

# **eIRB User Manual for Committee Members**



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## **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](mailto: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

**Page for IRB Committee Member**

Welcome to your Personal Folder, the central resource for managing your Study applications. Your Personal Folder provides all the tools you need in order to complete your role in the Study application process. Use the following guidelines to process your Studies:

- Complete reviews for all items in your inbox by clicking on the study name
- Meetings for your committee are listed on the Upcoming Meetings tab
- A listing of prior reviews is located in the 'All submissions' tab

ID	Name	Study Number	Type	Role	Current Study
Mod201300216	Modification 2 for IRB Study #P1420201001	0092013 4-01	Modification	In Review	Newark: The Validity of New Ballard Score for Cardiorespiratory Age Assessment in Narcosis-Exposed Neonates
CR0000010	2014 Review for P1420201001	0142013 0111	Continuing Review	In Review	Newark: Test Of
CR0000070	2013 Review for P1420201001	0132013 4-02	Continuing Review	In Review	Newark: Long-term Health Assessment

To review a submission, click on the study name.

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.

The screenshot shows the Rutgers eIRB Sandbox workspace. The left navigation bar (white area) contains links for 'IRB SANDBOX HOME', 'IRB STUDIES', 'USER PROFILES', 'Current State', 'New Continuing Review', 'Printer-Friendly Version', 'My Activities', 'Log Private Comment', 'Display Reviewer Notes', 'Reviewer Checklist for Expedited Review Categories', 'Reviewer Checklist Continuing Review', and 'Submit Review'. The top navigation bar includes 'IRB SANDBOX HOME', 'IRB STUDIES', and 'USER PROFILES'. The main content area displays the 'Current State' for a 'Continuing Review' (2014 Review for Pro2013003183). It includes fields for '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' (85), 'Review Type' (Expedited), 'Study Coordinator', 'Type of report' (Continuing Report), and 'Are any changes to the research being proposed at this time?' (no). Below these fields are 'Related Modifications' and 'Related Reportable Events'. At the bottom, there are tabs for 'History', 'Attachments', 'Submitted Documents', 'Modifications', 'Reportable Events', 'Reviewer Notes', and 'Change Log'. A table below the tabs shows a history of activities, including 'Forward to Expedited Review', 'Selected IRB Committee', 'Assigned to Green', 'Re-assign Owner', 'Assigned to Charbel Vega', 'Submitted', and 'Printed / Submitted / Archived'.

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

Left Navigation Bar

Tabs

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 displays the Rutgers eIRB Sandbox interface. At the top, the Rutgers logo and 'eIRB Sandbox' are visible. The user is logged in as 'IRB Committee Member (St. Home)'.

The main content area shows details for a study titled 'Continuing Review: 2014 Review for Pro2013002183 (CR0000015 - Pro2013002183 - Newark)'. The study status is 'Approved'. The study title is 'Test Q1'. The initial study submission type is 'Research Protocol Study'. The review type is 'Expedited'. The study coordinator is 'Training Principal Investigator / Medicine - Robert Wood Johnson Medical School'. The study status is 'Active - Open to Enrollment, Enrollment has begun'. The number of subjects enrolled to date is '00'. The type of report is 'Continuing Report'. The question 'Are any changes to the research being proposed at this time?' is answered 'no'.

On the left sidebar, under 'My Activities', the 'Printer-Friendly Version' button is highlighted with a red circle. Below this, there is a 'Printer-Friendly Version' button with a printer icon.

At the bottom, there is a table with columns: Filter by, Activity, Author, and Activity Date. The table lists several activities:

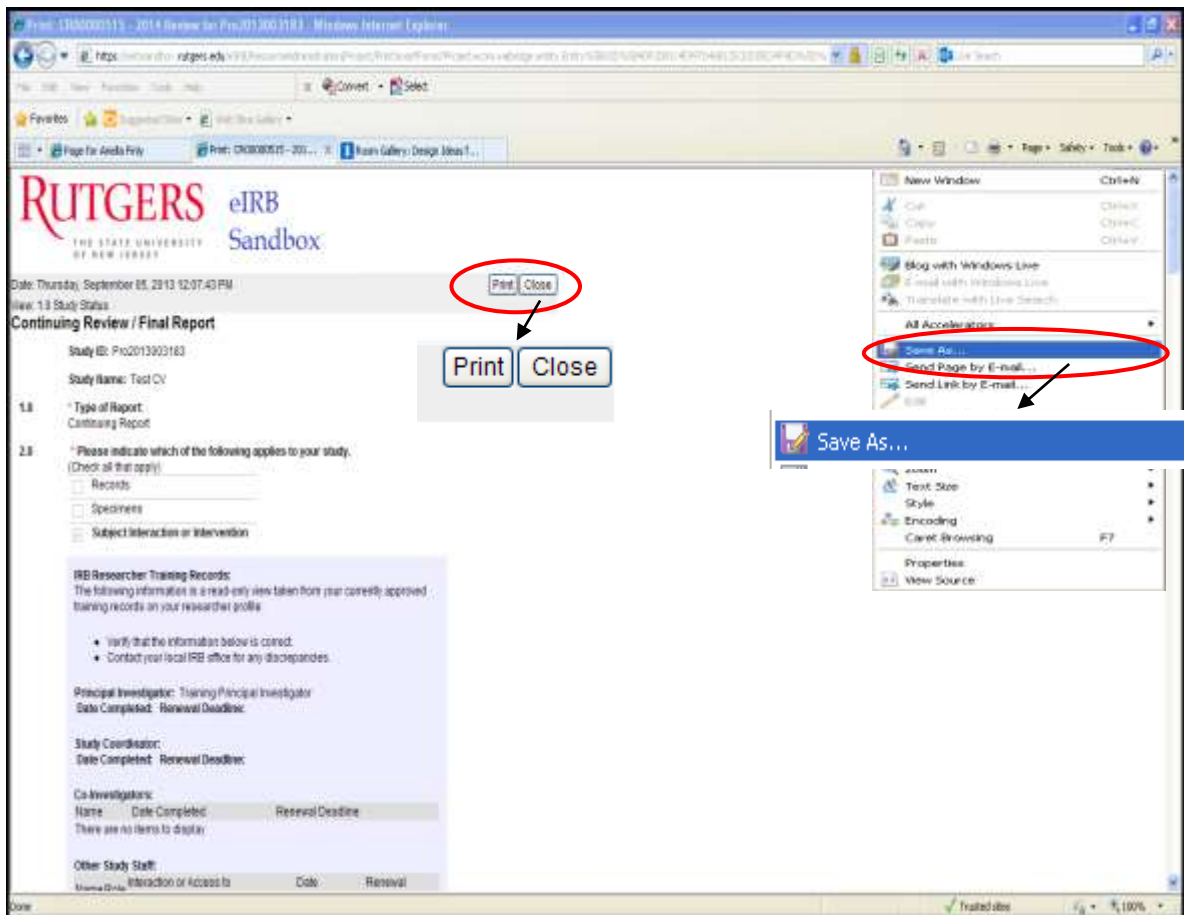
Filter by	Activity	Author	Activity Date
Proposed	Forward to Expedited Review	Vega, Chantal	8/14/2013 10:11 AM EDT
Proposed	Selected IRB Committee	Vega, Chantal	8/14/2013 10:11 AM EDT
Assigned to Green	Re-assign Owner	Vega, Chantal	8/14/2013 10:12 AM EDT
Assigned to Chantal Vega	Submit	Principal Investigator, Training	8/14/2013 10:04 AM EDT
Proposed	Forward to Expedited Review	Principal Investigator, Training	8/14/2013 10:04 AM EDT



