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

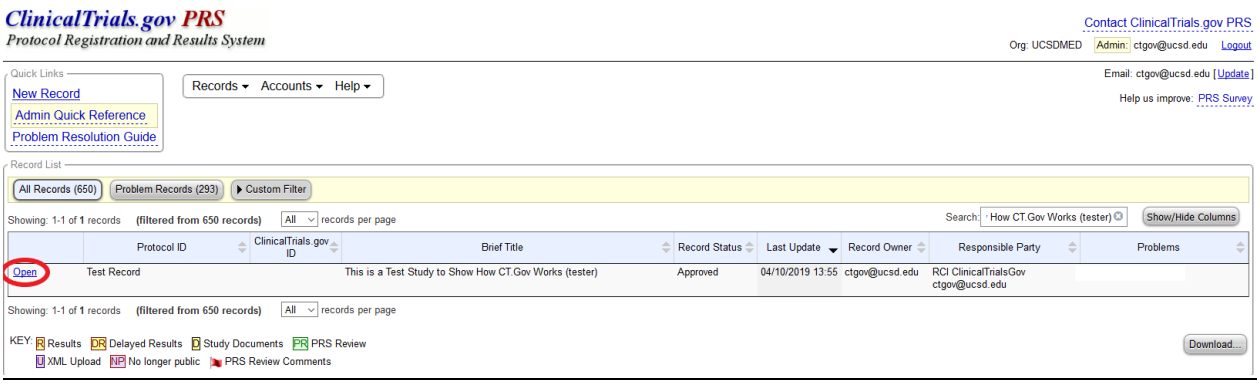
Throughout the course of a clinical trial, the study record will need to be updated. Some updates are required within 15- 30 days of changes made and others are required annually. The following guide covers the changes that must be made to the study record and the timeline to make those changes. It is 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

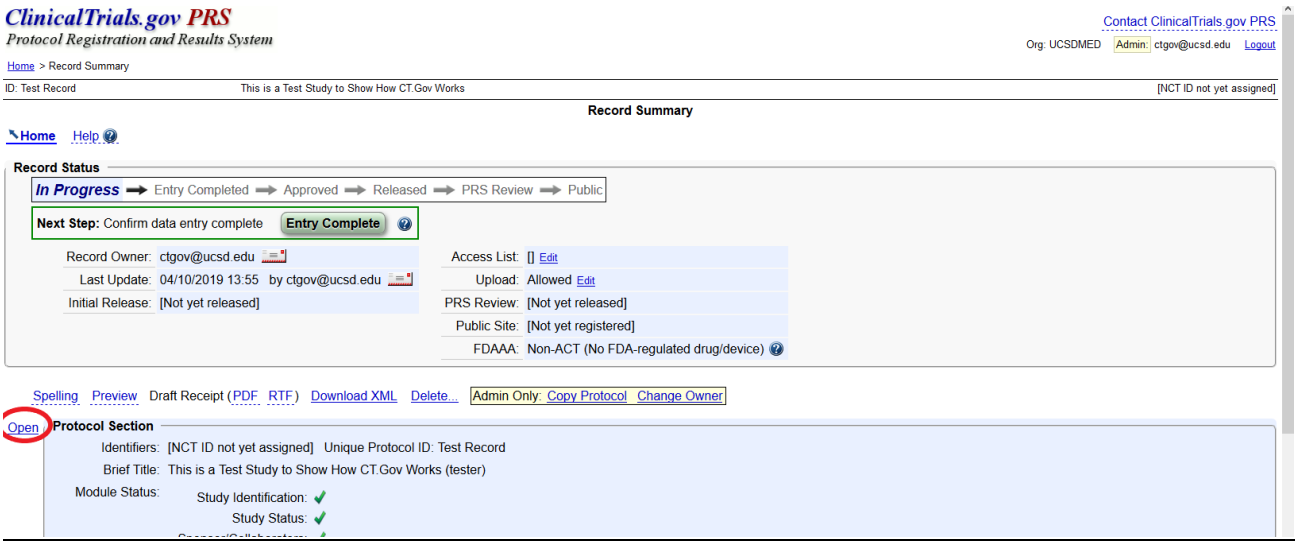
Every record must be reviewed for accuracy, and the "Record Verification Date", must be updated, at least every 12 months, even if there have been no changes to the study. The Responsible Party must: (1) Review the ClinicalTrials.gov study record for accuracy and completeness; (2) Update the Record Verification 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

