicle of Higher Education, August 17, 2016.]

Aufderheide writes that the AU IRB, "which primarily deals with social-science and humanities research, has been more helpful to me than I ever expected it to be." IRB staff review, she writes, helped her and a colleague think through reasons why the people they interviewed might hesitate to be interviewed, and the protocols they worked out gave them "a clear signal at the start of our work together that we were conscientious and considerate professionals."

Aufderheide credits the people involved. The IRB includes faculty in marketing, public opinion research, government, psychology, international relations, as well as a librarian. This is a far larger range of disciplines than most social scientists can hope to face, and AU is to be applauded for securing such intellectual diversity. Moreover, Aufderheide credits the unfailing patience of Matt Zembrzuski, the research compliance manager, who directs IRB operations.

But Aufderheide's raises some troubling issues as well, which suggest that not everything is as rosy at AU as she suggests, and that other universities may have trouble replicating the experience.

Why is Aufderheide destroying records?

The only research project that Aufderheide describes in any detail is an ongoing collaboration with Peter Jaszi to interview "creative colleagues on how they did their work, given their understanding of copyright." As she describes the protocol,

> Our research team gave interviewees an informed-consent form that said in simple words what we were trying to find out and why, why we valued their time, what we thought the risks were, and how we would deal with those risks. We promised not to use their names in any published material, unless they wanted to be named (a surprising number did). We kept all the information in a passworded project-management site (Basecamp), and we deleted all the data after we completed our research.

If respondents are willing to have their names used, why destroy all data? Why not give the participants the chance to have their interviews archived so that future generations can learn how copyright affected creative practice in the early 21st century? There's gold in the interview outtakes. As Pat Bowne comments on the Chronicle site, "the phrase 'delete the data afterwards' sounds about as bad as 'kill all the witnesses."'

Does the AU IRB understand minimal risk?

Again, the essay is mostly vague about the projects reviewed by the IRB and the changes it demands, but it quotes Molly O'Rourke, a public-opinion researcher, in more detail:

> "Example, asking about the number of children someone has or marital status seems very standard — but not for a respondent who lost a child or is in the process of a painful divorce or separation," said O'Rourke, the public-opinion researcher. "Appreciating that and writing research instruments that reflect that is hard but important." She added: "I will never forget moderating a focus group about terrorism/national security

> in 2002, and I had someone in the session whose brother was killed in the World Trade Center on 9/11. … We somehow missed it in the prescreening. Having been invited to a focus group about 'policy priorities for our country,' she (rightfully) felt misled."

The first statement confuses the questions of whether a question is standard and whether the response to that question is standard. Questions about marital status are in fact quite standard. Every year the IRS asks about whether I've lost any family members, and for that reason my marital status is listed on my pay stub, issued twice a month. I rather doubt that someone who is grieving a dead child needs a questionnaire to be reminded of that fact. And while I feel sympathy for the woman whose brother was killed, I find it hard to believe that anyone in 2002 could imagine that a discussion of national policy priorities would not address responses to 9/11. What else did people talk about in 2002? O'Rourke appears to be trying to shield research participants from risks comparable to "those ordinarily encountered in daily life," and that is not the IRB's job.

Does the whole system depend on a benevolent despot?

Aufderheide's emphasis on Zembrzuski rings true to me; I've seen at other universities (including my own) the importance of a patient, reasonable compliance manager. But academic freedom should not depend on one person's temperament, which is why structural reforms, such as a guaranteed appeals process, are so important.

Are other AU researchers as pleased as Aufderheide?

Aufderheide's essay quotes only members of the IRB, not any researchers who have faced the IRB without serving on it. This is like asking the foxes how they feel about guarding the henhouse. To be sure, I have not found in my notes any IRB horror stories emanating from AU. But I do recall one conference, some years back, when a VP of another major research university spoke confidently about how well the IRB worked at her institution, only to be immediately contradicted by a graduate student from the same university, who told the VP how deluded she was. I would be interested to hear from other AU researchers if their experience matches Aufderheide's.

1. http://www.chronicle.com/article/Does-This-Have-to-Go/237476

More failures of "local precedents" (2016-09-19 17:53)

Laura Stark's 2012 book, [1]Behind Closed Doors: IRBs and the Making of Ethical Research, devotes a chapter to what Stark calls "local precedents," her term for "the past decisions that guide board members' evaluations of subsequent research." "By drawing on local precedent," Stark claims, "board members can read new protocols as permutations of studies that they have previously debated and settled based on members' warrants. The result is that IRBs tend to make decisions that are locally consistent over time." (47)

But I keep getting stories about IRBs that are locally inconsistent.

Stark made her generalization after observing a handful of cases in which IRBs claimed to be either basing decisions on ones they had previously made, or making new decisions that would guide future rulings. But as far as I can tell, she did not systematically audit IRB files to test the degree to which IRB decisions are in fact locally consistent.

I have long had my doubts about this claim of consistency, since so many stories from frustrated researchers concern identical studies presented to the same IRB with differing results. "The process that was [2]approved in the first application was denied in the second because it was deemed coercive," one complaint notes. "In every case in which we submitted the approved IRB application from the previous year, [3]the IRB required additional changes," another

laments. A candid IRB chair admits that “Investigators may get [4]quite different and inconsistent advice from the committee depending on what it feels like that day.”

Two comments posted in response to Patricia Aufderheide’s essay, “[5]Does This Have to Go Through the IRB?,” cast further doubt on claims of local consistency. Here they are, with the screen names of the authors:

kgs _ssu

> At a university I don’t work at, I had a series of go-rounds regarding a caveat I placed in a proposal that boiled down to explaining that the participant pool I was working with is very small and there’s a chance some of the participants will talk to one another about this research. I had used identical language in two previous proposals at the same university. To appease the reviewer (who also strayed from reviewing to critique other areas of the proposal) I eventually removed the statement, even though I felt it was ethically appropriate to point this out and an unavoidable outcome of the type of research I am doing. The IRB personnel I worked with in that office helped as a go-between, but what a waste of time for her and for me, and I felt a tad compromised in the process.

ergative:

> At one of my previous institutions, the IRB disliked the size of the font on the recruitment flyer I wanted to put up around campus, saying that the size in which I indicated the amount of compensation was too big relative to the size of the words saying “research study,” and therefore that constituted undue influence to participate. Silly, but I guess I can run with it, except that I used the exact poster template that my lab had been using for years under a different protocol. Depending on who or when the protocol was reviewed, absurd ticky-tack font-size objections would require corrections and resubmissions of the protocols, which resulted in an additional three or four weeks of waiting for approval.

Such stories do not reveal the extent of IRB inconsistency, but neither do Stark’s observations. Without further investigation, I don’t think she can support the claim that “IRBs tend to make decisions that are locally consistent over time.”

Also, note how in the first story, the IRB interference had the effect of denying useful information to prospective participants.

1. http://press.uchicago.edu/ucp/books/book/chicago/B/bo12182576.html
2. http://www.institutionalreviewblog.com/2014/12/horror-story-buffet.html
3. http://www.institutionalreviewblog.com/2016/05/texas-irb-imposed-review-for-surveys-of.html
4. http://www.institutionalreviewblog.com/2015/09/schrag-reviews-klitzman-ethics-police.html
5. http://www.institutionalreviewblog.com/2016/09/a-satisfied-customer-at-american.html

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IRB consent form spooked respondents **(2016-09-30 17:03)**

Commenting on Patricia Aufderheide’s essay, “[1]Does This Have to Go Through the IRB?,” a writer with the screen name “reinking” relates:

> I was investigating a routine instructional intervention in a school district serving a large hispanic population. IRB required, not just that the consent form be translated into Spanish (not unreasonable if a consent form was necessary), but also that I develop several versions in different dialects. Nonetheless, when sent to parents, remarkably few were returned, and I eventually determined why. The standard template for IRB consent (modeled on far riskier medical research) indicated that any questions or concerns should be directed to me as "principal investigator." "Investigator" was apparently a term (in English or Spanish) that set off alarm bells among parents in this hispanic community.

