

# ClinicalTrials.gov

## Protocol Registration and Results System (PRS)

Federal requirements and voluntary reporting options exist for submitting clinical trial registration and results information to ClinicalTrials.gov. The relevant regulations are intended to make it clear to sponsors, investigators, and the public which trials must be reported, when they must be reported, and whether compliance with requirements has been achieved. Check out [this page](#) for regular updates on data submission requirements.

Here is an overview of steps you will take during the ClinicalTrials.gov lifecycle of your registered clinical trial:

### 1) Apply for a ClinicalTrials.gov account.

- a. CSU already has a Protocol Registration System account. To request a new account:
  - i. Submit to the [CSU Account Request Page](#)
  - OR
  - ii. Contact CSU Administrator Cat Bens [[cat.bens@colostate.edu](mailto:cat.bens@colostate.edu) ; 970-491-5445] for login information.
- b. Upon receipt of your account login information, log into the [PRS Login Page](#).
  - i. The first time you enter, please change your password.
- c. Review the following at the ClinicalTrials.gov website:
  - i. Quick Start Guide
  - ii. User's Guide



### 2) Enter your study data.

*It is important that your trial only be entered once. Be sure to coordinate with other study members to determine who will be the Responsible Party ensuring the trial is registered and data entered. Multi-site and multi-collaborator studies are registered as one study.*

- a. To enter a new trial
  - i. Start by reviewing the [“How to Register Your Study”](#) to see what to include and how to enter your trial.



**RESEARCH INTEGRITY &  
COMPLIANCE REVIEW OFFICE**  
COLORADO STATE UNIVERSITY

**CSU Institutional Review Board**

[RICRO\\_IRB@colostate.edu](mailto:RICRO_IRB@colostate.edu)

970-491-1553

<https://www.research.colostate.edu/ricro/irb/>

- ii. Log into the [PRS Login Page](#)  
Your login information will follow this format:

Organization: ColoradoSU  
User Name: JDoe  
Password: \*\*\*\*\*

- iii. At the standard functions menu, select **Create**
- iv. Complete your trial entry and **Release** the trial record.

*Releasing the record is **required** before the CSU Administrator can initiate PSR review or establish a PSR trial approval.*

### 3) Monitor your trial records during PSR review.

- a. If errors are noted during review, you will need to respond and update the submission as appropriate.
- b. When review is complete, the trial will be approved and a National Clinical Trial (NCT) number established.

### 4) Maintain your trial record.

- a. At a minimum review your records annually and update information.
  - i. Be sure to update trial results within one year of trial completion as appropriate.

*Note: This is a good task to pair up with your annual IRB renewal!*

