



Rowan University 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.

<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

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

ID: [Pro2014000054](#)

Study number

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

Description: 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

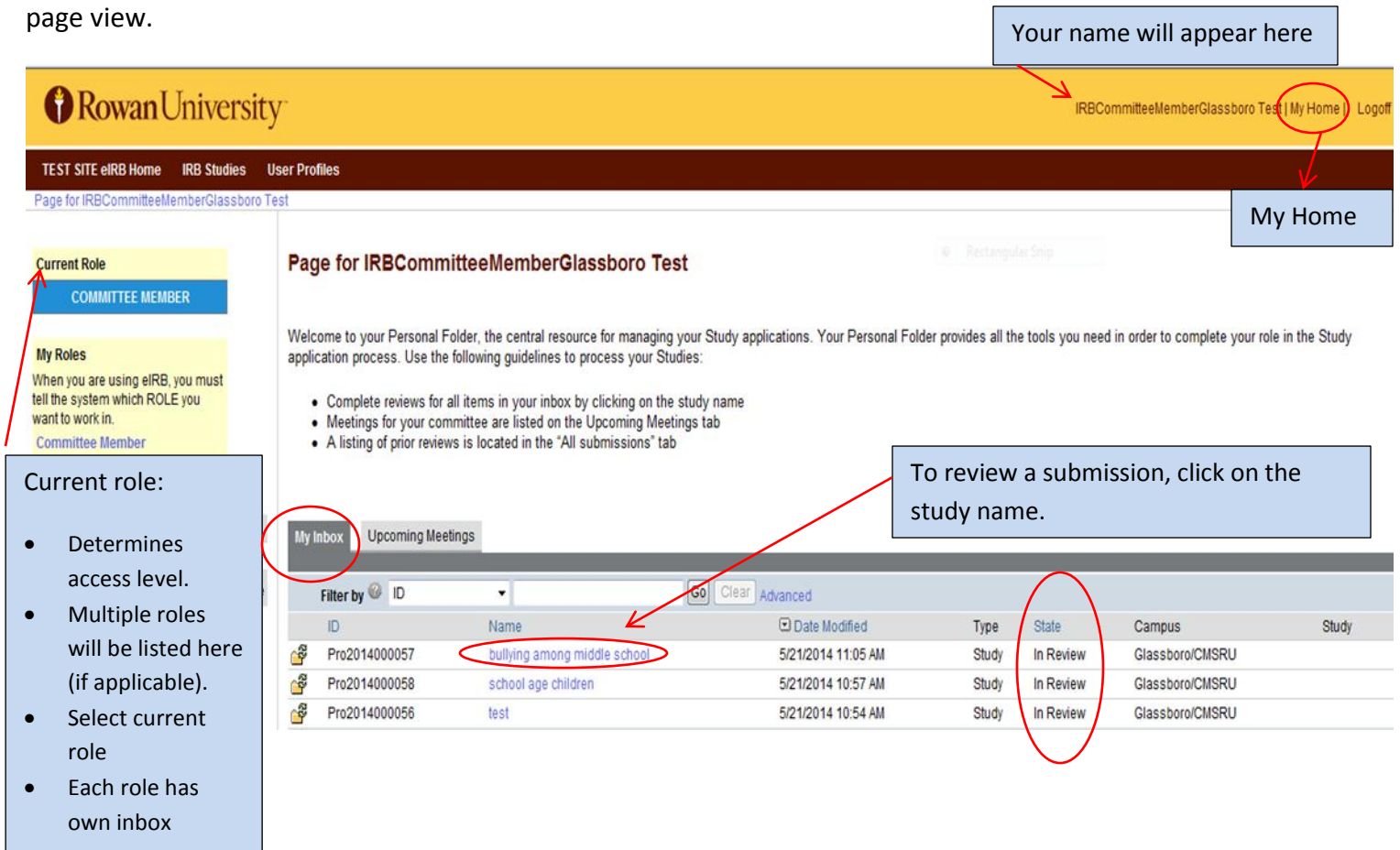
NOTE: If you require additional help and/or guidance with this review, please contact RouterIRBStratfordWIRBGlassboro Test simonsc@rowan.edu. Please **do not** reply to this email notification. The originating email account is not monitored.

Additional help and guidance is available at the following:
<http://www.rowan.edu/som/hsp/som-eirb>

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 recipients(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, secure the contents in a manner that conforms to all applicable state and/or 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.



Current Role

COMMITTEE MEMBER

My Roles

When you are using eIRB, you must tell the system which ROLE you want to work in.

Committee Member

Current role:

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

Page for IRBCommitteeMemberGlassboro Test

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

My Inbox Upcoming Meetings

Filter by ID [Go] Clear Advanced

ID	Name	Date Modified	Type	State	Campus	Study
Pro2014000057	bullying among middle school	5/21/2014 11:05 AM	Study	In Review	Glassboro/CMSRU	
Pro2014000058	school age children	5/21/2014 10:57 AM	Study	In Review	Glassboro/CMSRU	
Pro2014000056	test	5/21/2014 10:54 AM	Study	In Review	Glassboro/CMSRU	

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:

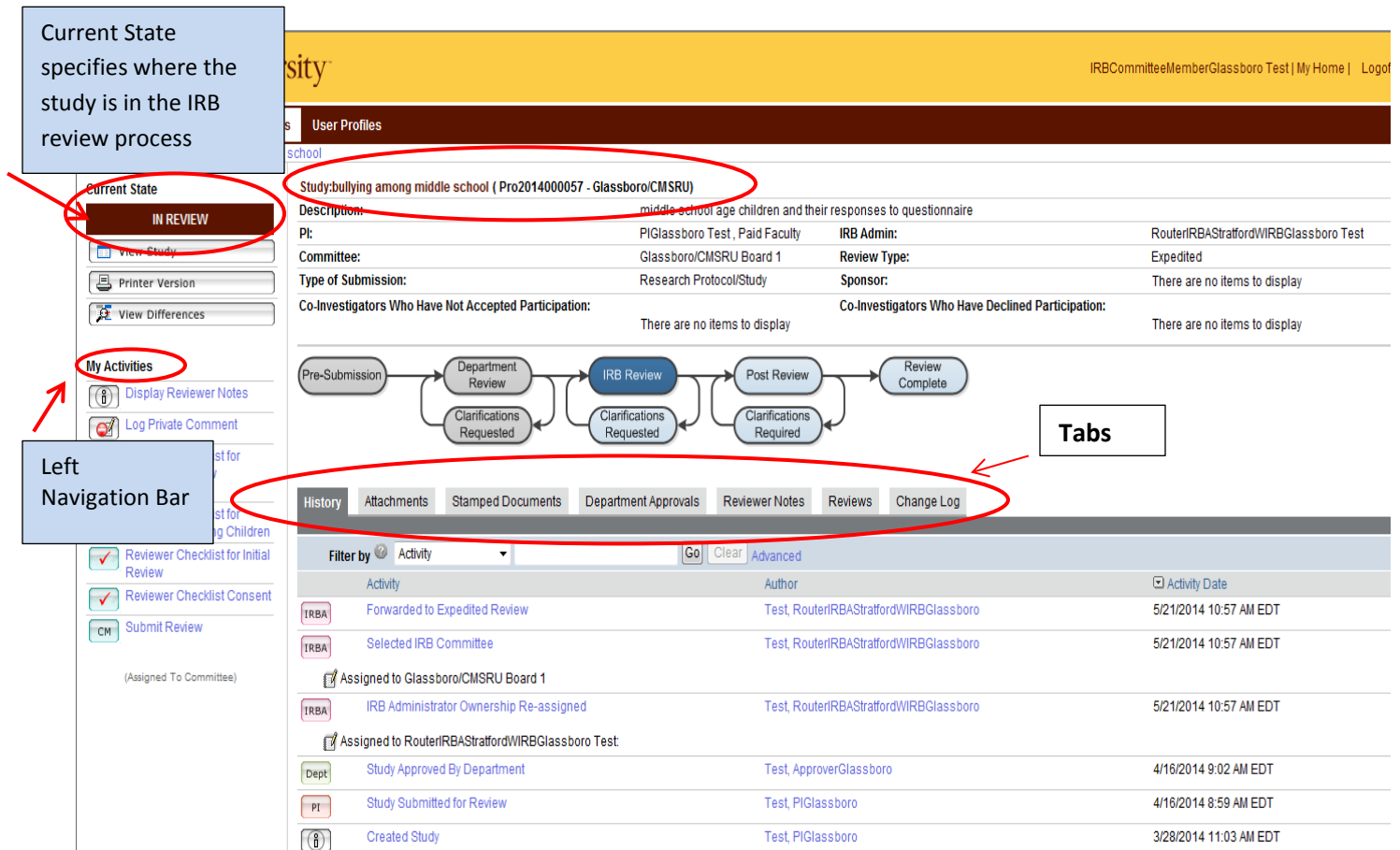
- Study (Initial Submissions)- ‘Pro’
- Continuing Reviews- ‘CR’
- Reportable Events- ‘RE’
- Modifications- ‘Mod’

Study Workspace

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

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

Left Navigation Bar



Current State

IN REVIEW

My Activities

Left Navigation Bar

Study:bullying among middle school (Pro2014000057 - Glassboro/CMSRU)

Description: middle school age children and their responses to questionnaire

PI: PIGlassboro Test, Paid Faculty

Committee: Glassboro/CMSRU Board 1

Type of Submission: Research Protocol/Study

Co-Investigators Who Have Not Accepted Participation: There are no items to display

Co-Investigators Who Have Declined Participation: There are no items to display

Workflow Diagram:

```

graph LR
    A[Pre-Submission] --> B[Department Review]
    B --> C[IRB Review]
    C --> D[Post Review]
    D --> E[Review Complete]
    B --> F[Clarifications Requested]
    F --> B
    C --> G[Clarifications Requested]
    G --> C
    D --> H[Clarifications Requested]
    H --> D
  
```

Tabs

History Attachments Stamped Documents Department Approvals Reviewer Notes Reviews Change Log

Activity	Author	Activity Date
Forwarded to Expedited Review	Test, RouterIRBASTratfordWIRBGlassboro	5/21/2014 10:57 AM EDT
Selected IRB Committee	Test, RouterIRBASTratfordWIRBGlassboro	5/21/2014 10:57 AM EDT
Assigned to Glassboro/CMSRU Board 1		
IRB Administrator Ownership Re-assigned	Test, RouterIRBASTratfordWIRBGlassboro	5/21/2014 10:57 AM EDT
Assigned to RouterIRBASTratfordWIRBGlassboro Test		
Study Approved By Department	Test, ApproverGlassboro	4/16/2014 9:02 AM EDT
Study Submitted for Review	Test, PIGlassboro	4/16/2014 8:59 AM EDT
Created Study	Test, PIGlassboro	3/28/2014 11:03 AM EDT

There are several items that appear in all workspace types:

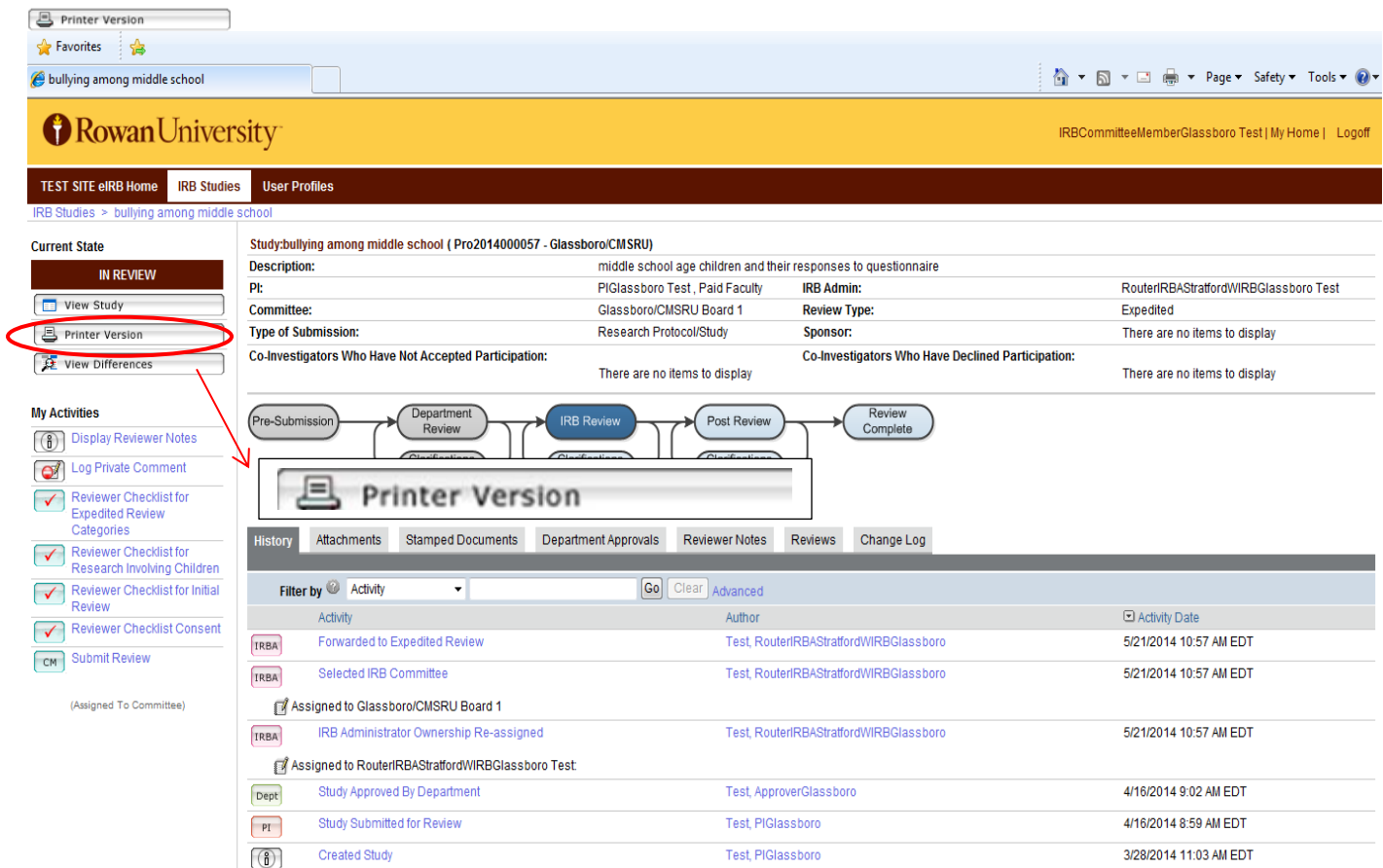
- The left navigation bar is the white area that appears on the left side of each workspace page
- Activities are available to reviewers in the navigation pane
- A history of all the project's activities appears under the **History tab**. Other tabs include documents submitted in the project and reviewer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



The screenshot shows the Rowan eIRB interface. On the left sidebar, under 'Current State', the 'Printer Version' button is highlighted with a red circle and a red arrow pointing to it. The main content area displays the study details for 'bullying among middle school (Pro2014000057 - Glassboro/CMSRU)'. Above a table of activities, there is a workflow diagram showing the process from Pre-Submission to Review Complete, with 'IRB Review' highlighted. The table below lists various activities and their dates.

