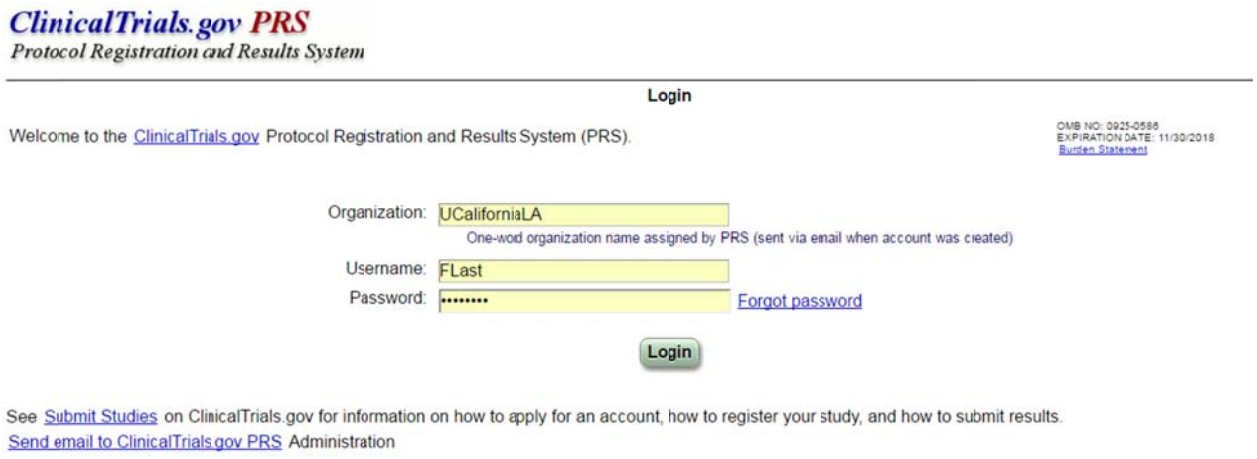
ClinicalTrials.gov PROBLEM RECORD RESOLUTION GUIDE

This guide explains each type of problem that may appear on the PRS Home page, or in a PRS Problem Report, and lists steps for problem resolution.

- General instructions may be performed by the **Responsible Party, Record Owner**, any **User** who is on the record's Access List or by an organization's **PRS Administrator**. UCLA **Principal Investigators** or **Sponsor-Investigators** usually will be both **Record Owner** and **Responsible Party** for their study registration record.
- **Responsible Party** steps are performed by the Investigator when **Responsible Party** is **Principal Investigator** or **Sponsor-Investigator**.
- For more information on responsibilities of **PRS Record Owners, Users and Responsible Parties**, see the Quick Start Guide.

Access the Protocol Registration System (PRS) for ClinicalTrials.gov at https://register.clinicaltrials.gov.

- Enter your organization name (**UCaliforniaLA**), username (First initial + Last name*, e.g.* **JSmith**), and password.
- If you do not remember your username and/or password, please use the "Forgot Password" link on the PRS login page.
    - The PRS will send a message to the email address associated with your PRS User account.



After logging in, click on "**Problem Records**" to bring up a list of problem record(s) in your PRS User account. If you have problems listed, please use the guide below to resolve each one individually. Note a given study can have more than one problem and each must be resolved separately.

Entry Not Completed

The record has not been marked Completed, following initial entry or modification. A record (or update) must be marked Completed, Approved and Released in order to undergo review and be made public on ClinicalTrials.gov.

Problem resolution:

1. Review the record and modify it if necessary.
2. Mark the record as Entry Completed.
3. Responsible Party: Review, edit as needed, Approve and Release the record.

Tip: If the study does not need to be made public (registered) on ClinicalTrials.gov and the record has never been Released, delete the record.

FDAAA 801 Issues

Identifies trials that may be "applicable clinical trials" subject to Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) and that are missing required information or appear to be overdue for results submission. It is recommended that the data elements used to identify trials for the report be reviewed for accuracy and updated, as needed: Study Type, Intervention Type(s), Study Phase, Facility Locations, IND/IDE Protocol?, Primary Completion Date, Study Completion Date and Overall Recruitment Status. For additional information see the FDAAA Issues information page in the PRS and the FDAAA 801 Requirements page on the ClinicalTrials.gov website.

Older studies that are not subject to FDAAA 801 (completed before December 26, 2007) may show FDAAA 801 issues if completion date is not provided. Entering the actual completion date may remove an older study from the report.

Late Results – per FDAAA

The record appears to be an Applicable Clinical Trial (ACT) that is overdue for results submission per FDAAA 801.