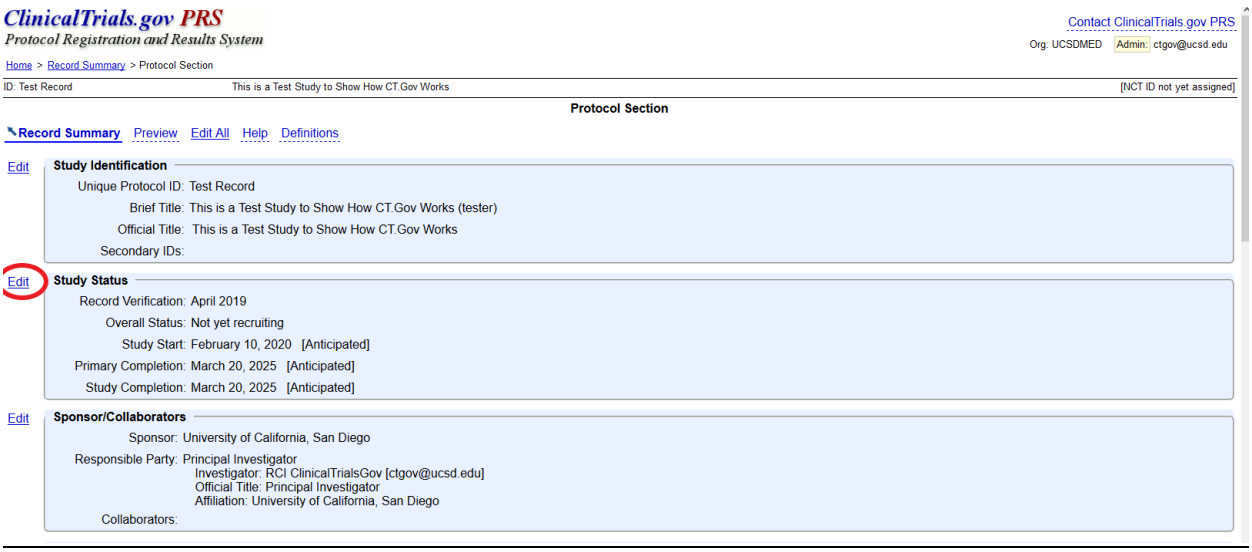
2. Click "Open" next to the study that needs to be updated:



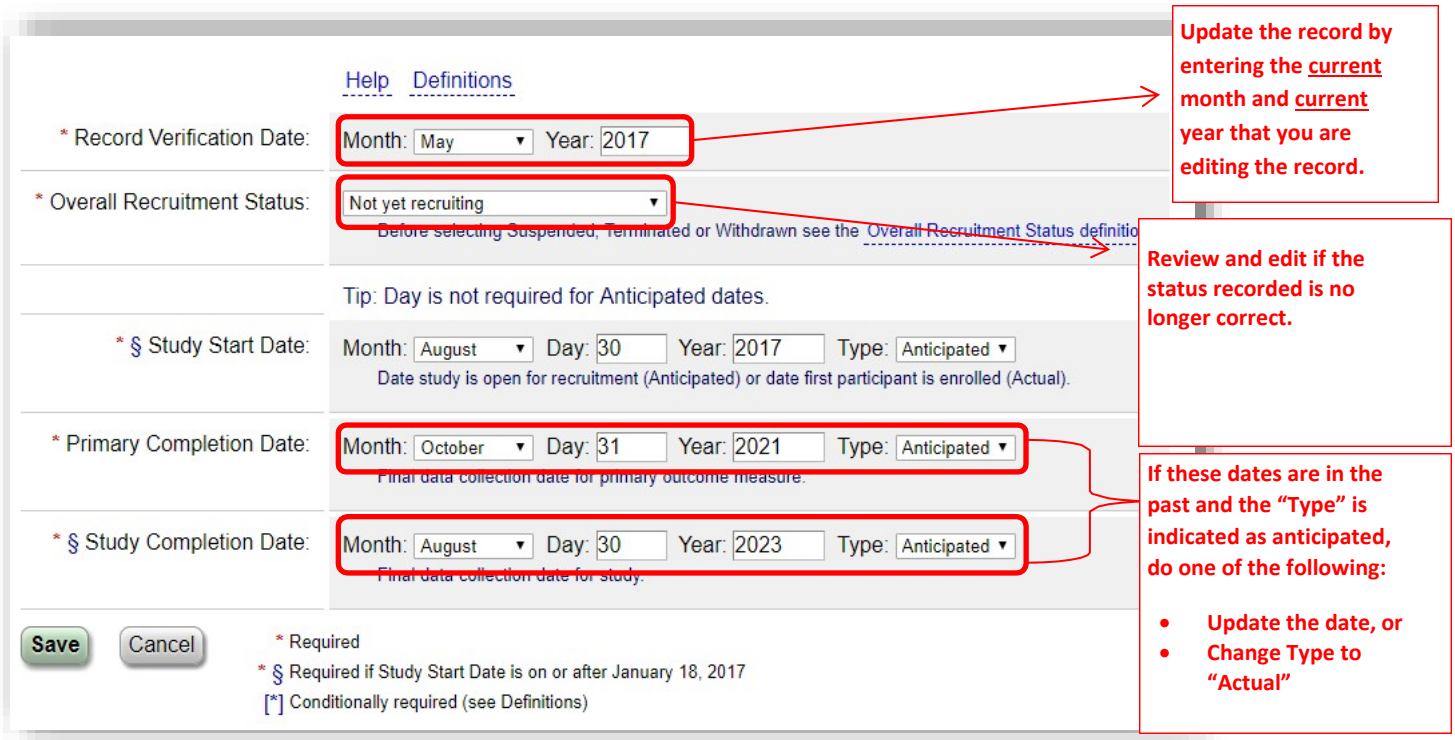
3. Click "Open" next to the Protocol Section



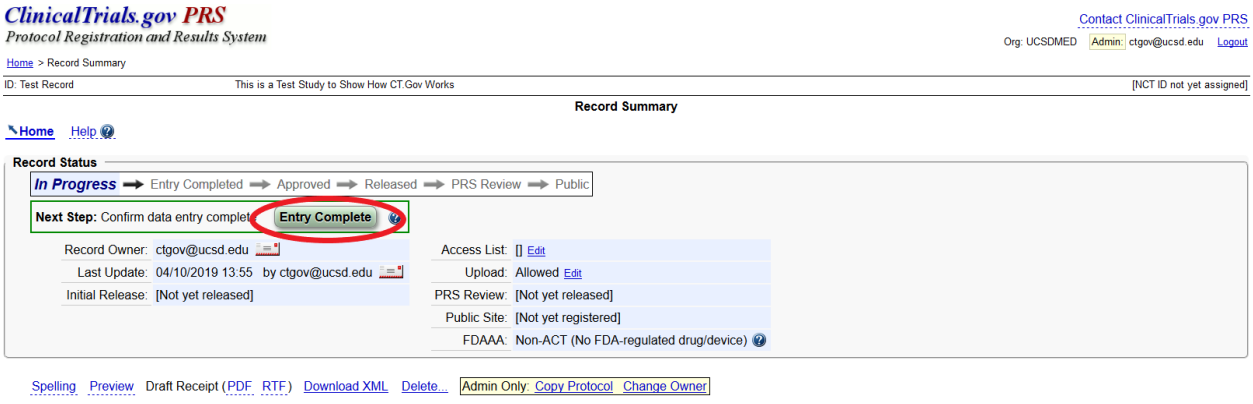
4. Click "Edit" next to the study status



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

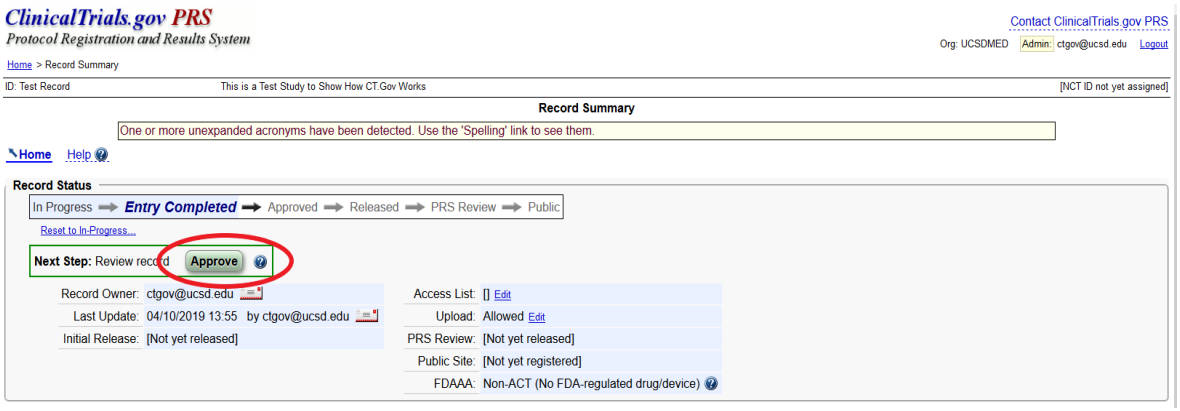


6. Click "Save"
7. After updating the record click "Entry Complete," this sends an email notice to the Responsible Party that the record is ready for the "Approval" and "Release" actions

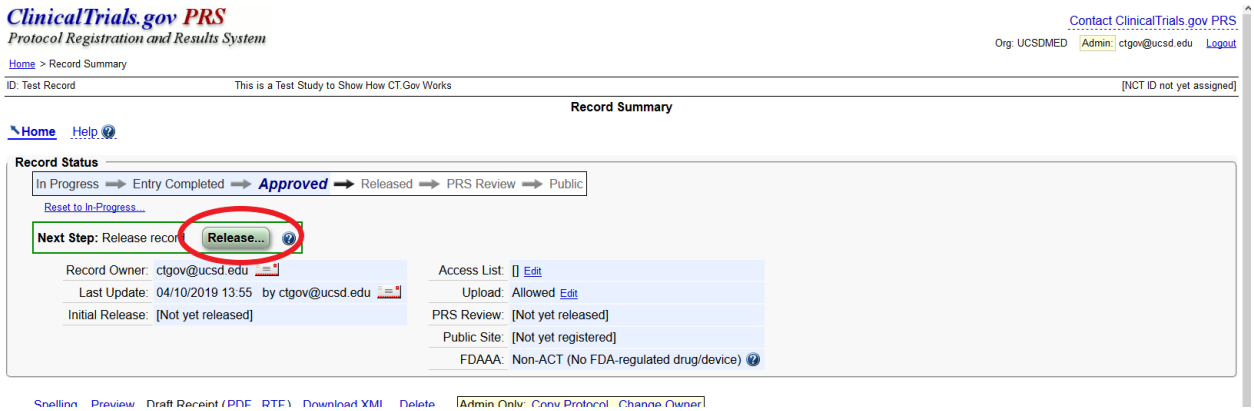


8. The Responsible Party will review the record and review it for completeness and accuracy, and then the Responsible Party should click "Approve"

Research Compliance and Integrity
Tel: 858 822-4939 / Email: rci@ucsd.edu
https://blink.ucsd.edu/sponsor/rci/index.html

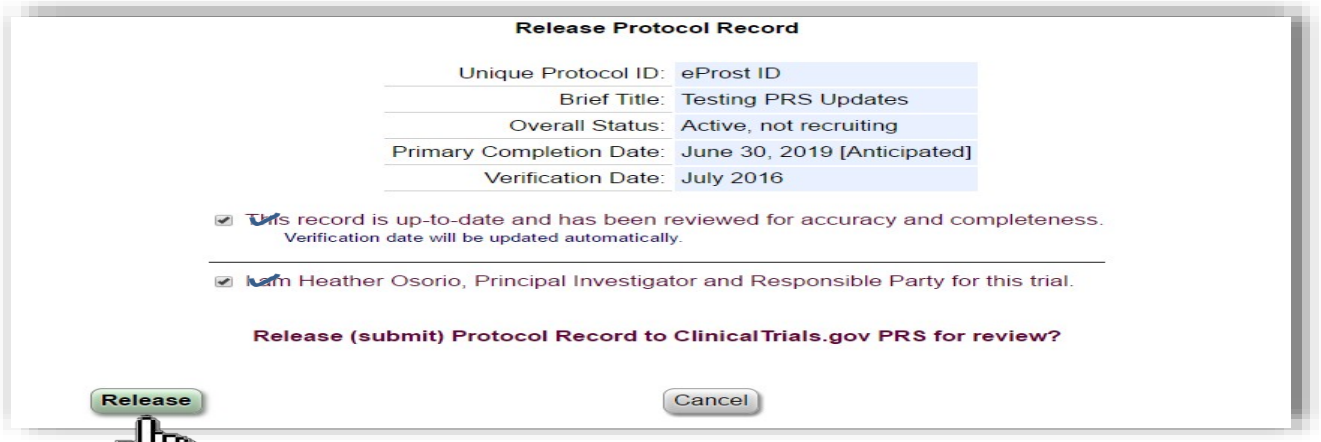


9. After the record has been "Approved" by the Responsible Party, they will need to "Release" the record by clicking "Release"



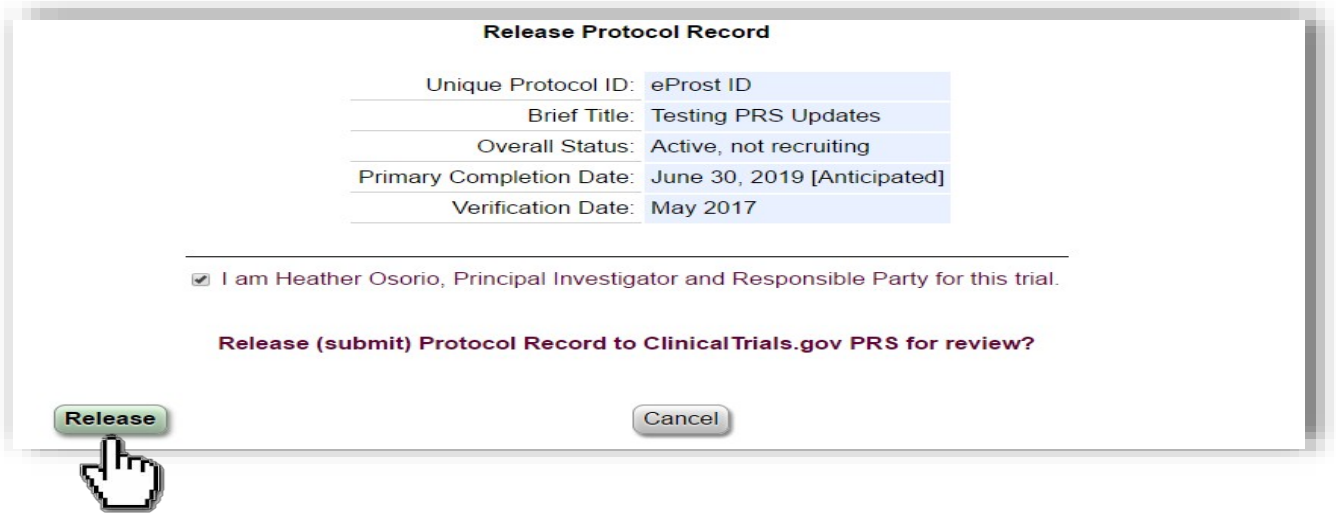
10. The Record Protocol Record Verification is required by the Responsible Party

    a. If the Verification Date (Step 5) was not previously updated, the Verification date and Responsible Party check boxes will appear, and click "Release"



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

check box will appear, and click "Release"



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:

Clinical Trial Registration Data Elements for More Frequent Updating	
Data Element	**Deadline for Updating (i.e., not later than the specified date)**
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 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 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. Include the NCT number of the record, the name of the new organization, and the name of the new owner in the email message.