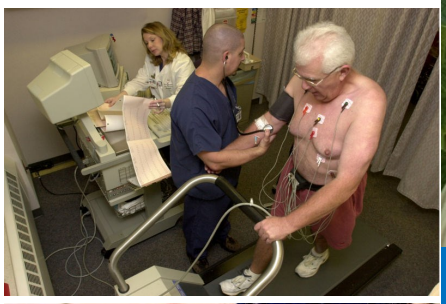


UNIVERSITY of DENVER

OFFICE OF RESEARCH & SPONSORED PROGRAMS
Research Integrity & Education

What You Need to Do When Your Research Meets the NIH Definition of a Clinical Trial

ClinicalTrials.gov

SECTION 1

Determine whether your research meets the NIH definition of clinical trial

NIH Definition of Clinical Trial

The following questions should be used to determine whether a study meets the NIH clinical trial definition:

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 on a health-related biomedical or behavioral outcome?**

If the answers are all "**YES**", then this is a clinical trial and you need to register your research on ClinicalTrials.gov.

If any answers are "**NO**", then this is not a clinical trial and you do not need to register your research.

Frequently Asked Questions NIH Clinical Trial Definition

Who can you contact if you have questions about registering your study or establishing a PRS account?

If you have questions or need help registering or updating your record, you can contact the **DU PRS Administrator** directly at mary.travis@du.edu or send an email to **register@clinicaltrials.gov** If the question is about a specific study record, you'll need to provide the NCT Number or the Unique Protocol ID (if an NCT Number has not yet been assigned).

NIH U.S. National Library of Medicine

ClinicalTrials.gov

SECTION 2 — Determine who will serve as the Responsible Party to register your research

When you are ready to register your research on ClinicalTrials.gov, a **Responsible Party** must be identified when setting up your account in the Protocol Registration and Results System (PRS).

The **Responsible Party** may be:

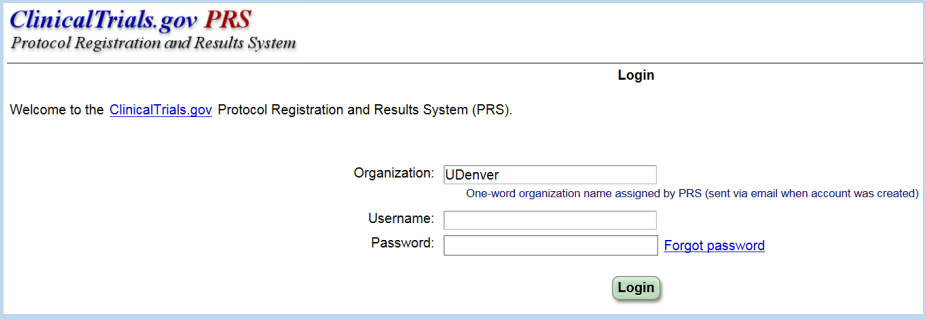
- the **Sponsor Organization** (a company, university, or other research organization that conducts clinical trials),
- the **User or Record Holder** (a PRS account holder who is authorized to enter information into the PRS, create and modify their own study record in the PRS) or
- the **PRS Administrator** (an individual designated by DU to manage DU's PRS account, create accounts for users, and serve as the point of contact for PRS staff and DU users.)

SECTION 3 — Obtain a PRS Account to Register Your Research on ClinicalTrials.gov

The Responsible Party (an individual or organization identified to enter information about the research study) must establish an account with the Protocol Registration and Results System (PRS) to register study information on ClinicalTrials.gov.

The University of Denver is included in the list of organizations with an established PRS organization account. The next step is for the Responsible Party (i.e., investigator) to establish a PRS Account for the research study and link it with the University of Denver account. The **DU PRS Administrator** can be contacted directly to request a username and password in order to register your research on ClinicalTrials.gov utilizing the PRS system.

Once a username and password is established in the PRS, the Responsible Party can log into PRS and begin entering study information into the online system. Refer to section 4 on 'Creating a ClinicalTrials.gov Record.'



