VIRGINIA COMMONWEALTH UNIVERSITY

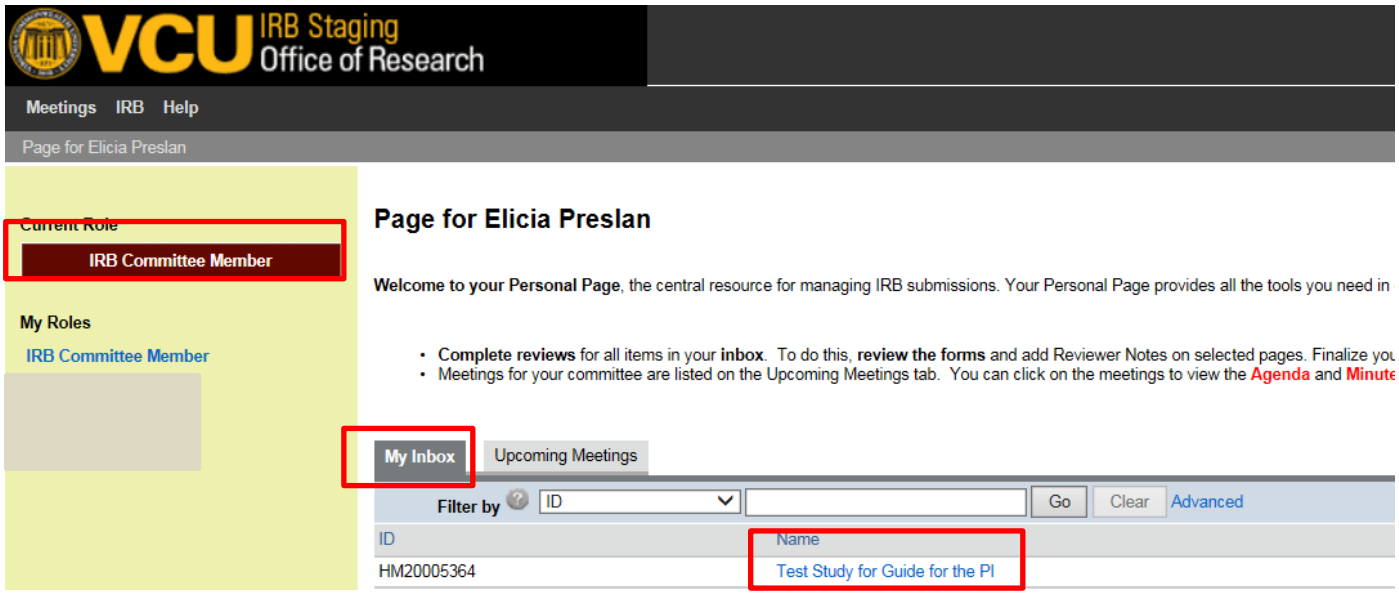
VCU Office of Research and Innovation

RAMS-IRB for Expedited Reviewers

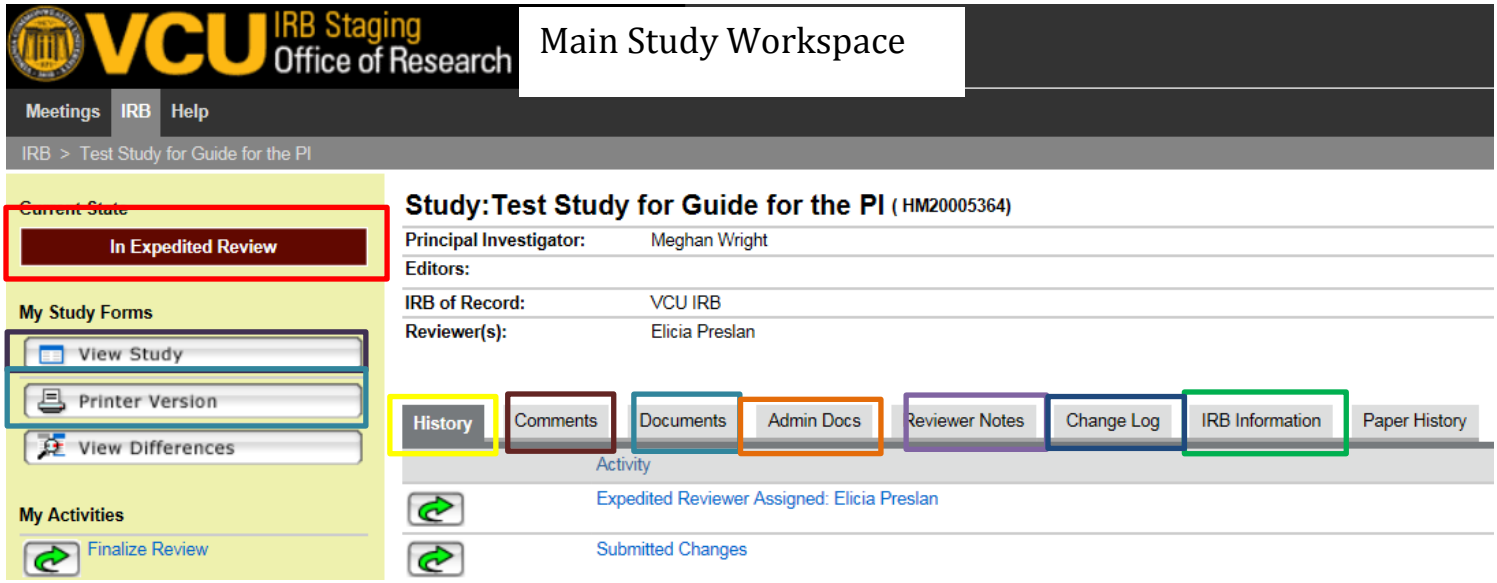
Virginia Commonwealth University
Office of Research and Innovation
BioTech 1 Building, Suite 3000
800 East Leigh St.
PO Box 980568
Richmond, VA 23298
(804) 828-0868

