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IRBism: Prejudice Against Institutional Review Boards

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By Donelson Forsyth

Alexander Pope, who opined that "the proper study of man is man," did not have to convince an Institutional Review Board (IRB) of the wisdom of his words. Just this week I was told that I could not use the question "What city does your romantic partner live in?" to check if the subject was in a long-distant relationship (made the partner too identifiable). Earlier in the year a reviewer objected to asking students about their mother and father's parenting style (reports on the behavior of unconsented third parties). When I said I would recruit participants from classes, the reviewer wanted to know the precise wording of the speech that would be used in the recruitment, and warned that ad libs would not be tolerated. I comply with these requests, feeling very much like a subject in Milgram's obedience study pushing the lever down one more time.

But my university's IRB, despite its persistent intrusion into the research process, is better than the IRB I had in the 1990s. That IRB rarely quibbled with the research methods I used, for it concentrated its attention on the work being done on the medical campus of my university. I was sometimes upsetting people for a couple of minutes by telling them they failed on a bogus test of social sensitivity, but people were dying in the studies conducted by medical researchers; the IRB felt that behavioral research was small potatoes. But that IRB did not meet the standards set forth by the Office for Human Research Protection (OHRP, formerly OPRR) in the U.S. Department of Health and Human Services (DHHS, formerly DHEW). Its inadequacies were so worrisome that on January 11, 2000 OHRP suspended all human-subjects research at my university after receiving an insufficient response to its complaints about procedures and omissions in oversight. This OHRP "death penalty" was triggered by two specific incidents in which subjects in studies conducted on the medical campus of the university complained to OHRP. No one was physically injured in the research, but OHRP was displeased by virtually all aspects of our regulatory system: our IRB was not correctly constituted, panel members were not trained in IRB regulations, the outcome of studies were not being monitored, and most behavioral sciences studies were being reviewed by a shadow IRB rather than the university-level IRB. The costs of this shut-down in terms of science, education, and health-care were extraordinary. All research stopped, completely. Patients in clinical trials could not be given their treatments for several weeks. Their treatment could be resumed when researchers received approval on a case-by-case basis. Grant-supported and industry-sponsored research ceased, along with all locally funded research, including student theses and dissertations. To jumpstart these studies the university contracted with an external, pay-by-the-study, IRB, and for a year researchers submitted their protocols to this group. These reviews took several months to complete, and in many cases only studies that were part of multisite projects were green-lighted. Since medical grants received priority in that review, and the review was very expensive, very few behavioral studies were reviewed.

Because of the shut-down some investigators could not start studies that were funded and so surrendered federal funds back to the sponsor. At least 2 researchers in psychology who were conducting longitudinal studies were unable to collect data for 6 months, creating a clump of missing data that reduced the value of the data set. Because untenured faculty could no longer conduct research their tenure clocks had to be reset, and standards for merit pay were revised downward. Several older faculty who were active researchers before the shutdown did not have the drive to restart their research programs. And some faculty changed their areas of research and their methods, recognizing that procedures they had used in the past would be too hard to move through the IRB process.

Students also suffered as a consequences of the death penalty. Some departments waived the requirement for data-based dissertations for 2 years, and many students had to receive additional funding for that period. The number of new students admitted into programs was reduced for 2 admissions cycles since funds were being used to support students whose research was blocked by the IRB crisis. Many students also made use of data collected by faculty on large grants for their theses and dissertations rather than collecting their own data.

This disaster also triggered a substantial change in our local IRB. It took nearly a year for the university to build an IRB system that met standards set by the federal government. The number of staff members who worked in the IRB office increased ten-fold, as did paperwork and time commitments to the task. Web sites were built, forms generated, submission guidelines hammered out, and training workshops were put in place for all investigators. Now we have four IRB panels that review every study—from studies conducted by undergraduates in their research-methods classes to multisite mega-grants—in a carefully managed process. I am a member of one of these panels, for I wanted to watch the group at work and learn how to get my studies and my students' studies approved. Our panel strives to apply, systematically and without bias, the federal regulations to each proposal but an IRB is a group and hence displays some of the decisional biases that social psychologists have come to

