Department:	**UAMS Institutional Review Board**
Policy Number:	**15.6**
Section:	**Consent**
Effective Date:	**August 15, 2022**
Revision Date:	

SUBJECT: Posting of Clinical Trial Consent Forms for Clinical Trials Conducted or Supported by a Federal Agency

POLICY

The 2018 Common Rule requires one IRB-approved consent form used to enroll subjects be posted to a publicly available Federal Web site for non-exempt clinical trials conducted or supported by a Federal department or agency. The consent form must be posted on the Federal Web site 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. The UAMS IRB will participate in the Human Research Protection Program's efforts to ensure this requirement is met.

This requirement does not apply to studies not subject to the Revised Common Rule.

DEFINITIONS

Clinical trial – 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.

PROCEDURE

A. The requirement to post consent forms as described in this policy applies to two categories of clinical trials conducted or supported by HHS:
   1. Nonexempt clinical trials initially approved by an IRB on or after January 21, 2019.
   2. Nonexempt clinical trials initially approved by an IRB before January 21, 2019, that continue on or after January 21, 2019, and for which both of the following are true:
      i. The clinical trial transitioned to comply with the 2018 requirements, and
      ii. The transition determination was documented and dated by the IRB before the posting timeframe has passed, i.e. the clinical trial is closed to recruitment and 60 or fewer or days before the last protocol-required study visit by any enrolled subject.

B. IRB Responsibilities
   1. IRB staff will assess continuing review forms and study closure forms to determine if the form pertains to a clinical trial subject to this reporting requirement.
   2. If a continuing review form indicates recruitment has ended and all subjects have completed study activities, IRB staff will discuss with the study staff whether the consent form should be posted.
   3. IRB office staff will also contact the study team if the closure form appears to pertain to a clinical trial to which this posting requirement applies.
   4. IRB staff and study staff will collectively determine who is responsible for ensuring the consent form is posted as required and will proceed accordingly.
   5. IRB staff may consult ORRA for assistance on studies meeting this posting requirement that are already listed on clinicaltrials.gov.

REFERENCES

45 CFR 46.116(h)
AAHRPP Standard II.3.F
OHRP Informed Consent Posting Guidance