### *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 Rutgers eIRB Sandbox interface. The 'View Study' button is highlighted in a red circle. The interface displays the following information:

**Study Training (Proc0130E1047 - Newark)**

**Description:** Training  
**Training Principal Investigator:** [Name]  
**IRB Admin:** Jennifer Pansal  
**IRB:** [Name]  
**Review Type:** Expedited  
**Sponsor:** Department Funded  
**Type of Submission:** Research Protocol/Study  
**Co-Investigators Who Have Declined Participation:** There are no items to display

**Current State:** N REVIEW  
**View Study** (highlighted)  
**Print Version**  
**View Differences**

**History** | Attachments | Stamped Documents | Department Approvals | Reviewer Notes | Reviews | Change Log

**Filter by:** Activity [Go] [Advanced]

Activity	Author	Activity Date
Submitted Review: Approval with conditions	Committee Member, IRB	5/5/2013 2:55 PM EDT
Completed Reviewer Checklist - Waiver Informed Consent	Committee Member, IRB	5/5/2013 2:47 PM EDT
Completed Reviewer Checklist for Initial Review	Committee Member, IRB	5/5/2013 2:47 PM EDT
Completed Reviewer Checklist for Research Involving Pregnant Women	Committee Member, IRB	5/5/2013 2:47 PM EDT
Completed Reviewer Checklist for Expedited Review Categories	Committee Member, IRB	5/5/2013 2:44 PM EDT
Forwarded to Expedited Review	Pansal, Jennifer M	5/2/2013 9:48 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:*

The screenshot shows the 'Study Smart' form view in the Rutgers eIRB Sandbox. The interface is divided into several sections:

- Top Navigation Bar:** Contains 'Back' and 'Continue' buttons. A 'Jump To' menu is also present, which is highlighted with a red circle and an arrow labeled '3'.
- Reviewer Notes:** A section on the left with a 'New' button and a 'Type' dropdown. It is highlighted with a red circle and an arrow labeled '1'.
- Main Content Area:** Displays the 'Study Identification, IRB: Network' form. It includes sections for '1.0 Select the type of submission for your study', '2.0 Full Title of Research', and '3.0 Short Title (Study Name)'. A red arrow labeled '2' points to the '1.0' section.
- Form Sections:** The form is divided into several sections, each with a red number:
  - 1. Study Identification
  - 2. IRB Researcher Training Records
  - 3. Confict of Interest
  - 4. Required Departmental/Division Reviews
  - 5. Review Type
  - 6. Review Type/Risk Determination
  - 7. Review Type/Risk Determination - Expedited Qualification
  - 8. Study Funding
  - 9. Funding
  - 10. Adding Sponsors
  - 11. Other Funding Source
  - 12. Coverage of Study-Related Costs
- Right Sidebar:** A list of the form sections, each with a red number. A red arrow labeled '1' points to the '1. Study Identification' section.

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 web application in a Windows Internet Explorer browser. The page title is 'eIRB Sandbox'. The main content area has a yellow header with a 'Reviewer Notes' section. This section contains a 'Type' dropdown menu and three buttons: 'Add', 'Delete', and 'Next'. A red circle highlights the 'Add' button, and a red arrow points to it. Below this, there is a section titled 'Study Identification, IRB: Stratford/Camden' with a sub-header 'This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.' The form includes three numbered sections: 1.0 'Select the type of submission for your study' with radio buttons for 'Research Protocol/Study', 'Facilitated Review', 'Emergency Permission', and 'Western IRB (WIRB)'; 2.0 'Full Title of Research:' with the text 'Glutamic Acid to decrease vincristine toxicity in children with cancer--kj'; and 3.0 'Short Title (Study Name):' with the text 'Kids with cancer-kj'.

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 a '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. A red circle highlights the 'OK' button.