Activity	Author	Activity Date
Forwarded to Expedited Review	Test, RouterIRBStratfordWIRBGlassboro	5/21/2014 10:57 AM EDT
Selected IRB Committee	Test, RouterIRBStratfordWIRBGlassboro	5/21/2014 10:57 AM EDT
Assigned to Glassboro/CMSRU Board 1		
IRB Administrator Ownership Re-assigned	Test, RouterIRBStratfordWIRBGlassboro	5/21/2014 10:57 AM EDT
Assigned to RouterIRBStratfordWIRBGlassboro Test		
Study Approved By Department	Test, ApproverGlassboro	4/16/2014 9:02 AM EDT
Study Submitted for Review	Test, PIGlassboro	4/16/2014 8:59 AM EDT
Created Study	Test, PIGlassboro	3/28/2014 11:03 AM EDT



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.

Print: Pro2014000057 - bullying among middle school - Windows Internet Explorer provided by Rowan University

http://sttsomeirbstg01.rowan.edu/test/ResourceAdministration/Project/PrintSmartForms?Project=com.webridge.entity.Entity%5B0ID%5BBEEC34EDB2B8854C822F6E49E74883A0

File Edit View Favorites Tools Help

Home | Rowan University | RowanSOM: Human Subje... | Research at Rowan Univers... | Page for Patricia Gessner | Print: Pro2014000057 - ...

Rowan University

Date: Wednesday, May 21, 2014 12:02:48 PM

View: 1 - Study Identification Information

1.0 Study Identification. IRB: Glassboro/CMSRU

This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.

1.0 * Select the type of submission for your study:

- ☒ Research Protocol/Study
- ☐ Facilitated Review
- ☐ Emergency Permission
- ☐ Humanitarian Use Device (HUD)
- ☐ Quality Assurance/Quality Improvement Only
- ☐ Western IRB (WIRB)

2.0 * Full Title of Research:

Middle school children and bullying

3.0 * Short Title (Study Name):

bullying among middle school

4.0 * Principal Investigator:

PIGlassboro Test

5.0 Study Coordinator:

6.0 Co-Investigators:

Last Name	First Name	Department/Division	Institutional Status	On Probation
There are no items to display				

7.0 Other Study Staff:

Name	Department	Role	Interaction or access to individuals	Institutional Status	On Probation
There are no items to display					

NOTE:

Done

Trusted sites | Protected Mode: On

100%



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](#)

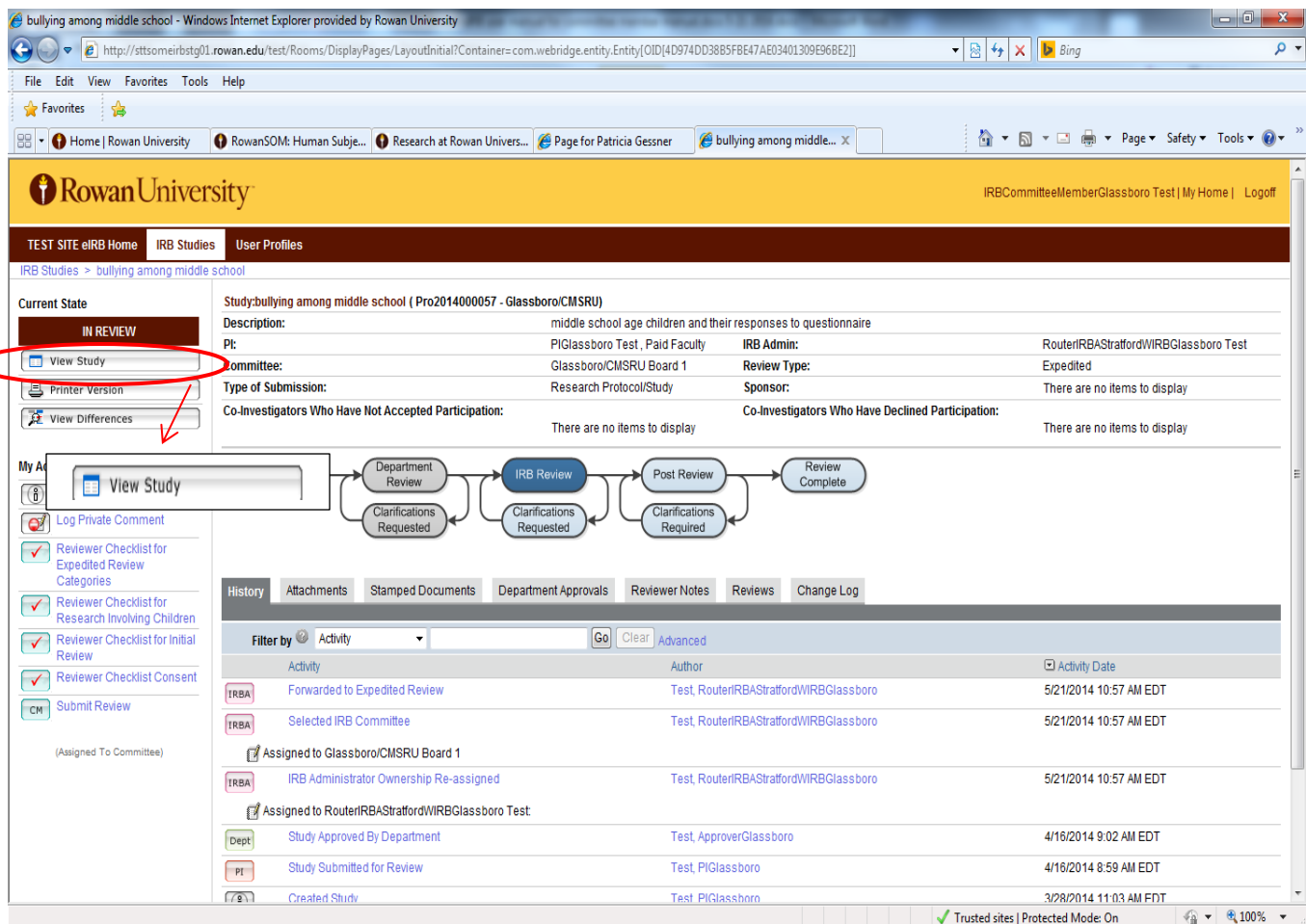


[Defer Review](#)

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.



The screenshot shows the Rowan University IRB system interface. The 'View Study' button is highlighted with a red circle and an arrow. The interface displays the study details for 'bullying among middle school' (Pro2014000057 - Glassboro/CMSRU). The study is currently in the 'IN REVIEW' state. The 'View Study' button is located in the 'Current State' section. The interface also shows a workflow diagram and a history table.

Current State

Study: bullying among middle school (Pro2014000057 - Glassboro/CMSRU)

Description: middle school age children and their responses to questionnaire

PI: PIGlassboro Test, Paid Faculty

IRB Admin: RouterIRBAstraffordWIRBGlassboro Test

Committee: Glassboro/CMSRU Board 1

Review Type: Expedited

Type of Submission: Research Protocol/Study

Sponsor: There are no items to display

Co-Investigators Who Have Not Accepted Participation: There are no items to display

Co-Investigators Who Have Declined Participation: There are no items to display

Workflow:

```

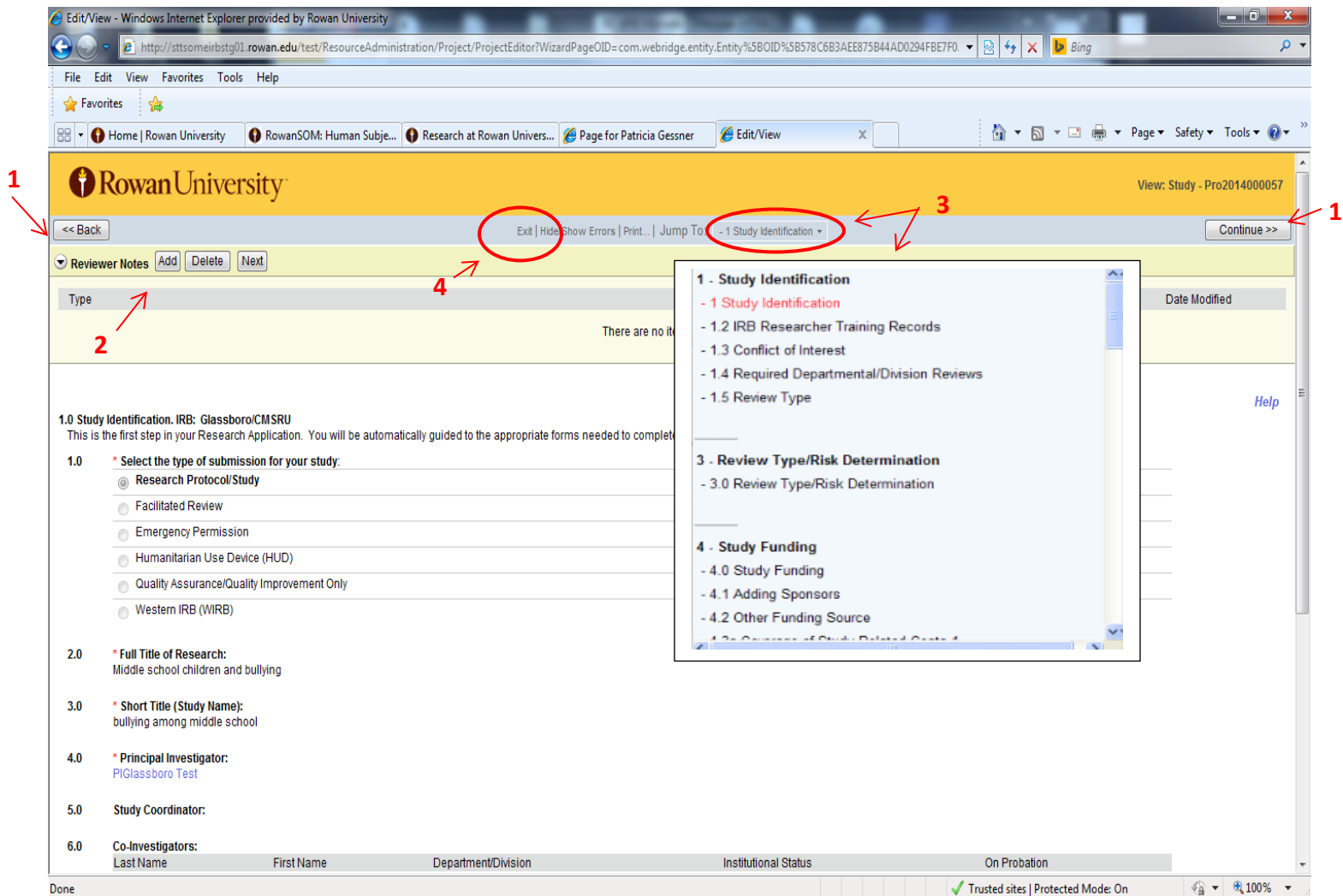
graph LR
    A[View Study] --> B[Department Review]
    B --> C[IRB Review]
    C --> D[Post Review]
    D --> E[Review Complete]
    B --> F[Clarifications Requested]
    F --> B
    C --> G[Clarifications Requested]
    G --> C
    D --> H[Clarifications Requested]
    H --> D
  
```

History

Activity	Author	Activity Date
Forwarded to Expedited Review	Test, RouterIRBAstraffordWIRBGlassboro	5/21/2014 10:57 AM EDT
Selected IRB Committee	Test, RouterIRBAstraffordWIRBGlassboro	5/21/2014 10:57 AM EDT
Assigned to Glassboro/CMSRU Board 1		
IRB Administrator Ownership Re-assigned	Test, RouterIRBAstraffordWIRBGlassboro	5/21/2014 10:57 AM EDT
Assigned to RouterIRBAstraffordWIRBGlassboro Test		
Study Approved By Department	Test, ApproverGlassboro	4/16/2014 9:02 AM EDT
Study Submitted for Review	Test, PIGlassboro	4/16/2014 8:59 AM EDT
Created Study	Test, PIGlassboro	3/28/2014 11:03 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 Rowan University Study Smart form view in a web browser. The interface includes a header with the Rowan University logo and navigation links. The main content area is divided into sections for 'Reviewer Notes' and 'Study Identification'. The 'Study Identification' section contains a list of steps: 1. Study Identification, 2. IRB Researcher Training Records, 3. Conflict of Interest, 4. Required Departmental/Division Reviews, and 5. Review Type. A 'Jump To' menu is visible, allowing users to select a specific page. The 'Continue' button is located at the bottom right of the form.

Annotations in the image:

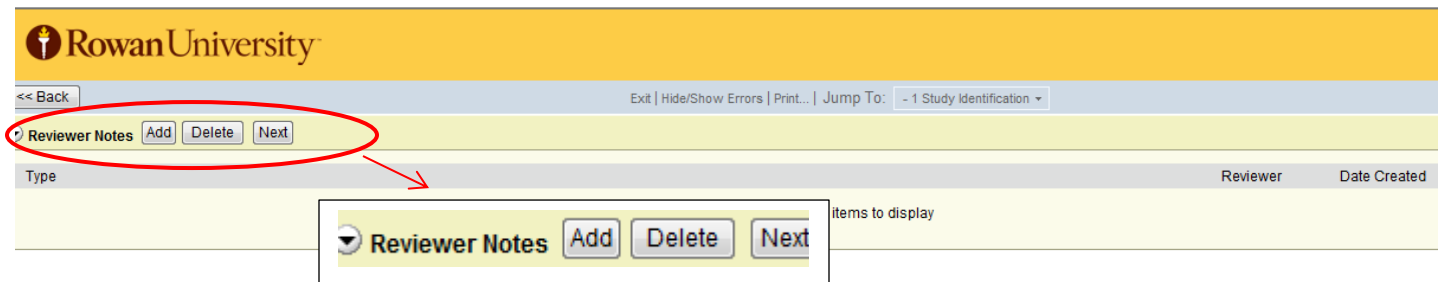
- 1: Points to the 'Back' button in the top left corner.
- 2: Points to the 'Add' button in the 'Reviewer Notes' section.
- 3: Points to the 'Continue' button in the top right corner.
- 4: Points to the 'Jump To' menu in the top right corner.

