

## UC SAN DIEGO CLINICALTRIALS.GOV INSTRUCTIONS TO POST ANNUAL REPORT AND UPDATE THE STUDY RECORD

Throughout the course of a clinical trial, the study record will need to be updated. Some updates are required within 15- 30 days of changes made and others are required annually. The following guide covers the changes that must be made to the study record and the timeline to make those changes. It is up to the Responsible Party of the study to review, revise and verify all information. Clinicaltrials.gov will not send a notice or reminder when review or modifications are required. For more information, see [How to edit your study record.](#)

### **Annual Review**

Every record must be reviewed for accuracy, and the “Record Verification Date”, must be updated, at least every 12 months, even if there have been no changes to the study. The Responsible Party must: (1) Review the ClinicalTrials.gov study record for accuracy and completeness; (2) Update the Record Verification Date (and other data elements, as needed); and (3) Approve and release the update to ClinicalTrials.gov.

1. Log in to the Ct.gov [Protocol Registration and Results System](#) (PRS) with your login credentials
2. Click “Open” next to the study that needs to be updated:

The screenshot shows the ClinicalTrials.gov PRS interface. At the top, it says "ClinicalTrials.gov PRS Protocol Registration and Results System". On the right, there are links for "Contact ClinicalTrials.gov PRS", "Org: UCSDMED", "Admin: ctgov@ucsd.edu", and "Logout". Below that, there are "Quick Links" for "New Record", "Admin Quick Reference", and "Problem Resolution Guide". A "Records" dropdown menu is set to "Accounts" and "Help". The main section is titled "Record List" and shows a table with columns: Protocol ID, ClinicalTrials.gov ID, Brief Title, Record Status, Last Update, Record Owner, Responsible Party, and Problems. The first row is highlighted and has an "Open" button circled in red. The record details are: Protocol ID (blank), ClinicalTrials.gov ID (blank), Brief Title "This is a Test Study to Show How CT.Gov Works (tester)", Record Status "Approved", Last Update "04/10/2019 13:55", Record Owner "ctgov@ucsd.edu", Responsible Party "RCI ClinicalTrialsGov ctgov@ucsd.edu", and Problems (blank). Below the table, there is a "KEY" section with icons for Results, Delayed Results, Study Documents, PRS Review, XML Upload, No longer public, and PRS Review Comments. A "Download..." button is at the bottom right.

3. Click “Open” next to the Protocol Section

ClinicalTrials.gov Instructions to Post Annual Report and Update the Study Record  
Issued: March 2019

ClinicalTrials.gov PRS  
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS  
Org: UCSDMED Admin: ctgov@ucsd.edu Logout

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

**Record Summary**

Home Help

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

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

Record Owner: ctgov@ucsd.edu	Access List: [ ] Edit
Last Update: 04/10/2019 13:55 by ctgov@ucsd.edu	Upload: Allowed Edit
Initial Release: [Not yet released]	PRS Review: [Not yet released]
	Public Site: [Not yet registered]
	FDAAA: Non-ACT (No FDA-regulated drug/device)

Spelling Preview Draft Receipt (PDF RTF) Download XML Delete... Admin Only: Copy Protocol Change Owner

**Open Protocol Section**

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Test Record  
Brief Title: This is a Test Study to Show How CT.Gov Works (tester)  
Module Status: Study Identification: ✓  
Study Status: ✓

4. Click "Edit" next to the study status

ClinicalTrials.gov PRS  
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS  
Org: UCSDMED Admin: ctgov@ucsd.edu

Home > Record Summary > Protocol Section  
ID: Test Record This is a Test Study to Show How CT.Gov Works [NCT ID not yet assigned]

**Protocol Section**

Record Summary Preview Edit All Help Definitions

**Edit Study Identification**

Unique Protocol ID: Test Record  
Brief Title: This is a Test Study to Show How CT.Gov Works (tester)  
Official Title: This is a Test Study to Show How CT.Gov Works  
Secondary IDs:

**Edit Study Status**

Record Verification: April 2019  
Overall Status: Not yet recruiting  
Study Start: February 10, 2020 [Anticipated]  
Primary Completion: March 20, 2025 [Anticipated]  
Study Completion: March 20, 2025 [Anticipated]

**Edit Sponsor/Collaborators**

Sponsor: University of California, San Diego  
Responsible Party: Principal Investigator  
Investigator: RCI ClinicalTrialsGov [ctgov@ucsd.edu]  
Official Title: Principal Investigator  
Affiliation: University of California, San Diego  
Collaborators:

5. Update and/or verify the relevant study status information

**Update the record by entering the current month and current year that you are editing the record.**

**Review and edit if the status recorded is no longer correct.**

**If these dates are in the past and the "Type" is indicated as anticipated, do one of the following:**

- Update the date, or
- Change Type to "Actual"

6. Click "Save"
7. After updating the record click "Entry Complete," this sends an email notice to the Responsible Party that the record is ready for the "Approval" and "Release" actions

**Record Status**

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

Next Step: Confirm data entry complete

Record Owner: ctgov@ucsd.edu  
Last Update: 04/10/2019 13:55 by ctgov@ucsd.edu  
Initial Release: [Not yet released]

Access List: [] Edit  
Upload: Allowed Edit  
PRS Review: [Not yet released]  
Public Site: [Not yet registered]  
FDAAA: Non-ACT (No FDA-regulated drug/device)

8. The Responsible Party will review the record and review it for completeness and accuracy, and then the Responsible Party should click "Approve"

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ClinicalTrials.gov PRS  
Protocol Registration and Results System

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

Contact ClinicalTrials.gov PRS  
Org: UCSDMED    Admin: ctgov@ucsd.edu    Logout

**Record Summary**

One or more unexpanded acronyms have been detected. Use the 'Spelling' link to see them.

