**UConn / UConn Health**

**Guidance for Posting Clinical Trial Consent Forms:**

**Purpose:**

In January of 2019 a revised version of the federal regulation regarding the protection of human subjects in research (i.e. 45 CFR 46) took effect. One of the revisions to 45 CFR 46 Subpart A, also referred to as the Common Rule, requires that for any clinical trial conducted or supported by a Common Rule department or agency, one IRB-approved consent form that was used to enroll subjects be posted on a publicly available federal website within a specific time frame. The purpose of this document is to inform the research community of this requirement and to provide guidance for how to fulfill this requirement.

**Applicability:**

This guidance applies to any prime awardee of a federal grant from a Common Rule Agency (see Appendix A) that is used to support a biomedical clinical trial or social and behavioral clinical trial at UConn or UConn Health which was approved by the IRB on or after January 21, 2019. This guidance also applies if the federally supported clinical trial was initially approved prior to January 21, 2019 but subsequently transitioned to become compliant with the revised version of the regulation. Both UConn and UConn Health are transitioning all federally funded studies to become compliant with the revised regulation as the studies come due for continuing approval.

Clinical trial is defined as 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.

Therefore, if the answer to each of the following questions is yes this guidance is applicable:

1. Is your 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 (i.e., a clinical trial)?

2. Is your trial funded by a Federal department or agency that applies the Common Rule?

**Requirement:**

The revised version of 45 CFR 46 contains the following requirement:

For each clinical trial conducted or supported by a Federal department or agency that subscribes to the Common Rule, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms.

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), such Federal department to agency may permit or require redactions to the information posted.

The goal of this requirement is to increase transparency for federally-funded clinical trials and simultaneously improve quality by creating a repository of sample consent forms that may be used as a reference for future research.

**What to Post:**

An IRB-approved consent form that was used to enroll one or more subjects is required to be posted.

If there is more than one IRB-approved consent form that has been used to enroll subjects associated with the clinical trial (e.g. a different consent for each arm of the study) only one form is required to be posted.

The version of the informed consent form that should be posted is the most recent IRB-approved version that was used to enroll a subject. However, if after posting the document the informed consent form is subsequently revised, the posted version does not have to be replaced.

Any requests to redact certain information from the informed consent form prior to posting must be submitted to the Federal department or agency supporting the clinical trial. Only the Federal agency supporting the clinical trial may permit or require redactions to the information posted.

***The posted consent document must never contain the signature of a subject in the trial.***

**When to Post:**

An IRB-approved informed consent form that was used to enroll subjects must be posted on a Federal website 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.

**Where to Post:**

When posting an English language IRB-approved informed consent form that was used to enroll subjects, the document can be submitted to either [ClinicalTrials.gov](https://register.clinicaltrials.gov/) or to regulations.gov [Docket ID: HHS-OPS-2018-0021](https://www.regulations.gov/docket?D=HHS-OPHS-2018-0021). If the clinical trial is already registered on ClinicalTrials.gov that website should be selected. If selecting regulations.gov, maintain a copy of the regulations.gov receipt and tracking number.

If a trial used only a non-English IRB-approved consent form to enroll subjects, the document must be submitted to [Docket ID: HHS-OPS-2018-0021](https://www.regulations.gov/docket?D=HHS-OPHS-2018-0021) on the regulations.gov website and the regulations.gov receipt and tracking number should be maintained. At this time ClinicalTrials.gov can only accept documents in English.

When submitting to ClinicalTrials.gov, if the trial is already registered on that site, documents are to be uploaded in accordance with the instructions posted in section [A.1 Document Upload Information](https://prsinfo.clinicaltrials.gov/results_definitions.html#DocumentUpload) within the document titled ClincialTrials.gov Results Data Element Definitions for Interventional and Observational Studies. The consent form should be uploaded at the time the overall status is updated to reflect the trial is closed to enrollment and no later than 60 days after the last study visit by any subject, as required by the protocol. General points to keep in mind when uploading to ClinicalTrials.gov include the following:

* The document date to be entered is the date of IRB approval that is stamped on the consent document.
* The consent form is to be accompanied by a cover page that contains the following elements:
	+ Study Title
	+ Document Date (i.e. date of IRB approval stamped on the consent form)
	+ NCT number (the unique identification code given to the clinical study record registered on ClinicalTrials.gov; also called the ClinicalTrials.gov identifier
* The consent form and corresponding cover page must be saved in a PDF/A format for uploading.

When submitting to regulations.gov, [detailed instructions](https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html) for posting to the specific docket folder are available on that website.

***The posted consent document must never contain the signature of a subject in the trial.***

**Responsible Party:**

The prime awardee of the grant is responsible for ensuring that the posting of the IRB-approved consent form is done within the required time frame. The prime awardee of the grant may submit the document; may obtain and keep confirmation that the funding department or agency will post the document; or may delegate the task; however that delegation should be documented and the prime awardee still retains ultimate responsibility.

**Support:**

For assistance with uploading to ClinicalTrials.gov at UConn or UConn Health, please contact Ellen Ciesielski, eciesielski@uchc.edu, 860-679-6004.

Inquiries may also be directed to the Office of Policy for Extramural Research Administration by Email to grantscompliance@mail.nih.gov or by calling 301-435-0949.

**References:**

[45 CFR 46.116(h)(1-3)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-110.html)

[NOT-OD-19-110, May 17, 2019](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-110.html)

[Clinical Trial Informed Consent Form Posting](https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html)

[Johns Hopkins Guidance](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/posting_cf_federally_funded_clinical_trials.html)

[University of Washington Guidance](https://www.washington.edu/research/hsd/clinical-trials/how-to-post-a-consent-form-to-a-federal-website/)

**Appendix A**

**Federal Departments and Agencies that Apply the Common Rule**

Agency for International Development; 22 CFR 225

Department of Agriculture; 7 CFR Part 1c

Department of Commerce; 15 CFR Part 27

Department of Defense; 32 CFR Part 219

Department of Education; 34 CFR Part 97

Department of Energy; 10 CFR Part 745

Department of Health and Human Services; 45 CFR Part 46

Department of Homeland Security; 6 CFR Part 46

Department of Housing and Urban Development; 24 CFR Part 60

Department of Labor; 29 CFR Part 21

Department of Transportation 45 CFR Part 11

Department of Veterans Affairs; 38 CFR Part 16

Environmental Protection Agency; 40 CFR Part 26

National Aeronautics and Space Administration; 14 CFR Part 1230

National Science Foundation; 46 CFR Part 690

Social Security Administration; 20 CFR Part 431

**Appendix B**

**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.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention: Both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical records).

Identifiable Private Information/Identifiable Biospecimen: Private information or a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimen.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.