

# 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.

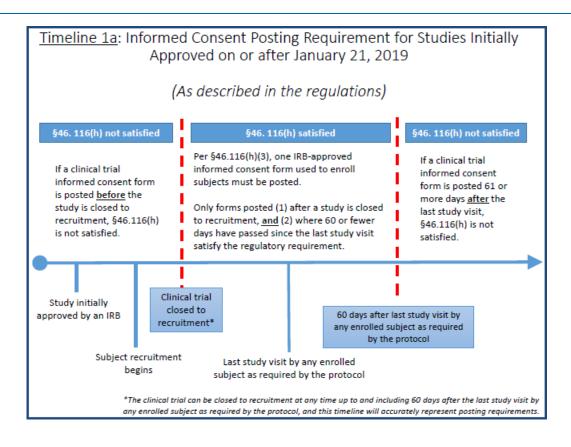
On May 17, 2019, the National Institutes of Health (NIH) published guidance for this HHS requirement. *Other* Common Rule *departments and agencies* plan to develop similar guidance - the intention is to aim for a common policy across HHS.

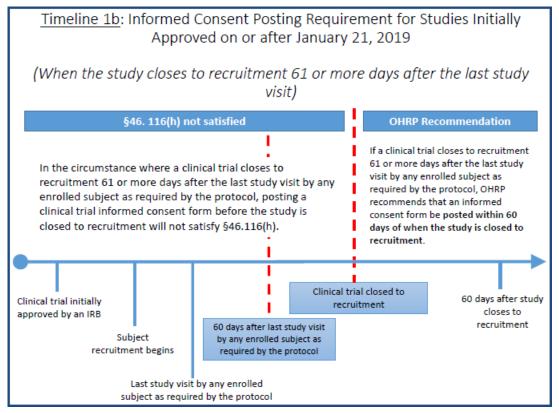
## NIH Policy (NOT-OD-19-110)

- 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* <u>non-English</u> consent forms, the copy of the IRB-approved translated consent form may be uploaded to:
    - Regulations.gov
- Important note: upload <u>one blank copy</u> of the approved consent form (to protect research participant privacy), and adhere to any applicable <u>terms and conditions of the</u> 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 <u>adhere to the 2018 HHS requirement</u>
  - trials initiated < 1/21/19 do not require consent forms to be posted</li>
  - uploading a consent form to Regulations.gov are for trials that are <u>not</u> already registered on ClinicalTrials.gov, or for trials that <u>only use a translated consent</u> form
  - <u>only one</u> consent form is required to be uploaded even if there are multiple consent forms for different populations / phases in the research
- OHRP Timelines:





Timeline2: Informed Consent Posting in Ongoing Research that Transitions to the 2018 Requirements after January 21, 2019 Activities where the study closes to recruitment 60 or fewer days before the last study visit by any enrolled subject, as required by the protocol **Posting Required Posting Not Required** If an institution transitions a clinical If an institution transitions a If an institution transitions a trial to comply with the 2018 clinical trial initiated before clinical trial initiated before Requirements after a study is closed January 21, 2019 to the 2018 January 21, 2019 to the 2018 to recruitment, and 60 or fewer days Requirements after a study is Requirements before the have passed since the last study visit closed to recruitment and 61 clinical trial is closed to as required by the protocol, a consent or more days after the last recruitment, a consent form form must be posted. study visit, posting a consent must be posted. form is not required. Study initially 60 days after last study visit Study closed to approved by by any enrolled subject as recruitment an IRB required by the protocol Subject recruitment begins Last study visit by any enrolled subject as required by the protocol

# 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



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