**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 shows the Rutgers eIRB Sandbox interface. At the top, the Rutgers logo and 'eIRB Sandbox' are visible. The page title is 'View: Study - Pro2013003140'. Below the header, there are navigation buttons: '<< Back', 'Exit', 'Show Errors', 'Print...', 'Jump To', and 'Continue >>'. The 'Reviewer Notes' tab is selected and highlighted with a red circle. Below the tab, there is a yellow panel with a 'Go' button, a 'Clear' button, and an 'Advanced' link. A red circle highlights the 'Exit' button. Below the yellow panel, there is a table with columns: 'Reviewer', 'Date Created', and 'Date Modified'. The table contains one row: 'IRB Committee Member', '8/7/2013 3:34 PM', and '8/7/2013 3:34 PM'. Below the table, there is a 'CM' button and a link 'Committee Member Change Request', both highlighted with a red circle. A yellow box highlights the 'CM' button. Below the yellow box, there is a section titled '1.0 Study Identification, IRB: Newark' with a description: 'This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.' Below this, there is a form with a dropdown menu 'Select the type of submission for your project' and several radio button options: 'Research Protocol/Study', 'Research [Tissue or Data] Bank', 'Facilitated Review or NCI-CIRB Independent Review', 'Emergency Permission', 'Humanitarian Use Device (HUD)', 'Quality Assurance/Quality Improvement Only', and 'Western IRB (WIRB)'. Below the form, there is a section titled '2.0 Full Title of Project: (if Research [Tissue or Data] bank, Describe where the research [tissue OR data] bank is physically located (i.e., Institution / Department/ Building / Floor / Room))'. At the bottom right, there is a 'Help' link and a 'Trusted sites' status bar.

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' and 'IRB Committee Member (My Home) | Logout'. The main content area is titled 'Study: training (Pro2013003140 - Newark)'. It shows a workflow diagram with steps: Pre-Submission, Department Review, IRB Review, Post Review, and Review Complete. The 'IRB Review' step is highlighted. Below the workflow, there are tabs for History, Attachments, Stamped Documents, Department Approvals, Reviewer Notes (selected), Reviews, and Change Log. The 'Reviewer Notes' tab is active, showing a list of notes. The first note is a 'Committee Member Change Request' with a 'Jump To: 7 to Study Summary / Protocol Section 1' link. The second note is another 'Committee Member Change Request' with a 'Jump To: 1 Study Identification' link. The table below shows the details of these notes.

Type	Reviewer	Date Created	ID	Date Modified
Committee Member Change Request Jump To: 7 to 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:

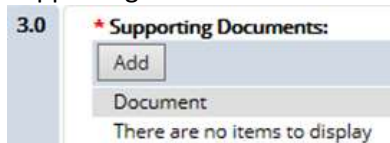
- Download (save each file to your computer's desktop) and complete ALL available *Required Checklists* found in the Submit Designated Review window when your review is complete (see instructions provided in *Submit Review* window).



### 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.



- 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 Rutgers eIRB Sandbox interface. The top navigation bar includes 'eIRB Sandbox' and 'IRB Committee Member | My Home | Logout'. The left sidebar shows 'Current Role: COMMITTEE MEMBER' and 'My Roles' with a 'Committee Member' role selected. The main content area is titled 'Page for IRB Committee Member' and includes a welcome message and guidelines. Below this, there are tabs for 'My Inbox' and 'Upcoming Meetings'. The 'My Inbox' tab is active, displaying a table of review items. A red box highlights a row with ID 'CR00000515', titled '2014 Review for Pro2013003183', dated '8/14/2013 10:11 AM', and labeled 'Continuing Review'. A callout box below the table provides more details for this item.

ID	Name	Date Modified	Type	Status	Campus	Study
Mod2013000216	Modification 2 for IRB Study #Pro2012001855	8/28/2013 4:35 PM	Modification	In Review	Newark	The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
CR00000515	2014 Review for Pro2013003183	8/14/2013 10:11 AM	Continuing Review	In Review	Newark	Test CV

Callout box details for CR00000515:

CR00000515	2014 Review for Pro2013003183	8/14/2013 10:11 AM	Continuing Review	In Review	Newark	Test CV
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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'.

The screenshot displays the Rutgers eIRB Sandbox interface. At the top, the Rutgers logo and 'eIRB Sandbox' are visible. The user is logged in as an 'IRB Committee Member'. The main navigation bar includes 'eIRB SANDBOX HOME', 'IRB STUDIES', and 'USER PROFILES'. The breadcrumb trail shows 'IRB Studies > Test CV > 2014 Review for Pro2013003183'. The 'Current State' section shows 'Continuing Review: 2014 Review for Pro2013003183 (L: R00000515 / Pro2013003183 - Newark)'. The 'IN REVIEW' section contains two buttons: 'View Continuing Review' and 'Printer-Friendly Version'. The 'My Activities' section on the left lists various actions like 'Log Private', 'Display Report', 'Reviewer Expedited Categories', 'Reviewer Continuing Review', and 'Submit Review'. The 'View Continuing Review' button is highlighted with a red box and an arrow pointing to a larger version of the same button. The 'Printer-Friendly Version' button is also highlighted with a red box. The 'History' tab is selected, showing a list of activities with columns for Activity, Author, and Activity Date. The activities include 'Forward to Expedited Review', 'Selected IRB Committee', 'Assigned to Green', 'Re-assign Owner', 'Assigned to Claribel Vega', 'Submit', and 'Printed Continuing Review'.

**Continuing Review: 2014 Review for Pro2013003183 (L: R00000515 / 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

**Notice:**

**Related Reportable Events:**

Name	Link to Reportable Event	State
There are no items to display		

**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
Forward to Expedited Review	Vega, Claribel	8/14/2013 10:11 AM EDT
Selected IRB Committee	Vega, Claribel	8/14/2013 10:11 AM EDT
Assigned to Green		
Re-assign Owner	Vega, Claribel	8/14/2013 10:10 AM EDT
Assigned to Claribel Vega:		
Submit	Principal Investigator, Training	8/14/2013 10:04 AM EDT
Printed 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'.