So much for IRB sensitivity to local conditions.

1. http://www.chronicle.com/article/Does-This-Have-to-Go/237476

5.10 October

"One more impediment to getting a worthwhile project done" (2016-10-01 11:37)

A final horror story posted in response to Patricia Aufderheide's essay, "[1]Does This Have to Go Through the IRB?."

[2]Brian Abel Ragen writes,

> Eventually you will probably find a reasonable person to stop the nonsense. That was my experience when one of my graduate students was told that his plan to interview a writer for the New York Review of Books meant he was using "human subjects" and therefore needed to submit his thesis proposal to the IRB after filling out all the appropriate forms and applications. A student asking a professional literary critic why he had championed the reputation of a certain novelist was, quite rightly, seen as an interaction WITH a fellow human being, not research ON a human subject. But that should have been obvious from the beginning. What the whole process did for me as an English professor and my student in the humanities was to create just one more impediment to getting a worthwhile project done—this new obstacle laced with fear of getting in trouble with the Federal government if we made a mistake. It also protected a writer from hearing from someone who admired his work and wanted to explore it with him for a few weeks. So I would say that the limits of the IRB's powers need to be more clearly drawn, so as to remove one more hazard from the already obstacle-strewn path to completing a degree or a research project. I won't say that i can't imagine projects in literary studies that don't involve using people as actual "human subjects," but I think the default assumption should be that any project that involves neither deception nor asking the interlocutor to do anything but talk about something is beyond the scope of an IRB.

An IRB need not block a project to discourage curiosity.

1. http://www.chronicle.com/article/Does-This-Have-to-Go/237476
2. http://brianabelragen.net/

Brazil calls for "equitable representation from the Social Sciences and Humanities" (2016-10-02 10:59)

Brazil is revising its research ethics standards in ways that will help tailor them to research in the social sciences and the humanities. The standards provide for greater representation by scholars in those fields when policies and

decisions are made, and they decenter some of the medical assumptions that had previously governed all research. But they do not go as far as the Canadian TCPS2 in recognizing the legitimacy of critical inquiry.

[Iara Coelho Zito Guerriero, "Approval of the Resolution Governing the Ethics of Research in Social Sciences, the Humanities, and Other Disciplines That Use Methodologies Characteristic of These Areas: Challenges and Achievements," Ciência & Saúde Coletiva 21, no. 8 (August 2016): 2619–29, [1]doi:10.1590/1413–81232015218.17212016.]

In Brazil, a National Research Ethics Committee (Comissão Nacional de Ética em Pesquisa, or CONEP) oversees each local Research Ethics Committee (Comitê de Ética em Pesquisa, or CEP). As in other countries, medical researchers and health officials have dominated the crafting of policy, resulting in restrictions that make little sense for research in the social sciences and humanities (SSH).

Since 2013, public health researcher Iara Guerriero and other members of a Working Group in Social Sciences and Humanities have labored to improve this situation, and in April 2016 they won National Board of Health approval for their resolution. In her article, Guerriero publishes the resolution and notes four major advances:

1. Equitable composition of CONEP and involvement of SSH members in reviewing the protocols for these areas.
2. Recognition that scientific merit must be assessed by competent areas.
3. Discrimination between the process of obtaining and registering consent.
4. Explanation of studies that do not require analysis by the REC/CONEP system, where the preliminary steps are not assessed.

Since a major finding of [2]Ethical Imperialism was that inappropriate regulations are the product of the exclusion of social scientists and humanities research from policy making, I am particularly encouraged by the first advance. Article 26 of the resolution states that

> The ethical analysis of the study projects to which this Resolution refers can only be done by Research Ethics Committees that have an equitable representation of members from the Social Sciences and Humanities area, with the reporters being selected from among those members qualified in this area of knowledge.

Achievements 3 and 4 are also potentially quite significant. One of the enduring complaints of social scientists over the decades has been the poor fit between experimental models, which expect protocols to be designed in advance of any research, and the actual practices of qualitative researchers, whose projects evolve less predictably. [3]Canada's TCPS2 states that "REBs should be aware that it is quite common for specific questions (as well as shifts in data sources or discovery of data sources) to emerge only during the research project," and it sounds as though Brazil is moving in that direction as well.

The Brazilian resolution does not mention historical research, journalism, or any form of critical inquiry, and I am troubled by Article 3, section VIII, which presents the principle of "Researcher assurance that the information obtained as a result of the study will not be used to harm participants." As I have [4]repeatedly noted on this blog, journalists, historians, political scientists, sociologists, and even anthropologists have acknowledged that some research is legitimately critical of the people it concerns, and there is nothing wrong in using someone's freely given words against them.

"This is a time of celebration and much hard work," writes Guerriero, and it certainly sounds as though Brazil's social science and humanities researchers have taken a step forward. But I hope that as they challenge the imposition of medical norms on nonmedical fields, they will follow [5]Canada's lead in recognizing the legitimacy of critical inquiry.

1. http://dx.doi.org/10.1590/1413-81232015218.17212016
2. https://jhupbooks.press.jhu.edu/content/ethical-imperialism
3. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/
4. http://www.institutionalreviewblog.com/search/label/critical%20inquiry
5. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a

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Final Rule in 2016? (2016-10-25 11:05)

[1]Theresa Defino reports that OHRP "hopes to get 'something' out by year end."

If OHRP were to liberate oral history on the [2]10th anniversary of this blog, that would be OK with me.

1. https://twitter.com/theresadefino
2. http://www.institutionalreviewblog.com/2006/12/introduction.html

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Qualitative Sociologists Find Standard Randomness (2016-10-31 11:16)

Sociologists Sarah Babb, Lara Birk, and Luka Carfagna surveyed qualitative sociologists about their IRB experiences and heard many of the usual horror stories, from insistence on inappropriate consent forms to the dribbling out of concerns over several rounds of comments. Few of their respondents are happy with the present system, though getting the right people in key positions can help.

[Sarah Babb, Lara Birk, and Luka Carfagna, "Standard Bearers: Qualitative Sociologists' Experiences with IRB Regulation," American Sociologist, October 6, 2016, 1–17, [1]doi:10.1007/s12108–016–9331-z. Note: I read a version of this article in manuscript and am so credited in the article.]

Standardization and arbitrariness can coexist

The authors begin with a puzzle:

> Researchers … have raised concerns about two apparently contradictory problems. On the one hand many studies have observed that different local IRBs arrive at inconsistent decisions regarding the same research proposal, causing significant difficulties for biomedical researchers working across multiple institutions… . On the other hand, researchers in the social sciences and humanities, especially qualitative interview researchers, are more likely to charge IRBs with extending homogeneous, biomedical standards to different kinds of research . . . Why does standardization appear to be such a dominant theme in qualitative researchers' experiences with their IRBs?

As the following page makes clear, this is not so difficult a conundrum. What researchers colloquially call the "IRB" is more properly understood as a human research protection program (HRPP) with two parts. First, the institutional review board itself, composed (in a university setting) mostly of faculty, and second, the IRB administrative staff that conducts the initial screening and sets up forms and procedures. The staff component imposes highly standardized rules, then feeds any procedures raising concerns to the IRB itself, which abandons standards.

