



VCU

Office of Research and Innovation

RAMS-IRB for Expedited 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.

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.”

VCU IRB Staging Office of Research

Main Study Workspace

Meetings | IRB | Help

IRB > Test Study for Guide for the PI

Current State
In Expedited Review

My Study Forms
View Study
Printer Version
View Differences

My Activities
Finalize Review

Study: Test Study for Guide for the PI (HM20005364)
Principal Investigator: Meghan Wright
Editors:
IRB of Record: VCU IRB
Reviewer(s): Elicia Preslan

History | Comments | Documents | Admin Docs | Reviewer Notes | Change Log | IRB Information | Paper History

Activity
Expedited Reviewer Assigned: Elicia Preslan
Submitted Changes

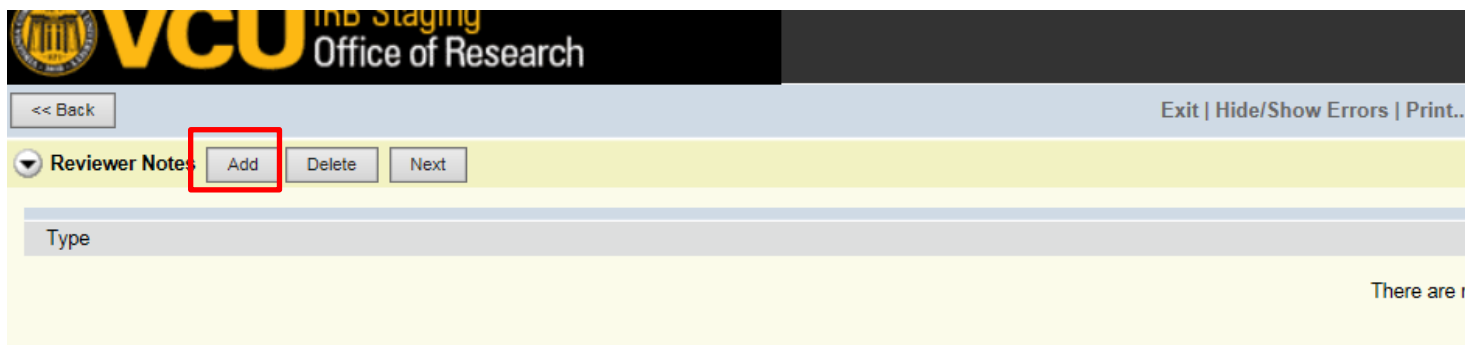
- **Current State** You will see the study is in Expedited Review by the maroon "Current State" box
- Click **"View Study"** to read through the smartform and add reviewer notes. The smartform are the questions answered to create the submission.
- Click **"Printer Version"** to view a printer-friendly 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.
- **IRB Information:** This tab shows a quick summary of key/important information about the submission.

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.