The screenshot shows the eIRB Home page with the following details:

- Current State:** In Review
- Continuing Review: 2011 Review for Pro2010000787** (CR00000136 / Pro2010000787 - Stratford/Camden)
- Current study status:** Approved
- Initial study submission type:** Research Protocol/Study
- Principal Investigator:** Stratford PI / Health Systems and Policy - Stratford/Camden (HSAP) / School of Public Health
- Study Status:** Active - Open to Enrollment. No enrollment to date.
- Number subjects enrolled to date:**
- Related Modifications:** Name Link to Modification State: There are no items to display.
- Review Type:** Full IRB Review
- Study Coordinator:** Stratford Study Coordinator
- Type of report:** Continuing Report
- Are any changes to the research being proposed at this time?** no
- Related Reportable Events:** Name: Link to Reportable Event: State: There are no items to display.

The 'My Activities' section on the left includes buttons for 'Log Private Comment', 'Acknowledge Review', and 'Defer Review'. The 'Acknowledge Review' and 'Defer Review' buttons are circled in red. A modal window is open over these buttons, showing 'Acknowledge Review' and 'Defer Review' options with 'CM' icons.

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.

The 'Acknowledge Review' dialog box contains the following elements:

- Comments:** A text area for entering comments.
- Add Documents:** A section with an 'Add' button and a table.
- Table:**

Name	Description
There are no items to display	
- Buttons:** 'OK' and 'Cancel' buttons at the bottom right. The 'OK' button is circled in red.

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'

The screenshot displays the Rutgers eIRB Sandbox interface. The left sidebar contains a 'My Activities' section with a 'Submit Review' button circled in red. A callout box labeled 'CM Submit Review' points to this button. The main content area shows a form for submitting a review, including fields for 'Review Documents', 'Review Type', 'Review Motion', 'Revisions to be reviewed by', 'Risk Level', and 'Should review occur more frequently than once a year?'. A dropdown menu is open for 'Review Motion', showing options like 'Approval with conditions', 'Approved', 'Approved with Stipulations', 'Deferred', 'Request Changes', 'Request Clarification', 'WRB - Denial', and 'WRB - OK to Process'. The 'WRB - OK to Process' option is selected. The bottom of the page shows a 'Trusted site' status bar.

## 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 Rutgers eIRB Sandbox interface. The left sidebar contains navigation links: 'Current Role' (Committee Member), 'My Roles' (Committee Member), and 'My Committees'. The main content area is titled 'Page for IRB Committee Member' and includes a welcome message and a list of guidelines. Below this is a table of study modifications under the 'My Inbox' tab. A red box highlights a specific modification entry, and a tooltip provides more details about it.

ID	Name	(Date Modified)	Type	Status	Campus	Study
Mod2013000216	Modification 2 for IRB Study #Pro2012001855	8/28/2013 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 8/28/2013 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 screenshot shows the eIRB Sandbox interface for viewing a modification. The browser address bar indicates the URL is <https://eirsandbox.rutgers.edu/eIRB/Forms/DisplayPage.aspx?ID=2013000216&StudyID=2012001855>. The page title is 'Modification 2 for IRB Study #Pro2012001855'. The sidebar on the left contains a 'My Activities' section with links to 'Log Private Comment', 'Review Checklist Modification', 'Submit Review', and 'Display Reviewer Notes'. The main content area shows the modification details for 'Modification 2 for IRB Study #Pro2012001855 (Mod2013000216 - Newark)'. A dropdown menu is open, showing options: 'View Modification', 'Print-Friendly Modification', 'View Modified Study', 'Print-Friendly Study', and 'View Changes'.

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.

The screenshot shows the 'Acknowledge Review' dialog box. It has a 'Comments' section with a text area for input. Below this is an 'Attach Documents' section with a table showing 'Name' and 'Description'. At the bottom right, there are 'OK' and 'Cancel' buttons. The 'OK' button is circled in red.



## 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'.

The screenshot shows the 'Modification Request' form in a web browser. The form includes a navigation bar with 'Exit | Hide/Show Errors | Print... | Jump To: Modification Request'. Below this, there's a 'Reviewer Note' section with 'Add' and 'Delete' buttons. The main form area is divided into sections: 'Modification Information' (with a dropdown menu showing 'Modification Request', 'Minor, Non-Substantive Change Justification', 'Subject Notification', and 'Final Page'), 'Created', and 'Date Modified'. The 'Modification Request' section contains four numbered items:

