

## UC SAN DIEGO CLINICALTRIALS.GOV REGISTRATION INSTRUCTIONS

The Food and Drug Administration Amendments Act (FDAAA), National Institutes of Health (NIH) and International Committee of Medical Journal Editors (ICMJE) require registration of certain studies on a publicly accessible website, [ClinicalTrials.gov](http://ClinicalTrials.gov). The following is a quick start users guide on how to carry out some of the most common functions on ClinicalTrials.gov when registering a study.

### 1. ***How to Obtain a User Account:***

- 1) Email [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu) and ask for a user account under UC San Diego's (UCSD) Institutional Protocol Registration and Results System (PRS) Account, "UCSDMED"
- 2) A UCSD administrator will setup your account and then submit your account information to ClinicalTrials.gov to create a new account
- 3) ClinicalTrials.gov will then create a new user PRS account within two business days of receiving the request
- 4) Once the account has been created, an email will be sent from ClinicalTrials.gov to the new user with a username, password and instructions for logging in to UCSD's Institutional PRS account

### 2. ***Logging in for the First Time:***

- 1) Go to <https://register.clinicaltrials.gov/> to sign in

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

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**Login**

Welcome to the [ClinicalTrials.gov](http://ClinicalTrials.gov) Protocol Registration and Results System (PRS). OMB NO: 0925-0086  
EXPIRATION DATE: 02/29/2020  
[Burden Statement](#)

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

Username:

Password:  [Forgot password](#)

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.  
[Send email to ClinicalTrials.gov PRS Administration](#)

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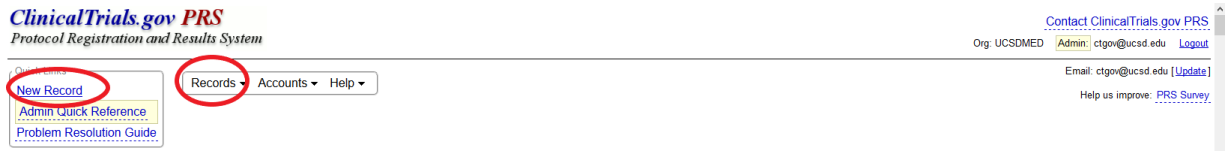
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

- 2) Enter Organization: UCSDMED
- 3) Enter the username and password emailed to you by ClinicalTrials.gov
- 4) Change your password once you log in for the first time
  - i. Go to Accounts > Change password



3. **Creating a New Study Record:** The person who creates the record becomes the Record Owner. All email messages about the study record will be sent to this person.

- 1) [Log in to PRS](#) with your assigned organization name, username, and password
- 2) Click on Records > New Record or use the quick links to the left hand side and click on “New Record”



- 3) Enter all the applicable information regarding the study you are registering
  - a. *Tip: Data is saved as each page is filled in, so that you can “Quit” at any time, saving the record for later completion*

- 4) After filling in the last data entry page, the “Protocol Section” page appears with all of the information provided. Review and “Entry Complete” if all information is complete. Address any ERROR messages, if any populate.

Record Summary

[Record List](#) [Help](#)

**Record Status**

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

**Next Step:** Confirm data entry complete **Entry Complete**

Record Owner: Test User	Access List: [ ]
Last Updated: 12/08/2014 10:04 by Test User	Upload: Allowed
Initial Release: [Not yet released]	PRS Review: [Not yet released]
Results Expected: January 2018	Public Site: [Not yet registered]

5) Next the Responsible Party (RP) will review the record for completeness and appropriateness, and then click “Release” to submit the record for review by a PRS staff member.

4. **Responsible Party Designation:** One of the pages that will populate when creating a new record is the “Edit Sponsor/Collaborators” page. UCSD requires the Principal Investigator be designated as the Responsible Party (RP).

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

[Contact ClinicalTrials.gov PRS](#)  
Org: UCSDMED Admin: [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu)

Home > Record Summary > Protocol Section > Sponsor/Collaborators

ID: Test Record This is a Test Study to Show How CT Gov Works [NCT ID not yet assigned]

**Edit Sponsor/Collaborators**

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

\* Responsible Party: **Principal Investigator**

Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

**Investigator Information**

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: Principal Investigator  
Investigator Affiliation: University of California, San Diego

\* Sponsor: University of California, San Diego  
Primary organization conducting study and associated data analysis (not necessarily a funding source)

Collaborators: [ ] x Delete

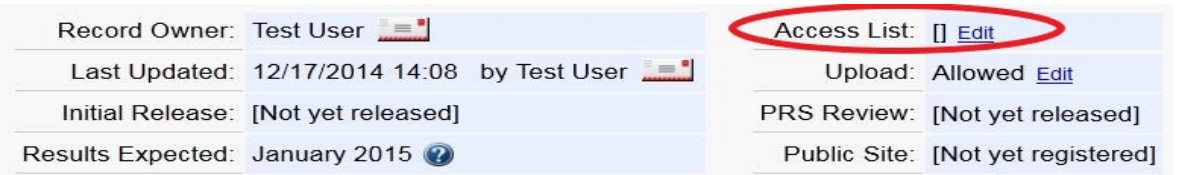
+ Add Collaborator  
Organization(s) providing support: funding, design, implementation, data analysis or reporting.  
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO).  
Enter only the organization name.

