

1.33 Posting of Clinical Trial Consent Forms

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for posting of clinical trial consent forms, per requirements of 45 CFR 46.116(h).

2.0 Policy

- **2.1.** It is the policy of the Organization that, for clinical trials conducted or supported by a Common Rule department or agency, the awardee of a grant will post one IRB approved informed consent form used to enroll subjects on a publicly available Federal Web site that will be established as a repository for such informed consent forms. Posting shall occur after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.
-

3.0 Definitions

- **3.1.** Clinical Trial (for the purpose of this Policy) 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 those interventions on health-related biomedical or behavioral outcomes."
-

4.0 Investigator Responsibilities

- **4.1.** If the UNMC/UNO/CHMC/BMC investigator is the awardee of the grant from a Common Rule agency or department, or is the principal investigator of a clinical trial conducted by a Common Rule agency or department, then he/she is responsible for posting the consent form as described in this policy.
- **4.2.** The PI must notify the ORA when the clinical trial is closed to recruitment.
- **4.3.** The PI must post one IRB approved unsigned consent form to [ClinicalTrials.gov](https://clinicaltrials.gov) (or other website as designated by OHRP) after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol (per 45 CFR 46.116(h)). In practice, the ORA requires that the consent form be posted

within 30 days of enrollment of the last subject.

- **4.3.1.** The consent form need not be the current version.
 - **4.3.2.** If there are multiple consent forms, only one must be posted. That is, if there are different consent forms for different classes of subjects (for example, for adults and for minors), or for different phases of the research (for example, screening and intervention) or for different interventions in different groups (for example, for an investigational group and a control group) only one needs to be posted.
 - **4.3.3.** If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (for example, confidential commercial information), such Federal department or agency may permit or require redactions to the information posted. Without such permission or requirement, the consent form must be posted as it had been approved.
 - **4.4.** The PI must notify the ORA when the consent form has been posted.
-

5.0 ORA Procedures

- **5.1.** At the time the ORA is notified that the clinical trial is closed to recruitment, the administrator will log the date into the RA database, and the ORA will notify the investigator of the requirements and advise that consent form must be posted within 30 days.
 - **5.1.1.** Notification of the ORA can come from the investigator (in the form of a completion report, or direct communication); from the Clinical Trial Management System (in the form of an automated notification when the last subject is accrued); or at the time of Continuing Review when status changes to “Subject Accrual Completed.”
 - **5.2.** After 30 days the ORA will query the investigator to verify that the consent form has been posted. In addition, the ORA may choose to review CT.gov to determine if consent form has been posted.
 - **5.3.** Failure to report relevant events (per section 4.2 and 4.4), or to respond the ORA queries, constitute non-compliance subject to disciplinary actions as per HRPP policy #8.5.
 - **5.4.** Failure to post consent forms as per section 4.3 constitutes serious non-compliance subject to disciplinary actions as per HRPP policy #8.5, and per the Office of the Vice-Chancellor for Research.
-

DOCUMENT HISTORY:

? Written: 2/27/2019 (Approved: 2/27/2019) - original author not recorded

? Revised: 9/18/2019 - revision not documented

Revision #6

Created 21 October 2019 21:55:09 by Autumn M Eberly

Updated 31 August 2023 19:41:13 by Robert A Lewis