

The Informed Consent Posting Requirement, 45 CFR 46.116(h)

Julia Gorey, JD

Division of Policy and Assurances
HHS Office for Human Research Protections ([OHRP](#))

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Regulations, Policy & Guidance

OHRP has published a variety of policy and regulatory guidance materials to assist the research community in conducting ethical research that is in compliance with the HHS regulations. These include guidance documents and frequently asked questions (FAQs) addressing various topics, findings in the form of OHRP letters addressing regulatory issues, and other media including decision tree graphics and educational videos.

I would like info on...

- > [The documents that are open for public comment](#)
- > [Human Subject Regulations Decision Charts](#)

Belmont Report

Read the Belmont Report and learn about its history.

Informed Consent Posting 45 CFR 46.116(h)

- The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, **one** consent form must be posted on a publicly available federal website within a specific time frame
- The consent form must have been used in enrolling participants in order to satisfy this new provision
- At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified:
 - [ClinicalTrials.gov](https://clinicaltrials.gov)
 - A docket folder on [Regulations.gov](https://www.regulations.gov) (Docket ID: HHS-OPHS-2018-0021)
- OHRP recently issued guidance and instructions on this posting requirement

The Basics of Complying with 45 CFR 46.116(h)

Posting is required for:

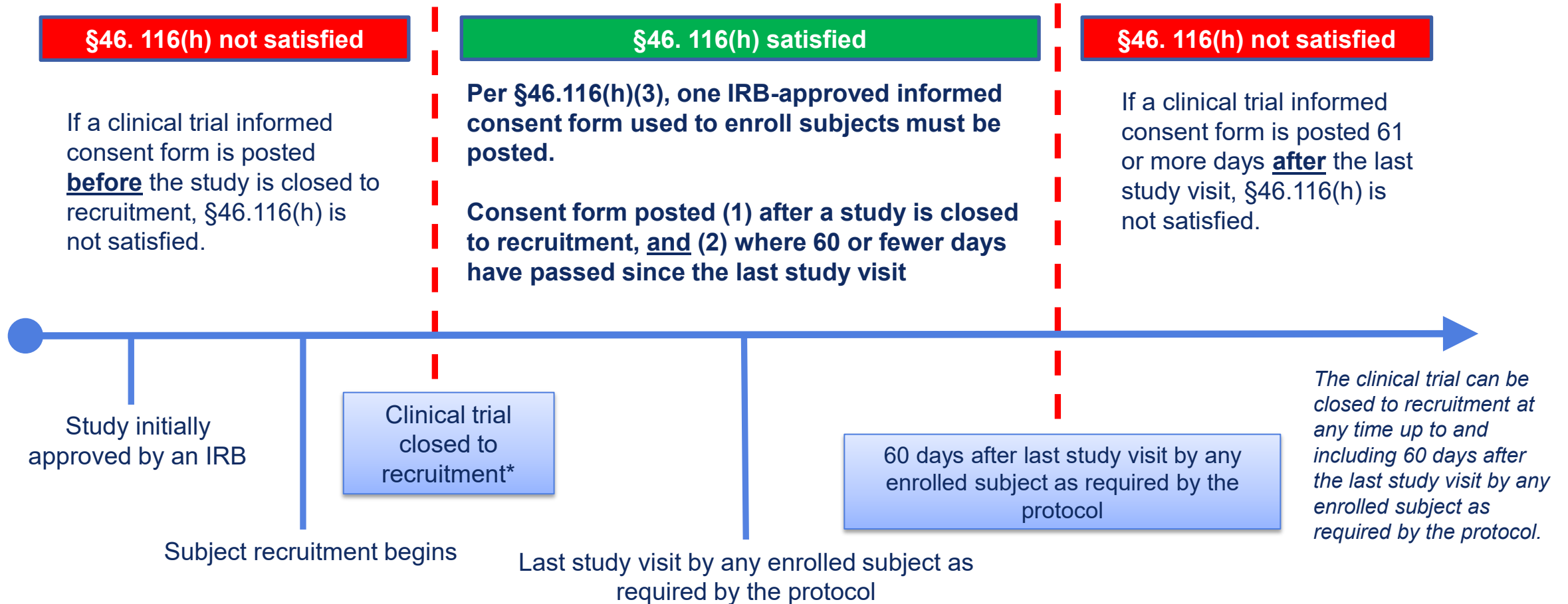
1. Clinical trials conducted/supported by HHS initially approved ON or AFTER January 21, 2019, or
2. Clinical trials conducted/supported by HHS initially approved BEFORE January 21, 2019, that continue on or after January 21, 2019, and for which both are true:
 - Transitioned to comply with 2018 Requirements (45 CFR 46.101(I))
 - Transition was documented and dated by the IRB or institution before timeframe specified in 45 CFR 46.116(h)(3) has passed

When Must the Informed Consent Form Be Posted?

