The Revised Common Rule: What It Means for Researchers

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). A final rule was published in the Federal Register (FR) on January 19, 2017, and was amended to delay the effective and compliance dates on January 22, 2018 and June 19, 2018.

The revised Common Rule is effective July 19, 2018; note that from July 19, 2018 through January 20, 2019 institutions are not permitted to implement the entirety of the revised Common Rule. This is explained in the transition provision (45 CFR 46.101(l), as amended June 19, 2018). These changes are meant to ease some researcher burden while enhancing the protection of human subjects.

Recommendations for Researchers

The IRB is working to implement the revised Common Rule changes, and no action is required by researchers at this time. However, it's important to note that researchers submitting their studies to the IRB on or after January 19, 2018 will be reviewed under the revised Common Rule. If you have flexibility in the timing of your study and are starting a new study, we recommend waiting to submit on or after January 19 to have your study reviewed under the revised Common Rule. New templates to use for review under the revised Common Rule will be available later this year.

Common Rule Changes: Highlights

Of particular interest to many researchers are changes in three areas: expanded exemption categories, continuing review changes, and consent form changes. Below are a few highlights regarding the changes in these areas.

New Exempt Categories

The Common Rule defines three levels of review for human subjects research: exempt, expedited, and full (committee). The new Common Rule broadens the types of research that may be determined to be exempt from IRB review. For example, starting January 19, benign behavioral interventions conducted with adults may be determined to be exempt. Researchers must submit to the IRB for a determination that research activities are exempt. Another example: the collection of identifiable, sensitive information from adults may also be exempt; however, this new category requires a limited IRB review to determine that appropriate privacy and confidentiality protections are in place.

Continuing Review Changes

Some minimal risk studies will no longer be required to renew their IRB approval on an annual basis (continuing review). Investigators conducting eligible studies will be informed of post-approval requirements at the time of initial approval.

Consent Form Changes

Consent forms will need to include a brief summary that explains the research to potential participants in an easy-to-understand and clear manner. It is now required that consent forms be concise while also giving the full context of a study, including its risks and benefits, so potential participants have all the information they need to make an informed decision. Consent forms will also need to include information regarding the potential for future use of de-identified data and biospecimens.

Single Site IRB Review: Changes to the Common Rule for January, 2020

In addition, there is a new requirement that cooperative research studies involving more than one institution to use a single IRB for review. The implementation date for this requirement is January 19, 2020.