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.



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



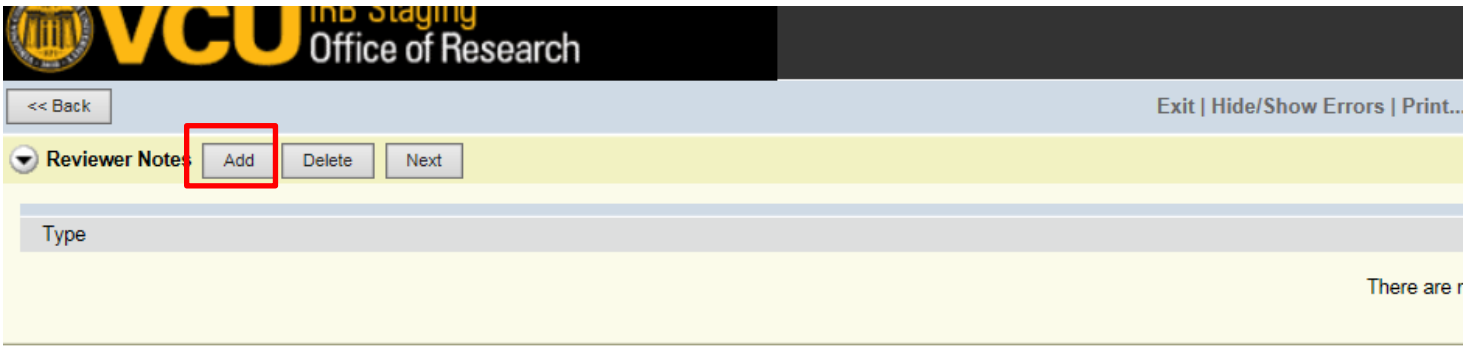
- Current State: You will see the study is in Expedited Review by the maroon "Current State" box
- Click "View Study" to read through the smartform and add reviewer notes. The smartform are the questions answered to create the submission.
- Click "Printer Version" to view a printer-friendly version of 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

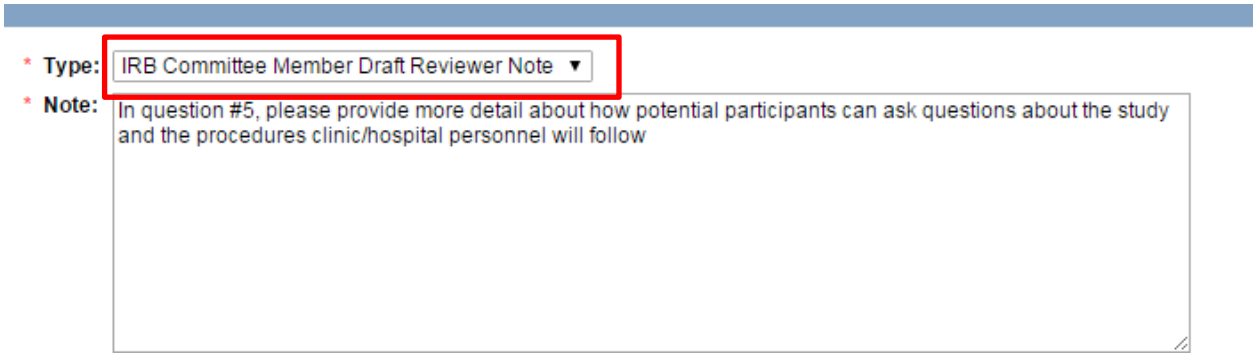
- Click on the **title of the study** to access the study. Click "View Study" to be able to add reviewer notes.

