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# PRS User's Guide

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## Overview

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing protocol records using the PRS. Records submitted through the PRS (<http://register.clinicaltrials.gov>) are available to the public at ClinicalTrials.gov (<http://clinicaltrials.gov>). A guided tour of the PRS and account application information are available at <http://prsinfo.clinicaltrials.gov/>

PRS users enter information about their clinical trials, ensuring that the information is correct, readily understood by members of the public, and updated in a timely manner.

PRS Administrators are responsible for the process by which clinical trial information is released to ClinicalTrials.gov on behalf of their organization. This process includes creating accounts for PRS users and editing and approving clinical trial records prior to initial release and after record updates. They serve as points of contact for the ClinicalTrials.gov team and resolve questions associated with the information that is provided.

The ClinicalTrials.gov team maintains the PRS and the ClinicalTrials.gov site and may make minor corrections to records.

## Procedures for Users

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## A. Log In to PRS

1. Go to <http://register.clinicaltrials.gov>.
2. Complete the three fields on the **Login** screen:
  - Organization: organization login name
  - Username: user login name
  - Password: (case-sensitive)
3. Click [Login] and the **Main Menu** of the PRS appears.
4. To log out of the PRS, select [Logout] from the **Main Menu** screen.

## B. Create a ClinicalTrials.gov Record

A record may be created at a single session or created and saved for completion at later sessions. To create a record during a single session:

1. Click [Create] from the **Main Menu** screen.
2. Enter the Unique Protocol ID and Brief Title for your record on the **Create New Protocol Record** screen.
3. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.
4. After clicking [Continue] on the final data entry screen (**Links**), click [OK] on the **Study Completed** screen.

To create a record and save for completion at later sessions, after step 2. (above) or any successive screen, click [Quit] to stop data entry

- Click [Save Protocol Record] to keep your data. The record is saved for later sessions.
- Click [Delete Protocol Record] to erase the record.

### Data entry tips:

Use language that is easily understood in Brief Summary.

Paragraph separation: leave a blank line between paragraphs (press enter twice).

Create lists:

- Keep each item on a separate line (press return after entering text for each line)
- Bullet items by starting each line with two spaces, a hyphen, and a space before entering the text
- Press return after text for each item

All of the data screens are clustered into 11 groups (by topic).

Click on any data entry field name to obtain a description of the field.

All fields may be modified at a later date.

Protocol records progress through the PRS with record status values as explained in the table below.

Description	Record Status
User is creating (or modifying) the record.	In Progress
User has finished - record is ready for review.	Completed
Administrator has reviewed record and has made any necessary changes.	Approved
Administrator has released the record to ClinicalTrials.gov.	Released

### C. Submit Record to Your Administrator

1. Click [Modify] from the Main Menu.
2. Click [Edit] next to the record you wish to submit.
3. Review and make any necessary changes indicated by messages below the data fields on the **Edit Protocol Record** screen:

 **ERROR** messages indicate serious problems that need to be addressed.

 **ALERT** messages indicate problems that need to be addressed.

 **NOTE** messages indicate potential problems that should be reviewed and corrected as needed.

4. After data entry for a record has been completed, enter any comments about the record for the Administrator and click [Complete] in the Record Status area of screen. This generates automatic e-mail notification to the Administrator that the record is complete.

Your Administrator will review the record. Approved records are released to [ClinicalTrials.gov](http://ClinicalTrials.gov).

### D. Modify Record

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be modified on the **Select Protocol Record - Edit** screen  
*Repeat steps 3-6 for all data fields to be modified.*
3. Locate the data field to be modified on the **Edit Protocol Record** screen.
4. Click on the corresponding [Edit] for that field.
5. Make changes on the data entry screen.
6. Click [OK] to save the changes and return to **Edit Protocol Record**.
7. Update Record Verification Date (using steps 3-6 above).

## E. View Record

1. Click [View] on the **Main Menu**.
2. Click [View] next to record to be displayed on the **Select Protocol Record - View** screen.
3. **View Protocol Record** is *read-only*. To edit records see [D. Modify Record](#).

## F. Preview Record as it Appears on ClinicalTrials.gov

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be previewed.
3. Click [Preview] to see the record displayed similar to how it appears on ClinicalTrials.gov.
4. Click [Continue] to return to the **Edit Protocol Record** screen.

## G. Delete Record

*NOTE: Protocol information is made available on ClinicalTrials.gov for completed studies as well as those that are actively recruiting, thus the Delete function is only provided for records which have never been released.*

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be deleted.
3. Click [Delete].
4. Click [OK] on the **Delete Protocol** screen or click [Cancel] to return to the **Edit Protocol Record** screen without deleting the record.

A deleted record can be recovered via the [Undelete] option on the **Main Menu**.

## H. Change Your Password

1. Click [Change password] on the **Main Menu**.
2. Enter:
  - old password
  - new password
  - new password again for verification
3. Click [Change Password] to save the new password.

Contact your Administrator if you forget your password.