- 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 ☐

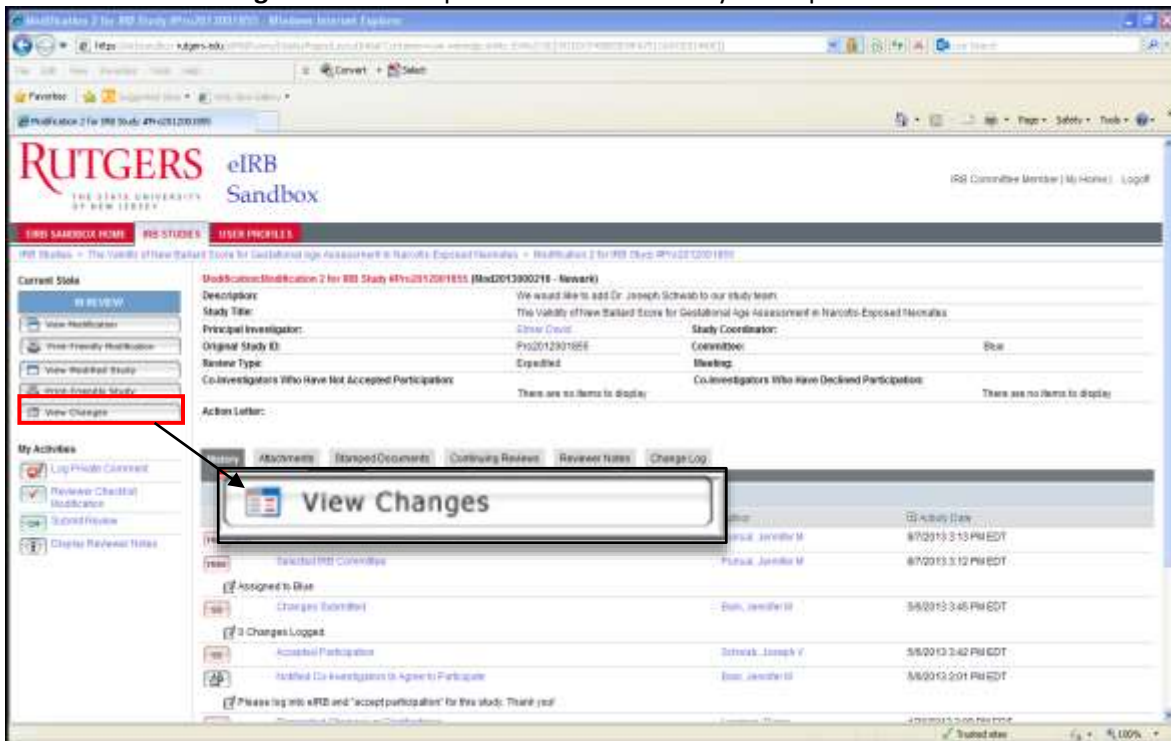
Annotations with arrows point to the 'Exit' button in the navigation bar, the '2.0' field, and the '3.0' field. A large callout box highlights the '3.0' field with the text: '\* Description of Changes – briefly summarize the change: We would like to add Dr. Joseph Schwab to our study team.'

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'.

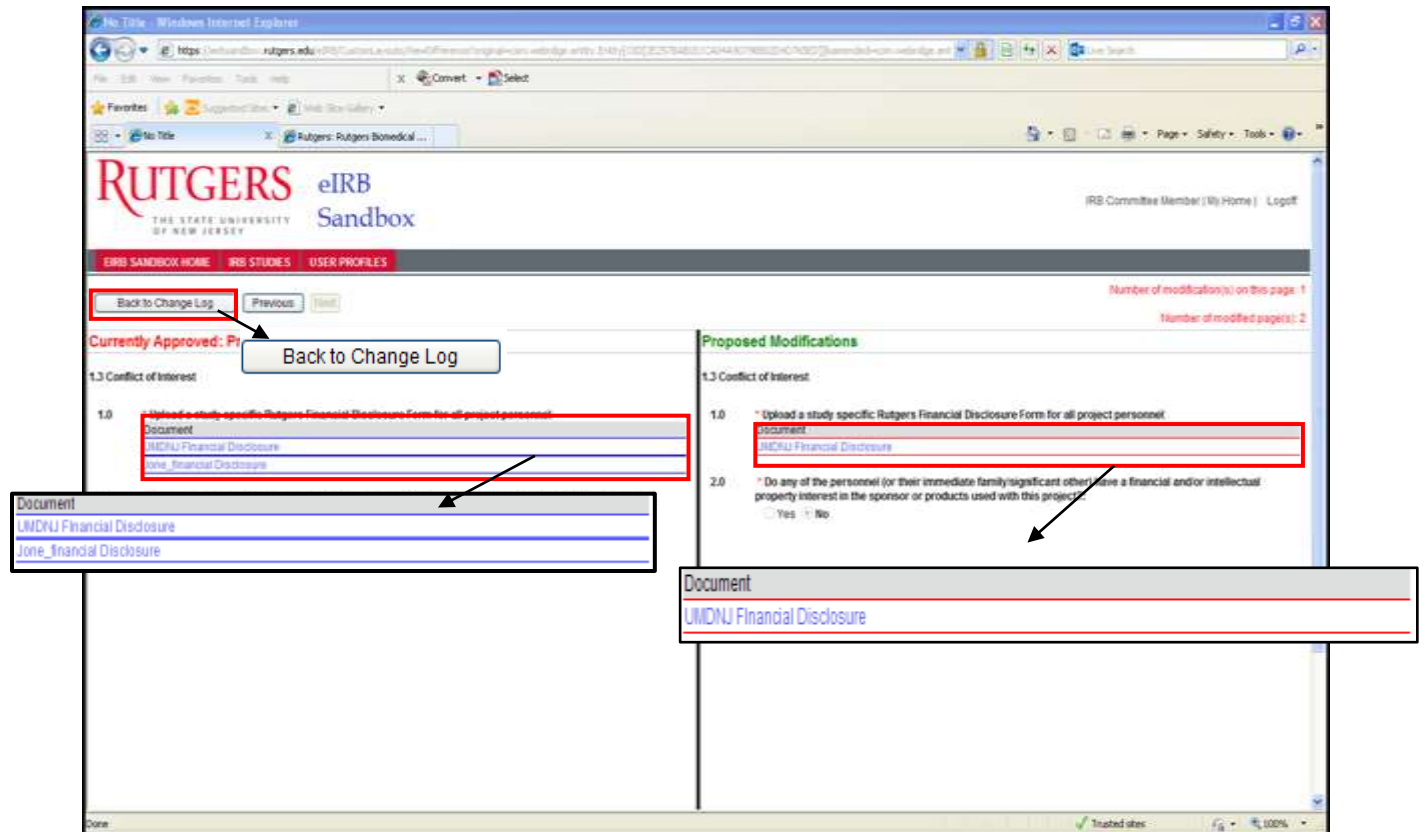
The screenshot shows a web browser window displaying the eIRB Sandbox interface. The title bar of the browser window reads "The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates - Windows Internet Explorer". The address bar shows the URL: [https://eirb.sandbox.rutgers.edu/IRB/Forms/DisplayPage.aspx?ID=211&?Content=con:webpage\\_entity\\_display/20254488679/WEBFORMS/20254488679](https://eirb.sandbox.rutgers.edu/IRB/Forms/DisplayPage.aspx?ID=211&?Content=con:webpage_entity_display/20254488679/WEBFORMS/20254488679). The page header includes the Rutgers University logo and "eIRB Sandbox". The navigation pane on the left has tabs for "eIRB SANDBOX HOME", "IRB STUDIES", and "USER PROFILES". Under "IRB STUDIES", there is a link to "The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates". The main content area shows the study details for "Modified Study: The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates (MS2\_Pro2012001855 - Newark)". The study description, principal investigator (Elmer David), study coordinator, expiration date (8/2/2013), and letter are displayed. A red box highlights the "View Differences" button in the left navigation pane. Another red box highlights the "View Differences" button in the main content area. An arrow points from the button in the left pane to the button in the main content area. Below the "View Differences" button, there is a table of activities:

