UC SAN DIEGO
CLINICALTRIALS.GOV REGISTRATION INSTRUCTIONS

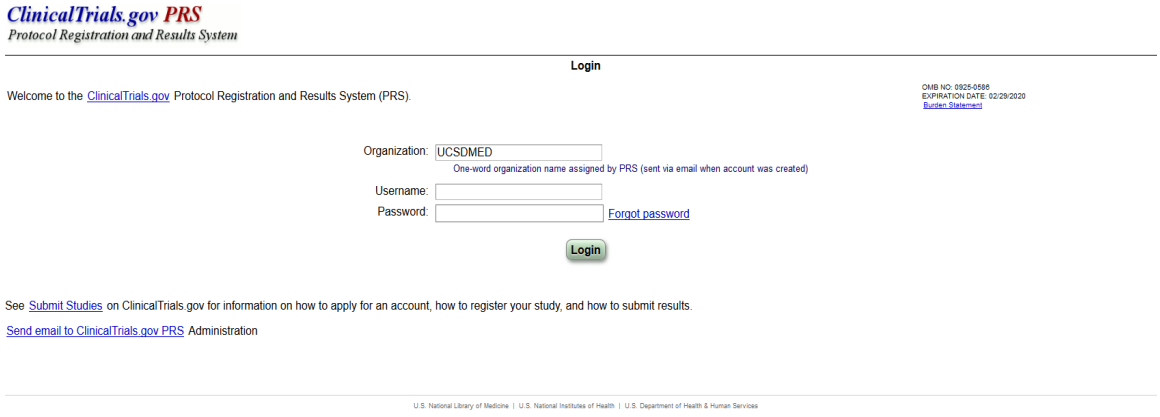
The Food and Drug Administration Amendments Act (FDAAA), National Institutes of Health (NIH) and International Committee of Medical Journal Editors (ICMJE) require registration of certain studies on a publicly accessible website, ClinicalTrials.gov. The following is a quick start users guide on how to carry out some of the most common functions on ClinicalTrials.gov when registering a study.

1. ***How to Obtain a User Account:***

1) Email ctgov@ucsd.edu and ask for a user account under UC San Diego's (UCSD) Institutional Protocol Registration and Results System (PRS) Account, "UCSDMED"
2) A UCSD administrator will setup your account and then submit your account information to ClinicalTrials.gov to create a new account
3) ClinicalTrials.gov will then create a new user PRS account within two business days of receiving the request
4) Once the account has been created, an email will be sent from ClinicalTrials.gov to the new user with a username, password and instructions for logging in to UCSD's Institutional PRS account

2. ***Logging in for the First Time:***

1) Go to https://register.clinicaltrials.gov/ to sign in



2) Enter Organization: UCSDMED
3) Enter the username and password emailed to you by ClinicalTrials.gov
4) Change your password once you log in for the first time
    i. Go to Accounts > Change password

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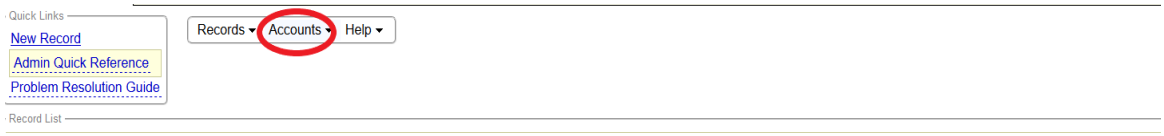
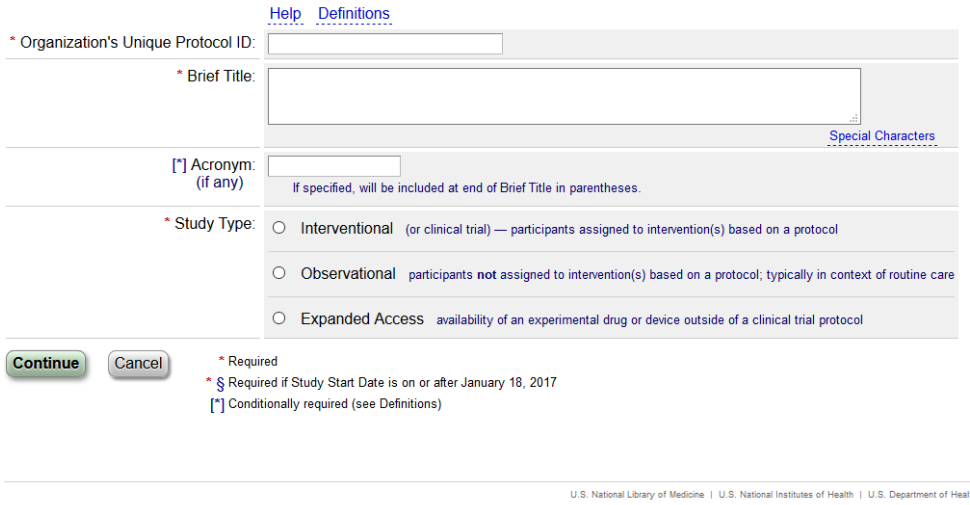


