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New Rules for Human-Subject Research Are Delayed and Debated

By Christopher Shea

When I. Glenn Cohen, a professor at Harvard Law School and director of a bioethics center there, helped to organize a conference in 2012 about the future of research on human subjects, he says he worried about being "late to the party."

In 2011, the Department of Health and Human Services had floated some ideas for changes in the rules governing such research. The aim was both to better protect the subjects and to reduce the much-resented bureaucratic burden on professors and university staff members.

Mr. Cohen needn't have worried about tardiness. Today, more than two years after the conference, the regulations remain just where they were in 2011: still under development.

Human-subjects rules are designed to prevent such horrors as the Nazis' medical experiments as well as homegrown examples of abuse, such as the Tuskegee studies, in which black men with syphilis were falsely told they were receiving treatment. The revelation, in 1972, of that research, in particular, led to a requirement that grants from the U.S. Public Health Service for research on human subjects receive close scrutiny.

In their current form, which dates to the early 1990s, the federal regulations are known collectively as the "Common Rule," because more than a dozen federal agencies have agreed to abide by them.

Any revision involving so many agencies, on such a sensitive topic, is bound to be slow. But Mr. Cohen, echoing other observers, says, "I have to believe that something has gone wrong with this process."

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."

Much of the oversight of human-subjects research devolves onto institutional review boards, or IRBs, at research institutions. (The rules technically apply only to federally funded research, although many institutions voluntarily apply them to all research.) Professors complain that IRBs bog down their studies by micromanaging consent forms and research protocols, and fretting unnecessarily about psychological harm that might be caused by asking people questions, whether in the lab or in the field.

Although many of the most pointed complaints come from social and behavioral scientists, biomedical researchers, too, find the regulations onerous.

"It is a very sick system, which is why it's being reimagined and worked on now," says Michelle N. Meyer, an assistant professor and director of bioethics policy at the Union Graduate College-Icahn School of Medicine at Mount Sinai. She's a contributor to a new book that has emerged from the conference Mr. Cohen oversaw: *Human Subjects Research Regulation: Perspectives on the Future* (MIT Press), co-edited by Mr. Cohen and Holly Fernandez Lynch, executive director of Harvard's Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics.

'Licensing of Speech'

Entire disciplines, including anthropology and oral history, argue that the human-subjects rules should not apply to them. Anthropologists, for example, say that simply observing people in their daily routines poses no threat. Some universities have exempted oral history from IRB rules, while others have not; the Oral History Association says the rules "have cast a pall over our research."

Only the most potentially risky research is supposed to be reviewed in detail by IRBs, which include professors as well as members of the communities in which research centers sit. But some researchers complain that even so-called exempt or expedited research gets unduly scrutinized, out of an overabundance of caution.

The most sweeping recent argument against IRBs has been made by Philip Hamburger, a professor of law at Columbia University. He believes that, even in biomedical research, the system amounts to flagrant "licensing of speech," a violation of the First Amendment.

For the government to demand in advance the right to review and edit the questions researchers ask people, or to micromanage the biomedical questions they explore, is inherently unconstitutional, he contends. The problems run so deep, he says, that they "cannot be washed away with small-scale reform."

The news this past summer that Facebook had "experimented" on users by manipulating their news feeds, to see how that affected the tone of their own postings, raised anew the question of where the ethical line should be drawn on sociopsychological research.

The incident also made clear how expansive the definition of human-subjects research truly can be. Facebook alters the algorithms of its feeds all the time, without anyone's knowing the effects. Would systematically studying the effects of those changes

somehow increase the risk of harm to users? (A professor at Cornell University who was involved in the Facebook study did run it past his IRB, which determined that it was not human-subject work, because he was analyzing data already collected by the social network.)

Likewise, professors at Stanford University and Dartmouth College came under fire in October for mailing official-looking "voter guides" to see how the fliers affected voter turnout. The research was not submitted to Stanford's IRB, and Dartmouth officials say they are still investigating. Both universities have apologized.

In an article for the September/October issue of *Washington Monthly,* Zachary M. Schrag, a historian at George Mason University and a longtime observer of IRBs, recounts cases in which the review boards have allegedly affected research for the worse. For her 2013 book *Becoming Right: How Campuses Shape Young Conservatives,* for example, Amy Binder, a sociologist at the University of California at San Diego, was told by one university she profiled to remove all identifying details about the place. Since some of the housing and social arrangements there helped to shape students' political choices, that restriction weakened the book, she believes.

Simplicity and Clarity

The Office for Human Research Protections says one of its main priorities is to simplify and clarify the consent process for subjects. Some consent forms run to dozens of pages of complex language.

Additionally, the office has asked universities to comment on whether researchers conducting low-risk activities, such as asking people to solve puzzles or answer survey questions, should be allowed to file paperwork and then proceed with their work before getting approval. The office has also asked if some disciplines should be exempted entirely, and how IRBs should measure the risk caused by asking about sensitive topics, such as sexual abuse

or drug addiction.

Less controversially, the office has signaled that it would like the rules to cover all studies at institutions that get any federal research money, and has suggested that studies that take place at multiple sites be vetted by a central IRB.

The proposed rules also attempt to catch up with advances in biomedicine. At present, research using human-tissue samples that have not been collected for research purposes can proceed without informed consent, providing that certain identifying data are removed. But, working from the premise that advances in biological research have made many tissue samples "reidentifiable" in certain circumstances, the office has suggested requiring consent for such research. Tissue banks created before the new rules go into effect might be grandfathered in.

The office has also proposed tightening privacy rules for tissue samples in ways that some researchers fear will be onerous.

In his contribution to *Human Subjects Research Regulation,* Mr. Schrag criticizes IRBs' attempts to define which studies, and fields, are designed to produce "generalizable knowledge"—a key term in the federal definition of research—which sets in motion the review process. The perverse result has been that some fields, like history and journalism, find themselves claiming not to care about generalizable knowledge, in order to avoid IRB scrutiny.

Promoting 'Good Consent'

Ms. Meyer, of Mount Sinai Hospital's Union Graduate College, says in an interview that it is "absurd" to task IRBs with deciding whether the typical participant in a social-science study will suffer undue mental trauma by thinking about a question. Given differences among people, there is rarely one answer.

She prefers a more empirical approach, in which IRBs would have researchers explain to participants that, say, 10 percent of the

subjects in a similar study said the questions had prompted painful thoughts but still found participation worthwhile (or didn't).

"IRBs should be information brokers," she says, promoting "good consent" rather than making a paternalistic call in advance.

But Heidi Li Feldman, a professor of law and philosophy at Georgetown University and a former head of its social-and-behavioral-sciences IRB, makes a robust case for holding the social sciences to a high standard.

Social scientists complain about being analyzed using a "biomedical model," but "empirically, there is no reason to think every social-scientific experiment that involves human subjects is less threatening to someone's mental or physical well being than every biomedical experiment," she says. Think of the sociologist Laud Humphreys's study in the 1960s of anonymous bathroom sex: He followed subjects home and interviewed them under false pretenses.

Given the disputes generated by proposing to change the rules, Mr. Cohen says that if the government had to do it over again, "it's possible they would have done it differently—in pieces, rather than the redo the whole thing at once."