

eIRB User Manual for Committee Members





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| REQUEST CHANGES/ CLARIFICATIONS |
| NO FURTHER ACTION REQUIRED |
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| ACKNOWLEDGED |
| CONTACT US |



eIRB Access

The website is available via any Internet connection anytime with a supported browser.

http://eirb.rutgers.edu

Confidentiality

While PHI is typically not included in eIRB studies, there are study designs, ideas, methodology, and other proprietary information for which IRB members are responsible for safeguarding.

Precautions should be taken to protect Rutgers information in eIRB. Please protect this information in the following ways:

- Do not select the "Remember Me" feature of the eIRB log in page from laptop or home computers, as this may compromise the security of confidential information.
- Do not share your eIRB password.
- Do not leave your computer unattended while working in eIRB.
- If possible, do not print the Investigators Brochure, the protocol or other study materials.
- If you do print from eIRB, take precautions to destroy the paper upon completion of your review.

Getting Help

If you have problems, need help, or have questions about eIRB please contact your local IRB office.



Designated Reviewer Workflow

eIRB enables IRB members to conduct review of new studies, progress reports, study modifications, continuations and reportable events in an electronic environment that improves record-keeping and reduces environmental impact.

There are three ways that reviewers may access submissions to the IRB:

- 1) Login to eIRB and view the Inbox
- 2) Click on the link in email notifications
- 3) Go to the meeting agenda in eIRB

This manual demonstrates the recommended process for designated reviewers:

- Login to eIRB
- Select the submission you wish to review
- Preview the study
- Enter reviewer notes
- Submit your review and upload the reviewer worksheet

Email Notifications

When a study has been assigned for you to review, you will receive an email from <u>eirb@ored.rutgers.edu</u>. The ID will link you to the eIRB Log-In Page and, after you log in, the Study Workspace.



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Personal Workspace: "My Home"

When you log in to eIRB, all submissions assigned to you will be listed under "My Inbox"

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You can always return to this view by selecting 'My Home' in the upper right-hand corner. Studies requiring your review will appear in 'My Inbox'.

There are four types of submissions:

- Initial Submissions- 'Pro'
- Continuing Reviews- 'CR'
- Reportable Events- 'RE'
- Modifications- 'Mod'



Study Workspace

Each type of submission (new study, continuing review, study modification, and reportable event) will have its own Workspace.



There are several items that appear in all workspace types:

- The left navigation bar is the white area that appears on the left side of each workspace page
- Activities are available to reviewers in the navigation pane
- A history of all the submission's activities appears under the **History** tab. Other tabs include documents submitted in the project and reviewer notes.



Reviewing a New Study

To conduct a review in eIRB, you will:

- Preview the study
- Acknowledge or Defer Review
- View the study
- Enter reviewer notes
- Complete required checklist
- Submit the review

Preview the study: A convenient way to preview a study is to click on the 'Printer-Friendly Version' button.

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Printer Version:

The printer-friendly version allows reviewers to preview all questions and answers presented to, and answered by, study staff. Additionally, any files uploaded into the form appear as clickable links within the printer-friendly version.

You may print or close the printer friendly version by selecting the two buttons at the top of the page. You may also save the page by selecting 'File' then 'Save As'...in your internet browser.





Acknowledge Review

After previewing the printer version of the study, you will decide whether to 'Acknowledge Review or Defer Review' located under My Activities. Once you "Acknowledge Review", you can begin your review. You will want to view the study so that you can enter comments and questions about the study. If you "Defer Review" you may send a comment to the IRB Office noting the reasons for the deferral.





Viewing a New Study

To access the study, select the 'View Study' button.

Once you have selected 'View Study', a window will open containing the smart-form pages completed by the study staff.

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Open files uploaded to the project from links with the smart-form view. Attachments can also be found in the 'Attachments' tab in the 'Study Workspace'



Study Smart form view:



3.0 Short Title (Study Name): Tosving

From this view, you may:

- 1. Navigate using the 'Back' or 'Continue' button
- 2. Add, edit, and delete reviewer notes
- 3. Use the 'Jump To' menu to select the specific page you wish to see (the name of the page is the link, to the text, 'Jump To')
- 4. 'Exit' to return to the study workspace



Adding Reviewer Notes

Reviewer notes are added to each page where the designated reviewer wishes to make comments. These notes will only be viewable by IRB Staff who will finalize them for study staff, and other reviewers.

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To add Reviewer Notes, select 'Add'.

A new window will open where you will add your comments about the section in question. Click 'OK' after you write your note or 'Cancel' to cancel the activity.

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Note: Please restrict these notes to the item you would like changed or clarified on a given smart-form page. General comments about the study should be reserved for when you submit your review.

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Your reviewer note will become visible on the page it is related to by selecting the small black arrow on the left side of the yellow panel.

You may **delete** the note or **add** an additional note. To edit the existing note, click on the link, 'Committee Member Change Request'.

Once you have completed all reviewer notes for each appropriate smart form page, select 'Exit' at the top of the page to return to the 'Study Workspace'.



Viewing Reviewer Notes

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A summary of reviewer notes can be viewed from the 'Study Workspace' under the 'Reviewer Notes' tab. Again, these notes will only be visible for IRB staff and other reviewers.



