New Requirement for Posting the Informed Consent Form per the revised Common Rule

Frequently Asked Questions (FAQ)

As of January 21, 2019, section 46.116(h)(1) of the revised Common Rule requires that an IRB approved version of informed consent form be posted on a publicly available Federal Web site after recruitment is closed and within 60 days after the last study visit by any subject. This FAQ has been developed to help the research community adhere to the new requirement.

The posting of the ICF is applicable to all clinical trials as defined by 45 CFR 46.102(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 behavioral health-related outcomes.*

Examples would include any trial using an intervention where Penn or a Penn Faculty member is the sponsor; including IND/IDE exempt trials that are receiving funding from a department that is required to follow the common rule for research (NIH, Department of Defense, etc.)

*What Clinical Trials are included in the scope of this requirement?*

This requirement applies to all clinical trials that must comply with the revised common rule inclusive of studies conducted or supported via funding by a Common Rule department or agency, such as the NIH. This requirement does not apply to trials “grandfathered” under the pre-2018 Common Rule. The requirement applies to all applicable Clinical Trials approved by the IRB on or after January 21, 2019.

*Where do I post the ICF?*

ClinicalTrials.gov. Follow instructions for uploading the ICF provided in the Document Section of the ClinicalTrials.gov website. [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/)

Exception: If the clinical trial is taking place in another country and the ICF is in a different language, post the consent form at [https://www.regulations.gov/](https://www.regulations.gov/)

*Which version of the ICF should I post?*

**Post a Blank (unsigned),** IRB approved version of the informed consent form to ClinicalTrials.gov. Only one version is required (even if there were multiple versions and sites) and there is no restriction as to which version is used. **Ensure that the version posted does not contain a subject’s signature and does not contain any PHI.**
Can I post the IRB approved version of the ICF when the clinical trial begins?
No as this will not meet the requirement of the revised Common Rule to post the ICF at the end of recruitment and within 60 days of last subject visit.

When should I post the unsigned IRB approved version of the ICF?
For single site trials post the ICF after recruitment has closed, and no later than 60 days following the last study visit by any subject. For multi-center trials, post the ICF after recruitment has closed for the trial and no later than 60 days of the LSLV at the last enrolling site.

What if I decide to recruit more subjects after the last subject last visit date (LSLV) has passed?
If a decision is made to extend the study recruitment period longer and enroll more subjects after the planned LSLV has passed, the ICF must be posted within 60 days of when recruitment for the extended period is closed.

Whom can I contact if I have questions?
The Office of Clinical Research (OCR) PRS Administrators are available to provide guidance for ClinicalTrials.gov postings. To contact OCR’s PRS administrators, please e-mail psom-ocrctgov@pobox.upenn.edu.

Additional Resources:
1. Federal Policy for the Protection of Human Subjects:
2. 45 CFR 46.116(h)(1)
4. Link to list of Common Rule Agencies -
5. KnowledgeLink Training for how to create and maintain ClinicalTrials.gov PRS records
6. OCR Procedure Clinical Trials.gov
7. ClinicalTrials.Gov PRS System Online Module – OCR
8. clinicaltrials.gov

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