

eIRB User Manual for Committee Members



Table of Contents

Table of Contents.....	2
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	17
Reviewing a Study Modification	21
Modified Study Workspace	24
Reviewing a Reportable Event	32
Reviewing an IRB Meeting Agenda	34
Glossary.....	36
IRB Determinations Guide	38
Approved.....	38
Approval with Conditions	38
Approved with Stipulations	39
Approval Denied	39
Tabled.....	40
Deferred.....	40
Administratively Closed.....	41
Suspended	41
Request Changes/ Clarifications.....	41
No further action required	42
Action required	42
Acknowledged	42
Contact Us	43

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:

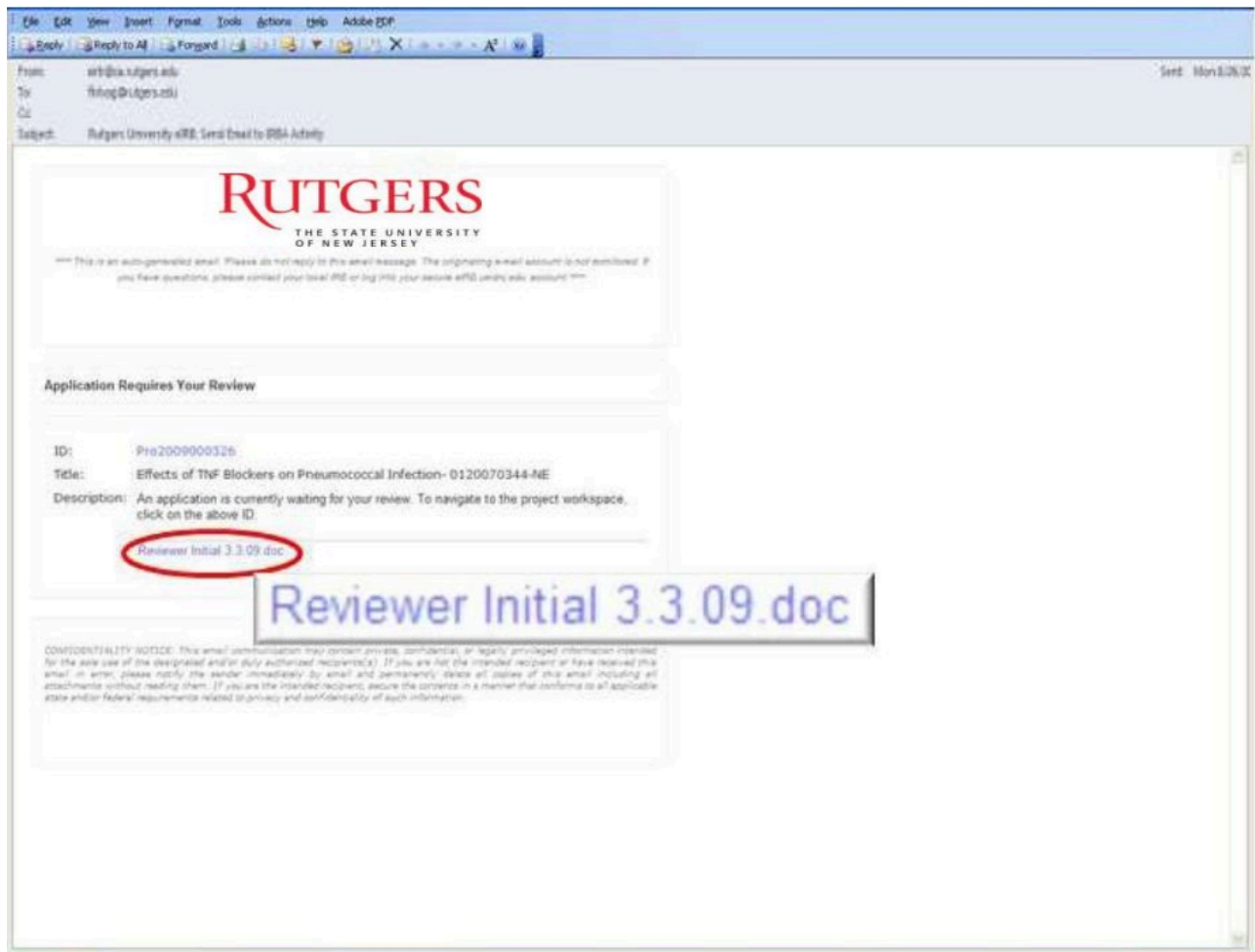
- 1) Login to eIRB and view the Inbox
- 2) Click on the link in email notifications
- 3) Go to the meeting agenda in eIRB

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 eirb@ored.rutgers.edu. The ID will link you to the eIRB Log-In Page and, after you log in, the Study Workspace.



Personal Workspace: “My Home”

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

Current Role:

- Determines access level
- Multiple roles will be listed here(if applicable)
- Select correct role
- Each role has own inbox

To review a submission, click on the study name.

ID	Name	Effective Date	Type	Role	Current Study
Mod201308216	Modification 2 for IRB Study #142013011001	8/29/2013 4:59 PM	Modification	IR	Newark The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
CR00000215	2014 Review for Pro20130821601	8/14/2013 10:11 AM	Continuing Review	IR	Newark Test CI
CR00000478	2012 Review for Pro20130821601	8/13/2013 4:02 PM	Continuing Review	IR	Newark Long-term Needs Assessment

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.

Current State specifies where the study is in the IRB review process

Left Navigation Bar

Tabs

Activity	Author	Date
Forward to Expedited Review	Vega, Charbel	8/14/2013 10:11 AM EDT
Selected IRB Committee	Vega, Charbel	8/14/2013 10:11 AM EDT
Assigned to Green	Vega, Charbel	8/14/2013 10:10 AM EDT
Assigned to Charbel Vega:	Vega, Charbel	8/14/2013 10:04 AM EDT
Submit	Principal Investigator, Training	8/14/2013 10:04 AM EDT
Forward to Expedited Review	Principal Investigator, Training	8/14/2013 10:04 AM EDT

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.

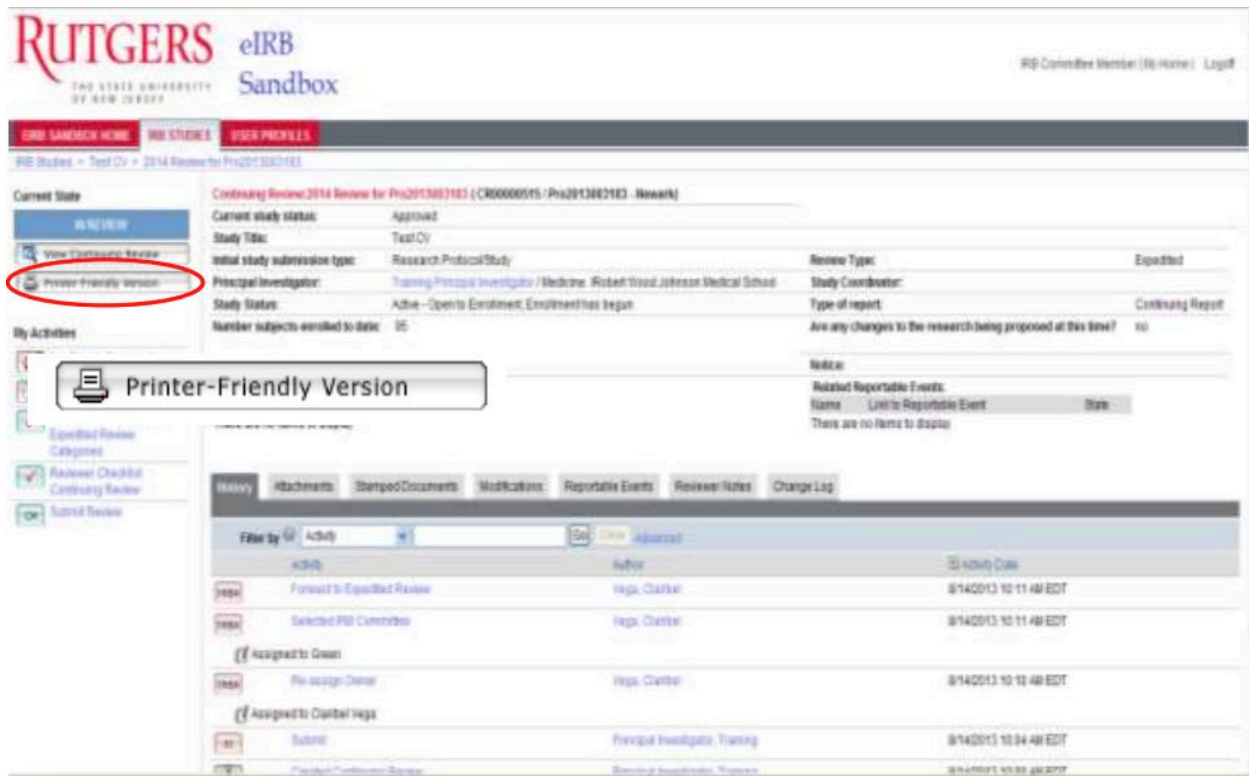
Reviewing a New Study

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.

