Human Ethics
Manual for Reviewers

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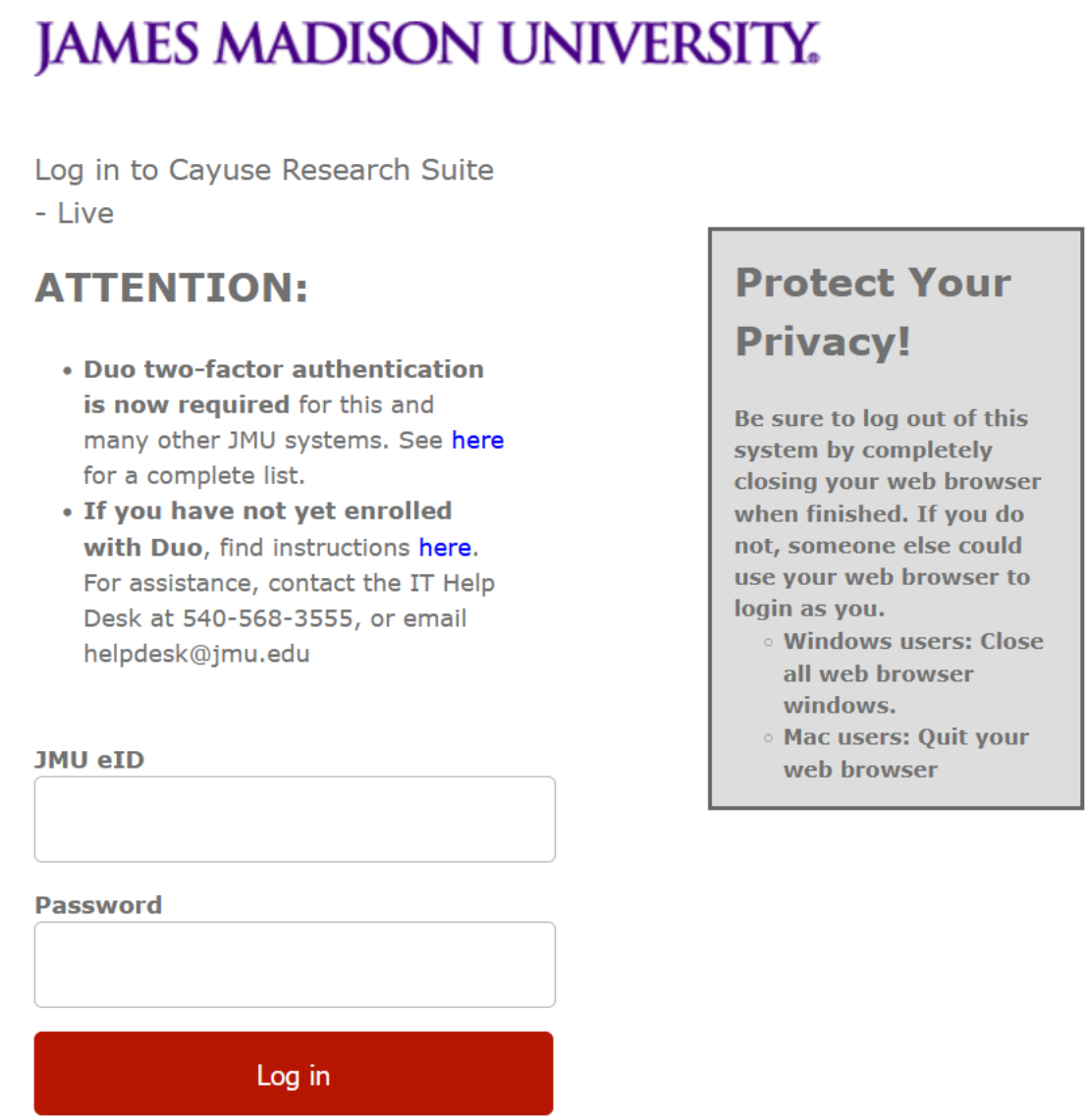
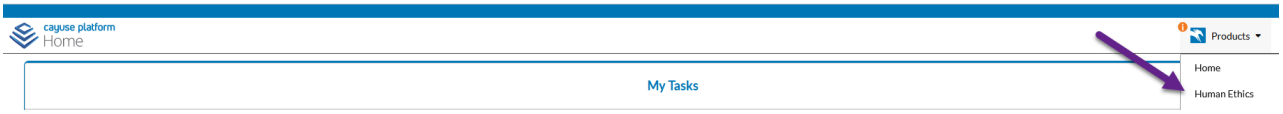
Table of Contents

Accessing Cayuse

To access Cayuse Human Ethics, go to https://jmu.app.cayuse.com/ and login with your JMU eID and password via Duo.

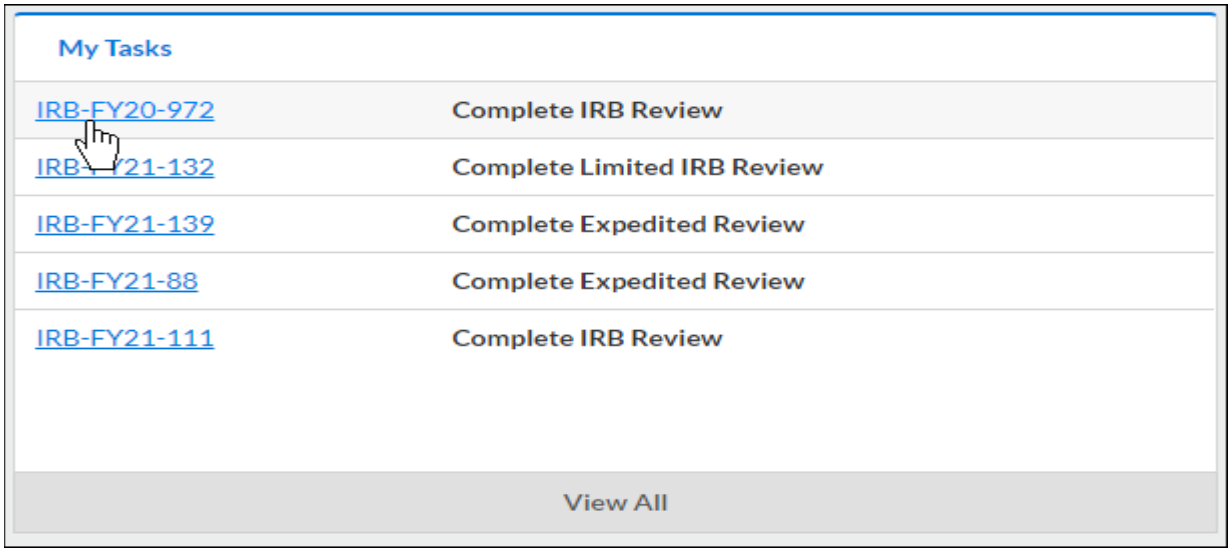


Under Products, click on Human Ethics:

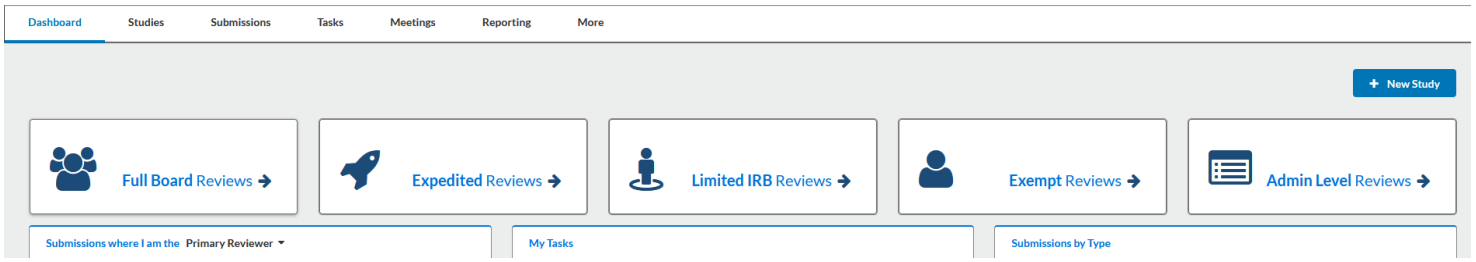


Reviewing as a Board Member in Human Ethics

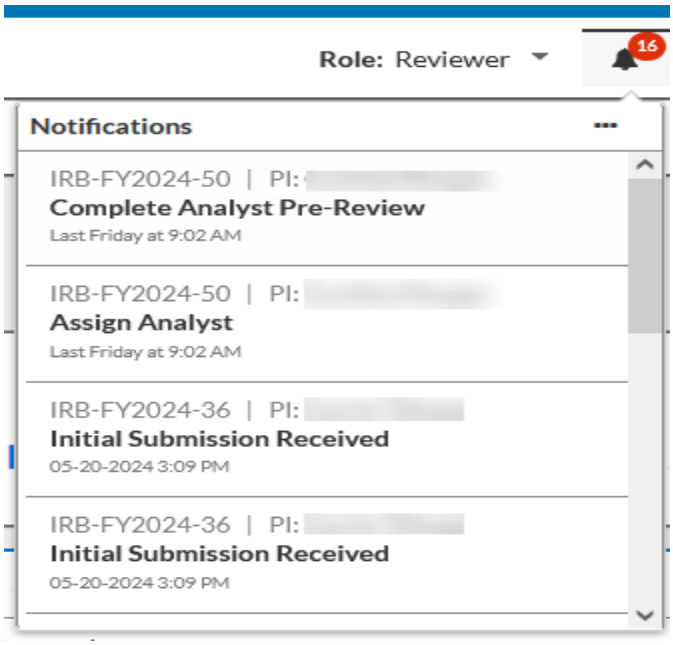
As a Board Member, you may need to log in to Cayuse Human Ethics in order to access a submission, which you'll see in the **My Tasks** widget on your dashboard.