Activity	Author	Activity Date
Change Log: Page 1.3 Conflict of Interest	Bain, Jennifer M	5/6/2013 1:53 PM EDT
On Page 1.3 Conflict of Interest		
Change Log: Page 1 Study Identification	Bain, Jennifer M	5/6/2013 1:35 PM EDT
On Page 1 Study Identification		

To see the changes to a study,

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





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.)

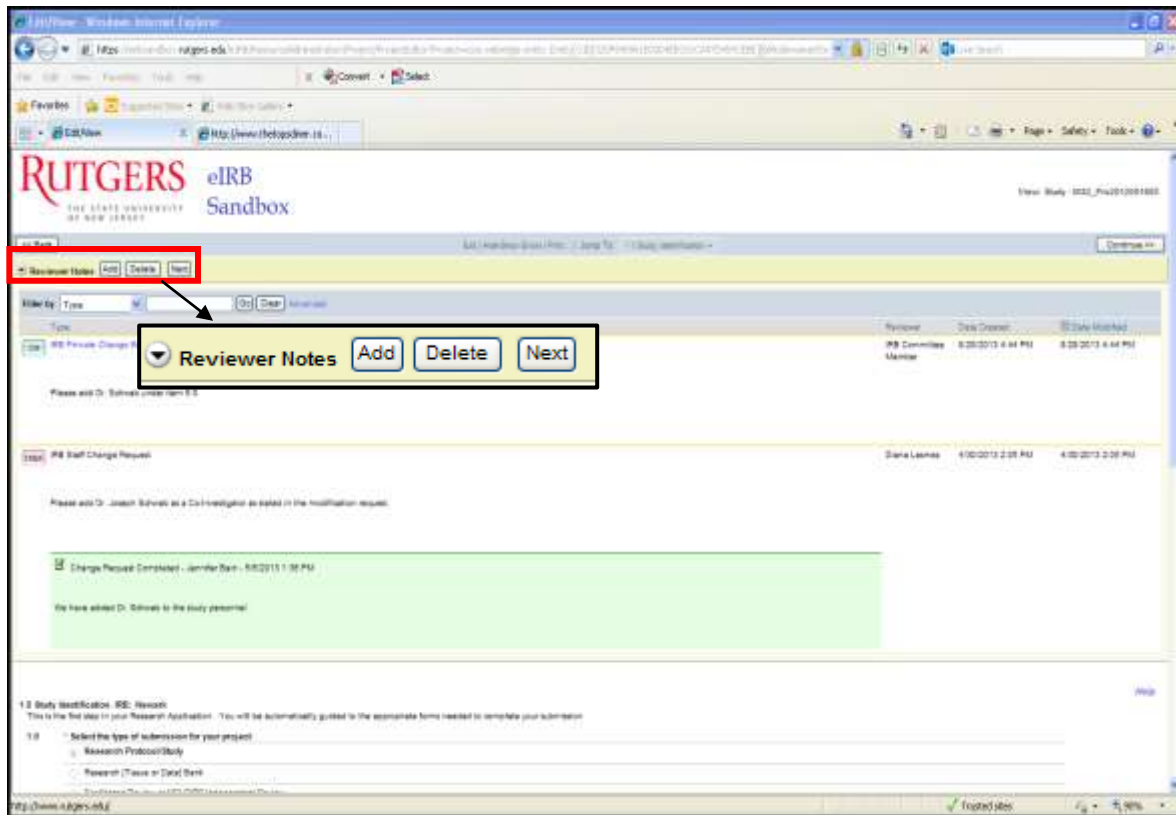
The screenshot shows the Rutgers eIRB Sandbox interface. The browser address bar displays the URL: <https://eirb.sandbox.rutgers.edu/IRB/Forms/ChangePage.aspx?StudyID=2013001855&StudyName=The%20Validity%20of%20New%20Ballard%20Score%20for%20Gestational%20Age%20Assessment%20in%20Narcotic-Exposed%20Neonates>. The page title is "The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates".

The interface includes a navigation bar with "eIRB Sandbox" and "USER PROFILES". The main content area shows the study details for "Modified Study: The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates (MS2\_Pro2012001855 - Newark)".

On the left sidebar, under "Current State", the "Edit Study" button is highlighted with a red box. An arrow points from this button to the "Edit Study" button in the main content area. Other buttons in the sidebar include "MODIFICATION OPEN", "Printer Version", and "View Differences".

