



CHRISTOPHE VORLET FOR THE CHRONICLE

Rethinking Protections for Human Subjects

HAS THE PENDULUM SWUNG too far in the application of human-subject protections to scholarly research? Several well-publicized deaths—including that of Jesse Gelsinger, an 18-year-old who died during a gene-therapy experiment—in clinical trials, along with scientific advances in cloning, human genetics, and stem-cell research, have led to heightened scrutiny of academic research by the government and the news media. As a result, some universities have become hypercautious about approving any research that involves human subjects. The excessive caution has its costs. In particular, it has begun to hinder scholarly work in the humanities and social sciences, although that work puts no human subject at risk.

Rules governing the use of human subjects are rooted in scandal. Unethical experiments in the past resulted in the creation of federal regulations in the mid-1960s that led to today's regulations requiring institutional review boards to approve in advance any research that involves human subjects and is supported by federal funds. (Interestingly, human subjects of research that does not receive federal money are not protected. Any experiment with animals, however, is subject to federal oversight, no matter who pays for the research.) Those regulations require researchers to assess each study's level of risk; to ensure that prospective subjects are voluntarily participating in the study, understand the dangers involved, and give informed consent to their participation; and to protect the subjects' privacy.

Today, the process of protecting human subjects has expanded far beyond its roots. Virtually all universities, along with a variety of other institutions that receive federal research funds, have institutional review boards to review and approve all research involving

human subjects. Following publicity of federal agencies' shutting down research programs to protect subjects, members of IRB's have become increasingly cautious and are expanding their jurisdictions. That mission creep has turned IRB's into *de facto* gatekeepers for a huge amount of scholarly inquiry.

On the positive side, greater attention to research can lead to the better protection of subjects and their privacy. But there is a growing risk of harm to academic freedom and scholars' First Amendment rights if the authority of IRB's is interpreted too broadly or becomes too intrusive.

For instance, one IRB administrator directed that an English professor's article, which had been accepted for publication, be withdrawn because it contained a partially fictionalized account of a student who submitted a paper describing his alleged participation in a murder—and the article had not been submitted for review by the IRB.

In other examples of overzealous IRB's, a historian working on oral histories of the civil-rights movement was cautioned not to ask subjects about the laws they might have broken in the course of civil disobedience. And journalism professors have encountered roadblocks when they or their students want to write about topics like binge drinking and date rape. One faculty member says he now restricts his students to "bland topics and archived records" because of delays and limitations from the local IRB.

In a 2000 report on the oversight of social-science research, the American Association of University Professors concluded that IRB's "too often mistakenly apply standards of clinical and biomedical research to social-science research, to the detriment of the latter." Heated discussions of the problem have occurred at

meetings of other scholarly associations, including the American Sociological Association, the American Historical Association, and the American Anthropological Association.

SEVERAL SCHOLARS are calling for changes to the institutional-review system that would exclude research from oversight unless it posed a risk of physical harm. That seems unrealistic: We have had 40 years of debate about regulating research, and the public has made it clear that it does not trust scholars alone to judge what may be harmful.

Instead, we need to organize a series of conversations within and across disciplines to create rules and regulations that work in ways appropriate to particular disciplines and, perhaps even more important, different methodologies to ensure that researchers are following accepted ethical principles. The need for scholars to reach a consensus has become even more urgent now that the Bush administration has allowed the charter of the National Human Research Protections Advisory Committee, which had been studying those issues, to expire (the administration recently announced the creation of a new Advisory Committee on Human Research Protections in the Department of Health and Human Services, but the committee has no members yet and its mission remains unclear).

The crux of the problem is the regulatory definition of research. In the 1960s, when policy makers began wrestling with how to define and regulate research, they focused primarily on medical research. For example, efforts to define the boundaries of research considered such questions as how to distinguish research from treatment. Even today, only 11 paragraphs out of hundreds of pages in the federal handbook for IRB's are devoted to behavioral research. Yet the regulatory definition of research that has been in use for more than 30 years is relatively broad: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

One rule of thumb regularly used by IRB members to determine whether an activity is research is whether the activity was undertaken with an eye to eventual publication. That approach works fairly well for traditional biomedical research: If a practitioner or scientist planned a project and assembled data in a way that would support publication in the peer-reviewed literature, the likelihood is reasonably high that some

kind of research was under way, and that, consequently, the subjects of the experiment had a right to protection. But the approach can cause problems in other settings.

If a faculty member writes about a particularly illuminating classroom exchange, or comments anecdotally about the difference between freshmen now and 25 years ago, it is hard to see how that could be considered research with human subjects. Faculty members must grapple with how to treat personal disclosures made by students, stay within the boundaries of academic integrity, respect intellectual property, and follow the laws governing student privacy. But those and other serious professional and ethical issues seem unrelated to the protection of human subjects.

Nonetheless, members and administrators of institutional review boards have defined examples like those as research with human subjects. We all interact with other people every day. What turns someone we interact with into a human subject needing regulatory oversight and protection?

Although the growing power of IRB's has been receiving attention in the literature of some disciplines, there has been little consideration of the larger implications for higher education. In particular, we seem to be lacking an adequate touchstone to distinguish research from personal reflections by a faculty member about classroom experiences. We seem confused about whether it is the nature of the interaction or the place where it occurs that makes an activity research—why else would anybody believe that a newspaper reporter who interviews people and publishes stories about them isn't doing research, but that a journalism professor and students performing the same tasks are doing research? By extension, we also lack a clear sense of how much weight to give academic freedom in deciding whether scholarly work should be subject to prior review by an IRB.

We need to consider current regulations thoughtfully, and to improve the balance of protection and burden in setting public policy on human subjects. We must focus on who we are really protecting, from what, and why.

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