Another way to access submission by review types is to click on the review type at the top of the dashboard:



You can also check your notifications:



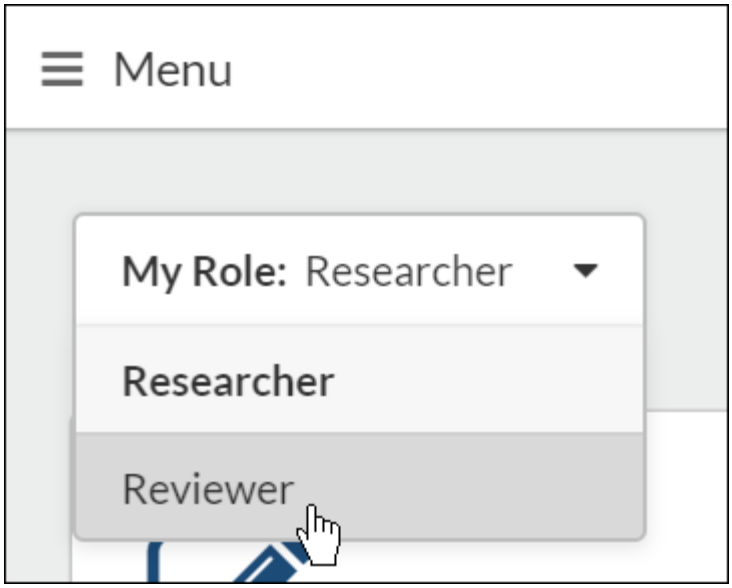
Types of Submissions

- **Initial:** This is the first submission that a PI creates when they enter a new study in the system.
- **Modification:** A PI has amended an approved protocol.
- **Renewal:** A PI wants to continue the study past the expiration date. These are approved by ORI unless the PI is requesting changes to the research.
- **Incident:** Adverse events, unanticipated problems, and protocol violations submitted by the PI.
- **Legacy:** Used for studies imported from the previous system. The legacy submission replaces the initial submission for imported studies. Once the legacy submission is finalized, a PI can create additional submissions such as modifications, renewals, etc. The legacy protocol is uploaded as a PDF so the PI is unable to make changes within the protocol.

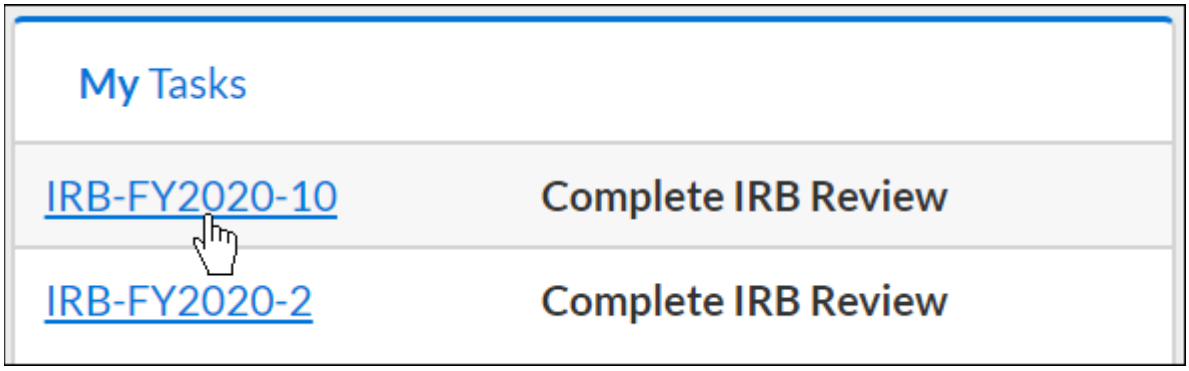
Reviewing and Commenting on Submissions in Human Ethics

After an Analyst (personnel in ORI) assigns a submission to you for review, you will receive an email letting you know that the submission requires your review.

On your dashboard, change your role to Reviewer if it is not your default role.

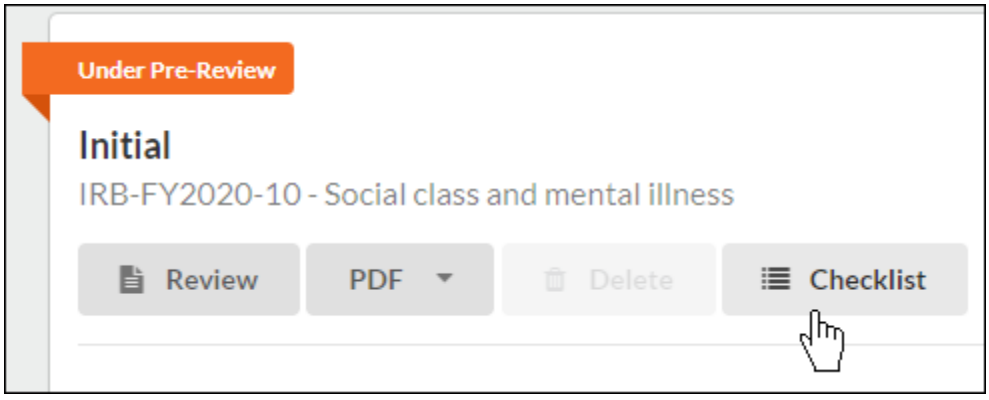


Click on the review in need of submission beneath My Tasks.

