



VCU

Office of Research and Innovation

RAMS-IRB for Full Board Reviewers

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HOME SCREEN

- Connect through RAMS [VPN](#) if off campus
- Log into RAMS-IRB by using your VCU eID and Password at <https://irb.research.vcu.edu>
- Make sure your role says “**IRB Committee Member**”
- Your IRB Committee Member home screen looks like this (see below). Any study needing action from the reviewer will be in your **inbox**. Click on the **name** to access the study. action.

The screenshot shows the VCU IRB Staging Office of Research home screen for Elicia Preslan. The page has a dark header with the VCU logo and navigation links (Meetings, IRB, Help). Below the header, the user's name 'Page for Elicia Preslan' is displayed. The main content area is divided into two columns. The left column, titled 'Current Role', shows 'IRB Committee Member' and 'My Roles' with 'IRB Committee Member' listed. The right column, titled 'Page for Elicia Preslan', contains a welcome message and a list of actions: 'Complete reviews for all items in your inbox' and 'Meetings for your committee are listed on the Upcoming Meetings tab'. Below this, there are two tabs: 'My Inbox' and 'Upcoming Meetings'. The 'My Inbox' tab is active, showing a table of studies. The table has columns for 'ID' and 'Name'. The first row shows 'HM20005364' and 'Test Study for Guide for the PI'. The 'Name' column is highlighted with a red box.

VCU IRB Staging Office of Research

Meetings IRB Help

Page for Elicia Preslan

Current Role

IRB Committee Member

My Roles

IRB Committee Member

Page for Elicia Preslan

Welcome to your Personal Page, the central resource for managing IRB submissions. Your Personal Page provides all the tools you need in

- Complete reviews for all items in your inbox. To do this, review the forms and add Reviewer Notes on selected pages. Finalize you
- Meetings for your committee are listed on the Upcoming Meetings tab. You can click on the meetings to view the Agenda and Minute

My Inbox Upcoming Meetings

Filter by ID Go Clear Advanced

ID	Name
HM20005364	Test Study for Guide for the PI

- Anytime you want to return to your inbox, click “My Home.”

ACUP AIRS CORES **IRB** SPOT REPORTS

Meetings **IRB** Help

IRB > Test4354236

Main Study Workspace

Current State

Assigned To IRB Meeting

My Study Forms

[View Study](#)

[Printer Version](#)

[View Differences](#)

My Activities

Study: Test4354236 (HM20005251)

Principal Investigator: Meghan Wright

Editors: Meghan Wright

IRB of Record: VCU IRB

Reviewer(s): Meghan Wright
Christine Davison

[History](#) [Comments](#) [Documents](#) [Admin Docs](#) [Reviewer Notes](#) [Change Log](#)

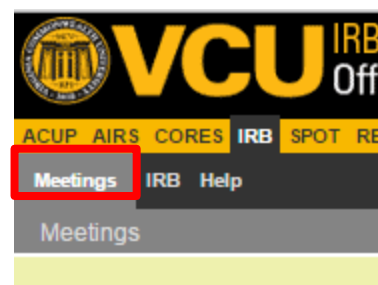
Activity

- **Current State** You will see the study is in full board review when it says “Assigned to IRB Meeting” in the maroon box
- Click **“View Study”** to read through the smartform and add reviewer notes. The smartform are the questions answered to create the submission.
- Click **“Printer Version”** to view a printer-friendly version of the smartform (all pages shown as one document without clicking from section to section).
- **History:** All actions through the life of the submission are listed with the most recent actions listed first. The link for each action provides more detail.
- **Comments:** Shows a list of all public and private comments through the life of a submission.
- **Documents:** All uploaded documents related to the study are housed here.
 - Approval status found along right side and who uploaded the document
 - Important to ensure working from the correct/ approved version.
- **Admin Documents:** This tab contains other documents that need to be included for documentation purposes. The PI can’t see these. Examples include COI determinations, email correspondence, etc.
- **Reviewer Notes:** Reviewer Notes are the comments that reviewers enter throughout the smart form where a change is needed. This tab shows a list of all logged reviewer notes.
 - Link takes you directly to the smartform where the change is needed
- **Change Log:** Shows a list of all changes that were made to the smartform during the initial submission.

