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# Drastic Changes Proposed for Clinical Research Rules

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The U.S. Department of Health and Human Services ("HHS") and fifteen other Federal Departments and Agencies have announced a proposal to update the Federal Policy for the Protection of Human Subjects known as the "Common Rule," originally promulgated in 1991. A Notice of Proposed Rulemaking ("NPRM"), published on September 2, 2015, seeks comments on the proposal, which includes some dramatic changes for researchers.According to HHS, the NPRM is intended to strengthen protections for human subjects while at the same time facilitating important research. Additionally, the changes recognize that the volume and landscape of research involving human subjects has changed considerably since 1991, including increased use of sophisticated analytic techniques for use with human biospecimens and the growing use of electronic health data and other digital records to enable very large data sets to be analyzed and combined in novel ways. Here are some highlights:


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1) Informed Consent Process Updates. The NPRM proposes to improve the informed consent process by eliminating unduly long consent forms that bury important information. Additionally, there is a proposal for increasing transparency by requiring a one-time, public posting of consent forms.

2) Restrictions on the Use of Stored Biospecimens. HHS believes that research participants prefer to be asked for their consent before their biospecimens are used for research. Accordingly, the NPRM proposes to require informed consent for the use of stored biospecimens for secondary research (for example, leftover blood or tissue samples), even if the samples will be de-identified. The consent would be obtained by means of broad consent (i.e., consent for future, unspecified research studies) to the storage and eventual research use of leftover biospecimens.

> Continuing to allow secondary research with biospecimens collected without consent for research places the publicly-funded research enterprise in an increasingly untenable position because it is not consistent with the majority of the public's interests, which reflect legitimate autonomy interests

3) New IRB Review Requirements. The NPRM proposes to make changes to the IRB review process, so that the level of IRB review is proportional to the level of risk presented by a particular study. Additionally, HHS proposes excluding from IRB review 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) New Exemption Categories. The NPRM proposes to add new categories of exempt research. Additionally, HHS proposes the creation of a web-based decision tool for determining exempt status. Use of the tool by investigators would be viewed as an appropriate determination of exempt status, in contrast to requiring an IRB to make the exemption determination, which is the current best practice.

New exemption categories would include:

- research involving benign interventions with adult subjects;
- 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;
- secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given; and
- 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) Limited Availability of Consent Waiver for Secondary Research. The NPRM proposes waiver of consent for research involving biospecimens (regardless of identifiability) will occur only changing the conditions and requirements for waiver or alteration of consent so that in very rare circumstances.

6) Cooperative IRB Review Requirement. The NPRM includes a mandate that U.S. institutions engaged in cooperative research rely on a single IRB.

7) Elimination of the Continuing Review Requirement for Certain Studies. The NPRM proposes eliminating the continuing IRB 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) Expanded Scope of Common Rule Applicability. Currently, the Common Rule applies to federally-funded human subject research. The NPRM proposes extending the scope of the rule 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.

Comments on the NPRM must be received within 90 days following publication of the NPRM in the federal register, which is expected to be on September 8, 2015. Researchers or sponsors relying on access to data and tissue banks or existing tissue samples should consider commenting given the numerous NPRM provisions affecting this type of research.