ADDING REVIEWER NOTES

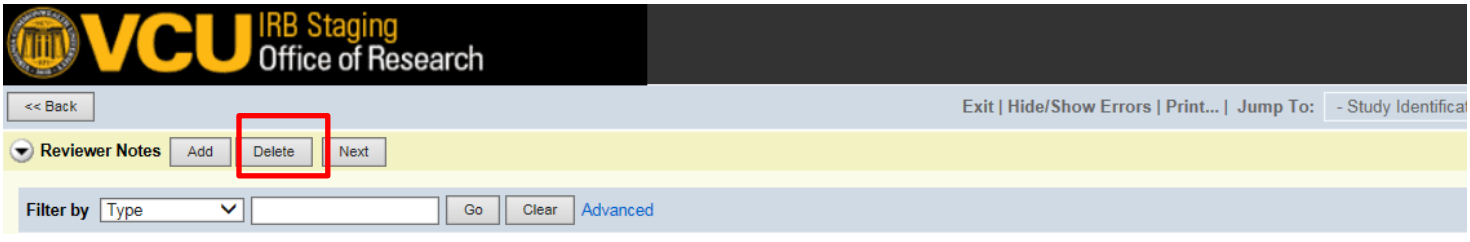
- If you want to request a change, add a reviewer note by clicking "Add"
- You can jump between notes by clicking "Next."



- 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.

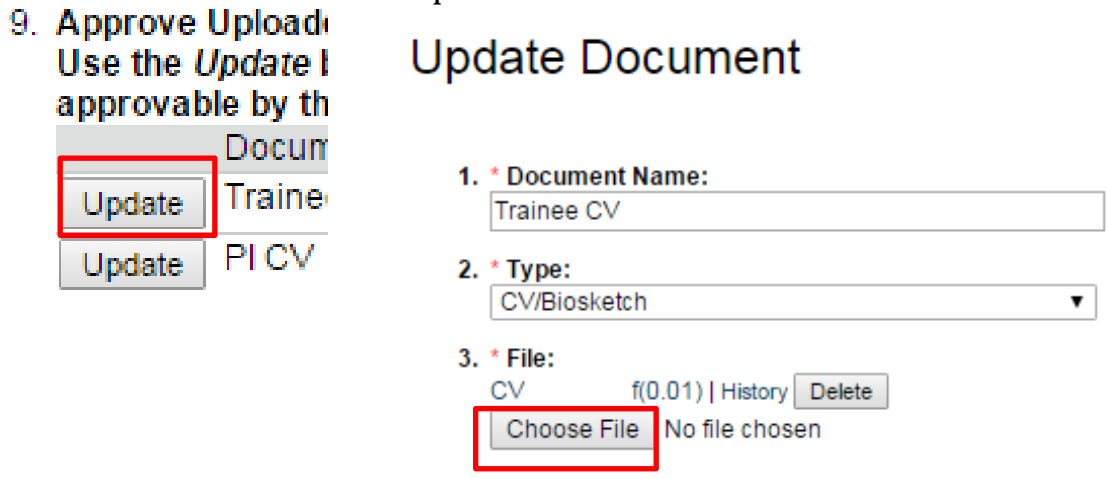


- To delete a note, click "Delete" and find the note by time posted.



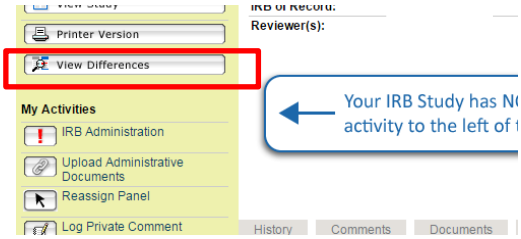
- When you are done adding reviewer notes, go back to the submission workspace by clicking the "Exit" button.
- Your change requests should be done as reviewer notes, but if you have general questions, you can also contact the PI by logging public comments.
- To send the study back to the PI for changes, 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"

