Updates to the Common Rule for the Protection of Human Subjects Research

Introduction

On Sept. 8, 2015, the U.S. Department of Health and Human Services (HHS) issued a Notice of Proposed Rule Making (NPRM) to seek input on changes to the Federal Policy for the Protection of Human Subjects, otherwise known as the "Common Rule" as set forth under 45 CFR Part 46, Subpart A. From the NPRM, it appeared as though human subject protections would be considerably tightened and that conducting research, especially with biospecimens, was going to be an administrative nightmare. Alas, it was not so. On Jan. 19, 2017, HHS and 15 other federal agencies issued a Final Rule to update the Common Rule. Revisions to the Common Rule are intended to enhance protections for research participants and minimize the administrative and regulatory burden for researchers by providing flexibility in the ever-changing human subjects research landscape. The majority of the Final Rule is expected to go into effect Jan. 19, 2018.

This summary features an overview of the notable changes required by the Final Rule, and the implications for clinical research sponsors, researchers, research sites, institutional review boards (IRBs), and research participants. Such parties should be aware of the changes discussed in the Final Rule and the necessary steps to ensure compliance.

Informed Consent Updates

Updates under the Final Rule impose changes to the informed consent process, provide a new waiver exception, require public disclosure of certain protocols, and enhance the standards for informed consent in biospecimen research.

Process. Informed consent forms under existing rules are often considered too long, difficult to understand, and lack important information. Requirements for the consent process under the Final Rule address these concerns. The Final Rule seeks to provide more transparency to the existing consent process by imposing new, more stringent requirements regarding information that must be given to prospective subjects and the manner in which it is given to them. Specifically, the "new" consent process is required to be concise and focused, with key information being organized and presented in a manner that is understandable by potential participants and provides them the opportunity to discuss the information presented. Specifically, consent forms should disclose information that a "reasonable person" would want to have in order to make an informed decision about whether to participate, including a disclosure as to whether or not identifiable information or biospecimens collected during a research study will be de-identified and used (or not used) for future research.

Waiver. Provided certain conditions are met, IRBs are allowed flexibility to approve research proposals for which researchers collect information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective human subjects, without prospective informed consent. This is a deviation from existing rules, which require the informed consent of prospective subjects before approval of research proposals for the foregoing purposes.

Public Access. If the study is funded by a federal agency or department, the IRB-approved consent form used for enrollment must be publicly accessible via a federal website. This is a new requirement to the informed consent process and is intended to facilitate the sharing of information to prospective subjects.

Biospecimen Consent Requirements. Researchers utilizing identifiable private information or identifiable biospecimens must include additional elements that are relevant to the conduct of secondary research, including statements that address the use of such information or biospecimens for future research, research commercialization, performance of whole genome sequencing, and disclosure of results to individual subjects. These requirements were not explicitly in effect prior to the Final Rule.

Broad Consent Applicability

Subject to compliance with certain requirements articulated in the Final Rule, researchers are permitted to obtain and rely on a one-time broad consent for future research covering the storage, maintenance, and secondary research use of identifiable data or identifiable biospecimens. This approach is a "new" alternative, in lieu of seeking waiver of informed consent from the IRB or study-specific consent under existing rules, in that the Final Rule prescribes requirements for this broad consent approach that cannot be altered and/or omitted by researchers. Under the Final Rule researchers are able to use non-identifiable data or biospecimens without obtaining consent.

Limited IRB Review and Continuing Review

Under existing rules, all research, regardless of the level of risk, undergoes exempt, expedited, or full board IRB review. In an effort to balance human subject protections with administrative efficiency, the Final Rule establishes new categories of research with a lower risk profile that are permitted to undergo a limited IRB review (via a streamlined procedure), and also addresses instances in which certain research may be exempt from the continuing review process.

Limited Review. Under limited review, the IRB must determine that the researcher obtained broad consent **or** waiver of consent; that broad consent or waiver of consent is appropriate for the research; and that there are adequate privacy protections in place to protect study subject privacy and confidentiality, particularly when protocol changes are made related to data or specimen storage. Examples of research that may be qualified for limited IRB review include secondary research involving identifiable private information that is already subject to HIPAA rules, and activities relating to storing and maintaining biospecimens and identifiable private information for potential secondary research (if broad consent is obtained).

Continuing Review. IRBs are no longer required to engage in continuing review of ongoing research for studies that have been approved under expedited review **and** have completed study intervention where activity is limited to data analysis or accessing follow-up clinical data from standard of care clinical procedures.

Exempt Research Categories

The Final Rule creates two new exempt research categories that apply to studies involving identifiable private information and identifiable biospecimens that have been approved through the IRB limited review process. Researchers can now: (i) store and maintain this data for potential secondary research, and (ii) use this data for secondary research, so long as broad consent or IRB approved waiver of consent is obtained.

Single IRB and Cooperative Research

With few exceptions, institutions engaged in federally funded multi-institutional cooperative research will be required to rely on approval from a single IRB in contrast with the multiple IRBs used for multi-institutional cooperative research under existing rules. The sole reviewing IRB under the Final Rule must either be the IRB proposed by the lead institution of the study, or will be chosen and approved by the federal funding department or agency. This requirement is expected to go into effect Jan. 20, 2020.

For more information regarding the impact of these changes on your clinical research operations, contact Emily K. Weber in our Health Care Group.

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