3. ***Creating a New Study Record:*** The person who creates the record becomes the Record Owner. All email messages about the study record will be sent to this person.
    1) Log in to PRS with your assigned organization name, username, and password
    2) Click on Records > New Record or use the quick links to the left hand side and click on "New Record"

    3) Enter all the applicable information regarding the study you are registering

    a. *Tip: Data is saved as each page is filled in, so that you can "Quit" at any time, saving the record for later completion*



    4) After filling in the last data entry page, the "Protocol Section" page appears with all of the information provided. Review and "Entry Complete" if all information is complete. Address any ERROR messages, if any populate.

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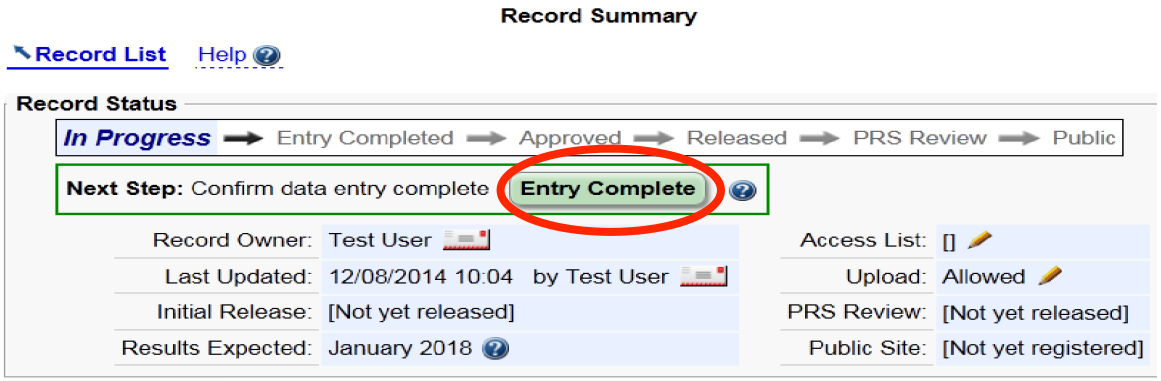
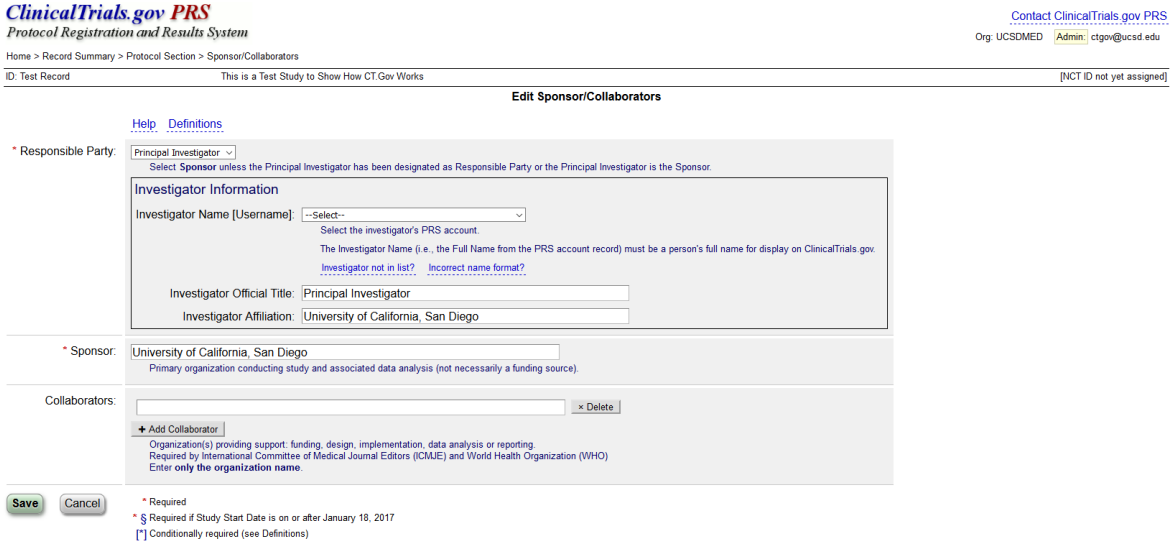