Finalize and Submit Your Review

1. To begin click on the *Submit Designated Review* activity:



Submit Designated Review

- 2. You will then be prompted to:
 - Download (save each file to your computer's desktop) and complete ALL available *Required Checklists* found in the <u>Submit Designated Review</u> window when your review is <u>complete</u> (see instructions provided in <u>Submit Review</u> window).

Submit Designated Review

Submit Review



- Confirm you do not have any conflicting interests with the study being reviewed.
- Add additional review notes or comments (if applicable).
- Upload your completed checklists (which were previously saved to your computer's desktop) and/or any related documents (if applicable); e.g. Review Notes or tracked documents with reviewer revisions- by clicking on the "Add" button in Section 3.0 Supporting Documents.

| 3.0 | * Supporting Documents: | |
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- Select a 'Review Motion' (required)
- 3. <u>Submit your review</u> by selecting '*OK*' in order to send the reviewed submission back to the IRB office.



Reviewing a Continuing Review

To view a study's continuing review workspace, return to 'My Home', select the name of the continuing review listed under 'My Inbox'.

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The 'Continuing Review Workspace' is similar to that of a New Submission Review, except that the header information will include a continuing review ID and a description of the continuing review.



You may open the 'Printer Version' or view the continuing review the same way you view the smart form pages with a new submission, by selecting 'View Continuing Review'.

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To begin the review, 'Acknowledge' or 'Defer' the Continuing Review by clicking the appropriate buttons under 'My Activities'.

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When you view the Continuing Review in its smart form version, you can use the 'Jump-to' menu and add reviewer notes in the same way as a new study.

After you have added all your reviewer notes to the smart-form, exit the study and submit:

- Any Additional notesAdd any documents
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Reviewing a Study Modification

Study modifications are different from other workspace views within eIRB since there are several steps that study staff must take to initiate the activity. Each step in the process has its own workspace; the 'Modification Request' comes first, followed by the changes applied to a 'Modified Study'.

To view the Modification workspace, click the name of the modification listed under 'My Inbox'.

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Viewing the Modification Workspace

The Modification workspace is where study staff initiates the form that describes the proposed changes (the Modification or 'Amendment').

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The Modification workspace contains the same 'Printer Version' and header description as a new study. You must '**Acknowledge**' or '**Defer**' the review to begin and click 'OK' in the new window that opens.

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Viewing the Modification

Click 'View Modification' to open the Modification smart form. The Modification will contain information about the proposed changes to a study. The actual changes to the study are accessed through 'View Modified Study'.

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Click 'Exit' to return to the Modification Workspace.



Modified Study Workspace

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Modified Study Workspace

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To see the changes to a study,

Click on the 'View Differences' button located on the left navigation pane.



View Differences

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This page highlights a change in which a revised document was uploaded.

Note: The view differences feature may show differences in documents and in certain lists that may not always be accurate. If you are unsure about a change, please contact the IRB for clarification.

To exit the 'View Differences' application, click the 'Back to Changes Log' button.



Viewing the Modified Study

After you have used the 'View Differences' feature, you may click 'Edit Study' to enter reviewer notes.

(Note: 'Edit Study' does not actually allow you to edit the study; because the Modified Study workspace is a copy of the original study, it appears identical.)





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The 'Modified Study' is a copy of the originally approved study. The reviewer notes work the same way in this view as the previous submission examples.



After you enter your reviewer notes and continue through the entire smart-form application, you will end at the 'Final Page' of the Modified Study. To return to the 'Modified Study Workspace', select *Finish*.

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In the 'Modification Workspace', submit your review by clicking on the 'Submit Review' button then:

- Upload any documents
- Record any comments
- Select 'Review Motion'
- Check off 'Review Complete
- Select 'OK' to submit.



Reviewing a Reportable Event

To review a reportable event, select the title of the study listed under 'My Inbox'.

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Note: Reportable Events are easy to recognize because their icon is an exclamation point as compared to other study states.



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The process for reviewing a Reportable Event is the same as the previous submission examples.

- Decide whether to Acknowledge or Defer the Reportable Event
- View the Reportable Event by selecting 'View Reportable Event'
- 'Add' Reviewer Notes in the same manner as before within the smart-form application



Reviewing an IRB Meeting Agenda

Each month, you will receive an email from eIRB indicating that the meeting agenda is ready to view. To view studies assigned to other reviewers, select the 'Upcoming Meetings' tab in the grey menu bar at the top of your 'My Home' page view. Select the name of the upcoming meeting you wish to view.

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- You can 'Confirm' or 'Decline' your meeting attendance by selecting the appropriate button located on the left navigation pane.
- Select 'View Meeting Agenda' to open the smart form page of the agenda.



Glossary

Attachments: Lists documents attachment to a study.

Change Log: Lists changes made to the initial application.

Conditions: Status of contingencies for the approval of the study.

Current State: Specifies where the study is in the IRB review process. Three possible study states include: In Review, Meeting in Progress, or In Revisions Review.

Department Approvals: Lists the department(s) that approved the study.

eIRB Home: Brings you back to the eIRB homepage.