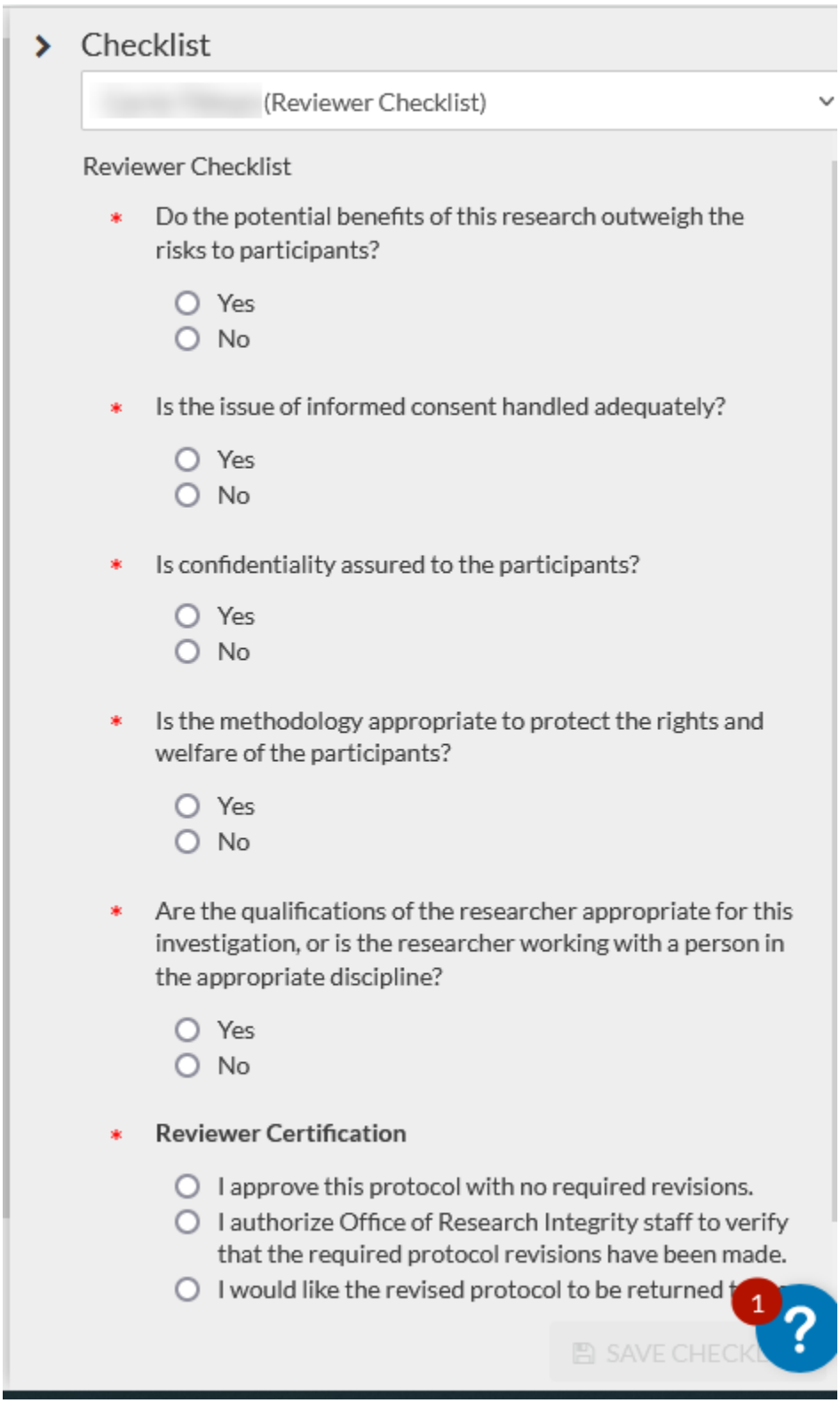


Reviewing a Submission with Your Checklist

1. From the Submission Details page, click on **Checklist**.



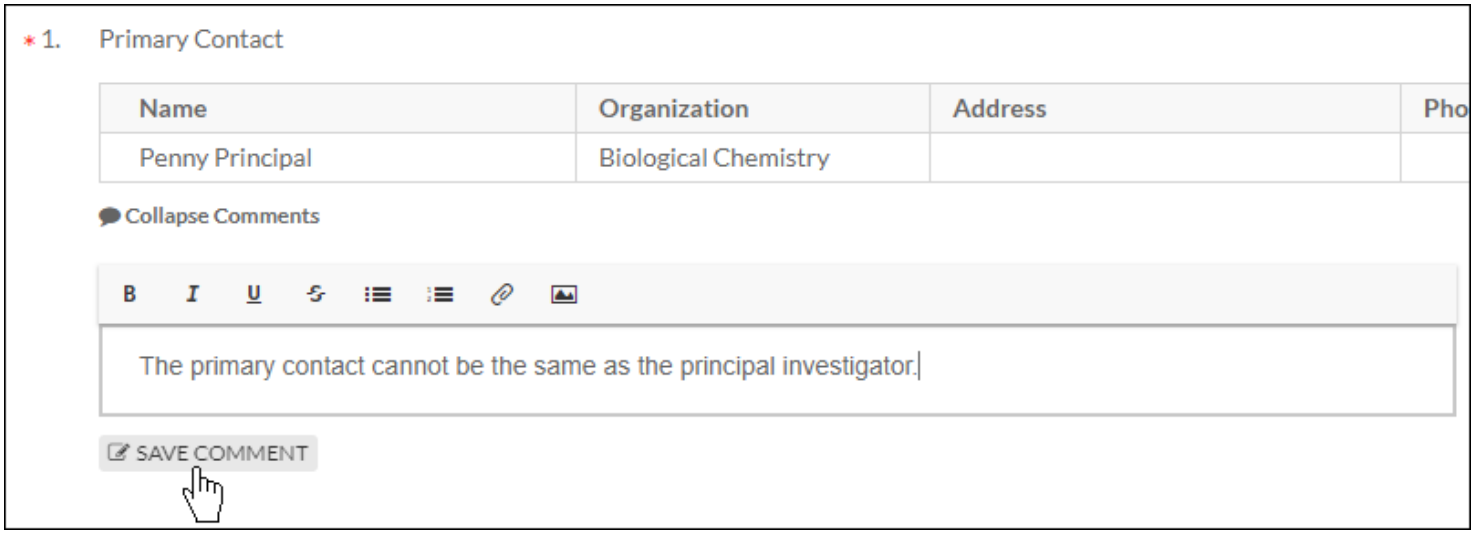
2. Review the submission using the provided checklist. If you need to leave your computer before you are finished, clicking **Save Checklist** will save what you have checked off until you return.



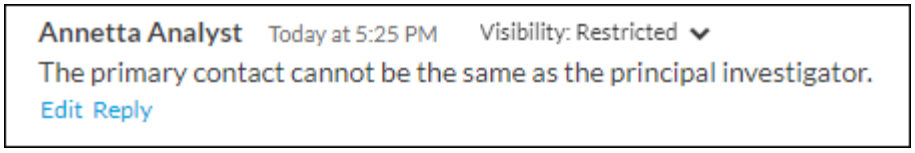
At the end of the checklist, you can approve the protocol pending the required modifications instead of having the protocol sent back to you once revised.

Commenting on a Submission

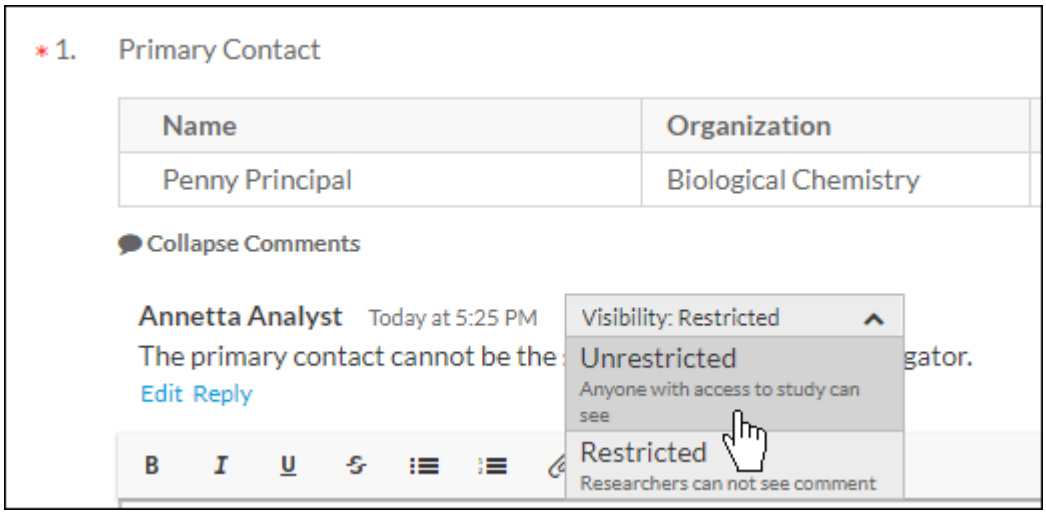
To leave a comment on a submission, click + Add Comment beneath a submission question. Type up your comment, and click **Save Comment**.



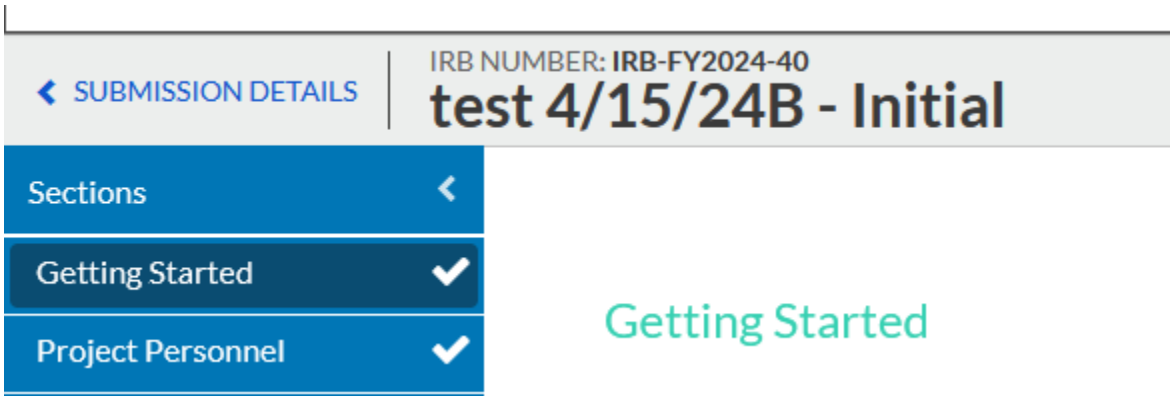
Once your comment is saved, you can **Edit** or **Reply** to the comment, or toggle the visibility of the comment.



You can toggle visibility be clicking on the down arrow. Restricted visibility means that researchers cannot see your comments, and unrestricted means that they can see your comments. If your comment is directed toward the researcher, you will want to toggle the visibility to **Unrestricted**.



Once you're finished reviewing and commenting, click on **Submission Details** to return to the Submission Details page.

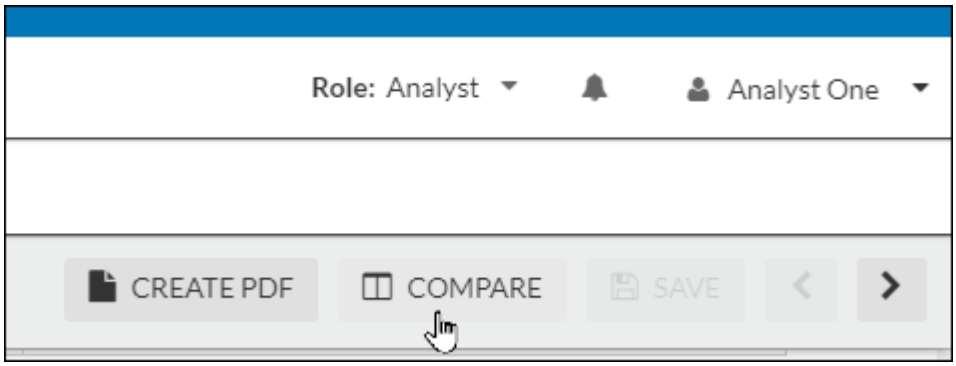


Comparing Submission and Attachment Versions in Human Ethics

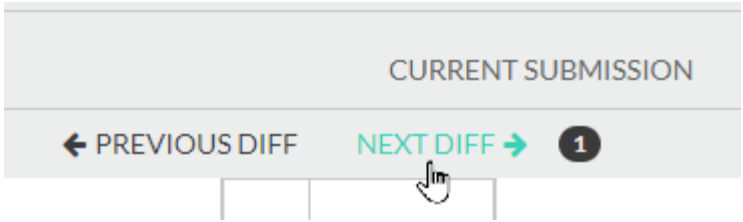
When you are reviewing a submission in Human Ethics, you can compare different versions of the submission. This includes comparing different submission questions, as well as comparing versions of documents attached to the submission.

Comparing Submission Versions

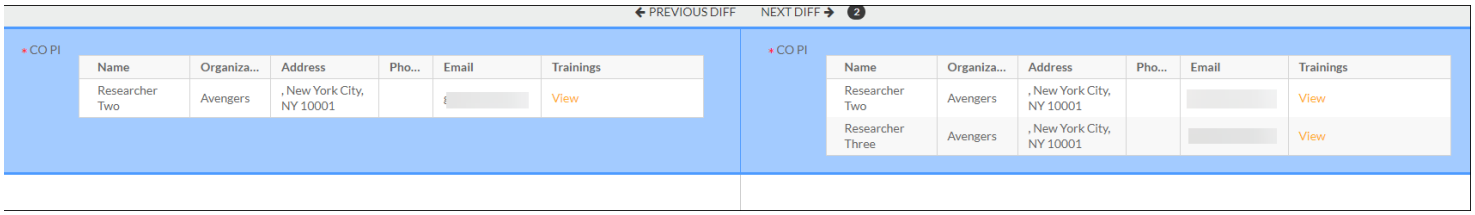
When reviewing a submission, click on the **Compare** button in the top right-hand corner.



