UCI Office of Research
News & Announcements

Posting an Informed Consent Form for Federally Supported Clinical Trials

Background

The Department of Health and Human Services (HHS) Regulation ("revised Common Rule") requires a clinical trial *conducted or supported* by a Common Rule *department or agency* to post a copy of the approved consent form to a publicly available federal website within a specific timeframe.

On May 17, 2019, the National Institutes of Health (NIH) published guidance for this HHS requirement. *Other* Common Rule *departments and agencies* plan to develop similar guidance - the intention is to aim for a common policy across HHS.

NIH Policy (NOT-OD-19-110)

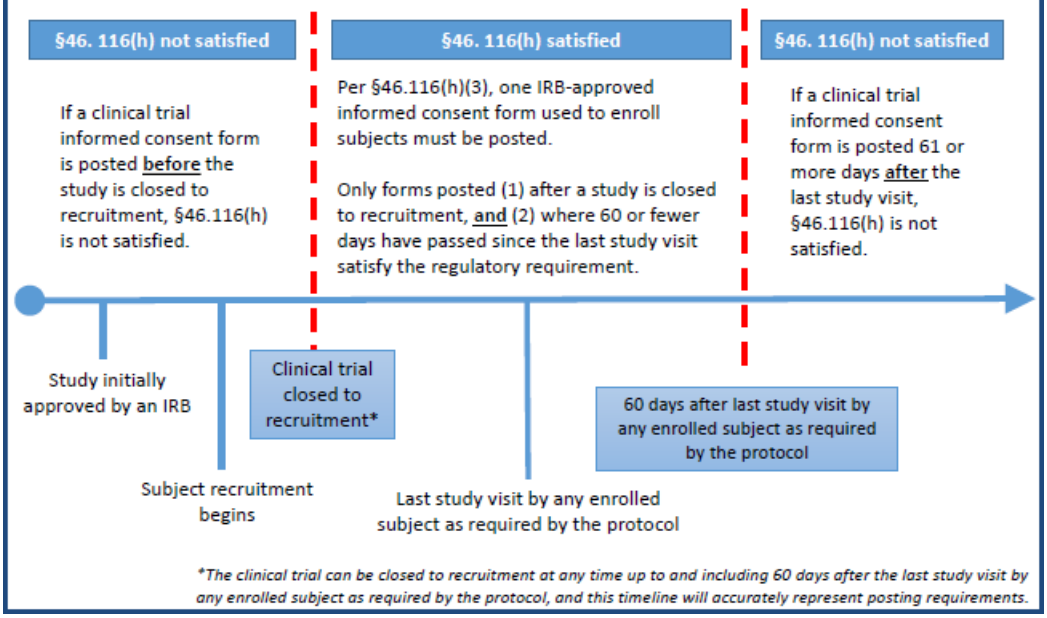
- Scope:
  - *funded* Clinical Trials *as defined* in 45 CFR 46.102(b)
- Application of the requirement:
  - a copy of an IRB-approved English-language consent form may be uploaded to:
    - ClinicalTrials.gov, or
    - Regulations.gov
  - for studies that *use only* non-English consent forms, the copy of the IRB-approved translated consent form may be uploaded to:
    - Regulations.gov
- **Important note:** *upload one blank copy of the approved consent form* (to protect research participant privacy), and *adhere to any applicable terms and conditions of the NIH award*

HHS Regulation [45 CFR 46.116(h)]

- Scope:
  - Clinical Trials [*as defined* in 45 CFR 46.102(b)] *conducted or supported* by a Common Rule *department or agency*
- Specifics of the **requirement**:
  - trials initiated ≥ 1/21/19 must adhere to the 2018 HHS requirement
  - trials initiated < 1/21/19 do not require consent forms to be posted
  - uploading a consent form to Regulations.gov are for trials that are not already registered on ClinicalTrials.gov, or for trials that *only use* a *translated* consent form
  - only one consent form is required to be uploaded even if there are multiple consent forms for different populations / phases in the research
- OHRP Timelines:

Timeline 1a: Informed Consent Posting Requirement for Studies Initially Approved on or after January 21, 2019