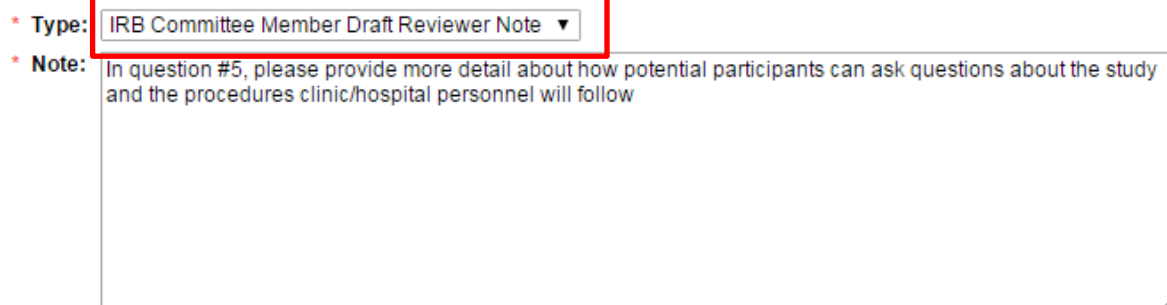
ADDING REVIEWER NOTES

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



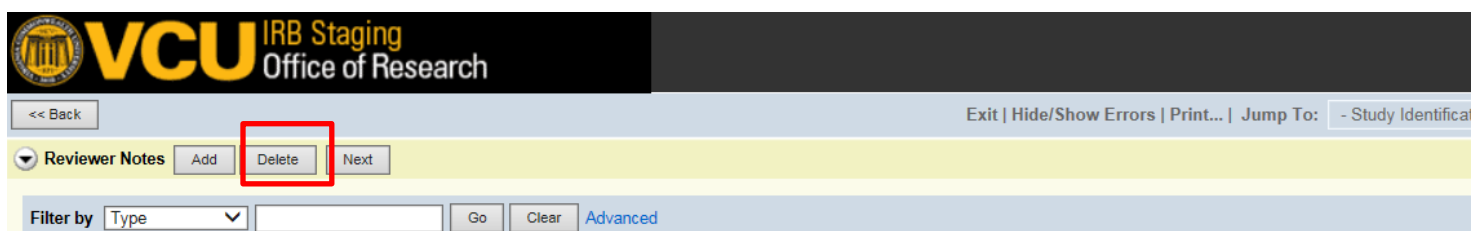
The screenshot shows the VCU IRB Staging Office of Research interface. At the top, there is a header with the VCU logo and the text "IRB Staging Office of Research". Below the header, there is a navigation bar with a "<< Back" button on the left and "Exit | Hide/Show Errors | Print..." on the right. 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" and a small text "There are r" on the right.

- 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 the VCU IRB Staging Office of Research interface. It displays the "Reviewer Notes" section with a dropdown menu for "Type" and a text area for "Note". The "Type" dropdown menu is highlighted with a red box and shows the selected option "IRB Committee Member Draft Reviewer Note". The "Note" text area contains 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.



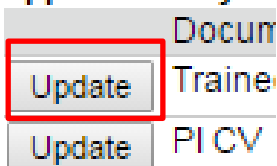
The screenshot shows the VCU IRB Staging Office of Research interface. It displays the "Reviewer Notes" section with buttons for "Add", "Delete", and "Next". The "Delete" button is highlighted with a red box. Below the buttons, there is a "Filter by" section with a dropdown menu for "Type" and a text input field. To the right of the input field are "Go" and "Clear" buttons, and a link for "Advanced". At the top right, there is a "Jump To:" dropdown menu with the option "- Study Identical".

- 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.
- To send the study back to the PI for changes, and click “Finalize Review” on the left hand side of the submission workspace and choose “Changes Requested” in the drop down menu for question #1.



- Note: Question #5 – An answer is required before the review can be finalized.
- Documents:
 - *Approving Documents:* At this stage, you may approve documents that do not require changes by clicking “Update” and use the drop down menu in question 4 to mark your **approval**.
 - *Documents with Changes:* If a document requires change, make a comment in question 8 to tell the PI that you have uploaded a Red Line document.
 - Click “Update” and upload the redline version.
 - Select “Choose File” and find your redline version on your computer to upload
 - Click “open” and “ok”

9. Approve Upload:
Use the *Update* I
approvable by th



Update Document

- * Document Name:
- * Type:
- * File:
CV f(0.01) | History
 No file chosen

VIEWING CHANGES

- Once the PI submits changes, you will get an email notification.
- Go back to the submission and click on “View Differences”



- In the green response to every reviewer note, you will be able to see the PI's comments.
 - Any differences in the smartform responses will appear in **green highlighting** (New/added text) or **red** (Old text) within the form.
- If there were multiple revised pages of the smartform, click >> to go to the next revised page.

View Changes to IRB Study

Show Changes made between Current Version (0.5) and 0.4 8/24/2015 10:40 AM

Changed Steps: Study Identification << >> ☒ Limit Steps to Current SmartForm Path

Reviewer Notes Add Delete Next

Filter by Type Go Clear Advanced

Type

IRB Staff Change Request


Please make the title more descriptive of the study.

☒ Change Request Completed - Meghan Wright - 8/24/2015 10:43 AM

We made the changes.

Study Identification

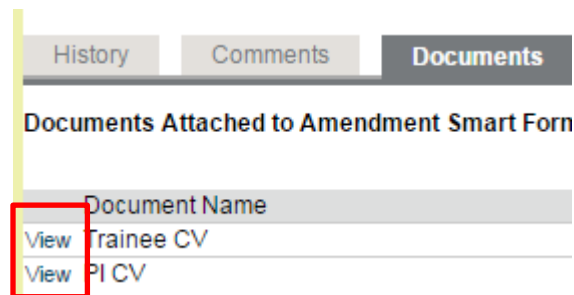
1. * **Select the Principal Investigator:** 
Meghan Wright

2. * **Study Title:** 
Test Study for Guide **for the PI**

Test Study for Guide

VIEWING DOCUMENT CHANGES

- Once you've viewed all of the differences in the smartform, click the documents tab to view differences in the documents.
- Click "View" next to each document



- Click "HISTORY" and you will be able to see all revisions, including red-lined documents.