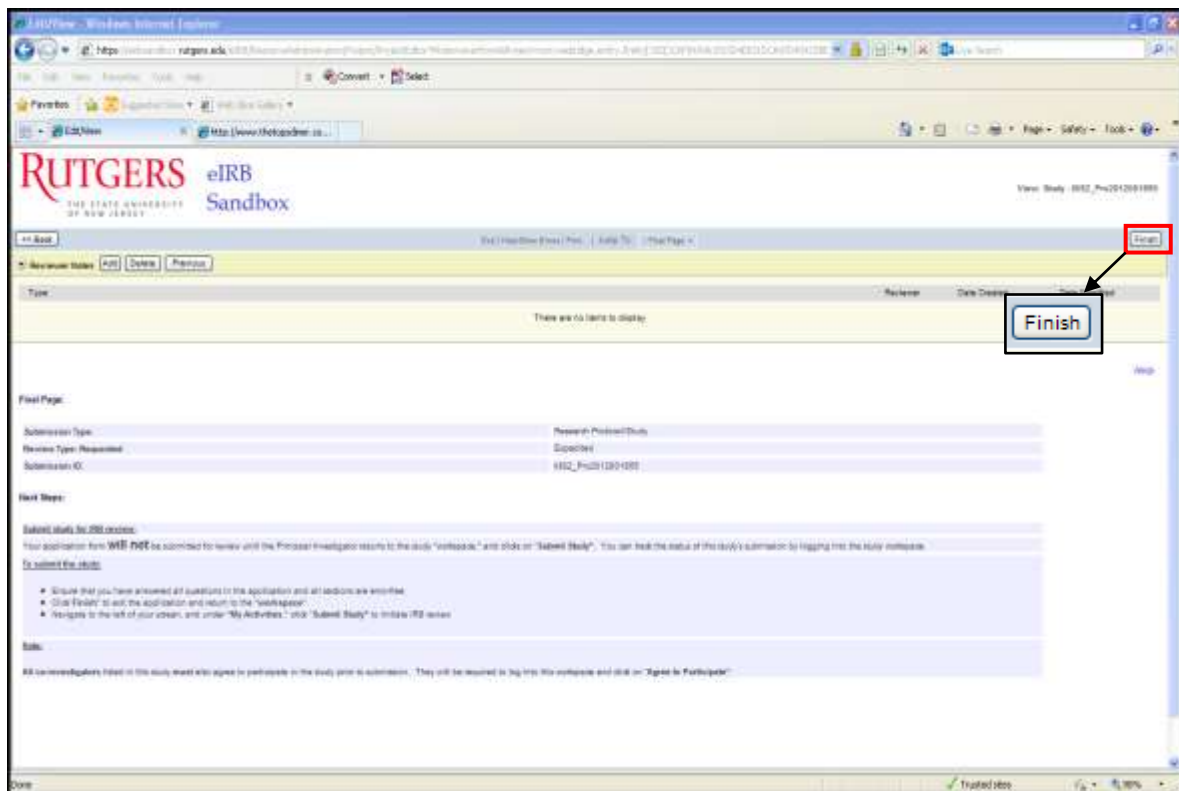
The main content area also features a "Change Log" table with the following data:

Activity	Author	Activity Date
Change Log Page 1.3 Conflict of Interest	Bain, Jennifer M	5/6/2013 1:53 PM EDT
On Page 1.3 Conflict of Interest		
Change Log Page 1 Study Identification	Bain, Jennifer M	5/6/2013 1:35 PM EDT
On Page 1 Study Identification		



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'.

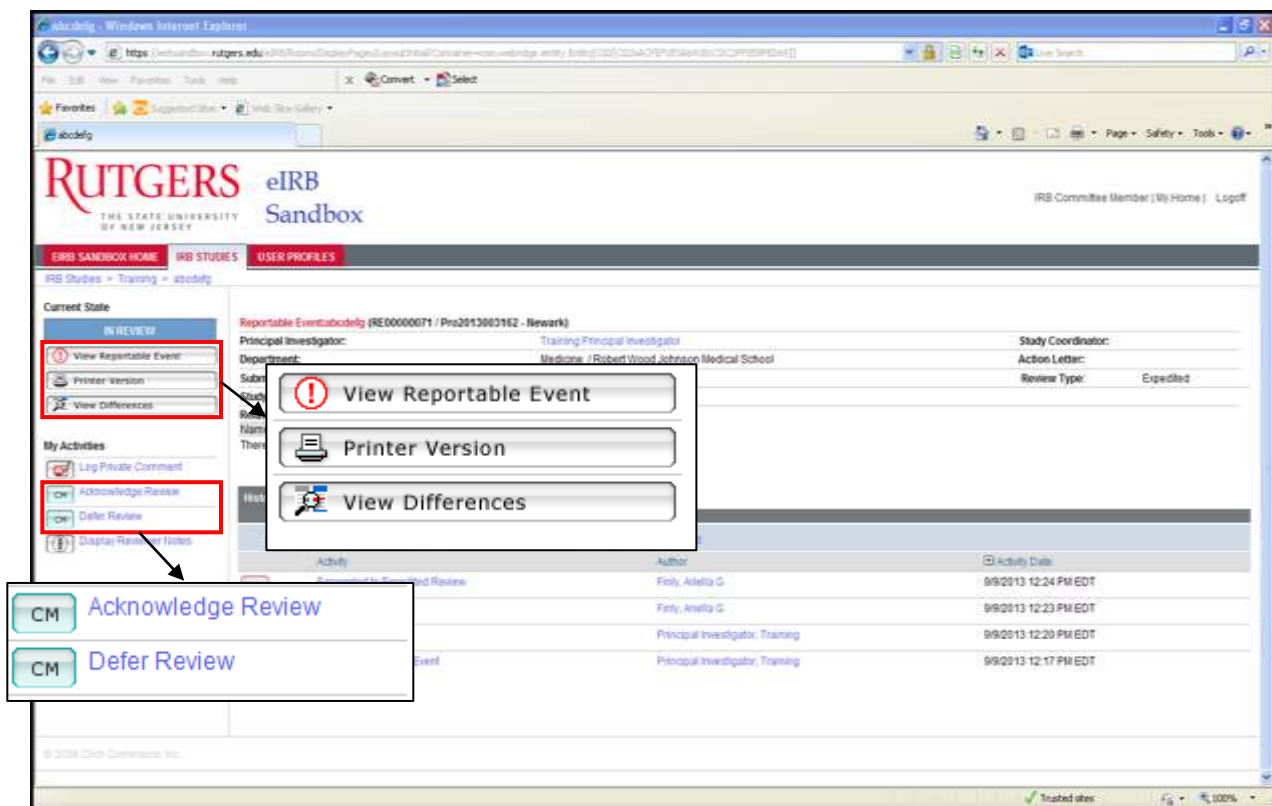
The screenshot shows the Rutgers eIRB Sandbox interface. The top navigation bar includes links for 'eIRB Sandbox', 'IRB STUDIES', and 'USER PROFILES'. The main content area is titled 'Page for IRB Committee Member' and includes a welcome message and guidelines. A sidebar on the left shows 'My Roles' (Committee Member) and 'My Committees'. The main table, titled 'My Inbox', lists study applications. The first row is highlighted with a red box and contains an exclamation mark icon, indicating a reportable event.