SECTION 4

Creating a ClinicalTrials.gov Record

The ClinicalTrials.gov **Protocol Registration and Results System (PRS)** is a web-based tool used to submit clinical study information to ClinicalTrials.gov. All Responsible Parties must obtain a PRS Account prior to creating a ClinicalTrials.gov record for a study.

1. **Log into ClinicalTrials.gov PRS** (PRS URL: **https://register.clinicaltrials.gov**)
2. **Enter Organization**: **UDenver**
   User Name: (*must obtain user name from DU PRS Administrator*)
   Password: (*must obtain password from DU PRS Administrator*)
3. **Create a new record**
   The person who creates the record becomes the Record Owner. All email messages about the record will be sent to this person.
4. **Enter (or edit) study information**
   Provide information summarizing the study protocol, enter the Unique Protocol ID (IRBNet number), Brief Title, Study Type (interventional, observational, or expanded access), Outcome Measures, Arms and Interventions, Eligibility Criteria, Contacts, and Study Site Locations for your record on the Create New Record page.
5. **Submit the study record for PRS Review**
   After all study information is entered, the person entering the information clicks on the **Entry Complete**.
   The Responsible Party (the entity or individual responsible for verifying the accuracy of a study record and releasing it to ClinicalTrials.gov) for the study clicks on **Approve** to accept the content.
   The Responsible Party clicks on **Release** to submit the record for review by the PRS staff.
6. **PRS Staff reviews the record**
   After the Responsible Party releases the record, PRS Staff reviews it for apparent errors, deficiencies, and/or inconsistencies. If PRS Staff find any potential issues with the record, they will add comments to the record and send an email notification. The user must log into PRS to view the comments. He or she then edits the study record to address the comments and resubmits the record for PRS Review, using the same procedures described in steps 4 and 5.
7. **Record is registered and posted**
   Once the study record passes PRS Review, an email notification will be sent with the ClinicalTrials.gov identifier (**NCT number**), indicating that the study is registered. Generally, within 2 business days of registration, the system will post the record on ClinicalTrials.gov website. Once registered, a study record becomes a permanent part of ClinicalTrials.gov and cannot be removed.
8. **Keep record up to date**
   The study record needs to be verified and/or updated at least once a year (as described in steps 4 and 5), with some data elements requiring more rapid updates, until the study is completed and/or the PRS Review process has concluded for submitted results information.
9. **Add results**
   U.S. law requires some studies to submit results to ClinicalTrials.gov. Generally, results must be submitted within 1 year of the Primary Completion Date.

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SECTION 5

After You Register Your Study

If you need to Update/Modify User Information or Change Your Password—contact the **DU PRS Administrator.** Your Administrator can help answer questions about your account, updating record(s), or the PRS. The Administrator can also reset your password if you forget it.

PRS RECORD STATUS—As a record progresses through the PRS, its status changes

RECORD STATUS	DESCRIPTION
In Progress	User is creating (or modifying) the record.
Entry Completed	User has finished and clicked on **Entry Complete**. Record is ready for review by Administrator (or Responsible Party).
Approved	Administrator (or Responsible Party) has reviewed record, made any necessary changes, and clicked on **Approve**.
Released	Administrator (or Responsible Party) has submitted the record to ClinicalTrials.gov by clicking on **Release**.
PRS Review	The record is currently being reviewed by the PRS Team. The record is locked while PRS Review is being performed.
Public	The record is or soon will be posted (or updated) on the ClinicalTrials.gov website.

When will the NCT Number for my study be assigned?

The NCT Number, also called the ClinicalTrials.gov Identifier, is assigned after the protocol information has been Released (submitted) by the Responsible Party and has passed review by ClinicalTrials.gov staff. At that time an e-mail notification containing the NCT Number is sent. The record, including its NCT Number, will typically be available on ClinicalTrials.gov within 2–5 business days after it is Released.

REFERENCE INFORMATION

DU PRS Administrator: Mary Travis (mary.travis@du.edu)

PRS URL: https://register.clinicaltrials.gov

U.S. National Library of Medicine https://clinicaltrials.gov

ClinicalTrials.gov

NIH National Institutes of Health https://nih.gov

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