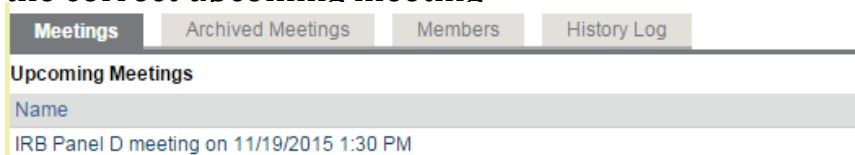
MEETING WORKSPACE & ATTENDANCE

- Before the meeting, you will want to log your attendance and view the electronic agenda.

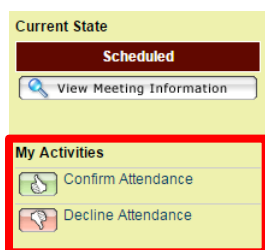
1) Click “Meetings” in upper left hand corner of screen.



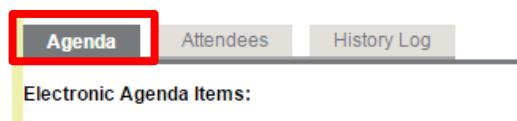
Click the correct upcoming meeting



2) To confirm or decline attendance, click the appropriate button on the left hand side of the screen.



3) To view the meeting agenda, click the “Agenda” tab.

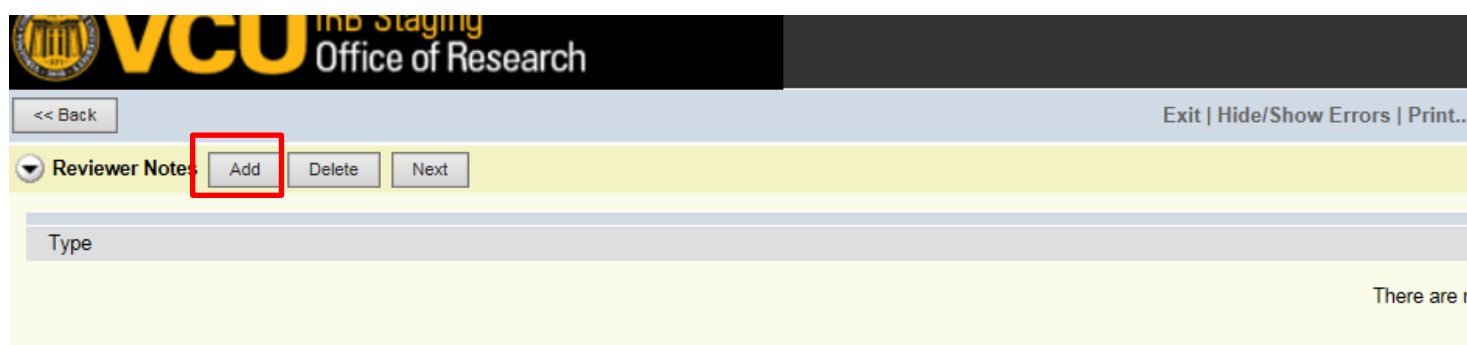


REVIEWING AN INITIAL SUBMISSION

- Click on the **title of the study** to access the study. Click “View Study” to be able to add reviewer notes.

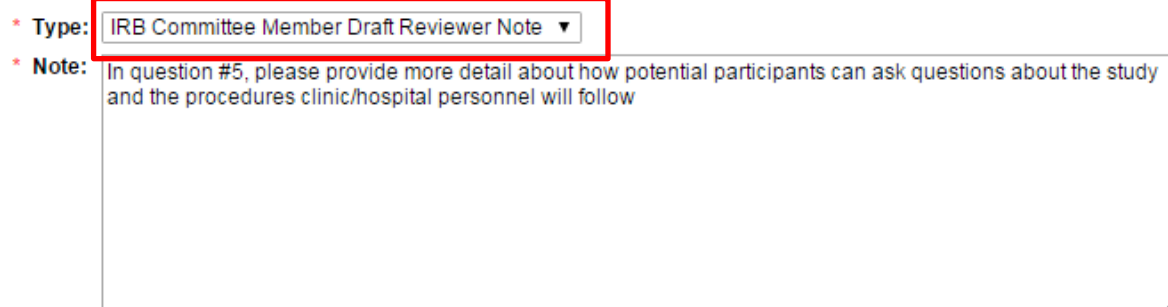
ADDING REVIEWER NOTES

- If you want to request a change, add a reviewer note by clicking “Add”
- You can jump between notes by clicking “Next.”



