# Table of Contents

Rowan University eIRB ACCESS .................................................................................................................. 3  
DESIGNATED REVIEWER WORKFLOW ..................................................................................................... 4  
PERSONAL WORKSPACE: “MY HOME” ................................................................................................. 6  
STUDY WORKSPACE .................................................................................................................................. 7  
REVIEWING A NEW STUDY ......................................................................................................................... 8  
ADDING REVIEWER NOTES ....................................................................................................................... 13  
REVIEWING A CONTINUING REVIEW ....................................................................................................... 18  
REVIEWING A STUDY MODIFICATION .................................................................................................... 24  
MODIFIED STUDY WORKSPACE ............................................................................................................. 27  
REVIEWING A REPORTABLE EVENT ......................................................................................................... 36  
REVIEWING AND IRB MEETING AGENDA ............................................................................................... 39  
GLOSSARY .................................................................................................................................................. 41  
IRB DETERMINATIONS GUIDE ................................................................................................................. 43  
APPROVED ............................................................................................................................................... 43  
APPROVED WITH CONDITIONS ................................................................................................................. 43  
APPROVED WITH STIPULATIONS .............................................................................................................. 43  
APPROVAL DENIED .................................................................................................................................. 44  
TABLED .................................................................................................................................................... 44  
DEFERRED ............................................................................................................................................... 44  
ADMINISTRATIVELY CLOSED .................................................................................................................. 45  
SUSPENDED ............................................................................................................................................ 45  
REQUEST CHANGES/ CLARIFICATIONS ................................................................................................. 45  
NO FURTHER ACTION REQUIRED ....................................................................................................... 45  
ACTION REQUIRED ............................................................................................................................... 45  
ACKNOWLEDGED ..................................................................................................................................... 45  
CONTACT US ........................................................................................................................................... 46  

Version 1 dated 6-2-2014
eIRB Access

The website is available via any Internet connection anytime with a supported browser.
https://eirb.rowan.edu

Confidentiality

While PHI is typically not included in the Rowan 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 Rowan University information in the Rowan eIRB. Please protect this information in the following ways:

- Do not select the “Remember Me” feature of the Rowan eIRB log in page from laptop or home computers, as this may compromise the security of confidential information.

- Do not share your Rowan eIRB password.

- Do not leave your computer unattended while working in the Rowan eIRB.

- If possible, do not print the Investigators Brochure, the protocol or other study materials.

- If you do print from the Rowan eIRB, take precautions to destroy the paper upon completion of your review.

Getting Help

If you have problems, need help, or have questions about the Rowan eIRB please contact the Rowan University IRB office.
Designated Reviewer Workflow

The Rowan eIRB enables IRB members to conduct review of new studies, progress reports, study modifications, 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 the Rowan eIRB and view the Inbox
2) Click on the link in email notifications
3) Go to the meeting agenda in the Rowan eIRB

This manual demonstrates the recommended process for designated reviewers:

• Login to the Rowan 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 http://eirb.rowan.edu. The ID will link you to the Rowan eIRB Log-In Page and, after you log in, the Project Workspace.
** This is an auto-generated email. Please do not reply to this email message.
   The originating e-mail account is not monitored.
   If you have questions, please contact your local IRB office.**

Full Board Review: An eIRB Submission Requires Your Review

**Rowan University**

**Full Board Review: An eIRB Submission Requires Your Review**

IRB Administrator: RoutinRBAStratfordWIRBGlassboro Test
Board: Glassboro/CMSRU Board 1
Meeting: 4/2/2014

ID: Pro2014000054
Title: sstest study Glassboro

An eIRB submission is currently waiting for your review. To navigate to the project workspace, click on the above ID.

**Steps to review IRB Submission:**

1) Click on study ID link located in this email notification
2) Click on the ACKNOWLEDGE REVIEW activity
3) Review the submission by clicking on the "Printer Version" or "View Study" activities
4) Add reviewer notes on the application by clicking on the "View Study" activity, and navigating to the appropriate smart form section
5) Complete ALL Reviewer Checklist activities
6) Finally, click on Submit Review in order to send the submission back to the IRB office

**NOTE:** If you require additional help and/or guidance with this review, please contact RoutinRBAStratfordWIRBGlassboro Test. salmons@rowan.edu. Please do not reply to this email notification. The originating email account is not monitored.

Additional help and guidance is available at the following:
http://www.rowan.edu/som/bspsom-eirp

**CONFIDENTIALITY NOTICE:** This email communication may contain private, confidential, or legally privileged information intended for the sole use of the designated and/or duly authorized recipient(s). If you are not the intended recipient or have received this email in error, please notify the sender immediately by email and permanently delete all copies of this email including all attachments without reading them. If you are the intended recipient, please review the contents in a manner that conforms to all applicable state and federal requirements related...
Personal Workspace: “My Home”

When you log in to the Rowan eIRB, you can see all submissions assigned to you by selecting your ‘My Home’ page view.

