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Ignorance Is Strength: Pseudo-Expertise and the Regulation of Human Subjects Research

Author’s note: These are notes prepared for delivery at Brigham Young University on 28 February 2013. While many quotations and facts are cited in the endnotes, I have not attempted to polish this text to the standards of scholarly publication. For more complete references and arguments, please consult my published writings about IRBs and my blog, Institutional Review Blog, http://www.institutionalreviewblog.com/

Ignorance Is Strength: Pseudo-Expertise and the Regulation of Human Subjects Research, 28 February 2013, by Zachary M. Schrag is licensed under a Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported License.
I have been asked to speak today about the subject of my second book: the regulation of research with human subjects. I will get to some of the details in a moment, but the basic story is that over the past half century, governments—led by the United States—have sought to protect people who participate in medical, psychological, or social research by imposing systems of oversight over the researchers. In other words, this is not merely a story of who has authority over scientific knowledge, but rather who has authority over those who claim authority, and perhaps who has authority over those who claim authority over those who claim authority.

There is power to be had in questioning the experts and subordinating them to people with alternative claims to wisdom. That power is often a good thing, but it is power nonetheless and must be regarded with the same skepticism as power based on expertise. Knowledge may be dangerous, but ignorance can be pretty dangerous too.

**Opening Vignette. Scott Atran Talks to the Enemy**

*Atran*

To give you a sense of what I am talking about, I would like to start with the story of Scott Atran. Atran is anthropologist with broad interests, including “Middle East ethnography and political economy; natural history of Lowland Maya, cognitive and commitment theories of religion.”

Some years ago, Atran joined a team investigating one of the most pressing problems faced by the United States: terrorism. Along with researchers from leading universities in the United States and elsewhere, he planned to interview jihadis, including some who had been jailed for attempted suicide bombings.

Because he planned to interact with the people he was studying, his work came under the federal definition of human subjects research. This meant that before proceeding, he would have to submit his plans to the institutional review board, or IRB, at the University of Michigan, his home institution.

As Atran later reported, the IRB imposed significant restrictions on his research. He could only interview failed suicide bombers in prison if their parole boards and their lawyers were involved. “But,” Atran explains, “it's nigh impossible to do serious anthropology or psychology with a lawyer present, and there are no parole boards in Indonesian military prisons. Nor is there any reasonable likelihood of that this sort of research will worsen the condition of convicted mass killers.”

The IRB also imposed restrictions on “interviewing freely operating jihadis and would-be suicide bombers.” Atran would not be allowed to name the groups, like Hamas, to which terrorists belonged, nor could he ask personal details of the people he interviewed, details he felt he needed to understand their motivation. Ultimately, these restrictions significantly hampered

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Atran’s work. “My own view,” Atran concluded, “is that most of this is nuts: how is anybody in academia ever going have as much as possible to offer in this whole mess – though people in academia keep complaining that the government doesn't pay attention to serious scholars – if no one can even talk to the people most involved?”

For our purposes today, what’s most interesting about this episode is the nature of the authority that restricted Atran’s research. Who was it that told him he could not interview jihadis? A fellow anthropologist? A specialist in religious studies? A scholar of the Middle East or Southeast Asia?

Sayer

Well, the chair of the University of Michigan Behavioral Sciences Institutional Review Board was Dr. James Sayer, Assistant Research Scientist, Human Factors Division, University of Michigan Transportation Research Institute. Sayer’s own research concerned neither Islam nor political violence, but rather “the effects of hydrophobic and hydrophilic glass coatings, window tinting, and defrosters/defoggers on visual performance and driving behavior.”

To his credit, Sayer seems to have tried hard to get outside reviewers to comment on Atran’s work. But when that failed, the expert was subordinated to the layman.

This is not unique to the University of Michigan; it is the product of a national system that is a hybrid of expert and non-expert review.

In the remainder of my time, I want to address three questions.

First, How did we get here? Why did the designers of the IRB system mix expert and nonexpert review?

Second, what friction does this mixture cause?

And third, how might the nation as a whole and individual institutions reduce this friction?

Born in Scandal

Ethical Imperialism

I don’t want to spend a lot of time on the history of the IRB system; if you are interested in that, I have a book you can buy. But I need to note a few key points about the origins of that system.

Heller

First, the system was initially modeled on the system of scientific peer review. The background was an explosion of research of all kinds—from the design of nuclear weapons and spacecraft to


medical breakthroughs like the polio vaccines to controversial social research like Alfred Kinsey’s reports on human sexual behavior. Much of this work was financed by the federal government, particularly the Public Health Service, which included the National Institutes of Health, or NIH.