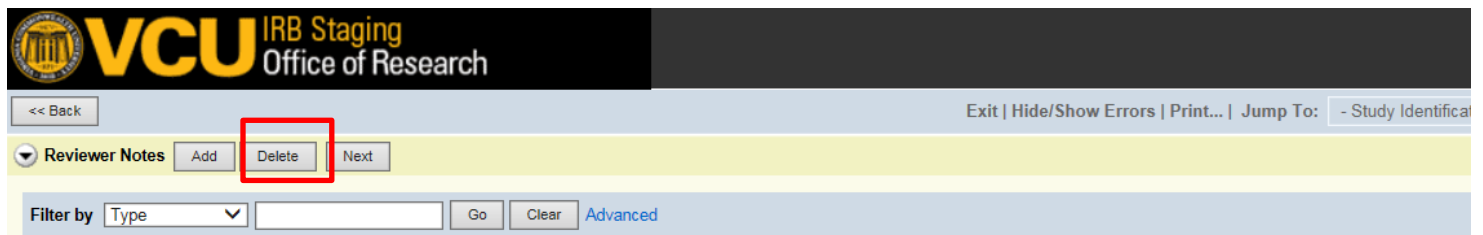
The screenshot shows the VCU IRB Staging Office of Research interface. At the top, there is a header with the VCU logo and the text "IRB Staging Office of Research". Below the header, there is a navigation bar with a "<< Back" button on the left and "Exit | Hide/Show Errors | Print.." on the right. The main section is titled "Reviewer Notes" and contains three buttons: "Add", "Delete", and "Next". The "Add" button is highlighted with a red box. Below the buttons, there is a text input field labeled "Type". To the right of the input field, there is a small text that says "There are r".

- In the text box, request the revision or information that you want to have included in the smartform. Remember to be clear and precise about what you want changed, specify where the change should be made in the form, and if appropriate, offer your rationale or context for the request.



The screenshot shows a specific reviewer note in the VCU IRB Staging Office of Research interface. The note is titled "Type: IRB Committee Member Draft Reviewer Note" and is highlighted with a red box. Below the title, there is a text input field labeled "Note:" containing the text "In question #5, please provide more detail about how potential participants can ask questions about the study and the procedures clinic/hospital personnel will follow".

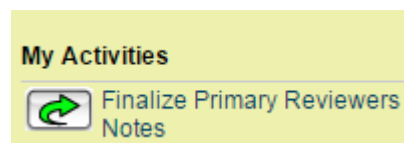
- To delete a note, click “Delete” and find the note by time posted.



- When you are done adding reviewer notes, go back to the submission workspace by clicking the “Exit” button.
- Your change requests should be done as reviewer notes, but if you have general questions, you can also contact the PI by logging public comments.
- The PI will be able to see your reviewer notes in the “Snapshot” (if they know where to look), however they will not be able to respond or make changes.

FINALIZE REVIEW POP-OUT SCREEN

- Please finalize your review BEFORE the meeting. You may wish to contact the PI to ask questions before you finalize your review.
- For a full board study, you will be making a recommendation to the panel of what action the panel should take, as the study and your findings will be presented to the full panel for review and a vote.



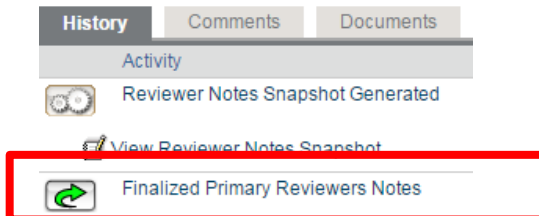
- In the blank box, you should be adding the information to be displayed and discussed at the meeting, such as a summary, if the criteria for approval are met, if the study involves vulnerable populations, risk determination, recommendation etc.

 A screenshot of the 'Finalize Primary Reviewer Notes' form. The form has a title 'Finalize Primary Reviewer Notes' and a subtitle 'Use this activity to mark your review complete for this study.' Below this, there's a numbered list item '1. Provide any additional comments that would be useful during the committee meeting.' followed by a large, empty text input box. The entire form area is enclosed in a red rectangular border.

Note: This information should NOT be logged anywhere else such as a private comment, unless something about your review changes after you’ve finalized the review.