It's like going to the airport and making it through a list of security procedures—photo ID, boarding pass, shoes off, belt off, liquids in a clear bag, laptop out—only to board a plane whose destination will be chosen based on the pilots' whim after they've taken off.

Few qualitative sociologists like the IRB process as it now exists

Babb et al. interviewed "26 sociologists at nine institutions of higher education in the Northeastern United States." Though they included institutions whose sociology chairs offered "a range of reported IRB experiences—two more negative, three more positive, and three mixed," only two of the 26 people they interviewed "believed that IRB review was both important and legitimate in its current form," and one of those serves on an IRB. Of the remaining 24 respondents, six "felt that IRB regulation of sociological research was antithetical to professional norms and illegitimate" and 18 described "a conflicted sense of regret that a system designed to attend to an important issue was causing problems."

Rejection isn't the problem

[2]IRB apologists occasionally point to a low rejection rate as a sign that the system works. This article reminds us that IRBs don't need to reject a proposal formally to hinder research.

> Michael, at State University remarked that "there's a lot of work to do to get the IRB to decide they're not all that interested in what you're up to." Completing an IRB protocol—an extended form describing a research project–can take a significant investment of time, even where the research is very low risk. However, the most common concerns about paperwork were related not to the burden of initial application, but rather to "serial reapplication"—that is to say, the submission of multiple versions of the same protocol before receiving approval. As one researcher put it, "they want a great deal of information on exactly what questions will be asked and procedures for maintaining confidentiality, and … they often then go back and ask for more information again" (George, Eastern University). Gabrielle, at State University, similarly recalled her experience:, "they'll send back a thing 'what about this, what about this, what about this' and now, you know, they can't possibly have a form that would imagine every possible situation… [I]t took a good 6 to 9 months of just trying to…come up with a protocol that would appease them."

and

> Several researchers reported that they had decided not to do specific projects in order to avoid the hassle of getting through IRB. One claimed that she had "sworn off of doing any human subjects research anymore… I've found the process so crazy-making that … I just don't want to deal with it anymore" (Gabrielle, State University).

IRBs lack expertise

- They know less than researchers:

Penelope, at Public University, recalled the months it took to process a student proposal to study a social movement in a conflicted region in Turkey—a situation about which IRB decision-makers had neither knowledge nor appropriate precedents. As she concluded: "it's a group of people trying to think through the repercussions of something that they probably have less familiarity with than the researcher does."

- They don't accept standard methods:

  At Urban University, a graduate student studying an anti-administration student social movement at another university was told he needed permission from that university's administration. Barbara, the student's advisor, remarked that "if the people studying the labor movement had to get permission from the factory owners, then nobody would have ever studied the labor movement!" Another example was the universal requirement of de-identifying informants–even in journalistic-style research where informants agreed to be quoted and where the credibility of the research rested on the attribution of quotes to well-known public figures. Still another example was snowball sampling: two researchers from Eastern University reported that their IRB had prohibited such sampling and suggested instead recruitment techniques commonly used in biomedical research, such as posting flyers in public places.

- They fetishize written consent forms:

  Thirteen of our 26 researchers mentioned the requirement of signed informed consent forms as an issue they had encountered. For example, Clara from Rural College wanted to interview adult passers-by at a conference convention booth. Clara's IRB required that she obtain signed consent forms; however, she found that the consent document posed insurmountable obstacles. As she put it "…[y]ou're asking them for all this personal information…and you want them to sign a form that says that they're giving permission for this interaction, and as soon as you pull out the form, they say, 'no I don't have time."' George at Eastern University had seen the problems IRB informed consent requirements posed for graduate students engaging in participant observation: "they somehow expect that everything will come to a halt while the graduate students pull out a form and explain to people they're talking with what it means and get their approval." Consent forms were seen as particularly problematic when they were long, legalistic, and difficult to read, as several of our respondents complained.

Researchers sometimes evade

In 2007, [3]Mark Ashcraft and Jeremy Krause interviewed 100 researchers, of whom 19 reported collecting data without IRB approval. An even higher percentage (6 of the 26, or 23 percent) of the respondents here "reported that they had either evaded IRB rules themselves or recommended that their students do so."

Clara from Rural College, for example, discovered that it was impossible to interview passers-by if she presented them with the lengthy informed consent form required by her IRB (see quote above). Upon finding that people were unwilling to talk to her as soon as she presented the form, she decided to dispense with it. As she put it, "I just decided that I could either do field research or I could work with the IRB, but I couldn't do both." George, who had mentored graduate students doing qualitative research that had encountered similar obstacles, felt that "graduate students really are faced … with a choice of … either conforming to these rules and … not being able to do participant observation the way it should be done, or ignoring the committee…" (George, Eastern University).

People matter

As much as we might wish for a magic structural fix to IRB issues, for now, the best hope is to fill the IRB with good people and, more importantly, to hire the right staff. Babb et al. describe two institutions that had generated horror stories in the past but now seem to be getting better:

> At Urban University, professional IRB administration appeared to be working relatively well for qualitative researchers. Urban's IRB was run by a dynamic administrator who was committed to meeting personally with all researchers before they submitted protocols and engaging in back-and-forth communication. Barbara described this administrator as an enormous improvement over her predecessor in the position: "prior to that it just felt a little bit more like a black box, you know the IRB has its own email address…now I know that when I send something to that address it's [the administrator's name]…before then, what happened at the other end [laughs] of that email address was much less clear." Because she was open to personal communication, it was possible for researchers to engage with her directly, and explain their reasoning if they thought a mistake was being made. An Urban University scholar described one case (the factory study that ran into the problem of site permission, described above) in which such engagement led to the reversal of the administrator's previous decision.

and

> At Yankee College, the old IRB chair had recently been replaced by Sam, a qualitative sociologist who had assembled a new group of faculty IRB volunteers to improve and clarify rules and procedures, and who made an effort to communicate with researchers directly rather than bureaucratically.

At its best, then, the IRB system works as a government of men, not of laws. Can we do better?

1. http://dx.doi.org/doi:10.1007/s12108-016-9331-z
2. http://www.institutionalreviewblog.com/2012/05/aahrpp-claims-irbs-rarely-disapprove.html
3. http://dx.doi.org/10.1080/10508420701309614

5.11 December

Will Cures Act Replace Common Rule Reform? (2016-12-07 15:58)

As of November 15, POLITICO thinks that Common Rule reform is dead:

> HHS's controversial revision of the Common Rule, the regulations that protect participants in clinical research, still hasn't been sent to OMB for review. That's not likely to get finished under Obama's watch.
>
> (David Pittman, "[1]Obama's HHS, Congress at Potential Odds over Pending Rule," POLITICO, November 15, 2016)

On the other hand, [2]Congress just passed the 21st Cures Act, which includes a provision for a [3]Research Policy Board designed, as Science puts it, to "examine excessive regulation of research."

In his [4]September 29 testimony before the Subcommittee on Research and Technology, James Luther of Duke University suggested that the congressional effort could replace the executive one. He complained "that HHS is still trying to move forward with a final rule [for human subjects research] for which many of the proposals remain unchanged from the ANPRM despite overwhelmingly negative comments" about its provisions on biospecimens. And he suggested that a Research Policy Board might do a better job.

Perhaps such a board would attend to questions of concern to the social sciences and humanities, but I am not hopeful. Luther's testimony cites the [5]May 2016 analysis by the Council on Governmental Relations (COGR) and the Association of Public and Land-grant Universities (APLU) and the [6]June report by the National Academies of Sciences, Engineering, and Medicine's Committee on Federal Research Regulations and Reporting Requirements. Both of those documents mostly ignored the social sciences and humanities.

The sun never sets on the Ethical Empire.