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.



1.0 Study Identification. IRB: Glassboro/CMSRU

This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.

1.0 * Select the type of submission for your study:

☒ Research Protocol/Study

☐ Facilitated Review

☐ Emergency Permission

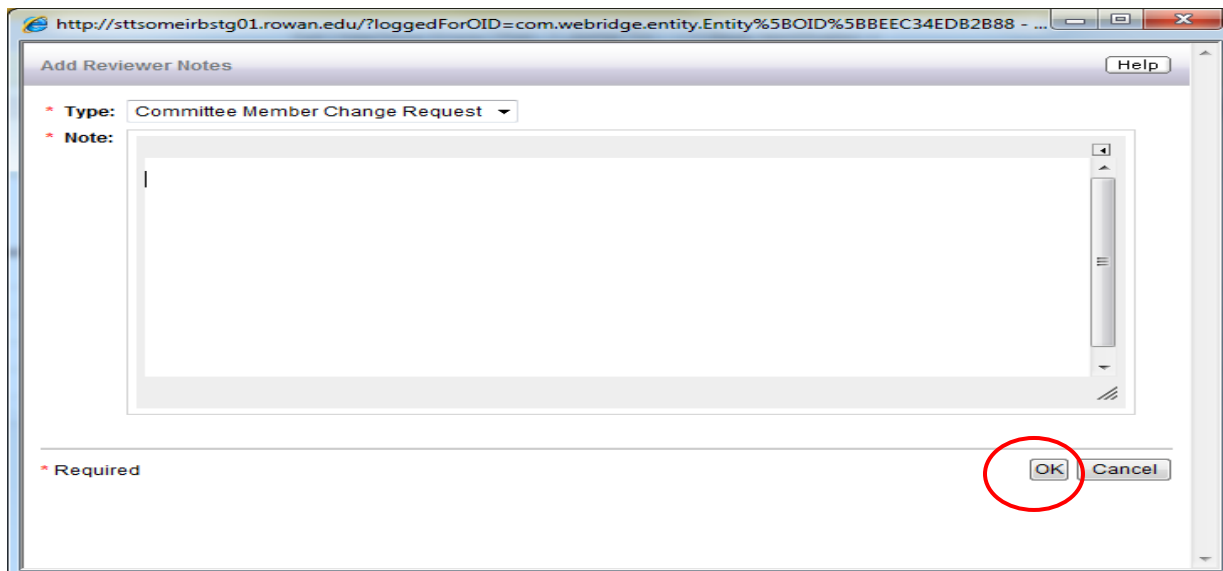
☐ Humanitarian Use Device (HUD)

☐ Quality Assurance/Quality Improvement Only

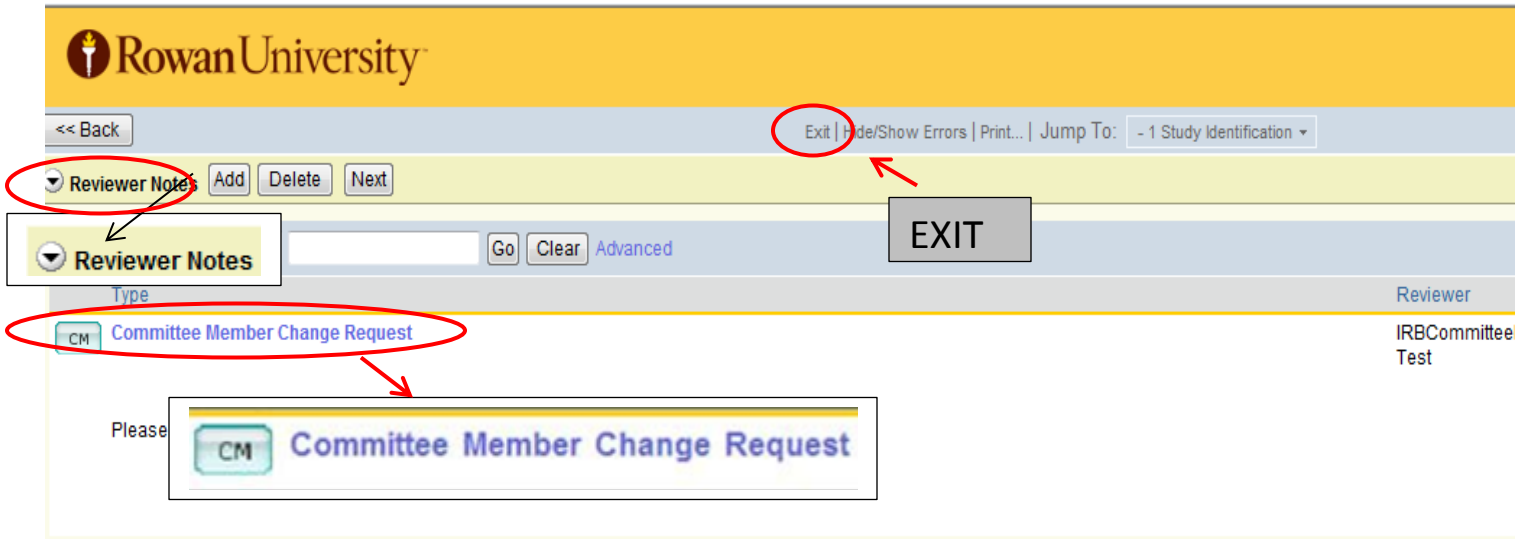
☐ Western IRB (WIRB)

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.



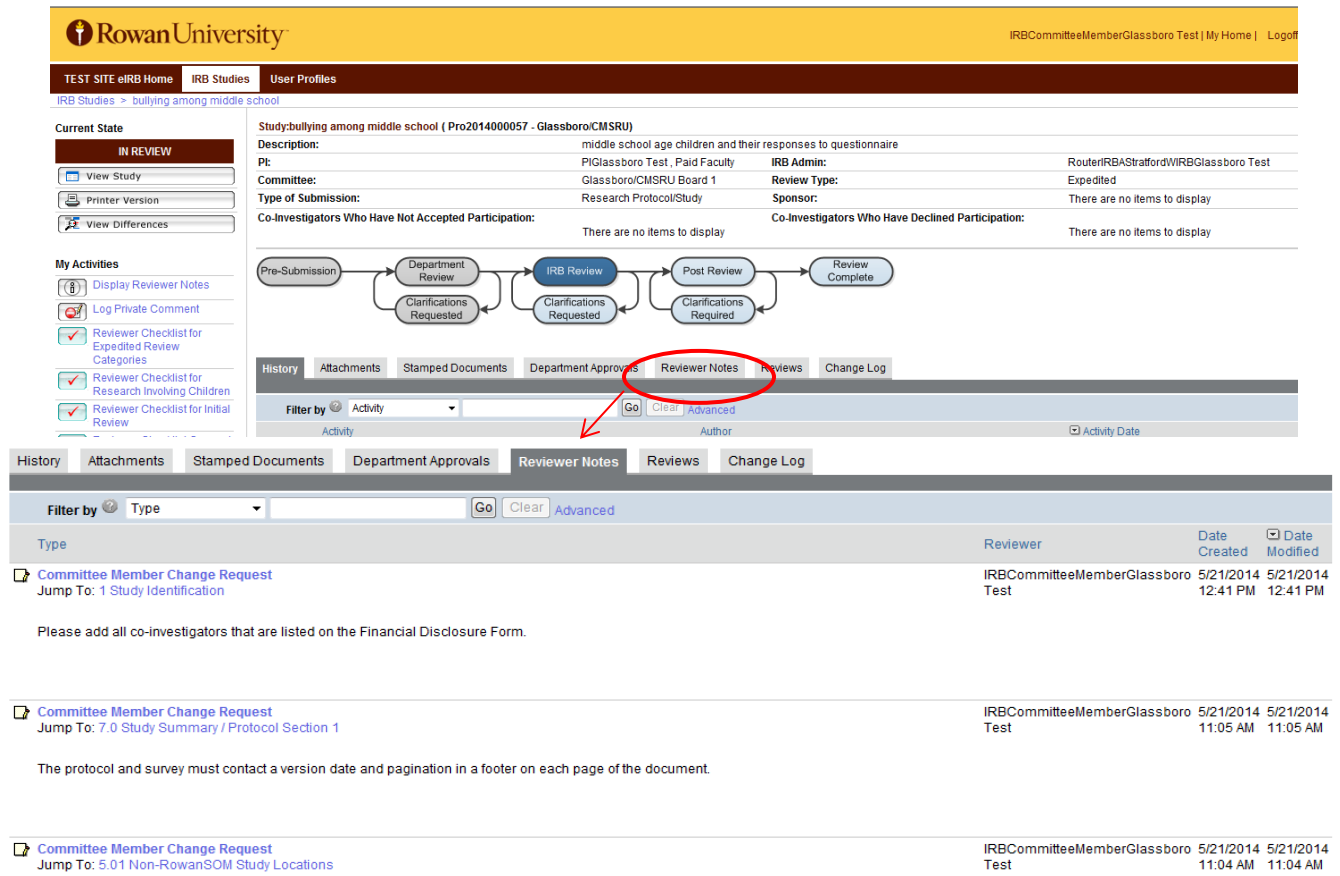
The screenshot displays the Rowan University IRB Committee Test interface. At the top, the Rowan University logo is visible. Below the header, there is a navigation bar with a '<< Back' button and an 'Exit | Hide/Show Errors | Print... | Jump To: - 1 Study Identification' dropdown menu. The main content area features a yellow panel with a 'Reviewer Notes' section. This section includes a dropdown arrow, 'Add', 'Delete', and 'Next' buttons. Below this, a 'Reviewer Notes' table is shown with a 'Type' column and a 'Committee Member Change Request' entry. A red circle highlights the dropdown arrow on the left side of the yellow panel, and another red circle highlights the 'Exit' button in the top navigation bar. A red arrow points from the 'Committee Member Change Request' entry to a larger 'EXIT' button. The bottom right corner of the interface shows 'IRB Committee Test'.

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



Rowan University IRBCommitteeMemberGlassboro Test | My Home | Logout

TEST SITE eIRB Home **IRB Studies** User Profiles

IRB Studies > bullying among middle school

Current State

IN REVIEW

View Study
Printer Version
View Differences

My Activities

- Display Reviewer Notes
- Log Private Comment
- Reviewer Checklist for Expedited Review Categories
- Reviewer Checklist for Research Involving Children
- Reviewer Checklist for Initial Review

Study: bullying among middle school (Pro2014000057 - Glassboro/CMSRU)

Description: middle school age children and their responses to questionnaire

PI: PIGlassboro Test, Paid Faculty IRB Admin: RouterIRBASTraffordWIRBGlassboro Test

Committee: Glassboro/CMSRU Board 1 Review Type: Expedited

Type of Submission: Research Protocol/Study Sponsor: There are no items to display

Co-Investigators Who Have Not Accepted Participation: There are no items to display Co-Investigators Who Have Declined Participation: There are no items to display

Pre-Submission → Department Review → IRB Review → Post Review → Review Complete

Clarifications Requested → Clarifications Requested → Clarifications Requested

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

Filter by Activity Go Clear Advanced

Activity Author Activity Date

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

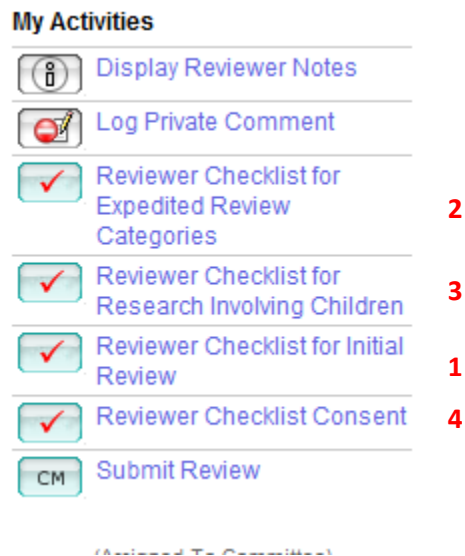
Filter by Type Go Clear Advanced

Type	Reviewer	Date Created	Date Modified
Committee Member Change Request Jump To: 1 Study Identification	IRBCommitteeMemberGlassboro Test	5/21/2014 12:41 PM	5/21/2014 12:41 PM
Please add all co-investigators that are listed on the Financial Disclosure Form.			
Committee Member Change Request Jump To: 7.0 Study Summary / Protocol Section 1	IRBCommitteeMemberGlassboro Test	5/21/2014 11:05 AM	5/21/2014 11:05 AM
The protocol and survey must contact a version date and pagination in a footer on each page of the document.			
Committee Member Change Request Jump To: 5.01 Non-RowanSOM Study Locations	IRBCommitteeMemberGlassboro Test	5/21/2014 11:04 AM	5/21/2014 11:04 AM

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

SUBMIT REVIEW: THIS IS YOUR FINAL STEP IN THE REVIEW PROCESS

Once you have completed this form and selected the OK option below:

- Your review will be complete
- The submission will be routed back to the assigned IRB Administrator
- You **will not** be able to change or modify your review comments
- You will be able to add PRIVATE comments regarding the study

Please Note:

- Please make sure that all Reviewer Checklists have been completed **prior to** selecting the OK option below. In order to complete the checklists, click on the **Cancel** button below.
- PUBLIC comments are visible by the PI and Study team, PRIVATE comments are visible by IRB personnel only.

Review Comments:

Review Documents:

Add

Name	Description
There are no items to display	

Review Type:

* **Review Motion:**

* **Revisions to be reviewed by:**

* **Risk Level:**

☐ Minimal Risk

☐ Greater than Minimal Risk

☐ Not Applicable

[Clear](#)

☐ Yes

☐ No

* **Should review occur more frequently than once a year:** ☐ NA

[Clear](#)

If YES, please specify how often:

* **Have you completed all Reviewer Checklists?** ☐ Yes ☐ No [Clear](#)

If No, please add reviewer checklist comments:

OK

Cancel

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'**.

Rowan University

IRBCommitteeMemberGlassboro Test | My Home | Logout

TEST SITE eIRB Home IRB Studies User Profiles

Page for IRBCommitteeMemberGlassboro Test

Current Role

COMMITTEE MEMBER

My Roles

When you are using eIRB, you must tell the system which ROLE you want to work in.

