October 8, 2011

IRBs Should Evaluate Risk Empirically

In July 2011, the Department of Health and Human Services released an advance notice of proposed rulemaking, entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." For the first time since 1981, the federal government is considering major changes to the regulations governing institutional review boards (IRBs), which are charged with protecting the rights and welfare of participants in biomedical and behavioral research.

Since 1981, the AAUP has expressed concern about the potential for human subjects research protections to interfere with academic freedom, most recently in the 2006 report *Research on Human Subjects: Academic Freedom and the Institutional Review Board*. In our comments on the new proposal, which were principally written by Zachary Schrag at George Mason University, the AAUP makes four main recommendations:

1. IRBs should evaluate risk based on empirical evidence.
2. There should be no IRB review of interview, observation, and survey research with legally competent adults.
3. Not all data should be considered as sensitive as current health data.
4. The federal government should not regulate research it does not pay for.

The advance notice itself, which includes instructions for submitting comments, can be viewed by clicking on the .pdf. The comment period has been extended to October 26, 2011.