CCTS

Center for Clinical and Translational Science

ClinicalTrials.gov

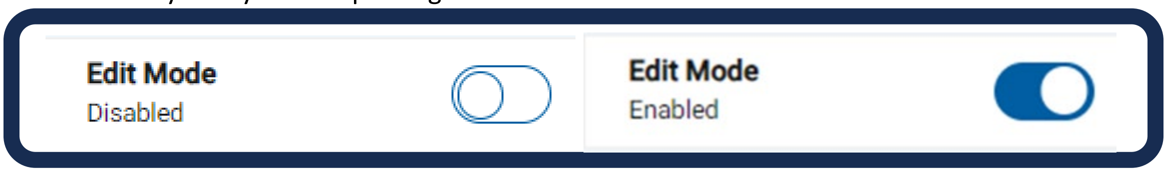
Step-by-Step Guide

CCTS Step-by-step guide for updating your record on the PRS Modernization

Questions contact: CCTSClinicalTrials.govHELP@uabmc.edu

If there is a guide you wish to have added, please email us at the address above and reference the step-by-step guide.

Note: To make edits you must enable Edit Mode. You may need to switch to edit mode for each new section of the study that you are updating.



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New Account

Please send the following information to email address above. We will set up an account for you.

(Fellows, Residents, and other visiting/temporary researchers must submit a protocol along with this request and note their mentor/supervisor.)

1. BlazerID:
2. Full name (i.e.: legal first and last name):
3. Your full job title (i.e.: Fellow, Coordinator, Professor):
4. UABMC or UAB email (most used):
5. Phone number:
6. Studies you need access to (NCT#) [if applicable]:

A reminder for the future: If you have faculty, fellows or residents leaving UAB, please have them transfer or complete his/her records in ClinicalTrials.gov prior to leaving.

Study Identification:

- Organization’s Unique Protocol ID

    Please change the ID to the UAB IRB# (i.e.: IRB-30000####)

    Grant/Funding number go in as Secondary IDs.

    - Under the ‘View Record’ column, Click ‘Open’ next to the study you wish to edit
    - Click ‘Protocol’ tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click ‘Study Identification’ on the left side bar
    - Change ‘Organization’s Unique Protocol ID to the UAB IRB number. (IRB-3000#####)
    - Scroll down and click ‘Save Changes’ at the bottom of the page
    - Click the ‘Record Summary’ Tab
    - On the right hand side click ‘Entry Complete’, ‘Approve’, and ‘Release’ (Reminder: Only PIs can release the record.)

- Secondary ID

    - Under the ‘View Record’ column, Click ‘Open’ next to the study you wish to edit
    - Click ‘Protocol’ tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click ‘Study Identification’ on the left side bar
    - Scroll down to ‘Secondary IDs’
    - Select the type of ID from the ‘Secondary ID’ dropdown box
    - Enter Grant/Contract Award number in the box provided
    - Enter Grantor or Funder Organization(s) in the box(es) provided

        <u>If you are adding more than one grant/funding number:</u>

        - <u>Click ‘+Add Other Grant/Funding Number’</u>
        - <u>Select ID Type and Click ‘Add’</u>
        - <u>Click the radio button next to the desired type (do not unclick previous buttons)</u>
        - <u>Enter new Grant/Contract Award number and Organization in the boxes provided</u>
    - Enter the funding organization’s name in the collaborator section
    - Scroll down and click ‘Save Changes’ at the bottom of the page
    - Click the ‘Record Summary’ Tab
    - On the right hand side click ‘Entry Complete’, ‘Approve’, and ‘Release’ (Reminder: Only PIs can release the record.)

Study Status:

- Record Verification Date
    - Under the ‘View Record’ column, Click ‘Open’ next to the study you wish to edit
    - Click ‘Protocol’ tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click ‘Study Status’ on the left side bar
    - Under ‘Record Verification Date’ select the current ‘Month’ from the dropdown box
    - Enter the current ‘Year’
    - If the Overall Recruitment Status has changed, select the current status from the drop down box. (If there ***is*** a status change, updates to the Contacts and Location section is also required. See Contacts and Location section for step-by-step directions.)
    - Scroll down and click ‘Save Changes’ at the bottom of the page
    - Click the ‘Record Summary’ Tab
    - On the right hand side click ‘Entry Complete’, ‘Approve’, and ‘Release’ (Reminder: Only PIs can release the record.)

- Study Start Date
    - Under the ‘View Record’ column, Click ‘Open’ next to the study you wish to edit
    - Click ‘Protocol’ tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click ‘Study Status’ on the left side bar
    - Scroll to ‘Study Start Date’
    - Select the ‘Month’ and ‘Day’ of the Anticipated or Actual Start Date from the dropdown box
    - Enter the Anticipated or Actual ‘Year’
    - Click the Radio button for Actual if the study is open to enrollment, or Anticipated if the study has not started enrollment yet
    - If the Overall Recruitment Status has changed, select the current status from the drop down box. (If there ***is*** a status change, updates to the Contacts and Location section is also required. See Contacts and Location section for step-by-step directions.)Scroll down and click ‘Save Changes’ at the bottom of the page
    - Click the ‘Record Summary’ Tab
    - On the right hand side click ‘Entry Complete’, ‘Approve’, and ‘Release’ (Reminder: Only PIs can release the record.)

- Primary Completion Date
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Study Status' on the left side bar
    - Scroll to 'Primary Completion Date'
    - Select the 'Month' and 'Day' of the Anticipated or Actual Start Date from the dropdown box
    - Enter the Anticipated or Actual 'Year'
    - Click the Radio button for Actual if the study is open to enrollment, or Anticipated if the study has not started enrollment yet
    - If the Overall Recruitment Status has changed, select the current status from the drop down box. (If there ***is*** a status change, updates to the Contacts and Location section is also required. See Contacts and Location section for step-by-step directions.)
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release'
      (Reminder: Only PIs can release the record.)

