
Today's News

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Protection of Humans in Research Has 'Serious' Flaws, Federal Agency Finds

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Washington

A federal watchdog agency has invited comments about whether it should require universities to train their scientists and members of institutional review boards about the rules for human-subjects research, like the need for informed consent. The office blamed a lack of training on the "serious, systemic noncompliance" it has found "at a significant number of major institutions."

The Office for Human Research Protections now "strongly encourages" federal grantees to provide that training, but a mandatory requirement might be necessary because that approach seems not to be working sufficiently, the office indicated in a [notice](#) in Tuesday's *Federal Register*.

The agency's notice does not identify the noncompliant institutions it found but says, "In OHRP's experience, inadequate training and education of individuals in the conduct or review of human-subjects research has been a major root cause of such noncompliance."

Federal officials had called for a mandatory training requirement 10 years ago after the human-research office and a predecessor unit suspended nine universities' licenses to conduct human-subjects research for not complying with federal rules ([The Chronicle](#), February 4, 2000). Seeking to avoid another costly regulatory burden, university officials and higher-education groups have instead called for voluntary efforts by universities to better train researchers and members of institutional review boards, the university panels that are charged under federal rules with overseeing human-subjects research.

In 2000 the National Institutes of Health, the largest source of funds for university research, required such training for all "key personnel" on studies involving human subjects.

The Office for Human Research Protections, which is an arm of the Department of Health and Human Services, proposed that same year to go further and require the training for review board and staff members as well. But the office instead settled in 2002 for a "strong" recommendation that grantee institutions provide the training.

A department advisory panel, the Secretary's Advisory Committee on Human Research Protections, raised the issue again last year when it "strongly recommended" mandatory training.

In the *Federal Register* notice, the human-research office invited comments about details of such training, like content, frequency, and cost.

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