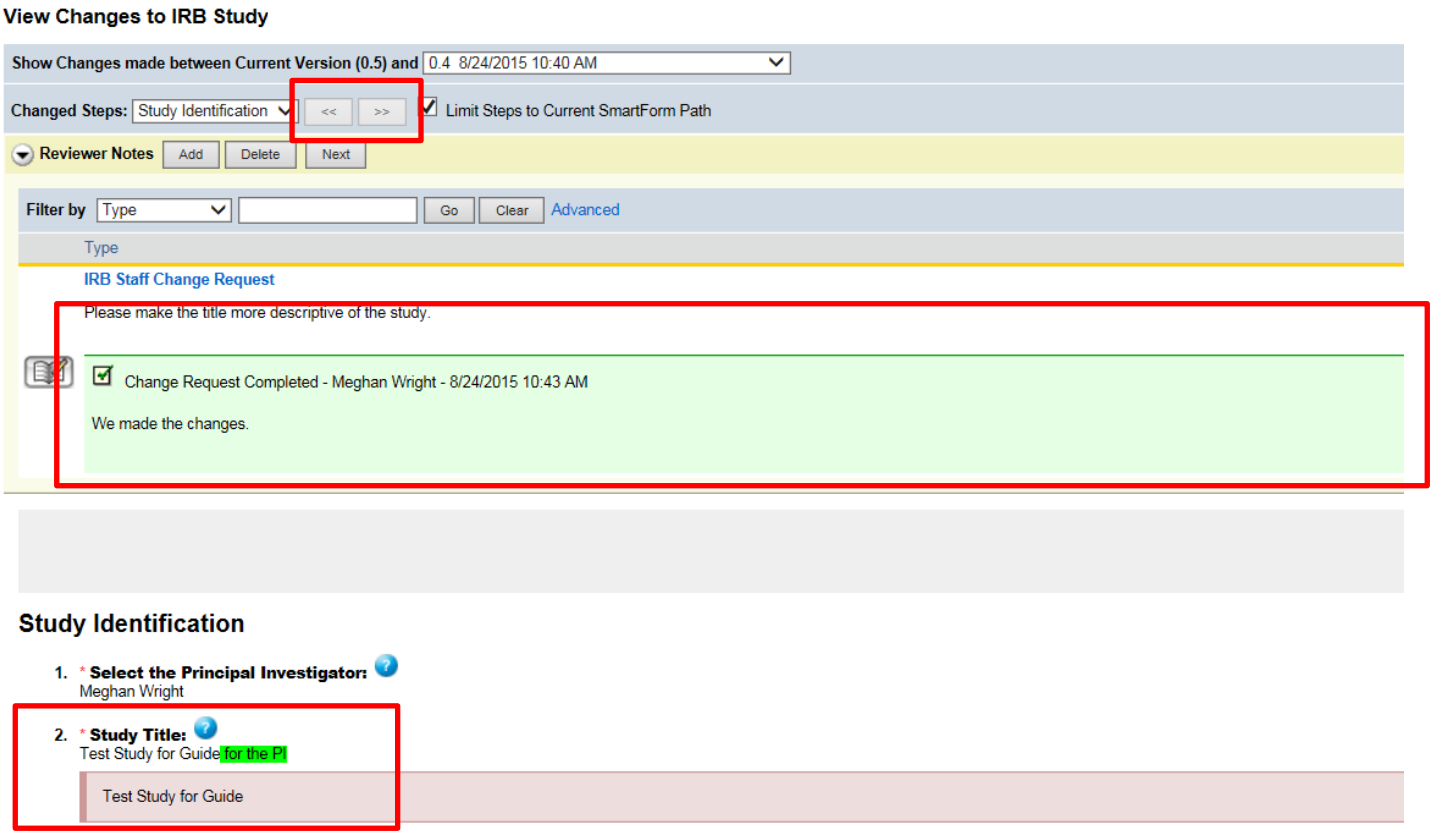


VIEWING CHANGES

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

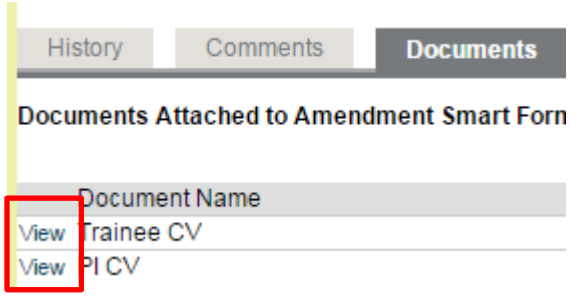


  - In the green response to every reviewer note, you will be able to see the PI’s comments.
    - Any differences in the smartform responses will appear in green highlighting (New/added text) or red (Old text) within the form.
  - If there were multiple revised pages of the smartform, click >> to go to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

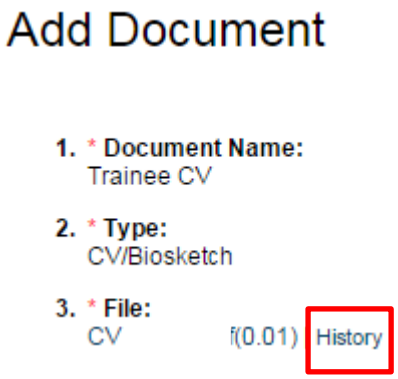


VIEWING DOCUMENT CHANGES

- 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



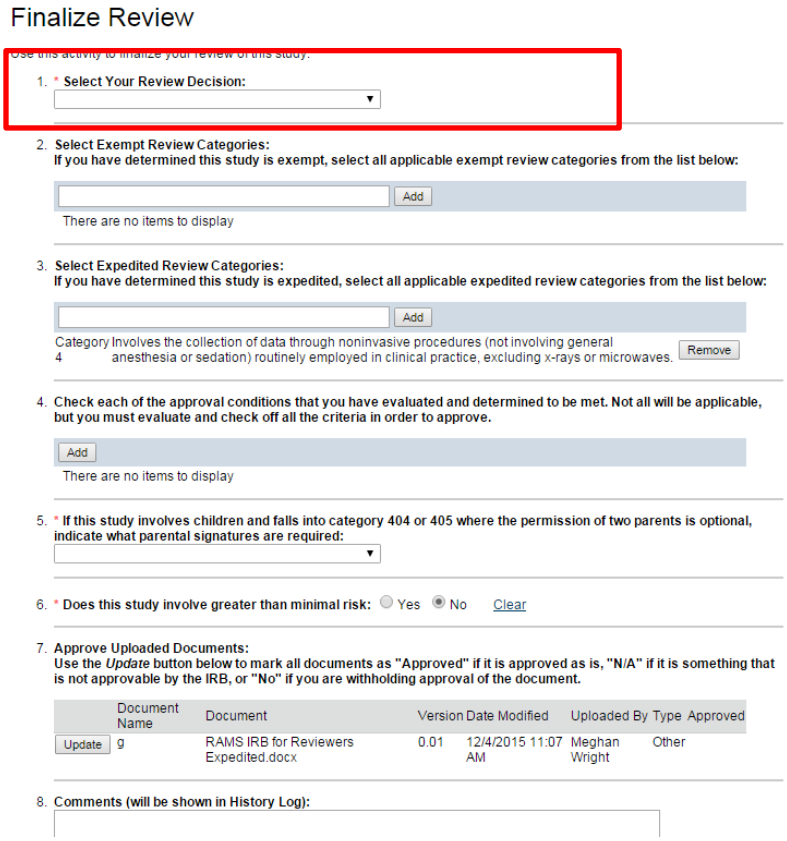
- Click "HISTORY" and you will be able to see all revisions, including red-lined documents.



