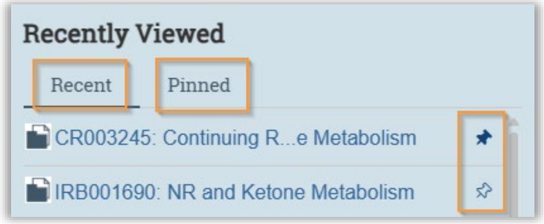
IRB Tip Sheet: PROTECT Tips for IRB Members

How to find Actions for upcoming IRB Meetings:

✓ *Using your personal Dashboard*

- **Recently Viewed List (Left Hand Side of Dashboard)**
  - **Recent:** This is a list of all recently reviewed submissions.
  - **Pinned:** You can pin submissions here to make an easy to access list.

You can pin your submissions here for a meeting so you can come back to them easily until the meeting is over. You will them have to remove them manually if you no longer want to see them and update the list for the next meeting.



✓ *Using your Inbox and your My Review Tabs on your Dashboard*

- **My Inbox:** This tab lists any in-process submissions where you are on the Study Team along with any submission where you have been assigned as a Primary or Secondary Reviewer. The rest of the submissions from your IRB meetings will *not* appear here.
- **My Reviews:** This tab will list any submission where you have been assigned as a Primary or Secondary Reviewer. The rest of the submissions from your IRB meetings will *not* appear here.

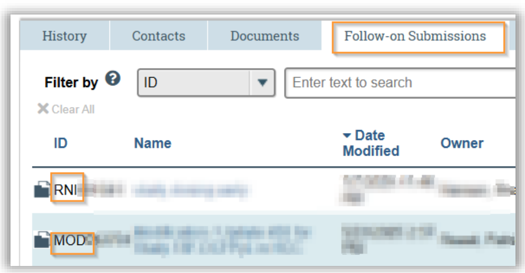
✓ *Finding your Meeting*

- Select the main **IRB** tab, **Meetings** subtab, and then find your meeting on the list of Upcoming Meetings.
- Select the Meeting you have signed up to attend.
- The submissions to be reviewed at the meeting are listed as Agenda Items.
- You can also view here the list of other Attendees and any supporting documents that are related to the overall meeting.

Viewing the life of a Study in PROTECT

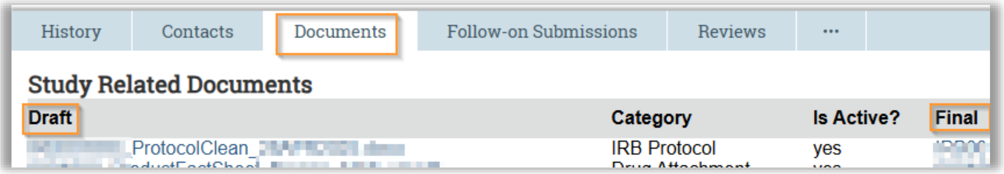
✓ *Main Study Page and viewing Follow-on Submissions*

- **Main Study Page is made at the Initial Review (IRB########)**
  - The Main Study Smart Form is made at Initial Review (IR) and may be modified after approval only by a MOD Follow-on Submission.
  - The History Tab of the Main Study page captures the life of the protocol including the IR and then links to each Follow-On Submission.
  - Follow-on submissions include MODs, MODCRs, and RNIs:
    - These can be more easily viewed in the Follow-on Submissions tab since each Follow-on Submission is accessed by one link.
    - You can then use the link for each submission to open a new tab for viewing.



You will not be able to view RNI forms that were not sent to the NIH IRB side of PROTECT unless you are an RCRC member or OHSRP staff. The RCRC side of PROTECT and the NIH IRB side of PROTECT are separate. You will need to request of copy of the RNI from the analyst.

- ✓ *Reviewing the Documents Tab*
  - **All documents can be found in the Documents tab: Protocol, Consents, Recruitment Materials, Surveys/Questionnaires, etc.**
    - The most recent **Draft** of the document is always listed in the far-**LEFT** column. The last approved version of the document is listed to the **RIGHT** under the **Final** column.

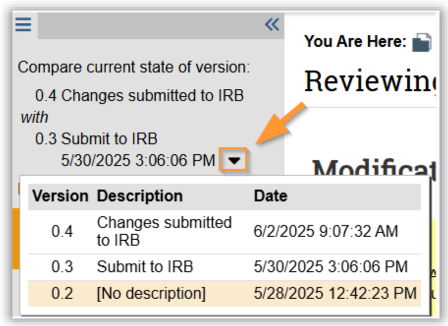


    - A link to every version of the document is listed to under the Document History column.

When comparing a document that has changed during a submission, you should always make sure to compare the most recent Draft to the last IRB approved version. Using the Documents tab makes it easier to check that you are comparing the correct version of the documents.

Finding information in your assigned Submission

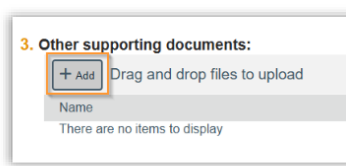
- ✓ *Review changes to the study made by the Study Team in the submission's PROTECT Smart Form*
  - In the upper left corner of any Smart Form, there is the option to "compare the current state of version" of the Smart Form to the most recent IRB approved version of the Smart Form.
  - If the submission was previously sent back to the Study Team to make changes, every time they did so a different version of the Smart Form would have been produced. The version on the bottom of the list will always be the last approved version of the Smart Form.



You can flip through the versions so see what changes the team made. However, only by comparing to the bottom version will you see the final changes that were made.

- ✓ *Reviewing the History Tab of Submissions*
  - Some information related to your review may not be in the Submission Smart Form. Instead, it may only be in the History Tab and will still need to be reviewed.
  - This includes the Pre-Review analyst notes, Pre-Review Clarification Requests and Responses, Added Comments from the Study Team, and Private Comments and Review Comments from other IRB members or analysts.

- ✓ *Enter reviewer notes into the system using the "Add Review Comments" activity*
  - If you are an assigned reviewer, enter a review comment even if it only states that you have no concerns.
  - Any IRB members that are not the assigned reviewer for a submission should also enter a review comment if they have any concerns. If not, they are welcome to add a review comment stating they have no concerns but are not required to do so.
  - Any proposed edits to the protocol, consent, or any other research documents can be attached to your review comment under "other supporting documents." The changes should be made to the document using the "tracked changes" function.



Providing your edits in a timely manner allows the IRB chair and IRB analyst time to review and compile any concerns. This also allows them time to contact the PI if additional information is needed. The goal is to address questions and concerns before the meeting and then approve the submission at the meeting whenever possible.