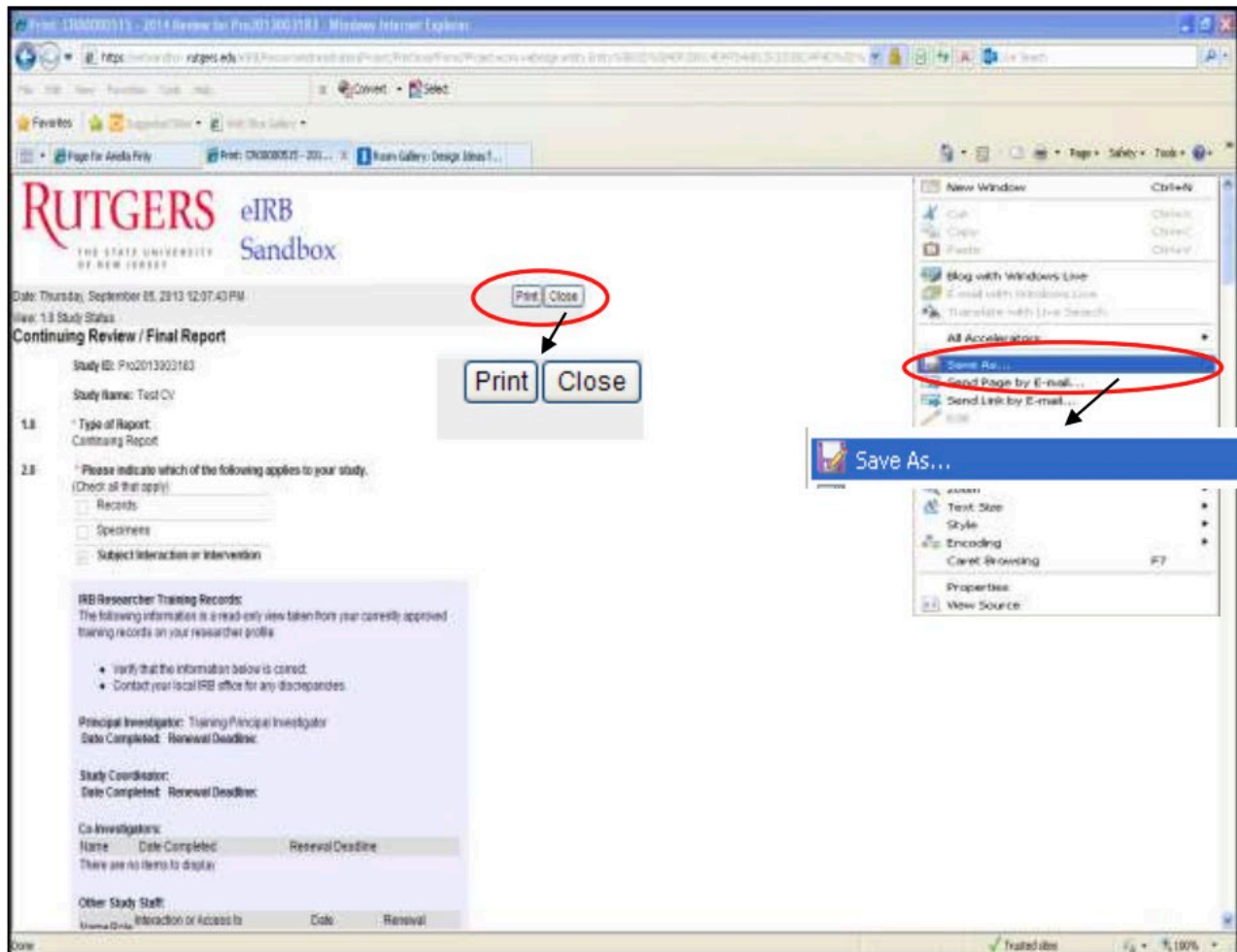


The screenshot shows the Rutgers eIRB Sandbox interface. The top navigation bar includes 'eIRB Sandbox HOME', 'IRB STUDIES', and 'USER PROFILES'. The main content area displays details for a study titled 'Continuing Review: 2014 Review for Pro2013003183 (CR00000515 / Pro2013003183 - Newark)'. The 'Current State' section shows 'IN REVIEW' and a 'Printer-Friendly Version' button, which is circled in red. Below this, a 'Printer-Friendly Version' button with a printer icon is visible. The right side of the interface shows a table of 'Related Reportable Events' with columns for Name, Link to Reportable Event, and Date. The bottom section shows a list of activities with columns for Activity, Author, and Activity Date.

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.

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.

The screenshot shows the eIRB Sandbox interface. The 'View Study' button is highlighted in a red circle. The main content area displays study details for 'Study: Training (Pro013001547 - Newark)'. The details include:

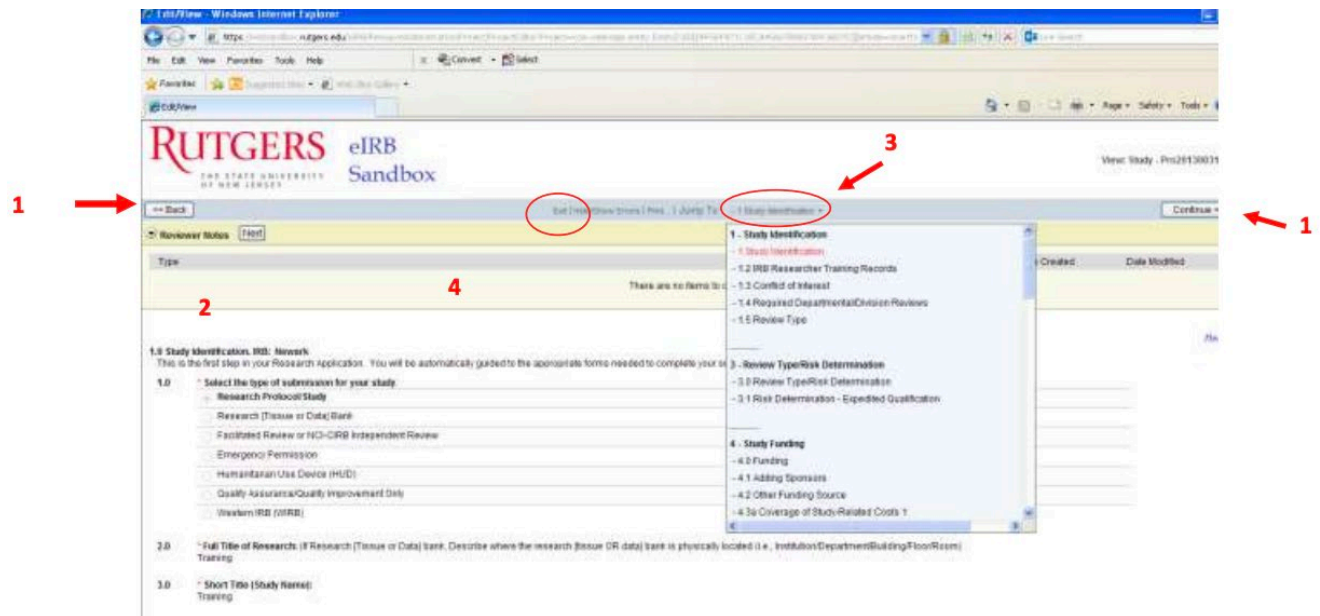
- Description:** Training
- PI:** Training Principal Investigator
- Committee:** IRB Admins
- Type of Submission:** Review Type: Expedited
- Research Protocol/Study:** Sponsor: Department Focused
- Co-Investigators Who Have Declined Participation:** There are no items to display
- Investigators Who Have Not Accepted Participation:** There are no items to display

Below the details is a workflow diagram showing the process from 'Certification Requested' to 'IRB Review', 'Post Review', and 'Review Complete'. The 'View Study' button is also highlighted in a blue box. The sidebar on the left contains links to 'View Study' and 'View Differences'. The bottom section shows a table of activities with columns for 'Activity', 'Author', and 'Activity Date'.

Activity	Author	Activity Date
Submitted Review: Approval with conditions	Committee Member, IRB	8/6/2013 2:55 PM EDT
Completed Reviewer Checklist - Waiver Informed Consent	Committee Member, IRB	8/6/2013 2:47 PM EDT
Completed Reviewer Checklist for Initial Review	Committee Member, IRB	8/6/2013 2:47 PM EDT
Completed Reviewer Checklist for Research Involving Pregnant Women	Committee Member, IRB	8/6/2013 2:47 PM EDT
Completed Reviewer Checklist for Expedited Review Categories	Committee Member, IRB	8/6/2013 2:44 PM EDT
Forwarded to Expedited Review	Park, Jennifer M.	8/7/2013 8:48 AM EDT

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:

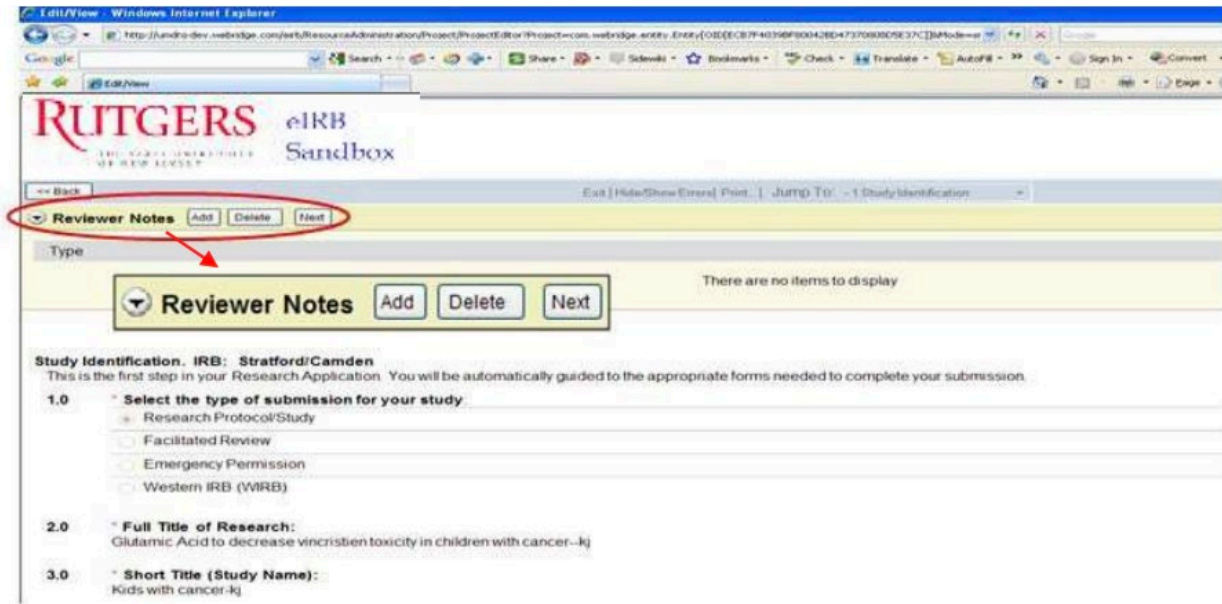


From this view, you may:

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

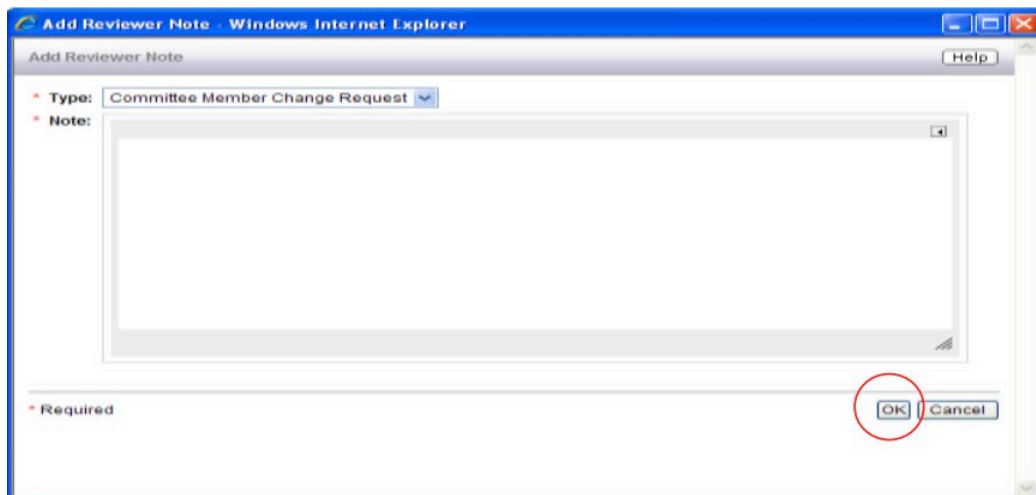
Reviewer notes are added to each page where the designated reviewer wishes to make comments. These notes will only be viewable by IRB Staff who will finalize them for study staff, and other reviewers.



The screenshot shows the Rutgers eIRB Sandbox interface in a Windows Internet Explorer browser. The top navigation bar includes 'Back', 'Forward', 'Home/Show Errors', 'Print', and 'Jump To: 1 Study Identification'. Below this, a yellow banner contains the 'Reviewer Notes' section with 'Add', 'Delete', and 'Next' buttons. A red circle highlights the 'Add' button. Below the banner, the 'Study Identification' section is visible, showing the IRB: Stratford/Camden and the first step in the Research Application. The form includes fields for 'Select the type of submission for your study' (with radio buttons for Research Protocol/Study, Facilitated Review, Emergency Permission, and Western IRB (WIRB)), 'Full Title of Research' (Glutamic Acid to decrease vincristine toxicity in children with cancer-Iq), and 'Short Title (Study Name)' (Kids with cancer-Iq).

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.



The screenshot shows the 'Add Reviewer Note' dialog box in a Windows Internet Explorer browser. The dialog box has a title bar 'Add Reviewer Note' and a 'Help' button. It contains a 'Type' dropdown menu set to 'Committee Member Change Request' and a 'Note' text area. At the bottom, there are 'OK' and 'Cancel' buttons, with the 'OK' button circled in red. A 'Required' label is also present.

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.

The screenshot displays the Rutgers eIRB Sandbox interface. At the top, the Rutgers University logo and 'eIRB Sandbox' text are visible. A navigation bar includes buttons for '<< Back', 'Exit | Show Errors | Print...', 'Jump To', and 'Continue >>'. The 'Reviewer Notes' section is highlighted with a yellow background and contains a 'Committee Member Change Request' link. The 'Exit' button is also highlighted. The main content area shows a form for '1.0 Study Identification, IRB: Newark' with a dropdown menu for 'Select the type of submission for your project' and a text field for 'Full Title of Project'.

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

The screenshot displays the Rutgers eIRB Sandbox interface. The top navigation bar includes 'eIRB Sandbox', 'IRB Committee Member (My Home)', and 'Logout'. The main content area shows the 'Study: Training (Pro2013082148 - Newark)' with details such as Description, PI, Committee, Type of Submission, and Co-Investigators. A workflow diagram illustrates the review process from Pre-Submission to Review Complete. The 'Reviewer Notes' tab is highlighted in red, and an arrow points to it. Below the main content, a table lists 'Committee Member Change Request' entries with columns for Type, Reviewer, Date Created, and Date Modified.

Type	Reviewer	Date Created	Date Modified
Committee Member Change Request Jump To: 7 Study Summary / Protocol Section 1	IRB Committee Member	8/7/2013 3:35 PM	8/7/2013 3:35 PM
Committee Member Change Request Jump To: 1 Study Identification	IRB Committee Member	8/7/2013 3:34 PM	8/7/2013 3:34 PM

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:

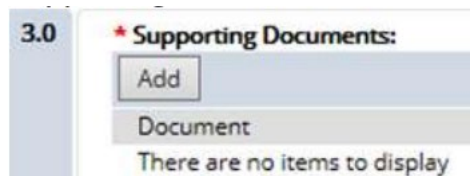


2. You will then be prompted to:

- Download (save each file to your computer's desktop) and complete ALL available *Required Checklists* found in the Submit Designated Review window when your review is complete (see instructions provided in *Submit Review* window).



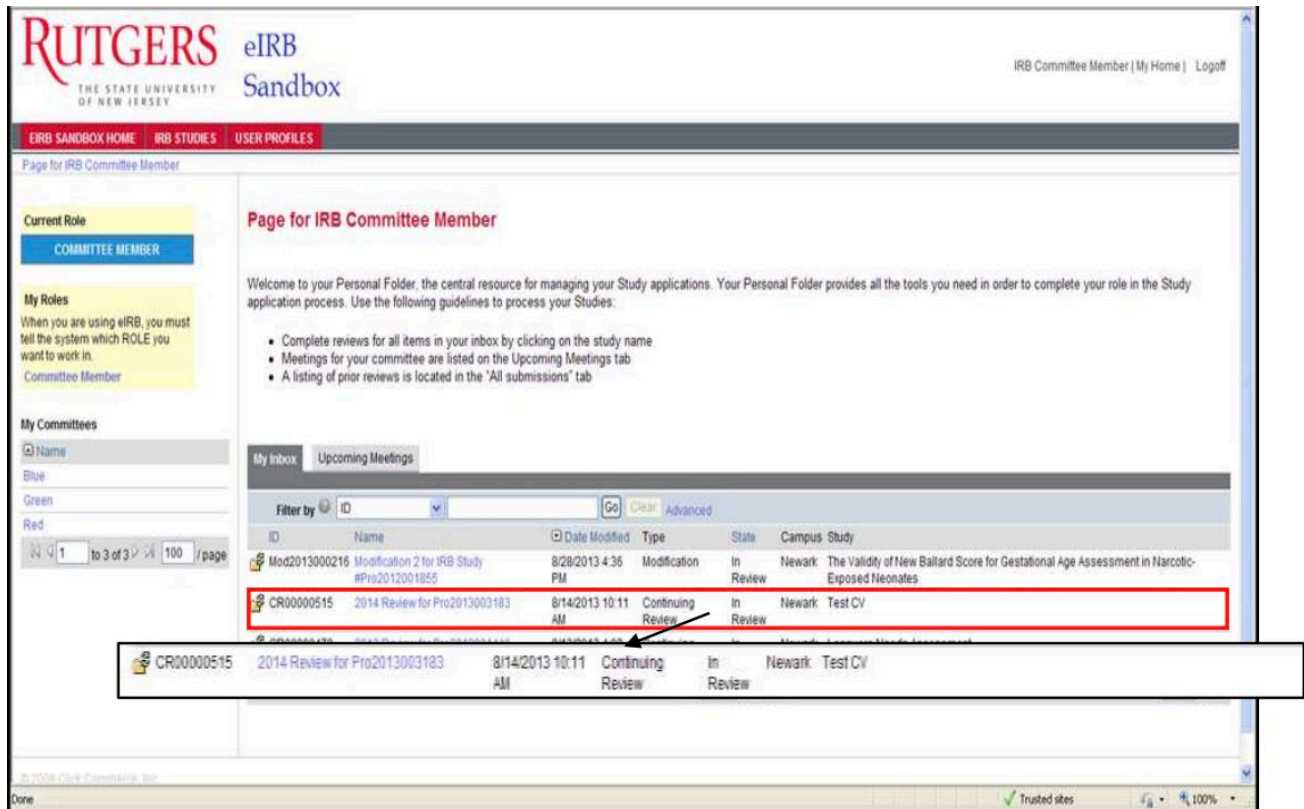
- Confirm you do not have any conflicting interests with the study being reviewed.
- Add additional review notes or comments (if applicable).
- Upload your completed checklists (which were previously saved to your computer's desktop) and/or any related documents (if applicable); e.g., Review Notes or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



- Select a 'Review Motion' (required)
3. **Submit your review** 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.'