In the 1960s, officials at the U.S. Public Health Service became alarmed by some of the practices of researchers using federal funds, and they wanted some mechanism to keep scientists from going crazy. But they still trusted scientists enough to give them the job of watching over each other.

**PPO 129**

So in 1966, the surgeon general—the head of the Public Health Service—issued a policy stating to get a research grant from the Public Health Service, an investigator would have to have his plans reviewed “by a committee of his institutional associates.” This committee would be charged with protecting the rights and welfare of the people involved in the study, the appropriateness of the methods to secure informed consent, and the risks and potential medical benefits of the investigation.\(^5\)

The key term here is *institutional associates*. The Public Health Service was not offering to review the ethics of a proposal with the kind of federal study group that evaluated grant applications. Nor was it asking investigators to submit their plans to a cross-section of the community, like a jury. Instead, the idea was that so long as a researcher’s plans did not grossly offend the sensibilities of his fellow experts, he could proceed.

For many officials within the Department of Health, Education, and Welfare—HEW—this seemed to strike just the right balance between centralizing authority in the federal government at the expense of professional and institutional autonomy, and leaving researchers to their own devices.

This model did not last long, in large part because new revelations of abuses kept appearing.

**Syphilis Victims**

Most notably, in the summer of 1972, Americans learned of the project now widely known as the Tuskegee Syphilis Study. The initial press coverage exaggerated some of the details, but the truth was, and is, shocking enough.

**Watergate**

And the early 1970s were not, of course, great times for authority in general. The United States was withdrawing its last troops from Vietnam, effectively losing its first war. President Nixon became ever more enmeshed Watergate scandal. The Senate opened hearings, and some members of Congress began discussing impeachment.

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Deep Throat

Scientists advised people to watch *Deep Throat*.

In this atmosphere, many shared an interest in challenging the autonomy and authority of scientists.

*Diamond*

As Bernard Diamond, chair of Berkeley’s IRB, caught the spirit:

“The University of California at Berkeley does not permit a researcher, be he Nobel prize winner or director of a world famous research laboratory, to be the sole judge of the ethical issues in his use of human subjects . . . Whether the researcher be a graduate student or distinguished scientist, he still must submit his research proposal to a review committee whose members are unconnected with his department and who are specially qualified to evaluate the ethical and legal aspects of his experimentation upon humans.”

[It’s worth noting that Diamond’s actions as IRB chair inspired the Berkeley faculty to form an Academic Freedom Committee to resist him.]

*Diamond highlight*

But my point here is the tension. Even as he derogates one form of scientific authority, Diamond claims that his committee will have another form; it will be “specially qualified” to evaluate ethics and law.

This ambivalence about authority is embedded in the regulations governing IRBs, which were developed between 1974 and 1981 and are more or less still operative today.

Let me just offer some examples of this internal tension.

*Levine quotation*

**IRBs would remain local, but would have to follow national regulations.** In 1978, critics objected to federal interference in university affairs. Robert Levine, who had served as consultant to the commission, denied the charge. “Each IRB is an agent of its own institution,” he claimed in 1979. “It is not a branch office of OPRR [the federal agency in charge of IRBs]. It is not a branch office of any other funding or regulatory agency.”

*regulations*

But the fact was, at least after 1974, IRBs did begin to function as branch offices of OPRR, and OPRR encouraged the trend. It distributed ever more elaborate regulations and model assurances—documents it expected universities to sign and send back—with detailed descriptions of how IRBs would operate.

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Belmont

IRBs would given the impossible task of reviewing all aspects of research. Belmont Report: “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.” There’s a pretty big gap between this impossible “ideal” and emulating it “insofar as possible.”

Research methods

IRBs should not judge whether the science is good, but they must judge whether it is worth doing. In 1973, the Senate recommended that each IRB have two subcommittees: “one to focus on the scientific merits of the protocol” and the other to watch out for the rights of the participants. In 1979, regulators proposed instead a single committee, that would mostly focus on ethics but would also have to determine that “The research methods are appropriate to the objectives of the research and the field of study.” After protests from scholars, this requirement was dropped, but IRBs still must consider the “importance of the knowledge that may reasonably be expected to result” from a study. So either they evaluate the science, or they don't.

IRBs composed of scientists, but also nonscientists. The 1974 regulations, for example, specified that no IRB could consist entirely of people affiliated with an organization, nor could all members be of the same profession. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, pictured here, embodied that view, giving a majority of seats to nonscientists.

