Clinical Trials Registration and Reporting Policy

Uniform Guidance Requirements and Seattle University Procedures

Responsible Offices:	Office of Sponsored Projects (OSP), Institutional Review Board (IRB)
Effective Date:	January 31, 2022
Applicable regulations:	NIH NOT-OD-16-149; 42 CFR 11.10(a); 81 FR 65139

Purpose

The following policy and procedure ensures Seattle University remains compliant with the applicable regulations regarding clinical trial studies.

Policy Statement

Public registration and reporting of clinical trials are required if:

- The project/ clinical trial is funded in part or whole by the National Institutes of Health, as directed by the "NIH Policy on Dissemination of NIH-Funded Clinical Trials Information" for competing applications and contract proposals submitted on or after 1/18/2017.

- The study qualifies as an Applicable Clinical Trial (ACT), regardless of funding source, under 42 CFR 11.22(b) for Clinical Trials on or after 1/18/2017. This includes:
    - Controlled clinical trials of FDA-regulated drugs or biologics (Phases II - IV); and
    - Controlled clinical trials and pediatric post-market surveillance of FDA-regulated devices (other than small feasibility studies).

Clinical trials registration and reporting requirements include:

- **Registration** – The study must be registered on ClinicalTrials.gov within 21 days after the first subject is enrolled.
- **Updates** – The information in the clinical trial records must be updated at least once every 12 months.
- **Results** – The study results must be reported on ClinicalTrials.gov within 1 year of the final collection of data.

Definitions

- Clinical trial – per NIH definition, a clinical trial is 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.

- Applicable Clinical Trial – Under the Final Rule, which implements Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), two types of ACTs are defined: •
    - Applicable device clinical trial: (1) a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or

520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes); (2) a pediatric postmarket surveillance of a device product as required under section 522 of the FD&C Act (21 U.S.C. 3601); or (3) a clinical trial of a combination product with a device primary mode of action under 21 CFR Part 3, provided that it meets all other criteria of the definition under this part. [Source: 42 CFR 11.10(a); 81 FR 65139]

- Applicable drug clinical trial: a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the FD&C Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 and "phase 1" has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR Part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. [Source: 42 CFR 11.10(a); 81 FR 65139]

- Registration – for the purposes of this policy, registration refers to the registration of a clinical trial at clinicaltrials.gov

- Responsible Party - The individual responsible for registering a clinical trial/study. At Seattle University, the Principal Investigator (PI) is expected to take on the role of the Responsible Party.

- Protocol Registration and Results System (PRS) – name of online system used to register clinical trials

- PRS Administrator – the individual at Seattle University responsible for managing our Protocol Registration and Results System (PRS) organizational account and providing logins to new Responsible Parties

- NCT number – unique number assigned to a clinical study after the registration has been accepted in PRS

Procedures

1. Determine if your study is a clinical trial by answering the following four questions (or by using the NIH decision tool):
    a. Does the study involve human participants?
    b. Are the participants prospectively assigned to an intervention?
    c. Is the study designed to evaluate the effect of the intervention on the participants?
    d. Is the effect being evaluated a health-related biomedical or behavioral outcome?

    If you answered yes to all four questions, your study is a clinical trial.

2. Determine if your study is an Applicable Clinical Trial to understand which regulations and/or policies apply to your clinical trial.

a. Use the Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial Under 42 CR 11.22(b) or Clinical Trials Initiated on or After January 18, 2017

If your project is considered a clinical trial per step 1, the Responsible Party must register the clinical trial with clinicaltrials.gov

Per federal regulations and NIH policy, clinical trials must register **no later than 21 days after the first participant is consented**. Seattle University recommends registering before beginning participant enrollment.

Registration with clinicaltrials.gov

3. Request an individual account to clinicaltrials.gov - Responsible Party submits a Protocol Registration and Results System (PRS) Administrator Contact Form for a user login
4. Register the clinical trial – log into the PRS system
5. Select "New Record" from the quicklinks menu
    a. The responsible party should be the "record owner"
6. Enter the required data. Use the protocol, informed consent document(s), and IRB application to complete the registration.
    a. For more guidance, please review the Protocol Registration Data Element Definitions.
7. Review and submit the registration record
8. Verify in PRS that the Record Status is "released." Clinicaltrials.gov will not process the record unless it is released.
9. Anytime the Responsible Party releases a record, PRS staff will review it for any apparent errors, deficiencies, and/or inconsistencies based on the PRS Review Criteria (link is external). If PRS Staff identify potential issues with your record, they will add comments to your record. Major comments must be corrected or addressed. Comments identified as Advisory, should be addressed to improve clarity of the record. Once a record is released, the Responsible Party should:
    a. Monitor the record for any PRS review comments.
    b. Respond, in a timely fashion, to any communications from oversight units (i.e. Regulatory Affairs, ORCR, etc.) regarding PRS review comments related to your study record.
    c. Make corrections in response to PRS review comments within 15 days.
    d. Release the record for PRS review, once all corrections have been made.
10. Once the record is accepted by ClinicalTrials.gov staff for publication, the record, including its NCT Number, will be available on ClinicalTrials.gov within 2–5 business days.

11. **Once the NCT number is available, provide the NCT number to your Sponsored Research Officer in OSP for the number to be noted in your grant file, to be shared with IRB for their files, and to confirm registration of your clinical trial.**

Updating an active clinicaltrials.gov record

The Responsible Party must review and update, as necessary, an active study record **at least annually**. Failure to do so will result in the record being identified as having a problem that needs to be addressed.

Some updates must be made more frequently than annually. Specifically, the Responsible Party must update the registration record in ClinicalTrials.gov **within 30 days of a change** to the following:

- Overall Recruitment Status
- Individual Site Status (i.e., the recruitment status of each participating facility in a multi-site clinical study).
- Primary Completion Date
    - The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.

As a best practice, anytime you review or make a change to the record, update the record verification date to the current month and year before releasing it for review.

Reporting Clinical Trial Results

Summary results are required to be submit to clinicaltrials.gov **no later than one year after the clinical trial completion date.**

1. Review the requirements for reporting results
    a. Review the Results Data Elements Definitions(link is external) to understand what information is required.
    b. Review the guidance for each of the four required results modules(link is external), which are tabular summaries of:
        i. Participant Flow-the progress of participants through each stage of a study.
        ii. Baseline Characteristics-the data collected at the beginning of the study for all participants
        iii. Outcome Measures and Statistical Analyses-the pre-specified primary and secondary outcome measure values
        iv. Adverse Events-all anticipated and unanticipated serious adverse events and unanticipated other adverse events exceeding a frequency threshold of five percent (5%) within any arm of the clinical trial.
2. Complete the Results Modules
    a. Log into clinicaltrials.gov, open the applicable record, and select "Enter Results"
    b. Complete the required and optional data elements. See ClinicalTrials.gov Results Review Criteria(link is external) for guidance.
3. Upload Supplemental Documentation
    a. Full study protocol
    b. Statistical analysis plan – if separate from the protocol
4. Release the Record

5. Address PRS Review Comments

6. **Submit a copy of the summary report to your Sponsored Research Officer in OSP for inclusion with your file and to confirm the report has been submitted.**

Procedures adapted from the University of Michigan Research Ethics and Compliance online guidance (January 2022)

Related Policies & Forms

- Seattle University IRB Policies & Procedures