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Small Groups with Small Minds in Research Ethics Review

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Behind Closed Doors: IRBs and the Making of Ethical Research

By Laura J. M. Stark,
The University of Chicago Press: Chicago and London, 2012

I make notes in the margins of books I'm reviewing, and in the series I created when reading Laura Stark's study of Institutional Review Boards (IRBs), a pattern quickly emerged: "nice!" began alternating with "'nice'." The first half of *Behind Closed Doors* reports a (mostly) observational ethnography to show how the members of IRBs collaborate to produce "IRB" or group decisions. The second half is a primary-sourced history that aims to explain how the main federal agency conducting and funding medical research, NIH, adopted the model that became the IRB in response to fears of institutional liability and demands from Congress members that research subjects be protected from abuse by investigators. The model was group decision making by other researchers ("peers") in local research organizations that operate independently from each other and only loosely interrelate under the mantle of federal regulations. Stark observed IRBs at the three universities; she wrote notes, or, when permitted, recorded. Her data cover what happened at 34 IRB meetings at which a total of about 120 "protocols" were reviewed. Her unusual combination of first-hand ethnography and original historical research is one of the "Nice!" features of the study.

That Stark refers to research proposals as "protocols" indicates the "nice" tone of the writing, which diplomatically adopts the biomedical mind-frame and minimizes the potential to offend her own research subjects (IRB members) by neglecting the implications for people who live outside the IRB's "closed doors." The impacted populations include subjects, researchers, and third parties with adversarial interests in the research findings. Qualitative researchers will feel they are mostly neglected in this book, which is the right message to take away about IRBs. IRBs were set up and evolved to operate without much attention to the methodological distinctiveness of social research, and without care for the impact on the freedoms of assembly, speech,

and press that are especially at risk in most qualitative forms of social research, which, unlike biomedical research, is often done in a way that is a close cousin to journalism, muckraking, and critical commentary by intellectuals who are uneasy about government power.

Within the methodologically justifiable blinders that Prof. Stark puts on, this is a creatively designed, sensitively analyzed, reliably documented, and elegantly terse study. Along with recent books by Will C. van den Hoonaard and Zachary Schrag (and Schrag's blog), and a 2007 issue of the *Northwestern Law Review* organized around the constitutionally grounded protest against IRBs by Philip Hamburger (see also his article in the 2005 *Supreme Court Review*), I would recommend *Behind Closed Doors* as an indispensable base for new sociological studies of IRBs. For all qualitative researchers the book will show what they are up against. And despite the author's inoffensive tone, her findings will be quite damning, at least for those worried about the institutionalization of censorship in democratic countries.

Taking a perspective that is tinged with an ethnomethodological sensibility, Prof. Stark insightfully brackets "the IRB," treating its collective reality as a product that must be recreated each time a research proposal is reviewed. She observed that the IRBs had between eleven and fourteen members, one or two of whom were from "the community," and they had to interact in a manner that would routinely (although not always) produce a consensus. Why consensus was essential is not clear, but the answer basically is so that the trains run, i.e., bring in research dollars on time. Apparently the university administrators who appoint members look for people who will be "reasonable." We don't know what happens when members consistently protest that freedoms of inquiry are being abridged or repeatedly resist what the majority wants to do. We do learn the social interaction processes through which consensus is produced.

One key process occurs when dissent percolates into the group discussion. Then someone pulls what might be called a trump card: he or she refers to a personal experience or to professional expertise. Prof. Stark does not quite put it this way but what happens is that the stakes are raised in a way that threatens group cohesion. To persist in the dispute is to personalize the argument, which becomes not only about how the research proposal fits the regulations but about one's own concern for the feelings and/or respect for the competency of one of the members. The dissident usually backs off. Those who have been in faculty meetings where these cards are played and tensions are not so quickly abridged will sense that something else must be going on, perhaps an administrator's care to select for "reasonable" people. When departments choose new faculty members, finding a reasonable colleague is either not so important or, in job candidates' short visits, is harder to discern, especially when one is trying to forecast behavior over a 30–40 year long appointment.

Another key process is the invocation of what Prof. Stark calls "local precedent." IRB members don't assess individual proposals by running them through the regulations to see which inconsistent bits light up. Much as Garfinkel would have

predicted, they do not act systematically as agents of logical deduction in the manner that outsiders, innocently reading the regulations as if they actually governed the exercise of power, might imagine. Instead they think along the lines: What proposal like this have we seen before, what did we do then, and how is this different? When they are uncomfortable with the proposal, or just to make a record that they have put attention to the matter and so have fulfilled their responsibility, they propose a change that the researcher probably will accept.

