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Alerts

Common Rule Research Alert: New Proposed "Federal Policy For The Protection of Human Subjects"

September 9, 2015
Health Law Alert

A proposed new federal policy regarding the protection of human subjects in research was posted as a "Notice of Proposed Rule Making" (NPRM) in the Federal Register on September 8, 2015; the notice seeks comments from stakeholders involved in human subjects research in order to finalize the updated Common Rule. Comments are due by December 7, 2015.

Background

The "Common Rule" is a federal standard of ethics, oversight, and transparency in government-funded research involving human subjects. The Common Rule is a joint effort to create uniform regulations across federal departments and agencies. Each agency publishes an identical version of the Common Rule in its own regulations. The Common Rule also contains three subparts that protect particular vulnerable populations (such as pregnant women, human fetuses, prisoners, and children).

Changes

The NPRM is lengthy at over 500 pages. However, for individuals involved in human subjects research in any capacity, it is a treasure trove of specific information. It contains not only the exact language the new Common Rule would use if it is adopted as written, but also examples of the underlying reasons for any proposed changes and calls for comments on specific changes.

Below are some details of the proposed changes:

Clinical Trials: Most significantly from the author's perspective, the proposed rule would vastly extend the scope of the Common Rule to cover *all* clinical trials, regardless of funding source, when those trials are conducted at an institution in the United States that receives federal support for non-exempt and non-excluded human subjects research, and when those trials are not already subject to FDA regulations. For example, a surgical clinical trial that is not receiving federal support for the particular trial and that is outside the scope of FDA regulations would be subject to the Common Rule.

Informed Consent: In another important change from the current Rule, the proposed changes require consent for the reuse of biomedical material unrelated to their original use ("secondary research"). Currently, researchers may use leftover material as long as the material is de-identified, or cannot be tied to a specific individual. Under the proposed rules, while this type of reuse would require informed consent, the consent would not need to be obtained for each specific, secondary research use of the specimen. Instead, the consent for secondary research could be obtained using a "broad" consent form in which a person gives consent to future, unspecified research uses.

In general, the proposed Rule also tightens whether informed consent is adequately provided to prospective subjects. It contains stricter requirements regarding the information subjects must receive and increases the transparency of informed consent documents. For instance, forms may not be "unduly long" and instead should clearly relay which information is key to the individuals' decisions to participate in the study. Transparency is also increased because informed consent documents will be posted online and subjected to public scrutiny.

IRB: Another substantial change is that a centralized Institutional Review Board (IRB) must be utilized to review cooperative research conducted at numerous locations. Previously, institutions frequently interpreted the Common Rule in such a way that each location conducted its own IRB in order to independently review research protocols, with often burdensome requirements and negative effects on timeliness. Because of concerns regarding establishing new joint policies, procedures, and agreements, this requirement will not be effective until three years after the final publication of the updated Common Rule.

The Rule also proposes to reduce the number of studies that are subjected to continuing review by eliminating that requirement for studies approved through expedited review. Continuing review would also be eliminated for studies that have completed study interventions and are only continuing to analyze data, and for studies that only involve observational follow-up in the course of standard clinical care.

Excluded and Exempt: The proposed rule also attempts to streamline IRB review by making the level of review proportional to the seriousness of the harm to be avoided. Accordingly, some research that is now exempt would be excluded from the Common Rule entirely, and other research that now requires IRB review would become exempt.

The excluded activities list clarifies areas that are not research (such as quality assurance activities or public health surveillance) and excludes those activities that are inherently low risk and/or have protections similar to those usually provided by IRB review (such as non-intervening surveys or observations). For example, this later exclusion includes "research involving the collection or study of information that has been or will becollected." This is a substantial expansion of what is currently an exemption that only applies to *existing* data that is either publicly available or non-identifiable. Altogether, excluded activities would not undergo any type of review process.

On the other hand, the additional categories of exempt research are intended to both accommodate changes and advances in the scientific arena and to make determining exemption easier. Some types of exempt research may still require certification for information protection and data security safeguards (such as use of sensitive information), but otherwise all exempt research would avoid IRB review. The expanded exempt category includes benign interventions with adult subjects, surveys or observations of public behavior, secondary research use of identifiable private information, and other low-risk research.

Decision Tool: In order to assist in making an exemption determination, the proposed rule envisions the creation of an online "decision tool" which the agency—or the investigators themselves—could rely upon in making an exemption determination.