Add Document

1. * Document Name:
Trainee CV
2. * Type:
CV/Biosketch
3. * File:
CV f(0.01) History

- If a change was not made appropriately or if you still have questions, log additional reviewer notes and finalize your review again as "Changes Requested." This process of logging reviewer notes and requesting changes may be repeated multiple times until the submission is approvable, but try to identify all the issues on the first round of changes.

FINALIZE REVIEW POP-OUT SCREEN

- Once all changes have been made, click “Finalize Review” again and then choose “**Approve as Expedited**” (or Approve as Exempt or even Not Human Subjects Research) on the drop down menu for question #1.

Finalize Review

Use this activity to finalize your review of this study.

1. * Select Your Review Decision:

2. Select Exempt Review Categories:
If you have determined this study is exempt, select all applicable exempt review categories from the list below:

There are no items to display

3. Select Expedited Review Categories:
If you have determined this study is expedited, select all applicable expedited review categories from the list below:

Category Involves the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves.

4. Check each of the approval conditions that you have evaluated and determined to be met. Not all will be applicable, but you must evaluate and check off all the criteria in order to approve.

There are no items to display

5. * If this study involves children and falls into category 404 or 405 where the permission of two parents is optional, indicate what parental signatures are required:

6. * Does this study involve greater than minimal risk: ☐ Yes ☒ No [Clear](#)

7. Approve Uploaded Documents:
Use the Update button below to mark all documents as "Approved" if it is approved as is, "N/A" if it is something that is not approvable by the IRB, or "No" if you are withholding approval of the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
<input type="button" value="Update"/>	g	RAMS IRB for Reviewers Expedited.docx	0.01	12/4/2015 11:07 AM	Meghan Wright	Other	

8. Comments (will be shown in History Log):



- Question #2 or 3– Categories should be correct already (however they may not be if the PI chose incorrectly) so please verify these selections. You may add or delete categories without sending it back to the PI. The selections in this approval overrides what was submitted in the smart form, so make sure they are accurate.
- Question # 4 is required, even though it doesn't have a *, so be sure to answer that question. Click “Add” and check off all 8 Criteria for IRB Approval (46.111) in the list. **Unless all 8 criteria are met, the study cannot be approved.**
- Question #7 Approve Documents (see next page) – click “Update” for each document, and indicate which documents are approved, and which are not. Make sure redline versions are “Not Applicable.” Refer to the following guidelines about whether or not to approve:
- In the Comments box, add anything else the coordinator or Panel chairperson needs to know about the study or your determination.
- Once you click “Ok,” the study goes to IRB staff who will read your review and confirm that all regulatory requirements have been met. If they have questions about your approval, it will be sent back to you for further review. They could also send the study back to the PI if further revisions are necessary.
- The IRB staff will draft a letter to the PI with your review determination. The letter and the study are then reviewed by the Panel chair (who may have questions or requested changes for IRB staff, reviewer and/or the PI).
- Once the chair approves the letter, documents will be finalized by the IRB staff and the letter with a determination is sent to the PI.**

Approving Documents:

Guidelines to approving, not approving, or not applicable documents:

Approved “Yes”	<ul style="list-style-type: none">○ The IRB approves the content of the document.○ Document or content of document is in the scope of IRB review. <p><u>Examples:</u></p> <ul style="list-style-type: none">▪ Required CVs / Bio-sketches (PI, etc.)▪ Sponsor’s protocols▪ Tables, figures that are referenced in the research description▪ Research measures▪ Case Report Forms when required by the IRB▪ Recruitment materials▪ Funding proposals that had congruency review▪ IND/IDE exemptions approved by IRB▪ All consent documents:<ul style="list-style-type: none">○ Standard consent forms○ Information sheets○ Research measures IF they contain a consent element
Not Approved “No”	<ul style="list-style-type: none">○ The IRB does not approve the content of the document.○ Document or content of document outside of IRB purview.○ Any time any option other than NO could cause confusion to anyone viewing document list. <p><u>Examples:</u></p> <ul style="list-style-type: none">▪ Research plan▪ Study roster▪ Special population forms▪ Appendix A: HIPAA for Research▪ Previous versions of documents that are no longer approved▪ Memos to the IRB or reviewer▪ Redline documents▪ Documents from other IRBs
Not Applicable “N/A”	<ul style="list-style-type: none">○ Considered as part of the review (within scope) but document or content management outside of control of PI or IRB.○ Acknowledged by the IRB. <p><u>Examples:</u></p> <ul style="list-style-type: none">▪ HIPAA standalone authorization forms▪ OSP Approval Form▪ Funding Proposals where congruency not reviewed▪ Required ancillary committee review letters:<ul style="list-style-type: none">○ PRMC○ DSMB reports○ Radiation Safety Committee▪ References/literature, tables, figures▪ FDA documents<ul style="list-style-type: none">○ IND/IDE documentation from FDA/Sponsor○ Forms 1572, 482, 483, 3500, etc.○ Drug/device brochures

