RAMS-IRB for

Full Board

Reviewers

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."

Main Study Workspace

- 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.
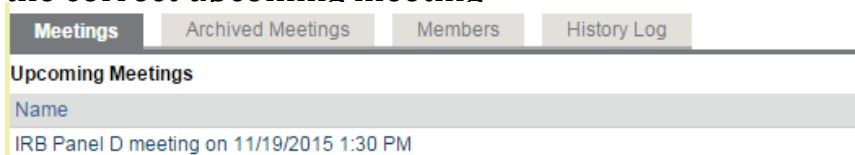
MEETING WORKSPACE & ATTENDANCE

- Before the meeting, you will want to log your attendance and view the electronic agenda.
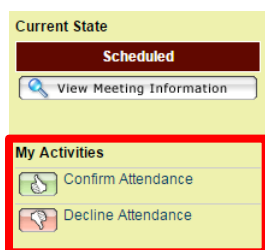
    1) Click "Meetings" in upper left hand corner of screen.
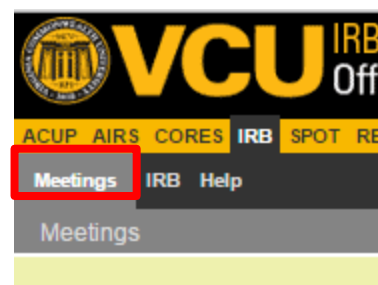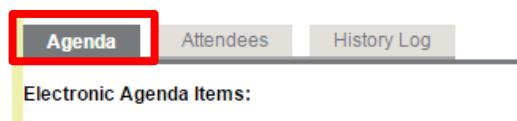

    Click the correct upcoming meeting

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

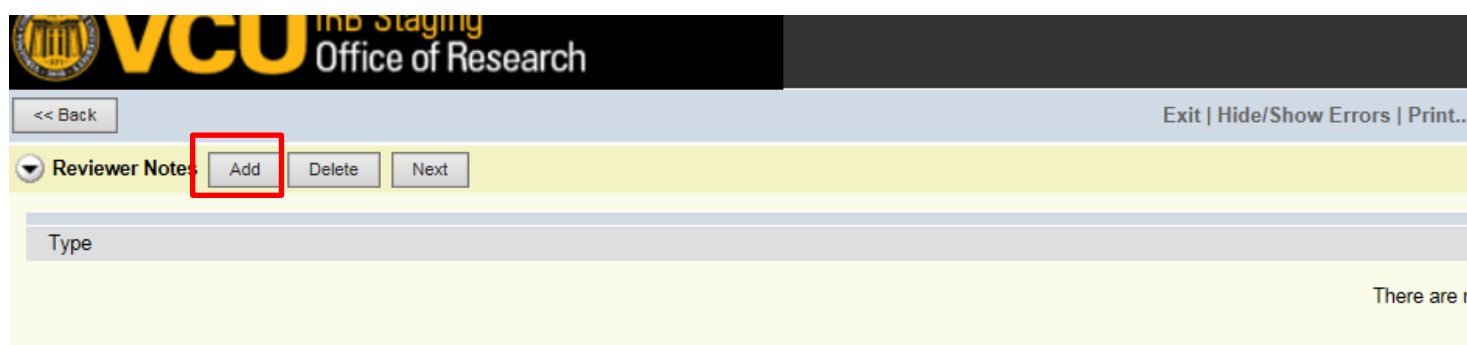   3) To view the meeting agenda, click the "Agenda" tab.

