UCI Office of Research

IRB EQUIP TIPS

Registering and Updating a Study on ClinicalTrials.gov

V 8.0 September 2024

The Food and Drug Administration Amendments Act (FDAAA), National Institutes of Health (NIH) and other entities require registration of certain studies on a publicly accessible website, ClinicalTrials.gov.

****Please review the detailed guidance on the UCI HRP webpage related to ClinicalTrials.gov**

Registration may be required if one (or more) of the following is true:

- The study is **funded by the National Institutes of Health** (NIH) **AND** meets the **NIH definition** of a clinical trial
- The study involves **drugs, devices, or biologics** that are **regulated by the Food and Drug Administration** (FDA)
- There is a plan to **publish the results in a medical journal** AND the study meets the International Committee of Medical Journal Editors **(ICMJE) definition of a clinical trial**
- If your clinical trial will bill routine costs to **Medicare,** the study must be registered on ClinicalTrials.gov
- If you have a clinical trial that includes a drug that available via **expanded access**.
- If your **clinical trial receives funding** from **Department of Defense** (check with program Officer), **PCORI**, **National Cancer Institute**, **Veterans Affairs**

A trial is registered in ClinicalTrials.gov after a new "protocol record" is created and passes QA review in the Protocol Registration and Results System (PRS) for ClinicalTrials.gov. **Once a record passes review with the PRS reviewers, it is assigned a clinical trial identifier (NCT#) and registered.**

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. For a general overview of the registration process and requirements, see the ClinicalTrials.gov page **How to Register Your Study.**

IMPORTANT:

- Per **UCI HRP Policy #2**, the ClinicalTrials.gov record may be released for PRS review AFTER IRB submission.
- **At UCI, each IRB Protocol** that requires ClinicalTrials.gov registration should correspond to **only one NCT# / PRS record.** If more than one NCT# is required for an IRB Protocol by a funding entity, **please contact your PRS administrator.**

INDEX: HYPERLINKS TO CONTENT: *Click on a topic below to review associated guidance*

Steps to register your study on ClinicalTrials.gov:

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Steps to update your ClinicalTrials.gov record:

- **When / how often must I update ClinicalTrials.gov registration information?**
- **Results Reporting**
- **Posting the consent form**

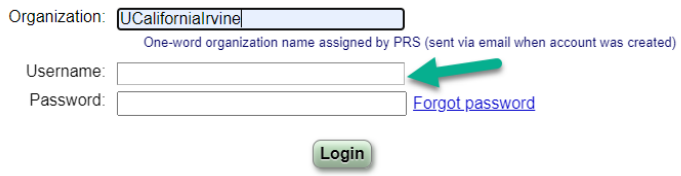
1. How to Obtain a User Account:

Once you have determined that your study needs to be registered on ClinicalTrials.gov, you will need to submit the record for the study in the Protocol Registration and Results System (PRS):
PRS guided tutorials can be found here

a. **For PRS access** (if you do not already have an account), please contact Electronic Research Administration: era@research.uci.edu.
b. **If you are unsure if your study should be registered, contact your PRS Administrator:**
   i. For UCI Health Science studies, please contact Jinah Chang (jinahec@hs.uci.edu)
   ii. For UCI Cancer Center studies, please contact Michelle Tran (mdich@hs.uci.edu)
   iii. For Non-UCI Health studies, please contact the EQUIP team (EQUIP@uci.edu).
c. 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 UCI's Institutional PRS account
d. For questions about the **registration process at UCI**, contact the EQUIP team (EQUIP@uci.edu), or contact PRS staff at register@clinicaltrials.gov.

2. Logging in for the First Time:

a. Go to https://register.clinicaltrials.gov/ to sign in
b. **Enter Organization**: UCaliforniaIrvine
c. **Enter the username and password** emailed to you by ClinicalTrials.gov



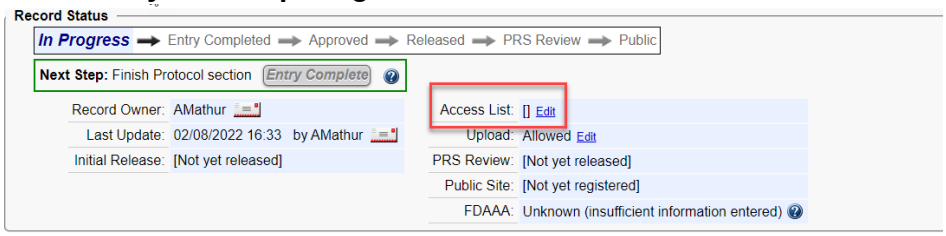
d. **Change your password** once you log in for the first time
   i. Go to Accounts > Change password
   ii. You will receive a temporary password via email

3. To begin a new PRS Record:

a. **Suggestion:** Print or save a copy of the 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 key fields in the protocol record.
b. Under "Quick Links", select **New Record** or use the quick links to the left-hand side and click on "New Record":

c. Complete the "**Create New Record**" initiation screen

4. **Sharing Access to a Study:**
   a. **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.
   b. For UCI Investigator Initiated studies, **the Principal Investigator (Lead Researcher) or the responsible Clinical Research Coordinator** can be listed as the "Record Owner".
   c. Other study staff requiring PRS access should be listed in the "Access List".



