IRB Revised Common Rule

The New Final Rule

In January of this year, the United States Department of Health and Human Services (HHS) published the notice of revisions to the Common Rule – the federal regulations establishing the rules governing human subjects research (45 Code of Federal Regulations 46, Subpart A). You may hear this referred to as the "new Common Rule" or the "Final Rule."

The goal is to better protect human subjects, facilitate research, and reduce administrative burdens for both researchers and compliance offices.

Initially these changes were set to go into effect January 19th, 2018, but the implementation has been delayed. These changes will now go into effect on January 21, 2019. Key Changes are below:

**Exempt Review Expansion**

There are new categories of research that will be eligible for exempt review from the Common Rule. This includes research involving secondary use of data collection for some other primary activity.

Some exemptions will require “limited Institutional Review Board (IRB) review” which will be similar to our expedited review process. The IRB will continue to require researchers to submit their research to be reviewed by for determination of whether an exemption applies.

**Informed Consent**

For federally funded research, a new section will be required at the beginning of consent forms that provides a concise summary of the key elements of the research.

**Single IRB**

Federally funded, multi-site studies will now be required to use a single IRB of record starting January 20, 2020. IRBs from the participating institutions will defer to the IRB of record for review, approval, and monitoring.

**New Definitions**

The definition of "vulnerable" no longer includes pregnant women or handicapped or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence. The new language describes vulnerable as "individuals with impaired decision-making ability" rather than "mentally disabled persons."

The definition of "human subject" now references "information and biospecimens" (replacing "data") and adds "obtaining, using, analyzing, or generating identifiable private information or identifiable biospecimens."

**Who does this effect?**

These new regulations affect any study approved on or after January 21, 2019 (except for the Single IRB requirement.)

Keep an eye on the Office of Regulatory and Research Compliance website. Soon, there will be updates and guidance as information becomes available.