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.
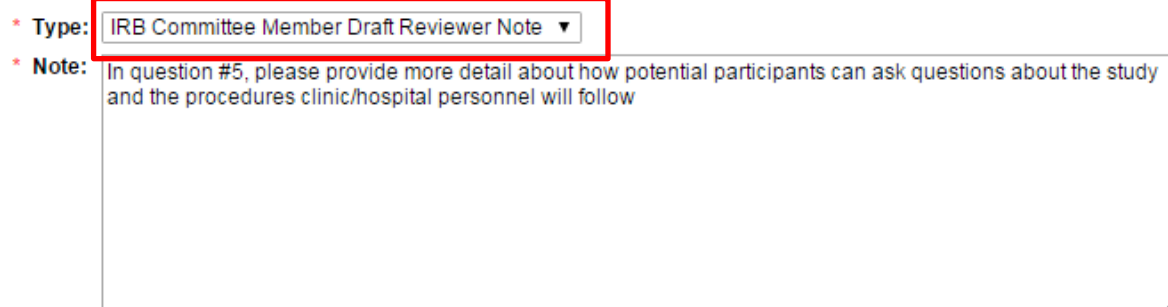
ADDING REVIEWER NOTES

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

- 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.
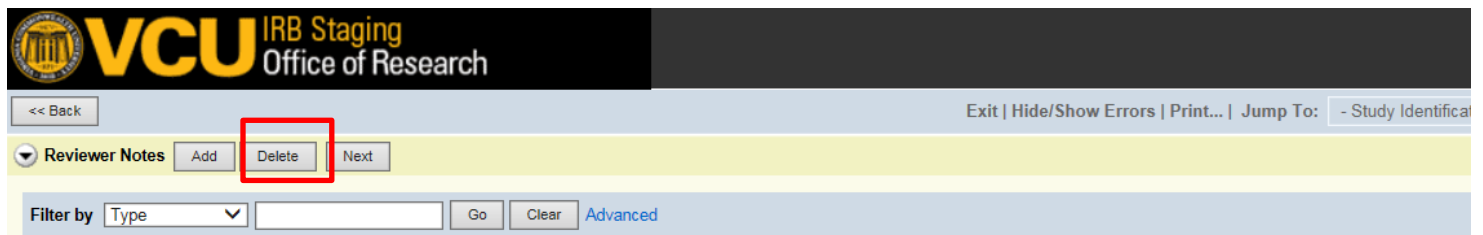
- When you are done adding reviewer notes, go back to the submission workspace by clicking the "Exit" button.
- Your change requests should be done as reviewer notes, but if you have general questions, you can also contact the PI by logging public comments.
- The PI will be able to see your reviewer 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.
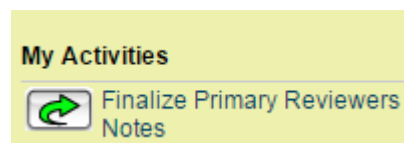
- In the blank box, you should be adding the information to be displayed and discussed at the meeting, such as a summary, if the criteria for approval are met, if the study involves vulnerable populations, risk determination, recommendation etc.

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.
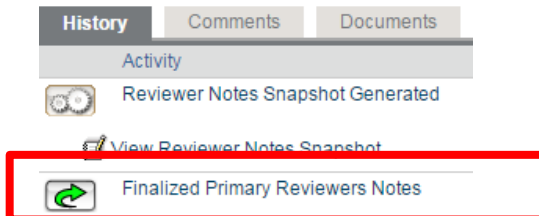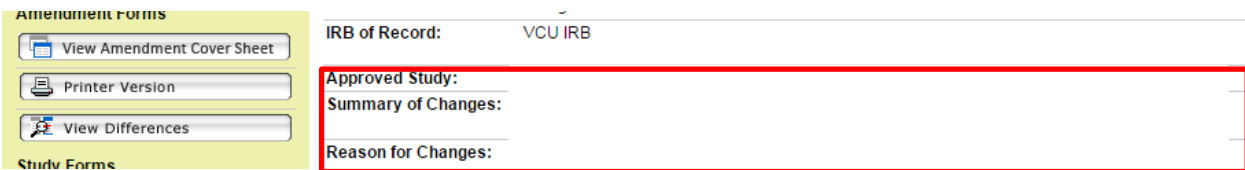