The screenshot shows the eIRB Sandbox interface for an IRB Committee Member. The left sidebar contains navigation links for 'Current Role' (Committee Member), 'My Roles', and 'My Committees'. The main content area is titled 'Page for IRB Committee Member' and includes a welcome message and guidelines. Below this is the 'My Inbox' section, which displays a table of continuing reviews. A red box highlights a row with the following details:

ID	Name	Date Modified	Type	State	Campus	Study
CR00000515	2014 Review for Pro2013003183	8/14/2013 10:11 AM	Continuing Review	In Review	Newark	Test CV

An arrow points to the 'Continuing Review' text in the 'Type' column of the highlighted row.

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.'

RUTGERS eIRB
THE STATE UNIVERSITY OF NEW JERSEY Sandbox

IRB Committee Member | My Home | Logout

IRB SANDBOX HOME **IRB STUDIES** **USER PROFILES**

IRB Studies > Test CV > 2014 Review for Pro2013003183

Current State

IN REVIEW

[View Continuing Review](#)
[Printer-Friendly Version](#)

Continuing Review: 2014 Review for Pro2013003183 (PRO00000515 / Pro2013003183 - Newark)

Current study status: Approved
Study Title: Test CV
Initial study submission type: Research Protocol/Study
Principal Investigator: Training Principal Investigator / Medicine / Robert Wood Johnson Medical School
Study Status: Active - Open to Enrollment, Enrollment has begun
Number subjects enrolled to date: 95
Review Type: Expedited
Study Coordinator:
Type of report: Continuing Report
Are any changes to the research being proposed at this time? no

My Activities

[Log Private](#)
[Display Report](#)
[Reviewer Expedited Categories](#)
[Reviewer Continuing Review](#)
[Submit Review](#)

View Continuing Review
Printer-Friendly Version

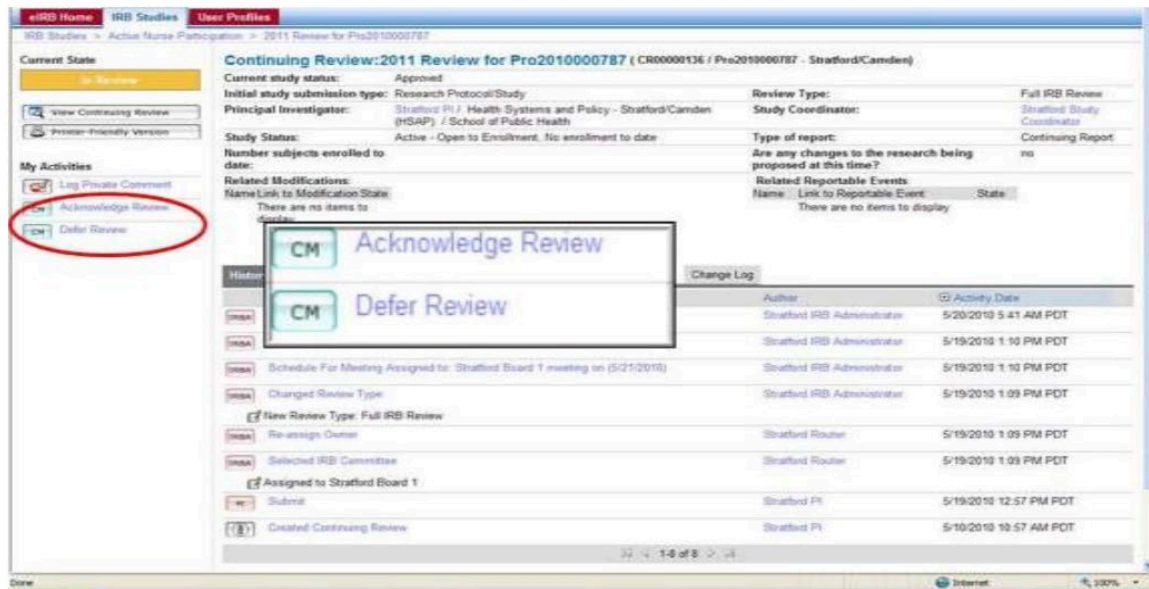
History Attachments Stamped Documents Modifications Reportable Events Reviewer Notes Change Log

Filter by Activity Go Clear Advanced

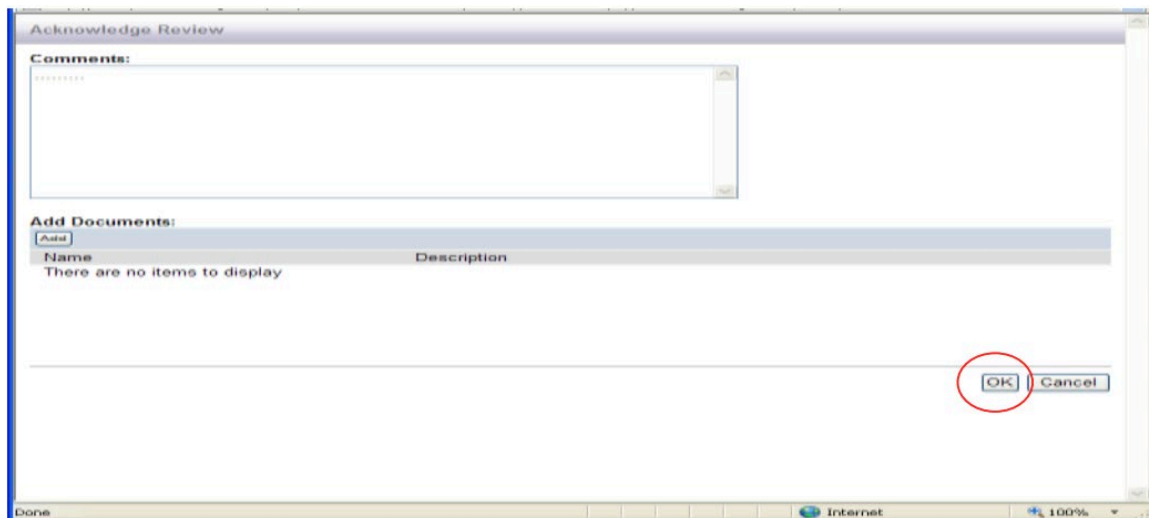
Activity	Author	Activity Date
IRBA Forward to Expedited Review	Vega, Claribel	8/14/2013 10:11 AM EDT
IRBA Selected IRB Committee	Vega, Claribel	8/14/2013 10:11 AM EDT
☒ Assigned to Green		
IRBA Re-assign Owner	Vega, Claribel	8/14/2013 10:10 AM EDT
☒ Assigned to Claribel Vega:		
PI Submit	Principal Investigator, Training	8/14/2013 10:04 AM EDT
PI Pre-stud Continuing Review	Principal Investigator, Training	8/14/2013 10:00 AM EDT

Trusted sites 100%

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



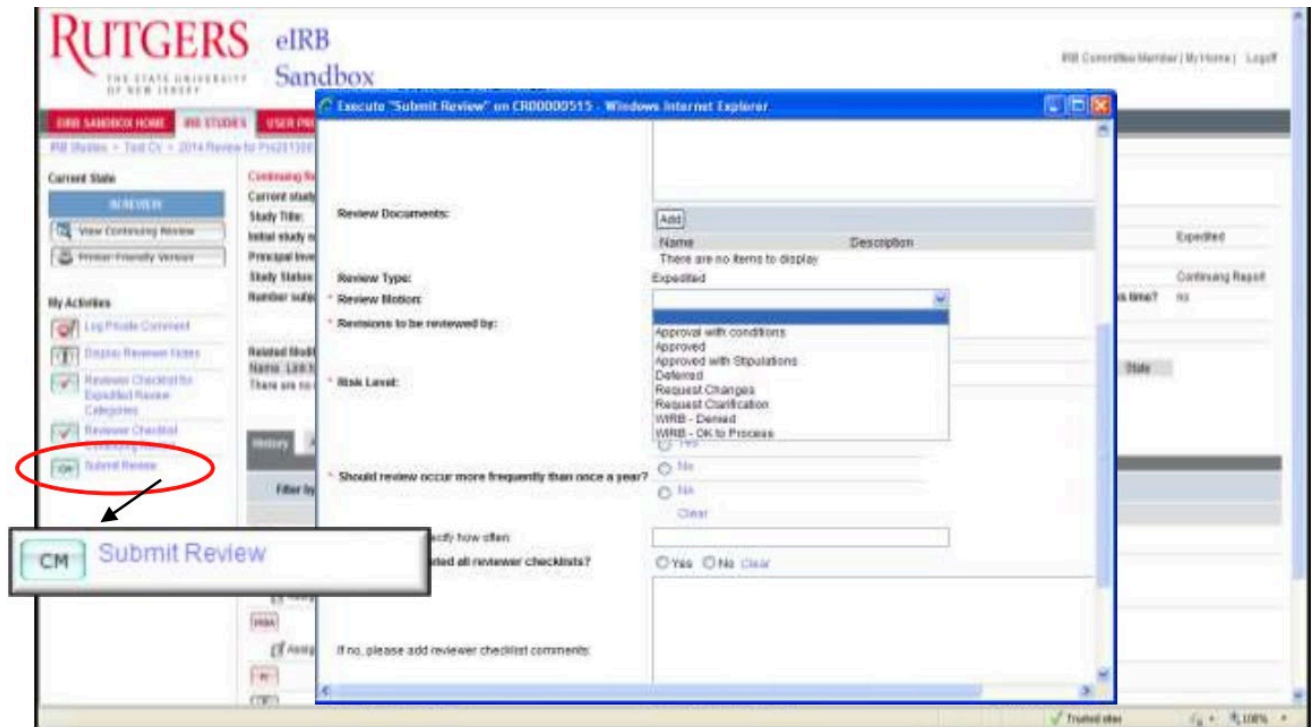
If you 'Acknowledge' the continuing review, a box will open allowing you to make comments or add documents. Click 'OK' to begin the review process.