- 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.



- 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:

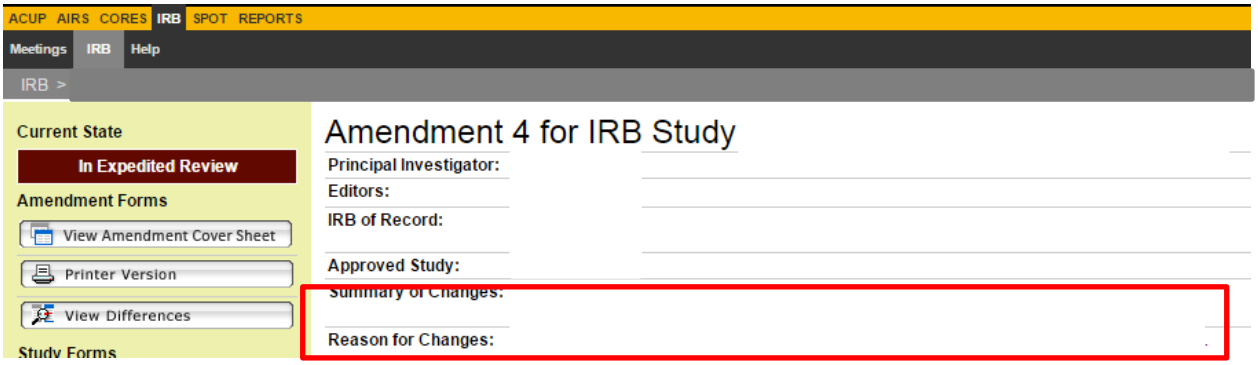
Guidelines to approving, not approving, or not applicable documents:

Approved "Yes"	o The IRB approves the content of the document. o Document or content of document is in the scope of IRB review. Examples: ▪ 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: o Standard consent forms o Information sheets o Research measures IF they contain a consent element
Not Approved "No"	o The IRB does not approve the content of the document. o Document or content of document outside of IRB purview. o Any time any option other than NO could cause confusion to anyone viewing document list. Examples: ▪ 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"	o Considered as part of the review (within scope) but document or content management outside of control of PI or IRB. o Acknowledged by the IRB. Examples: ▪ HIPAA standalone authorization forms ▪ OSP Approval Form ▪ Funding Proposals where congruency not reviewed ▪ Required ancillary committee review letters: o PRMC o DSMB reports o Radiation Safety Committee ▪ References/literature, tables, figures ▪ FDA documents o IND/IDE documentation from FDA/Sponsor o Forms 1572, 482, 483, 3500, etc. o Drug/device brochures

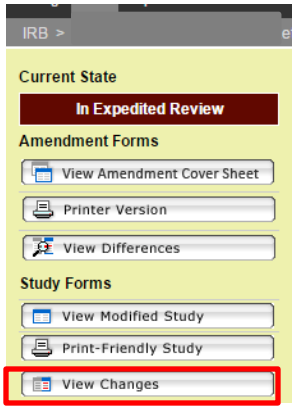
AMENDMENTS

- 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 approves as is, until the amendment is approved and changes are applied.

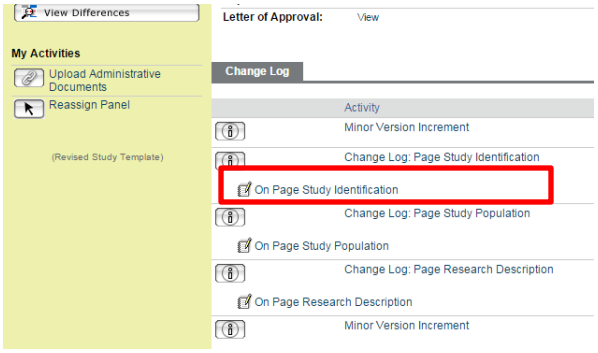
1. First, look at Reason for Changes & Summary of Changes