The 1981 revision took this idea further, requiring IRBs to be racially and culturally diverse, forbidding IRBs composed entirely of men or women, and demanding that “Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.”

Recall that in 1966, an investigator would have to have his plans reviewed “by a committee of his institutional associates.” Fifteen years later, the investigator’s gender was still presumed to be male (in at least one reference), but no longer would he be judged just by his fellow researchers. The federal government was not willing to trust them.

(No one quite knows what these non-scientists are supposed to contribute; some research suggests that they participate little until they learn to talk and think just like the scientists.)

IRBs must command respect, but their decisions cannot be overturned. Regulations require that each “IRB shall be sufficiently qualified through the experience and expertise of its members . . . to promote respect for its advice and counsel.” But they also forbid institutions from overruling an IRBs rejection of a project, and they provide no requirement of an appeal

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7 Senate Committee on Labor and Human Resources, National Research Service Award Act, 93d Cong., 1st sess., 1973, 30.
mechanism. How far do you suppose these boards go to promote respect when they command such power?

The point of all of this is that the IRB system embodies a deep ambivalence about scientific authority. And that ambivalence surfaces in the operations of IRBs all around the country today.

**The IRB System Today**

In the absence of up to date research and guidance from the federal government, local IRBs have a great deal of discretion. Some use it wisely, many do not.

A major grievance of researchers is that boards lack the expertise necessary to weigh the benefits and risks of the research before them—a key IRB task. Nor is this surprising; what half-dozen or dozen people would collectively have the expertise to weigh the risks of every kind of research conducted in a modern research university?

*Fitzgerald, folk devils*

In the absence of true expertise, IRBs fall back on guesswork and folklore. Maureen Fitzgerald observed ethics committees found them to rely on what she calls “folk devils and moral panics.” Longtime board members share favorite stories—true or not—and base their judgment on those.

**Trial and error**

One very common example concerns written consent forms. Researchers submit these, and IRBs read them carefully, changing a word here, a phrase there. But when the same form is submitted to multiple IRBs, or even to the same IRB at different times, the IRBs demand different changes—from past tense to present, or present to past. A 2007 study found that IRBs made the forms longer and more complex, and added errors.

*Board games*

As the journal *Nature* commented, these practices amount to “board games.”

A second trope to watch out for is the allegation that people can be traumatized—not just upset, but *traumatized*—by interviews. Believing this, many IRBs insist that interview researchers set up counseling if anyone needs it.

**Trauma**

Never mind that all available empirical research suggests that, if anything, interviews are beneficial to people who have suffered trauma.

**Internet**

Lest we imagine that IRBs are composed of experts on ethics, consider the issue of research on the Internet. Two leading scholars have found that “Few boards were aware of extant guidelines

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9 "Human-Subjects Research: Trial and Error," (Nature, 2 August 2007), Heidi Ledford
such as the Association of Internet Researchers Ethical Decision Making document,” and that many did not even know who to ask. Maybe the folks who can fix a hard drive?

**UCLA training**

Nor have IRBs proven eager to learn about the disciplines they govern. If you read the many, many published cases of researchers who have felt thwarted by IRBs, a common thread is that they did not feel their work was understood by the board. Atran’s terrorism case is unusual only in that the IRB chair admitted the problem.

**Mustanski**

A sexuality researcher had 24 months to complete a project, and spent ten of them getting IRB approval. He writes, “It can be extremely frustrating to agonize over perfecting every detail of a protocol to only then have it repeatedly questioned by anonymous individuals who may not have the same subject matter expertise.”

**Timmermans**

A mismatch between researcher and board is particularly apparent when when qualitative researchers face boards dominated by quantitative researchers asking irrelevant questions about sample size. An ethnographer had to face a hospital IRB, whose members shouted at him: “If you write something, we should know HOW MANY PEOPLE said WHAT, there should be NUMBERS in here. There is NO DATA in this paper.”

Researchers frequently complain that the wrong people are reviewing their work. As one comment on the *Chronicle of Higher Education* website put it,

ARGH YES. A network ("snowball") sample (so I don't know exactly who or how many yet!), semi-structured exploratory interview protocol that will evolve during the course of data collection--it was just too much for them. In principle, I'm OK with them watching out for ethical stuff, of course, but when they start questioning my research methods, they've gone too far. Back off. You're a chemist.