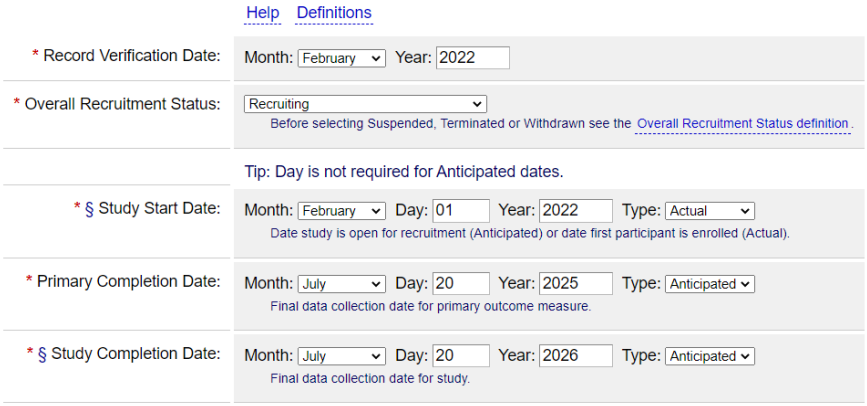
5. **To Begin Entry of Information For The Record:**
   a. "Open" the "Protocol Section":

6. **Study Identification Module:**
   a. You will be prompted for **Organization's Unique Protocol ID**.
   b. At UCI, the Unique Protocol ID **MUST** match the **IRB number (DIGITS ONLY no dashes, no #, same number as in KRP).**
   c. Add the brief and official title for your study
   d. if using any acronyms- specify in the "Acronym" section
   e. Select **Continue** to complete the "Create New Record" module, and add information into each module of the protocol record as appropriate to your study.
   f. **Secondary IDs:**
      i. Grant-funded projects MUST enter the sponsor-issued grant or award number in this field. [1]
      ii. For industry-funded projects, use the sponsor's protocol ID number
      iii. For **UCI Cancer Center studies**, in the **Secondary ID field**, select "Other Identifier" and add the **unique CFCCC identifier**, with "Issuing Organization" as "UCI CFCCC".
   g. To ensure compliance with the requirements for each data entry field and module, refer frequently to the **Definitions** and **Help** links at the top of each module.
   h. Under the "Help" menu, go to the QUICK START GUIDE.
   i. Instructional links embedded throughout the PRS will aid users with navigation and record completion.

7. **Study Status:**

[1] **U.S. National Institutes of Health (NIH) Grant/Contract Award Number: In the Secondary ID field, include activity code, institute code, and 6-digit serial number. Other components of the full award number (type code, support year, and suffix) are optional.**

a. **The Record Verification Date** reflects the last time the PRS record was updated. Revise this date each time the record is verified for accuracy and completeness.
b. Complete the rest of the required information **per guidance in this section**:



c. If unsure of dates, indicate the date as “anticipated” in the last dropdown under “Type”
d. If recruitment has begun, specify the “actual” date the first subject was enrolled.

8. Sponsor / Collaborators:

a. **For all UCI Investigator Initiated studies**, the **Principal Investigator (Lead Researcher) should be designated as the Responsible Party (RP).**
b. Under Responsible Party choose “**Principal Investigator” (PI)**
c. Select the Investigator name from the drop-down menu (email era@uci.edu if the PI does not have a PRS account)
d. Enter the Investigator’s Official Title
e. Investigator’s Affiliation should automatically populate to “University of California, Irvine”
f. **Sponsor:** Regardless of funding source, enter the “regulatory sponsor” (primary organization overseeing the implementation of the study), usually University of California Irvine.
g. Any collaborating sites should be entered under the Collaborators section
h. Click Continue

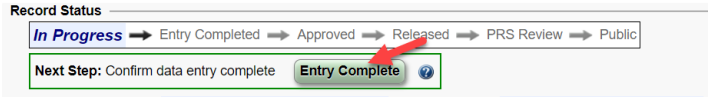
9. Oversight:

a. **U.S. FDA Regulated Drug / Device:** Indicate whether this study involves an FDA-regulated drug, biologic, or device.
b. **U.S. FDA Regulated Drug / Device:** Indicate whether this study will be conducted with a drug/device product under a U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE).
c. **Human Subjects Protection Review:** Enter the **current status** of your IRB Protocol in KRP (e.g., “submitted, pending” if an application has been submitted but is under review.
d. Add the following information for the UCI IRB:
    i. **Board Name:** University of California Irvine IRB
    ii. **Board Affiliation:** University of California Irvine
    iii. **Board Contact:** 949-824-8170
    iv. **Email:** irb@uci.edu
    v. **Business Address:** University of California, Irvine, Office of Research, Irvine, CA 92697-7600
e. **Data Monitoring:** Indicate whether a data monitoring committee (board) has been appointed for this study