VIEWING REVIEWER NOTES (AT MEETING)

- To view your finalized reviewer comments (for example, at the meeting), click on “Finalized Primary Reviewer Notes” under the **History** tab. Do NOT click on the snapshot.



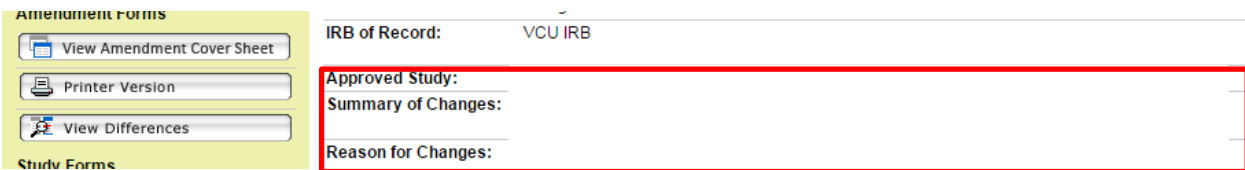
POST MEETING

- M1 (Approval) – the reviewers do not need to do anything further
- M2 (Conditional Approval) –
 - IRB staff will send a letter to the PI with specific changes.
 - Once the changes are submitted, if you are assigned as the designated reviewer, you will need to verify those changes were made as the panel requested.
 - If changes were made *exactly* as the panel requested (no more, no less), then the submission may be approved.
 - If the PI did not make the exact changes requested by the panel, you will need to request changes. If you’re unable to get the PI to make those changes, the submission will be referred back to full board.
- The Letter to the PI will be under the “History” tab

AMENDMENTS

- When the PI opens an amendment, it copies the *approved* existing smartform and documents into a new workspace to be edited, and therefore the full edited smartform is submitted as an amendment.
- The approved smartform remains approved as is, until the amendment is approved and changes are applied.

1. First, look at Reason for Changes & Summary of Changes



Amendment Forms

View Amendment Cover Sheet

Printer Version

View Differences

Study Forms

IRB of Record: VCU IRB

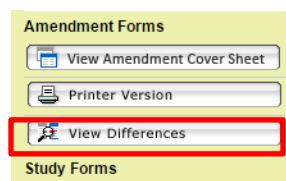
Approved Study:

Summary of Changes:

Reason for Changes:

2. Click “View Changes” first

- a. Note: “View Differences” refers to strictly the differences in the amendment ***cover sheet***.



Amendment Forms

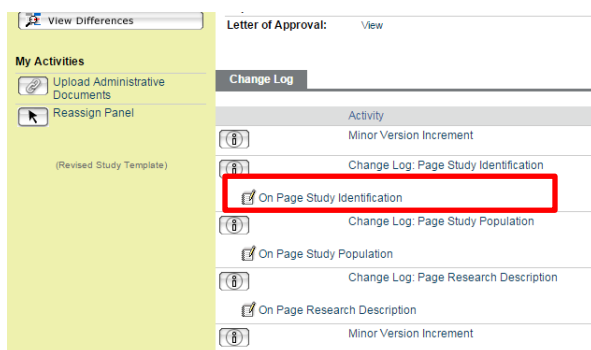
View Amendment Cover Sheet

Printer Version

View Differences

Study Forms

3. To view the specific changes to the smartform, either click **“View Differences”** or click on each individual change in the **change log**. “View Differences” is best used when there are many changes. Those changes will be highlighted, as with an initial submission.



View Differences

My Activities

Upload Administrative Documents

Reassign Panel

(Revised Study Template)

