

HHS Announces Proposal to Improve Rules Protecting Human Research Subjects

In July 2011, U.S. Department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rulemaking to seek the public's input on updating the Common Rule. The Notice of Proposed Rulemaking (NPRM) issued on September 2, 2015 reflects that input and requests comments for HHS to consider as it drafts the final rule. The proposed revisions are intended to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. It is expected that the NPRM will be published in the Federal Register on September 8, 2015. There are plans to release several webinars that will explain the changes proposed in the NPRM, and a town hall meeting planned to be held in Washington, D.C. in October.

The following list encompasses the most significant changes to the Common Rule proposed in the NPRM:

- 1) Improve informed consent by increasing transparency and by imposing stricter new requirements regarding the information that must be given to prospective subjects, and the manner in which it is given to them, to better assure that subjects are appropriately informed before they decide to enroll in a research study.
- 2) Generally require informed consent for the use of stored biospecimens in secondary research (for example, part of a blood sample that is left over after being drawn for clinical purposes), even if the investigator is not being given information that would enable him or her to identify whose biospecimen it is. That consent would generally be obtained by means of broad consent (i.e., consent for future, unspecified research studies) to the storage and eventual research use of biospecimens.
- 3) Exclude from coverage under the Common Rule certain categories of activities that should be deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated.
- 4) Add additional categories of exempt research to accommodate changes in the scientific landscape and to better calibrate the level of review to the level of risk involved in the research. A new process would allow studies to be determined to be exempt without requiring any administrative or IRB review. Certain exempt and all non-exempt research would be required to provide privacy safeguards for biospecimens and identifiable private information. New categories include:
 - a. certain research involving benign interventions with adult subjects;
 - b. research involving educational tests, surveys, interviews or observations of public behavior when sensitive information may be collected, provided that data security and information privacy protections policies are followed;
 - c. secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given;
 - d. storing or maintaining biospecimens and identifiable private information for future, unspecified secondary research studies, or conducting such studies, when a broad consent template to be promulgated by the Secretary of HHS is used, information and biospecimen privacy safeguards are followed, and limited IRB approval of the consent process used is obtained.

5) Change the conditions and requirements for waiver or alteration of consent such that waiver of consent for research involving biospecimens (regardless of identifiability) will occur only in very rare circumstances.

6) Mandate that U.S. institutions engaged in cooperative research rely on a single IRB for that portion of the research that takes place within the United States, with certain exceptions. To encourage the use of IRBs that are otherwise not affiliated with or operated by an assurance-holding institution (“unaffiliated IRBs”), this NPRM also includes a proposal that would hold such IRBs directly responsible for compliance with the Common Rule.

7) Eliminate the continuing review requirement for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data or involve only observational follow-up in conjunction with standard clinical care.

8) Extend the scope of the policy to cover all clinical trials, regardless of funding source, conducted at a U.S. institution that receives federal funding for non-exempt human subjects research.

- Read a [brief summary](#) of the proposed changes
- Read the [public display copy of the NPRM online](#).
- Access information about the 2011 [Advanced Notice of Proposed Rulemaking](#) that preceded the NPRM

We will keep you updated on new developments including Harvard’s plan to provide comments to HHS.

Stay tuned!