New Human Subjects Regulations

Requirements for Federally-Funded Research

01.24.2018

AUTOMATIC CERTIFICATE OF CONFIDENTIALITY (CoC)

- All NIH research that was commenced or ongoing on or after December 13, 2016, and will collect identifiable sensitive information as defined here (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html) now has a Certificate of Confidentiality.
- It is especially important to read the definition of identifiable sensitive information at the link above if you collect biospecimens or generate individual level, human genomic data from biospecimens.
- You will need to ensure that the overall consent and the use cases for which you seek permission are consistent with the Certificate of Confidentiality.
- See the consent form template for suggested wording for studies with a CoC.

CLINICAL TRIALS MUST POST CONSENT FORM

- Each clinical trial that is conducted or supported by a Federal department or agency is required to post one consent form used to enroll subjects to a public Federal Web site.
- The public Federal Web site is TBD.
- Posting is required after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.
- *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

UMMS Institutional Review Board
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https://www.umassmed.edu/ccts/irb/

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sIRB (SINGLE IRB MANDATE)

- NIH policy mandates single IRB review for non-exempt multi-site studies for submissions with due dates on or after January 25, 2018. (https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm)
- Effective January 20, 2020, the 2018 regulations require federally-funded cooperative research to use a single IRB for the portion conducted in the US, unless otherwise precluded (e.g., by tribal law) or deemed by the sponsoring agency as not required.
- Contact the UMMS IRB if you are seeking to use an external IRB or to use the UMMS IRB as the single IRB.