Some IRB chairs feel little hesitation about ruling on matters far distant from their own research. The chair of the Purdue IRB, a professor of foods and nutrition, insisted that conducting oral history interviews was “not different from creating a database of DNA.” He told a reporter,

"The people from the humanities ... are evaluated on their research, are they not? So they're engaged in the same activity as a biologist."

Some IRBs get around this problem by recruiting members with expertise in specific disciplines, who then have enormous influence over projects in those fields. This, I would suggest, is a perversion of the system, since it means that projects are being evaluated by a single person, not a board of experts.

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10 Lederman, Perils of Working at Home.
In other cases, IRBs judge projects arbitrarily. Sociologist Laura Stark observed three IRBs at work, and found that all of them judged the ethics of the proposals in part by counting the number of spelling and typographical errors. They claimed that the tidiness of a proposal would predict the researchers’ care in other matters. This is, I suggest, an example of magical thinking. Moreover, it may be a practice that violates civil rights laws, since it will have a disparate impact on researchers whose first language is not English.

Stark also reports on the disappointing role played by the community members whose presence is mandated by the regulations. In one case, a community member insisted that it was unethical to interview homeless people and was unwilling to consider scientific data on the subject. The IRB outvoted her, but the general trend that Stark reports is that community members are ignored until they have been on the board long enough to think and talk like scientists.

And let’s be clear. This lack of expertise isn’t just a problem for researchers. It endangers participants. Carl Elliott, author of *White Coat, Black Hat: Adventures on the Dark Side of Medicine*, warns, “I.R.B.’s are simply incapable of overseeing a global, multibillion-dollar corporate enterprise.”

While most of IRB errors in the social sciences concern overestimating the risks to participants, in some cases they may lead researchers to underestimate the risks, as when they encourage researchers to disguise their research sites, despite decades of experience showing that a researcher’s anonymized town or university is often revealed.

The big story in human subjects protection since 1995 has been the shift of power away from the faculty who compose the IRBs themselves. At smaller institutions, IRBs remain in charge. But for larger institutions, like research universities, the real power now resides not in the boards, but in the staff that serve them.

In the 1970s, as critics warned of censorship by IRBs, IRB defenders argued that such a thing was impossible, because IRBs themselves were composed of academics who would not dream of restricting free inquiry. One recent defense of IRBs claimed that “IRB members are not those folks who are looking to thwart your study. They are peer researchers who have a job to do.”

But in the late 1990s, more of the key decisions began to be made not by these academics, but by professional staff. In 1999, these staff could apply for a new credential: CIP, or “Certified IRB Professional.” This very term—Certified IRB Professional—marks a radical departure from the original premise that ethics review would be a form of peer review.

Some of these CIPs do their jobs well. Some do not. What is particularly frustrating about some of the latter is the audacity with which they make factual claims without the scholarly devices of evidence and citation.
Facebook policies

For example, as of February 2011, the Indiana University Office of Research Information was telling researchers

“When mining information from any source—be it a purchased data set or an internet based source—the IRB at IUB requires all researchers to comply with terms of use for that source. In the case of Facebook and MySpace, both sites explicitly state that their site is not for research but for social networking only.”

Real Facebook policy

This claim is simply false; I checked the terms of service and found no such provisions.

UMASS

Still, the same claim appeared—in identical language—in a newsletter distributed by UMASS Boston. I don’t know which university lifted the language from the other. But one university employs a fabricator and the other a plagiarist—and both people work in research ethics offices.

You can find similarly false claims about the provisions of regulations flitting from university to university, without citation. Thus, the University of Iowa states that “The IRB chair and/or their designees will determine if your study meets the definition of human subjects research. Federal regulations do not allow investigators to make this determination themselves.” Federal regulations say no such thing, but you can find the same falsehood at the University of Southern California.

You could find similar examples of sloppiness by scholars. But when a scholar makes a gross error like this, it doesn’t limit other scholars’ intellectual freedom.

IRB Forum

There are various mechanisms by which such falsehoods spread from one IRB office to another. One is IRB Forum, a discussion board run by Jonathan Merz of the University of Pennsylvania Center for Bioethics. When I first started arguing with the IRB office at Mason, the director suggested I join the forum, thinking—I suppose—that I would realize the depth of the knowledge underlying the decisions made by the Mason IRB. Instead, I was appalled to see that most queries are answered by IRB staffers explaining how they believe a situation ought to be handled, with no references to any sources beyond the Belmont Report and the federal regulations.