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 notes
- Add any documents
- Select ‘Review Motion’
- Check off ‘Review Complete’
- Submit review by selecting ‘OK’



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.’

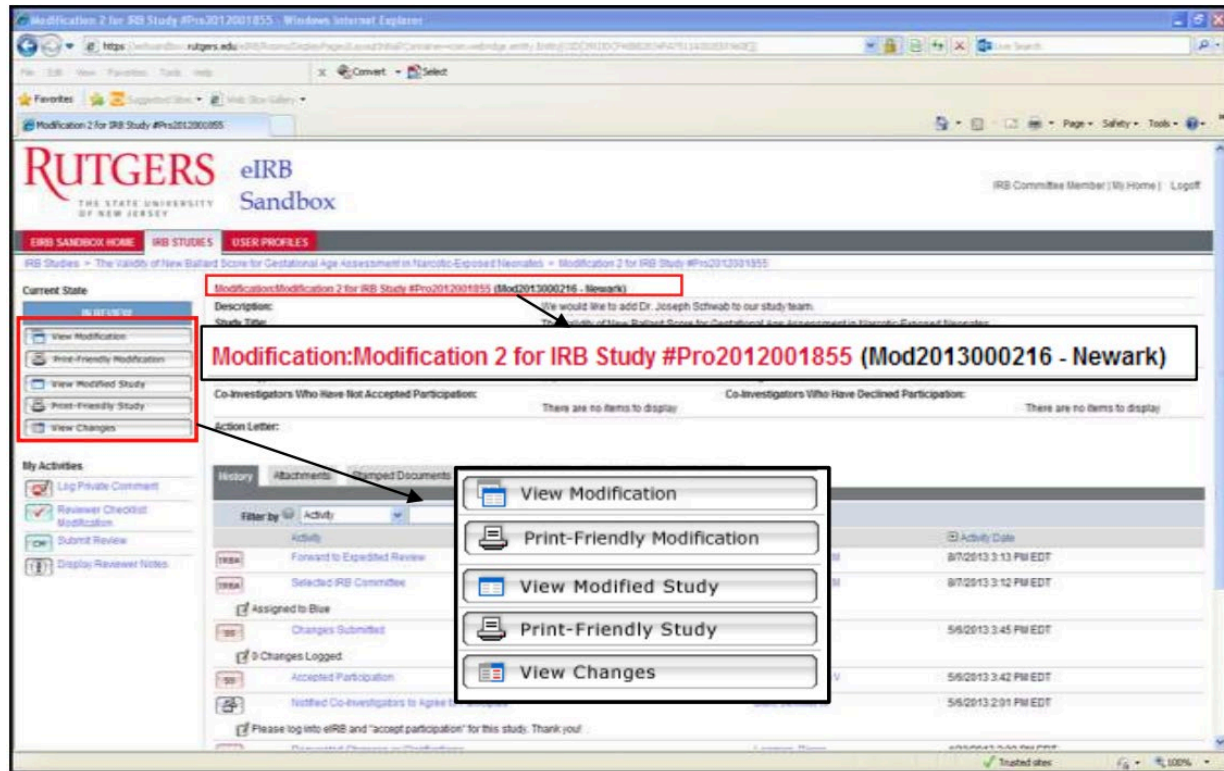
The screenshot shows the eIRB Sandbox interface for an IRB Committee Member. The 'My Inbox' tab is active, displaying a table of study modifications. A red box highlights a specific modification entry, and a tooltip provides more details about it.

ID	Name	ID Date Modified	Type	State	Comments
Mod2013000216	Modification 2 for IRB Study #Pro2012001855	8/29/2013 4:36 PM	Modification	In Review	Newark: The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates

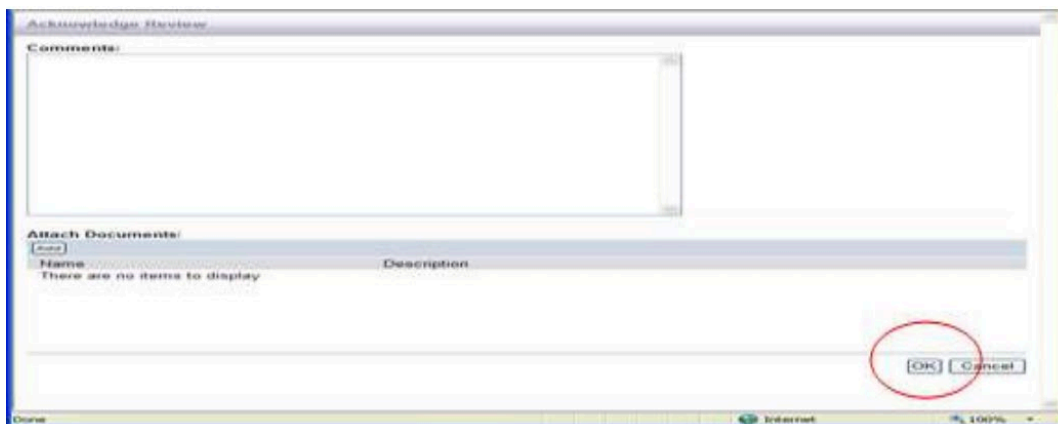
Mod2013000216 Modification 2 for IRB Study #Pro2012001855 8/29/2013 4:36 PM Modification In Review Newark: The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates

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 the 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.'

RUTGERS eIRB
THE STATE UNIVERSITY OF NEW JERSEY

Exit | Hide/Show Errors | Print... | Jump To: Modification Request

Modification Information
Modification Request
Minor, Non-Substantive Change Justification
Subject Notification
Final Page

Modification Request

1.0 * Degree of change:
Minor, Non-Substantive Change

2.0 * Indicate the type of change and/or addition. (Check all that apply)
Change in Study Personnel

3.0 * Description of Changes – briefly summarize the change:
We would like to add Dr. Joseph Schwab to our study team.

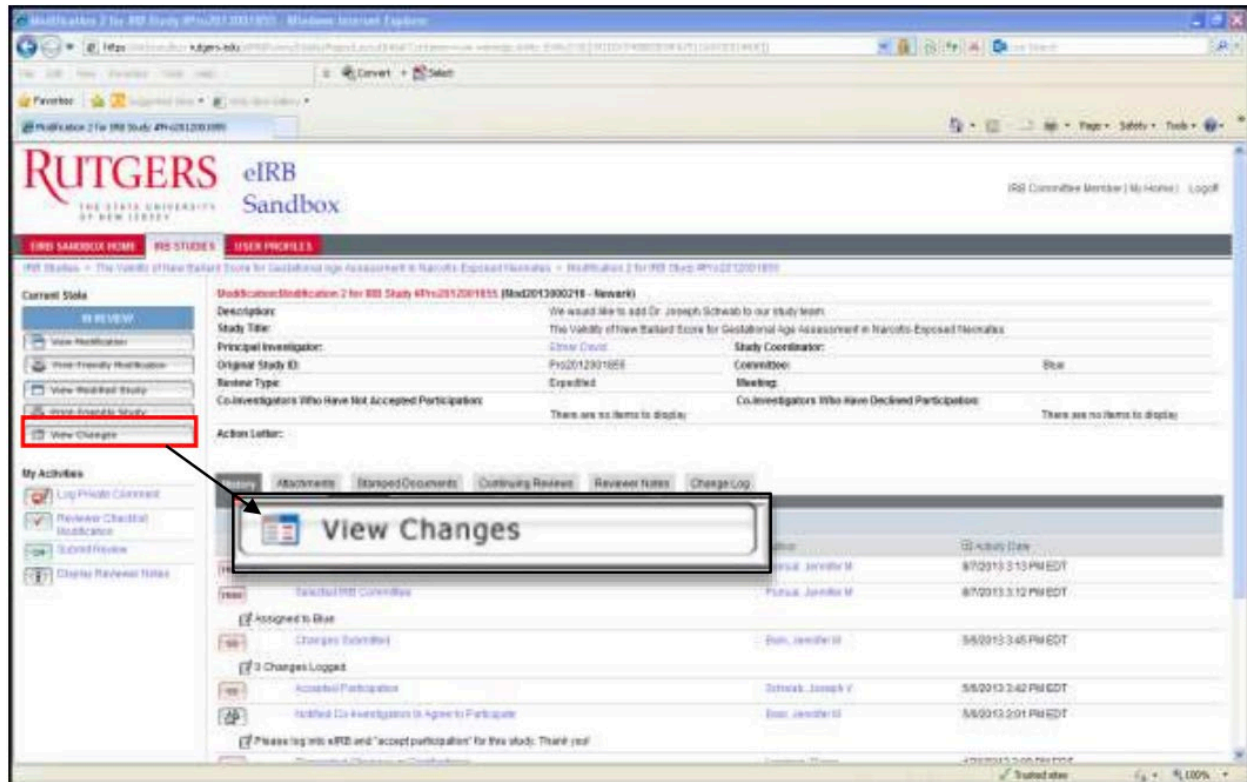
4.0 * Current Subjects - are any subjects currently enrolled in the study?:
Yes No

Click 'Exit' to return to the Modification Workspace.