Letter of Approval: View

Change Log

Activity

Minor Version Increment

Change Log: Page Study Identification

On Page Study Identification

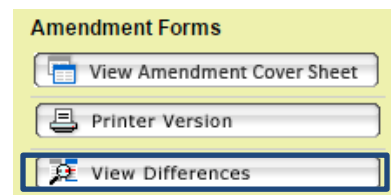
Change Log: Page Study Population

On Page Study Population

Change Log: Page Research Description

On Page Research Description

Minor Version Increment




Amendment Forms

View Amendment Cover Sheet

Printer Version

View Differences

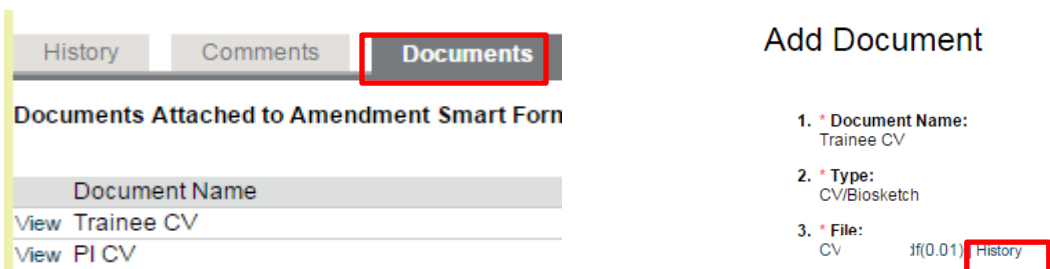
To get back to the Amendment workspace, click “Amendment __” in the top gray bar.



Modified Study:

Principal Investigator:		IRB Coordinator:
Editors:		IRB Panel:
Approval Date:		
Expiration Date:		Review Type:
Letter of Approval:		IRB of Record:

4. Once you’ve reviewed the specific changes they are requesting, click “View Modified Study” or “Print-Friendly” to look at the changes in context of the entire smartform. You should be looking at how those changes affect the rest of the submission and if anything else needs to be changed. (Example, if the recruitment plan changes, the study population of consent process might also need revisions).
- If you have requested changes, log a reviewer note just like reviewing an initial submission.
 - In addition, you should go to the Documents tab and review any modified documents.
 - Click “View” next to each document
 - Click “HISTORY” and you will be able to see all revisions, including redlined



History Comments **Documents**

Documents Attached to Amendment Smart Form

Document Name
View Trainee CV
View PI CV

Add Document

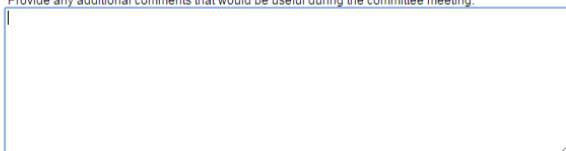
1. * Document Name:
Trainee CV
2. * Type:
CV/Biosketch
3. * File:
CV [jf\(0.01\) History](#)

5. Log reviewer notes with any changes you want to request.
6. Finalize your review by clicking “Finalize Primary Reviewer Notes”

Finalize Primary Reviewer Notes

Use this activity to mark your review complete for this study.

1. Provide any additional comments that would be useful during the committee meeting:



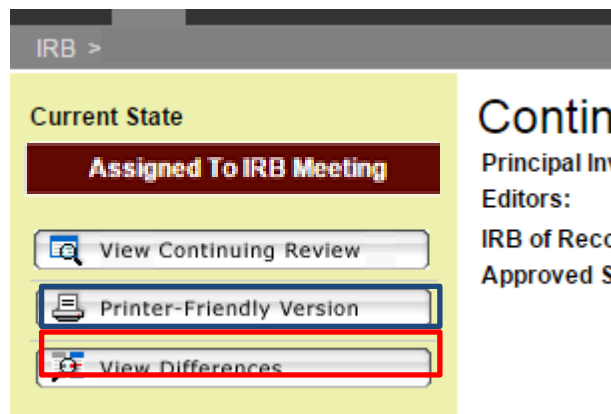
My Activities



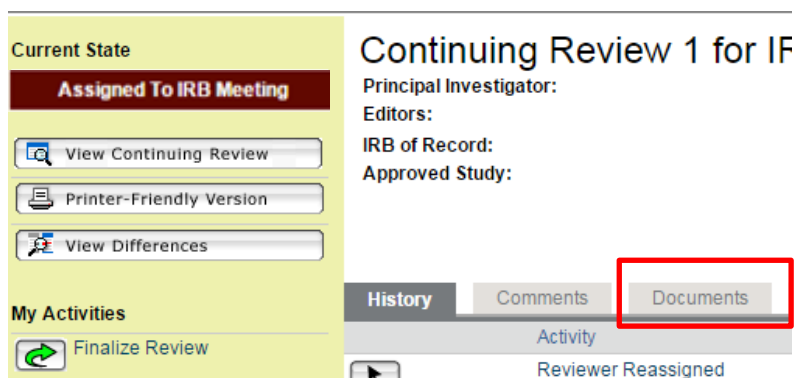
Finalize Primary Reviewers
Notes

CONTINUING REVIEW

1. Initial Read-Through - To read the continuing review submission initially, click **Printer-Friendly Version** – this is easier to read all at one time.
2. If you have questions and need to log a reviewer note, then click **“View Continuing Review.”** Reviewer Notes: Refer to the process indicated in the Initial Submission directions.