5) Next the Responsible Party (RP) will review the record for completeness and appropriateness, and then click "Release" to submit the record for review by a PRS staff member.

4. ***Responsible Party Designation:*** One of the pages that will populate when creating a new record is the "Edit Sponsor/Collaborators" page. UCSD requires the Principal Investigator be designated as the Responsible Party (RP).



1) Under Responsible Party choose "Principal Investigator"
2) Select the Investigator name from the drop down menu
    i. If the Principal Investigator is not listed there, then they do not have an account, have the Principal Investigator email ctgov@ucsd.edu for a new account

3) Enter the Investigator's Official Title

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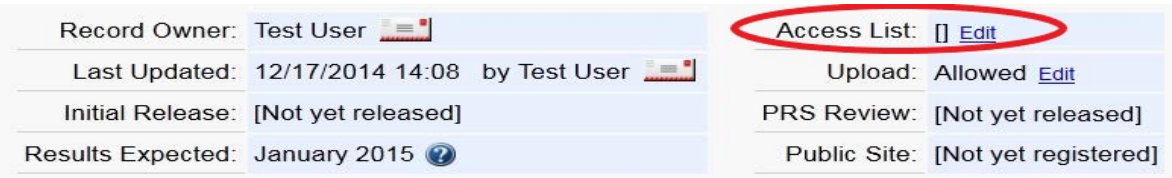
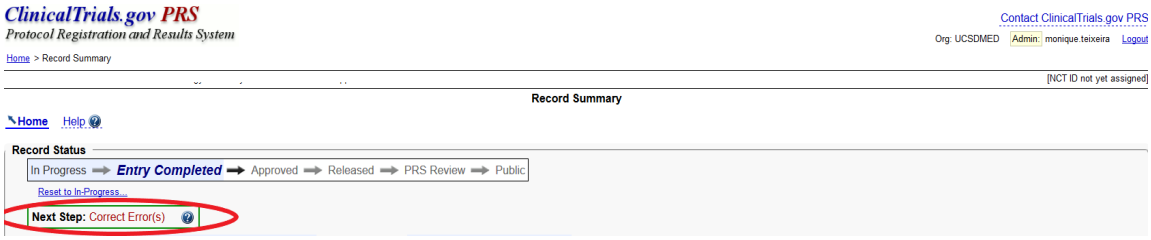
4) Investigator's Affiliation should automatically populate to "University of California, San Diego"
5) Any collaborating sites should be entered under the Collaborators section
6) Click Continue

5. ***Sharing Access to a Study:*** Only one Record Owner can be assigned to a study record, but the Record Owner can allow other users to edit the study record by granting them access.
   1) Log in to PRS with your assigned organization name, username, and password
   2) Open a study record
   3) Click on access list

