Creating a Study Record in ClinicalTrials.gov

ClinicalTrials.gov study records are created in a Web-based data entry system called the **Protocol Registration and Results System (PRS)**. A study record must meet standards established by the ClinicalTrials.gov PRS staff reviewers in order to be assigned a National Clinical Trial (NCT#) Identifier and registered in the public ClinicalTrials.gov database.

This document presents institution-specific guidance for University of California, San Francisco (UCSF) investigators to initiate a new record by filling in a series of data entry screens. From the ClinicalTrials.gov PRS login screen, detailed instructions, examples, data entry tips and a review checklist are available by selecting *Help > Protocol Data Entry.*
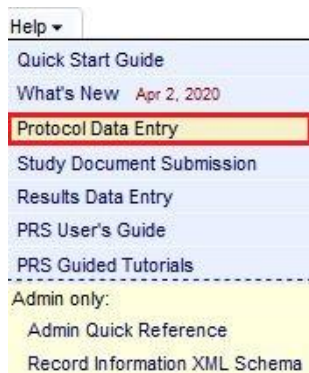
Suggestion: Print or save a copy of the Protocol Review Criteria (PDF) at *Help > Protocol Data Entry > Protocol Review Criteria (PDF)* for reference. This document provides general guidance for compliant record creation as well as helpful tips detailing specific requirements for completion of certain fields in the protocol record.

For questions about the registration process at UCSF, contact the UCSF PRS Administrators.

1: Log into the Investigator's ClinicalTrials.gov PRS user account

1. To obtain a new PRS user account, contact the UCSF PRS Administrators. Note that the practice at UCSF is to create the study record using the Principal Investigator's user account.
2. For existing user accounts, go to: https://register.clinicaltrials.gov
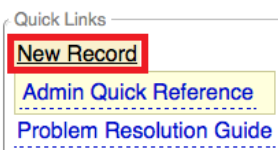3. Complete the 3 fields on the Login screen:

Organization: UCaliforniaSF

Username: *usually* **first initial+last name**

Password: If you forget your password, use the "Forgot password" link on the login page to receive a temporary password via your UCSF email

2: Under "Quick Links", select New Record

3: Complete required information on "Create New Record" screen

At UCSF, enter the *Organization's Unique Protocol ID* as follows:

- 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 Institutional Review Board (IRB) study number (YY-XXXXX)

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, Description, Conditions, Study Design, Arms and Interventions, Outcome Measures, Eligibility, Contacts/Locations, and References. On each page, select Continue to save data entered and proceed to the next page.

In addition to the Protocol Review Criteria (PDF), refer to the various "**Help**" and "**Definitions**" links embedded throughout the ClinicalTrials.gov PRS system to aid users with navigation and completion.

Help links contains examples and data entry tips.
Definitions links contains the meaning of terms and information about field lengths.

4: Edit Study Status

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

5: Edit Sponsor/Collaborators

Responsible Party:

- For investigator-initiated trials that will *not* be conducted under and an Investigational New Drug (IND) or an Investigational Device Exemption (IDE) (including trials that have been granted an IND Exemption, IDE Exemption and/or an NSR determination), leave the responsible party as **Sponsor**, and leave "University of California, San Francisco" in the Sponsor text field.
- For investigator-initiated trials that will be conducted under an IND or IDE and the PI is the holder of the IND or IDE, select **Sponsor- Investigator.** Then select the Principal Investigator's name from the drop-down list. For Investigator Official Title, enter the official title of the investigator at UCSF (e.g., Associate Clinical Professor).
- If neither option here applies, you may contact the UCSF PRS Administrators for guidance.

6: Edit Oversight

U.S. FDA-regulated Drug or Device? Indicate whether this study involves an FDA-regulated drug, biologic, or device:

- Select '*Yes*' if the study will be conducted under an IND or an IDE.
- Select '*Yes*' if the study will be conducted under an IND Exemption, IDE Exemption, or an NSR Determination.
- Otherwise, select '*No.*'

U.S. FDA IND/IDE? Indicate whether this study will be conducted under an IND or IDE:

- Select '*Yes*' if the study will be conducted under an IND or IDE.
- Select '*No*' if the study does not have an IND or IDE.
- Select '*No*' if the study has an IND Exemption, IDE Exemption, or NSR Determination.

Human Subjects Protection Review:
      Board Approval: enter IRB status, IRB study number (when approved)
      Board Name: Human Research Protection Program – Institutional Review Board
      Board Affiliation: University of California, San Francisco
      Board Contact:
- **Business Phone:** 415-476-1814
- **Business Email:** IRB@ucsf.edu
- **Business Address:** 490 Illinois Street, Floor 6; San Francisco, CA 94143

If you obtained approval from a non-UCSF IRB, enter the relevant information.