Problem resolution:

Determine whether results are required to be submitted. For more information, read When Do I Need to Register and Submit Results? on the ClinicalTrials.gov website.

1. If submitting Results for the first time, refer to Help: Results Data Entry for the full set of instructional resources.
2. Enter Results information using the Enter Results link on the Record Summary page.
3. Mark the record as Entry Completed.
4. Responsible Party: Review, edit as needed, Approve and Release the record.

This problem will continue to be listed for the record until Results information is entered and passes ClinicalTrials.gov PRS Review.

*Statisticians or other support staff assigned to enter results may be added to a record's "access list". Contact the UCLA PRS Administrator for assignment of a new user account if needed

Missing FDAAA Information

The record is missing one or more data elements required by FDAAA 801, such as: Responsible Party, Study Start Date, Primary Completion Date and/or Primary Outcome Measure. See "FDAAA 801 Issues," above.

Problem resolution:

1. Review the record and modify it as needed, ensuring that all WARNING messages have been resolved.
2. Mark the record as Entry Completed.

3. Responsible Party: Review, edit as needed, Approve and Release the record.

Never Released

A record has been created, but has never been Released and is therefore not yet "Registered" in ClinicalTrials.gov. A record must be marked as Entry Completed, Approved and Released in order to be reviewed by ClinicalTrials.gov PRS and made public on the ClinicalTrials.gov website.

Problem resolution:

1. Administrator/Responsible Party: Determine whether the study should be made public on ClinicalTrials.gov and who should finish data entry.
2. Administrator/Responsible Party: Change record ownership or update the record Access List, if necessary.
3. Record Owner: Finish initial data entry or update the record, as appropriate.
4. Record Owner: Mark the record as Entry Completed.
5. Responsible Party: Review, edit as needed, Approve and Release the record.

Tip: If the study does not need to be made public (registered) on ClinicalTrials.gov and the record has never been Released, delete the record.

Not Recently Updated

The record for a Recruiting (or Not yet recruiting) study has not been updated on the ClinicalTrials.gov public web site in more than six months, or the record for an Active, not recruiting (or Enrolling by invitation) study has not been updated in more than one year.

Problem resolution:

1. Record Owner: Review the record and modify it as needed, including update of the Verification Date.
2. Record Owner: Mark the record as Entry Completed.
3. Responsible Party: Review, edit as needed, Approve and Release the record.

This problem will continue to be listed for the record until the updated record has been Released and passes ClinicalTrials.gov PRS Review.

PRS Review Comments

The study has not yet been made public (or has not yet been updated) on the public ClinicalTrials.gov site because issues were identified during PRS Review. The record must be edited to address PRS Review Comments, and Completed, Approved and Released before the study (or update) can be re-reviewed made public.

Problem resolution:

1. Record Owner: Read the PRS Review Comments. Comments can be accessed from the Record Summary page.
2. Record Owner: Modify the record as needed to fully address the comments.
3. Record Owner: Mark the record as Entry Completed.
4. Responsible Party: Review, edit as needed, Approve and Release the record.

Ready for Review and Approval

The Record Owner (or other User) has marked a record as Entry Completed, following initial data entry or modification of the record. The record must be Approved and Released in order to be reviewed by ClinicalTrials.gov PRS and made public on the ClinicalTrials.gov website. A study is not considered to be "Registered" until it has passed review by ClinicalTrials.gov PRS and is assigned the clinical trial identifier (NCT#).

Problem resolution:

1. Responsible Party: Review, edit as needed, Approve and Release the record.

Record Has Errors

The record has one or more Error messages. Note that errors can arise due to the passage of time (e.g., anticipated primary completion date in the past).

Problem resolution:

1. Record Owner: Review the record and modify it as needed, including update of the Verification Date.
2. Record Owner: Mark the record as Entry Completed.
3. Responsible Party: Review, edit as needed, Approve and Release the record.

Update Not Released

A record that has been made public on ClinicalTrials.gov has been updated, but has not been Released. A record must be marked as Entry Completed, Approved and Released in order to be reviewed by ClinicalTrials.gov PRS and updated on the ClinicalTrials.gov website.

Problem resolution:

1. Administrator/Responsible Party: Determine who should finish updating the record.
2. Administrator/Responsible Party: Change record ownership or update the record Access List, if necessary.
3. Record Owner: Review and update the record, as appropriate.
4. Record Owner: Mark the record as Entry Completed.
5. Responsible Party: Review, edit as needed, Approve and Release the record.