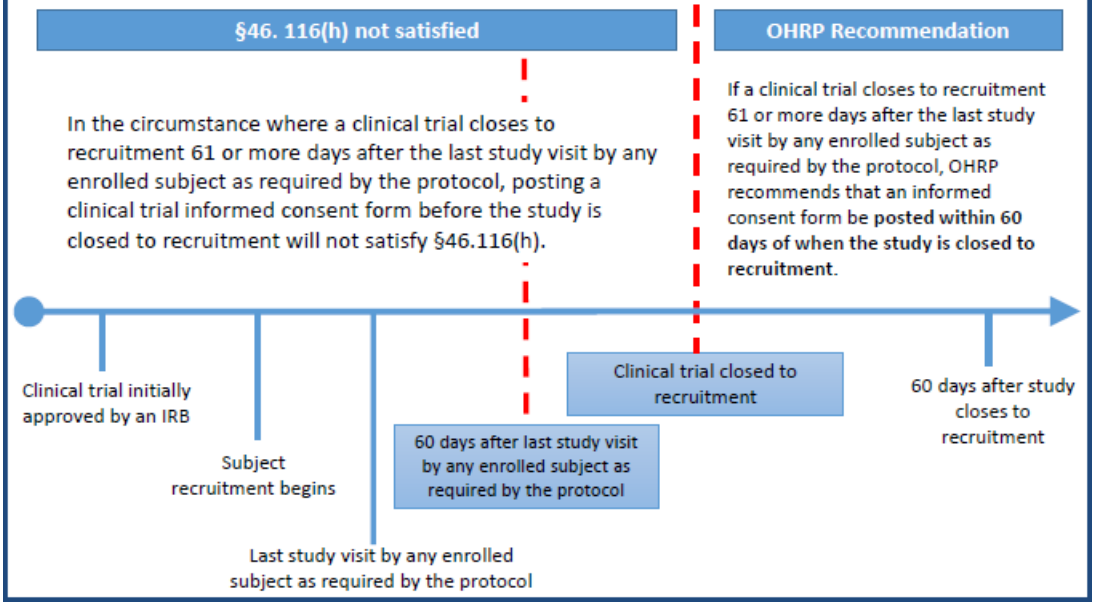
(As described in the regulations)

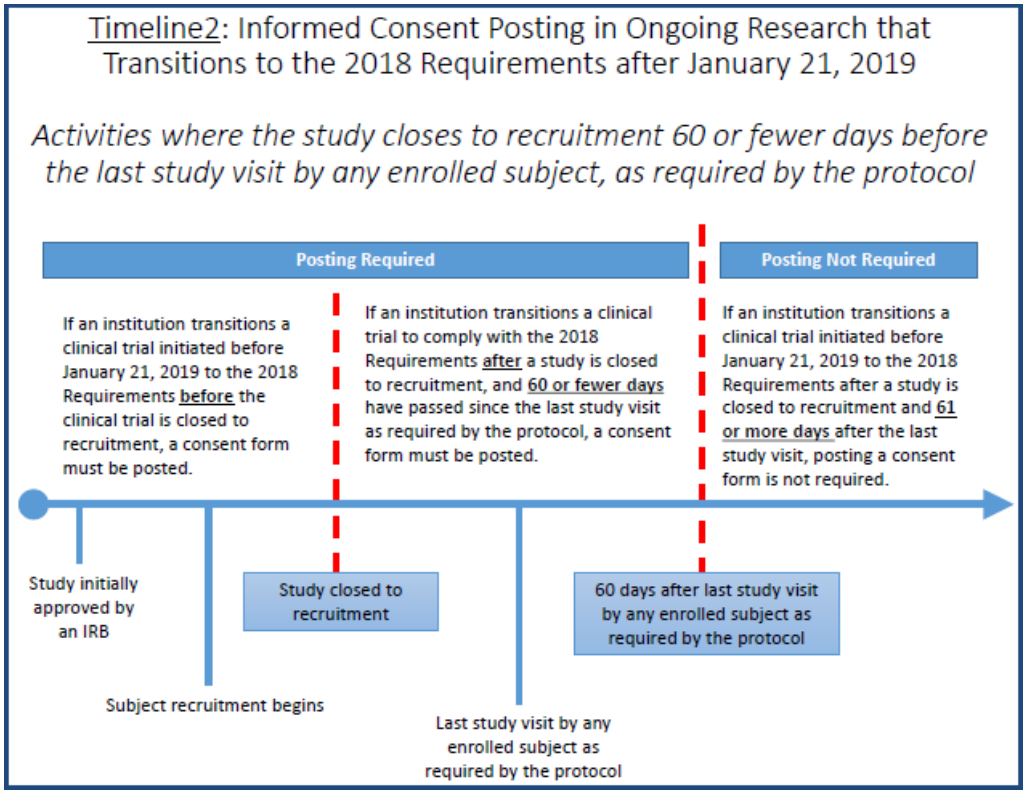


**The clinical trial can be closed to recruitment at any time up to and including 60 days after the last study visit by any enrolled subject as required by the protocol, and this timeline will accurately represent posting requirements.*

Timeline 1b: Informed Consent Posting Requirement for Studies Initially Approved on or after January 21, 2019

(When the study closes to recruitment 61 or more days after the last study visit)





Additional guidance:

- NIH: https://grants.nih.gov/policy/clinical-trials/informedconsent.htm
- OHRP: https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html