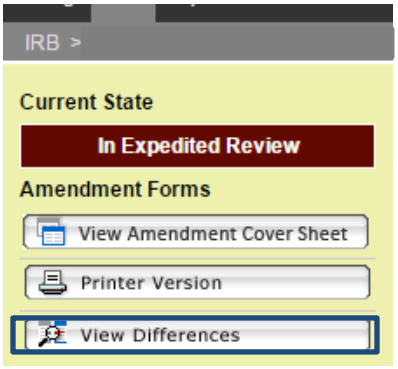


2. Click "View Changes" first
    a. Note: "View Differences" refers to strictly the differences in the amendment ***cover sheet.***

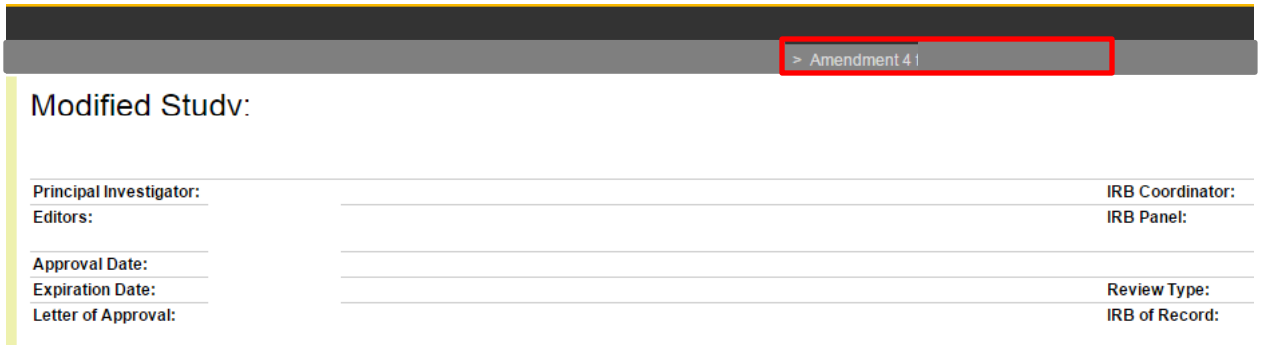


3. To view the specific changes to the smartform, either click "View Differences" or click on each individual change in the change log. "View Differences" is best used when there are many changes. Those changes will be highlighted, as with an initial submission.

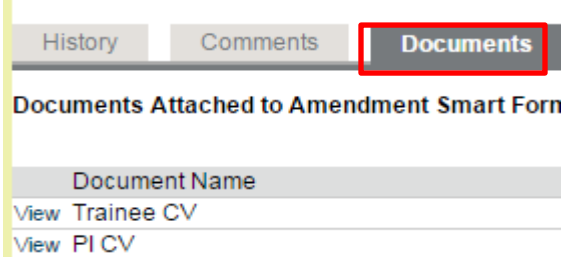


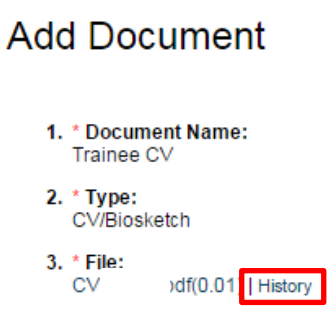


To get back to the Amendment workspace, click "Amendment __" in the top gray bar.



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

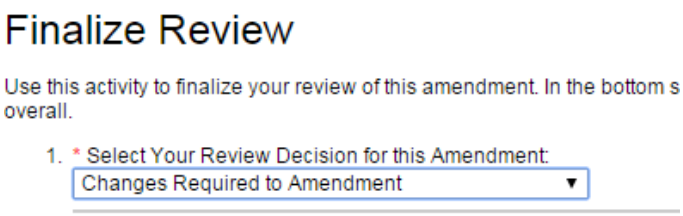




Log reviewer notes with any changes you want to request

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

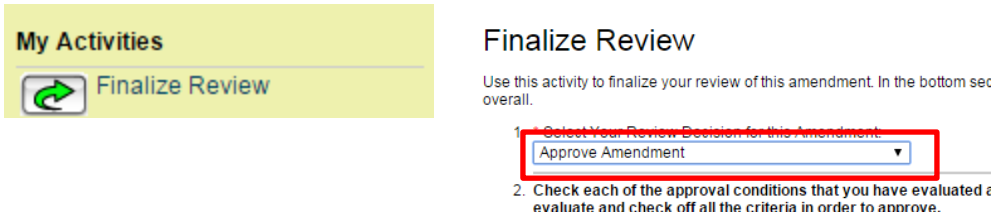
→ Finalize your review as Changes Required to Amendment to send it back to the PI



- *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.



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.