CITI

The most powerful engine of pseudo-expertise in the post 1995 IRB world is a service called the Collaborative Institutional Training Initiative, or CITI Program. Founded in 2000, it was designed to give universities and research hospitals an easy way to meet the new education policy requirements of the National Institutes of Health. Since then, it has expanded to become a one-stop shop for universities to show that their faculty and students have had some training in the protection of human research subjects, the responsible conduct of research, or other topics relating to good research practices.
This would be great, if the course offered good training in those subjects. Unfortunately, rather than being written by expert researchers, it has largely been written by administrators who value rote compliance over ethical reflection.

Let me give you an example. The page about the regulation of the social sciences specifically claims that scholars in the social sciences and humanities shouldn’t claim that the regulations weren’t written for them, because

a close reading of the regulations will find mention of research methods and topics of inquiry relevant for researchers in the social and behavioral sciences and the humanities. Methods include surveys, interviews, focus groups, oral history, participant observation, observations of public behavior, and the analysis of existing data. Topics include research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

A close reading of the regulations will show no such thing. The author of this section, who is neither a scholar in the social sciences and humanities nor a lawyer, has confused a supplementary ruling from 1998 with the regulations themselves, which were last modified in 1991. This has enormous significance for scholars and institutions trying to understand the intent of the regulations, and this error was one of the spurs that got me doing my research.

CITI critiques

CITI can drive conscientious researchers crazy. For example, in 2009, Sanjay Srivastava—a research psychologist at the University of Oregon—wrote to complain that the CITI Program was simplistically labeling as “scandals” pioneering studies by Stanley Milgram and Philip Zimbardo. “The attempt to create some sort of parallelism in the presentation (Tuskegee = Milgram? Nazis = Zimbardo?) is inaccurate and misguided,” he warned, “and does a disservice to the legacy of important social/behavioral research.”

Though CITI authors wrote back nicely, they did not change the course.

Other researchers are angrier. Jennifer Freyd, one of Srivastava’s colleagues at Oregon, writes, “Like many of my colleagues I complete the required CITI training because I must in order to be allowed to conduct research, but each time I go through this process I come out feeling like I’ve been force-fed a high-fat low-nutrition meal at McEthics.”

Ronald Bayer, who is co-chair of the Center for the History of Ethics of Public Health at Columbia University, has this to say:

I listen to people talk about taking these tests, and they talk about it the way Russian social scientists used to talk about having to learn the right Marxist [doxology] in the old Soviet Union. They have to learn something, spit it back and give the right answer, and if you don't get a good enough score, you can't do research, you have to take the test again . . .

That's not education. And the reason I see it as a matter of concern is what it does is it raises contempt for the idea of education and becoming kind of sensitive to ethical complexities.
In case anyone missed the point, he called the CITI Program “mortifyingly stupid.”

CITI claims that its customers are satisfied, but independent surveys by the University of Connecticut and the University of Michigan suggest that more than a third of researchers regard this training as a waste of time.\(^{11}\)

As critical as I am of IRBs and human protections staff, I do not blame them for the bulk of today’s problems. Rather, I blame federal regulators for putting them in impossible situations. For example, CITI Program exists because the federal government spits out requirements without providing resources for meeting those requirements, or even sensible guidance.

Instead, for decades the federal government has been discussing the problems of IRBs without doing anything to address them. I would go so far as to say that the federal government is the leading produce of pseudo-expertise on this issue.

\textit{Commissions}

Since the National Commission wound down in 1978, we’ve had several federal bodies dedicated in whole or in part to improving the protection of human subjects of research.

\textit{Books}

Equally significantly, in 2002 and 2003, the Institute of Medicine and the National Research Council released book-length reports specifically about the challenges of human research protection and the need for reform.

This gives the appearance of a sustained federal effort to continuously improve the system. But that is an illusion. These bodies have lacked both the knowledge and power to effect real change.

On the knowledge side, one can find any number of calls for empirical research on how the system is currently operating.

As far back as 1981, a staffer at the President’s Commission could complain, “fifteen years after this system was first put into place, government ignorance about how it actually operates is staggering.” I don’t think matters have improved much.

\textit{Responsible research}

Twenty years later, for example, the Institute of Medicine report complained that

Efforts to initiate QI measures in the research community have been stymied by the lack of empirical data regarding the performance of HRPPPs, measurable outcomes or other criteria for the ongoing evaluation of protection programs, and the scant formal knowledge of the approaches and methods by which effectiveness of protection programs has been improved.

