

Instructions for ClinicalTrials.gov Protocol Registration and Results Reporting Guide

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies involving human participants conducted around the world. This document is a guide to assist Principal Investigators (PIs) within Rutgers University in creating a user account and registering a clinical trial all while navigating the ClinicalTrials.gov Protocol Registration and Results Reporting System (PRS) website. (For information about when you must register a study, please see [Rutgers Clinical Trials Registration and Results Reporting Policy](#))

STEP I: Create User Account

The Principal Investigator is ultimately responsible for ClinicalTrials.gov registration. However, he/she may designate an individual (e.g. a study coordinator) to enter protocol information into the ClinicalTrials.gov website. Each individual is advised to set up a user account by following the instructions below.

- 1. Submit your request:** Contact RU ClinicalTrials.gov Protocol Registration System (PRS) Administrator Rebecca Chen at (973) 972-2630 or chenr@research.rutgers.edu / rutgersctgsupport@research.rutgers.edu to create an account. Please include “ClinicalTrials.gov Account Request” in the email subject line and provide the following five items:
 - a. ClinicalTrials.gov user name:** Create a user name that you will enter each time you log-in.
 - b. Full name:** Your full name and credentials (i.e. MD, DMD, Ph.D., etc..)
 - c. Department and school:** List the department and school responsible for the study oversight.
 - d. Telephone number:** A phone number that will be used for ClinicalTrials.gov purposes; this could be work and/or personal phone number(s).
 - e. Email address:** An email address you will use for ClinicalTrials.gov purposes; this could be work and/or personal email(s).
- 2. Obtain login information:** the PRS will send an auto email to the email with user account login and initial password. Please be sure to check your junk/spam mailbox if you didn't seem to receive it in time. Once a user account is created the password may be changed at any time.
- 3. Login at:** <https://register.clinicaltrials.gov/>. Remember, Organization name **RutgersSUNJ** is case-sensitive, and is sent to you from the PRS system via an automatic email when your account was created.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

OMB NO. 0925-0586
EXPIRATION DATE: 02/28/2023
[Burden Statement](#)

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

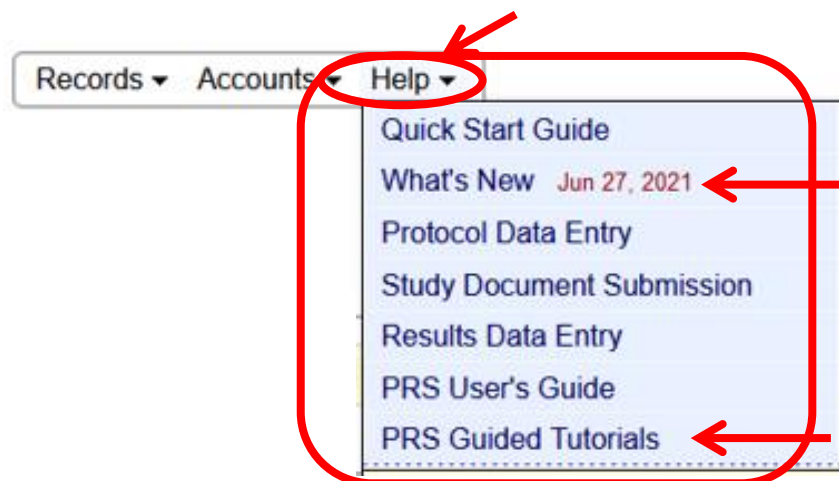
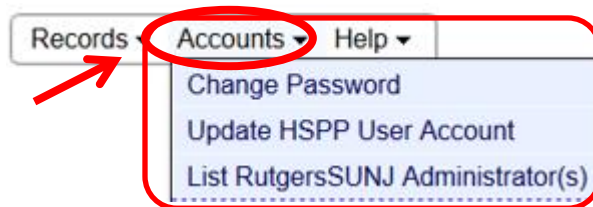
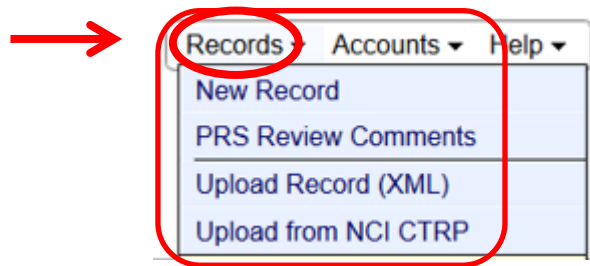
Password: [Forgot password](#)

Login

STEP II: Enter Study Information to Complete the Registration

With pertinent source information at hand, such as the protocol, informed consent document, and IRB application, protocol registration is expected to take 1-2 hours.