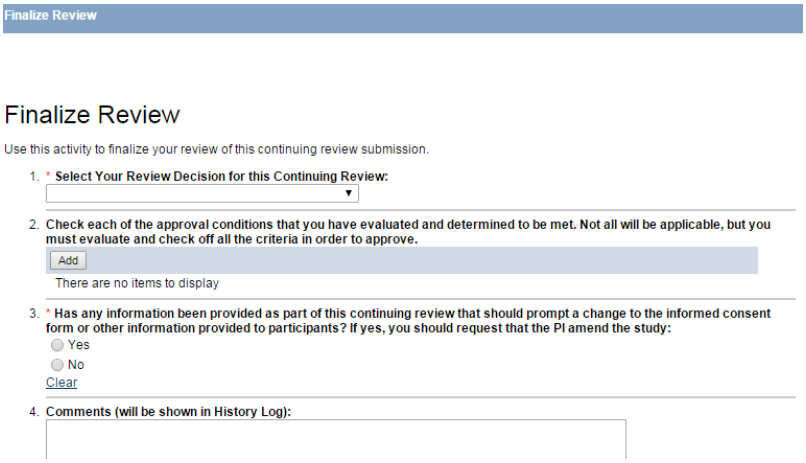
*If new revised documents have been submitted, approve documents as seen in initial submission

CONTINUING REVIEW

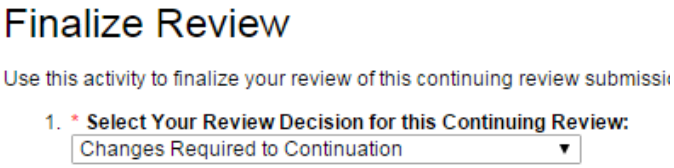
1. Initial Read-Through - To read the continuing review submission initially, click "Printer-Friendly Version" – this is easier to read all at one time.
2. If you have questions and need to log a reviewer note, then click "View Continuing Review." Reviewer Notes: Refer to the process indicated in the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

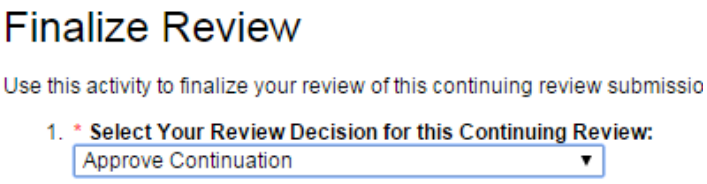
4. Read through the currently approved smartform (full study submission) to make sure that the Criteria for Approval are still met given the information provided in the continuing review.
5. If you find issues with the **Continuing Review** information, you will need to send it back to the PI for modification.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



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



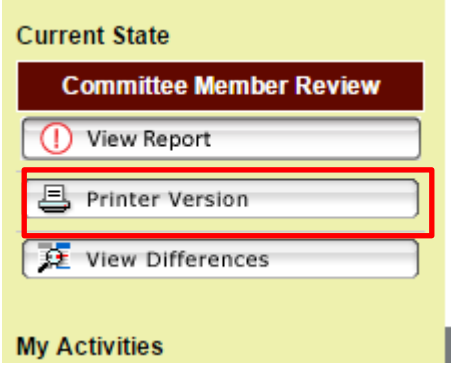
   d. Question 3: If you find issues with the **smartform**, outline these changes in the comments box in the finalize review screen. Ask the PI to submit an amendment with these changes.
   e. Question 4: Refer the PI to your final reviewer notes for specific changes. *These may require an amendment to 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.



REPORTS

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

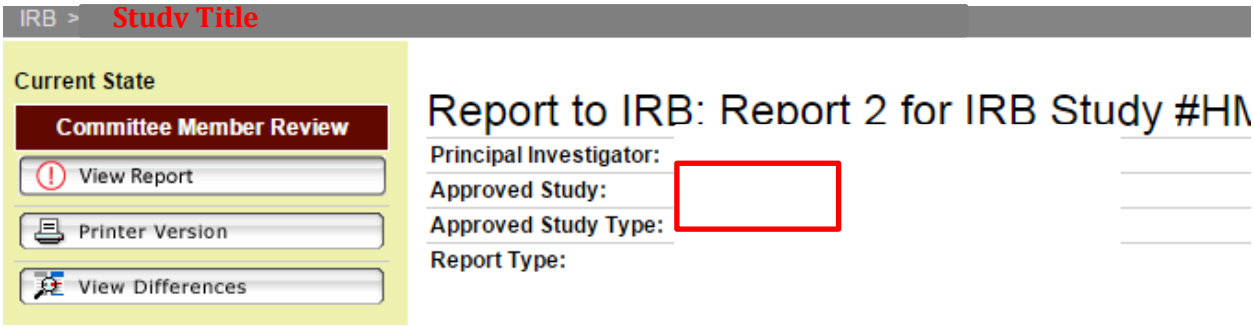
1. Click Printer Version – to view the report all on one page.



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.