\textit{Protecting participants}

The companion report on social and behavioral science agreed:

We found, as did the Institute of Medicine study, that there is little regularly available systematic information about the functioning of the U.S. human research participant protection system. Data on harms encountered by research participants and their economic and other costs are scant. Only a handful of major surveys, smaller surveys, and case studies have examined IRB operations and the consequences for participant protection and timely research.

Thus, when federal policy makers try to devise reforms, they must rely on scanty, old data. In 2010, the head of the Office for Human Research Protections co-authored an article that cited twelve-year-old data to make a major point.\textsuperscript{12}

Even if they had the knowledge, these bodies would still lack the power of the original National Commission of the 1970s. Most of their proposals have gone nowhere. For now, we are stuck with a system that has never worked well, and that has functioned particularly poorly for close to twenty years.

**What is to be done?**

In the long run, we need a regulatory regime grounded in the scientific principle of trial and error.

*TCPS*

Such a regime exists, to a degree, in Canada. Canada funds research through three national bodies: one on health, one on natural sciences and engineering, and one on the social sciences and humanities. In 1998, representatives of all three bodies collaborated on a document that came to be known as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, or TCPS. Thus, in Canada social scientists and humanities scholars were given the seat at the table that they have never had in the United States.

This did not solve all the problems. The first TCPS borrowed heavily from American precedents, including the Belmont Report. In 2004, a social science and humanities working group complained that “the granting agencies’ desire to create a regulatory structure to deal with the stereotypical clinical trial has resulted in a document and set of structures that assume different modes of research involving different relationships and different concerns than most social science and humanities researchers seek and encounter. . . . although the deleterious effects of the TCPS have been felt across the social sciences and humanities, it is the more collaborative, inductive, field- and text-based research traditions that have been the most adversely affected.”\textsuperscript{13}

*2d edition animation*

But then something astonishing happened. The Canadians revised their work to take account of such complaints. And in late 2010, the three councils released a second edition of the TCPS, featuring an entire chapter on qualitative research, one that addresses many of the complaints


\textsuperscript{13} Social Sciences and Humanities Research Ethics Special Working Committee, *Giving Voice to the Spectrum* (Ottawa, Canada: Interagency Advisory Panel and Secretariat on Research Ethics, 2004), 10.
that qualitative researchers in Canada, the United States, and elsewhere have voiced about ethics review.

Qualitative research

In particular, the new TCPS takes pains to explain to REBs how qualitative researchers work, and the differences between their ethics and methods and those of biomedical researchers. REBs, it cautions, should accept projects that focus on just a few people, or people more powerful than the researchers. They can expect some researchers to produce "research that is critical of settings and systems, or the power of those being studied." Consent may be "dynamic, negotiated, and ongoing," rather than spelled out in advance. While some qualitative researchers may offer confidentiality, others (including oral historians) show "respect for the participant's contribution . . . by identifying the individual in research publications, or other means of dissemination of the results from the research." REBs should not expect fixed protocols, since "Specific questions or other elements of data collection may be difficult to anticipate, identify and articulate fully in the research proposal in advance of the project's implementation.

Thus, Canadian regulators did two things their American counterparts failed to do. First, they included scholars in the social sciences and humanities in shaping the rules. And they revised those rules—including ethical pronouncements—in light of experience and criticism. Whereas American researchers are stuck with a 30-year old Belmont Report written by bioethicists, Canadians have a living document that reflects a broader range of ethical and methodological thought.

When the Canadian revision came out in December 2010, I thought it would be a warm day in Winnipeg before we saw anything like that down here.

ANPRM


It’s been a year and a half since this document was released, and at this point I have no idea whether it will lead to an actual revision of the regulations. In any case, there are a lot of remarkable things about this document, not least of which the title, which admits that current regulations produce Burden, Delay, and Ambiguity for Investigators. That alone is a step forward.

It is also worth noting that the chief mover behind the reform is Dr. Ezekiel Emanuel, who complained all the way back in 2002 that “A single IRB often reviews research on a wide variety of scientific topics and research settings, some of which are not aligned with the scientific expertise of the board members.” In August, he put it a bit more bluntly: “Right now, all we have on [risk] is your gut reaction and my gut reaction, which is worthless, in my opinion.”

But the question raised by this conference is whether the document integrates knowledge and power into something called authority. The record is mixed.
The proposed notice does suggest a respect for knowledge far more profound than is found, say, in the CITI Program. Its claims are supported by a respectable 88 footnotes—most of them to scholarly publications. Better still, three of those 88 footnotes are citations to my work, so you know it’s authoritative.