- ❖ **Navigate ClinicalTrials.gov PRS:** At the top left region of the ClinicalTrials.gov PRS homepage are three categories: **Records, Accounts, and Help**. These three functions allow you to create/edit protocol records, view QA review comments, and change your password and/or email associated with your user name. The **Help** section provides the most recent updates of the system, as well as helpful tools, such as the PRS Guided Tutorials, that can be used during protocol registration and results reporting.



1. On the menu, under Records, select “**New Record**” from the drop down and follow the instructions.



- **Organization’s Unique Protocol ID:** the RU assigned **IRB Protocol Number must be listed as the Unique Protocol ID.**

An IRB Protocol Number (starting with “**Pro**” when you create a record in eIRB) is assigned to the protocol when a new IRB application is created in the eIRB system. The investigator should initiate study registration on ClinicalTrials.gov once the IRB Protocol Number is available.

2. Note that the **ClinicalTrials.gov** required fields are marked with a red asterisk (*).

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

- If the required fields are left blank, the registration will be considered incomplete and therefore, an NCT Number (National Clinical Trial number, also called the ClinicalTrials.gov identifier) will not be assigned.
- Each field is labeled and linked to a definition. It is strongly recommended that you refer to the definitions to ascertain the accuracy of study information you provide.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Create New Record

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:

* Brief Title:

[Special Characters](#)

3. As you navigate through the pages, there are several fields which should be completed as follows:

- **Secondary ID:** Provide NIH Grant/Contract Award Number, other grant/funding number, unique identifiers from other registries etc., if applicable.

† Secondary IDs: (if any)

* US NIH Grant/Contract Award Number:	Examples: R01DA013131, U01HL066582, 5R01HL123451-01A2 Tip: Look up the grant/contract number using NIH RePORTER .
* Other Grant/Funding Number:	* Grantor or Funder:
+ Add Secondary ID	

- **Record Verification Date:** Enter the month and year in which the record is completed and submitted. Once the study is completely registered, you should enter the date the protocol information was last verified, even if no other changes are made.

Note: This field generates automatic reminders for required updates, do not leave it blank.

* † Record Verification Date: --Select-- Year:

- **Responsible Party (RP):** For trials not conducted under an IND or IDE, the **Principal Investigator** listed on the protocol is the RP, and must be indicated as such in the RP field in ClinicalTrials.gov at the time of registration. For trials conducted under IND or IDE, the IND/IDE holder is responsible and the **Sponsor-Investigator** is the RP and must be so designated in the RP field at the time of registration. **The RP must release the record for review by ClinicalTrials.gov.** Definition of an RP can be found at the [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial](#) (PDF) and the [Responsible Party data element](#) on ClinicalTrials.gov.
- **Sponsor:** The database will default to “Rutgers, The State University of New Jersey.” Although Rutgers is not actually the financial sponsor, choose “Rutgers, The State University of New Jersey.”

[Help](#) [Definitions](#)

* † Responsible Party:

Select **Sponsor** unless the Investigator has been designated as Responsible Party per FDAAA.

For Principal Investigator or Sponsor-Investigator only, provide:

Investigator Name [Username]: --Select--
Select the investigator's PRS account.
The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.
[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title:

Investigator Affiliation:

* † Sponsor:

Primary organization conducting study and associated data analysis (not necessarily a funding source).

- **Oversight:** *Board Name/Board Affiliation/Board Contact:* Please follow below to provide the requested information accordingly.

- **Board Name:** Rutgers IRB
- **Board Affiliation:** Rutgers, The State University of New Jersey
- **Board Contact:**
 - **Business Phone:** (732) 235-2866 / (732) 235-9806 / (973) 972-3608
 - **Business Email:** IRBOffice@research.rutgers.edu
 - **Business Address:** 335 George Street, Liberty Plaza, 3rd Floor, Suite 3100, New Brunswick, NJ 08901

- **Conditions, Keywords:** Use NLM’s Medical Subject Heading (MeSH) controlled vocabulary terms, avoid acronyms and abbreviations. If not, the ClinicalTrials.gov staff is likely to delete your term and choose one of their own.

[Help](#) [Definitions](#)

* † Conditions or Focus of Study: x Delete

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.
If there are no conditions under study, enter brief description of focus of study instead.

