HHS FINALIZES MAJOR UPDATES TO REGULATIONS FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

BACKGROUND

On January 18, 2017, the Department of Health and Human Services ("HHS"), through the Office of Human Research and Protection ("OHRP"), issued final regulations (the "Final Rule") implementing significant changes to the Federal Policy for the Protection of Human Subjects (the "Common Rule").

The Final Rule follows HHS's September 2015 notice of proposed rulemaking ("NPRM") in which HHS and 15 other federal agencies and departments announced their intent to revise the Common Rule to modernize the federal policy on human subjects research and to align the Common Rule with the many changes and advancements that have taken place in the research industry since the Common Rule was originally promulgated in 1991. An in-depth overview of the NPRM is available here.

HHS received over 2,100 public comments in response to the NPRM. In response to concerns raised by commenters, the Final Rule contains a number of significant revisions from the NPRM, including the removal of a controversial provision that would have required researchers to obtain consent before using non-identified biospecimens.

A majority of the provisions of the Final Rule will go into effect January 19, 2018.

OVERVIEW

Below is an overview of the major provisions of the Common Rule, including the key differences between the NPRM proposals and the finalized regulations.

I. Jurisdiction. In the NPRM, HHS proposed to significantly expand the scope of the Common Rule to cover all research studies, including those studies that are not federally funded but are conducted at institutions receiving federal funds for non-exempt human subjects research. In the Final Rule, HHS declined to expand the scope of the Common Rule and instead noted that institutions may choose to establish an institutional policy that would require Institutional Review Board ("IRB") review of research that is not funded by a Common Rule agency.

II. IRB Review. One of the most noteworthy proposals outlined in the NPRM was the requirement that all institutions participating in cooperative research studies use a single IRB as the reviewing body for the study. Under the NPRM, it was proposed that the federal funding agency or the lead institution would be responsible for selecting the single IRB. In the Final Rule, HHS ultimately adopted a modified version of the proposal, requiring a single IRB to be used for all cooperative research studies. Institutions may still choose to conduct additional internal IRB reviews for their own purposes; however, these reviews will not have any regulatory status in terms of Common Rule compliance. The lead institution will have the authority to propose the reviewing IRB, subject to the acceptance of the federal agency supporting the research.

Under the Final Rule, Common Rule agencies will also have direct regulatory authority over IRBs that are not subject to a Federalwide Assurance ("FWA"). This revision will alter OHRP's current practice of enforcing compliance through the institution and not the reviewing IRB, thereby increasing IRB accountability and protecting institutions that rely on IRBs that they do not operate.

HHS acknowledged that the single IRB requirement will require significant operational changes at the institutional level. Therefore, HHS has delayed the compliance date for the single IRB requirement until January 19, 2020.

III. Continuing Review of Research. The Final Rule removes the requirement to conduct continuing review of ongoing research studies that undergo expedited review and for studies that have completed interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. For studies initially reviewed by a convened IRB, once certain specified procedures are all that remain for the study, continuing review will not be required, unless specifically mandated by the IRB.

Despite these revisions, under the Final Rule investigators still have an obligation to report unanticipated problems or proposed changes to

the study to the IRB

IV. Biospecimens and the Definition of "Human Subject." In what was arguably the most controversial provision of the NPRM, HHS proposed to expand the definition of "human subject" to include biospecimens, whether or not the specimens contained identifiable information.

Due to hundreds of comments opposing the proposal to require consent for the secondary use of biospecimens, HHS declined to expand the definition of "human subject" under the Final Rule. As a result, the regulation related to the use of biospecimens remains unchanged, and biospecimens must be identifiable to be subject to the Common Rule.

V. Informed Consent. The NPRM proposed to modify the informed consent regulations in an effort to shorten consent forms and make it easier for research subjects to locate the key information necessary to make informed decisions regarding their participation in research studies. Changes in the way that information will be presented, including a "concise and focused presentation" requirement, and details regarding information that must be presented will result in significant changes in the content and appearance of informed consent forms. Further, informed consent forms must be publicly available in a bid to improve transparency.

VI. Excluded Research. The NPRM proposed to exclude 11 activities from regulation under the Common Rule. HHS declined to adopt the proposed exclusions. Generally, under the Final Rule, proposed excluded activities in the NPRM either now do not meet the definition of research under the Final Rule or are classified as exempt.

VII. Exempted Research. The Final Rule established new exempt categories of research based on their risk profile. Under some of the new categories, exempt research will be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens. The risk profiles of exempted research are divided into the following three categories.

- Low-Risk Interventions
- Collection of Sensitive Information Subject to Documentation and Security Standards
- Secondary Research Involving Biospecimens and Identifiable Private Information Subject to Privacy Safeguards, Broad Consent and Limited IRB Review

Within these three risk categories, HHS finalized eight separate exemptions.

1. Research conducted in established or commonly accepted educational settings when it specifically involves normal educational practices
2. Research that includes only interactions involving educational tests, survey procedures, interview procedures or observation of public behavior, subject to certain criteria
3. Research involving benign behavioral interventions in conjunction with the collection of information
4. Secondary research use of identifiable private information originally collected for non-research purposes
5. Research and demonstration projects conducted or supported by a federal department or agency that are designed to study, evaluate, improve or otherwise examine public benefit or service programs
6. Taste and food quality evaluation and consumer acceptance studies
7. Storage or maintenance for secondary research for which broad consent is required
8. Secondary research for which broad consent is required

PRACTICAL TAKEAWAYS

The changes to the Common Rule will require those participating in human subjects research to evaluate and revise many of their research processes, procedures and policies. Compliance with the new Common Rule regulations will be required as of January 19, 2018, with the exception of the rules mandating oversight of cooperative studies by a single IRB, which will require compliance by January 20, 2020.

The foregoing is a very brief overview of the Final Rule; there are many details that will require careful consideration and compliance. Look for our upcoming series of Health Law News articles that will delve into each of these areas in more detail and provide practical advice regarding potential impact of the changes to the Common Rule.

If you have questions or would like additional information about the changes to the Common Rule and how it may affect your clinical research practice, please contact a member of the Hall Render Life Sciences practice:

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