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## As Ethics Panels Expand Grip, No Field Is Off Limits

By PATRICIA COHEN

Ever since the gross mistreatment of poor black men in the Tuskegee Syphilis Study came to light three decades ago, the federal government has required ethics panels to protect people from being used as human lab rats in biomedical studies. Yet now, faculty and graduate students across the country increasingly complain that these panels have spun out of control, curtailing academic freedom and interfering with research in history, English and other subjects that poses virtually no danger to anyone.

The panels, known as Institutional Review Boards, are required at all institutions that receive research money from any one of 17 federal agencies and are charged with signing off in advance on almost all studies that involve a living person, whether a former president of the United States or your own grandmother. This results, critics say, in unnecessary and sometimes absurd demands.

Among the incidents cited in recent report by the American Association of University Professors are a review board asking a linguist studying a preliterate tribe to "have the subjects read and sign a consent form," and a board forbidding a white student studying ethnicity to interview African-American Ph.D. students "because it might be traumatic for them."

"It drives historians crazy," said Joshua Freeman, the director of the City University's graduate history program. "It's a medical model, it's inappropriate and ignorant." One student currently waiting for a board to approve his study of a strike in the 1970s, Mr. Freeman said, had to submit a list of questions he was going to ask workers and union officials, file signed consent forms, describe the locked location where he would keep all his notes, take a test to certify he understood the standards.

Review boards, first created in 1974, were initially restricted to biomedical research. In 1981 the regulations were revised to cover all research that involves "human subjects" and is designed to contribute to "generalizable knowledge."

Yet precisely how to interpret these rules has largely been left to each review board — 5,564 in all. And while the regulations apply specifically to research that gets federal dollars, many colleges use Institutional Review Boards to monitor all research, no matter where the funds come from. This system of helter-skelter enforcement, critics say, has no meaningful oversight and no appeal process.

Debbie S. Dougherty and Michael W. Kramer, two former members of a review board at the University of Missouri, Columbia, who wanted to study review boards, had to first get their own board's O.K. Although they thought their project was exempt from board approval, the only entity authorized to make that decision is the board itself, and the only appeal if the researchers had rejected the ruling is also the board.

Bernard A. Schwetz, director of the federal Office for Human Research Protections, which administers the

regulations, acknowledges that the guidelines covering the boards' actions have not been clear enough and says he intends to make public new proposed guidelines before the end of the year. Still, he said the priority is to protect human subjects and dismissed the notion that most nonmedical research carries few dangers. "Obviously the balance is very subtle," he said. "I think it's naïve to say there isn't any risk."

But to many faculty and graduate students, review boards are like a blister that gets worse with every step. Those outside of the hard sciences say the legitimate concerns over ethics and safety are largely irrelevant to most of their research.

According to a stack of reports, symposiums and studies by academic associations and scholars, the system's "mission creep" is having a pernicious and widespread effect on humanities and social science research. Legal scholars also argue the boards violate the First Amendment.

The growing number of complaints in recent years apparently stems from an overall crackdown after a series of medical-research blunders beginning with the death of an 18-year-old in a gene-therapy trial at the University of Pennsylvania in 1999.

A board is required to have a minimum of five members, including one nonscientist and one person unaffiliated with the institution, said Pat El-Hinnawy, spokeswoman for the Office for Human Research Protections. Larger universities often have several boards. Members are generally appointed for limited terms.

When Robert L. Johnson, the review board administrator for Appalachian State University, talks to students, he said he starts off by asking, "If you were going to participate in a study, what are the things you would like to know?"

The usual responses, he said, are: What are you doing? Will you use my name? Who's responsible if I get hurt? What's in it for me? Making sure those questions get answered, said Mr. Johnson, "that's the purpose of the I.R.B."

Mr. Johnson said his board met monthly and reviewed approximately 200 projects a year; most are routine, require what he called minor changes and get approved within two weeks. About 30 to 40 require full board review, which takes at least six weeks.

Timothy Wilson, a social psychologist at the University of Virginia, now in his second term as a member of Virginia's nonmedical review board, said that "I.R.B.'s naturally become cautious," but that given the constraints, "I think our board works extremely well."

In the past year, discussions about what some call the "I.R.B. wars" have sprung up in specialty publications like The Chronicle of Higher Education, conferences, scholarly journals and blogs. Although research proposals are rarely rejected, scholars argue that the requested changes in the wording of questions and consent forms can alter the nature of the study and scare off participants.

Bernadette McCauley, a historian at Hunter College, said she ran into trouble a couple of years ago when she tried to help students working with the Museum of the City of New York on an exhibition about Washington Heights. She asked if a few nuns who had grown up in that neighborhood and whom she knew from her

research would talk to the students. And that, Ms. McCauley said, was “when things went haywire.”

The review board discovered the request and lambasted Ms. McCauley for failing to consult with it, she said. The board also demanded proof that previous research for a completed book did not use any archival material involving living people and banned her from doing any research.

Michael Arena, the director of communications at City University, said in an e-mail message that Ms. McCauley initially refused to send in a “brief description” of her research so that board members could determine whether federal regulations covered her work. Ms. McCauley hired a lawyer and after six months of negotiations, the board agreed that her research was exempt.

Ms. Dougherty, an associate professor of communications at Missouri, said review boards were needed because “historically, social science has done things abhorrent to human subjects.” Unfortunately the current process “obliterates a lot of research,” she said, because untenured faculty and graduate students on a timetable cannot afford to spend months waiting for approval. So, for example, “instead of talking to people who are victims of violence, you might look at newspaper articles,” she said, echoing a common complaint that the requirements cause academics to steer clear of controversial topics. Research decisions “should be guided by science,” she said, “not whether or not it’s going to get through the board.”

Ms. Dougherty said she was willing to speak openly, unlike many graduate students and faculty, because she had tenure.

Professors also say that some board directives, like destroying interview recordings and notes after publication to ensure confidentiality, violate accepted scholarly practices. “There probably will be litigation,” predicted Philip Hamburger, a professor at Columbia Law School who argues that prior approval violates the First Amendment. “There are potentially hundreds of thousands of plaintiffs.”

Mr. Schwetz said there was no chance that some subjects like oral history and journalism would be altogether excluded from review, as some academic organizations have urged. “If we were just to say, ‘Assume you don’t have to take them before an I.R.B.,’ I think we would regret that,” he said. But he said the new guidelines “will give a lot of examples and will give more guidance on how to make the decision on what is research and what is not.”

Some critics fault the universities, placing blame either with overzealous panels or with university administrations that have not done enough to differentiate between research that receives federal money and research that does not.

Mr. Freeman of City University said that within the humanities “most faculty members don’t know these rules exist.” He added, “If they in fact followed these rules, the whole I.R.B. system would grind to a halt.”

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