You will see the previous submission and the current submission side by side. Number of differences will be listed as a number next to **NEXT DIFF**. Click on the arrows to toggle between differences.

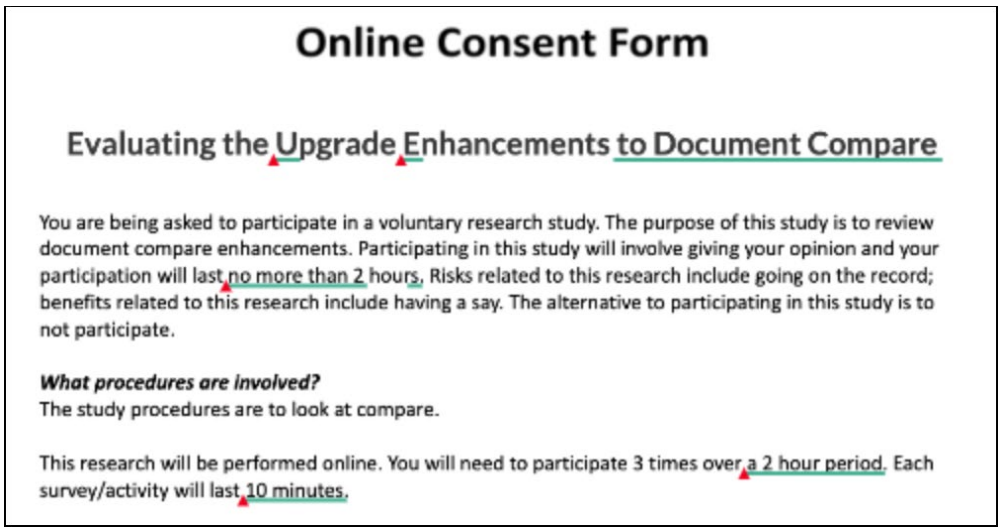


Differences will be highlighted blue for easy visibility.



Comparing Submission Text

Text that was added between submissions will be underlined green. Text that was deleted or replaced between submission will have a red triangle next to it.



Online Consent Form

Evaluating the Upgrade Enhancements to Document Compare

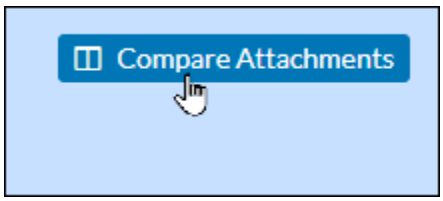
You are being asked to participate in a voluntary research study. The purpose of this study is to review document compare enhancements. Participating in this study will involve giving your opinion and your participation will last no more than 2 hours. Risks related to this research include going on the record; benefits related to this research include having a say. The alternative to participating in this study is to not participate.

What procedures are involved?
The study procedures are to look at compare.

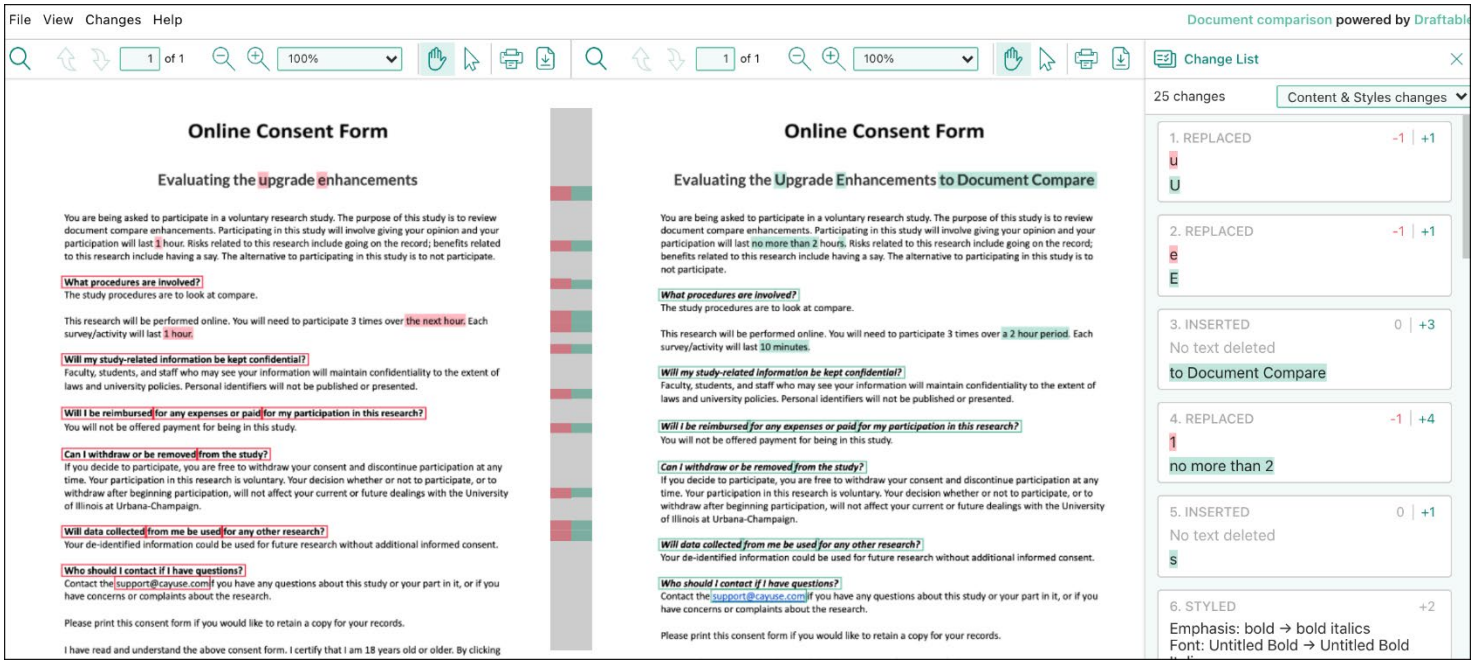
This research will be performed online. You will need to participate 3 times over a 2 hour period. Each survey/activity will last 10 minutes.

Comparing Submission Attachments

If an attachment has been revised or replaced, you will see a blue **Compare** button next to the attachment listing. Click **Compare** to see the two different versions of the attachment.



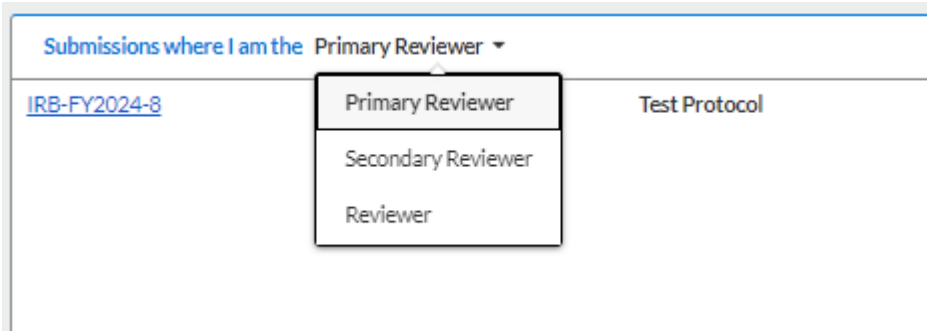
Like with submission text, red on the previous version means a section has been deleted or replaced. Green on the current version means the text was added.



Making Decisions for Limited IRB Reviews

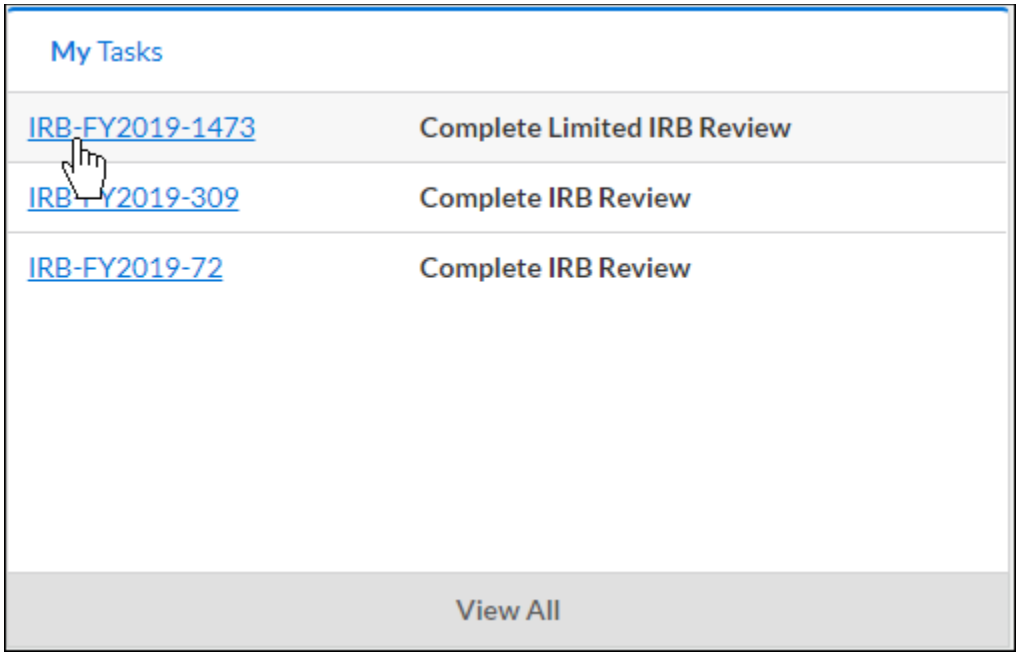
An Analyst may assign submissions to one or more IRB members for Limited IRB reviews. While non-primary reviewers have the option to review and comment on the submission directly, the primary reviewer is tasked with making a decision.

