

CLINICALTRIALS.GOV PROTOCOL REGISTRATION INSTRUCTIONS

Overview

ClinicalTrials.gov is a public database where clinical trials are registered through a web-based entry system called the [Protocol Registration and Results System \(PRS\)](#).

Clinical trials registration and uploading the consent forms are required by Law and required by journal publication. The background information can be found at: <https://clinicaltrials.gov/ct2/manage-recs/background>

WSU has a single protocol Registration and results system account. The WSU organization account is called WashingtonSU.

WSU's Principal Investigator is responsible for the registration of clinical trial(s). If it is a multisite federally funded study, and WSU PI is responsible for the overall study, WSU PI must register the study. Note: If the clinical trial is sponsored by Industry/company, WSU PI may not be responsible for the registration. Please contact WSU HRPP with any questions.

Procedures To Set Up A Single User Account

- WSU Principal investigators or their staff must set up individual user accounts through the organization account.
- Contact irb@wsu.edu for setting up a new individual user account.
- Please indicate 'individual user account for clinicaltrials.gov' in the subject line of the e-mail. Include your full name, telephone number, and WSU e-mail address.
- The HRPP administrator will review the request and will set up a new user account for the investigator. Upon receiving the acknowledgement message from the Protocol Registration and Results System (PRS) with your login name and a temporary password, log into the PRS system using WashingtonSU as the organization, your log in name and the temporary password.

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

Username:

Password: [Forgot password](#)

Login

- Navigate to the **Accounts** tab (as shown below) and select **Change Password** to replace temporary password.



- Once the investigator creates a user account to register clinical trials, the user account can be used to register more than one clinical trial, edit the trial record, and report the results.
- Initial registration should be completed no later than 21 days after enrollment of the first subject. Once the clinical trial is registered, the record must be updated throughout the study and results must be provided when the study ends. See more specific update information at: https://clinicaltrials.gov/ct2/manage-recs/faq#fr_23

Glossary

- **Sponsor (or Sponsor Organization):** WSU is the Sponsor Organization. It is listed in the PRS system as WashingtonSU.
- **Administrator:** individual designated by the organization to manage the organization's PRS account, create accounts for users, and serve as the point of contact for PRS staff. WSU HRPP staff serve as the Administrators for the WashingtonSU account. Contact them through irb@wsu.edu.
- **User:** Any PRS account holder who is authorized to enter information into the PRS, including investigators or research staff. Users create and modify their own records but cannot access other users' records unless authorized by the Record Owner or by an Administrator.
- **Record Owner:** PRS account holder who creates a study record in the PRS. Record Owners can maintain the record themselves or give other users access to a record to make changes.
- **Responsible Party:** Entity or individual responsible for verifying the accuracy of a study record and releasing it to ClinicalTrials.gov. Example WSU PI should be identified as the Responsible Party.
- **Official Representative:** The official contact person at the Sponsor Organization. Example: Designated HRPP staff.