1. http://politi.co/2fC1q0T.
2. http://www.nytimes.com/2016/12/07/us/politics/21st-century-cures-act-senate.html
3. http://www.sciencemag.org/news/2016/11/new-us-research-policy-board-would-aim-slash-regulatory-paperwork
4. http://docs.house.gov/meetings/SY/SY15/20160929/105394/HHRG-114-SY15-Wstate-LutherJ-20160929.pdf
5. http://www.institutionalreviewblog.com/2016/05/nprm-comments-focus-on-biospecimens.html
6. http://www.institutionalreviewblog.com/2016/07/the-ethical-imperialism-of-nas.html

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Big Data researchers call for IRB review, based on shaky premises (2016-12-09 13:27)

Jacob Metcalf of the Data & Society Research Institute and Kate Crawford of Microsoft Research, MIT Center for Civic Media, and New York University Information Law Institute (I think those are three different things) want to subject Big Data research to IRB review, at least in universities. Their argument rests on shaky premises.

[Jacob Metcalf and Kate Crawford, "Where Are Human Subjects in Big Data Research? The Emerging Ethics Divide," Big Data & Society 3, no. 1 (January–June 2016): 1–14, [1]doi:10.1177/2053951716650211.]

Assumptions about assumptions

Metcalf and Crawford understand that the current Common Rule does not require IRB review of publicly available datasets. Claiming to be "historicizing extant research ethics norms and regulations" and drawing lessons "from the history and implementation of human-subjects research protections," they proceed to invent a history of the relevant provisions.

They write,

> US research regulations (both the current rules and proposed revisions) exempt projects that make use of already existing, publicly available datasets on the assumption that they pose only minimal risks to the human subjects they document. (1)

And

> The Common Rule assumes that data which is already publicly available cannot cause any further harm to an individual. (3)

And

> The criteria for human-subjects protections depend on an unstated assumption that we argue is fundamentally problematic: that the risk to research subjects depends on what kind of data is obtained and how it is obtained, not what is done with the data after it is obtained. This assumption is based on the idea that data which is public poses no new risks for human subjects, and this claim is threaded throughout the NPRM. While this may have once been a reasonable principle, current data science methods make this a faulty assumption. (8. Italics in original.)

At no point do they cite any evidence that regulators excluded publicly available material from review out of the belief that it bore no risks.

Here's what the regulators had to say when they released the 1981 regulations, which introduced the present definition of research:

> Several commentators felt that the definition is too broad and should be restricted to biomedical research. These commentators felt that the definition should not encompass subjects not at risk, social science research, or historical research; and some preferred voluntary application of the regulations to behavioral research. In contrast, a few commentators suggested that the definition should encompass research which is so specific as not to yield generalizable results. One commentator argued that the definition violated the First Amendment or at least academic freedom in the area of biographic research …
>
> HHS has reinserted the term "private" to modify "information." This modification is intended to make it clear that the regulations are only applicable to research which involves intervention or interaction with an individual, or identifiable private information. Examples of what the Department means by "private information" are: (1) Information about behavior that occurs in a context in which an individual can resonably expect that no observation or recording is taking place, and (2) information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. In order to constitute research involving human subjects, private information must be individually identifiable. It is expected that this definition exempts from the regulations nearly all library-based political, literary and historical research, as well as purely observational research in most public contexts, such as behavior on the streets or in crowds.

In addition to the definition of human subjects research (which does not include studies of public information), the 1981 regulations introduced the exemption for "Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

HHS explained this decision as well:

> HHS is concerned about preservation of the confidentiality of data pertaining to human subjects but feels that other federal, state, and local laws or regulations are sufficient to protect the privacy of individuals and the confidentiality of records in cases where the research uses only existing information. It remains the responsibility of the investigator as well as the institution to ensure that such laws and regulations are observed and that the rights of subjects are protected.
>
> [Department of Health and Human Services, "[2]Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects," Federal Register 46 (26 January 1981): 8336–8392]

In neither case did HHS assume that data research would be harmless. In defining research, regulators responded to researchers' concern about freedom (a word that does not appear in the Metcalf and Crawford article). They explicitly responded to critics who argued that researchers should be able to do library research without getting anyone's permission. In crafting the exemption, regulators recognized a privacy risk but did not believe that IRBs were the correct solution to that problem.

IRBs are not the solution

And IRBs are not the solution. Metcalf and Crawford imagine wonderful things about IRBs.

> Importantly, the ethics regulations targeted by critics, and the codes that informed those regulations, have played no small part in maintaining that trust over time. Insofar as physician–researchers contributed to the formation of those codes and regulations, and the broader research community assented to them (even if begrudgingly), research ethics regulations have built the bedrock of trust that has ultimately enabled research to occur at all. Therefore, even if the research/practice distinction as codified in the Common Rule proves too unwieldy for the methods of data science, we still need regulatory options that build trust between data practitioners and data subjects. (5)

The citation here is to Polonetsky, Tene and Jerome, "[3]Beyond the common rule: Ethical structures for data research in non-academic settings," Colorado Technology Law Journal 13 (2015). That article speculates about how new institutions might build trust, but it does not claim, much less show, that IRBs serve this function.

Most people haven't heard of IRBs. IRB review has not calmed public controversy over studies like the Kennedy Krieger lead paint study or SUPPORT. And as [4]Murray Dyck and Gary Allen have noted, "Mandatory multiple reviews of multisite research indicate that IRBs do not trust the merit and integrity of other IRBs." If IRBs don't trust each other, why should the public?

"The Common Rule needs to reflect that even anonymous, public data sets can produce harms depending on how they are used," write Metcalf and Crawford. "The best way to do this in academic settings remains the IRB." They offer no reasoning behind this claim.

Indeed they continue,

> As for industry, there needs to be a more serious commitment to review and assessment of human data projects. Facebook, for example, responded to the public outcry about the emotional contagion experiment by setting up an internal review process for future experiments. Legal scholar Ryan Calo has argued that a body like the Federal Trade Commission could commission an interdisciplinary report on data ethics, and that those public principles could guide companies as they form small internal committees that review company practices. Polonensky et al. have similarly argued for a two-track ethics review model for use outside of the purview of the Common Rule that would blend internal and external perspectives. Dove et al. recently surveyed how research ethics committees have grappled with data-intensive research with ''bottom-up" approaches when more traditional ''top-down" approaches have fallen short. Others have also offered promising insights for integrating ethical reasoning into data science research and practice prior to the typical timing of formal ethical review.

Any one of those approaches, especially the last two, sound better than the current IRB system, which empowers pseudo-experts to arbitrarily block research they do not understand. So why single out university-based data researchers for the misery of a broken system they have so far escaped?

1. http://dx.doi.org/10.1177/2053951716650211
2. https://web.archive.org/web/20120925170358/http://www.hhs.gov/ohrp/archive/documents/19810126.pdf
3. http://ctlj.colorado.edu/?page_id=238
4. http://www.institutionalreviewblog.com/2012/09/could-guidance-and-feedback-replace.html

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Ten Years of Blogging (2016-12-12 16:08)

The Institutional Review Blog [1]launched ten years ago today. I would like to think that with or without a new Common Rule, it's done some good, but I would dearly love to see oral history liberated in the next 39 days.

[2] 

1. http://www.institutionalreviewblog.com/2006/12/introduction.html
2. https://1.bp.blogspot.com/-NOOGtHQho-I/WE8QncC34vI/AAAAAAAAQ38/Qv9F4kBAQU48MOWLHsQN7G1bBN76kUGPgCLcB/s1600/regz.gif

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Mary Clark (2017-01-18 18:02:01)
Thank you for all that you have done to support this movement to preserve oral history as a part of free speech! Well done.

