eIRB Training – Investigators/Research Coordinators

Topics Covered:

1. Home Page
2. My IRB Protocols
3. Completing New Protocols
4. Amendments & Continuing Reviews
5. Submitting a Protocol
6. Certifying a Protocol
7. Other Protocol Options
1. Welcome to the eIRB Home Page!

- Click here to manage existing protocols

The “Helpful Links” section offers other information such as IRB policy, FAQs and information about WCMC’s IRBs.

WCMC IRB Meeting schedules for the General and Cancer Boards; agendas are closed one week prior to the meeting date.

2. “My IRB Protocols” tab to Manage Existing Protocols

- All submissions awaiting action by the PI, co-investigator or coordinator.

All submissions in routing, either at the IRB Office or being reviewed by the Department Approver. Once a protocol is submitted into routing, it cannot be edited. If you would like to edit a protocol in this section, please contact the IRB office to have the submission returned to the research team.

All active protocols can be found here – Go here to create Amendments and Continuing Reviews

HELP & FAQS

To learn more about how to use eIRB and view the FAQs, please click here.

UPDATES

It’s strongly recommended that only Mozilla Firefox be used to access eIRB.

NOTES: Only the PI can submit (new protocols, amendments, renewals, etc.) using eIRB. PI’s must be given editing rights under “Access Permissions” in order to be able to submit anything related to a specific protocol.

NOTE: There is a 4900 character limit for each question. If you exceed this limit, you will get an error and the response won’t be saved. If you have more than 4900 characters, please attach the most recently approved IRB protocol application and reference the corresponding question in your response.
3. New Protocols

1. Complete all sections that the CSEC does not complete. This can be done once the CSEC creates the protocol and while the study is under CSEC review.

2. Make sure all investigators certify the protocol.

3. If you are not the PI, make sure the PI has editing rights to the protocol in order to submit. Please see the “Other Protocol Options” section of this eIRB training guide to learn how to grant the PI editing access.

As of August 15, 2013, the CSEC handles the Create New Protocol functionality. If you click on “Create New Protocol” at the top navigation, you will receive this pop-up prompting you to visit the CSEC website.
4. Creating Amendments & Continuing Reviews

**STEP 1.** Locate protocol within “All Active Protocols”

**STEP 2.** Open the protocol to create an Amendment or Continuing Review

**STEP 3.** Choose between 2 options located under “Protocol Options” on the lower left-hand navigation:

1. Continuing Review
2. New Amendment

Please note that only 1 Amendment or Continuing Review can be submitted at a time. If the protocol you are amending is close to expiring, we recommend that you select Continuing Review and simultaneously amend the protocol and submit the protocol for renewal. If you select the “New Amendment” within 30 days of a protocol’s expiration date, the system will suggest to create a Continuing Review.
Amendments

Continuing Reviews will act the same as amendments, except instead of filling out an Amendment Summary, you will fill out a Renewal Summary. Also, instead of filling out the Amendment Information section, you will fill out the Continuing Review Information section in which you are asked if you are submitting an Amendment with the Continuing Review. The Renewal Summary page will have the same checkboxes corresponding with a protocol section as displayed above. In order to amend a section, check the boxes for the sections you would like to amend and then hit “Save” before proceeding to the section on the left-hand navigation. Please note that all Continuing Reviews will require recertification of financial conflicts of interest by all investigators.
5. Submitting a Protocol, Continuing Review, Amendment or Response to Questions for IRB review

In order to submit, the PI will need editing access. Please see the “Other Protocol Options” section of this eIRB training guide to learn how to grant the PI editing access.

STEP 1. Click “Submission Options” on the lower left-hand navigation under “Protocol Options” to submit an Amendment, Continuing Review, Response to Questions or Initial submission for IRB review. This will send the submission into routing or to the IRB Office. Routing consists of department chairs and IRB approvers.

Please note that anyone with editing rights to the submission can re-submit a submission that has been returned to the research team by an IRB administrator. Anyone with editing rights can also re-submit a Response to Questions submission that was originally deemed “Modifications Required.” If your submission was “Deferred,” the PI will need to re-submit the Response to Questions.

STEP 2. Click “Submit For Review.” This allows a protocol to be submitted into routing and to the IRB Office.

This function validates that all sections, required uploads and conflict of interest certification of investigators are complete. If one or more of these items are incomplete, you will not be able to submit. The PI must submit the protocol and notification to the PI can be sent from the “Submit For Review” page once everything is complete.

Click “Where is My Protocol?” to see where your protocol is in the routing process.

You will be able to track the movement of the protocol through all the approvers and IRB Office.
6. Certifying a Protocol – Disclosing a potential conflict of interest

Add Investigators to a Protocol
Please note that a funding source must be added first before adding investigators.
If the funding source is ever changed, all investigators will have to recertify.

All investigators are required to “Certify” the protocol. This can only be done by the investigator.

Send an email notification to alert all or individual investigators to certify the protocol.

Please note that certifying a protocol is not equivalent to completing the required CITI training, which can be viewed here.

A green checkmark indicates that the investigator has certified the protocol and what the response was can be seen next to it under ‘Conflict.’
7. Other Protocol Options

Protocol Options
- Submission Options
- Comments
- Where is My Protocol?
- Amendments/New Protocol History
- View History
- Continuing Review
- New Amendment
- Access Permissions
- Print Summary

Communicate with the IRB office about this protocol.

View the amendment and renewal history for a particular protocol.

Grant editing or view-only rights to the protocol.

Create a PDF file of the protocol.

Access Permissions

Access Permissions

Click here to grant editing rights. The PI must be granted editing rights in order to submit an Initial, Amendment, or Continuing Review submission.

When a coordinator creates an Amendment or Continuing Review, only the coordinator has editing rights to that specific submission. The coordinator must grant editing rights to the PI in order to submit and to other coordinators who may need editing access.

Click here to remove a specific user’s editing rights.

Click here to grant view-only rights to the protocol.

Click here to remove a specific user’s view-only rights.