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

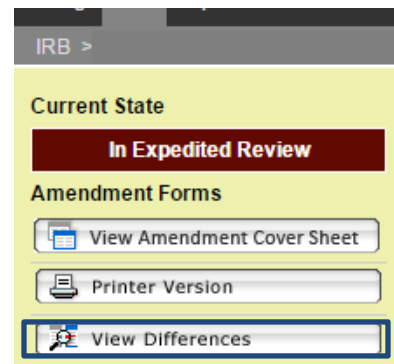
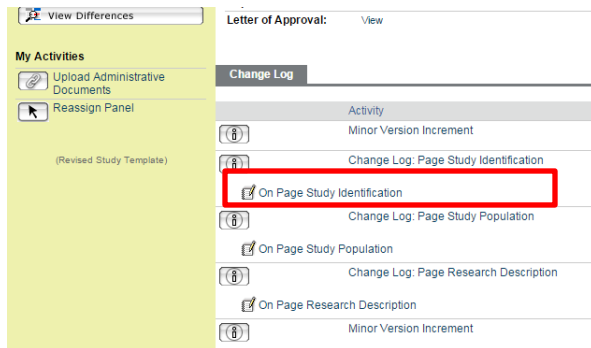
The screenshot shows the IRB system interface. At the top, there is a navigation bar with tabs for ACUP, AIRS, CORES, IRB, SPOT, and REPORTS. Below this is a sub-navigation bar with 'Meetings', 'IRB', and 'Help'. The 'IRB' tab is selected, and a breadcrumb trail shows 'IRB >'. The main content area is titled 'Amendment 4 for IRB Study'. On the left, there is a sidebar with 'Current State' (In Expedited Review), 'Amendment Forms' (View Amendment Cover Sheet, Printer Version, View Differences), and 'Study Forms'. The main form has fields for Principal Investigator, Editors, IRB of Record, Approved Study, Summary of Changes, and Reason for Changes. The 'Summary of Changes' and 'Reason for Changes' fields are highlighted with a red box.

2. Click “View Changes” first

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

This screenshot is a zoomed-in view of the sidebar from the previous image. It shows the 'View Changes' button at the bottom of the 'Study Forms' section, which is highlighted with a red box. Other buttons visible include 'View Modified Study', 'Print-Friendly Study', 'View Differences', 'Printer Version', and 'View Amendment Cover Sheet'.

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.



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

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



Add Document

1. * Document Name:
Trainee CV
2. * Type:
CV/Biosketch
3. * File:
CV >df(0.01 | History)

Log reviewer notes with any changes you want to request

→ If you have requested changes, and have logged reviewer notes

→ Finalize your review as Changes Required to Amendment to send it back to the PI

Finalize Review

Use this activity to finalize your review of this amendment. In the bottom section, you will be able to select your review decision and provide comments.

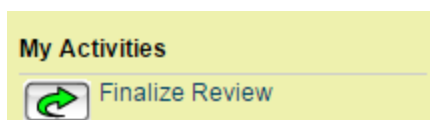
1. * Select Your Review Decision for this Amendment:

Changes Required to Amendment ▼

- Question #2: If changes are requested, then the Criteria for Approval are not met yet and should **skipped**. If the Criteria for Approval are met, the submission is approvable.
- Question #3 – Enter any comments you have for PI, including the fact that you have uploaded any redline documents (if applicable). Otherwise, the PI will not be notified and won't know to look for it.
- Questions #4-8 - Will be automatically filled in from the smart form, these should be checked, but most likely will not require a change. Be very sure you're correct before making a change to these questions.
 - Note: Full board studies remain full board regardless of whether the amendment qualifies for expedited review.
- Question #9 - Upload a redline document to the PI if applicable (refer to initial submission for directions on uploading a redline document)

→ Once the PI has addressed the changes requested, repeat the steps to view differences, and identify if anything else needs to be changed.