POST MEETING

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

1. First, look at Reason for Changes & Summary of Changes
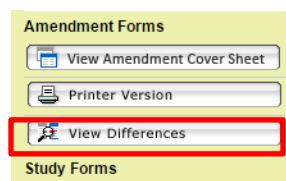
2. Click "View Changes" first
   a. Note: "View Differences" refers to strictly the differences in the amendment *cover sheet.*

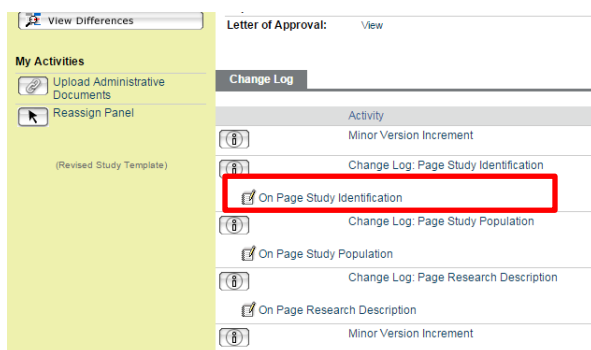3. To view the specific changes to the smartform, either click "View Differences" or click on each individual change in the change log. "View Differences" is best used when there are many changes. Those changes will be highlighted, as with an initial submission.
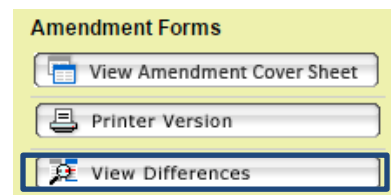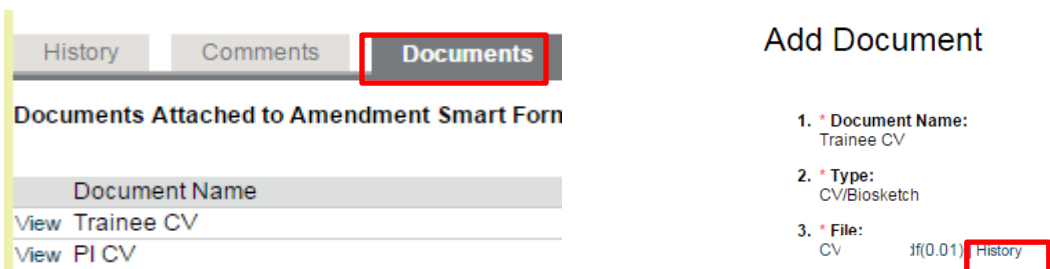
To get back to the Amendment workspace, click "Amendment __" in the top gray bar.

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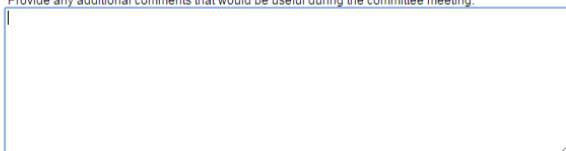
5. Log reviewer notes with any changes you want to request.
6. Finalize your review by clicking "Finalize Primary Reviewer Notes"

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.
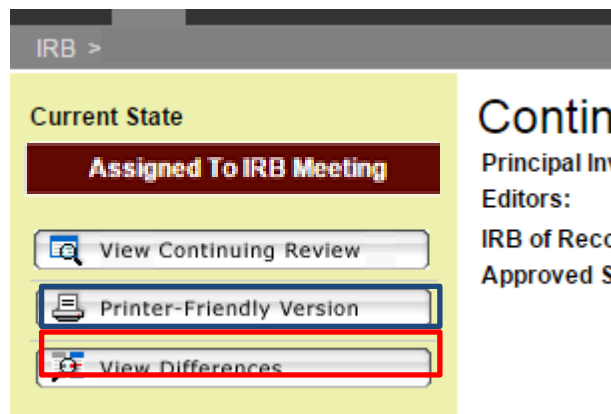