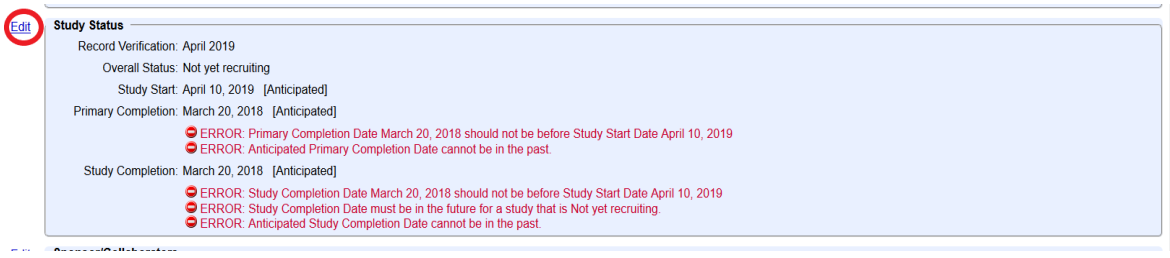


   4) Select the users you wish to grant access to and click "Save"

6. ***PRS Staff Review:*** After the RP releases the record, a PRS staff member will complete a manual review for apparent errors, deficiencies, and/or inconsistencies. The RP is responsible to respond to the PRS staff member's requests for information or changes within 15 days.
   1) If a PRS staff member finds any potential issues with the record, they will add comments to the record and send an email notification to the Record Owner
   2) The Record Owner must log in to PRS to view the comments
   3) Click on "Open" by the section where errors are identified



   4) The errors will be highlighted in red text
   5) Click "Edit" on the left hand side of the section to edit the errors



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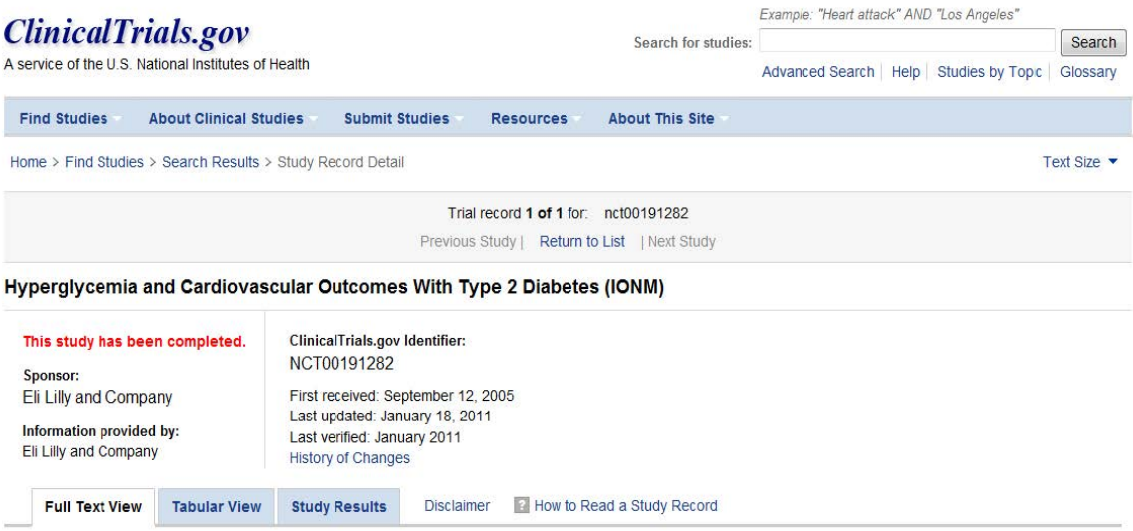
6) The user will then edit the study record to address the comments and click "Save"
7) After the issues have been addressed, resubmit the record for PRS Review by clicking "Entry Complete"

7. ***Record is Registered and Posted:***
   1) Once the study record is approved by the PRS staff member review, an email notification will be sent to the Record Owner with the ClinicalTrials.gov Identifier (NCT number), indicating that the study is registered



   2) Generally, within two business days of registration, the system will post the record on the ClinicalTrials.gov website

   3) Once registered, a study record becomes a permanent part of ClinicalTrials.gov and cannot be removed or deleted.