eIRB Quick Reference Guide For Researchers

Logging In

How to log in to the eIRB system

1. Go to eirb.rutgers.edu
2. Enter your NetID User name: and Password:
3. Click Log In to enter the site.

Your Personal Workspace

Your Personal Workspace, otherwise known as 'My Home', displays all the eIRB study submissions associated to you. If you are not already at your home page, click My Home at the top right of your screen.

The Study Workspace

When you open an existing application, modification, or continuing review from your Personal Workspace, you will be taken to the Study Workspace. The Study Workspace is the area where all activities associated with the study will be performed.

Creating a New Application

Applications for new research studies must be submitted by the Principal Investigator (PI). Student co-Investigators (co-Is) may complete, but not submit applications.

1. Click the Create New Study button to initiate a new IRB Sub-mission.
2. Begin by filling out the first page of an application.
3. Click Continue to advance to the next page of the application.
4. When you are finished, click Save to save your changes and then Exit to exit the application form and return to the Study

Adding Study Team Members

Student researchers will have the role of student co-Investigators (co-Is) on a study. The faculty advisor will assume the role of Principal Investigator (PI).

1. Start a new application or create a modification for an already approved study.
2. Click the Select or (Add) button beside the study team member to be added– Principal Investigators, Study Coordinators, co-Investigators, other team members.
3. Filter the list to find the team member you want to add.
4. Select the team member to be added by clicking beside his/her name.
5. Click OK.

How To Add Study Team Members Not In The Pick List

If study team member does not appear in the list for a particular role then they have not been assigned this role in eIRB. You may request a role by contacting your local IRB office.

CITI Certification

An IRB application cannot be approved until all study team members have current CITI certification dates in the eIRB system.

For CITI questions please visit https://orra.rutgers.edu/citi.

Uploading Documents

How to upload documents to your application

1. Click the Add button and a new window will appear.
2. Enter a Title for the document you are uploading
3. Click Browse...and select the file you want to attach.
4. Click Open.
5. Click OK.

Informed Consent Documents

How to upload an original informed consent

1. Informed Consent templates, and sample consent/assent forms can be found at the eIRB Home page (https://orra.rutgers.edu/hspp).
2. Select the Institutional Review Board link on the left.
3. Select the Form and Templates link.
4. Save the Informed Consent to your computer or network drive.
5. Open the Informed Consent template and modify the body of the template as required for your study.
6. Save the document.
7. Back in the eIRB application, use the Add button to attach the document.

How To Edit Informed Consent Documents

An application cannot be edited while it is under review.

1. Re-open the original Informed Consent document on your computer or network drive.
2. Turn on Track Changes and modify the body of the document as needed.
3. Save the redlined copy.
4. Turn off Track Changes, accept all changes, and save a clean copy of the document.
5. Once back in the eIRB application, use the [Edit] link to attach the revised clean copy in the Consent Forms section.
6. Use the Add button to attach the redline copy in the Redline Consent Forms section.

Editing and Deleting Study Documents Already Uploaded

Note: An application cannot be edited while it is under review.

<u>Editing a previously uploaded document in eIRB.</u>

1. Open the document on your computer or network drive.
2. Make the necessary changes.
3. Save the document.
4. Back in the eIRB application, select the checkbox beside the name of the currently uploaded document.
5. Use the [Edit] button to upload the revised copy.

<u>How to delete documents that have previously been uploaded.</u>

1. Select the checkbox in front of the name of the document to be deleted.
2. Click the Delete button

To Agree To Participate

Once the PI submits the study application, an e-mail will automatically be sent to the study team members with a link to log in to the application, review the protocol and agree to participate. Before the PI can submit the application, CoI's must access the application and accept their assigned role.

1. From your Inbox, in the Agree to Participate section, click the Study Title to access the Study Workspace.
2. OR click the link in the e-mail to take you directly to the Study Workspace.
3. Click the Agree to Participate button.
4. Complete the information on the Agree to Participate activity page.
5. Click OK.

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Submitting an Application

The Submit Study activity can only be performed by the PI. After submission, the study team will not have access to edit the application unless it is returned with changes requested by eIRB. The Submit Study activity is performed from the Study Work-space.

1. From the Study Workspace, click the Submit Study button.
2. Complete all questions on the Submit Study screen.
3. Click OK at the bottom of the Submit Study window.

Viewing Reviewer Concerns

When IRB Administrator or Committee concerns are sent to the study team, the application will be returned to the Personal Workspace Inbox of all study team members with an indication in the History log that concerns have been added. An e-mail will also be sent to study team members alerting them that concerns need to be addressed.

1. Use the link in your Personal Workspace Inbox or in your e-mail to enter the Study's Workspace.
2. Click the Reviewer Notes tab to see what concerns have been added.

Responding to Reviewer Comments

1. Use the Jump To: link to go to the section of the application where concerns have been added.
2. Make the necessary changes.
3. Once the changes have been made on the application, use the Click here to respond link at the top of the page to summarize your response to the reviewer.
4. Select the appropriate category and give your response.
5. Click OK.
6. When finished, Save and Exit the application form and return to the Study Workspace.
7. Click the Submit Changes button to return the application to the reviewer.

Create a Modification

Modifications can be submitted for approved active studies only. Only one modification can be in process at a time for each study.

1. Navigate to the Study Workspace of the approved active study.
2. Click the New Modification button on the left to start a new modification submission.
3. Complete the required information on each page of the Modification Request form.
4. When you reach the Summary of Changes and next steps screen, click the Smart Form link.
5. Click Continue.
6. Click Finish to return to the Modification Workspace.
7. After making all changes to the modified study, click the Submit Modification button on the left.
8. Click OK.

Submitting a Continuing Review

Study team members will receive an e-mail reminder that their application is due for a continuing review 90, 60 and 30 days prior to the study expiration date.

Continuing reviews can be submitted for approved active studies only. Only a Linked Modification can be created while a continuing review is in progress. This will be submitted separately. Scheduled continuing review applications should be submitted at least twenty-one days before the approval is to expire.

1. Navigate to the Study workspace of the approved active study.
2. Click the New Continuing Review button on the left to start a new continuing review submission.
3. Complete the required information on each page of the Continuing Review form.
4. Click Finish at the end of the continuing review.
5. Click Submit Scheduled Continuing Review button on the left.
6. Click OK.
7. To Submit Linked Modification select Submit Linked Modification button.
8. Click OK.

Printing an Application

The printer version of the study includes only the required application sections. Detailed information is printed at the end of the document.

1. Navigate to the Study Workspace.
2. Click the Printer Version button OR you can open the study application and click the Print button at the top of the screen to print specific pages of the application.
3. Click Print to open the Print dialog box.
4. Select a printer and click Print.