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Proposed Changes to the Common Rule

The U.S. Department of Health and Human Services (DHHS) and fifteen other Federal Departments and Agencies have announced proposed revisions 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. A Notice of Proposed Rulemaking (NPRM), which can be accessed at: <https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects>, seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. The deadline to submit comments is December 7, 2015.

Please note: In 2011, ASIP responded to an Advanced Notice of Proposed Rulemaking with a number of significant concerns (please see [ASIP comments](#) on Advanced Notice of Proposed Rulemaking). **The ASIP Research and Science Policy Committee is currently reviewing the NPRM with a particular emphasis on the proposal to limit or eliminate waiver of informed consent for research involving de-identified biospecimens. Please contact ASIP's policy consultant, Jennifer Dreyfus (jdreyfus@asip.org) if you would like to share your thoughts about the NPRM.**

The following summary is taken verbatim from a notice sent by DHHS to the Office of Human Protections listserv on September 2, 2015:

According to DHHS, some of the major changes being proposed that will better protect research subjects and help build public trust are the rules relating to informed consent. With regard to informed consent in general (such as consent to participating in clinical trials), the rules would be significantly tightened to make sure that the process becomes more meaningful. Consent forms would no longer be able to be unduly long documents, with the most important information often buried and hard to find. They would need to give appropriate details about the research that is most relevant to a person's decision to participate in the study, such as information a reasonable person would want to know, and present that information in a way that highlights the key information. In addition, to assure that these rules do indeed change current practices, there will be a one-time posting requirement for the consent forms for clinical trials, so that anyone drafting a consent form will do so knowing that it will eventually be subject to public scrutiny.

In addition, informed consent would generally be required for secondary research with a biospecimen (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. Such consent would not need to be obtained for each specific research use of the biospecimen, but rather could be obtained using a "broad" consent form in which a person would give consent to future unspecified research uses.



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The NPRM also attempts to strengthen the effectiveness and efficiency of the oversight system by making the level of review more proportional to the seriousness of the harm or danger to be avoided. Research that poses greater risk to subjects should receive more oversight and deliberation than less risky research. The NPRM seeks to avoid requirements that do not enhance protection and impose burden, which can decrease efficiency, waste resources, erode trust, and obscure the true ethical challenges that require careful deliberation and stakeholder input. Cumbersome and outdated regulatory standards overwhelm and distract institutions, IRBs, and investigators in ways that stymie efforts to appropriately address the real risks and benefits of research.

The result of these types of changes, as the NPRM proposes to implement them, is that some studies that currently require IRB review would now become exempt. Some that are currently exempt would specifically be declared as outside the scope of the regulations (“excluded”), and thus would not require any administrative or IRB review. Further, in terms of determining when a study is exempt, a web-based “decision tool” will be created. That decision tool will provide a determination of whether or not a study is exempt. That result, so long as the tool was provided with accurate information, will be presumed by the Common Rule agencies to be an appropriate determination of exempt status. It is expected that in many instances the tool would be used by the investigators themselves, thus obviating both the need for further review and the concern that the institution might be subjecting itself to future liability by allowing investigators to use the tool. For all of the excluded and exempt research activities, this NPRM also affirms the importance of applying the ethical principle of respect for persons, in addition to the importance of abiding by this principle in fully regulated non-exempt research involving human subjects.

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*



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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.

In sum, the proposed modifications described above are designed to continue to uphold the



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ethical principles upon which the Common Rule is based, as applied to the current social, cultural, and technological environment.