Committee Member

My Committees

Name

Glassboro/CMSRU Board 1

1 to 1 of 1 100 / page

Page for IRBCommitteeMemberGlassboro Test

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

My Inbox Upcoming Meetings

Filter by ID Go Clear Advanced


ID	Name	Date Modified	Type	Status	Committee	Study
CR00000553	2015 Review for Pro2014000054	5/21/2014 1:46 PM	Continuing Review	In Review	Glassboro/CMSRU	ssstest study Glassboro
Pro2014000057	bullying among middle school	5/21/2014 12:41 PM	Study	In Review	Glassboro/CMSRU	
Pro2014000058	school age children	5/21/2014 10:57 AM	Study	In Review	Glassboro/CMSRU	
Pro2014000056	test	5/21/2014 10:54 AM	Study	In Review	Glassboro/CMSRU	

1 to 4 of 4 10 / page

CR0000053 2015 Review for PRO2014000054 5/21/2014 1:46pm Continuing Review In Review Glassboro/CMSRU

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'**.


IRBCommitteeMemberGlassboro Test | My Home | Logoff

[TEST SITE eIRB Home](#)
[IRB Studies](#)
[User Profiles](#)

[IRB Studies](#) > [sstest study Glassboro](#) > [2015 Review for Pro2014000054](#)

Current State

IN REVIEW

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

Continuing Review:2015 Review for Pro2014000054 (CP00000553 / Pro2014000054 - Glassboro/CMSRU)

Current study status:

Approved

Study Title:

Full title sstest study

Initial study submission type:

Research Protocol/Study

Review Type:

Expedited

Principal Investigator:

PIGlassboro Test / College of Engineering /Glassboro/CMSRU

Study Coordinator:

Study Status:

Active - Open to Enrollment, No enrollment to date

Type of report:

Continuing Report

Number subjects enrolled to date:

25

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 Comment](#)
[CM Ackn](#)
[CM Defe](#)
[Dis](#)

View Continuing Review

Printer-Friendly Version

History

Attachments

Stamped Documents

Modifications

Reportable Events

Reviewer Notes

Change Log

Filter by

Activity

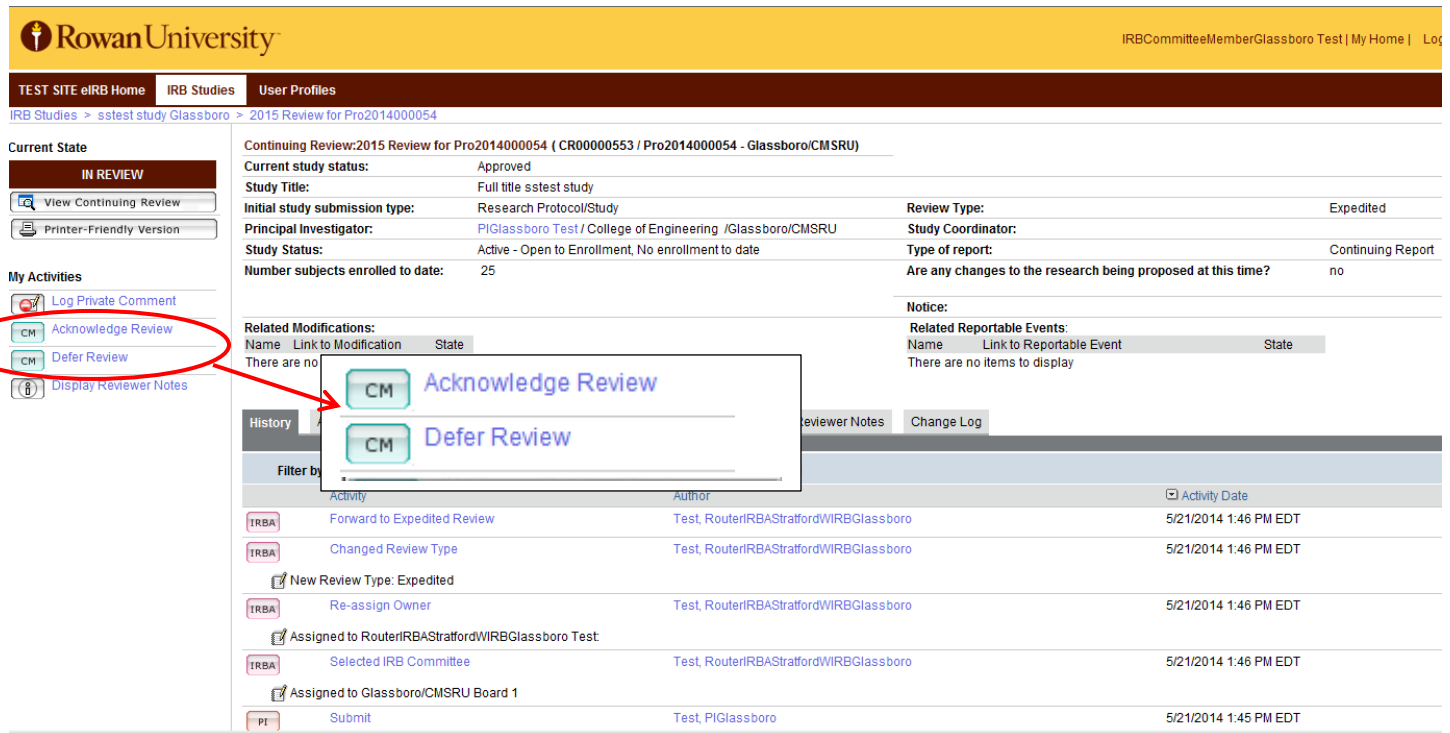
Go

Clear

Advanced

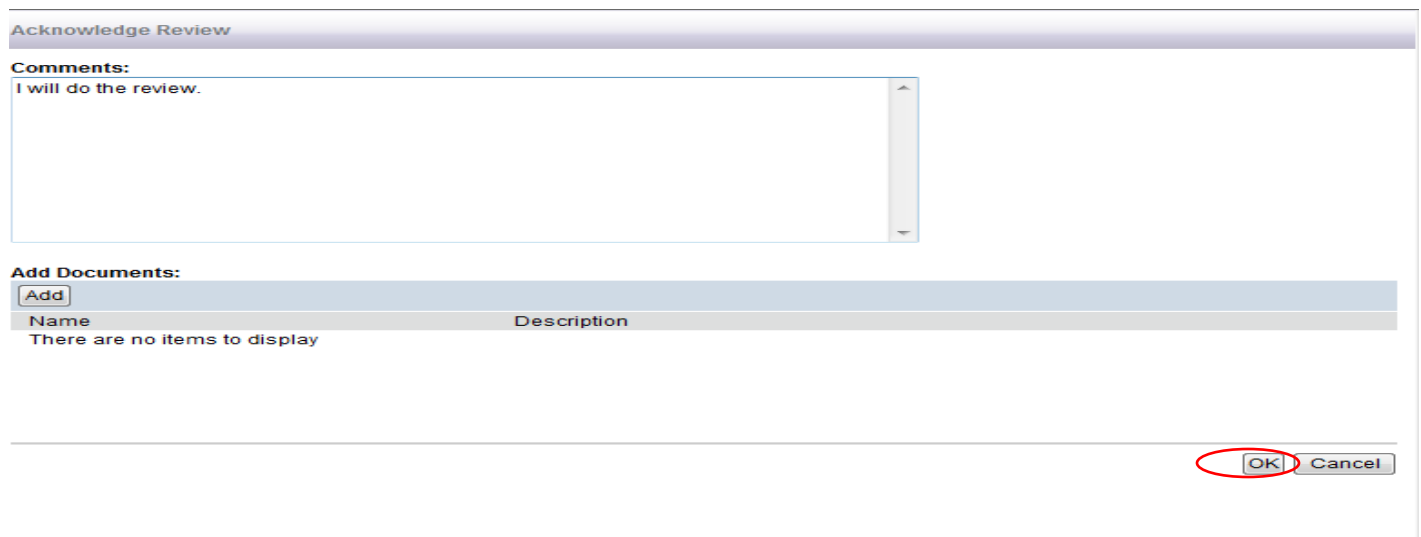
Activity	Author	Activity Date
IRBA Forward to Expedited Review	Test, RouterIRBAstratfordWIRBGlassboro	5/21/2014 1:46 PM EDT
IRBA Changed Review Type	Test, RouterIRBAstratfordWIRBGlassboro	5/21/2014 1:46 PM EDT
New Review Type: Expedited		
IRBA Re-assign Owner	Test, RouterIRBAstratfordWIRBGlassboro	5/21/2014 1:46 PM EDT
Assigned to RouterIRBAstratfordWIRBGlassboro Test		
IRBA Selected IRB Committee	Test, RouterIRBAstratfordWIRBGlassboro	5/21/2014 1:46 PM EDT
Assigned to Glassboro/CMSRU Board 1		
PI Submit	Test, PIGlassboro	5/21/2014 1:45 PM EDT

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



The screenshot shows the Rowan University IRB system interface. The top navigation bar includes 'TEST SITE eIRB Home', 'IRB Studies', and 'User Profiles'. The main content area displays the 'Current State' of a continuing review for 'Pro2014000054'. The 'My Activities' section on the left contains a list of actions: 'Log Private Comment', 'Acknowledge Review' (highlighted with a red circle), 'Defer Review' (highlighted with a red circle), and 'Display Reviewer Notes'. A tooltip box appears over the 'Acknowledge Review' and 'Defer Review' buttons, showing their respective icons and labels. The main content area also displays 'Related Modifications' and 'Related Reportable Events'.

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



The screenshot shows the 'Acknowledge Review' dialog box. It has a title bar 'Acknowledge Review'. Below the title bar, there is a 'Comments:' section with a text area containing the text 'I will do the review.'. Below the comments section, there is an 'Add Documents:' section with an 'Add' button and a table with columns 'Name' and 'Description'. The table is currently empty, displaying 'There are no items to display'. At the bottom right of the dialog box, there are 'OK' and 'Cancel' buttons, with the 'OK' button highlighted by a red circle.



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'**

Continuing Review / Final Report

Study ID: Pro2014000054

Study Name: sstest study Glassboro

1.0 * Type of Report:
Continuing Report

2.0 * Please indicate which of the following applies to your study.
(Check all that apply)

- ☐ Records
- ☐ Specimens
- ☒ Subject Interaction or Intervention

IRB Researcher Training Records:

The following information is a read-only view taken from your currently approved training records on your researcher profile:

- Verify that the information below is correct.
- Contact your local IRB office for any discrepancies.

Principal Investigator: PIGlassboro Test

Date Completed: Renewal Deadline:

Study Coordinator:

Date Completed: Renewal Deadline:


Co-Investigator:

How/When was review added?

Trusted sites | Disabled Mode On

10

Completing the Reviewer Checklists:


IRBCommitteeMemberGlassboro Test | My Home | Log

[TEST SITE eIRB Home](#)
[IRB Studies](#)
[User Profiles](#)

[IRB Studies](#) > [sstest study Glassboro](#) > [2015 Review for Pro2014000054](#)

Current State

IN REVIEW

[View Continuing Review](#)

[Printer-Friendly Version](#)

My Activities

[Log Private Comment](#)

[Display Reviewer Notes](#)

[Reviewer Checklist for Expedited Review Categories](#)

[Reviewer Checklist Continuing Review](#)

[Submit Review](#)

Continuing Review: 2015 Review for Pro2014000054 (CR00000553 / Pro2014000054 - Glassboro/CMSRU)

Current study status: Approved

Study Title: Full title sstest study

Initial study submission type: Research Protocol/Study

Principal Investigator: [PIGlassboro Test](#) / College of Engineering / Glassboro/CMSRU

Study Status: Active - Open to Enrollment, No enrollment to date

Number subjects enrolled to date: 25

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:

Related Modifications:

Name **Link to Modification** **State**

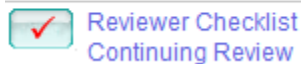
There are no items to display

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	Test, RouterIRBAStrattfordWIRBGlassboro	5/21/2014 1:46 PM EDT
IRBA	Changed Review Type	Test, RouterIRBAStrattfordWIRBGlassboro	5/21/2014 1:46 PM EDT
	New Review Type: Expedited		
IRBA	Re-assign Owner	Test, RouterIRBAStrattfordWIRBGlassboro	5/21/2014 1:46 PM EDT
	Assigned to RouterIRBAStrattfordWIRBGlassboro Test		
IRBA	Selected IRB Committee	Test, RouterIRBAStrattfordWIRBGlassboro	5/21/2014 1:46 PM EDT
	Assigned to Glassboro/CMSRU Board 1		
PT	Submit	Test, PIGlassboro	5/21/2014 1:45 PM EDT

Complete the Checklists



Submit Review

IRBCommitteeMemberGlassboro Test | My Home | Logoff

TEST SITE eIRB Home IRB Studies User Profiles

IRB Studies > sstest2 Glassboro > 2015 Review for Pro2014000063

Current State

IN REVIEW

View Continuing Review

Printer-Friendly Version

My Activities

Log Private Comment

Display Reviewer Notes

Reviewer Checklist

Continuing Review

Submit Review

Continuing Review: 2015 Review for Pro2014000063 (CR00000554 / Pro2014000063 - Glassboro/CMSRU)

Current study status: Approved

Study Title: sstest2 Glassboro full title

Initial study submission type: Research Protocol/Study **Review Type:** Exempt

Principal Investigator: PIGlassboro Test / College of Engineering /Glassboro/CMSRU **Study Coordinator:**

Study Status: Active - Open to Chart/Specimen/Record Collection - No collection to date **Type of report:** Continuing Report

Number subjects enrolled to date: **Are any changes to the research being proposed at this time?** no

Notice:

SUBMIT REVIEW: THIS IS YOUR FINAL STEP IN THE REVIEW PROCESS

Once you have completed this form and selected the OK option below:

- Your review will be complete
- The submission will be routed back to the assigned IRB Administrator
- You ~~will not~~ be able to change or modify your review comments
- You will be able to add PRIVATE comments regarding the study

Please Note:

- Please make sure that all Reviewer Checklists have been completed prior to selecting the OK option below. In order to complete the checklists, click on the Cancel button below.
- PUBLIC comments are visible by the PI and Study team, PRIVATE comments are visible by IRB personnel only.

Review Documents:

Name	Description
There are no items to display	

Review Type: Exempt

Review Motion: Exempt

Revisions to be reviewed by:

Risk Level:

☐ Minimal Risk

☐ Greater than Minimal Risk

☐ Not Applicable

☐ Clear

☐ Yes

☐ No

☐ NA

☐ Clear

Should review occur more frequently than once a year?

If YES, please specify how often:

Have you completed all reviewer checklists? ☐ Yes ☐ No [Clear](#)

OK Cancel



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'**.