ID	Name	Date Modified	Type	State	Campus	Study
RE0000071	abodefg	9/9/2013 12:24 PM	Reportable Event In Review	In	Newark	Training
MO2013000210	Investigation 2 for IRB Study #Pro2012001855	8/28/2013 4:36 PM	Modification	In	Newark	The validity of New Ballard score for gestational Age Assessment in Narcotic-Exposed Neonates
CR00000515	2014 Review for Pro2013000	8/14/2013 10:11 AM	Continuing	In	Newark	Test CV

A detailed view of the first row (RE0000071) is shown below the table, confirming its status as a 'Reportable Event In Review'.

**!** 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

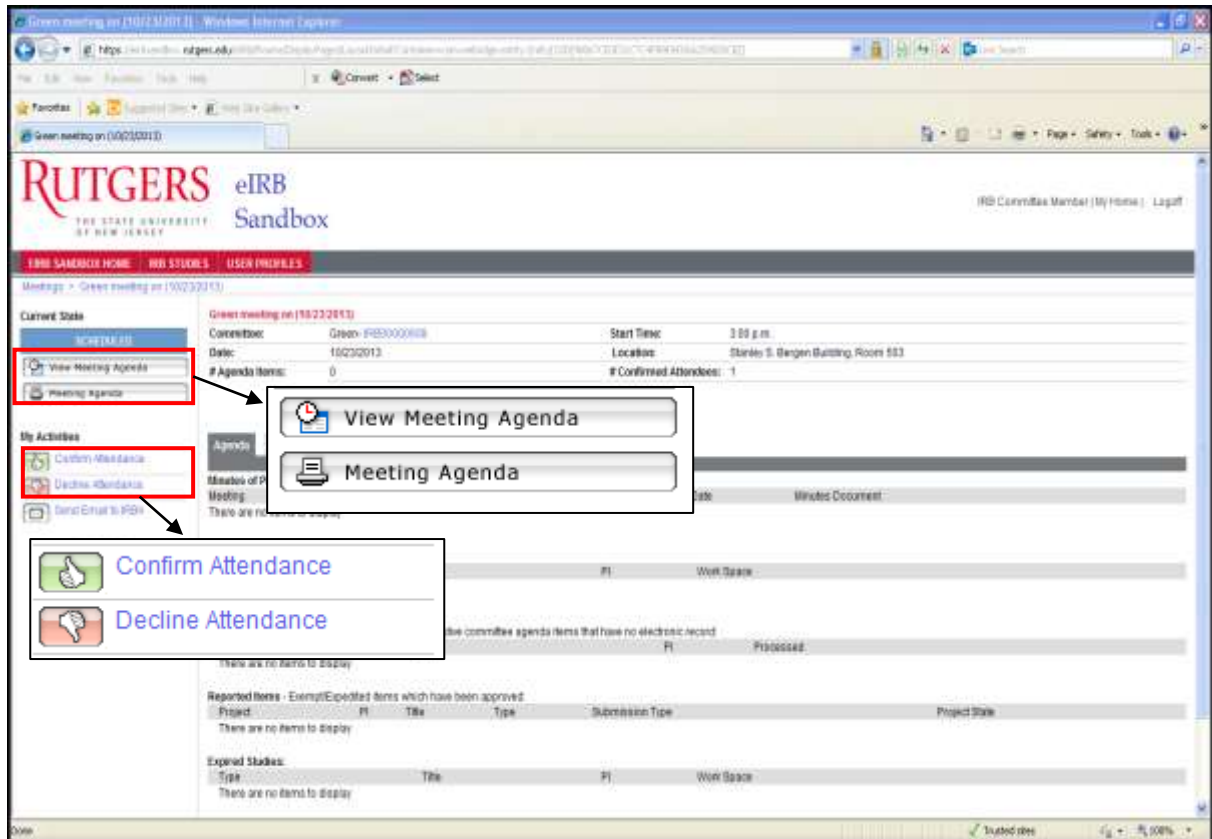
Each month, you will receive an email from eIRB indicating that the meeting agenda is ready to view. To view studies assigned to other reviewers, select the 'Upcoming Meetings' tab in the grey menu bar at the top of your 'My Home' page view. Select the name of the upcoming meeting you wish to view.

The screenshot shows the eIRB Sandbox interface for a Rutgers user. The 'Upcoming Meetings' tab is selected in the grey menu bar. A table lists upcoming meetings, with the first entry highlighted by a red box. An arrow points to the first entry in the table.

Name	Owner	Role	Q3 Last Review Change
Green meeting on (10/23/2013)	Administrator, System	Scheduled	11/7/2012 11:27 AM
Green meeting on (10/23/2013)	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 (11/8/2013)	Administrator, System	Scheduled	11/7/2012 11:15 AM

Expanded view of the first meeting:

Green meeting on (10/23/2013)	Administrator, System	Scheduled	11/7/2012 11:27 AM
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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

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- ☐ 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

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- ☐ 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

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- ☐ 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

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- ☐ 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

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- ☐ 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

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- ☐ 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>