Mary Marshall Clark, Center for Oral History Research, Columbia University, senior member, Columbia University IRB Board.

Calls for Ethical Pluralism (2016-12-15 10:36)

In separate essays, Nathan Emmerich and Igor Gontcharov argue for more flexible systems that would avoid imposing biomedical ethics on the social sciences. Emmerich calls for an emphasis on professional ethics, while Gontcharov

seeks “a set of ethical principles that would better reflect the position of [social sciences and humanities] researchers and participants.” I am left unsure what either proposed reform would look like in practice.

[Nathan Emmerich, “Reframing Research Ethics: Towards a Professional Ethics for the Social Sciences,” Sociological Research Online 21, no. 4 (2016): 7, [1]DOI: 10.5153/sro.4127; Igor Gontcharov, “A New Wave of Positivism in the Social Sciences: Regulatory Capture and Conceptual Constraints in the Governance of Research Involving Humans,” SSRN Scholarly Paper (Rochester, NY: Social Science Research Network, October 31, 2016), [2]DOI: 10.2139/ssrn.2861908.]

Emmerich seeks professional ethics

Emmerich argues that

> the social sciences can lay claim to a democratic ideal as its ‘higher good’ and, therefore, its guiding ethos or end… .
>
> Given this end – democracy – social science research is persuaded not for its own sake or for the sake of knowledge in itself. Rather, its pursuit is rooted in the (admittedly diverse) socio-political needs of ‘democracy,’ understood as an ethos or normative as an end in itself.

Because of the importance of this work, he argues, researchers should not be constrained by ethics committees. Instead, he proposes that social scientists be judged by the equivalent of clinical ethics committees (CECs), which Emmerich describes as

> forums healthcare professionals can attend in order to discuss any ethical issues they encounter. Committee members are usually healthcare professionals but may also include lawyers, theologians, (bio)ethicists, and patient representatives or lay persons. Debates are relatively informal and if a committee offers a collective opinion – which is not always the case – decisions regarding any action remain the responsibility of those professionals directly involved in the case. CECs therefore provide a forum for debate and, as such, a means to improve the quality of ethical reflection in practice.

Were social scientists trusted to the same degree as these healthcare professionals, they could

> justify the ethical aspects of their proposal with reference to the specific disciplinary norms that guide their work as professionals. The subsequent discussion would, of course, offer critique or raise additional issues as necessary. Such committees could, if they saw fit or if it were considered helpful to do so, produce a written comments or recommendations but, in so far as they are justified in doing so, the individual researcher could proceed within the boundaries of their own professional ethics.

I’ve long thought that [3]making ethics review voluntary could force ethics committees to improve the quality of their recommendations. As it stands, committees can use threats to impose their will, so they need not persuade researchers of the value of their suggestions. If stripped of this power, they would need to make suggestions good and clear enough to inspire voluntary compliance. But I’m less sure that such a switch requires or merits the wholesale reframing from research ethics to professional ethics. If your profession is research, aren’t research ethics a form of professional ethics?

I also wonder about Emmerich's comparison of social science to "the true professions of law, medicine, [and] the clergy." It strikes me that a key characteristic of these professions is the ability ([4]in theory) of fellow professionals to disbar, debar, or defrock. Social scientists do not have such power. In my essay, "Ethical Pluralism," in [5]The Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review, Will C. van den Hoonaard and Ann Hamilton, eds., (University of Toronto Press, 2016), I concluded that greater trust in the scholarly professions would likely require less reliance on threats. Does Emmerich agree?

Gontcharov attacks TCPS2

Gontcharov's main argument is that Canada's Tri-Council Policy Statement inappropriately imposes a "positivist understanding of research as a universal standard for all research disciplines." As a result, he argues

> it is unavoidable that some research initiatives based on alternative or mixed methods started to experience challenges in passing ethics review. Since the format of ethics review is tailored to positivist research, "qualitative" researchers try to fit in the required framework – even if it is hardly relevant – when/thus filling out REB forms, identifying risks of harm, answering questions about anonymity and generalizability of data, or designing written consent forms. If they anticipate significant challenges in passing ethics review, they will probably decide against pursuing the project. (26)

Unlike the United States, Canada has given social scientists formal roles in shaping human subjects guidelines. But Gontcharov suggests that quantitative social scientists sold out their less positivist fellows:

> The reason why many SSH (social science and humanities) researchers would not object the biomedical framework as a whole, searching for solutions to existing problems from within, is reflective of the overall methodological structure of the social sciences. This structure features a positivist core and antipositivist periphery. From this perspective – the expansion of the positivist framework can be seen as an attempt to colonize the periphery by the social sciences' methodological core. Accordingly, methodological colonialism is an inner business of the social sciences, rather than an effort of the biomedical sciences to bring them into their orbit. (15)

Gontcharov claims that while the 2010 and 2014 revisions to the TCPS introduced some "undoubtedly progressive" elements, "the biomedical conceptual framework remains largely intact, [so] all initiatives at knowledge production that do not fit the required protocol format continue to be censored or modified by researchers themselves in order to resemble the standard."

I am puzzled by this claim, since the 2010 revision addressed many of the problems that Gontcharov identifies. For instance, Gontcharov claims that under TCPS "it is assumed that researchers will follow the approved design until research is completed." But since 2010, TCPS2 has specifically noted that

> Although initial research questions may be outlined in the formalized research proposal, REBs should be aware that it is quite common for specific questions (as well as shifts in data sources or discovery of data sources) to emerge only during the research project. Due to the inductive nature of qualitative research and the emergent design approach of the research, some of these elements may evolve as the project progresses. (Article 10.5).

Researchers are free to tinker with their research design without additional review unless "changes of data collection procedures would represent a change in the level of the risk that may affect the welfare of the participants."

Similarly, Gontcharov complains that

> Written consent forms are a feature of REB oversight, which has a demoralizing effect on researchers, since they realize that they can only pass ethics by accommodating the elements that are native to research ethics boards, but potentially foreign to their projects.

Again, TCPS2 addressed this problem in 2010:

> In some types of research, and for some groups or individuals, written signed consent may be perceived as an attempt to legalize or formalize the consent process and therefore may be interpreted by the participant as a lack of trust on the part of the researcher. In these cases, oral consent, a verbal agreement or a handshake may be required, rather than signing a consent form. In some cultures, the giving and receiving of gifts symbolizes the establishment of a relationship comparable to consent. (Article 3.12)

As a final example, Gontcharov laments that

> REB professionals rely on a hierarchically-structured concept of power, power as dominance, assuming that researchers have power over their human participants. On the other hand, participatory researchers do not operate from within this "power over" perspective, since the context presupposes a more nuanced, multidimensional understanding of power, in which even the very distinction between researches and participants may be blurred or even irrelevant.

TCPS2 agrees:

> In some cases, participants hold equal or greater power in the researcher-participant relationship, such as in community-based and/or organizational research when a collaborative process is used to define and design the research project and questions, or where participants are public figures or hold other positions of power (e.g., research involving economic, social, political or cultural elites). (Chapter 10, General Approach and Methodological Requirements and Practices.)

To be sure, [6]as Nancy Janovicek has written, not all REBs are following the guidance in the revised TCPS. But I am baffled by Gontcharov's attack on a document that already includes key distinctions between biomedical and qualitative research that he wishes to highlight.