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

10. Record Completion:

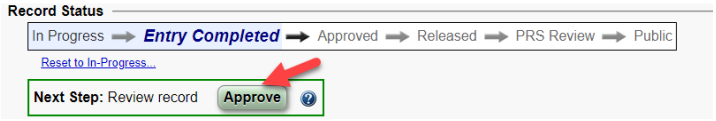
a. Enter all the applicable information regarding the study you are registering in the Study Description", "Conditions", "Study Design", "Arms and Interventions", "Eligibility" sections, as well as any other applicable sections.
b. Review and reference the PRS User Guide
c. After filling in the last data entry page, the "Protocol Section" page appears with all of the



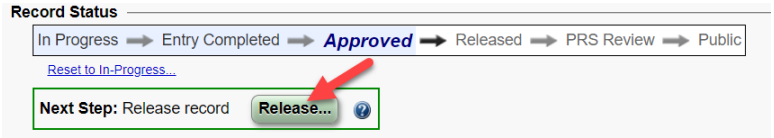
information provided. Review and "Entry Complete" if all information is complete.
d. Address any ERROR messages if populated.

11. Responsible Party: Record Review, Approval, Release:

a. **If the PI is the responsible party**, they will review all entries made by study staff prior to release.
b. Once the information is confirmed (passed internal review), under "Record Status" – click "Approve":



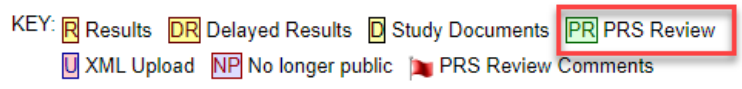
c. Select "Release" to submit the record to ClinicalTrials.gov. The responsible party confirms their identity, and that the record is up to date, reviewed for accuracy and completeness:
d. Once released, PRS staff perform final review and processing of the record.



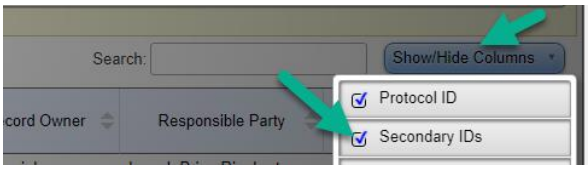
e. Note: some records may receive PRS Review Comments that identify major issues that **must be addressed by the responsible party** before the record will be made available on ClinicalTrials.gov.
f. Following successful PRS review, records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 days of Release.
g. The ClinicalTrials.gov Identifier (NCT number) is assigned as part of that process.

**GENERAL EQUIP TIPS:

- **Please download and review the IRB EQUIP TIPS guidance document called "CHECKLIST TO ADDRESS COMMON PRS ERRORS"** to avoid common issues noted by the ClinicalTrials.gov database **(PRS) staff** prior to public release.
- **Directly email PRS staff** if you have any questions or need help related to PRS Review Comments at *register@clinicaltrials.gov*
- **Once a record is created**, you can update it as long as it is not undergoing PRS review:



- If your department is utilizing the "Secondary ID" Section for a Unique department ID, click "Show/Hide Columns" next to the search bar in PRS, and select "Secondary IDs" as part of your records filter:



12. When / how often must I update ClinicalTrials.gov registration information?

- **The Record Verification Date** should be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and **not less than every 12 months**, even if no other updated information is submitted at that time.
- Responsible Parties should review the **Clinical Trial Registration Data Elements for More Frequent Updating Table** as **many elements must be updated within 30 days of a change**.
- It is recommended that the **Record Verification Date be updated at least every 6 months** for studies that are not yet completed, even if there were no changes to the record.

13. Results Reporting:

- **The Food and Drug Administration Amendments Act (FDAAA), National Institutes of Health (NIH)** require the **publication of results** for certain studies on ClinicalTrials.gov (Ct.gov).
  - See FDAAA 801 and the Final Rule for more information.
  - See How to Submit Your Results for details.
- The ICMJE Policy recommends results publication but it is not required.
- After a clinical trial has been registered on ClinicalTrials.gov **and the study is completed**, the Responsible Party must publish the results on ClinicalTrials.gov.
- Submission of results information is required **no later than 12 months after the Primary Completion Date (the last subject last visit)** of the clinical trial, which is defined as the date of final data collection for the primary outcome measure.

14. Posting the Consent Form:

- **WHICH STUDIES?**
  - **All clinical trials funded by an agency that has signed onto the Common Rule initially approved on or after January 21, 2019 OR that transitioned to the 2018 Common Rule Requirements** (45 CFR 46.101(l)) **and the transition determination was documented and dated by the IRB before the trial is closed to recruitment** and 60 or fewer days before the last protocol-required study visit by any subject enrolled in the protocol.
  - **Please see OHRP "The Informed Consent Posting Requirement" PowerPoint for details.**
- **WHAT DO I POST?**
  - **One IRB-approved consent form** used to enroll subjects
  - Even if multiple versions were approved by the IRB, only one must be uploaded.
- **WHEN?**
  - After the clinical trial is **closed to recruitment,** and **no later than 60 days after the last study visit by any subject**, as required by the protocol.
- **WHERE?**
  - Two federal websites have been identified as satisfying 45 CFR46.116(h): **ClinicalTrials.gov** and a designated docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).
- **HOW?**
  - OHRP - **Informed Consent Posting Instructions**