

Federal Office Leading Effort to Change IRB System

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The lead federal office for protecting human research subjects is making a concerted effort to respond to concerns voiced by psychologists and others from behavioral and social science with regard to institutional review board (IRB) treatment of grants in their field. For some time, investigators from psychology have expressed the view that IRBs operate on a biomedical model that does not recognize the realities of behavioral and social science research. The result has been delays or even rejection of legitimate research proposals.

The director of the Office for Human Research Protections, Greg Koski, recently met with representatives of behavioral and social science research organizations in Washington to express his support for changing the system of oversight and protection of human subject research.

The number of entities that engage in or support behavioral or social science research far exceeds the number concerned with biomedical research, according to Koski, who added that NIH officials tell him that one-third of their agency is non-biomedical. Simply put, Koski believes that the “magnitude of the protections” needs to be in line with the “magnitude of the risks” involved in a research project.

He said that in essence we’ve been seeing the IRB pendulum swing well toward the conservative side in part due to high profile cases involving the deaths of human research subjects. The challenge is to move the bureaucracy toward a system that is flexible and that is in tune with all types of research.

Koski, 50, has both a medical degree and a PhD. He said his early career interest was in sleep research, where his work involved the kinds of techniques generally associated with psychophysiology, such as GSR and enhanced potentials. Among other things, this experience has given him an appreciation for the IRB-related issues being raised by psychologists whose research involves non-invasive measures of stress responses and other physiological indicators used in behavioral research.

Before coming to Washington, Koski was director of human research affairs at Partners HealthCare System, Inc., in Boston, and associate professor of anesthesia at Harvard Medical School.

Last year, the OHRP replaced the former Office of Protection from Research Risks (OPRR) located within the National Institutes of Health (NIH). OHRP, which as its name indicates focuses solely on human research subjects, was elevated on the organization chart and now resides within the office of the Secretary of Health and Human Services, while the animal research responsibilities of the old OPRR remain at NIH as the Office of Laboratory Animal Welfare.

OHRP is aggressively pursuing changes in the human subjects protection system, particularly in IRBs. A National Human Research Protections Advisory Committee, which includes APS Member Felice Levine among its members, is in the process of developing recommendations for changes in IRBs. As part of this, the committee is examining possible models for considering research that poses minimal risk to

subjects. Ultimately, Koski hopes to conduct an “active educational campaign” jointly with the dozens of federal agencies concerned with or supporting research involving human subjects. One major thrust of this campaign, he said, would be to provide guidelines to IRBs for handling behavioral and social science research proposals.

Psychology investigators are encouraged to share their IRB anecdotes and opinions. Please email apsobserver@psychologicalscience.org.

For additional information on the OHRP, visit <http://ohrp.osophs.dhhs.gov/>.