You can view Submissions where you are a Primary Reviewer, Secondary Reviewer, or Reviewer from your Reviewer Dashboard:

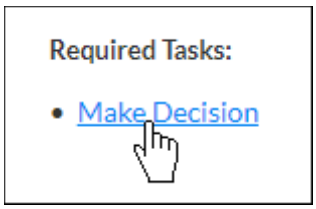


Primary Reviewers

If you are a primary reviewer assigned to a Limited IRB submission, you will see a task called **Complete Limited IRB Review** beneath My Tasks.



Clicking this link will bring you to the Submission Details page. Click **Make Decision** beneath Required Tasks after you have reviewed the submission.

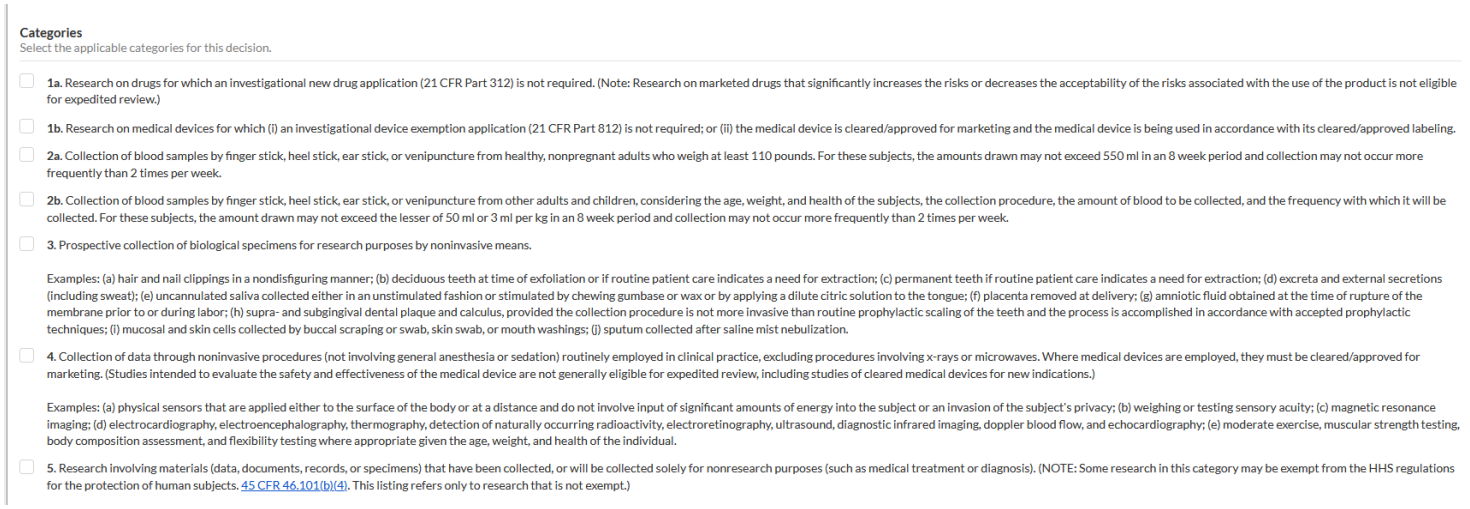


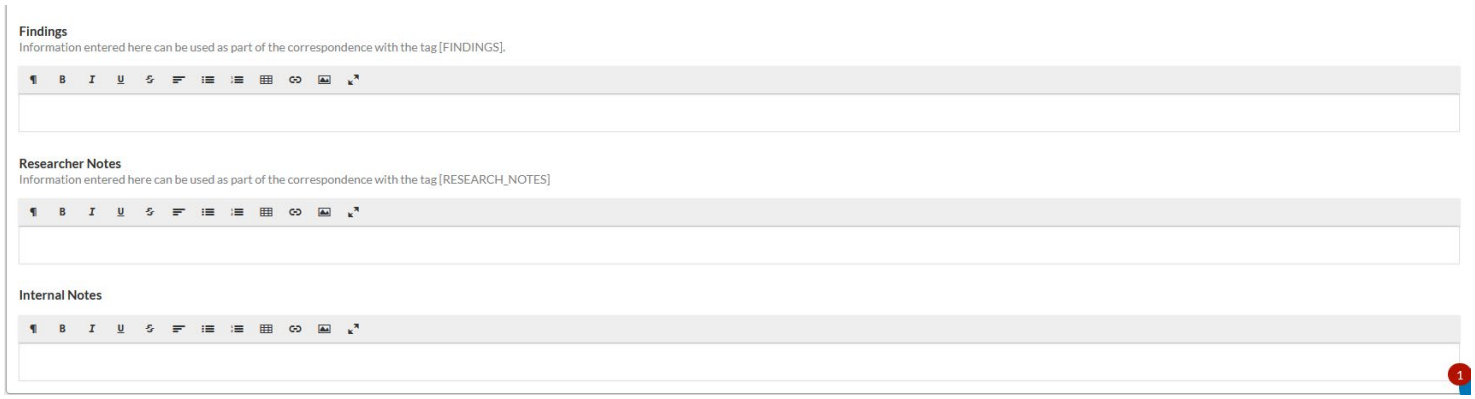
On the decision panel, you will be asked to complete a series of questions. All questions are optional with the exception of the **Decision**. The available decisions for **Limited Review** are:

- Exempt - Limited IRB
- Minor Stipulations
- No Engagement in Research
- No Human Subjects Research
- Not Limited IRB
- Rely on External IRB
- Rely on NCI-CIRB
- Return to PI
- Suspended

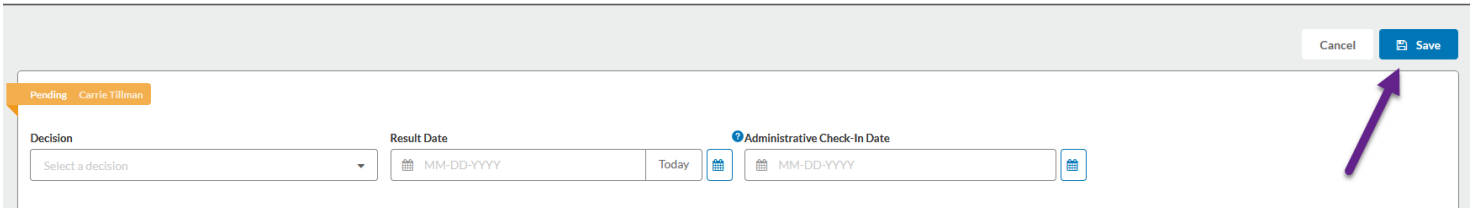
See the chart on Page 22 for Entering Decisions in Human Ethics for explanations of the different decision types.

You can also select the **Categories** applicable to the decision, enter information about **Findings**, and include **Researcher Notes** or **Internal Notes**.

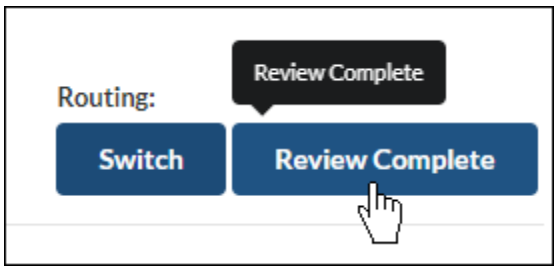




When you are finished filling out the questions on the decision panel, click **Save**.



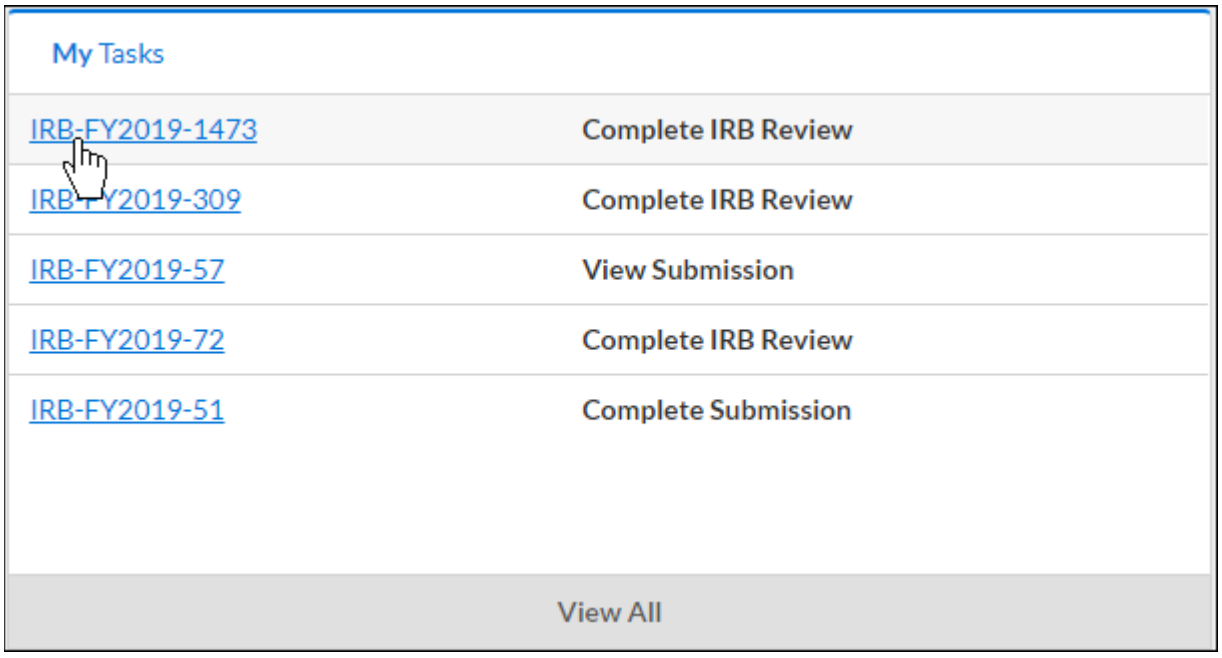
Beneath Routing, click **Review Complete**.



