

Proposed ‘Common Rule’ Changes Clarify Requirements for Social, Behavioral Research

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The U.S. government, in announcing its latest step toward overhauling the federal rules governing human-subjects research, is proposing some clear, modernized standards requested by social and behavioral scientists.

The Department of Health and Human Services (HHS) on Sept. 2 released a Notice of Proposed Rulemaking (NPRM) on revisions to the so-called Common Rule, the baseline standard of ethics for government-funded research involving human subjects. The proposed updates are designed to extend protections to people more effectively while simultaneously easing the oversight and paperwork requirements for scientists.

HHS will launch a 90-day public comment period on the NPRM beginning Sept. 8, and will take those comments into consideration when it drafts a final set of standards.

The government’s efforts to update the Common Rule, formally known as the Federal Policy for the Protection of Human Subjects, is a response to the rapid technological advances and the increasing volume of data available on individuals since the original regulations were enacted in 1991.

The revision process began in 2011, when HHS issued an Advance Notice of Proposed Rulemaking (ANPRM) to collect an initial round of public comments. The newly released NPRM reflects the input the department received, including recommendations from a special National Research Council (NRC) committee chaired by APS Past President **Susan Fiske**. That committee released a report in 2014 calling for better clarity in the Common Rule updates as they apply to behavioral and social science. Among other recommendations, the committee urged that the regulatory changes:

- define publicly available information as not human subjects research, as long as individuals have no reasonable expectation of privacy; and

- ease the required level of institutional review and consent documentation for low-risk research — including educational tests, surveys, focus groups, and benign interventions typical of most psychological science.

In the NPRM, HHS specifically credits the NRC panel's contributions.

[T]he NPRM more thoroughly addresses social science and behavioral research perspectives, benefiting from guidance provided by a National Research Council's consensus report entitled "Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences." ... The Panel made numerous recommendations, including recommendations about what research studies should not undergo review, about calibrating the level of IRB review to the level of risk, about the desirability of privacy and confidentiality protections in social and behavioral research other than those of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and about improving informed consent by placing greater emphasis on the process of consent. The NPRM revises some of the ANPRM proposals in light of those recommendations.

"We are especially happy to be listed first among their sources," Fiske says, "and to have them affirm more appropriate exemptions and ethical review for SBS research."

Other psychological scientists on the multidisciplinary NRC committee were APS William James Fellow **Richard Nisbett** (University of Michigan); APS Fellows **Celia B. Fisher**, (Fordham University) and **Felice J. Levine**, (American Educational Research Association); and Melissa Abraham (Harvard University Medical School).