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

FDA Regulated Intervention: Select '*Yes*' or '*No*.' If '*Yes*,' select if Section 801 Clinical Trial ('*Yes*' or '*No*').
- If U.S. FDA-regulated Drug or Device is '*Yes*' above, select '*Yes*'.
  - If yes, **Section 801 Clinical Trial** will appear.
    - Select '*Yes*' if an FDA "Applicable Clinical Trial"
    - Select '*No*' if not an FDA "Applicable Clinical Trial"

  If unsure, review the Applicable Clinical Trial (ACT) Checklist and/or contact the UCSF PRS Administrators.

- If U.S. FDA-regulated Drug or Device is '*No*' above, select '*No*'.

7: Complete Outcome Measures
- **Title:** be specific and state WHAT is being measured, only 1 variable can be assessed per outcome measure
- **Description:** explain WHAT is being measured, not WHY it is being measured
- Specify scoring scale name, score range, significance of upper and lower limits (if applicable)
- Specify **unit of measure**
- Specify **time frame** as a single time point or change between 2 time points

For examples of appropriate and inappropriate phrasing of outcome measures, see page 6 of the Protocol Review Criteria (PDF).

8: Verify the record is free from errors and address important notes 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** must be addressed before releasing the record
- **Warnings** indicate potentially serious issues that should be reviewed and addressed as needed
- **Notes** indicate other potential issues; address as needed

Use the Spelling feature available in the upper left portion of the *Record Summary* to resolve any spelling errors and confirm that first use of acronyms is expanded.
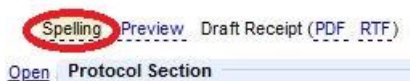

NOTE to satisfy WHO and ICMJE policy requirements:
- Name a Study Official in the Contacts section. The Study Official is usually the PI.
- Plan to Share IPD must be '*Yes*' or '*No*' ('*Undecided*' is not accepted). If you are undecided, select '*No*,' as it can be changed in the future.

9: Return to the Record Summary page, once your entries are final
Next Step: Confirm data entry, click on **Entry Complete**.
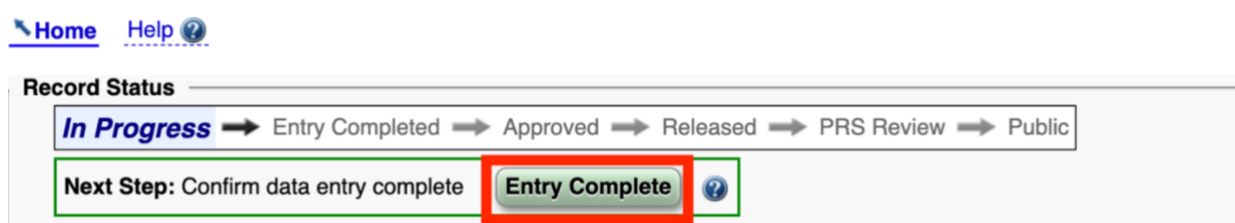
At this point, the **Responsible Party** (PI or UCSF PRS Administrators) will be prompted to review, approve, and release the record. The **Responsible Party** will need to select the **Release** button at the top of the record to initiate ClinicalTrials.gov PRS staff review.

10: Await confirmation of registration with NCT#, or Quality Assurance (QA) Comments
Once released, the record will be reviewed by ClinicalTrials.gov PRS staff 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 assigned an NCT# and published on the public ClinicalTrials.gov site.

If issues are identified, the PRS system will notify the Record Owner and Responsible Party to address PRS Review Comments by an expected date noted in the record (typically 15 days) and resubmit for review. If you need assistance in addressing the review comments, contact UCSF PRS Administrators.

11: Access QA Comments and make necessary corrections
- Log in to your PRS user account
- Open the study record
- Click on Review Comments link
- Read QA Comments and revise (Edit) the protocol record to address issues
- Select [**Complete**, **Approve**, **Release***]
    - o [*if you are not the **Responsible Party** for this study, the **Responsible Party** will be notified by PRS to **Release** the record]

If UCSF is listed as the Sponsor, UCSF PRS Administrators will pre-review the study record. If any common errors are found, comments, and requests for revisions will be sent to the record owner.

If the PI is listed as the Responsible Party, the record is not routed to UCSF PRS Administrators for a pre-review. If the PI would like the study record reviewed before release, send a request to UCSF PRS Administrators.