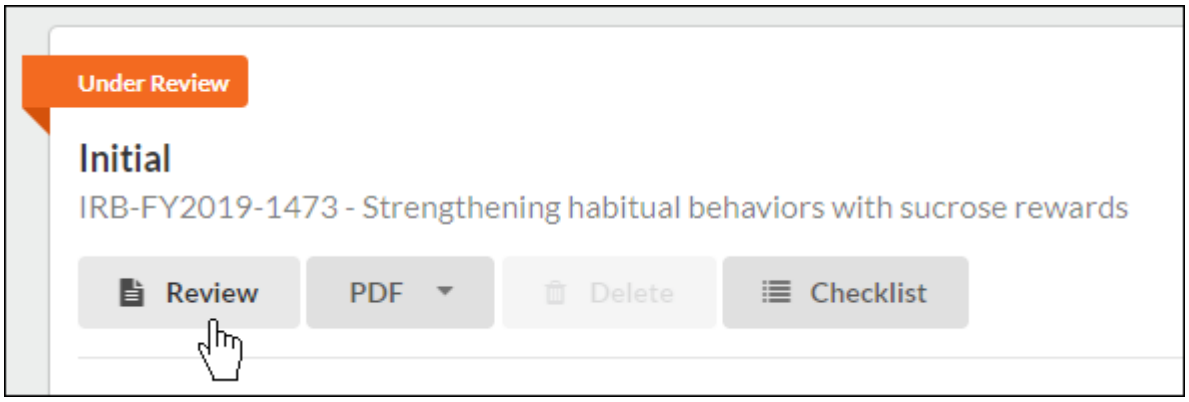
The submission's status will change to Under Post Review.

Non-Primary Reviewers

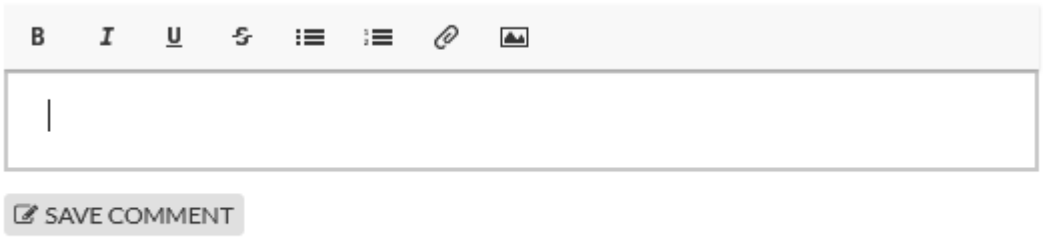
If you are a non-primary reviewer assigned to a Limited IRB review, you will see a task called **Complete IRB Review** beneath My Tasks.



Clicking this link will bring you to the Submission Details page. Click on **Review** to begin your review of the submission.



Within the submission, you can leave comments on each question by clicking **Add Comment**, typing your comment, and clicking **Save Comment**.



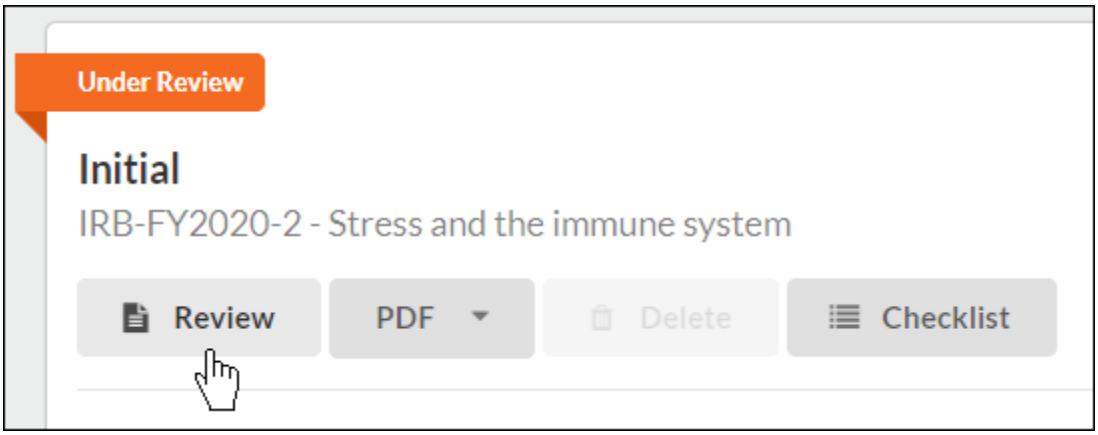
You can also toggle if the comment is **Restricted** (visible only to reviewers) or **Unrestricted** (visible to anyone with study access).

Making Decisions for Exempt and Expedited Reviews in Human Ethics

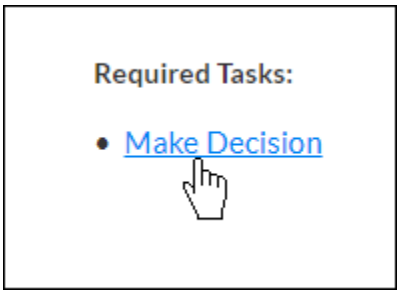
If a primary reviewer has been assigned to a submission with an exempt or expedited review, they will make the decision based on their review and comments from any other reviewers. Otherwise, all reviewers assigned to the submission may enter their decision, and the Analyst will make the final decision. All Exempt submissions have a primary reviewer, but Expedited submissions may not have one.

Making a Decision

1. Review and comment on the submission by clicking on **Review** on the Submission Details page.



2. Once the review is complete, click **Make Decision** beneath Tasks.

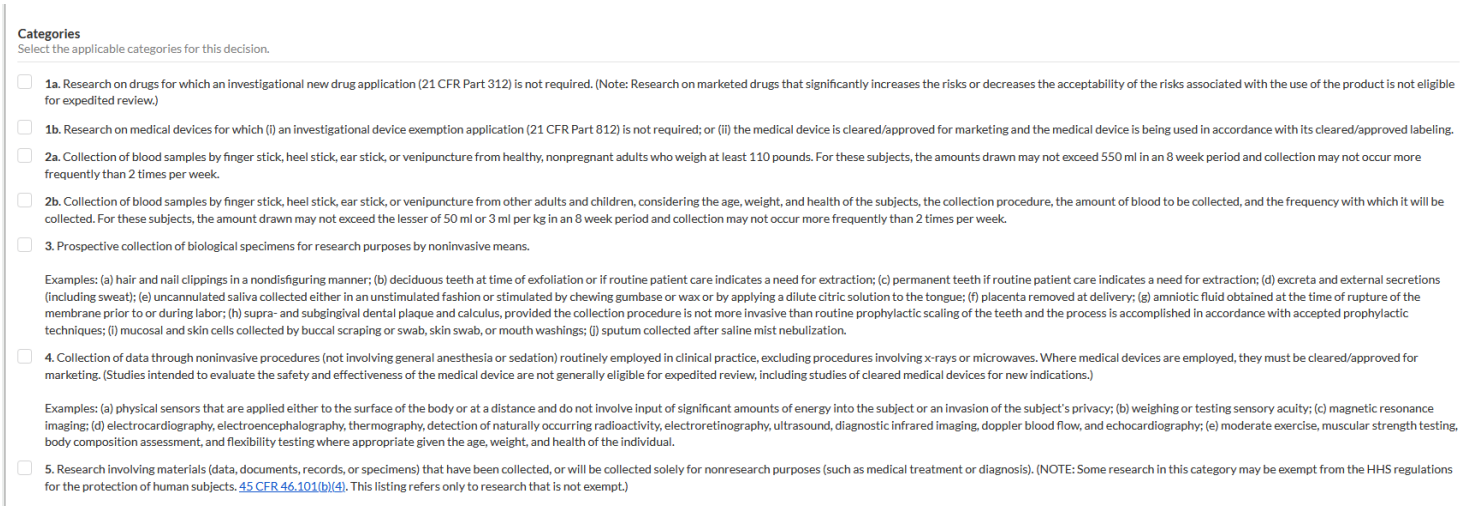


On the decision panel, you will be asked to complete a series of questions. All questions are optional with the exception of the **Decision**. The available decisions for **Exempt and Expedited Review** are:

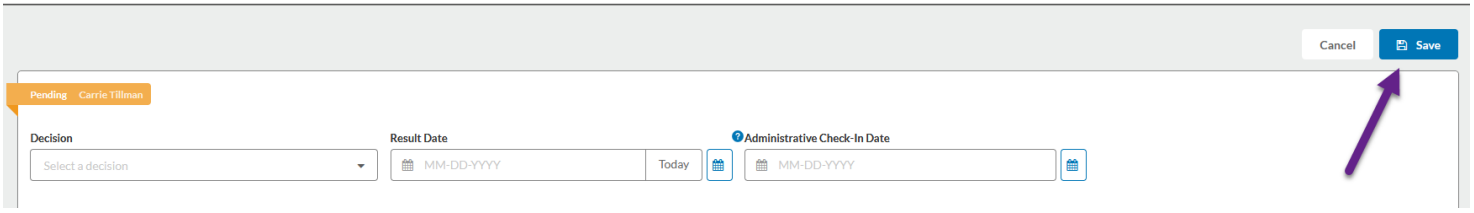
- Approved
- Deferred
- Exempt
- Exempt- Limited IRB
- Minor Stipulations
- No Engagement in Research
- No Human Subjects Research
- Not Approved
- Not Expedited
- Rely on External IRB
- Rely on NCI-CIRB
- Return to PI
- Voided

See the chart on Page 22 for Entering Decisions in Human Ethics for explanations of the different decision types.

