ClinicalTrials.gov (CT.gov)

ClinicalTrials.gov

ClinicalTrials.gov PRS
Protocol Registration and Results System

Check back to this page for more updates regarding clinicaltrials.gov information.

Please contact oract.gov@unmc.edu for more information.

When requesting a new user account for ClinicalTrials.gov, please provide the following information:

- Preferred user name
- Institutional email address or, if none, other email address
- Office phone number

Once the account is created, ClinicalTrials.gov will send an email with login information.

> Note: For Student Principal Investigators, if your research study will be registered on ClinicalTrials.gov, please list your Faculty Advisor as the Responsible Party and yourself as Record Owner.

CITI TRAINING COURSE FOR CLINICALTRIALS.GOV

A new CITI training course is available to UNMC and UNO learners that provides video instructions for registering, uploading documents, and submitting results in ClinicalTrials.gov. Currently optional, the course is highly recommended as a guide to investigators new to ClinicalTrials.gov requirements and to experienced investigators needing a refresher.

- Login into your UNMC or UNO CITI account
- Scroll down to 'Add a Course'
- Click the box for Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov
- Click 'Next'.

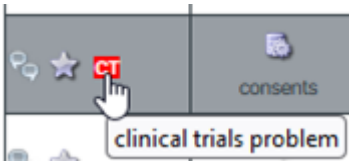
When you have successfully completed the course, please email a copy of the Completion Certificate to oract.gov@unmc.edu.

CLINICALTRIALS.GOV ICONS IN RSS

IRB protocols that are investigator-initiated and registered on ClinicalTrials.gov with an NCT# will now be denoted by an icon in RSS.

A green icon means no problems are currently identified by ClinicalTrials.gov on the record associated with the study.

A red icon means ClinicalTrials.gov has identified problems on the associated record.



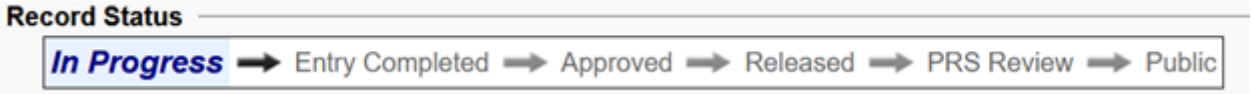
If your study has a red icon, please login at https://register.clinicaltrials.gov to correct the problem(s). Icons are updated daily, Monday-Friday, so once problems are resolved, the icon will be green after the next daily update. If you have difficulty correcting a problem in https://register.clinicaltrials.gov, please contact oract.gov@unmc.edu for assistance.

Outstanding problems with the ClinicalTrials.gov record may delay the review and approval of IRB submissions. Please ensure all problem records are addressed as soon as possible (UNMC HRPP Policy 1.29).

PROCESS FOR UPDATING A RECORD

Whenever a ClinicalTrials.gov record is updated, the process must be completed by approving and releasing the update.

Steps for completing an update of any type are displayed in the “Record Status” at the top of the record.

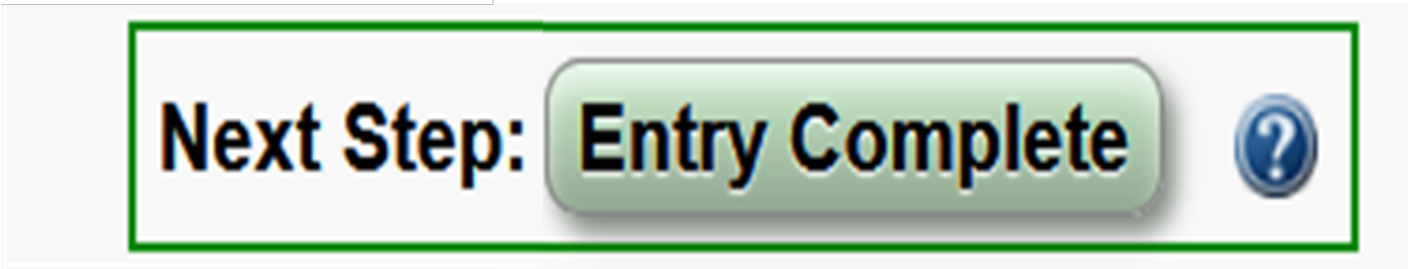


The “Next Step” box is displayed immediately below which describes the next action needed.

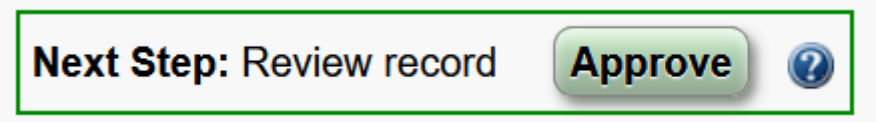
Any problems with the update are listed in the “Next Step” box and may include:

- Correct Error(s)
- Enter Results
- Finish Protocol/Documents/Results section
- Address Review Comments

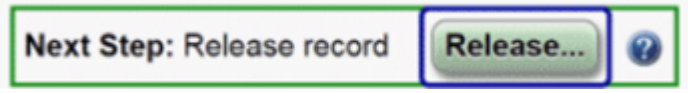
Once the update problems are resolved, the next step is to click the “Entry Complete” button:



The following step is to review the update, then click the “Approve” button:

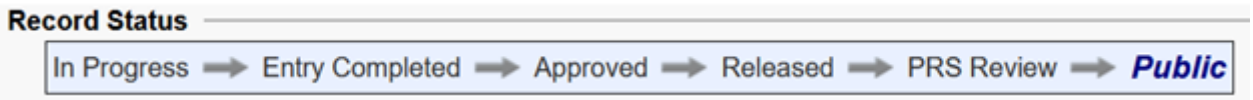


The last step is to click the “Release” button if you are the Responsible Party for the record:



If you are the Record Owner, this “Next Step” box will be displayed, and the Responsible Party will need to login and release the update.

When any problems with the update are resolved and the update has passed PRS review, the update is released to the public ClinicalTrials.gov site.



All the steps on the “Record Status” will be highlighted in blue.

POSTING CONSENT FORMS

For any clinical trial conducted or supported by a federal agency or department or agency, Federal Regulations require the awardee of a grant to post one IRB approved informed consent form used to enroll subjects on a publicly available Federal Web site.

“Clinical trial” means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

The PI must post:

- Only if the organization (UNMC, Nebraska Medicine, UNO or CHMC) is the lead site or grantee organization.
- Only clinical trials (defined above). As a general rule, if you reported to clinicaltrials.gov then you will also have to post the consent form.
- Only if conducted or supported by a Federal department or agency.

The PI only needs to post **ONE** consent form used to enroll subjects anytime during the course of the study.

The consent form must be posted no later than 30 days after the last subject is enrolled.

If your study is utilizes the Clinical Trials Monitoring System (CTMS) you will receive notification when your last subject is enrolled. The notification includes instructions about the requirement, and how to post to clinicaltrials.gov.

If your study does not utilize CTMS it is your responsibility to track subject enrollment, and post no later than 30 days after the last subject is enrolled.

Specific instructions on how to register with ClinicalTrials.gov and upload documents can be found here.

Revision #12
Created 12 July 2024 18:23:22 by Robert A Lewis
Updated 31 July 2024 16:59:39 by Robert A Lewis