3. Review Documents – Once you’re done viewing the form, you will need to look at the documents by clicking on the documents tab of the continuing review workspace.
 - a. Open each document and read them for informational purposes. There is no need for further action unless you have a question, in which case, you would log a reviewer comment.

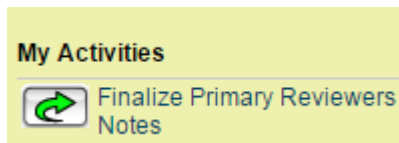


4. Read through the currently approved smartform (full study submission) to make sure that the Criteria for Approval are still met given the information provided in the continuing review.
5. If you find issues with the **Continuing Review** information, you will need to send it back to the PI for modification.
6. Finalize your review by clicking “Finalize Primary Reviewer Notes”

Finalize Primary Reviewer Notes

Use this activity to mark your review complete for this study.

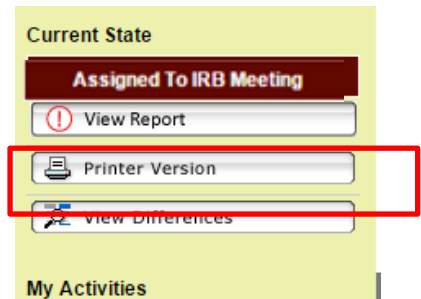
1. Provide any additional comments that would be useful during the committee meeting:



REPORTS

*Reviewers are less likely to see reports – most reports get assigned to chair, but procedures are panel specific.

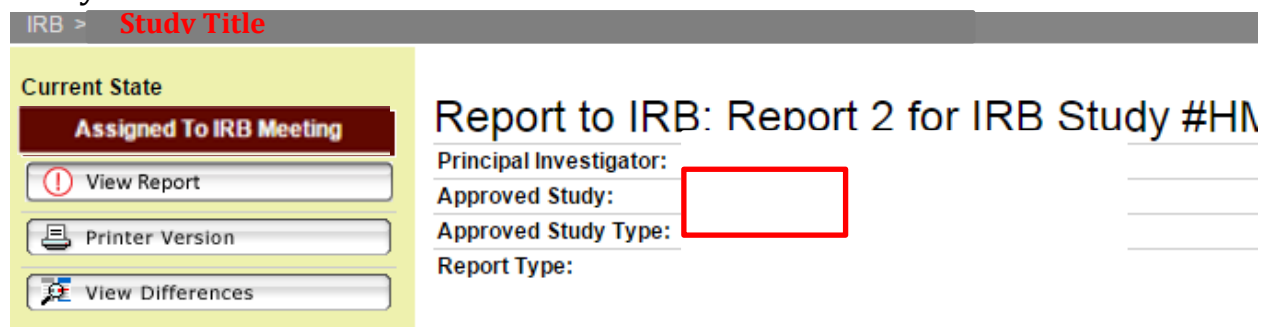
1. Click Printer Version – to view the report all on one page.



2. Read through the printer version and refer to the [WPP VII-6](#) for the procedures about how to review a report. If you have questions, consult your chair.

3. Reviewer Notes: If you have questions about the information in the report, you may log reviewer notes, and/or public/private comments just like any other submission. You may also decide to call the PI.

4. Read Smartform: Go back to the approved smartform (**click on the study title in the gray bar**) and read through the study to make sure that the PI's proposed changes will adequately address the changes that may be needed in the overall study.

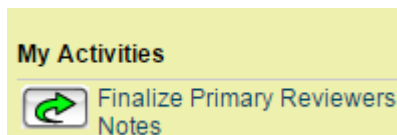


7. Finalize your review by clicking “Finalize Primary Reviewer Notes”

Finalize Primary Reviewer Notes

Use this activity to mark your review complete for this study.

1. Provide any additional comments that would be useful during the committee meeting:



CLOSURE

If a study closure requires a full board decision, the assigned reviewer will be notified by the IRB staff, and may be sent a PDF of the closure request. The reviewer will not see it in their inbox, but can find the closure in the meeting workspace agenda to view and log reviewer notes.

Review comments should be logged as a private comment.