Modified Study Workspace

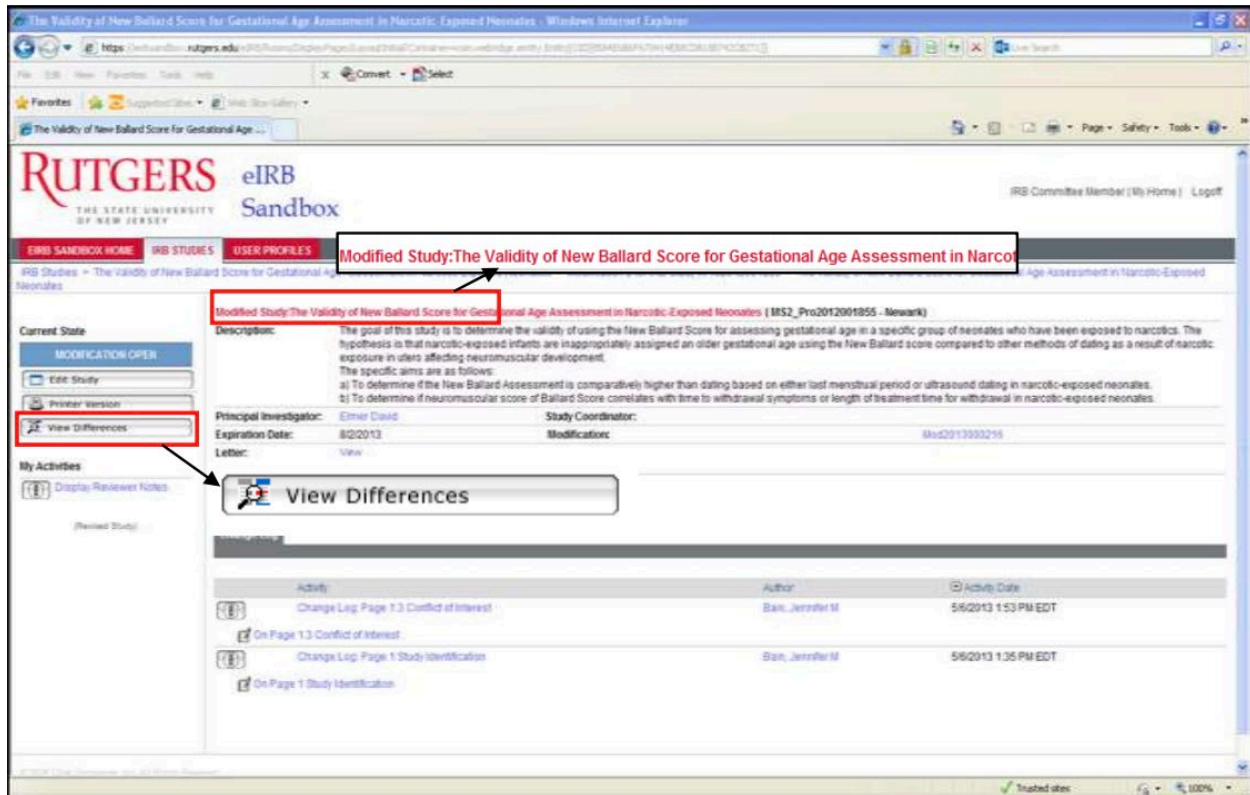
In the Modification workspace,

Click on '**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'.

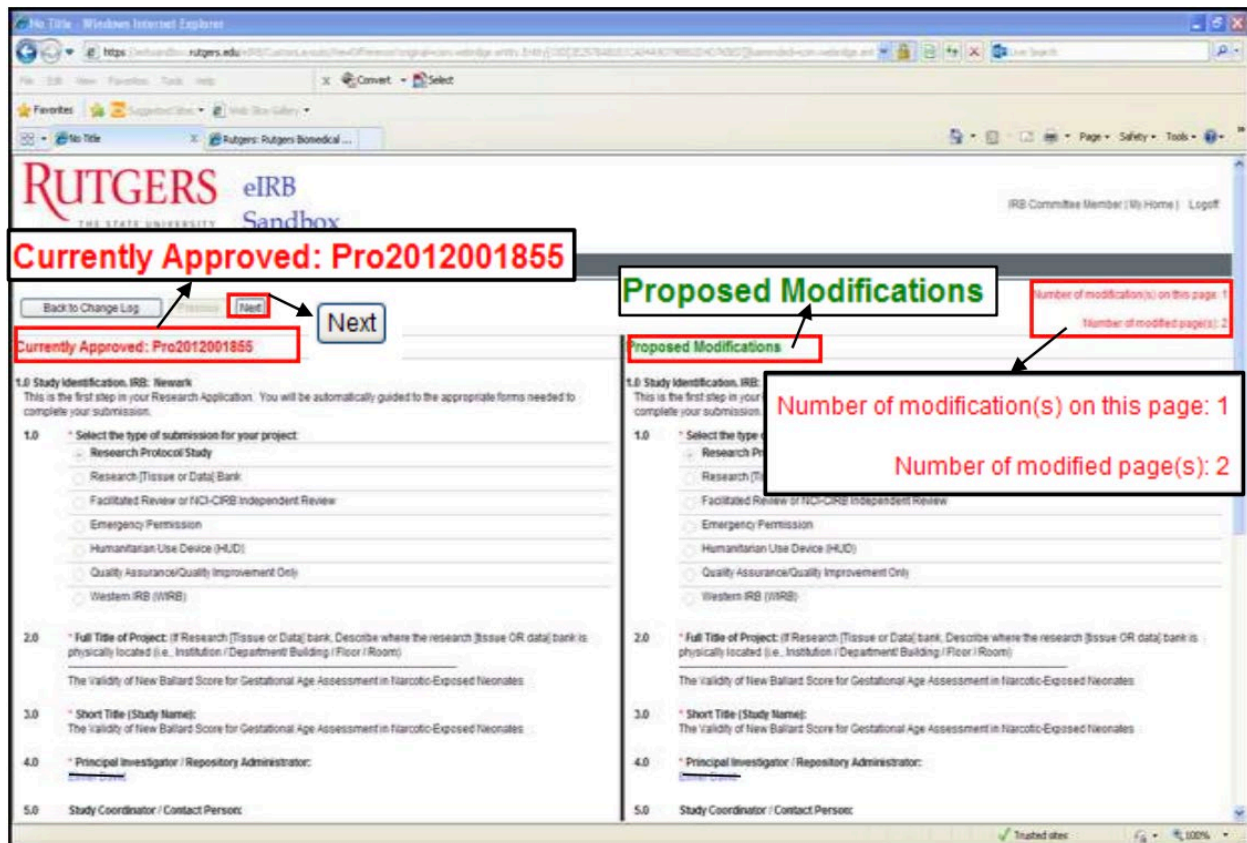


To see the changes to a study,

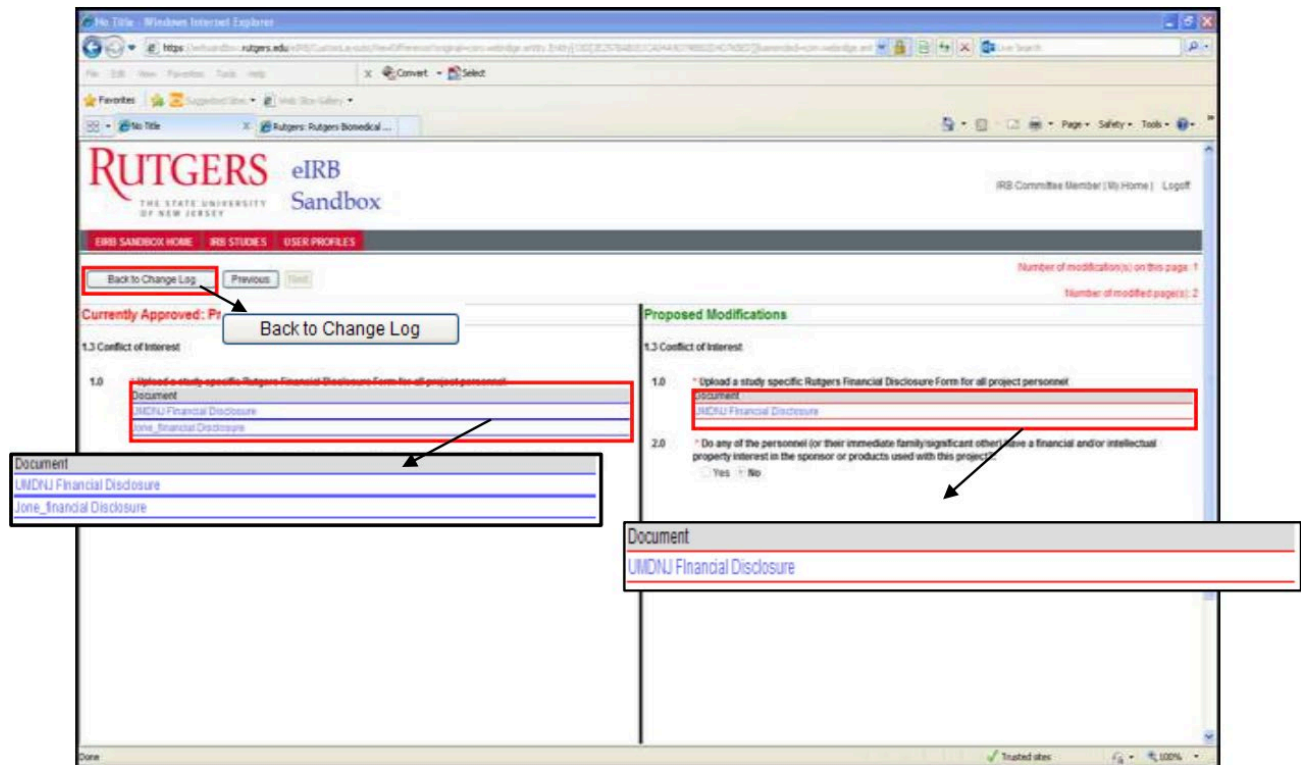
Click on the 'View Differences' button located on the left navigation pane.

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.