It all seems pretty innocuous, except for those rare occasions when the IRB flatly refuses to approve. There are also occasions when the IRB is so uncomfortable with either the proposal or its role that the committee delays a decision to the point that the researcher abandons the project. Whether intimidation might be occurring, i.e., which lines of inquiry are not being proposed in anticipation of hassle, the IRB does not know. Nor is there any indication that IRBs care at all about their "chilling" effects. But this is just how censorship, and other abridgments of what we (in the United States) label First Amendment freedoms, work their most massive effects, by altering the course of what would have happened more than by attacking what has happened. Ask for a permit to march 100,000 protestors in front of the president's office and you may have to wait months for an answer, and then not get approval until it's too late to make the necessary preparations. Ask for a permit for a 10 person march and you can do it next week.

Prof. Stark registers no discomfort with the exercise of censorship power through the emotional channels of local small group culture. She does not warn us that "local precedent" does not have the jurisprudential meaning it does in a legal system. No one outside the IRB is likely to know about these "precedents," which are kept behind closed doors, for no defensible reason other than to protect IRB discretion from critical review, which in turn is probably necessary to recruit "reasonable" members who would not agree to serve, even with the inducements of course release or salary supplements, if they had to defend their exercise of power publicly, which would mean rationalizing more articulately than by citing personal experience. "Local precedent" also sounds good if it indicates tailoring the exercise of power to the particularities of unique research technologies and regionally specific vulnerabilities of subject populations; but actually what invoking local precedent means is that a small group, which uses only the vagaries of personal memory to recall prior decisions, and does not publicize decisions so that outsiders could inspect them for consistency, and writes nothing to show how current decisions relate to past decisions, is informally doing small talk to convince itself it is consistent.

Just as the ethnographic part is brief but satisfying, if depressing, so is the historical part, which covers about ten years, stopping in the mid-1960s when the NIH adopted the model for the ethical control of medical research that became the national, now internationally adopted, network of IRBs (which are called by other names in other countries). Prof. Stark does not have to take us through the elaborations of this model, which subsequently was extended to social research,

equipped with regulations shaped by the Belmont Report and other review processes, expanded from NIH to all federal research funding agencies, expanded in most universities to cover unfunded as well as funded research, differentiated in some universities as between biomedical and social science IRBs, professionalized by specialized companies that have been hired by university administrations to review and certify procedures, equipped with computer-formatted applications, and so on.

Basically, doctor-administrators were forced to create a system of ethical certification of research when liability concerns over NIH funded research grew unavoidable. One especially important episode was the injection of cancer cells into aged patients at a Jewish hospital in Brooklyn, without their consent. Resonances with Nuremberg were hard to miss, and Jacob Javits, a Republican, Jewish Senator from New York, responded as might have been predicted, but by the benighted investigators was not. The IRB model was seen by the medical administrators in NIH as a least restrictive way of imposing ethics review—through peers, with some flexibility as to the form of consent to be obtained, and via the agency of independent local reviewing bodies as opposed to a centralized federal government processor.

When the federal government grew into a major funder of social science research, the IRB model was at hand to play the ethical supervision role for nonmedical research. Most of us balk at the conflation. I want to emphasize a bed rock, historical reason for resistance that virtually everyone writing on IRBs fails to appreciate. Even without IRBs, and even without federal funding, you can't legally go around injecting cancer cells, or anything else, into people without their consent. You don't need an IRB to know that it would be a serious violation that might get you locked up in one or another kind of facility. Medical licenses, i.e., a special grant from a government agency, enabled doctors to do lots of things that otherwise would be either crazy or criminal behavior. As Everett Hughes would have appreciated, without a medical license you can't legally take money from people on the promise that if they take their clothes off and let you touch them intimately, they will feel better. The government's role in supervising ethics in medical research is an elaboration of government's long standing role in authorizing conduct that the government had previously made illegal. In contrast, before the advent of IRBs, what we social researchers, especially qualitative social researchers do was never defined as requiring special government permission.

Revolutions in the Western world were fought in the name of the liberties we exercise in our research, not to keep biomedical research out of government control. This is not to say that we can rely on the Supreme Court to protect us. You can be sure that in oral arguments, at least one "original intent" justice would point out that employers, whether owners of newspapers or universities, have always restricted what their employees publish without running into constitutional problems. Our universities began as religious institutions, favoring some schools of thought and repressing others; not as bastions of tolerance or champions of the First Amendment. But if everyone studying IRBs would realize that when applied to

social and humanistic research, the most significant historical point to make about IRBs is that, as a matter of nationwide, federal government-mandated practice, they represent an unprecedented compromise of freedoms of inquiry, it would be really nice.

ABOUT THE CONTRIBUTOR(S)

Jack Katz is Professor of Sociology at UCLA. His current research is on the history and local meanings of neighborhoods in Hollywood, Los Angeles.