Home    Help

**Record Status**

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

Reset to In-Progress...

Next Step: Review record    **Approve**    ?

Record Owner: ctgov@ucsd.edu	Access List: [ ] Edit
Last Update: 04/10/2019 13:55 by ctgov@ucsd.edu	Upload: Allowed Edit
Initial Release: [Not yet released]	PRS Review: [Not yet released]
	Public Site: [Not yet registered]
	FDAAA: Non-ACT (No FDA-regulated drug/device) ?

9. After the record has been "Approved" by the Responsible Party, they will need to "Release" the record by clicking "Release"

ClinicalTrials.gov PRS  
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS  
Org: UCSDMED    Admin: ctgov@ucsd.edu    Logout

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

**Record Summary**

Home    Help

**Record Status**

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

Reset to In-Progress...

Next Step: Release record    **Release...**    ?

Record Owner: ctgov@ucsd.edu	Access List: [ ] Edit
Last Update: 04/10/2019 13:55 by ctgov@ucsd.edu	Upload: Allowed Edit
Initial Release: [Not yet released]	PRS Review: [Not yet released]
	Public Site: [Not yet registered]
	FDAAA: Non-ACT (No FDA-regulated drug/device) ?

Snellings    Preview    Draft Receipt (PDF)    RTE    Download XML    Delete    Admin Only    Copy Protocol    Change Owner

10. The Record Protocol Record Verification is required by the Responsible Party
  - a. If the Verification Date (Step 5) was not previously updated, the Verification date and Responsible Party check boxes will appear, and click "Release"

**Release Protocol Record**

Unique Protocol ID:	eProst ID
Brief Title:	Testing PRS Updates
Overall Status:	Active, not recruiting
Primary Completion Date:	June 30, 2019 [Anticipated]
Verification Date:	July 2016

**URS** record is up-to-date and has been reviewed for accuracy and completeness. Verification date will be updated automatically.

**URS** Heather Osorio, Principal Investigator and Responsible Party for this trial.

**Release (submit) Protocol Record to ClinicalTrials.gov PRS for review?**



- b. If the Verification Date was previously updated (Step 5), only the Responsible party

check box will appear, and click “Release”

**Release Protocol Record**


Unique Protocol ID:	eProst ID
Brief Title:	Testing PRS Updates
Overall Status:	Active, not recruiting
Primary Completion Date:	June 30, 2019 [Anticipated]
Verification Date:	May 2017

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I am Heather Osorio, Principal Investigator and Responsible Party for this trial.

**Release (submit) Protocol Record to ClinicalTrials.gov PRS for review?**

Release
Cancel



11. Click “Release”

### **Protocol Amendments**

If a protocol is amended and the changes are communicated to the subjects in the study, those changes must be made to the study record on ClinicalTrials.gov, within 30 calendar days after the protocol amendment is approved by the IRB.

### **Other Record Updates**

Several data elements must be updated within 15 or 30 days if the information changes during the study. Below is a complete list of clinical trial registration data elements that require more frequent updating:

<b>Clinical Trial Registration Data Elements for More Frequent Updating</b>	
<b>Data Element</b>	<b>Deadline for Updating (i.e., not later than the specified date)</b>
Study Start Date	30 calendar days after the first subject is enrolled (if the first human subject was not enrolled at the time of registration).
Intervention Name(s)	30 calendar days after a nonproprietary name is established.
Availability of Expanded Access	30 calendar days after expanded access becomes available (if available after registration); and 30 calendar days after an NCT number is assigned to a newly created expanded access record. [1]
Expanded Access Status	30 calendar days after a change in the availability of expanded access.

Expanded Access Type	30 calendar days after a change in the type(s) of available expanded access.
Overall Recruitment Status	30 calendar days after a change in overall recruitment status. [2]
Individual Site Status	30 calendar days after a change in status of any individual site.
Human Subjects Protection Review Board Status	30 calendar days after a change in status.
Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date.
Enrollment	At the time the primary completion date is changed to "actual," the actual number of subjects enrolled must be submitted.
Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date.
Responsible Party, by Official Title	30 calendar days after a change in the Responsible Party or the official title of the Responsible Party.
Responsible Party Contact Information	30 calendar days after a change in the Responsible Party or the contact information for the Responsible Party.
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
Record Verification Date	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.

This table was taken from CT.gov, FAQ, ["Updates to Clinical Trial Information"](#)

### **Updating the Record for a Change in Responsible Party**

In the event the Principal Investigator, acting as the Responsible Party (RP) on a ClinicalTrials.gov study record, (1) leaves UCSD, (2) is no longer involved with the clinical trial, or (3) becomes incapacitated or dies, an email must be sent to [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu) and the change must be made to the study record on ClinicalTrials.gov.

When a Responsible Party will no longer serve as the Responsible Party, they must notify [ctgov@ucsd.edu](mailto:ctgov@ucsd.edu) 30 days prior to an expected Responsible Party personnel change, or as soon as possible, if the Responsible Party personnel change is unexpected.

- If the clinical trial is active, the Responsible Party must modify the Responsible Party on the study record and notify the newly assigned Responsible Party of the responsibilities.
- If the clinical trial is not continuing, the Responsible Party must mark the record as completed/terminated/withdrawn and modify the record to reflect the current clinical trial.

### **Transferring a Record to/from a Different Organization**

If the Responsible Party has moved to another organization and the clinical trial will be following the Responsible Party, PRS Staff can assist in transferring a record to another PRS account.

The Record Owner or the Responsible Party can request the transfer by emailing the PRS Staff at [Register@ClinicalTrials.gov](mailto:Register@ClinicalTrials.gov). Include the NCT number of the record, the name of the new organization, and the name of the new owner in the email message.