Northeastern University
Human Research

Guidance: Defining & Registering Clinical Trials

Overview

The Protocol Registration & Results System (PRS) is a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Federal Law (42 CFR Part 11) requires that certain clinical trials are registered and provide results information on ClinicalTrials.gov.

Information on ClinicalTrials.gov is provided and updated by the sponsor or Principal Investigator (PI) of the clinical trial or designee. Studies are registered on the website before commencing and updated throughout the duration of the study. On occasion, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry and results database."

NU-RES can assist PIs with account setup and registration, but it is the PI's responsibility to ensure their applicable study is registered on ClinicalTrials.gov.

Definitions

Federally funded studies that meet the NIH definition of a clinical trial and any study (regardless of funding) that meets the FDA definition of an applicable clinical trial must be registered.

NIH definition: 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.

FDA definition: Any experiment that involves a test article[1] and one or more human subjects and is subject to requirements for submission to the Food and Drug Administration. Clinical investigations must not be initiated unless that investigation has been reviewed and approved by an IRB.

Does your study meet NIH's definition of a clinical trial?

The NIH suggests the following four questions be addressed to determine if research efforts meets the definition of a clinical trial:

[1] FDA defines a test article as: any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Your study meets the NIH definition of clinical trial, even if:

- Your study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study utilizes a behavioral intervention
- Your study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon (See more information about Basic Experimental Studies with Humans).

Your study does not meet the NIH definition of a clinical trial when…

- Your study is intended to solely to refine measures.
- Your study involves secondary research with biological specimens or health information.

The NIH provides guidance and a decision tool to assist with understanding if your project meets the definition of a clinical trial.

Investigator responsibilities

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow requirements. The clinical research team may include but is not limited to the following members:

- Principal Investigator (PI)
- Sub-Investigator (Sub-I)
- Clinical Research Manager (CRM)
- Clinical Research Specialist (CRS)
- Clinical Research Coordinator (CRC)
- Clinical Research Assistant (CRA)
- Other Research Staff as appropriate
- Administrative & Support Staff

- Principal Investigators must ensure that all research personnel have completed all required training prior to conducting any research activities.
- For biomedical trials involving greater than minimal risk, Principal Investigators must ensure that a responsible person is available to provide medical care to research participants whenever the Principal Investigator is unavailable to provide said care.
- When a Principal Investigator leaves his/her position at Northeastern University, they are to perform one of the following actions with respect to all clinical trials and clinical investigations for which they are the Principal Investigator:

- Close the study.
- Transfer the study to a qualified Principal Investigator at NU.
- Work with IRB Administration to develop an alternative plan for supervision of the research.

Procedures

The steps detailed below briefly address registering and maintaining a study in clinicaltrials.gov. There is also a detailed User Guide for using the Protocol Registration & Results System (PRS).

- PRS User accounts are created, maintained, enabled and disabled by the PRS Administrator.
  - Principal Investigators require a PRS User account to be listed as the Responsible Party of a study. If an account is needed, the Principal Investigator can request one by contacting NU-RES.
  - The PRS administrator has the ability to change the ownership of the ClinicalTrials.gov record, as necessary.
  - An applicable clinical trial is entered by the PRS User.
  - Northeastern University is the study sponsor for NU investigator-initiated studies.
  - The Responsible Party is the protocol Principal Investigator.
- Once a protocol record has been published on ClinicalTrials.gov, it remains in the system even after a trial has closed and cannot be deleted.
- Records released to the public website are required to be updated periodically depending on the protocol's recruitment status.
  - Recruiting records require updates every six months.
  - Non-recruiting records require annual updates.
  - Responsible Parties should update their records within 30 days of a change to (i) recruitment status; (ii) overall recruitment status; or, (iii) completion date.
  - Results generally must be submitted not later than one year after the trial's primary completion date.
- After a protocol has been entered or updated and marked Complete, it must be Approved and Released by a PRS Administrator.
  - If the Investigator is designated as the Responsible Party for a study, that individual has the authority and responsibility to Approve and Release the record, even if not a PRS Administrator.
- The PRS Administrator has the overall responsibility to ensure that the organization's records are verified, updated, and re-released as needed, or at least every six months.
  - The PRS sends an automatic email notification to the PRS Administrator when a protocol is entered or modified in the registration database.
  - The PI will receive an automatic notification from the PRS to alert them that an update to their record is required If the PI has not completed the update within two weeks, the system will send a reminder notice. Failure to complete the

update within the deadline given in these notices will be deemed non-compliance with the requirement to register and maintain the record.

The NIH has additional guidance on specific topics, as follows:

Step 1	Determine if the competing application, contract proposal, funded grant, or awarded contract supports a clinical trial.
Step 2	Determine which regulations and/or policies apply to your NIH-funded clinical trial.
Step 3	Certify compliance in NIH grant applications, contract proposals and progress reports.
Step 4	Determine who is responsible for clinical trial registration and results reporting.
Step 5	Ensure the responsible entity registers the clinical trial no later than 21 days after enrolling the first subject.
Step 6	Ensure the responsible entity updates information in the clinical trial record at least once every 12 months.
Step 7	Ensure the responsible entity reports summary results not later than a year after clinical trial completion date.

Informed consent language

There is standard language that is to be incorporated when a study is defined as a clinical trial. The purpose of this is to notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank.

- NIH funded clinical trials that began on or after 1/18/2017 must refer to ClinicalTrials.gov in their informed consent document (unless they are conducted under a grant submitted prior to that date, with no competing renewals on or after 1/18/2017). The following language is to be incorporated in the informed consent documents.

  "This trial will be registered and may report results on https://www.ClinicalTrials.gov, a publicly available registry of clinical trials."

- FDA regulated studies, the following language is to be incorporated in the informed consent documents.

  "A description of this clinical trial will be available on https://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."

Facility Information

Facility Name: The full name of the organization where the clinical trial is being conducted.

Facility Location: To include city, state, country, and zip code for U.S. locations (including territories of the United States) and city and country for locations in other countries.

Contact Information (select one as applicable to the study):

- Facility Contact, including the name or title, telephone number, and email address of a person to whom questions concerning the trial and enrollment at that site can be addressed; or
- Central Contact Person, including the name or title, toll-free telephone number, and email address of a person to whom questions concerning enrollment at any location of the trial can be addressed.

Resources

ClinicalTrials.gov

Federal law (42 CFR Part 11)

Food & Drug Administration Regulations (50 CFR Part 21)

National Institutes of Health (NIH)

NIH Definition of *Clinical Trial*

NIH Decision tree for Clinical Trials

NIH Clinical Trial Registration Steps

National Library of Medicine

Protocol Registration & Results System (PRS) User Guide