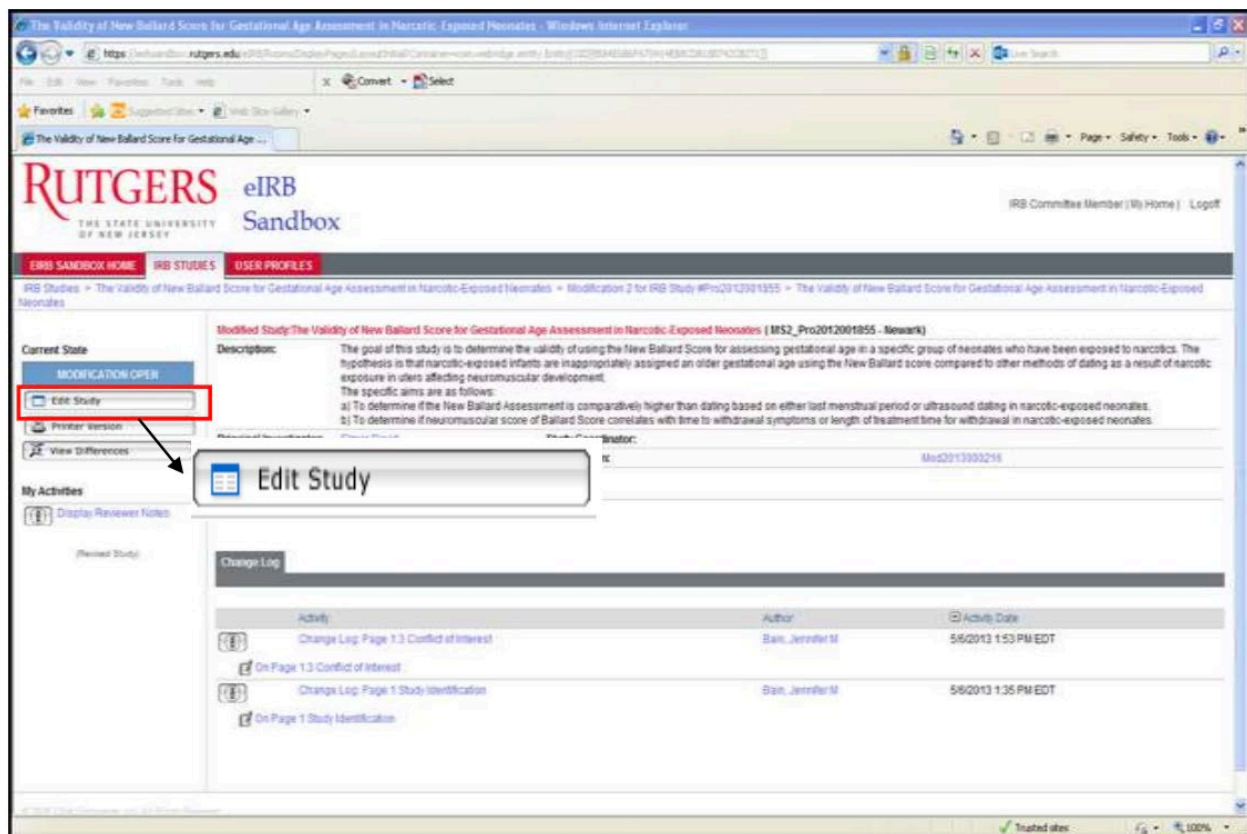
Note: The view differences feature may show differences in documents and in certain lists that may not always be accurate. If you are unsure about a change, please contact the IRB for clarification.

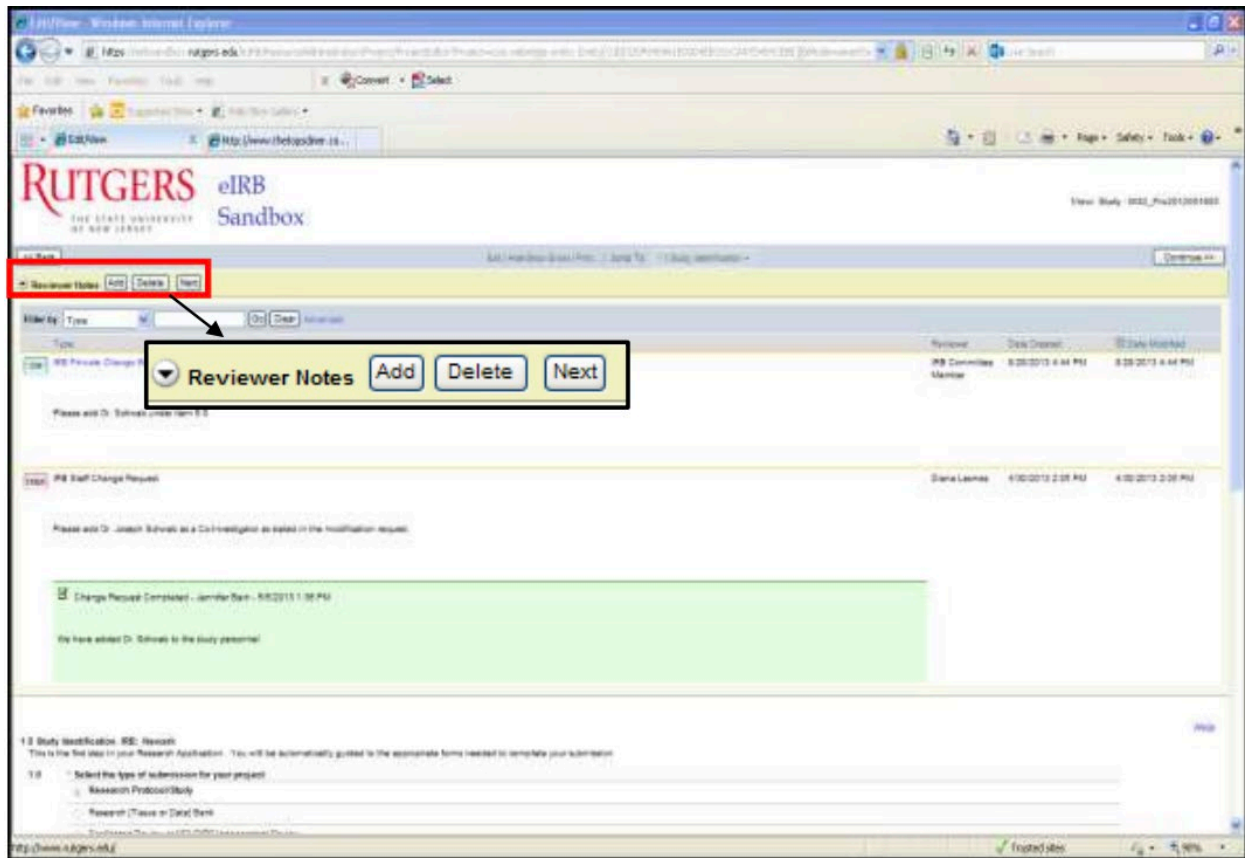
To exit the 'View Differences' application, click the 'Back to Changes Log' button.

Viewing the Modified Study

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

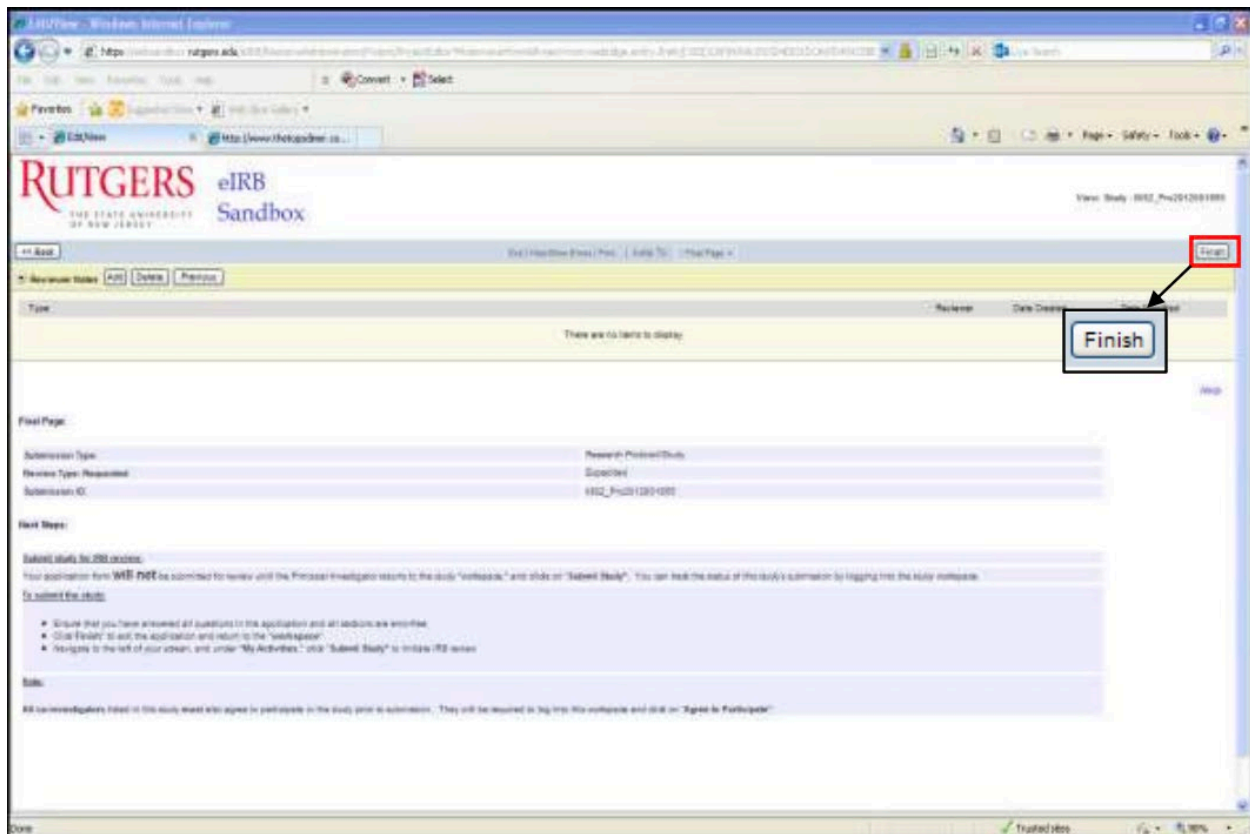
(Note: 'Edit Study' does not actually allow you to edit the study; because the Modified Study workspace is a copy of the original study, it appears identical.)