History: List of all actions performed on this study submission.

IRB Studies: Lists all eIRB studies.

Jump-To Menu: A tool located at the top of a smart form in a project which enables users to navigate through the submission pages without having to search through pages unnecessarily.

Logoff: Ends your eIRB session.

Modification: The form which study staff completes indicating the proposed changes made to a Study.

Modified Study: A copy of an approved study where study staff has made actual changes to the IRB.

My Activities: Displays the actions that you can perform at this point in a study.

Log Private Comment: Allows you to add a comment or upload a document only viewable by IRB Staff and Committee Members.

My Committees: Provides a quick link to the IRB committees you serve on.

My Home: The default user page. Always takes you back to your personal workspace page.

My Roles: Shows your current role and lists multiples roles, if applicable. This section determines your access level and personal workspace.

Navigation Pane: The location in every workspace which holds all available activities for the study.



Printer Version: Opens a page to view an entire document that displays all sections in its entirety, and prints easily on most printers. The printer version view contains clickable links to certain study documents which opens in a new window. You cannot add reviewer notes to this version.

Reviewer Notes: Lists notes left by the reviewer.

Reviews: Lists assigned reviews for reviewer.

Stamped Documents: This section lists all IRB stamped documents. These PDF documents are watermarked with an IRB approval and expiration date.

User Profiles: Lists personal profile and contact information for eIRB members.

View Differences: Opens a page to view and compare changes made to the original application.

View Study: Opens smart-form applications and allows committee members to submit reviewer notes.

Your name: Access/Modify personal contact information. This tab also allows you to change your password.



IRB Determinations Guide

Approved

□ The IRB determines that based upon all applicable federal regulations, and a review of all submitted documents, the research may proceed without any conditions. An Approval notice will be issued at which time the research may be initiated or continued.

Approval with Conditions

- □ At the time the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires that, before research begins, as a condition of approval that the investigator
 - (a) make specified changes to the research protocol or submitted document(s)

or

(b) submit clarifications or additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval.

Applicability:

For this level of re-review, the clarifications/changes required are minor, (for example, revised language to be incorporated into consent documents, clarification of information provided in the application, or submission of training certificates for study personnel.)



Approved with Stipulations

- □ The IRB is able to make all of the determinations required for approval of proposed research or changes as submitted with stipulations. Research activities may be initiated or continued if the investigator either,
 - (a) adheres to the stipulation(s) as required by the IRB
 - or
 - (b) submits clarifications or additional documents, such that, based on the assumption that the stipulations are satisfied, the IRB is able to make a determination that the stipulation(s) are met.

Applicability:

Stipulations mandated by the IRB may prohibit the investigator(s) from conducting or initiating certain aspects of the study. Stipulations may only be removed by submitting corresponding documents for review by the IRB. Approval will only be granted if the IRB determines that the supporting documents satisfactorily address the stipulations. (Examples are Approval notices from other IRBs, COCs, letters of agreement)

Approval Denied

□ The IRB determines that based on all applicable federal regulations, the research cannot be approved. Research activities may not be conducted at Rutgers or by Rutgers employees or agents.



Tabled

□ The IRB determines that there are major substantive issues that must be resolved or there is a lack of sufficient information about the research to proceed with its review. The IRB review may not proceed and approval may not be granted until the convened IRB has approved a revised application incorporating all requested information or changes.

Applicability

For this level of review, the changes required are major and complex; the protocol is judged to have serious problems or lack sufficient information for the committee to appropriately assess the risks to subjects..

Deferred

- □ The IRB is not able to make all the determinations due to (a) lack of sufficient time for discussion, (b) because it feels it lacks the required expertise, or (c)an Expedited Reviewer does not feel it meets the criteria for Expedited Review. At that time the study must be
 - (a) reviewed at a later convened meeting providing sufficient discussion time
 - or
 - (b) reviewed by the campus Executive IRB committee for sufficient expertise

or

(c) reviewed by a fully convened IRB committee



Full Board Committee Actions or Requests

Administratively Closed

□ This is an administrative process by which a previously approved study has expired, and the principal investigator has not submitted a *Continuing Review* application or a *Final Closure*, indicating study completion.

Suspended

□ The IRB determines that, in the best interest of human subjects, some or all aspects of the research must cease temporarily. This may occur when a study is under investigation due to compliance issue(s), following a protocol deviation, adverse event, or unanticipated event involving risks to human subjects or others.

Request Changes/ Clarifications

- □ At the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requests modification of the application at which time the investigator must either
 - (a) provide clarifications to specific questions,



(b) submit requested changes to revised documents, such that, based on the assumption that these changes or clarifications are satisfactory, the IRB is able to make all of the determinations required for approval

No further action required

□ The IRB Executive committee determines that no further changes, revisions or corrections are required on the part of the investigator or the IRB committee.

Action required

□ The IRB Executive committee determines that further changes, revisions or corrections are required on the part of the investigator or the IRB committee.

Acknowledged

□ Upon receipt of a reportable event, the IRB reviews and issues confirmation of the submission.



Contact Us

https://orra.rutgers.edu/contactus