Guidance on Posting Informed Consent Forms for NIH-Funded Clinical Trials

Notice Number: NOT-OD-19-110

Key Dates

Release Date: May 17, 2019

Related Announcements

NOT-OD-19-050

Issued by

National Institutes of Health (NIH)

Purpose

The purpose of this notice is to provide guidance to the extramural research community regarding where to post clinical trial informed consent forms, as required by Section 46.116(h) of the Revised Common Rule (Subpart A of 45 CFR 46).

For clinical trials conducted by or supported by a Federal department or agency, the Revised Common Rule requires the posting of an IRB-approved consent form on a public federal website designated for posting such consent forms. Recipients of NIH funding subject to the Revised Common Rule and conducting a clinical trial as defined in 45CFR46.102(b) must submit an IRB-approved consent form in accordance with Section 46.116(h).

- **NIH-funded recipients using an English-language informed consent form to enroll participants may either:**

Submit an IRB-approved English-language informed consent form to ClinicalTrials.gov. Documents that are uploaded to ClinicalTrials.gov should be uploaded in accordance with the instructions at https://prsinfo.clinicaltrials.gov/. ClinicalTrials.gov does not currently support upload of non-English documents. Or:

Submit an IRB-approved informed consent form to Regulations.gov following the instructions in the paragraph below. NIH recipients submitting informed consent forms to Regulations.gov should maintain a copy of their Regulations.gov receipt and tracking number.

- **NIH-funded recipients using only non-English informed consent forms to enroll participants**: Submit an IRB-approved informed consent form to Docket ID: HHS-OPHS-2018-0021 on the Regulations.gov website in accordance with guidance issued by the Office for Human Research Protections at https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html. NIH recipients submitting informed consent forms to Regulations.gov should maintain a copy of their Regulations.gov receipt and tracking number.

Institutions submitting documents to either ClinicalTrials.gov or Regulations.gov must protect participant privacy in accordance with applicable federal, state, and local laws and regulations (e.g., the HIPAA Privacy Rule, Certificates of Confidentiality) and any applicable terms of their NIH award.

Resources

- Additional information on posting clinical trial consent forms

https://grants.nih.gov/policy/clinical-trials/informedconsent.htm

- OHRP's draft guidance on the Revised Common Rule Compliance Dates and Transition Provision (45 CFR 46.101(l))

https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-revised-common-rule-compliance-dates-transition-provision-45-cfr-46-1011/index.html

- OHRP webpage with information of the Revised Common Rule's clinical trial informed consent form posting requirement

https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html

Inquiries

Please direct all inquiries to:

Office of Policy for Extramural Research Administration
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Email: grantscompliance@mail.nih.gov

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