1. http://dx.doi.org/10.5153/sro.4127
2. http://dx.doi.org/10.2139/ssrn.2861908
3. http://www.institutionalreviewblog.com/2007/01/why-not-make-irb-review-voluntary.html
4. http://www.vox.com/2014/6/24/5838690/why-is-dr-oz-still-a-doctor
5. http://www.utppublishing.com/The-Ethics-Rupture-Exploring-Alternatives-to-Formal-Research-Ethics-Review.html
6. http://www.institutionalreviewblog.com/2016/08/will-tcps2-improvements-reach.html

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nathan (2016-12-19 10:17:33)
Hi Zachary

Thanks for reading, and commenting. You say:

"If your profession is research, aren't research ethics a form of professional ethics?"

Well, yes! As you and Stark (and Hedgcoe's latest) show, for various reasons biomedical research ethics was deliberately created as something independent of the existing structures of biomedical professional ethics. Given the methodological and epistemic commitments in the biomedical (natural) sciences this was tenable. Part of the reason it has proved problematic in the social sciences is because this is not the case in these disciplines. Like medical practice, the social sciences are both science and art! Rethinking research ethics as a professional ethics does not necessitate a wholesale rejection of the former in favour of some wholly original creation in terms of the latter. Rather it requires the ethical terms of research to be restated and their meaning, purpose and logic to be reconsidered.

You also question whether we can (or should) expect the social sciences to become institutionalised in the same way as medicine, law, the clergy (or the military). And if this will compromise a necessary ethical pluralism. First, i don't think it is possible or desirable to institutionalise in this way - having a professional body to credentialise and disbar or defrock social scientists doesn't seem likely or a good idea! There are too many sub-specialisms and we lack the requisite overarching unity. I'd rather see existing professional bodies articulate standards of professional research ethics and have research (and RECs) make actual use of them.

Trust in social science is important, but at this point what is vital is that distrust is not allowed to take hold. Regardless of fault, the case of the Boston College Project and in the example of Marie-Ève Maillé show current promises of confidentiality are highly suspect. This needs to be addressed sooner rather than later, and preferable at a collective level.

Nathan

6. 2017

6.1 January

Reforms for “21st century science” would have been good for the 20th too (2017-01-02 12:08)

A group of 11 researchers and IRB professionals, most of them affiliated with the University of California, San Diego, report on a brainstorming session from early 2015. They argue that readable consent forms, expert review, a less punitive system, and more exemptions would better serve researchers and participants. While they present their ideas as “a human research protections system that is responsive to 21st century science,” the measures they propose are equally valid for research as it has been practiced for decades.

[Cinnamon Bloss et al., “Reimagining Human Research Protections for 21st Century Science,” Journal of Medical Internet Research 18, no. 12 (2016): e329, [1]doi:10.2196/jmir.6634.]

Five recommendations

The team presents its proposals under five headings, but I see the second and fifth as similar in intent.

- Redesigning the Consent Form and Process

There’s broad consensus that [2]written consent forms often fail to give prospective research participants the information they need to make a good decision. The UCSD team proposes consent forms based on Creative Commons licenses (like the one used by this blog). “Research studies,” they explain, “could create three consent forms: one that contains all the legalese and scientific exposition; one in plain English that presents the facts; and a third that is simplified even further and presents risks in bullet point format.”

- Empowering Researchers to Protect Participants

Though the authors call for “empowering researchers,” really they are calling for expert peer review:

> Researchers intending to engage in human-participant research could produce a document that lays out plans and risks of the research. They could then offer those documents, along with an outline of the proposed consent process, for review by their peers. Peers would be researchers in the field of relevance for the research. These documents could be posted on the Web in the same way clinical trials are registered; not to get approval but to create a public record of the research …
>
> Using [a] Web-based resource, within a few hours, researchers posing questions such as “How do I ensure that I won’t cause harm by asking this interview or survey question?” would receive answers from researchers who have been rated in terms of experience and expertise in human research protections. Elements of the plans could ultimately become like “protection modules” that could be swapped in and out of consent forms and research protocols, drawing attention to highly ranked modules.

- Reinforcement and Learning From Experience

Like [3]Greg Koski, the San Diego team sees the aviation safety system as a promising model. To encourage the sharing of important information, that system relies on more transparency, and less punishment for non-compliance.

> Pilots who have a "bad" landing or make another safety-related error who self-report their mistake are spared from punishment, but those who do not report it themselves are penalized if someone elects to report. Analogously, as an alternative to an IRB, in this system, researchers who create a protocol they believe to be safe, who then observe a harm during the research and who report that harm to their university or institution, present an opportunity for the research institution and community to learn how to prevent future harm.

- Increasing Efficiency of the Institutional Review Board

The authors call for several measures to track and ultimately reduce the costs of IRB review. Of particular concern to this blog is their suggestion that IRBs "use the 'exempt' category to a greater degree, as it was intended. The exempt category is frequently appropriate for the vast majority of social and behavioral science studies, yet it is underused, which leads to delays in review and approval and, thus, wasted resources."

- Review of Research That Leverages Technological Advances

The authors claim that new technologies, such as "mobile, visual imaging, pervasive sensing, and geolocation tracking technologies present new ethical and regulatory challenges," and suggest that "virtual network composed of researchers, technologists, and bioinformatics experts may prove to be a workable solution to augment or replace the traditional IRB review process resulting in an informed and meaningful human protections review of 21st century science." This sounds a lot like their second recommendation.

These aren't new problems

Like [4]Metcalf and Crawford, the San Diego authors implausibly suggest that today's IRB structure once made sense, but has been overtaken by events.

> While IRBs have helped address this critical need, the IRB system has not kept pace with the evolution of research methods and practices or current and emerging trends in science and technology. The fact that the system has become antiquated calls into question whether the IRB continues to foster the protection of human research participants per the principles originally put forth in the Belmont Report. New forms of research enabled by technological advances in information technology and data science appear to be particularly challenging to IRBs, yet clear standards to guide best practices are not well established.

In fact, most of the problems they raise are not unique to "21st century science." IRBs have wasted resources meddling with social science wasteful and inappropriate regulation of social science research since the 1960s. In the 1970s, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research discussed participants' struggle to understand consent forms and the need to get expert judgment to understand the risks of specific methods. The exemptions which the authors want to see applied date to 1981. Punishing researchers, rather than encouraging them to learn from mistakes, has been a bad idea from the start.

The authors are thus wrong to suggest that these problems arose with cellphones and social media. It is not that the IRB system has become antiquated; rather, it never scaled up well from its small start in the 1960s. The reforms suggested here would have been as useful half a century ago.

1. http://dx.doi.org/10.2196/jmir.6634
2. http://www.institutionalreviewblog.com/search?q=consent+form
3. http://www.irbnetresources.org/news/081109_IIS.pdf
4. http://www.institutionalreviewblog.com/2016/12/big-data-researchers-call-for-irb.html

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Common Rule reform still in suspense (2017-01-07 22:25)

A proposed final rule on human subjects protections made it to the Office of Management and Budget on Wednesday, January 4.

Jeannie Baumann of Bloomberg thinks this means that we'll see it in the Federal Register before January 20. But she also quotes Lisa Nichols, director of research and regulatory reform for Council on Governmental Relations, predicting that Congress will overturn the reform, since it appears on the [1]House Freedom Caucus hit list.

Wake me up when it's over.

[Jeannie Baumann, "[2]White House Takes Final Steps to Revamp Medical Research Rule," Bloomberg BNA, January 6, 2017.]

1. https://meadows.house.gov/first-100-days
2. https://www.bna.com/white-house-takes-n73014449436/

United States of America Frees Oral History! (2017-01-18 13:51)

This morning sixteen federal agencies announced revisions to the Federal Policy for the Protection of Human Subjects, effective 19 January 2018. The final rule preserves and clarifies the NPRM's deregulation of oral history. This is a great victory for freedom of speech and for historical research.