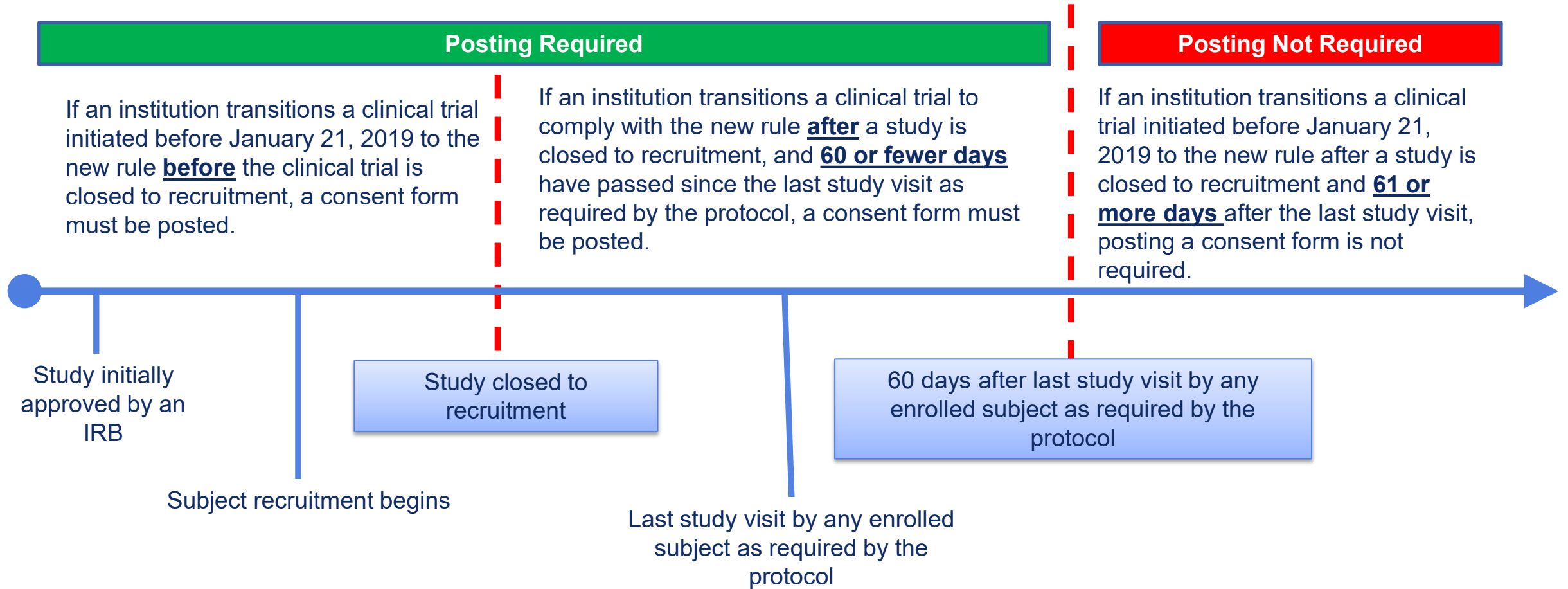
After the clinical trial has closed to recruitment, and no later than 60 days *after* the last study visit by any subject, as required by the protocol.

- While a consent form could be posted *before* a clinical trial closes to recruitment, it does not satisfy 45 CFR 46.116(h).
- OHRP's DCO recently updated its evaluation checklists to ask about the consent posting process and how institutions verify compliance with this regulatory requirement. OHRP expects this information to be part of institutional written procedures.

Informed Consent Posting for Studies Initially Approved On or After January 21, 2019



Clinical Trial Consent Form Posting in Transitioned Research



What is Considered the “Last Study Visit by any Subject”?

- Visit occurs only because of the research project (not because of clinical care)
- Does not have to be an in-person visit
- With respect to multisite studies, OHRP considers that the last study visit by any subject refers to the last study visit that occurs at any of the sites, *not* to the last study visit that occurs at a particular site.

Who May Post the Consent Form?

- The awardee or a federal agency component conducting a trial are responsible for compliance with the posting requirement. However, this responsibility may be assigned to an investigator or IRB staff person, or others.
- If multiple awardees or agency components are conducting the trial, any of these can post the form. However, remember- only ONE clinical trial informed consent form must be posted.

Cooperative Research Questions...

- How many ICF need to be posted?
One! Just one.
- If a trial involves multiple sites that close to recruitment at different times, what is the earliest an ICF can be posted to satisfy 46.116(h)?
When all sites have closed to recruitment.

Contacts and Resources

- Contact us or submit your questions to OHRP@hhs.gov
- Visit OHRP website at www.hhs.gov/ohrp