**Save** **Cancel**

\* Required  
§ Required if Study Start Date is on or after January 18, 2017  
[\*] Conditionally required (see Definitions)

- 1) Under Responsible Party choose “Principal Investigator”
- 2) Select the Investigator name from the drop down menu
  - i. If the Principal Investigator is not listed there, then they do not have an account, have the Principal Investigator email [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu) for a new account
- 3) Enter the Investigator’s Official Title

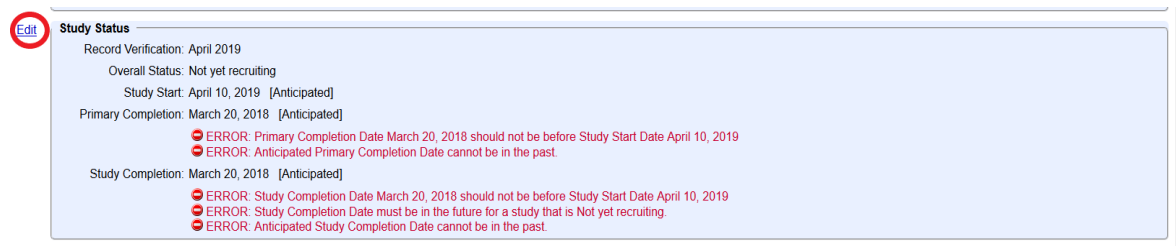
- 4) Investigator’s Affiliation should automatically populate to “University of California, San Diego”
  - 5) Any collaborating sites should be entered under the Collaborators section
  - 6) Click Continue
5. **Sharing Access to a Study:** Only one Record Owner can be assigned to a study record, but the Record Owner can allow other users to edit the study record by granting them access.
- 1) [Log in to PRS](#) with your assigned organization name, username, and password
  - 2) Open a study record
  - 3) Click on access list



- 4) Select the users you wish to grant access to and click “Save”
6. **PRS Staff Review:** After the RP releases the record, a PRS staff member will complete a manual review for apparent errors, deficiencies, and/or inconsistencies. The RP is responsible to respond to the PRS staff member’s requests for information or changes within 15 days.
- 1) If a PRS staff member finds any potential issues with the record, they will add comments to the record and send an email notification to the Record Owner
  - 2) The Record Owner must [log in to PRS](#) to view the comments
  - 3) Click on “Open” by the section where errors are identified



- 4) The errors will be highlighted in red text
- 5) Click “Edit” on the left hand side of the section to edit the errors



- 6) The user will then edit the study record to address the comments and click “Save”
- 7) After the issues have been addressed, resubmit the record for PRS Review by clicking “Entry Complete”

7. **Record is Registered and Posted:**

- 1) Once the study record is approved by the PRS staff member review, an email notification will be sent to the Record Owner with the ClinicalTrials.gov Identifier (NCT number), indicating that the study is registered

The screenshot shows the ClinicalTrials.gov website interface. At the top, there is a search bar with the example text "Heart attack" AND "Los Angeles" and a "Search" button. Below the search bar are navigation links: "Advanced Search", "Help", "Studies by Topic", and "Glossary". A blue navigation bar contains links for "Find Studies", "About Clinical Studies", "Submit Studies", "Resources", and "About This Site". The breadcrumb trail reads "Home > Find Studies > Search Results > Study Record Detail". The main content area displays "Trial record 1 of 1 for: nct00191282" with links for "Previous Study", "Return to List", and "Next Study". The study title is "Hyperglycemia and Cardiovascular Outcomes With Type 2 Diabetes (IONM)". A red banner states "This study has been completed." Below this, the sponsor is listed as "Eli Lilly and Company". The ClinicalTrials.gov Identifier is "NCT00191282". Other details include "First received: September 12, 2005", "Last updated: January 18, 2011", "Last verified: January 2011", and a link for "History of Changes". At the bottom, there are tabs for "Full Text View", "Tabular View", and "Study Results", along with links for "Disclaimer" and "How to Read a Study Record".

- 2) Generally, within two business days of registration, the system will post the record on the [ClinicalTrials.gov](http://ClinicalTrials.gov) website
- 3) Once registered, a study record becomes a permanent part of ClinicalTrials.gov and cannot be removed or deleted.