Seriously, the authors of the proposed notice have done some good homework. They have acknowledged the existing scholarship and critiques of the IRB system, in a way that I have not seen the frequent posters at IRB Forum do.

But there are some worrisome aspects too.

Researchers would be subject to "mandatory data security and information protection standards for identifiable information and rules protecting against the inappropriate re-identification of de-identified information that is collected or generated as part of a research study.” These data security rules would, in turn, be based on the provisions of the Health Insurance Portability and Accountability Act, or HIPAA. Once again, social scientists would be wrestling with rules designed for medicine.

Why is this a problem? Well, for one thing, medical data is generally collected in private settings. The receptionist hands you a clipboard, or you answer a doctor’s question. If a librarian wants to conduct a focus group, that kind of confidentiality immediately disappears. Would this require full IRB review?

Moreover, under HIPAA, data must be stripped of identifiers of "all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes." Unless modified, this would prevent many social scientists from identifying the site of their research, a scholarly norm. If you wanted to write an article based on the survey of your patrons, you would either have to secure full IRB review or disguise the research site, which I think would mean denying yourself a byline.

Finally, and this should be really scary, the notice imagines imposing rules designed for biological specimens—your blood, for example—on medical and even non-medical data. I quote: “The allowable current practice of telling the subjects, during the initial research consent, that the data they are providing will be used for one purpose, and then after stripping identifiers, allowing it to be used for a new purpose to which the subjects never consented, would not be allowed.”

That sounds nice, right? And it may be appropriate for blood samples. (Though experts in biobanking have their own critiques.)

But what if a political pollster calls you up, and asks you to comment on the national debt for a story that will run in the newspaper that week? That gets published, and then, ten years later, a historian wants to write about it. Wouldn’t that be using the data for a new purpose to which the subjects never consented?
And keep in mind that HIPAA requirements do not expire after 75 years or any set time. So depending on how the final rule is worded and interpreted, you could see data stop flowing to your libraries, or flowing in but never getting back out to researchers.

**ANPRM responses**

It is this sort of thing that had led some scholars in the social sciences and humanities to seek wholesale exclusion from the IRB regime. Notably, in its response to the ANPRM, the American Anthropological Association called for the “delimiting [of] the regulatory object more specifically as ‘human experimentation’ and/or ‘biomedical procedures.’” In other words, you can regulate the medical researchers, but leave us alone.

Freeing research from regulatory oversight need not mean leaving researchers without guidance or incentives to do the right thing. Rather, it would open up a number of alternatives.

**Macalester**

One possibility would be to have boards that look like IRBs, only with fewer bureaucratic procedures and more emphasis on expertise. For example, Macalester College, which is primarily a teaching institution, subjects student proposals to review by boards constituted solely within a division or a department, something forbidden for work that is subject to federal regulation.  

**Klitzman**

Or we can imagine bolder proposals. Robert Klitzman and Paul Appelbaum suggest that shifting research oversight to the retrospective review of a subset of projects, rather than prospective review of proposals, could reduce the "variability and subjectivity across IRBs" that now characterize ethics review.

Some reformers have called for a shift away from reliance on threats, even for medical research. Scott Burris has proposed stripping IRBs of the power to block research. Instead, they would need to “persuade the investigator through discussion that a study had ethical problems.”

Similarly, former OHRP director Greg Koski has called for a shift to “a paradigm of professionalism,” relying on training and certification, rather than prior restraint of proposals, to protect the rights and welfare of research participants.

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AAA calls for commission

Finally, the American Anthropological Association has called for

the creation of a commission constituted specifically of social scientists (e.g., sociologists and the like), humanistic social researchers (e.g., cultural anthropologists and the like), and humanists (e.g., historians, legal scholars, and the like). Rather than adapting strategies developed to protect biomedical information—which are fundamentally incompatible with core intellectual and ethical commitments of humanistic social studies—this commission would be tasked with developing alternative guidance appropriate for their fields.

Does this sound like common sense or a call for revolution? Unfortunately, to me it sounds like both.

I want to make clear that I do not hold individual universities or IRBs primarily responsible for the problems facing researchers in the social sciences and humanities. Federal regulators crafted stupid rules, and real reform may require the kinds of regulatory changes I’ve just described.

That said, even under the current regulatory regimes, universities can institute some measures that could align ethics review to the academic culture of scholarly authority.

OSU Policy

One is to embrace faculty governance. The principle of faculty governance is under attack in an age of professional university administrators and declining proportions of tenured faculty. But it is alive enough that faculty at several universities have established IRB advisory committees. Though their powers vary, I think they all represent a reassertion of scientific authority.