→ Once all requested changes have been made and the amendment can be approved, click Finalize review.



Finalize Review

Use this activity to finalize your review of this amendment. In the bottom section, you will be able to select your review decision and provide comments.

1. * Select Your Review Decision for this Amendment:

Approve Amendment ▼

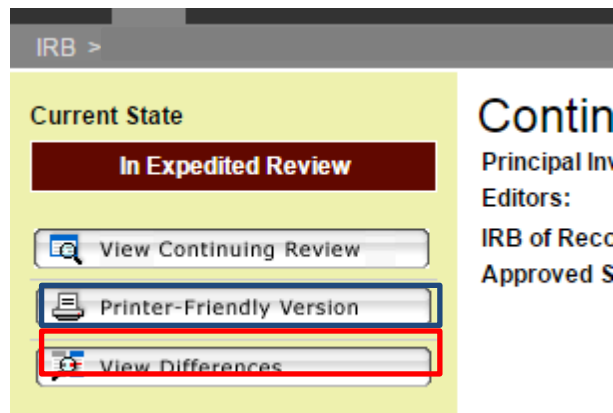
2. Check each of the approval conditions that you have evaluated and evaluate and check off all the criteria in order to approve.

Note: The Finalize Review screen automatically fills with the previous responses, so please make sure to change question #1 to "Approve Amendment." Add all 8 criteria for approval to question #2, and add any comments about your review, or to the coordinator or chair to question #3.

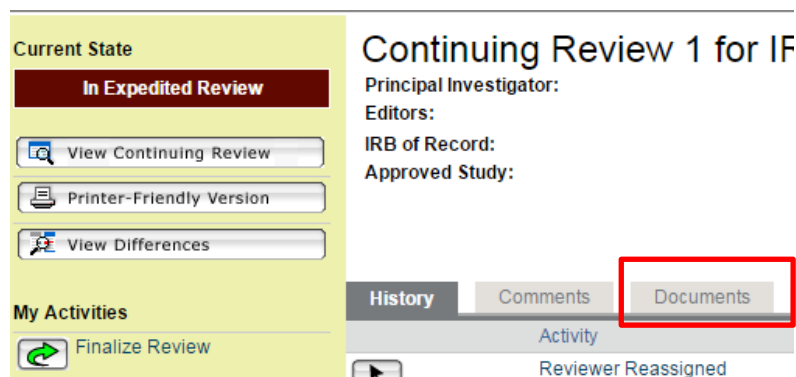
*If new revised documents have been submitted, approve documents as seen in initial submission

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 Review: Click “Finalize Review”
 - a. *Note: Before submitting your finalized review, please refer back to the History Tab for any specific instructions the coordinator may have provide.*
 - b. Fill out the Finalize Review screen.

Finalize Review

Finalize Review

Use this activity to finalize your review of this continuing review submission.

1. * Select Your Review Decision for this Continuing Review:
2. Check each of the approval conditions that you have evaluated and determined to be met. Not all will be applicable, but you must evaluate and check off all the criteria in order to approve.

Add

There are no items to display
3. * Has any information been provided as part of this continuing review that should prompt a change to the informed consent form or other information provided to participants? If yes, you should request that the PI amend the study:

☐ Yes
☐ No

[Clear](#)
4. Comments (will be shown in History Log):

- c. **Changes Required:** Select that option for question #1, and **skip** question #2.

Finalize Review

Use this activity to finalize your review of this continuing review submission

1. * Select Your Review Decision for this Continuing Review:

Changes Required to Continuation

- d. Question 3: If you find issues with the **smartform**, outline these changes in the comments box in the finalize review screen. Ask the PI to submit an amendment with these changes.
- e. Question 4: Refer the PI to your final reviewer notes for specific changes. *These may require an amendment to be submitted.*
- f. **No Changes Required:** If everything is complete, and no changes are required, select “Approve Continuation,” for question #1, “Add” and check off all 8 Criteria for Approval in question #2.

Finalize Review

Use this activity to finalize your review of this continuing review submission

1. * Select Your Review Decision for this Continuing Review:

Approve Continuation

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.