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expect from groups. Rarely do any disastrous group processes set in--we don't experience groupthink (because we don't like each other much), we don't oversample shared information (mostly because we use the two-reader method in which each protocol is reviewed by the entire group but two members are primary and secondary readers), and we use appropriate decision rules. But we are sensitive to reading into the proposals evidence of the investigator's savvy regarding ethics. Like a manuscript reviewer who begins to question the quality of a paper because there are just too many typos in the references, each inattention to some (admittedly small) detail of ethics raises a red flag. If too many flags are raised, then the protocol is in trouble. Investigators who are precise in their attention to the details of the ethics of their work move quickly through the review. Investigators who commit basic errors in the protocols (e.g., they fail to use the word "research" in the consent form; they do not describe steps to take to protect the confidentiality of the data; they do not explain the risks clearly; they do not provide a contact address of the office which processes complaints about the ethics of research; they do not provide a verbatim list of each and every question they will include on their surveys and questionnaires; they do not provide assent forms even though they will be studying students who are 17 years old your younger; they ask questions that are considered highly risky, such as "have you ever felt so angry you wanted to harm someone else" or "are you ever bothered by thoughts of suicide?") find that their work is bogged down. But once an investigator establishes a reputation for being aware of, and in compliance, with the "rules," then their protocols are reviewed more expeditiously.

The IRB also has a poor memory, as most groups do. If a protocol comes back after a year has passed, an entirely new set of issues may be raised and the group may reverse its earlier decision. Hence the researcher who helps the IRB remember key aspects of its earlier decision will be rewarded. The IRB also has a fascination for minutia, and so sometimes obeys Parkinson's *Law of Triviality*, which states that the time a group spends discussing any issue will be in inverse proportion to the consequentiality of the issue. Undeniably, social and personality research often raises questions about ethics and human rights. Do we have the right to intrude on the privacy of others? Do we have the right to deceive others by giving them a cover story that provides a rationale for the manipulations and measurements, or expose them to noxious stimuli to test their reactions? Unfortunately, IRBs spend so much time dealing with typos and the size of the check boxes on the consent form that they sometimes overlook these more fundamental matters.

Perhaps even more irritating is the tendency for IRBs to change their collective mind (even though collective minds do not actually exist). These shifts are natural and unavoidable, and are caused both by changes in federal focuses and by local events. For example, our university's standard template made no mention of the requirements of "recruitment of subjects" until a subject complained to the ethics office that she was being called, repeatedly, by a researcher who was pressuring her to take part in his study. A meeting was held on the matter, and from that moment on all protocols needed to describe their recruitment methods, and to be approved they needed to use such language as "no subject will be contacted a second time if he or she declines participation initially". Because of the IRBs' sensitivity to emerging issues, researchers must also be ready to comply with the demands of the system--even when the rules change rapidly.

These limitations of IRBs, although frustrating, are not sufficiently grating that they justify IRBism: an irrational hatred of Institutional Review Boards. Perhaps my own tolerance of IRBs

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Where did Part 46 of the Code of Federal Regulations, titled Protection of Human Subjects, come from? According to OHRP lore the federal regs were developed by a group—an unhappy, unstable triad, in fact. When issues of subject abuse in the medical profession arose in the 1970s DHEW staff members were asked to draw up federal regulations for improving oversight in the area of medical and social science research. Two members of the group disliked each other so much that they refused to talk to one another, and so communicated all their points to the third person—who created the basic tenets of the current regulations. And while we many not agree with the content of the regulations, they are so deeply enmeshed in the documents of so many governmental entities they can probably never be amended in a substantial way.

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merely confirms the contact hypothesis of prejudice, for my membership on a panel has caused me to be more accepting of their meddlesome ways. But my current IRB system, despite its cost, is a far better system that the poorly-functioning IRB that cost me and many of my colleagues two years of research productivity. Indeed, if your IRB does not have a full-time staff member, training for IRB members and investigators, a web-site that includes a consent form template and protocol guide, a system for distinguishing between the three types of studies (exempt, expedited, and full-board review), face-to-face meetings where minutes are taken, and a means of responding very promptly to subject complaints, then I would pressure your university's administration to shift some resources in that direction. As with any social trap, the short-term advantages may be seductive, but the long-term costs of noncompliance with federal IRB regulations are huge. ■