Clinical Trial Consent Document Posting Requirement

New: Posting of Consent Documents for Federally Funded Clinical Trials

Under the revised 2018 Common Rule federally-funded clinical trials are now required to post one IRB-approved informed consent document used to enroll subjects on a publically available Federal repository website. The goal of this requirement is to improve the quality, increase transparency and accountability, as well as aid in the development of future consent forms.

Document posting must occur after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit is completed. In some cases, redactions to information posted may be allowed.

The Office for Human Research Protections has identified two websites that will satisfy the posting requirement:

1. ClinicalTrials.gov
2. A docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021)

Additional federal websites may be identified in the future. Currently, no instructions regarding posting procedures have been issued.

Clinical Trial

- *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. (46 CFR 102(b))
- When social and behavioral research meets the definition of a clinical trial, the posting requirement applies.

Posted forms must:

- Be IRB approved
- Have been used for enrollment
- Be posted after the trial is *closed* to enrollment, but within 60 days after the last study visit by any subject

- If multiple versions of consent are approved (e.g. multiple iterations for study modifications, different participant or condition groups) only ONE version needs to be posted
- Only one posting is required for a multi-institution study
- Redactions may be allowed if the federal department or agency supporting/conducting the trial determines that certain information should not be made publicly available.

46.116(h)(1-3)