Current State

Committee Member Review

 View Report

 **Printer Version**

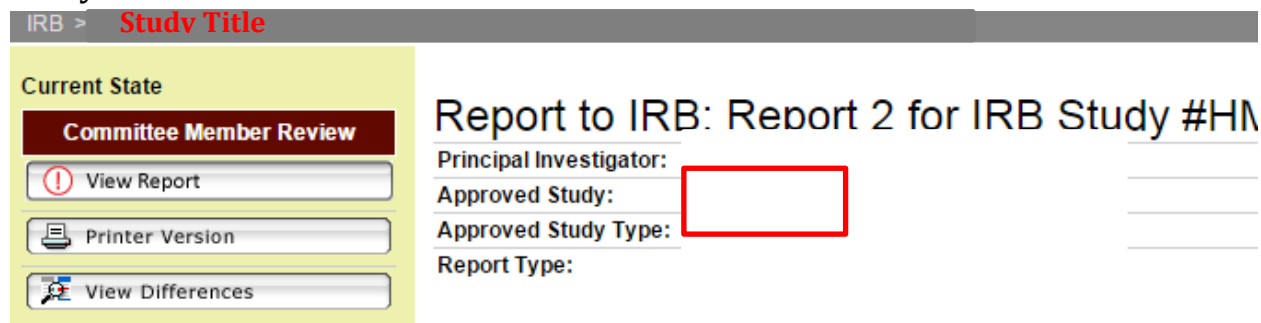
 View Differences

My Activities

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 I 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.





IRB > **Study Title**

Current State

Committee Member Review


 View Report

 **Printer Version**

 View Differences

Report to IRB: Report 2 for IRB Study #HM

Principal Investigator: _____

Approved Study:  _____

Approved Study Type: _____

Report Type: _____

5. Finalize Review

* *Before you finalize your review, check to see if the PI already submitted an amendment related to this report. If not, and an amendment **is** required, say “Yes” to question 2.*

- **Changes Required**
Finalize Review

Use this activity to finalize your review of this report.

Review Notes: If this meets the criteria of an Unanticipated Problem, select *Refer to Full Board* as your decision. If it does not meet the criteria of an Unanticipated Problem, select *Acknowledge* as your decision. If you need additional information to make your decision, add Reviewer Notes to the applicable sections and select *Changes Required to Report* as your decision.

1. * Select Your Review Decision:

Changes Required to Report ▼

2. * Is an Amendment to the approved study required before this report is resolved?

☐ Yes ☐ No

*Once changes have been addressed, click “View Differences” to see the changes that were made, or look at the reviewer notes tab to see the response the PI provided. *With reports, it is more likely that changes are not made within the report form, but the PI responds to*

The screenshot displays the 'Finalize Review' interface. On the left sidebar, under 'Current State', the 'Committee Member Review' section includes buttons for 'View Report', 'Printer Version', and 'View Differences' (the latter is highlighted with a red box). Below this, the 'My Activities' section shows a 'Finalize Review' button. On the right, a horizontal tabbed interface contains 'History', 'Comments', 'Documents', and 'Reviewer Notes' (the last tab is highlighted with a red box). Below the tabs is an 'Activity' section.

- **No Changes Required:** Once you’re ready to make a determination of approval, click “Finalize Review” again, read the instructions and WPP to determine if the report should be referred to Full Board*, or “Acknowledge”** and click OK.

*If you refer to the Full Board, you will likely be assigned as a reviewer, so be prepared to finalize your review again with Full Board comments.

**If a report is “Acknowledged,” the PI will get an automatically generated letter informing them of the determination.

CLOSURE

Before completing a Study Closure, consider if anything needs to be done before the closure to protect human subject. (Example: If the study is closing early, do subjects need to be notified?)

1. Click “Complete Study Closure” and fill out pop-out screen.

The screenshot displays the IRB system interface. On the left, a sidebar titled 'My Activities' lists various actions, with 'Complete Closure Review' highlighted by a red box. The main content area shows the 'Study Closure for IRB Study' page, which includes fields for 'Principal Investigator:', 'Editors:', 'IRB of Record:', and 'Approved Study:'. Below these fields are tabs for 'History', 'Comments', and 'Documents'. The 'Complete Closure Review' form is a pop-out window that prompts the user to 'Review this closure submission and click OK below.' It contains two main sections: '1. * Select Your Review Decision for Closure:' with a dropdown menu, and '2. Comments (will be shown in History Log):' with a large text area. At the bottom right of the form are 'OK' and 'Cancel' buttons.

- When a closure is acknowledged, the PI gets an automatically generated letter informing them of the closure.
- If a closure should be referred to the full board, consult the Chair & IRB staff for instructions. Do not finalize the review.