3. Review Documents – Once you're done viewing the form, you will need to look at the documents by clicking on the documents tab of the continuing review workspace.
   a. Open each document and read them for informational purposes. There is no need for further action unless you have a question, in which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

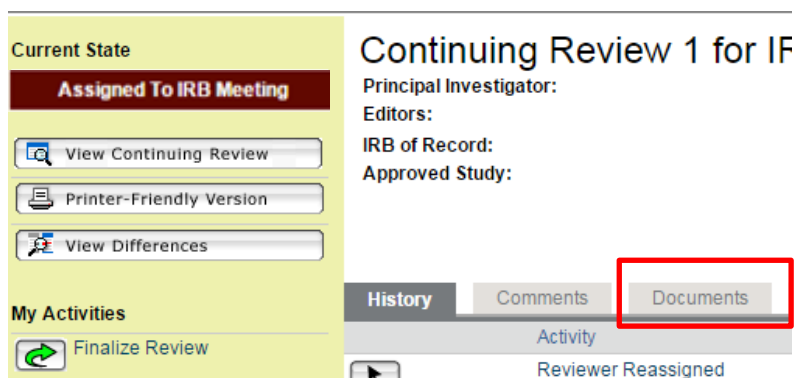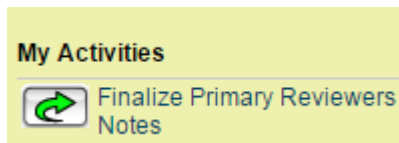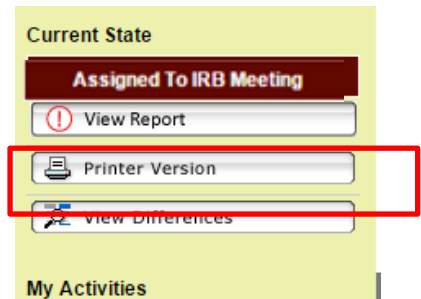1. Provide any additional comments that would be useful during the committee meeting:

My Activities

Finalize Primary Reviewers Notes

REPORTS

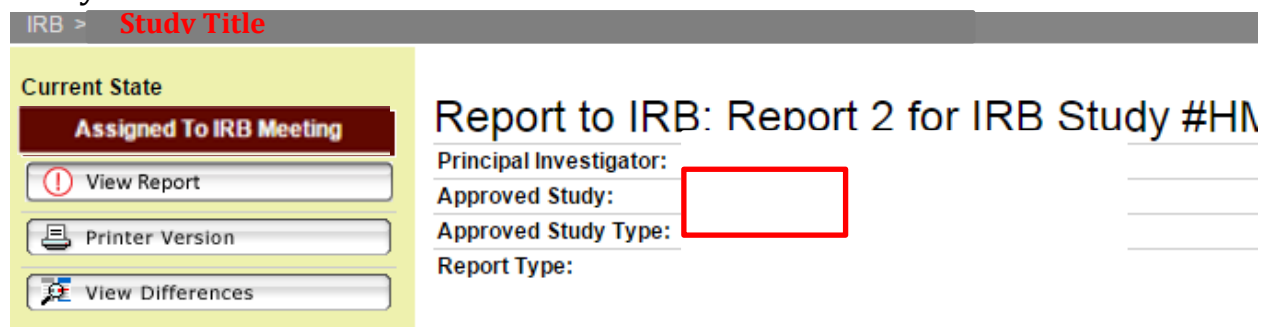*Reviewers are less likely to see reports – most reports get assigned to chair, but procedures are panel specific.

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.
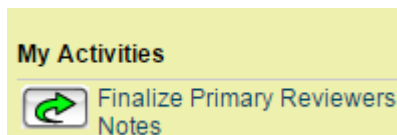

7. Finalize your review by clicking "Finalize Primary Reviewer Notes"

CLOSURE

If a study closure requires a full board decision, the assigned reviewer will be notified by the IRB staff, and may be a 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.