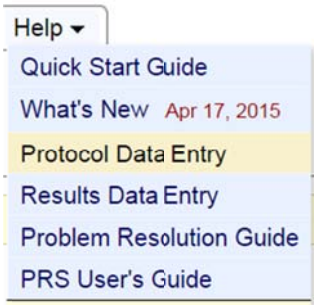
Creating a New Study Record

A trial is registered in ClinicalTrials.gov after a new "protocol record" is created and passes QA review in the Protocol Registration System (PRS). A new record must pass review by the ClinicalTrials.gov (PRS) staff reviewers to be assigned its clinical trial identifier (NCT#) and be registered in the public ClinicalTrials.gov database.

This document presents institution-specific guidance for UCLA investigators, plus selected tips on how to initiate a new record by filling in a series of data entry screens. In addition to these instructions, please refer to the various "Help" and instruction links embedded throughout the PRS to aid users with navigation and completion. Clicking on various fields in the record will access instructions for that field. From the PRS home screen, detailed instructions, examples, data entry tips and a review checklist are available by selecting *Help > Protocol Data Entry.*



Suggestion: Print or save a copy of the Registration Review Criteria (.pdf) at **Help > Protocol Data Entry > Protocol Review Criteria (PDF)** for reference. This document provides general guidance for compliant record creation as well as "Hints" detailing specific requirements for completion of certain fields in the protocol record.

For questions about the registration process at UCLA, contact the institutional PRS Administrator at UCLA, Elaine Cooperstein at ecooperstein@mednet.ucla.edu or contact the PRS at register@clinicaltrials.gov

Step 1: Log in to the investigator's PRS user account

1. To obtain a new PRS user account, contact the UCLA PRS Administrator
2. For existing user accounts, go to Website: https://register.clinicaltrials.gov
3. Complete the 3 fields on the Login screen:
    a. **Organization Name :** UCaliforniaLA
    b. PRS Username: first initial+last name
    c. **Password:** If you forget your password, use the "Forgot password" link on the login page to receive a temporary password via email

Step 2: Under “Quick Links”, select New Record

Step 3: Complete required information on “Create New Record” screen

You will be prompted for **Unique Protocol ID**. At UCLA, the Unique Protocol ID may be entered as:

- For grant-funded projects, use the sponsor-issued grant or award number
- For industry-funded projects, use the sponsor’s protocol ID number
- For all others, if no other unique identifier assigned by funder is available, use IRB number

Complete the “Create New Record” module by selecting **Continue**, and add information into each module of the protocol record as appropriate to your study: Study Identification, Study Status, Sponsor/Collaborators, Oversight, etc.

To ensure compliance with the requirements for each data entry field and study module, refer frequently to the **Help** links within each protocol module to understand the requirements, and to the guidances available at the following links:

- **Protocol Review Criteria (.pdf)** described on page 1
- **Definitions** - Protocol Data Element Definitions - Check the definition for each field to ensure the correct information is entered

Step 4: Edit Study Status

Complete all required fields. Guidance and definitions are available on the page or via the Help links.

Record Verification Date: This date refers to the month and year that information in the record was updated or confirmed. When updating a record, always enter the current month-year as the Record Verification Date.

Step 5: Edit Sponsor/Collaborators

Sponsor: Regardless of funding source, enter the “regulatory sponsor” (primary organization overseeing the implementation of the study), usually University of California, Los Angeles.

- For industry-initiated trials, **STOP** and verify you are the appropriate responsible party to register the study; typically the industry sponsor – not a participating investigator - will register an industry-initiated study.

Responsible Party:

- For investigator-initiated trials without an Investigational New Drug (IND) or Investigational Device Exemption (IDE), select **Principal Investigator**, and select the investigator's PRS username from the list (first initial+last name)
- For investigator-initiated trials with an IDE or IDE and the PI will be the holder of the IND or IDE, select **Sponsor- Investigator** and select the investigator's PRS username from the list (first initial+last name)
- If neither option here applies, you may contact the UCLA PRS Administrator for guidance

Step 6: Edit Oversight

FDA Regulated Intervention? Indicate whether this study involves an FDA-regulated drug, biologic, or device

IND/IDE Protocol? Indicate whether this study will be conducted under an IND or IDE

Board Approval: enter IRB status, IRB number
Board Name: Institutional Review Board
Board Affiliation: University of California Los Angeles
Board Contact:

- **Business Phone:** (310) 825-5344 **(for medical studies)**; (310) 825-7122 **(for general studies)**
- **Business Email:** mirb@research.ucla.edu **(for medical studies)**; gcirb@research.ucla.edu **(for general studies)**
- **Business Address:** 11000 Kinross Ave, Suite 211, Box 951694; Los Angeles, CA 90095

Data Monitoring: Indicate whether a data monitoring committee (board) has been appointed for this study

Oversight Authorities: Name each national or international organization with authority over the protocol (e.g. DHHS, FDA, NIH, DOD, DOE, etc.)

Step 7: Verify the record is free from errors prior to completing.

Resolve any ERRORS &/or WARNINGS indicated in the record (NOTES may optionally be addressed). Possible problems may be identified as follows:

- ERRORS indicate serious problems that must be addressed
- WARNINGS indicate items that are (or may be) required by FDAAA 801
- NOTES indicate potential problems that should be reviewed and corrected as needed.

Ensure that your entries comply with the **protocol review criteria** described on page 1 and available from the PRS home screen: **Help > Protocol Data Entry > Protocol Review Criteria (PDF)**

Step 8: Once your entries are final, select *Next Step: Completed* at the top of the record.

At this point, the **Responsible Party** (PI or UCLA Administrator) will be prompted to review and release the record. The **Responsible Party** will need to select the **Release** button at the top of the record. [until the RP selects **Release**, the record will not be routed for review or registration]

Step 9: Await confirmation of registration and NCT# assignment, or Reviewer Comments

Once released, the record will be reviewed by ClinicalTrials.gov reviewers for apparent validity, meaningful entries, logic and internal consistency, and formatting as described in **Help>Protocol Data Entry>Protocol Review Criteria (PDF)**

If review criteria are met, record will be published.

If errors exist, The PRS system will notify the Record Owner and Responsible Party to address Reviewer Comments and resubmit for review.

Step 10: To access Reviewer Comments and make necessary corrections:

- Log in to your PRS user account
- Open the study record
- Select **PRS Review: [Review Comments]**
- Read Comments and revise (Edit) the protocol record to address issues
- Select [**Completed**, **Approve**, **Release***]
    - [*if you are not logged in as the **Responsible Party** for this study, the **Responsible Party** will be notified by the PRS to **Release** the record]

Step 11: Maintain the study record:

- Responsible Parties should update their records within 30 days of a change to any of the following:
    - Recruitment Status and Overall Recruitment Status data elements
    - Completion Date
- Other changes or updates to the record must be made within 12 months of the study change
- The Record Verification Date must be updated at least every 6 months for studies that are not yet completed, even if there were no changes
- For Applicable Clinical Trials subject to FDAAA801, the Responsible Party should submit summary results no later than 12 months after the Primary Completion Date, defined in the law as the date of final data collection for the prespecified “Primary Outcome Measure.”