Rowan University IRBCommitteeMemberGlassboro Test | My Home | L

TEST SITE eIRB Home IRB Studies User Profiles

Page for IRBCommitteeMemberGlassboro Test

Current Role
COMMITTEE MEMBER

My Roles
When you are using eIRB, you must tell the system which ROLE you want to work in.
[Committee Member](#)

My Committees
Name
Glassboro/CMSRU Board 1

Page for IRBCommitteeMemberGlassboro Test

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

My Inbox Upcoming Meetings

Filter by ID Go Clear Advanced

ID	Name	Date Modified	Type	State	Campus	Study
Mod20140000002	Modification 2 for IRB Study #Pro2014000054	5/21/2014 2:52 PM	Modification	In Review	Glassboro/CMSRU	ssstest study Glassboro
CR00000553	2015 Review for Pro2014000054	5/21/2014 2:11 PM	Continuing Review	In Review	Glassboro/CMSRU	ssstest study Glassboro
Pro2014000057	bullying among middle school	5/21/2014 12:41 PM	Study	In Review	Glassboro/CMSRU	

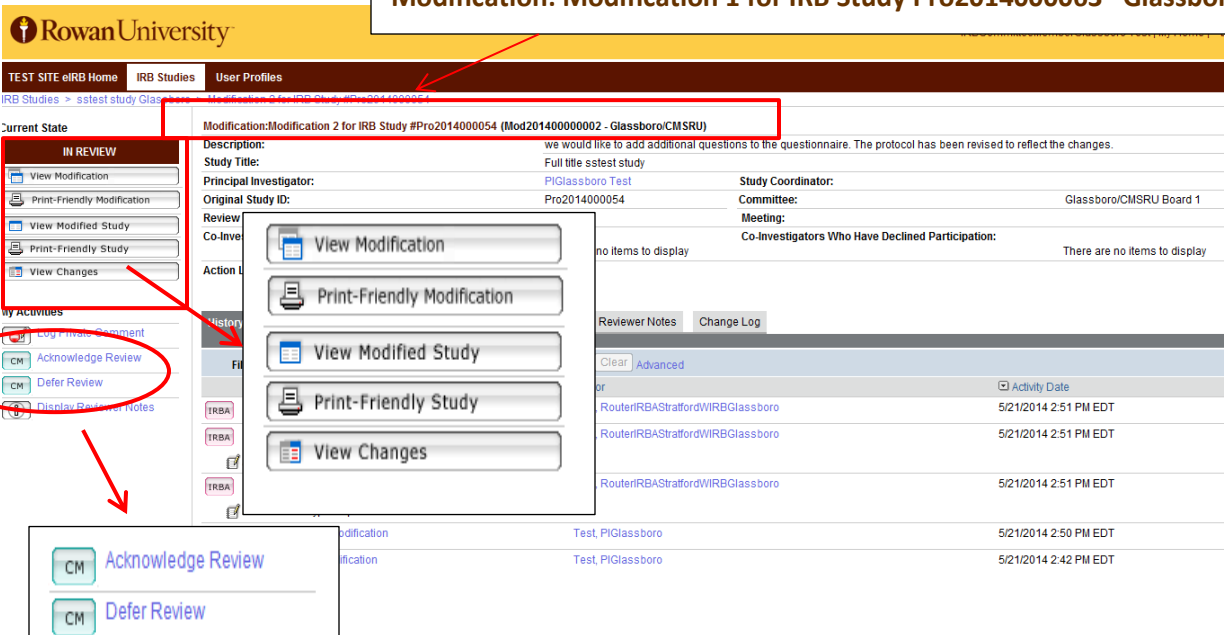
Mod2014000002 Modification 2 for IRB Study PRO2014000054 5/21/2014 Modification In Review Glassboro/CMSRU

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Viewing the Modification Workspace

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

Modification: Modification 1 for IRB Study Pro2014000063 Glassboro



The screenshot shows the Rowan University IRB system interface. The top navigation bar includes 'TEST SITE eIRB Home', 'IRB Studies', and 'User Profiles'. The main content area displays the 'Modification: Modification 1 for IRB Study Pro2014000063 Glassboro' workspace. The 'Current State' section shows the modification details, including the description, study title, principal investigator, and original study ID. The 'IN REVIEW' section contains buttons for 'View Modification', 'Print-Friendly Modification', 'View Modified Study', 'Print-Friendly Study', and 'View Changes'. The 'My Activities' section contains buttons for 'Acknowledge Review' and 'Defer Review'. A red arrow points from the 'View Modification' button in the 'IN REVIEW' section to the 'Acknowledge Review' button in the 'My Activities' section. Another red arrow points from the 'Acknowledge Review' button in the 'My Activities' section to a red circle around the 'Acknowledge Review' button in the 'My Activities' section.

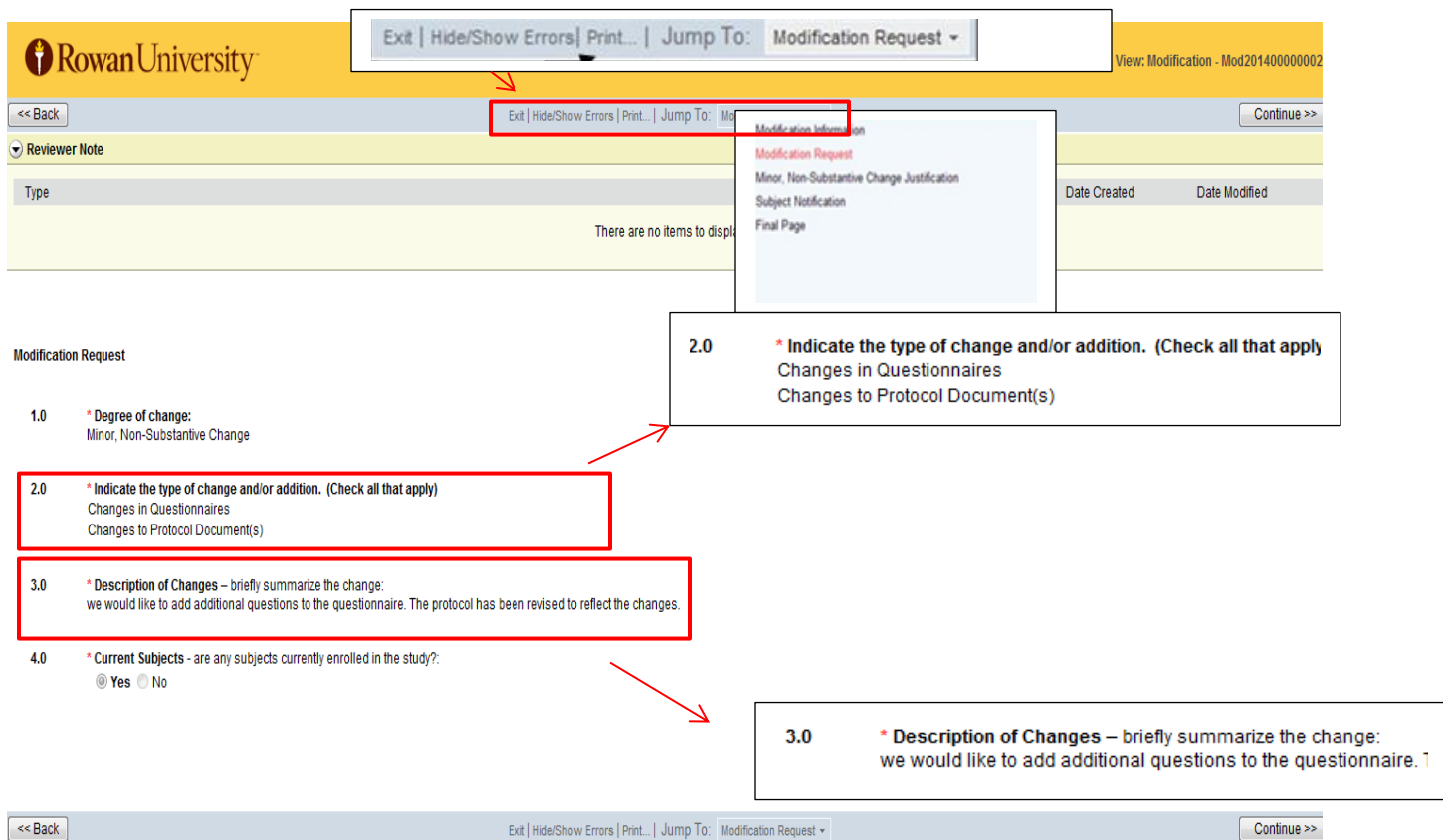
The Modification workspace contains the same **'Printer Version'** and header description as a new study. You must **'Acknowledge'** or **'Defer'** the review to begin and click **'OK'** in new window that opens.



The screenshot shows the 'Acknowledge Review' window. The title bar displays the URL 'http://sttsomeirbstg01.rowan.edu/?ActivityType=com.webbridge.entity.Entity%5B0ID%5BCED0FE45E3D6A - Windows Internet ...'. The main content area has a 'Comments:' section with a text area and an 'Attach Documents:' section with a table. The table has columns 'Name' and 'Description' and contains the text 'There are no items to display'. At the bottom right, there are 'OK' and 'Cancel' buttons, with the 'OK' button 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 the Rowan University system. The form is titled 'Modification Request' and includes a navigation bar at the top with links: 'Exit | Hide/Show Errors | Print... | Jump To: Modification Request'. The form is divided into several sections:

- Reviewer Note:** A section for the reviewer's notes, currently empty.
- Modification Request:** The main section for the modification request, containing 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)**
 - Changes in Questionnaires
 - Changes to Protocol Document(s)
 - 3.0 Description of Changes – briefly summarize the change:** we would like to add additional questions to the questionnaire. The protocol has been revised to reflect the changes.
 - 4.0 Current Subjects - are any subjects currently enrolled in the study?:** ☒ Yes ☐ No

Annotations with red boxes and arrows highlight specific parts of the form:

- A red box around the 'Exit | Hide/Show Errors | Print... | Jump To: Modification Request' navigation bar at the top.
- A red box around the '2.0 Indicate the type of change and/or addition. (Check all that apply)' section.
- A red box around the '3.0 Description of Changes – briefly summarize the change:' section.
- A red box around the '3.0 Description of Changes – briefly summarize the change:' section, with an arrow pointing to the '3.0' label.

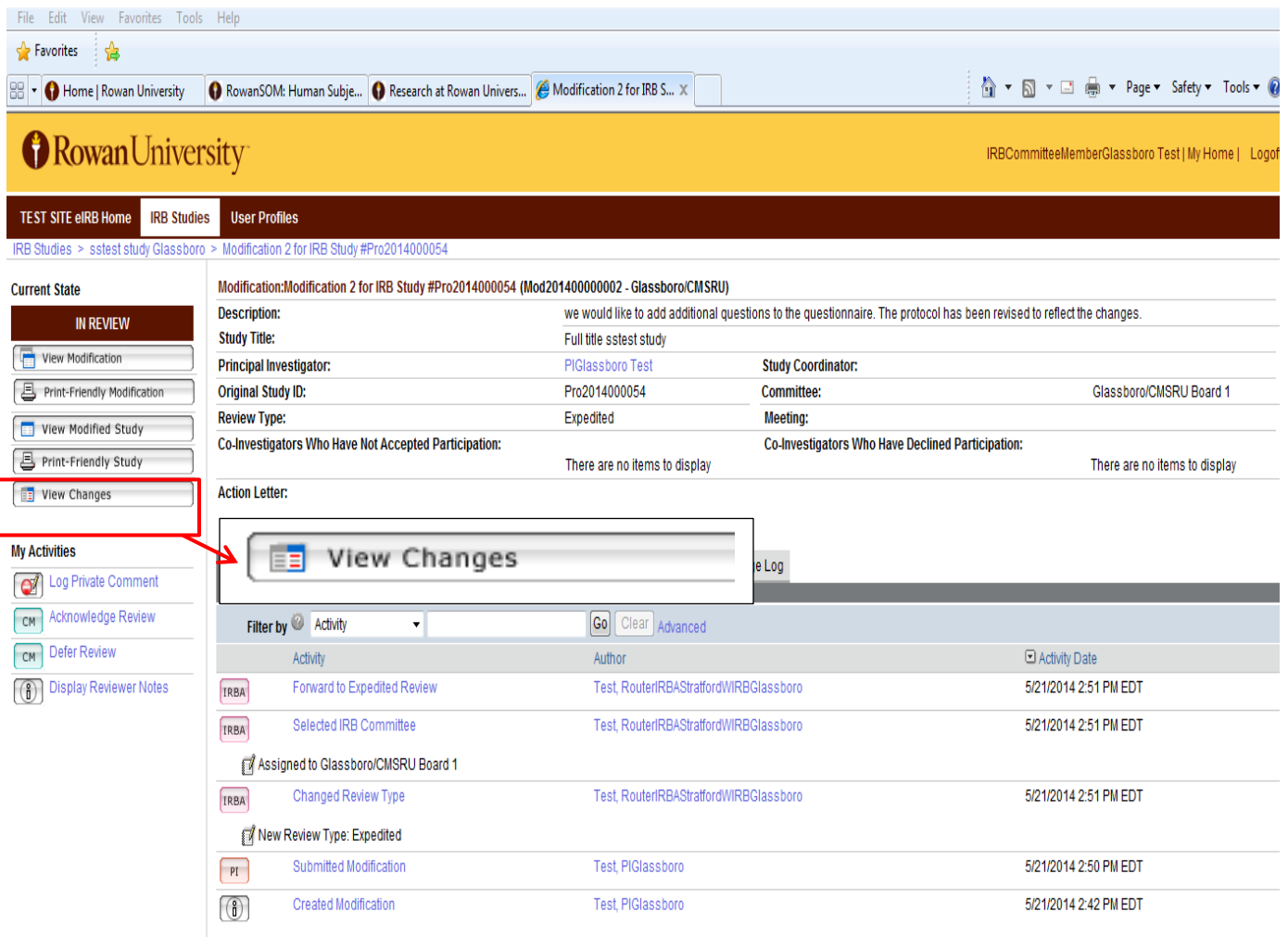
The form also includes a 'Continue >>' button at the bottom right and a '<< Back' button at the bottom left.

Click **'Exit'** to return to Modification Workspace.

Modified Study Workspace

In the Modification workspace,

Click on **'View Changes'** button to open the **'Modified Study workspace'**.



The screenshot shows the Rowan University IRB Studies workspace. The 'View Changes' button is highlighted in red in the left sidebar. The main content area displays the details for Modification 2 for IRB Study #Pro2014000054 (Mod20140000002 - Glassboro/CMSRU).