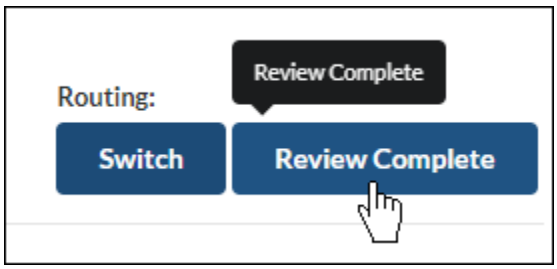
You can also select the **Categories** applicable to the decision, enter information about **Findings**, and include **Researcher Notes** or **Internal Notes**.



When you are finished filling out the questions on the decision panel, click **Save**.



Beneath Routing, click **Review Complete**.

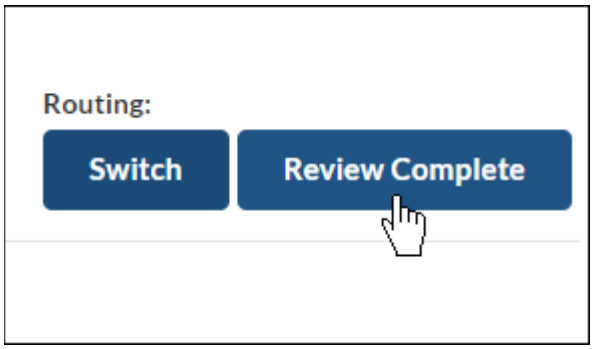


The submission's status will change to Under Post Review.

Review Information

- **Decision:** If you need to return the submission to the analyst to arrange a full board review, you should select **Not Exempt** or **Not Expedited** as the decision and complete the review.
- **Result Date:** This is the date that the decision was made.
- **Administrative Check-In Date:** This field will appear for expedited and exempt reviews guided by post-Common Rule 2018 policy with no expiration date. When an Administrative Check-In date for a review is set, it will trigger an email to the research team on that date. The email template for this message can be configured by an Analyst or administrator.
- **Continuing review is mandatory:** When checking this box, an expiration date can still be enforced on post-Common Rule 2018 expedited review submissions.
- **Expiration Date:** The expiration date is automatically calculated for Initial and Renewal submissions that have been approved. Modification, Incident, and Closure submissions will display the expiration date set in the most recent Initial or Renewal submission for the study. You can also manually edit the expiration date for "Rely on NCI-CIRB" and "Rely on External IRB" decisions. Setting an expiration date is an option on initial and renewal submissions under expedited review.
- **Justification for expiration:** You can use this field to explain an unconventional expiration date for the submission.
- **Categories:** You can select categories explaining why this study qualifies for an expedited or exempt decision.
- **Findings:** Any text entered in the Findings box may be used as part of the letter(s) sent to the research team in relation to this submission.
- **Researcher Notes:** Notes that are intended for the research team and can be used as part of the letters(s) sent in relation to this submission.
- **Internal Notes:** Private notes that will not be visible to the research team.

Once you have recorded and saved your decision, return to the Study Overview and select **Review Complete** to return the submission to the Analyst.

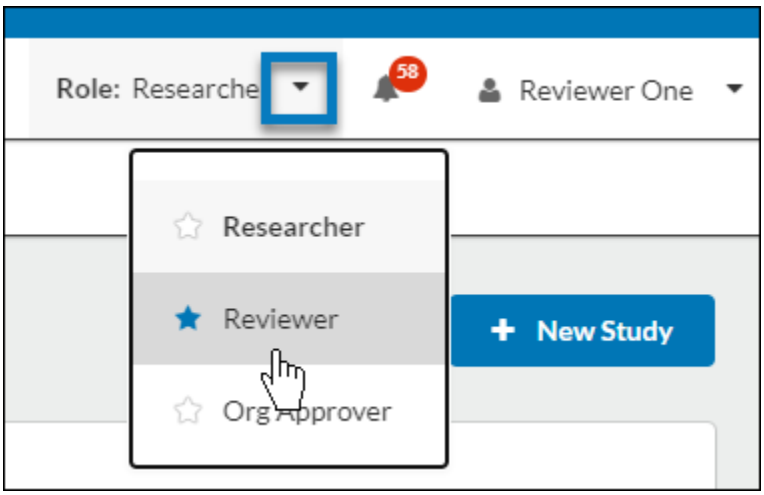


Full Board Protocols

Protocols assigned to you will appear your dashboard. The Chair and Vice Chair are assigned as Primary Reviewers. All other members are assigned as Secondary Reviewers. You can view the protocols assigned to you on your Reviewer dashboard.

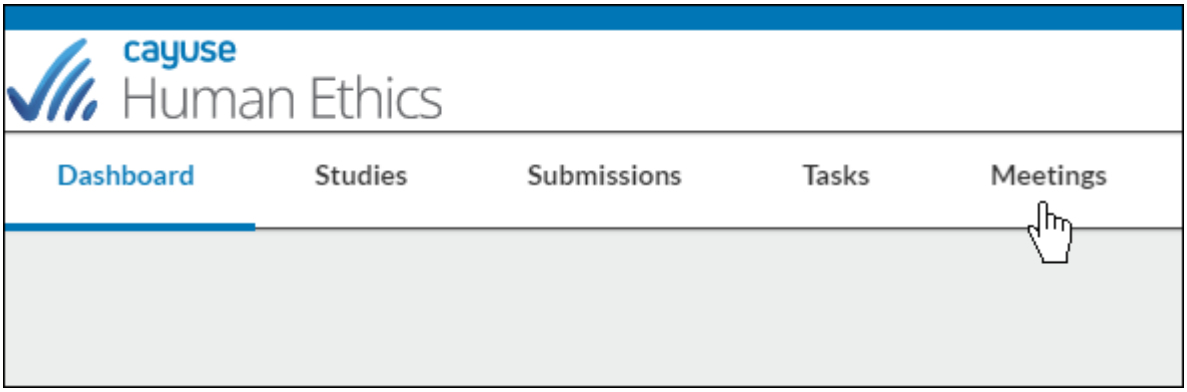
To see the list of Full Board protocols on the agenda.

1. On the dashboard, make sure your role in the top right corner of your screen reads **Reviewer**, or change it to Reviewer using the drop-down menu.

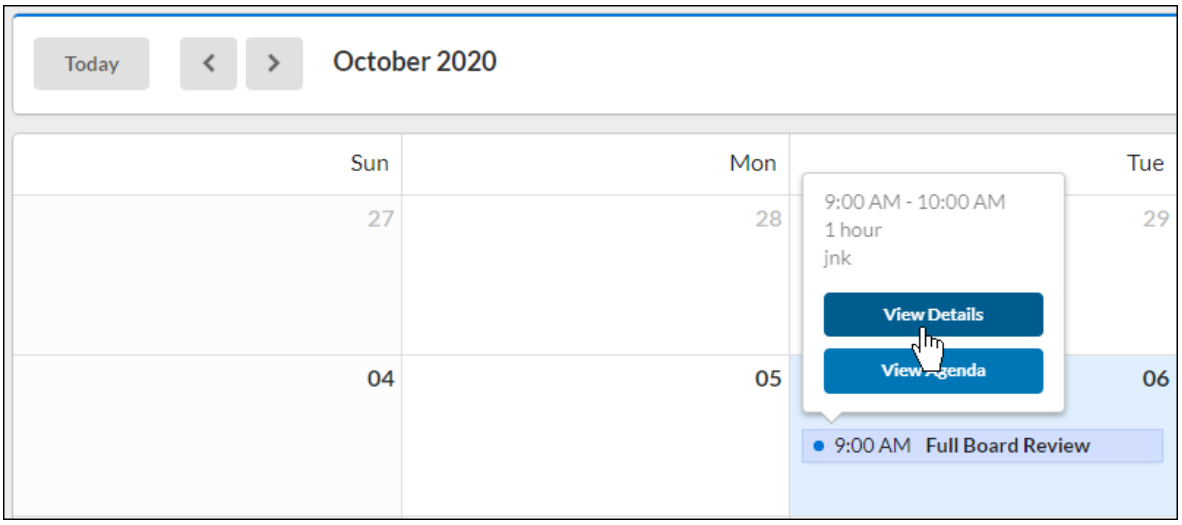


Note: You can change your default role at any time by clicking on the star.

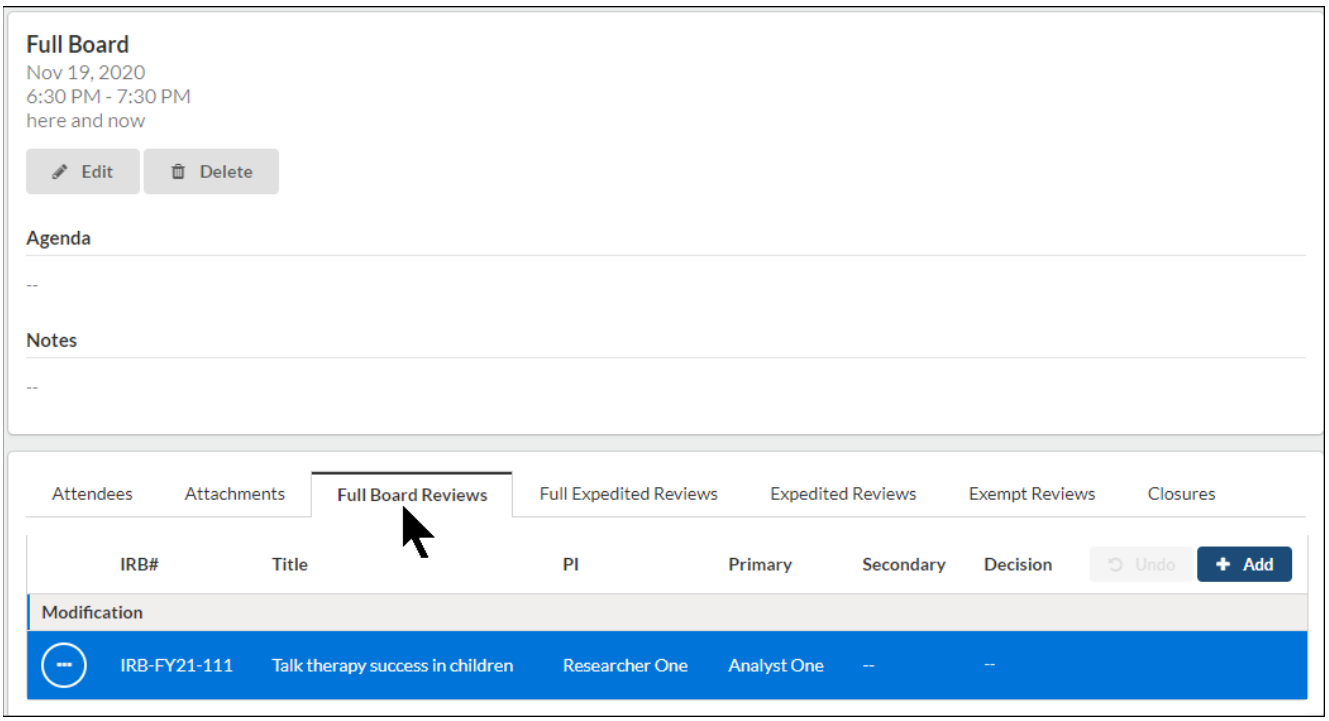
2. In the menu, click on **Meetings**.



