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New Requirements for Posting Informed Consent Forms for clinical trials conducted or supported by a US Federal department or agency

For clinical trial studies approved on or after January 21, 2019

Definition of a clinical trial

102 (b) *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 behavioural health-related outcomes

Posting Requirement

116(h) *Posting of clinical trial consent form*

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted *by the awardee or the Federal department or agency component conducting the trial* on a publicly available Federal web-site that will be established as a repository for such informed consent forms. [Update: Now confirmed as Clinicaltrials.gov or Regulations.gov (Docket ID: HHS-OPHS-2018-0021)]

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web-site (e.g. confidential commercial information) such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web-site 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.

Note: In general, the Federal sponsor or the Lead Investigator will ensure that the informed consent form is posted. If you are the Lead Investigator in a US Federal government funded study, you should check with the funder as to whether it will be coordinating the posting, or whether it is something that the Lead Investigator must do. If you are responsible for clinical trial registration, it is likely that you will be responsible for posting of the consent form.