Keywords:

- **IPD Sharing Statement:** As a condition of publication of clinical trial results, [ICMJE journals](#) require that a data (IPD) Sharing statement be included in the ClinicalTrials.gov registration.

- Applies to clinical trials that begin enrolling participants on/ after 1/1/2019.
- The statement must be **in the original clinicalTrials.gov registration**.
- The **answer to “will data be available?” must be No or Yes**. Per official ICMJE correspondence – even though ClinicalTrials.gov provides an “Undecided” option.
- The answer can change; explain in the Plan Description when updating the record.
- Should match the data sharing statement required to be submitted (as of July 1, 2018) with the results manuscript for publication in ICMJE journals.

IPD Sharing Statement Examples:

Table. Examples of Data Sharing Statements That Fulfill These ICMJE Requirements*

ICMJE Questions	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (<i>Link to be included</i>).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (<i>Link to be included</i>).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (<i>Link to be provided</i>).	Not applicable

* These examples are meant to illustrate a range of, but not all, data sharing options.

4. Address common errors: Verify there are no warning messages or errors when completing the application. These are common errors which will prevent the approval/release of your registration.

ERROR(S) in Protocol Section. See ERROR or information required messages below. Additional information may be required per FDAAA. See WARNING messages below.

[Edit](#)


Study Status

Record Verification: March 2017

Overall Status:

 **ERROR: Overall Recruitment Status is a required field.**

Study Start:

 **WARNING: Study Start Date has not been entered.**

Primary Completion:

 **ERROR: Primary Completion Date has not been entered.**

Study Completion:

 **WARNING: Study Completion Date has not been entered.**

[Edit](#)

Oversight

U.S. FDA-regulated Drug:

⚠ WARNING: U.S. FDA Regulated Drug has not been entered.

U.S. FDA-regulated Device:

⚠ WARNING: U.S. FDA Regulated Device has not been entered.

U.S. FDA IND/IDE Study:

⚠ WARNING: U.S. FDA IND/IDE Study has not been entered.

Human Subjects Review: Board Status:

⚠ WARNING: Review Board Status has not been entered.

Data Monitoring:

Plan to Share IPD:

💡 NOTE: Plan to Share IPD? has not been entered.

[Edit](#)

Outcome Measures

Primary Outcome Measure:

1.

[Time Frame:] [Safety Issue:]

❌ ERROR: Outcome Measure Title is a required field.

⚠ WARNING: Safety Issue? has not been entered.

❌ ERROR: At least one Primary Outcome Measure must be specified.

❌ ERROR: Time Frame has not been entered.

STEP III: PI Review Registry Record to Complete Application Prior to Submission to the PRS Reviewers

Upon completion of information entry, the PI/ Responsible Party should review and verify study record information as necessary. Please ensure the Primary Completion Date reflects the study status. It is important that “Record Verification” is updated to reflect the most recent revision of the record.

Click ‘*Complete*’ when the application is completed in full and is ready to be submitted for review/ approval. This will notify the Institutional RU PRS Administrator that a record is pending his/her review and approval to the NLM ClinicalTrials.gov.

Record Status

In Progress → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Confirm data entry complete

Entry Complete ⓘ

STEP IV: ClinicalTrials.gov PRS Reviewers’ Review Prior to the Public Release

PIs are ultimately responsible for accuracy of the study information, and should address comments, if any, that the PRS Review Team provided, and revise accordingly.

Generally speaking, it takes approximately 1 – 3 weeks for a study record to be reviewed, approved and eventually released to the ClinicalTrials.gov public website. The length of the time is dictated by the number of rounds required for the PRS Team to review the record and the revisions made by the investigators to address comments from the PRS Reviewers. The PIs are ultimately responsible for ensuring that clinical trials are registered in a timely manner.

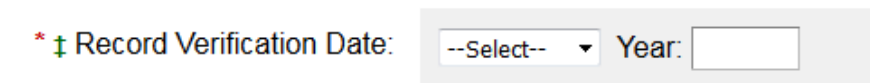
MANDATORY UPDATE

After initial registration of a clinical trial, it will be necessary to make updates to the record to reflect changes during the conduct of the trial. It is particularly important to keep the *Primary Completion Date* (anticipated or actual) current because it will impact when the basic results information needs to be entered for Applicable Clinical Trials under FDAAA, and all NIH-funded interventional studies.