The NPRM somewhat confusingly listed a number of activities "deemed not to be research" in § _ _.101, then presented the definition of research itself in § _ _.102. The final policy more logically defines research, then lists "activities … deemed not to be research."

Whereas the NPRM excluded "Oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected," the final rule offers a broader exclusion:

> For purposes of this part, the following activities are deemed not to be research:
> (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. [§ _ _.102(l)(1)]

(Emphasis added, because I can.)

So freedom depends on the activity, not the discipline, with literary critics, law professors, and others who interview individuals benefiting. Another section of the announcement notes that this provision will also apply to political scientists and others who hope "to hold specific elected or appointed officials up for public scrutiny, and not keep the information confidential."

The announcement explains the reasoning:

> In these activities, the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not necessarily to protect them from public scrutiny. For example, a biographer might collect and present factual information to support the biographer's opinion about the character of an individual to show that the individual does not deserve the positive reputation he or she enjoys in society. These fields of research have their own codes of ethics, according to which, for example, consent is obtained for oral histories. We note that this consent standard should address the issue of oral histories of tribal members. For these reasons, we have determined that it is appropriate to remove these activities from the definition of research and from the scope of the Common Rule.
>
> In response to public comments, § _ _.102(l)(1) refers to more fields and methodological traditions than were proposed in the NPRM. The final rule also explicitly cites those fields and traditions as examples, in order to clarify that the focus is on the specific activities that collect and use information about specific individuals themselves, and not generalizing to other individuals, and that such activities occur in various fields of inquiry and methodological traditions. Literary criticism has been added as an example because while a piece of literary criticism might focus on information about the author(s), it would typically focus on the specific author(s) in view. Legal research has been added as an example because it would often focus on the circumstances of specific plaintiffs or parties involved in a case. It is not the particular field that removes the activity from the definition, but rather the particular activity's focus on specific individuals.

I will be posting more later about the potential effects of the revised rule on the humanities and social sciences more generally. For now, I salute all those who worked for so many years to liberate oral history, especially Jonathan Knight, Cliff Kuhn, Don Ritchie, Roy Rosenzweig, Linda Shopes, Rob Townsend, and everyone who took the time to comment on the ANPRM and NPRM.

Unknown (2017-01-18 17:56:12)
Zach, thanks for your explanation of these changes in human subjects regulations governing oral history - and other activities - and for YOUR advocacy of these changes for many years. We shall see how IRBs actually implement them - I have concerns, for example, about the failure to define an explicit "exclusion" category for oral history and other practices and the potential for some IRBs to decide what constitutes oral history, what does not, based on limited knowledge (and, I suppose, some researchers, too). But we shall see how it all shakes down. –Linda Shopes, Independent Historian

A social scientist's guide to the Final Rule (2017-01-19 09:08)

On 18 January 2017, sixteen federal agencies announced revisions to the Federal Policy for the Protection of Human Subjects. As I noted earlier, this marks a [1]huge victory for historians, who have spent the last 20 years working to end the inappropriate interference of IRBs with oral history research.

In addition, the final rule includes several provisions of note to scholars in the humanities and social sciences. Here are some of them; I don't claim it is a complete list.

No biospecimens overhaul; less controversy

The final rule "does not adopt the proposal to require that research involving nonidentified biospecimens be subject to the Common Rule, and that consent would need to be obtained in order to conduct such research." This was the target of the greatest criticism from groups like the [2]National Academies of Sciences, Engineering, and Medicine and [3]SACHRP. So while this change has little direct bearing on the work of social scientists and scholars in the humanities, it will likely reduce the controversy surrounding the regulatory reform as a whole.

The abandonment of the biospecimens proposal could also reduce opposition to reform by conservatives. The [4]House Freedom Caucus opposed a new Common Rule on the grounds that it would cost $13.334 billion over 10 years. This figure seems to have been drawn from the NPRM's quantified costs of $13.342 billion (using a 3 percent discount rate), and ignored the NPRM's quantified benefits of $2.6 billion. If all the Freedom Caucus cares about is money, it may like the final rule a lot more. Of the $13.3 billion estimated costs, $12.2 billion came from complying with the new rules on secondary use of biospecimens (80 FR 54021). The new estimate is that changes will have benefits of $1.9 billion over 10 years and costs of only $528 million (at a 3 percent discount rate, which is where the $13.3 billion figure came from). If Republicans can consider benefits as well as costs (as the House Freedom Caucus has so far failed to do), perhaps the jettisoning of those rules will reduce hostility to the overall reform.

Agencies continue to ignore statutory limits

Like previous versions of 45 CFR 46, this final rule claims as its statutory authority 42 U.S.C. 289, which applies to "biomedical and behavioral research," yet it fails to restrict its provisions to such activities. The announcement explains:

> Regarding the concerns expressed that the Common Rule departments and agencies are not authorized to regulate humanities and social science research, this challenge had been asserted previously against the 1981 HHS protection of human subjects regulations, as well as the 1991 Common Rule, and in each case the regulatory agencies concluded that the regulation of humanities and social science research is justified. We continue to assert the authority to regulate humanities and social science research that falls within the scope of the final rule.

Note the verb "assert." Not find, show, explain, reason. No statutory analysis. Just raw assertion of power.

The announcement cites the 1981 and 1991 Federal Register announcements, neither of which states that "the regulatory agencies concluded that the regulation of humanities and social science research is justified." I know of no such formal finding.

Similarly, the final rule abandons the NPRM's proposal to impose review on clinical trials "regardless of the funding source of the specific clinical trial" without reference to the statute. Rather than concede that HHS lacks the statutory

authority for such a requirement—something it did concede in 1981 (46 FR 8369)—it claims, "our proposal for extending the Common Rule to currently unregulated clinical trials would benefit from further deliberation."

Oral history is clear; ethnography is still regulated

As I noted in my [5]previous post, the new definition of research includes a provision [§ _ _.102(l)(1)] explicitly excluding "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected." This is a big deal not only for historians and journalists, but also for literary critics, law professors, and political scientists who do on-the-record interviews.

The final rule eliminated the special exemption for research with public officials on the grounds that it is no longer needed. Now, if you are running a low-risk survey of public officials, you seek clearance under the exemption for low-risk surveys, while if you want to "hold specific elected or appointed officials up for public scrutiny," you aren't doing research under the revised definition of research. This strikes me as an improvement, since it provides the same clearance for research about corporate executives, rock stars, lobbyists, and other public figures as it does for the more narrow category of officials and candidates.

Unfortunately, the new rule continues to cover ethnography:

> Activities described in § _ _.102(l)(1) may sometimes be performed in the fields of anthropology or sociology, but not all activities characteristic of these fields are outside of the rule. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research of the final rule.

How exactly ethnographers are supposed to do their work is another question. At the [6]20 October 2015 Town Hall, OHRP officials could not figure out how the NPRM would govern ethnography. And I'm not sure the final rule is any clearer.

Changes to ethnography and surveys

The final rule does make some changes that may affect ethnography and surveys, perhaps to the good.

- Easier to talk with prisoners, pregnant women, and the disabled

For ethnography and other social science work that still falls under the definition of research, but that is exempt, it will be possible to maintain that exemption if the population studies "only incidentally includes prisoners." And "pregnant women or 'handicapped' or physically disabled individuals" are now considered able to think for themselves, so no special review of research involving them is required.

- Modified exemption for interviews and surveys

> (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
> (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § _ _.111(a)(7).

The addition of "by the investigator" in part (i) is helpful. If a participants wants to take notes, that doesn't affect the researcher's exemption. The addition of part (iii) allows another path to exemption not present before. At some point in the future, HHS will issue guidance explaining what privacy procedures qualify a study for this exemption.