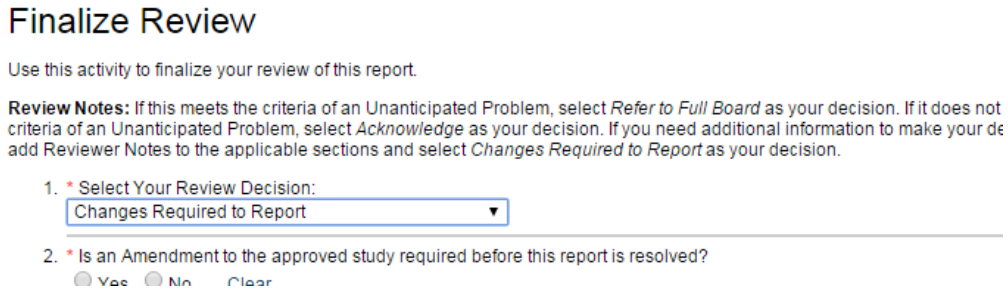
4. Read Smartform: Go back to the approved smartform (click on the study title I the gray bar) and read through the study to make sure that the PI's proposed changes will adequately address the changes that may be needed in the overall study.



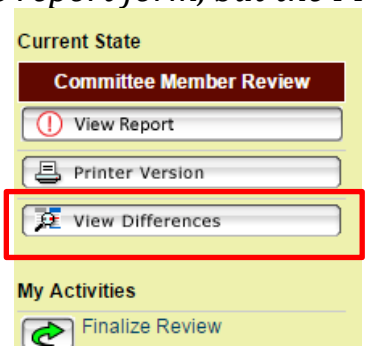
5. Finalize Review

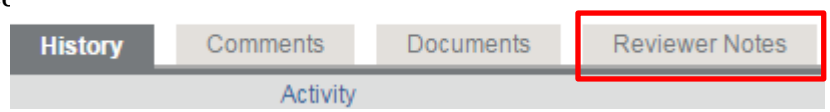
* *Before you finalize your review, check to see if the PI already submitted an amendment related to this report.* If not, and an amendment **is** required, say "Yes" to question 2.

- Changes Required



*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 t*





- 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.

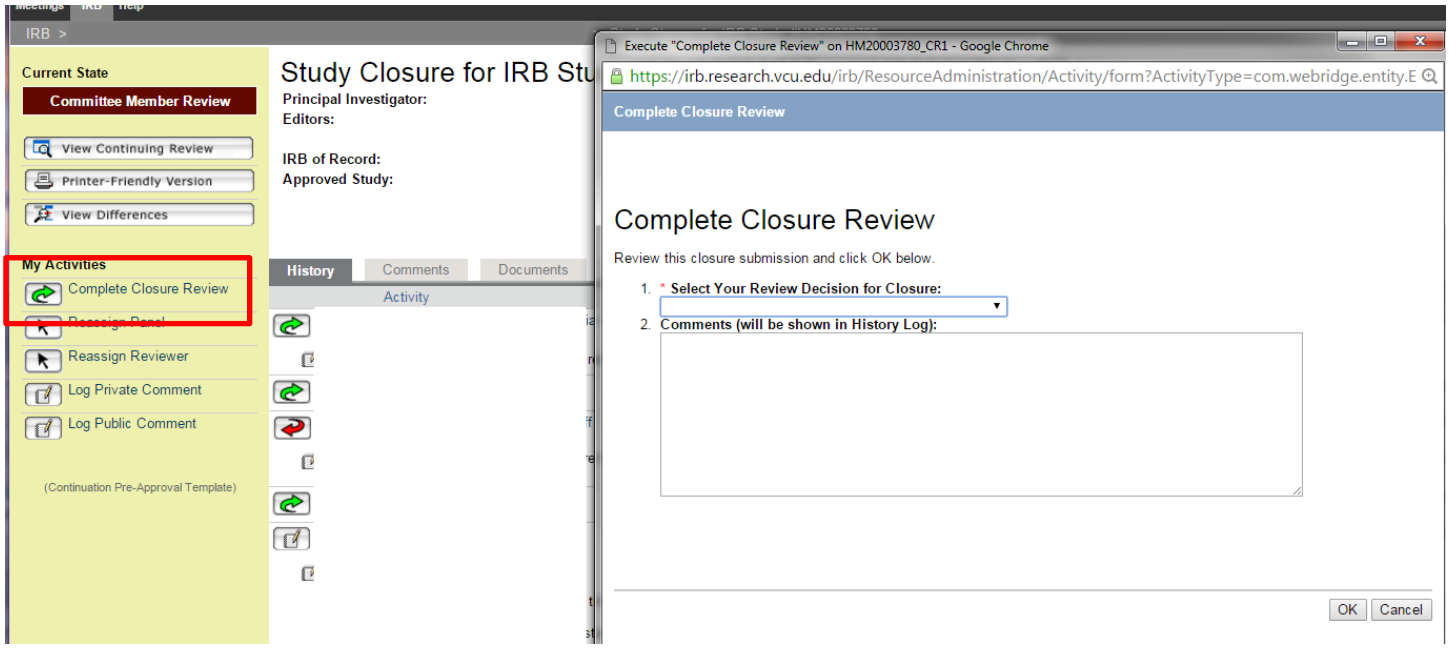
*If you refer to the Full Board, you will likely be assigned as a reviewer, so be prepared to finalize your review again with Full Board comments.

**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.



- 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 no finalize the review.