

**Policy:** Federal Policy for the Protection of Human Subjects "Common Rule"

<https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>

**Common Rule – ICF Upload:**

Requires any clinical trial conducted or supported by a Common Rule department or agency to post on a publicly available federal website<sup>1</sup> a trial consent form (ICF) within a specific period. The consent form must have been used in enrolling participants to satisfy this new provision. Posting requirements:

- Supported by a Common Rule department or agency
- Meets the definition of a clinical trial
- Any study ICF that is IRB-approved<sup>1</sup>
- Posting must occur after the clinical trial is closed to recruitment, no later than 60 days after the last study visit by ANY subject, as required by the protocol.

**Institutional Common Rule – ICF Upload Requirements:**

- ClinicalTrials.gov is our determined repository
- At the time of enrollment closure, upload the most recent IRB-Approved version of the consent form used to consent at least one participant.
  - Upload a blank form
- The Responsible Party is to refer to their granting department or agency for more information when requesting redactions to the informed consent form prior to posting.

**ICF Language:**

Any time a trial is in ClinicalTrials.gov specific disclosure language needs to be in the ICF. The language below is provided in the University of Utah IRB consent template:

*"A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

It is best practice to keep the above template language in the consent.

Informed Consent Resources: <https://irb.utah.edu/forms/index.php>

**Common Rule Departments/Agencies:<sup>1</sup>**

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

- Department of Homeland Security, Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Consumer Product Safety Commission, Social Security Administration, Agency for International Development, Department of Housing and Urban Development, Department of Labor, Department of Defense, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, Department of Health and Human Services (Food and Drug Administration not included), National Science Foundation, and Department of Transportation.

<sup>1</sup> Common Rule agencies are subject to change. Please review the web link to verify that no new agencies are listed.