Current State

IN REVIEW

View Modification
Print-Friendly Modification
View Modified Study
Print-Friendly Study
View Changes

My Activities

Log Private Comment
Acknowledge Review
Defer Review
Display Reviewer Notes

Modification: Modification 2 for IRB Study #Pro2014000054 (Mod20140000002 - Glassboro/CMSRU)

Description: we would like to add additional questions to the questionnaire. The protocol has been revised to reflect the changes.

Study Title: Full title sstest study

Principal Investigator: PIGlassboro Test **Study Coordinator:**

Original Study ID: Pro2014000054 **Committee:** Glassboro/CMSRU Board 1

Review Type: Expedited **Meeting:**

Co-Investigators Who Have Not Accepted Participation: There are no items to display **Co-Investigators Who Have Declined Participation:** There are no items to display

Action Letter:

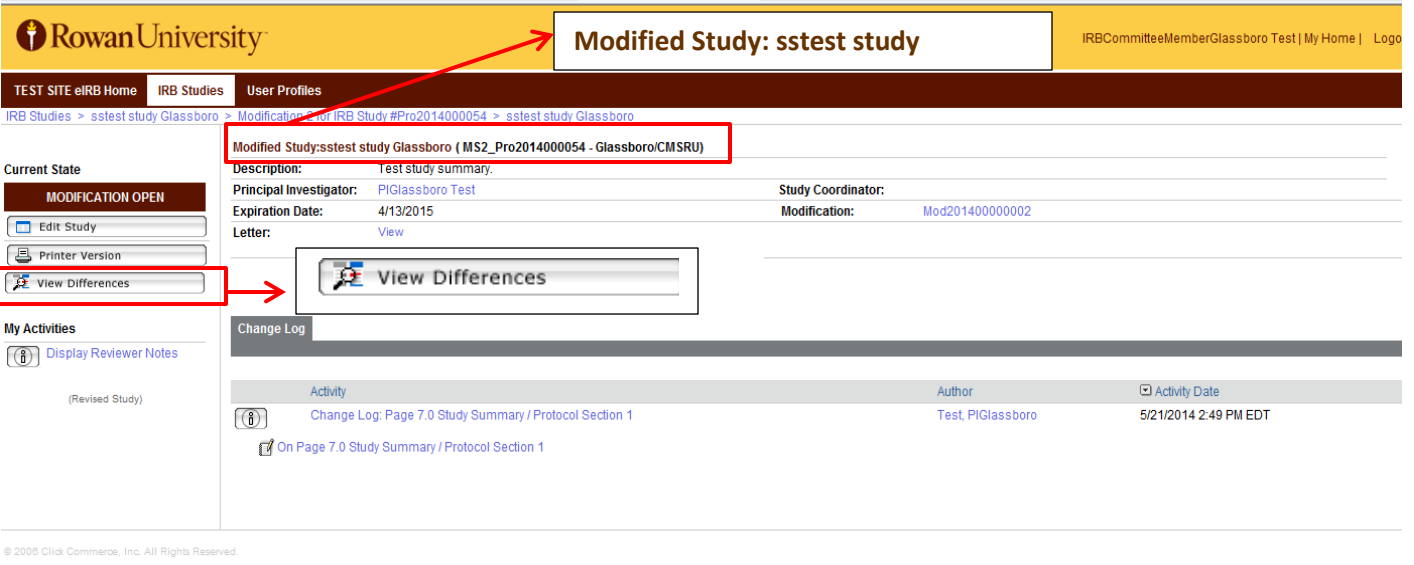
View Changes

Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
IRBA Forward to Expedited Review	Test, RouterIRBASTratfordWIRBGlassboro	5/21/2014 2:51 PM EDT
IRBA Selected IRB Committee	Test, RouterIRBASTratfordWIRBGlassboro	5/21/2014 2:51 PM EDT
Assigned to Glassboro/CMSRU Board 1		
IRBA Changed Review Type	Test, RouterIRBASTratfordWIRBGlassboro	5/21/2014 2:51 PM EDT
New Review Type: Expedited		
PI Submitted Modification	Test, PIGlassboro	5/21/2014 2:50 PM EDT
PI Created Modification	Test, PIGlassboro	5/21/2014 2:42 PM EDT

Modified Study Workspace

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



Rowan University

Modified Study: sstest study

IRBCommitteeMemberGlassboro Test | My Home | Logo

TEST SITE eIRB Home IRB Studies User Profiles

IRB Studies > sstest study Glassboro > Modification of IRB Study #Pro2014000054 > sstest study Glassboro

Current State

MODIFICATION OPEN

Edit Study

Printer Version

View Differences

My Activities

Display Reviewer Notes

(Revised Study)

Modified Study: sstest study Glassboro (MS2_Pro2014000054 - Glassboro/CMSRU)

Description: Test study summary.

Principal Investigator: PIGlassboro Test

Expiration Date: 4/13/2015

Letter: View

Study Coordinator: Mod201400000002

Modification: Mod201400000002

View Differences

Change Log

Activity	Author	Activity Date
Change Log: Page 7.0 Study Summary / Protocol Section 1	Test, PIGlassboro	5/21/2014 2:49 PM EDT
On Page 7.0 Study Summary / Protocol Section 1		

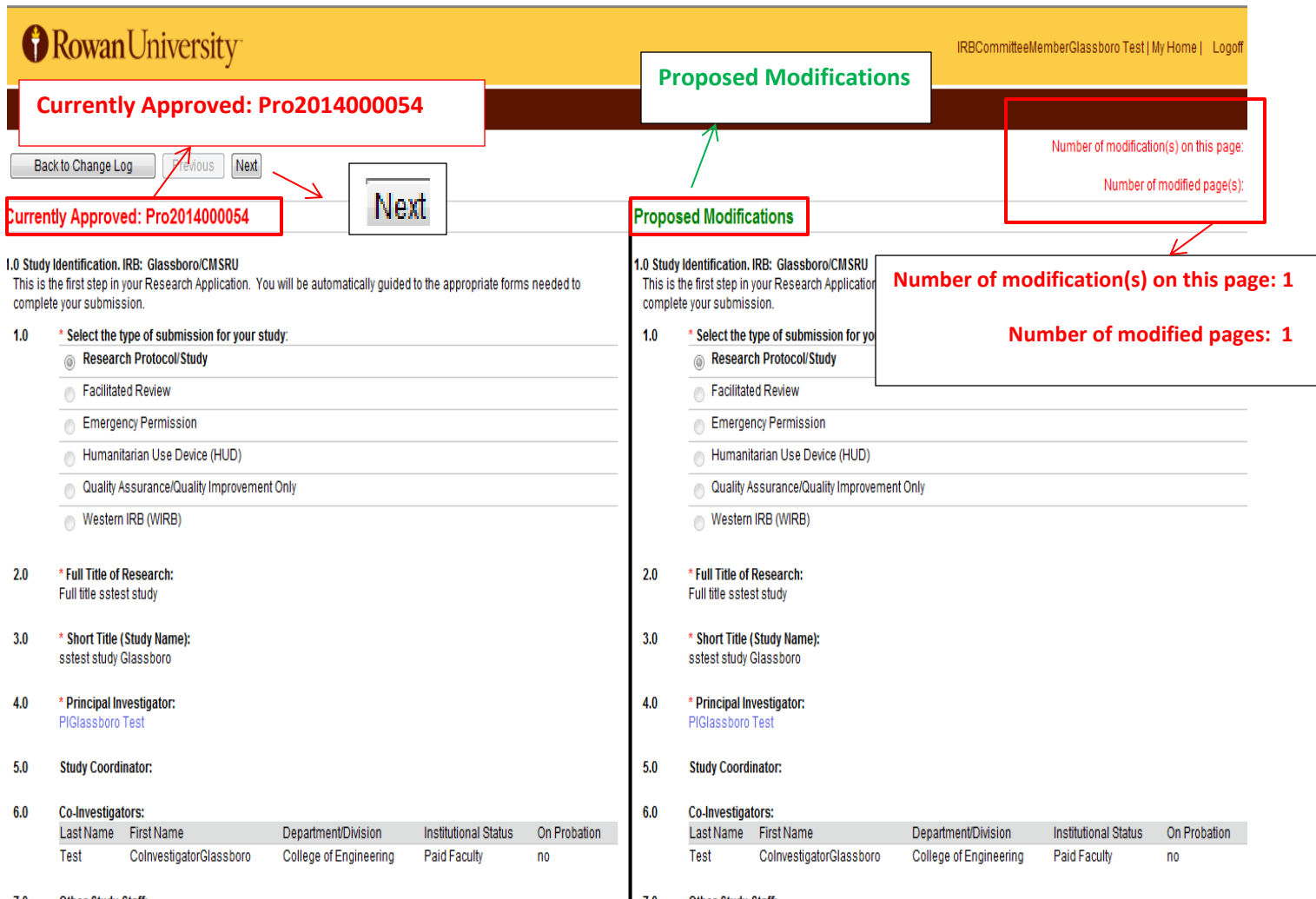
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To see the changes to a study,

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

View Differences

The **'View Differences'**, page enables reviewers to easily compare changes made to a study.



Rowan University IRBCommitteeMemberGlassboro Test | My Home | Logoff

Currently Approved: Pro2014000054

Proposed Modifications

Back to Change Log **PREVIOUS** **Next**

Currently Approved: Pro2014000054

Proposed Modifications

Number of modification(s) on this page:
Number of modified page(s):

Number of modification(s) on this page: 1
Number of modified pages: 1

1.0 Study Identification. IRB: Glassboro/CMSRU
This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.

1.0 * Select the type of submission for your study:

- ☒ Research Protocol/Study
- ☐ Facilitated Review
- ☐ Emergency Permission
- ☐ Humanitarian Use Device (HUD)
- ☐ Quality Assurance/Quality Improvement Only
- ☐ Western IRB (WIRB)

2.0 * Full Title of Research:
Full title sstest study

3.0 * Short Title (Study Name):
sstest study Glassboro

4.0 * Principal Investigator:
PIGlassboro Test

5.0 Study Coordinator:

6.0 Co-Investigators:

Last Name	First Name	Department/Division	Institutional Status	On Probation
Test	ColinvestigatorGlassboro	College of Engineering	Paid Faculty	no

7.0 Other Study Staff:

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.

Snipping Tool

File Edit Tools Help

Rowan University

IRBCommitteeMemberGla

TEST SITE eIRB Home IRB Studies User Profiles

Back to Change Log Previous Next

Currently Approved: Pro2014000054

0 Study Summary

1.0

Upload Protocol with version date (Microsoft Word format is required). Include screening instruments, questionnaires, data collection forms, etc.

Please upload consent/assent forms, surrogate consent forms, information sheets, and verbal script documents in [Section: 13.2 Consent Forms & Process of Consent](#).

For eIRB conversion requests there are two requirements:

1. Please upload most recently approved stamped versions of all , recruitment materials, questionnaires, etc.
2. Please upload a clean (unstamped) Word version (non-pdf) of all recruitment materials, questionnaires, etc.

Name	Modified	Version
Questionnaire testing History	4/14/2014 12:37 PM	0.01
Study Protocol version 4.2.2014 History	4/2/2014 2:10 PM	0.02

Proposed Modifications

7.0 Study Summary

1.0

Upload Protocol with version date (Microsoft Word format is required). Include : questionnaires, data collection forms, etc.

Please upload consent/assent forms, surrogate consent forms, information sheets, and verbal script documents in [Section: 13.2 Consent Forms & Process of Consent](#).

For eIRB conversion requests there are two requirements:

1. Please upload most recently approved stamped versions of all , recruitment materials, questionnaires, etc.
2. Please upload a clean (unstamped) Word version (non-pdf) of all recruitment materials, questionnaires, etc.

Name	Modified
Questionnaire revised 5-21-2014 History	5/21/2014 2:49 PM
Questionnaire testing History	4/14/2014 12:37 PM
Study protocol revised 5-21-2014 History	5/21/2014 2:49 PM
Study Protocol version 4.2.2014 History	4/2/2014 2:10 PM

Name Modified

Questionnaire testing | History 4/14/2014 12:37 PM

Name Modified

Questionnaire revised 5-21-2014 | History 5/21/2014 2:49 PM

Questionnaire testing | History 4/14/2014 12:37 PM

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.)

Rowan University

IRBCommitteeMemberGlassboro Test | My Home | Logoff

TEST SITE eIRB Home | IRB Studies | User Profiles

IRB Studies > sctest study Glassboro > Modification 2 for IRB Study #Pro2014000054 > sctest study Glassboro

Current State

MODIFICATION OPEN

[Edit Study](#)

[Printer Version](#)

[View Differences](#)

My Activities

[Display Review](#)

(Revised Study)

Modified Study: sctest study Glassboro (MS2_Pro2014000054 - Glassboro/CMSRU)

Description: Test study summary.

Principal Investigator: [PIGlassboro Test](#)

Study Coordinator: [Study Coordinator](#)

Expiration Date: 4/13/2015

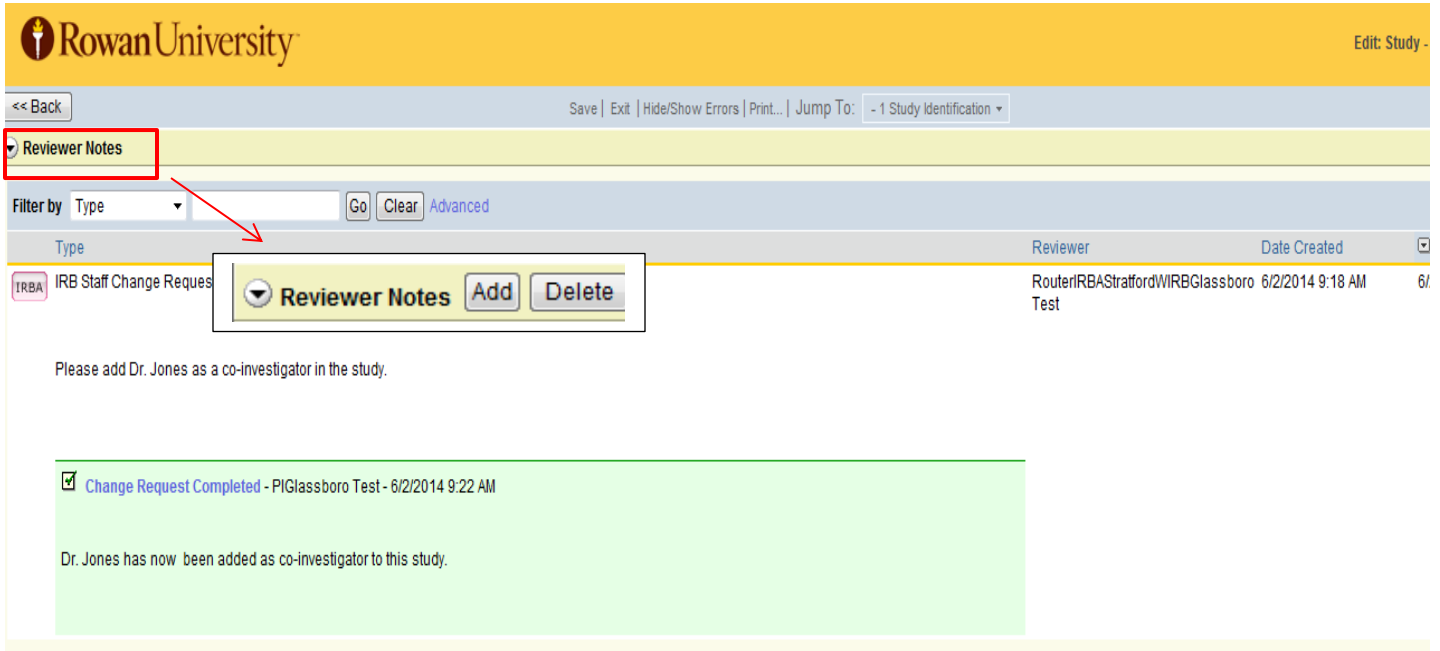
Modification: [Mod201400000002](#)

Letter: [View](#)

Activity	Author	Activity Date
Change Log: Page 7.0 Study Summary / Protocol Section 1	Test, PIGlassboro	5/21/2014 2:49 PM EDT

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Trusted sites | Protected Mode: On



This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.

