The Department of Health and Human Services Announces Proposal to Improve Rules Protecting Human Research Subjects.

On September 2, 2015, the U.S. Department of Health and Human Services (HHS) announced proposed revisions to the 1991 Federal Policy for the Protection of Human Subjects (45 CFR 46 Part A), which is commonly known as the Common Rule (“Common Rule”). According to an HHS press release that accompanied the announcement, the current Common Rule regulations were developed at a time when research was predominantly conducted at universities, colleges and medical institutions, and each study generally took place at a single site. The expansion of research into new scientific disciplines, such as genomics, along with an increase in multisite studies and significant advances in technology, has highlighted the need to update the regulatory framework. Notably, a more participatory model of research has also emerged, with individuals looking for more active engagement with the research enterprise. Thus, the intent of the proposed revisions is to modernize, strengthen and make more effective the Common Rule.

Subsequently, on September 8, 2015, the HHS, along with fifteen other Federal Departments and Agencies, published in the Federal Register a notice of proposed rulemaking (NPRM) regarding the previously announced proposed revisions to the Common Rule. The proposed revisions, when and if finalized, will have a profound impact on human research protection operations. Below is a list of the most significant proposed revisions to the Common Rule:

1. **Informed Consent.** The NPRM proposes stricter new requirements regarding what information 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. In addition, the NPRM proposes a one-time posting requirement for clinical trial consent forms; so that anyone drafting a consent form will do so knowing that it will eventually be subject to public scrutiny.

2. **Secondary Research Involving Biospecimens.** The NPRM proposes that, in general, informed consent will be required 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 the individual to whom the specimens belong. According to the NRPM, such consent could 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. **Excluded Activities.** The NPRM introduces a new category called excluded activities. Such activities would be excluded from coverage under the Common Rule because such activities are deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated.

4. **Exempt Research.** The NPRM proposes new categories of exempt research. In addition, the NPRM puts forth a new exempt research process. Under this new process, studies could be deemed exempt without requiring any administrative or IRB review. Instead, the NRPM proposes the use of a not yet created web-based “decision tool.” According to the NRPM, the decision tool will take the place of administrative or IRB review and 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. According to the NRPM, it is expected that in many instances the decision 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. Lastly, under the proposed exempt research process, certain exempt and all non-exempt research would be required to provide privacy safeguards for biospecimens and identifiable private information.

5. **Waiver or Alteration of Informed Consent.** The NPRM proposes to 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. **Continuing Review.** The NRPM proposes to 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 activities in conjunction with standard clinical care.
7. **Use of Single IRB.** The NRPM proposes to require that all U.S. institutions engaged in cooperative research rely on a single IRB for research taking 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"), the NPRM also includes a proposal that would hold such IRBs directly responsible for compliance with the Common Rule.

8. **Common Rule Coverage.** The NPRM proposes to extend the scope of the Common 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.

In addition to putting forth all of the proposed revisions to the Common Rule, the NPRM also seeks public comment on more than 80 questions related to the Common Rule proposed revisions. Individuals wishing to submit comments regarding the NPRM in general or in response to specific questions, must do so by December 7, 2015.

**Next Steps:**

Following closing of the comment period, HHS, along with the fifteen other Federal Departments and Agencies that published the NPRM, will need to review the comments that were submitted in response to the NRPM. The collective agencies will need to take these comments under consideration when drafting a final rule; the next phase in this regulatory process. At the final rule phase of the rulemaking process, the agencies must base their rationale and conclusions on the rulemaking record, consisting of, among other things, the comments, expert opinions, and facts accumulated during the pre-rule and proposed rule stages. To move forward with the final rule, the agencies must conclude that the proposed solution will help accomplish the goals or solve the problems identified during the rulemaking process. It must also consider whether alternate solutions would be more effective or cost less. See A Guide to the Rulemaking Process, prepared by the Office of the Federal Register, available https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

Whether and when a final rule on this topic will be ultimately issued is anyone’s guess given the NRPMs request for public comment on more than 80 specific questions (not to mention public comment on the NPRM in general), coupled with the upcoming change in administration. Nevertheless, it is important to note that if a final rule is issued on this topic, per the NPRM, the effective date of the final rule will be one year after publication in the Federal Register. Moreover, the compliance date of the final rule will be one year from the publication of the final rule, except that compliance with the proposal for the Common Rule to cover all biospecimens and the proposal regarding identifying a single IRB to be responsible for the review of certain multi-institutional clinical trials would be three years after the publication of the final rule in order to allow institutions the necessary time to develop institutional policies and procedures necessary to implement these two provisions.

**How the Proposed Rule will Impact Your Organization:**

Finalization of the proposed rule will directly impact several important facets of organizational policies and process related to human research protections, including the following:

1. Although the proposed rule lessens requirements around IRB oversight of minimal risk research, organizational processes will require development or enhancement in a manner that supports compliance with HIPAA regulation and adherence to the basic ethical principles governing human research. Moreover, organizations might require some level of protocol registration and/or oversight for excused and exempt research. Subsequently, development of additional policies and procedures will be required.

2. Organizations must establish or enhance existing controls related to ceding IRB review for multi-centered studies. Development or enhancement of process related to investigator training, review and management of conflicts of interest, evaluations of adverse events, and review of noncompliance are some of the most common issues that warrant attention. The desirability of AAHRPP accreditation may escalate under the requirement of a single IRB of record since AAHRPP accredited organizations as a rule will not cede IRB oversight to an IRB that has not achieved accreditation.

3. Finally, the IRB Office will need to realign their work flows, electronic systems, job descriptions and staffing levels to synchronize with the requirements of the final rule.

These are just a few examples of the many organizational changes that will be required once the final rule is issued.

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