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:

- Study (Initial Submissions)- ‘Pro’
- Continuing Reviews- ‘CR’
- Reportable Events- ‘RE’
- Modifications- ‘Mod’
Study Workspace

Each type of project (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 project’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 the Rowan eIRB, you will:

- Preview the study
- Acknowledge or Defer Review
- View the study
- Enter reviewer notes
- Upload the completed worksheet
- Submit the review

Preview the study: A convenient way to preview a study is to click on the ‘Printer Version’ button.
**Printer Version:**

The *printer 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 view*.

You may print or close the *printer view* 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 and 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.

### My Activities

- [Log Private Comment](#)
- **[Acknowledge Review](#)**
- **[Defer Review](#)**
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.

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:

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.

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.
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.

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’.
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.
**Complete Checklists**

When you have completed adding your reviewer notes, you will also have to complete the reviewer checklists under *My Activities*. In order to fill out the Reviewer’s Checklist forms, simply click on checklist on the left hand side:

1. Complete the Reviewer checklist for Initial Review
2. Complete the Reviewer Checklist for Expedited Review Categories
3. Complete the Reviewer Checklist for Research Involving Children
4. Complete the Checklist for Consent (if applicable).

Additional Checklists when applicable to the study are:

1. Complete the Reviewer Checklist for Research involving Pregnant Women (if applicable)
2. Complete the Reviewer Checklist for Research involving Neonates (if applicable)
3. Checklist for Prisoner (if applicable)
**Submitting Your Review**

Once you are satisfied with your reviewer notes, you will want to click on ‘Submit Review’ and complete the form.

Once complete, select ‘OK’, then select “Submit Review”, under “My Activities”.
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’.

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

If you ‘Acknowledge’ the continuing review, a box will open allowing you to make comments or add documents. Click ‘OK’ to begin review process.
When you view the Continuing Review in its smart form version, you can use the 'Jump.to' menu and add review 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 notes
- Add any documents
- Select 'Review Motion'
- Check off 'Review Complete'
- Submit review by selecting 'OK'
Completing the Reviewer Checklists:

- Reviewer Checklist for Expedited Review Categories
- Reviewer Checklist for Continuing Review

Complete the Checklists
Submit Review
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’.

Mod2014000002      Modification 2 for IRB Study PRO2014000054      5/21/2014      Modification      In Review      Glassboro/CMSRU
Viewing the Modification Workspace

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

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 new window that opens.
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’.

Click ‘Exit’ to return to Modification Workspace.
Modified Study Workspace

In the Modification workspace, click on the 'View Changes' button to open the 'Modified Study workspace'.
Modified Study Workspace

The Modified Study workspace looks similar to the original study workspace; however you’ll notice the title says ‘Modified Study’.

To see the changes to a study, 

Click on the ‘View Differences’ button located on the left navigation pane.
View Differences

The ‘View Differences’, page enables reviewers to easily compare changes made to a study.

The Study Identification page will always appear, regardless of whether there are changes to that page. You will be able to see at a glance the changes on each page in the upper right-hand corner. To navigate to the other revised pages, click ‘Next’. You will only see the pages that have been revised.
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.
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.)
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’.
Complete Reviewer Checklist Modification
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’.

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

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
Submit Reportable Event

Select ‘Submit Review’

Complete the form and select ‘OK’
Reviewing and IRB Meeting Agenda

Each month, you will receive an email from Rowan University eIRB indicating that the meeting agenda is ready to view. To view projects 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.
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 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 Review Revisions.

**Department Approvals**: Lists the department that approved the study.

**Rowan University eIRB Home**: Brings your back to the eIRb homepage.

**History**: Lists of all actions performed on this study submission.

**IRB Studies**: Lists the studies

**Jump-To Menu**: A tool located at the top of a form in a project which enable users to navigate through the submission pages without having to land on pages unnecessarily.

**Logoff**: Ends your eIRB session.

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

**Modified Study**: The copy of an approved study where study staff make actual changes to the IRQ.

**My Activities**: Displays the actions that you can perform at this point. Log Private Comment allows you to add a comment or upload a document only viewable by IRB Staff and Committee Members.

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

**My Home**: Default user page. Always takes your back to 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 on every workspace which holds all available activities for the project.
**Printer Version**: Opens page to view 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 Profile**: Lists your personal profile and contact information.

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

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

**Your name**: Access/Modify personal contact information. 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.

Approved 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 Rowan or by Rowan’s 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,
   or
   (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 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.
RowanSOM
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UEC 1106
Stratford, NJ 08084
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Website: http://www.rowan.edu/open/provost/grants/index.cfm