- ☒ Research Protocol/Study
- ☐ Facilitated Review
- ☐ Emergency Permission
- ☐ Humanitarian Use Device (HUD)

Version 1 dated 6-2-2014



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'**.

View: Study - MS2_Pro2014000054

Finish

Finish

Final Page:

Submission Type:	Research Protocol/Study
Review Type- Requested:	Full IRB Review
Submission ID:	MS2_Pro2014000054

Next Steps:

Submit study for IRB review:

Your application form **will not** be submitted for review until the Principal Investigator returns to the study "workspace," and clicks on "Submit Study". You can track the status of this study's submission by logging into the study workspace.

To submit the study:

- Ensure that you have answered all questions in the application and all sections are error-free
- Click "Finish" to exit the application and return to the "workspace"
- Navigate to the left of your screen, and under "My Activities," click "Submit Study" to initiate IRB review

Note:

All co-investigators listed in this study **must** also agree to participate in the study prior to submission. They will be required to log into this workspace and click on "Agree to Participate".

Current State

IN REVIEW

- View Modification
- Print-Friendly Modification
- View Modified Study
- Print-Friendly Study
- View Changes

My Activities

- Log Private Comment
- Reviewer Checklist Modification**
- Submit Review
- Display Reviewer Notes

Complete Reviewer Checklist Modification

Modification: Modification 2 for IRB Study #Pro2014000054 (Mod201400000002 - Glassboro/CMSRU)

Description:	we would like to add additional questions to the questionnaire. The protocol has been revised to reflect the changes.		
Study Title:	Full title sstest study		
Principal Investigator:	PIGlassboro Test	Study Coordinator:	
Original Study ID:	Pro2014000054	Committee:	Glassboro/CMSRU Board 1
Review Type:	Expedited	Meeting:	
Co-Investigators Who Have Not Accepted Participation:	There are no items to display		Co-Investigators Who Have Declined Participation: There are no items to display
Action Letter:			

History Attachments Stamped Documents Continuing Reviews Reviewer Notes Change Log

Filter by	Activity	Author	Activity Date
Activity	Forward to Expedited Review	Test, RouterIRBStratfordWIRBGlassboro	5/21/2014 2:51 PM EDT
Activity	Selected IRB Committee	Test, RouterIRBStratfordWIRBGlassboro	5/21/2014 2:51 PM EDT
Activity	Assigned to Glassboro/CMSRU Board 1		
Activity	Changed Review Type	Test, RouterIRBStratfordWIRBGlassboro	5/21/2014 2:51 PM EDT
Activity	New Review Type: Expedited		

Reviewer Checklist Modification

REVIEWER CHECKLIST FOR MODIFICATIONS

When completing this form, please note if the modification impacts any of the regulatory criteria for IRB approval.

* 1. Is the modification being requested a "minor change" in the previously approved research? (i.e. Minor Revisions to approved research expedited procedure set forth in 45 CFR 46.110b2 and/or 21 CFR 56.110.b2)
☐ Yes ☐ No [Clear](#)

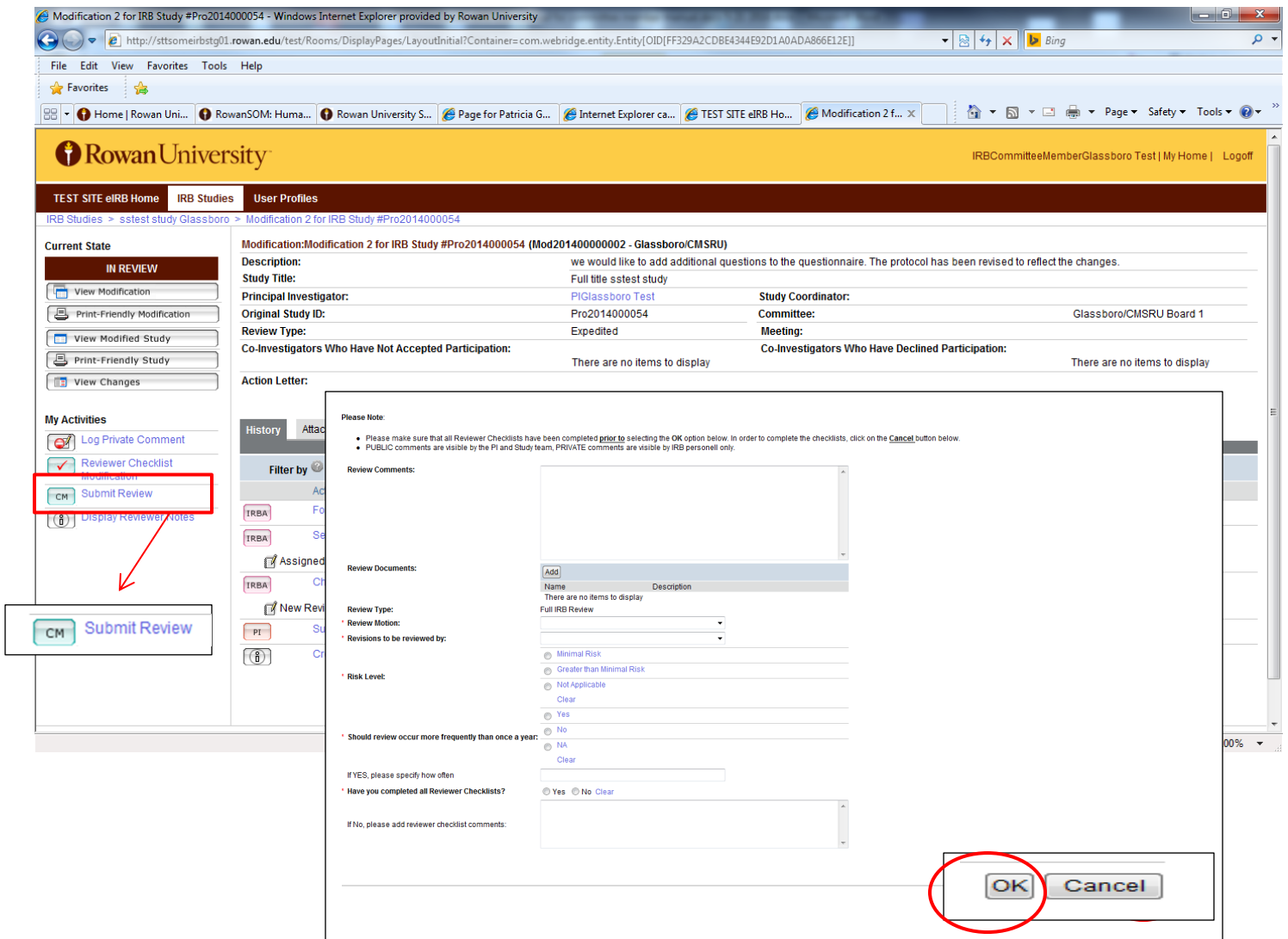
NOTE: If NO, modification is not eligible for expedited review

* 2. If the consent form has been revised, is re-consenting of previously enrolled subjects required?
☐ Yes ☐ No ☐ NA [Clear](#)

* 3. Has the Risk-Benefit ratio changed because of this change?
☐ Yes ☐ No [Clear](#)

* 4. Do the proposed changes have any impact on vulnerable population requirements?
☐ Yes ☐ No ☐ NA [Clear](#)

OK Cancel



Modification 2 for IRB Study #Pro2014000054 - Windows Internet Explorer provided by Rowan University

http://sttsomeirbstg01.rowan.edu/test/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity[OID[FF329A2CDBE4344E92D1A0ADA866E12E]]

Rowan University

IRBCommitteeMemberGlassboro Test | My Home | Logoff

TEST SITE eIRB Home IRB Studies User Profiles

IRB Studies > sstest study Glassboro > Modification 2 for IRB Study #Pro2014000054

Current State

IN REVIEW

View Modification

Print-Friendly Modification

View Modified Study

Print-Friendly Study

View Changes

My Activities

Log Private Comment

Reviewer Checklist

Submit Review

Display Reviewer Notes

Modification: Modification 2 for IRB Study #Pro2014000054 (Mod20140000002 - Glassboro/CMSRU)

Description: we would like to add additional questions to the questionnaire. The protocol has been revised to reflect the changes.

Study Title: Full title sstest study

Principal Investigator: PIGlassboro Test

Study Coordinator: Glassboro/CMSRU Board 1

Original Study ID: Pro2014000054

Committee: Glassboro/CMSRU Board 1

Review Type: Expedited

Meeting:

Co-Investigators Who Have Not Accepted Participation: There are no items to display

Co-Investigators Who Have Declined Participation: There are no items to display

Action Letter:

History **Attach**

Filter by

Assigned

New Review

Review Comments:

Review Documents:

Review Type:

Review Motion:

Revisions to be reviewed by:

Risk Level:

Should review occur more frequently than once a year:

If YES, please specify how often

Have you completed all Reviewer Checklists?

If No, please add reviewer checklist comments:

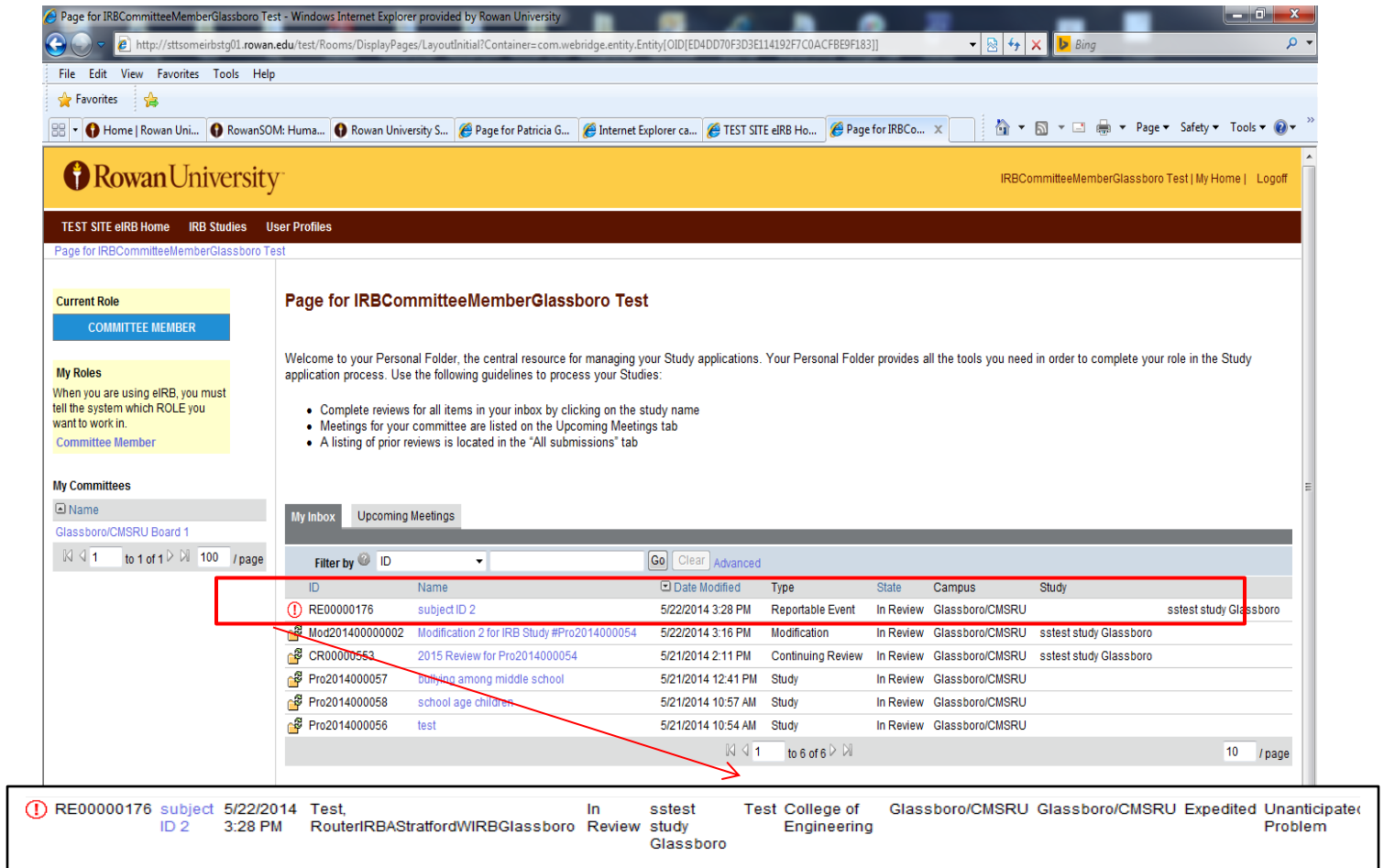
OK **Cancel**

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'**.