- Study Completion Date
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Study Status' on the left side bar
    - Scroll to 'Study Completion Date'
    - Select the 'Month' and 'Day' of the Anticipated or Actual Start Date from the dropdown box
    - Enter the Anticipated or Actual 'Year'
    - Click the Radio button for Actual if the study is open to enrollment, or Anticipated if the study has not started enrollment yet
    - If the Overall Recruitment Status has changed, select the current status from the drop down box. (If there ***is*** a status change, updates to the Contacts and Location section is also required. See Contacts and Location section for step-by-step directions.)
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release'
      (Reminder: Only PIs can release the record.)

Sponsors and Collaborators:

- Investigator Information
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Sponsors and Collaborators' on the left side bar
    - Click the Radio button for "Principal Investigator'
    - Choose the PI's name from the dropdown box (Hint: PIs are listed in alphabetical order by first name.)
    - Enter the Investigator Official Title. (i.e.: Fellow, Associate Professor, Professor, Researcher IV, etc.)
    - For Investigator Affiliation enter 'University of Alabama at Birmingham'
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release'
(Reminder: Only PIs can release the record.)

- Collaborators
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Sponsors and Collaborators' on the left side bar
    - Scroll down to 'Collaborators'
    - Begin typing the Collaborator's name in the box. A dropdown of options will appear. Select the correct Collaborator
    - Click 'Add Collaborator'
    - Continue adding as many Collaborators as necessary in this same way; there is no limit to the number of Collaborators you list
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release'
(Reminder: Only PIs can release the record.)

Oversight:

- Human Subjects Protection Review
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Oversight' on the left side bar
    - Scroll down to 'Human Subjects Protection Review'
    - Select the 'Board Status' from the dropdown box provided
    - Board Name: UAB Institutional Review Board
    - Board Affiliation: University of Alabama at Birmingham
    - Board Contact Information
        - Phone: (205) 934 – 3789
        - Ext.: leave blank
        - Email: irb@uab.edu
        - Address: UAB Office of the IRB
          AB 470
          1720 2nd Avenue South
          Birmingham, AL 35294-0104
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release' (Reminder: Only PIs can release the record.)

Eligibility Section:

- Age Limits (These values must match exactly with HSS or Assist)
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Eligibility' on the left side bar
    - Scroll down to 'Age Limits'
    - For Minimum Age select the radio button for either:
        - No Limit (NA)
        - Minimum Age Limit
            - Enter number value for 'Minimum Age' (note: Zero = at Birth)
            - Select the 'Unit of Time' from the drop down box
    - For Maximum Age select the radio button for either:
        - No Limit (NA)
        - Maximum Age Limit
            - Enter number value for 'Maximum Age' (note: Zero = at Birth)
            - Select the 'Unit of Time' from the drop down box
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release' (Reminder: Only PIs can release the record.)

Contacts and Locations

(Note: Each section is shown in a different field on the public site. Please fill in completely.)
Sub-Is are listed in the Locations section under Investigators.

- Contacts
  - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
  - Click 'Protocol' tab near the middle of the screen
  - If Necessary: Click the radio button to enable Edit Mode on the left side bar
  - Click 'Contacts and Locations' on the left side bar
  - Click 'Edit'
  - For Central Contact Person, enter the following information:
    (Note: This can be the PI or the Coordinator.)
    - First Name
    - Middle Initial
    - Last Name
    - Degree
    - Phone number (This is number will be public. Do not put your cell number if you don't want patient's calling this number.)
    - Email
  - For Central Contact Backup, enter the information as you did for the Central Contact Person.
    (Note: If the first person was the PI, enter the coordinator or vice versa.
  - For Overall Study Official enter the PIs information:
    (Note: Each section is shown in a different field on the public site. Please fill in completely.)
    Sub-PIs are listed in the Locations section under Investigators.
  - Scroll down and click 'Save Changes' at the bottom of the page
  - Click the 'Record Summary' Tab
  - On the right hand side click 'Entry Complete', 'Approve', and 'Release'
    (Reminder: Only PIs can release the record.)

- Locations (You must enter a location even if it is at UAB. But only enter one location for UAB unless it is off site. TKC, Whitaker, and Highlands do not have to be listed separately unless you are tracking for each individual site or otherwise noted in your protocol.)
    - Under the 'View Record' column, Click 'Open' next to the study you wish to edit
    - Click 'Protocol' tab near the middle of the screen
    - If Necessary: Click the radio button to enable Edit Mode on the left side bar
    - Click 'Contacts and Locations' on the left side bar
    - Scroll down to 'Locations'
    - Click 'Edit'
        - Edit Location:
        - Change Site Recruitment Status to match Study Status

    or

    - Click 'Add Location' for each individual site:
        - Select Country
        - Select State (if prompted)
        - Enter Facility Name
        - Enter City, State/Province, and Zip/Postal Code
        - Select 'Site Recruitment Status' from the dropdown box
        - Add Facility Contact (i.e.: Study Coordinator)
        - Add Facility Contact Backup (i.e.: Backup Study Coordinator)
        - Enter Investigator(s) Name and Degree
        - Select 'Role' from the dropdown box
        - Click 'Add Investigator' for each additional Sub-I
    - Repeat 'Add Location' steps for each site
      (Note: Each section is shown in a different field on the public site. Please fill in completely.)
    - Scroll down and click 'Save Changes' at the bottom of the page
    - Click the 'Record Summary' Tab
    - On the right hand side click 'Entry Complete', 'Approve', and 'Release'
      (Reminder: Only PIs can release the record.)