

## CLINICALTRIALS.GOV PROTOCOL REGISTRATION AND RESULTS SYSTEM (PRS) QUICK START GUIDE

### Overview

This guide is a quick introduction to registering and maintaining records on ClinicalTrials.gov using the Protocol Registration and Results System (PRS). For more assistance with using the PRS, see the [PRS User's Guide](#).

### Change Your Password

If you have not already done so, select Change Password from the Accounts menu on the Home page and complete the form.

### Create A Record

A study is registered in the ClinicalTrials.gov system by creating a protocol record. Select New Record on the Home page (either from Quick Links or the Records menu). Fill in a series of data entry pages.

- **Tip:** Data is saved as each page is filled in, so that you can "Quit" at any time, saving the record for later completion using the "Modify a record" instructions provided below.

### Ensure That Records Are Kept Up To Date

The administrator has overall responsibility to ensure that the organization's records are verified, updated, and re-released as needed (at least yearly while a study is active). Email messages are automatically sent by the PRS to administrators for significant user actions, such as completing data entry for a record or modifying a previously Released record.

### Mark The Record As Entry Completed

After filling in the last data entry page, the Protocol Section page appears with all of the information provided. Review the information for accuracy and completeness, and use the Edit links to address ERROR messages, if any.

Return to the Record Summary page to see current status of the record. Follow instructions in the Next Step box to finish the registration process, using the Entry Complete button to indicate that data entry is done. Your organization's PRS Administrator will Approve and Release the record for PRS Review and processing by ClinicalTrials.gov.

- The record should be available on the public site within **2-5 business days** of Release by the administrator.
- **Exception:** If you are designated as the Investigator and Responsible Party for a record, you have the authority (and responsibility) to Approve and Release the record even if you are not an administrator. Open the record and follow instructions in the Next Step box on the Record Summary page to perform these steps at the appropriate times. More information on Responsible Party is accessible from the Edit Sponsor/Collaborators page.

## Modify A Record

After initial registration, a record can be modified at any time (except when the record is locked for PRS Review). The Record List on the Home page lists all of your records along with status information for each record. Open the record that you wish to update. The Record Summary page for that record appears. Use the Edit link(s) on the left to modify the desired section of the record. When a record's status is Entry Completed, Approved, Released or Public, and the record is modified, the record status is automatically reset to In Progress. Remember to mark the record as Entry Completed when finished editing. Your organization's PRS Administrator will Approve and Release the modified record as described above.

## Keep Records Up To Date

Study records for active studies should be reviewed and modified, as needed, at least once every 12 months. Some data elements must be updated sooner (e.g., within 30 days of a change) based on the requirements in Section 801 of FDAAA and 42 CFR 11.64. Pay special attention to recruitment statuses, location, and contact information, as the accuracy and timeliness of this information is extremely important to patients and health care professionals. Update the Record's Verification Date (in the Protocol section, Study Status module) to confirm that the record has been reviewed.

## Check For Problems

The Record List on the Home page includes a Problems column listing issues for each record. To address problems, open the record and make the necessary changes, following the instructions in the Next Step box near the top of the Record Summary page.