Page for IRBCommitteeMemberGlassboro Test

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

My Inbox | Upcoming Meetings

Filter by ID [Go] [Clear] [Advanced]

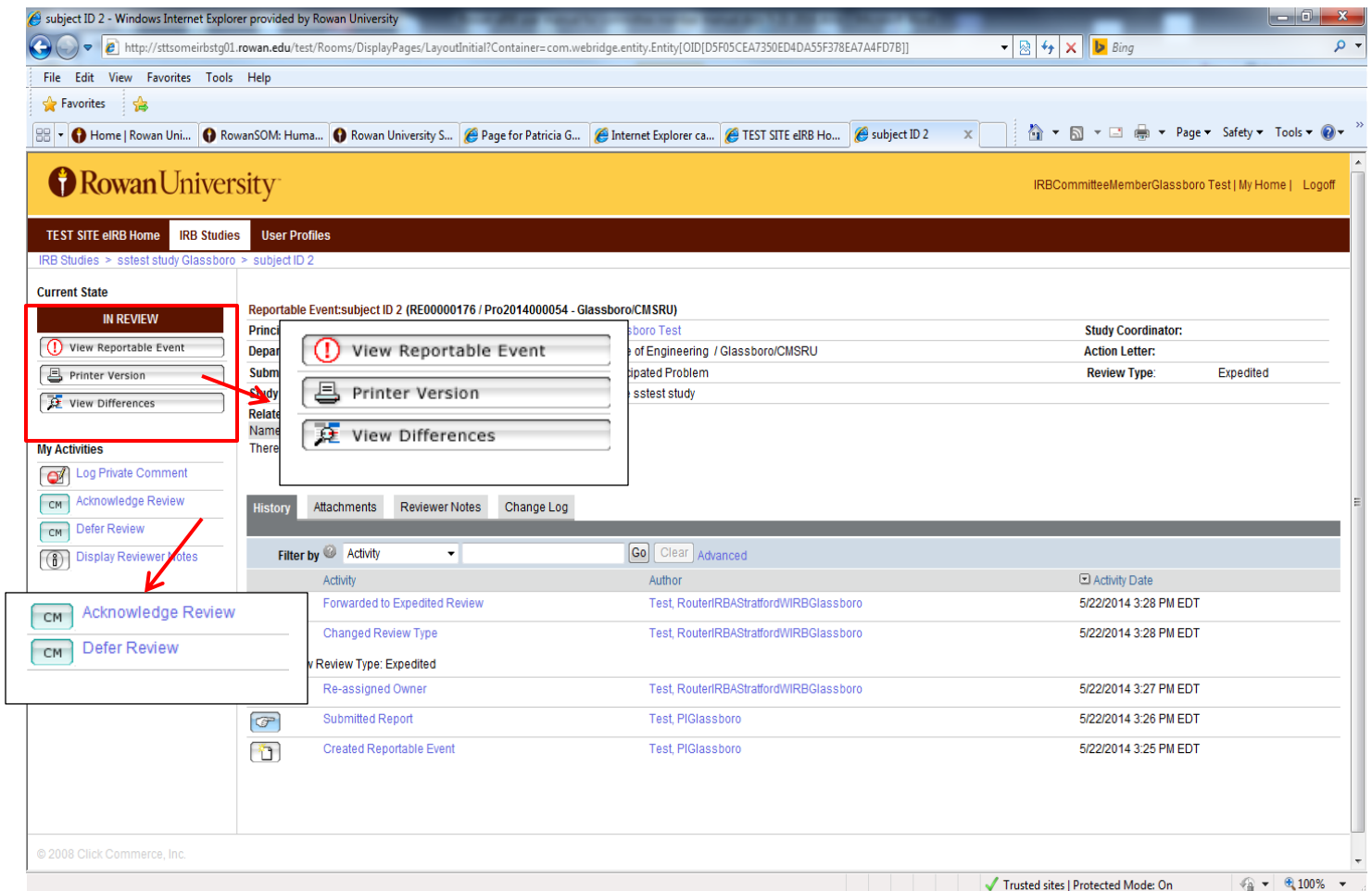
ID	Name	Date Modified	Type	State	Campus	Study
RE00000176	subject ID 2	5/22/2014 3:28 PM	Reportable Event	In Review	Glassboro/CMSRU	ssstest study Glassboro
Mod201400000002	Modification 2 for IRB Study #Pro2014000054	5/22/2014 3:16 PM	Modification	In Review	Glassboro/CMSRU	ssstest study Glassboro
CR00000553	2015 Review for Pro2014000054	5/21/2014 2:11 PM	Continuing Review	In Review	Glassboro/CMSRU	ssstest study Glassboro
Pro2014000057	bullying among middle school	5/21/2014 12:41 PM	Study	In Review	Glassboro/CMSRU	
Pro2014000058	school age children	5/21/2014 10:57 AM	Study	In Review	Glassboro/CMSRU	
Pro2014000056	test	5/21/2014 10:54 AM	Study	In Review	Glassboro/CMSRU	

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RE00000176 subject ID 2 5/22/2014 3:28 PM Test, RouterIRBStratfordWIRBGlassboro In Review ssstest study Glassboro Test College of Engineering Glassboro/CMSRU Glassboro/CMSRU Expedited Unanticipated Problem

! 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 screenshot displays the Rowan University IRB system interface. The browser window title is "subject ID 2 - Windows Internet Explorer provided by Rowan University". The URL is "http://sttsomeirbstg01.rowan.edu/test/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity[OID[D5F05CEA7350ED4DA55F378EA7A4FD7B]]".


The interface features a navigation bar with "TEST SITE eIRB Home", "IRB Studies", and "User Profiles". The sidebar on the left includes "My Activities" (Log Private Comment, Acknowledge Review, Defer Review, Display Reviewer Notes) and "Current State" (View Reportable Event, Printer Version, View Differences). The main content area shows the "Reportable Event: subject ID 2 (RE00000176 / Pro2014000054 - Glassboro/CMSRU)". It includes a "View Reportable Event" button, a "Printer Version" button, and a "View Differences" button. Below this is a "History" table with columns for Activity, Author, and Activity Date.

Activity	Author	Activity Date
Forwarded to Expedited Review	Test, RouterIRBASTraffordWIRBGlassboro	5/22/2014 3:28 PM EDT
Changed Review Type	Test, RouterIRBASTraffordWIRBGlassboro	5/22/2014 3:28 PM EDT
Review Type: Expedited		
Re-assigned Owner	Test, RouterIRBASTraffordWIRBGlassboro	5/22/2014 3:27 PM EDT
Submitted Report	Test, PIGlassboro	5/22/2014 3:26 PM EDT
Created Reportable Event	Test, PIGlassboro	5/22/2014 3:25 PM EDT

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



IRBCommitteeMemberGlassboro Test | My Home | Log


TEST SITE eIRB Home IRB Studies User Profiles


IRB Studies > sstest study Glassboro > Subject ID 130

Current State


IN REVIEW


 View Reportable Event


 Printer Version

 View Differences

My Activities

 Log Private Comment

 Display Reviewer Notes

 **Submit Review**

Reportable Event: Subject ID 130 (RE00000177 / Pro2014000054 - Glassboro/CMSRU)

Principal Investigator: [PIClassborn Test](#) Study Coordinator:

Department:

Submission Type:

Study Title:

Related Modifications:

Name	Link to Modification
There are no items to display	

History Attachments Rev

Filter by Activity

Activity

IRBA Forwarded to Expedited

IRBA Changed Review Type

IRBA New Review Type: Expedited

IRBA Re-assigned Owner

IRBA Submitted Report

IRBA Created Reportable Event

SUBMIT REVIEW

This is your final step in the review process

Once you have completed this form and selected the OK option below:

- Your review will be complete
- The submission will be routed back to the assigned IRB Administrator
- You will not be able to change or modify your review comments
- You will be able to add PRIVATE comments regarding the study

Review Comments:

Review Documents:

Name	Description
There are no items to display	

Review Type:

Review Motion: Expedited

Revisions to be reviewed by:

Have you completed all Reviewer Checklists?
☐ Yes ☐ No [Clear](#)

If no, please add reviewer checklist comments:

OK Cancel

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.

IRBCommitteeMemberGlassboro Test | My Home | Logoff

TEST SITE eIRB Home IRB Studies User Profiles

Page for IRBCommitteeMemberGlassboro Test

Current Role

COMMITTEE MEMBER

My Roles

When you are using eIRB, you must tell the system which ROLE you want to work in.

Committee Member

My Committees

Name

Glassboro/CMSRU Board 1

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Page for IRBCommitteeMemberGlassboro Test

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

My Inbox Upcoming Meetings

Filter by Name

Go Clear Advanced

Name	Owner	State	Last State Change
Glassboro/CMSRU Board 1 meeting on (8/14/2014)	Administrator, System	Scheduled	5/12/2014 2:38 PM
Glassboro/CMSRU Board 1 meeting on (7/16/2014)	Administrator, System	Scheduled	5/12/2014 2:38 PM
Glassboro/CMSRU Board 1 meeting on (6/12/2014)	Administrator, System	Scheduled	5/12/2014 2:37 PM

1 to 3 of 3 10 / page

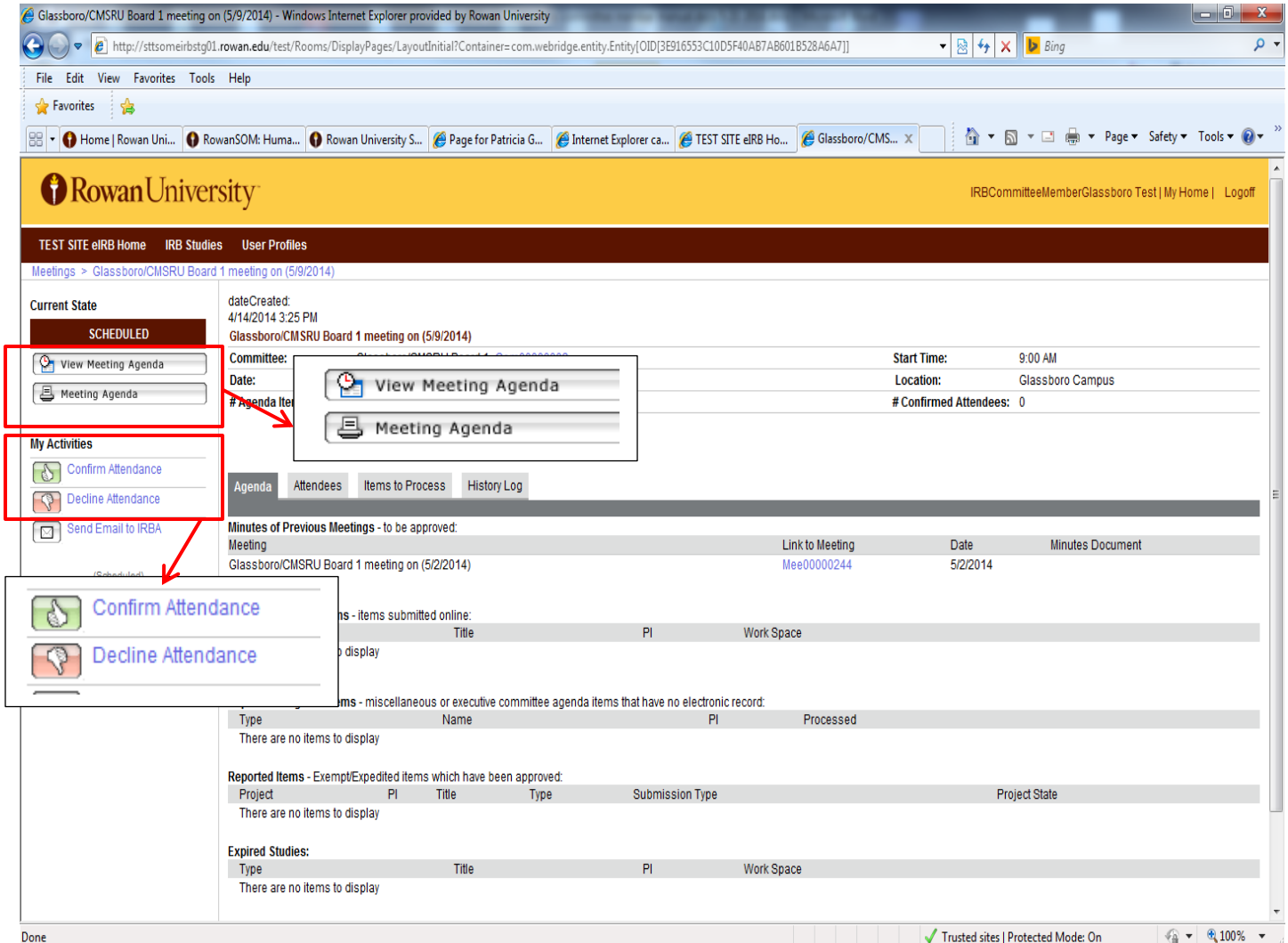
Glassboro/CMSRU Board 1 meeting on (6/12/2014)

Administrator, System

Scheduled

5/12/2014 2:37 PM

Viewing Meeting Agenda



Glassboro/CMSRU Board 1 meeting on (5/9/2014) - Windows Internet Explorer provided by Rowan University

http://sttsomeirbstg01.rowan.edu/test/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity[OID[3E916553C10D5F40AB7AB601B528A6A7]]

File Edit View Favorites Tools Help

Rowan University

IRBCommitteeMemberGlassboro Test | My Home | Logoff

TEST SITE eIRB Home IRB Studies User Profiles

Meetings > Glassboro/CMSRU Board 1 meeting on (5/9/2014)

Current State

SCHEDULED

View Meeting Agenda

Meeting Agenda

My Activities

Confirm Attendance

Decline Attendance

Send Email to IRBA

dateCreated: 4/14/2014 3:25 PM

Glassboro/CMSRU Board 1 meeting on (5/9/2014)

Committee:

Date:

Start Time: 9:00 AM

Location: Glassboro Campus

Confirmed Attendees: 0

View Meeting Agenda

Meeting Agenda

Agenda Attendees Items to Process History Log

Minutes of Previous Meetings - to be approved:

Meeting	Link to Meeting	Date	Minutes Document
Glassboro/CMSRU Board 1 meeting on (5/2/2014)	Mee00000244	5/2/2014	

Items submitted online:

Title	PI	Work Space
There are no items to display		

Items - miscellaneous or executive committee agenda items that have no electronic record:

Type	Name	PI	Processed
There are no items to display			

Reported Items - Exempt/Expedited items which have been approved:

Project	PI	Title	Type	Submission Type	Project State
There are no items to display					

Expired Studies:

Type	Title	PI	Work Space
There are no items to display			

Done

Trusted sites | Protected Mode: On

100%

- 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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40 East Laurel Road,

UEC 1106

Stratford, NJ 08084

Office: 856-566-2712

FAX: 856-566-7195

Website: <http://www.rowan.edu/som/hsp/index.html>

Rowan University

Office of Sponsored Programs

James Hall, 3rd Floor, Rm 3121

Glassboro, NJ 08028

Office: 856-256-4058

Website: <http://www.rowan.edu/open/provost/grants/index.cfm>