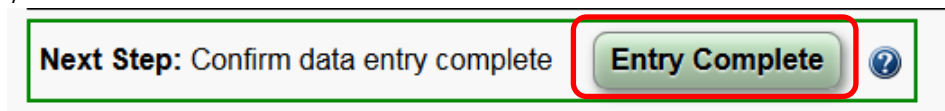
For Active Studies

- Registration information must be updated no less than once every **6 months**.
- If recruitment status for the study changes, (e.g., recruitment suspended), the registration must be updated within **30 days**.

1. Log into ClinicalTrials.gov and click on “Open” for the prospective study record.
2. If changes have been made to the protocol that affects information listed in the ClinicalTrials.gov registration, make appropriate changes.
3. **Always remember to update the Record Verification Date even if you didn't make any change to the record.**



4. Click “*Complete*” when completed in full for submission to the PRS Administrator for approval/release.



For Closed Studies

1. If the trial is complete (whether concluded or terminated prior to conclusion), registration must be updated within **30 days**.

POSTING of INFORMED CONSENT FORM:

- One IRB-approved informed consent used to recruit study participants is required of being uploaded to a publicly available federal website, such as ClinicalTrials.gov, after recruitment closes, and no later than 60 days after the last study visit, if applicable, per the [2018 Common Rule](#).

- Documents must be uploaded in PDF Archive (PDF/A) format. See [instructions](#) of converting files to PDF/A format.

REPORTING RESULTS

- Final and aggregate results including basic results and adverse events for Applicable Clinical Trials and NIH-supported studies are expected to be reported **within twelve (12) months of the trial's Primary Completion Date, regardless of whether the clinical trial was completed as planned or terminated prematurely.** The Principal Investigator is responsible for the provision, review, and approval of study data and results information that will be submitted.
 - Allow ample time for PRS Review, which include the time needed by the PRS reviewers to conduct the review, and the time needed by investigators to address the comments from the reviewers, if applicable, and re-submit.
- This requirement is irrespective of IRB regulations; the Principal Investigators/ Responsible Parties are ultimately responsible for fulfilling this disclosure requirements regardless the IRB status.
- Uploading of Study Protocol and Statistical Analysis Plan (SAP)** are required with results information submission for studies with a Primary Completion Date on or after January 18, 2017.
 - Be sure to redact proprietary and sensitive information.
 - Documents must be in English and in PDF Archive (PDF/A) format. See [instructions](#) of converting files to PDF/A format.
 - A cover page with official title, NCT number and document date must be included in each document.
- Detailed instructions for submission of study results may be obtained on the ClinicalTrials.gov website at <https://clinicaltrials.gov/ct2/manage-recs/how-report>.
 - Use [CONSORT Flow Diagram](#) to organize study information. Lay out study data with these tools: [Checklists and Templates for each of the four scientific modules](#)

ADDITIONAL INFORMATION:

1. I forgot my password, Help!

As long as you know your username and which email the account was set up with, you may request assistance on the ClinicalTrials.gov PRS login site:

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

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EXPIRATION DATE: 02/28/2023
[Burden Statement](#)

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

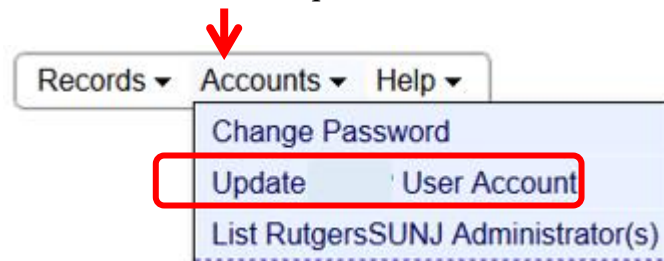
Username:

Password: [Forgot password](#)

You may also contact RU PRS Administrator Rebecca Chen at chenr@research.rutgers.edu, rutgersctgsupport@research.rutgers.edu, or (973) 972-2630 for assistance.

2. How do I change the email address associated with my username?

- **Login** at: <https://register.clinicaltrials.gov/>
- On the menu, under *Accounts*, choose “*Update User Account*”



- **Enter new email:** Messages from ClinicalTrials.gov will be sent to this address.

3. Resources: PRS User's Guide & PRS Guided Tutorials

The resources provide step-by-step instructions for entering, modifying, and releasing protocol records using the ClinicalTrials.gov Protocol Registration System.

- Go to: <https://register.clinicaltrials.gov/> and log into your ClinicalTrials.gov account.
- Select *User's Guide* and *PRS Guided Tutorials* in menu's Help Section list.