At most universities, IRBs are effectively creatures of the administration, specifically of the chief research officer, such as a Vice President for Research, who serves as the “institutional official,” responsible for the university’s compliance with federal regulations. If this official appoints IRB members and lets them, or the IRB staff, establish human subjects policy, they have effectively bypassed established systems of faculty governance by which the faculty select committee members and have a role in shaping university policy.

I have found at least eight research universities—Michigan State, Northwestern, Ohio State, UCLA, the University of Cincinnati, the University of Michigan, the University of Texas at Austin, and Virginia Commonwealth University—that have established IRB advisory committees, and George Mason is in the process of creating one. The duties of these committees vary, but they do not approve or reject individual research proposals. (A partial exception is Virginia Commonwealth, whose committee has a role in creating a new IRB panel to rule on disputed projects.) Rather, they help shape general policies governing human subjects reviews and handle researcher feedback about the process. They provide a channel to get input from faculty who may be expert in one area but don’t want to join an IRB whose main job is to review an endless stream of proposed psychology experiments.
A second step would be to share ethics proposals. As it stands, many researchers craft their proposals in a vacuum, knowing little about how other researchers have faced similar ethical challenges. At best, they can hope to reinvent the wheel.

*TEAR*

Martin Tolich of the University of Otago in New Zealand has created The Ethics Application Repository (TEAR) as a place for researchers to deposit their successful applications. The point here is not merely to allow researchers to swap tips for getting ethics approval, but to share ideas for conducting ethical research.

*MQ Training*

A third step is the creation of alternatives to standard training regimes. In 2009, ethnographers at Macquarie University in Australia created an online module called “Human Research Ethics for the Social Sciences and Humanities.” Portions of the training system recapitulate the largely irrelevant history of medical research ethics that form the core of more standardized curricula. But the module also offers stories of dilemmas faced in recent years by ethnographers. And rather than demand simplistic multiple-choice answers, it often asks readers to reflect on the possibilities. “Say you are doing research on cigarette smoking,” it asks, “but as you talk to the smokers, they start telling you about the illicit drugs they use. What do you do?”

At Princeton University, historians Angela Creager and John Haldon designed a two-day course on research ethics—including human subjects issues—for graduate students in history and the history of science. Publications of the American Historical Association were one source among many used in the seminar. So were detailed accounts of specific controversies, such as historians’ testimony in lawsuits over tobacco liability and sexual discrimination.

*Shelton Risk*

A fourth step, the boldest, would more directly address the problem of ignorance that I have raised today. And that is to adopt evidence-based ethics review.

This is not a new idea. In 1999, for example, a working group of federal officials recommended that IRBs limit their worries to realistic risks.

“In determining whether there might be a reasonable risk or damage related to divulging the sensitive information, etc., it is not enough that there be merely some hypothetical possible risk that can be construed. Rather, the risks resulting from disclosure must be readily appreciable and significant.”

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If this standard were in place, there would be a lot less friction between IRBs and researchers. But it is not an official standard anywhere.

JERHRE

In recent years, a number of scholars have devoted time to empirical research about interactions among researchers, ethics committees, and participants, some of which I have drawn on today. There’s even a journal devoted exclusively to this subject.

Anderson/DuBois

Most recently, the concept of evidence-based ethics review was fleshed out particularly well by Emily Anderson and James DuBois in the Winter 2012 issue of the *Journal of Law, Medicine & Ethics*. They note the findings of many studies of IRB operations that indicate that IRBs rely on gut feelings even when empirical evidence is available.

To make IRB decisions more informed, 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 these authors 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."

Conclusion

It’s hard to know what to recommend, since it’s much easier to find unhappy researchers than to find a university where everyone is satisfied. But I would like to suggest a common thread among the many calls for reform, both at the local and national levels.

Whether it is the establishment of a new national commission to recruit experts in a broad range of the humanities and social sciences, or the adoption of a new workflow at one IRB, what all these reforms have in common is that they seek to get us away from the “worthless gut reactions” that Dr. Emanuel characterizes as IRBs’ mode of reasoning, and replace them with something more based on experience, expertise, and evidence. And what I want to suggest is that
exhortations for IRBs to learn about research and for researchers to learn about ethics rules will never be sufficient until the power imbalances are addressed.

Oversight is a good thing. Shared authority is a good thing. But seizing authority from those who have abused it means giving it to others who have the potential to abuse it. So it’s not enough to question authority. One must question those who question authority.