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*.



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.

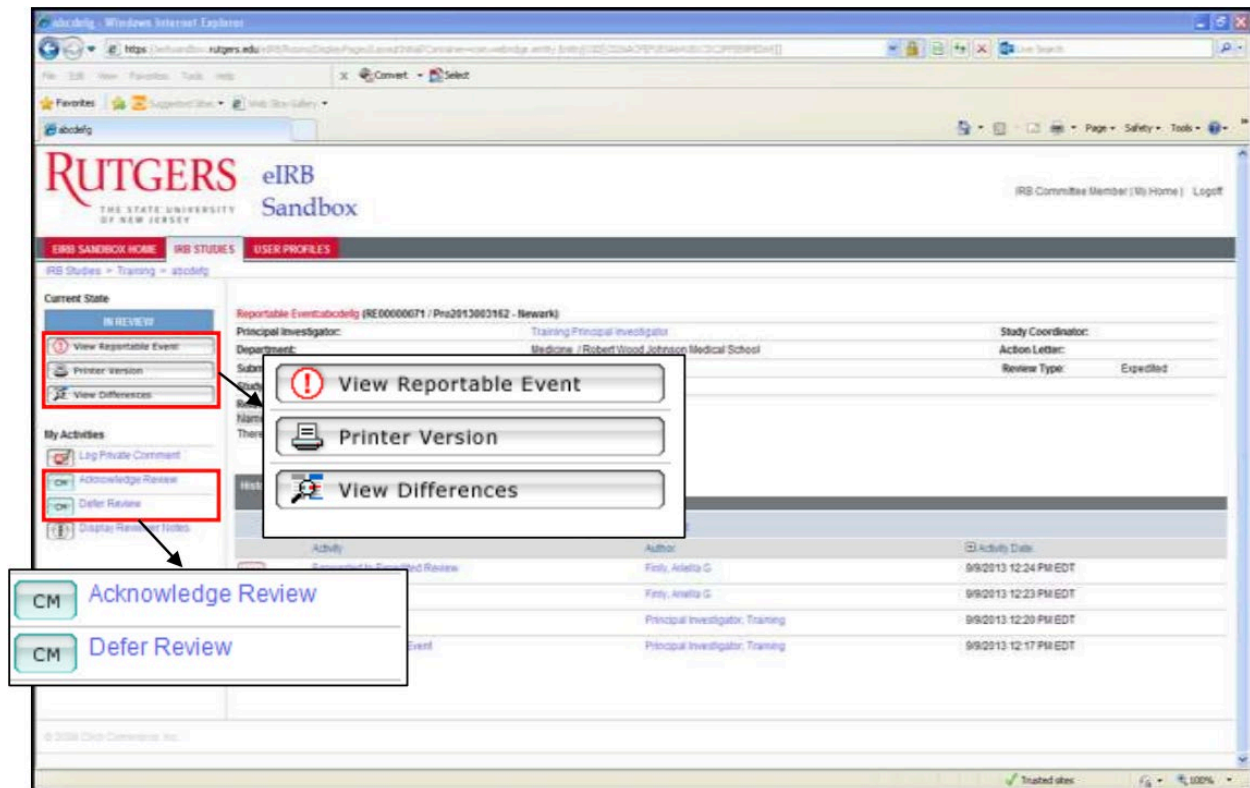
Reviewing a Reportable Event

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

The screenshot shows the Rutgers eIRB Sandbox interface. The 'My Inbox' tab is selected, displaying a table of study applications. A red box highlights a row with an exclamation point icon, indicating a reportable event. An arrow points to the study title '2014 Review for Pro2013003'.

ID	Name	Date Modified	Type	Status	Campus	Study
RE00000071	abodejg	9/9/2013 12:24 PM	Reportable Event In Review	In	Newark	Training
PRO2013000215	Winkler, John - 2 for IRB study #Pro2012001855	8/26/2013 4:36 PM	Modification	In Review	Newark	The validity of new Ballard score for gestational age assessment in newborns Exposed Neonates
CR00000015	2014 Review for Pro2013003	8/14/2013 10:11 AM	Continuing Review	In Review	Newark	Test CV

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



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

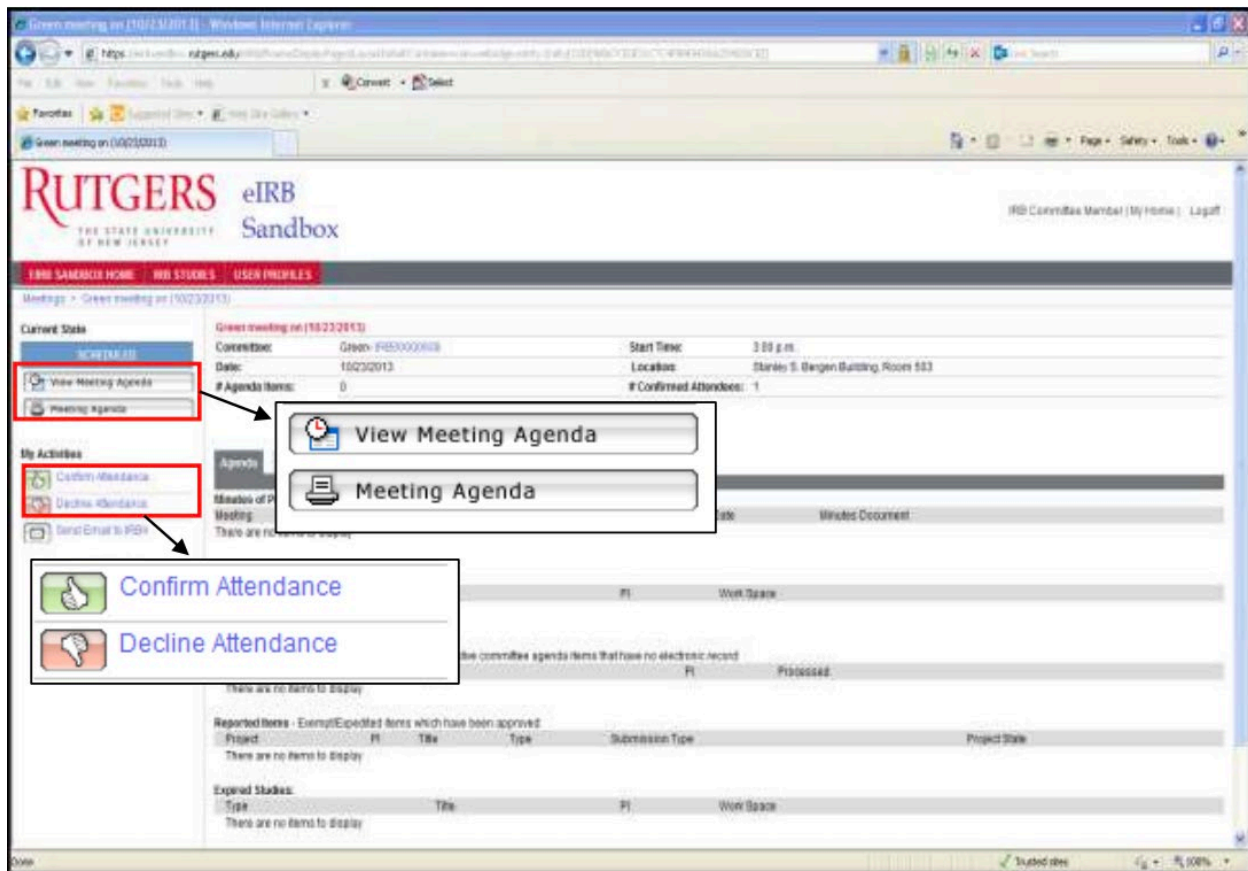
Each month, you will receive an email from eIRB indicating that the meeting agenda is ready to view. To view studies assigned to other reviewers, select the 'Upcoming Meetings' tab in the grey menu bar at the top of your 'My Home' page view. Select the name of the upcoming meeting you wish to view.

The screenshot shows the 'Page for IRB Committee Member' interface. The 'Upcoming Meetings' tab is selected, displaying a table of scheduled meetings. The first meeting, 'Green meeting on (10/23/2013)', is highlighted with a red box. An arrow points to this entry, and a callout box provides more details about the meeting.

Name	Owner	Status	Next Date Change
Green meeting on (10/23/2013)	Administrator, System	Scheduled	11/7/2012 11:27 AM
Green meeting on (12/20/2013)	Administrator, System	Scheduled	11/7/2012 11:28 AM
Red meeting on (12/18/2013)	Administrator, System	Scheduled	11/7/2012 11:15 AM
Red meeting on (11/28/2013)	Administrator, System	Scheduled	11/7/2012 11:15 AM

Callout box details for 'Green meeting on (10/23/2013)':

Name	Owner	Status	Next Date Change
Green meeting on (10/23/2013)	Administrator, System	Scheduled	11/7/2012 11:27 AM
Blue meeting on (11/13/2013)	Administrator, System	Scheduled	11/7/2012 11:37 AM
Blue meeting on (10/22/2013)	Administrator, System	Scheduled	11/7/2012 11:38 AM



- 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,

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 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>