- No more checking the box

HHS "plan[s] to implement the proposed nonregulatory change to the assurance mechanism to eliminate the voluntary extension of the FWA to nonfederally funded research." The final rule explains:

> We expect this change to have the beneficial effect of encouraging some institutions to explore a variety of flexible approaches to overseeing low-risk research that is not funded by a Common Rule department or agency, without reducing protection of human subjects, thus furthering the goal to decrease inappropriate administrative burdens.

Conceivably this could help ethnographers win exemption.

- Modified consent rules

I confess that I haven't been able to digest the complex new rules about obtaining consent. I do note that the final rule allows IRBs to waive the requirement for a signed informed consent form if

> the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

The regulations have, since 1981, allowed waivers of consent forms for "procedures for which written consent is normally required outside of the research context," like talking with people. (Whether IRBs have heeded this provision is another matter.) So I'm not sure that the addition of distinct groups here will change anything for ethnographers.

Delayed changes to "minimal risk," exemption determination, and privacy protections

The final rule abandons some NPRM proposals in favor of buying time by reducing them to matters of guidance. These include:

- Changing the definition of minimal risk. HHS may still develop a list of examples of minimal-risk activities, but it will do so outside of the regulatory track.
- Creating an "exemption determination tool," which researchers could use to determine if their proposals were exempt from review. Like the list of minimal-risk activities, this is something that HHS can continue to work on without a regulatory change.
- Privacy protections. "Rather than promulgate a regulation that lacked sufficient specificity, we determined it would be preferable to maintain the requirement that IRBs review research studies to ensure that appropriate privacy and security safeguards are in place to protect research subjects, but include a commitment that the Secretary of HHS will issue guidance to assist IRBs in appropriately protecting subjects' privacy and confidentiality. This guidance would take into consideration, among other things, the level of identifiability and sensitivity of the information being collected."

Limited restraints on IRBs

The final rule states that "An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § _ _.104 for which limited IRB review is a condition of exemption." It does not explicitly forbid IRB review of exempt research. And since the big problem with exempt research has been jumping through hoops erected by IRB staff, it's not clear how much of a difference this will make either way.

IRBs now must document their reasons for escalating review:

> The final rule includes the NPRM proposal that IRBs document decisions to require continuing review or full board review even in circumstances when such review is not required because we believe it is important to document why an IRB is making a determination that differs from the regulatory baseline. This also helps to promote the principle of justice (as applied to IRB operations). Note that nothing in these regulations prevents an institution from authorizing an IRB to apply standards that exceed those in the regulations, if indeed the institution has chosen to do so.

Beyond that, there's scant due process protections in the final rule. No guaranteed appeals, for instance. No requirement that IRBs base their decisions on evidence.

In sum, the final rule is great news for researchers whose work will no longer be subject to IRB oversight. I'm less sure it will significantly help those still subject to regulation.

1. http://www.institutionalreviewblog.com/2017/01/united-states-of-america-frees-oral.html
2. http://www.institutionalreviewblog.com/2016/07/the-ethical-imperialism-of-nas.html
3. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2016-january-5-recommendation-nprm-attachment-a/index.html
4. https://meadows.house.gov/first-100-days
5. http://www.institutionalreviewblog.com/2017/01/united-states-of-america-frees-oral.html
6. http://www.institutionalreviewblog.com/2015/11/does-nprm-exclude-or-exempt-ethnography.html

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Why is Felice Levine satisfied? (2017-01-19 10:56)

Inside Higher Ed reports that Felice J. Levine, executive director of the American Educational Research Association, is happy with the final rule. I'm curious about why; it doesn't seem to give her anything she asked for in 2011.

[Scott Jaschik, "[1]U.S. Issues Final Version of 'Common Rule' on Research Involving Humans," Inside Higher Ed, January 19, 2017.]

[Edited at 11:12AM to mention the normal educational practices in penultimate paragraph.]

Here's Scott Jaschik's reporting on social science reactions to the final rule:

> Early reactions from social science groups to the changes in the common rule were positive. Various provisions suggest that institutional review boards, which must review proposals to study humans, work to understand the needs of different kinds of researchers, and that there are different levels of risk associated with taking an experimental drug and answering confidential survey questions.
>
> A statement from Felice J. Levine, executive director of the American Educational Research Association, said, "The revised regulations definitely show the care and hard work that went into this extensive effort to modernize the common rule. An open process that began in July 2011 has led in January 2017 to regulations that are more nuanced and that far better align human research protection and social and behavioral science research, taking into consideration level of risk and benefits. It is a fine outcome for research participants and for human science."
>
> For anthropology, the reaction was more mixed. Anthropologists pushed hard for specific mention of "participant observation" (a key tool of their discipline). The hope is that mention of this methodology will make it easier for institutional review boards to approve projects involving this approach. Sometimes in the past, [Edward Liebow of the American Anthropological Association] said, IRB members or others have not understood that the relationship between an anthropologist engaged in participant observation isn't the same as a scholar who is interviewing his or her research subjects.
>
> But he said that his association was "especially concerned" that the final version of the rule did not exempt participant observation, as his organization had urged.

I can understand Liebow's disappointment; the final rule offers little aid to frustrated ethnographers.

I have more trouble understanding Levine's satisfaction. In response to the 2011 ANPRM, she drafted the "[2]Social and Behavioral Science White Paper," which called for dramatic reforms to the IRB process. The final rule is largely unresponsive to the concerns expressed in that paper:

- The White Paper objected to the current §46.116(a)(2) requirement that informed consent include a "description of any reasonably foreseeable risks or discomforts to the subject," suggesting that "reasonably foreseeable harms" might better apply. The final rule does not make that change.
- The White Paper objected to the current rule's "general mandate to apprise subjects as part of the informed consent process of alternatives to treatment or why it may be in their best interest not to participate. (Such requirements are sometimes appropriate, but add complexity and foster confusion where they are not.)" The final rule maintains the current rule's language on this point.
- The White Paper "strongly support[ed] the requirement of an appeals process." This was not included in the NPRM or final rule.

- The White Paper argued that "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." The final rule [§ _ _.115(a)(3)] takes a small step in requiring documentation of "the rationale for conducting continuing review of research that otherwise would not require continuing review," but it does not require such a rationale for denying an exemption.

The final rule, with its announcement, is 543 pages long in its initial format, so perhaps it includes some of the White Paper's recommendations that I have overlooked.

It's also possible that Levine is thinking primarily of the final rule's provisions for research "involving normal educational practices," which I have not examined so closely. But the new rule seems to make this research harder; to win exemption, research must be "not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction," something not required by the current regulations.

So far, I can't see why Levine is calling this a win.

1. https://www.insidehighered.com/news/2017/01/19/us-issues-final-version-common-rule-research-involving-humans.
2. http://www.institutionalreviewblog.com/2012/01/sbs-white-paper-calls-for-drastic.html

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You know, it's very strange (2017-01-19 18:02)

On 19 January 2007, [1]Inside Higher Ed reported the launch of this blog. Here is the kicker from that story:

> 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."

Ten years later, to the day, the amended regulations are in the Federal Register.

[2]You know, it's very strange—I have been in the revenge business so long. Now that it's over, I don't know what to do with the rest of my life.

Should I consider piracy?

1. https://www.insidehighered.com/news/2007/01/19/irb
2. https://books.google.com/books?id=cSQT4aQ7r10C&lpg=PA382&dq=%22revenge%20business%20so%20long%22&pg=PA382#v=onepage&q=%22revenge%20business%20so%20long%22&f=false

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BlogBook v0.9,
LaTeX 2ε & GNU/Linux.
https://www.blogbooker.com

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