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1. PURPOSE

1.1. This policy establishes the posting of clinical trial consent forms to a federal website.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

- 3.1. The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a federal department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal department or agency. 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 website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.
- 3.2. Until further guidance is provided by the appropriate federal agency, when MU is the primary awardee, the investigator should consult with the grant officer regarding how to satisfy this requirement.