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)

<table>
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<tr>
<th>$46.116(h) not satisfied</th>
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<tbody>
<tr>
<td>If a clinical trial informed consent form is posted before the study is closed to recruitment, $46.116(h)$ is not satisfied.</td>
<td>Per $46.116(h)(3)$, one IRB-approved informed consent form used to enroll subjects must be posted. Only forms posted (1) after a study is closed to recruitment, and (2) where 60 or fewer days have passed since the last study visit satisfy the regulatory requirement.</td>
<td>If a clinical trial informed consent form is posted 61 or more days after the last study visit. $46.116(h)$ is not satisfied.</td>
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*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.*

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**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)

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<th>$46.116(h) not satisfied</th>
<th>OHRP Recommendation</th>
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<td>In the circumstance where a clinical trial closes to recruitment 61 or more days after the last study visit by any enrolled subject as required by the protocol, posting a clinical trial informed consent form before the study is closed to recruitment will not satisfy $46.116(h)$.</td>
<td>If a clinical trial closes to recruitment 61 or more days after the last study visit by any enrolled subject as required by the protocol, OHRP recommends that an informed consent form be posted within 60 days of when the study is closed to recruitment.</td>
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*Clinical trial initially approved by an IRB*

Subject recruitment begins

Clinical trial closed to recruitment

60 days after last study visit by any enrolled subject as required by the protocol

Last study visit by any enrolled subject as required by the protocol

60 days after study closes to recruitment
Additional guidance: