

Access to ClinicalTrials.gov Protocol Registration System:

1. To request a user account, contact your Department PRS Administrator. If your department does not have a PRS Administrator, contact the PRS Administrator in the Office of Quality Compliance (OQC) at OQC@utah.edu for an account request.
2. Please provide the following information:
 - First, Last Name
 - uNID #
 - E-mail
 - Phone
 - Department
 - Role (e.g., PI or Coordinator)
3. The OQC PRS Administrator will provide the user with an organization and username. A temporary password will be generated by the ClinicalTrail.Gov PRS system and sent to the user via email.
4. Departments may be required to appoint a designated PRS Administrator. If required, a request will be sent from the OQC.

If you are interested in learning more about ClinicalTrials.gov, the University of Utah Research Education offers a self-paced ClinicalTrials.gov training module available at:

<https://utah.catalog.instructure.com/browse/research-education/research-education-red/courses/rats-online-introduction-to-clinicaltrials-gov>

Training is *not* required for study teams or PIs. Training is only required for the role of PRS Administrators.

Responsible Party:

1. The University of Utah requires the Sponsor-Investigator or lead PI funded by NIH, or other Common Rule department or agency, be the designated Responsible Party for each respective record on ClinicalTrials.gov.
2. The Responsible Party is required to "approve" and "release" a record any time changes have occurred. The Responsible Party is required to "release" the record no later than ten (10) business days after the record updates have occurred.
3. The University of Utah should not be designated as the Responsible Party

<https://clinicaltrials.gov/ct2/manage-recs/faq#responsibleParty>

Record Owner:

1. Primary contact for the study record. Record Owner receives email communications about the record. Record ownership can be transferred.
 - a. Automatically receives PRS emails. Responsible Party will also receive PRS emails, if not Record Owner.