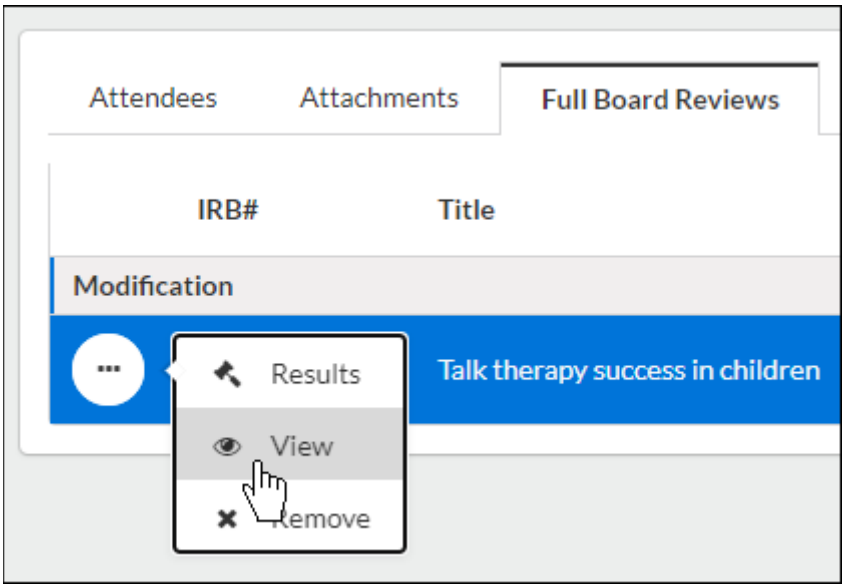
3. Click on the meeting for the submission within your calendar and then click **View Details**.



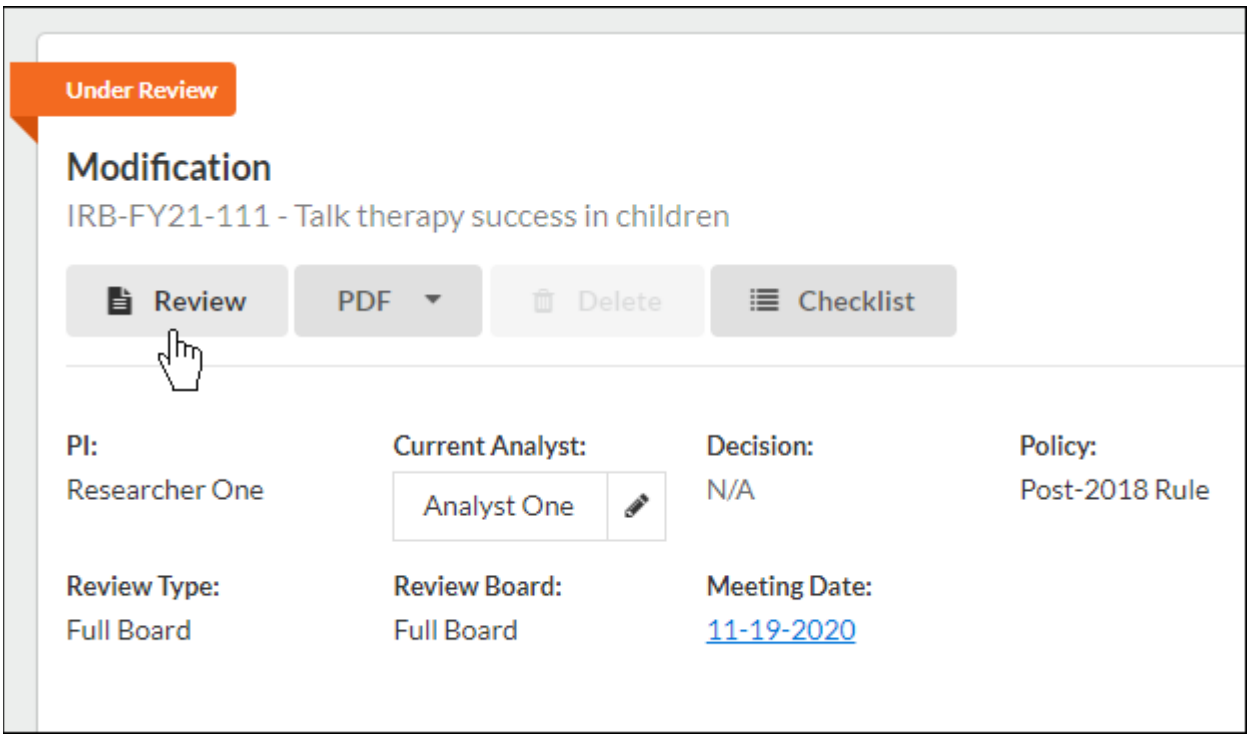
4. On the meeting details screen, click on one of the review tabs to view the attached submissions.



5. Click the menu button to the left, and click **View**.



6. Click on **Review** to begin your review of the submission.



Important Notes:

- All members should make comments using the comments feature on the application.
  - These are viewable to all board members, not to investigators.
- Every board member will have an individual checklist they can complete.
  - Only the IRB Analyst/Admin can view all checklists.
- Unlike Exempt and Expedited, you will not make a decision. The decision will be made during the convened meeting.
  - The protocol will remain on your dashboard until the meeting occurs and a decision is made.

Understanding Decision Types in Human Ethics

When entering decisions, you can choose from the following selections. You will see different options depending on the type of review.

Decision	Explanation	Resulting Study Status (*Note: Study Status will not change for legacy studies)*	Routing
Approved	The study is approved.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Deferred	The reviewer(s) identified **major** issues that the research team must correct before the submission can be approved.		Submission is returned to the PI and reopened for editing.
Minor Stipulations	The reviewer(s) identified **minor** issues that the research team must correct before the submission can be approved.	Requires Changes	Submission is returned to the PI and reopened for editing.
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.	Requires Changes	Submission is returned to the PI and reopened for editing.
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Exempt	Submission is approved and no longer editable. The research team can add additional submissions to the study.
No Human Subjects Research	The study does not include human subjects research and therefore does not require IRB approval.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Not Expedited/Not Exempt	The study will be returned to the IRB Analyst to reassign it to the correct review type.	N/A	Submission is returned to the Analyst to reassign the review type and reviewers.
Not Approved	The **full board** identified major issues with the study or submission and disapproved the research. In the case of a disapproved initial study, a new study and submission will need to be created. For disapproved renewal, modification, etc. submissions, the research team will need to create a new submission if they wish to proceed.	Disapproved	The submission and/or study are disapproved and no longer editable. Disapproving an initial submission archives the study.
Not Reviewed	Documents that the submission was unable to be discussed at the meeting. The "Not Reviewed" decision is logged in the decision history so that a new decision can be made at a subsequent meeting. This decision type is only available for full board reviews of	N/A	Submission is returned to the Analyst to assign to a new meeting.

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	initial, modification, incident, and renewal submissions.		
Suspended	A study is suspended when the IRB decides that the research needs to stop until changes have been made to the research. A suspended decision is available on Incident Reports, Modifications, and Renewals. Suspension can only be lifted by selecting the "Suspension Removed" decision for a modification submission after it has had a full, full expedited, or expedited review. Lifting the suspension changes the study's status back to "Approved". **Note:** Renewal submissions for an expired suspended study can receive a decision of "Approved" in order to extend the date without lifting the suspension, or "Suspension Removed" in order to extend the date and lift the suspension.	Suspended	Submission is returned to the PI and is no longer editable.
Closed	A closure submission is created and submitted when the research is done and the study can be closed.	Closed	The study is closed and no further research can be done.
Withdrawn	The research team decided not to proceed with the initial submission. This decision is only available for withdrawal submissions. The research team can choose to withdraw the study at any point until the initial submission has been approved. If the initial submission has been approved, the research team must create a closure submission instead.	Withdrawn	The study is closed and no further research can be done.
Voided	Request sent for the study no longer needed and changes need to be discharged. Decisions to be used mainly for Modifications and Renewals where changes will no longer be needed or Initials where research will no longer occur within the institution.	Not Approved	Changes requested for the study are discharged.
Rely on External IRB	The study and submission were reviewed and approved by an external IRB and their decision has been recorded by the IRB.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Rely on NCI-CIRB (National Cancer Institutional	The study and submission were reviewed and approved by an NCI-CIRB and their decision has been recorded by the IRB.	Approved	Submission is approved and no longer editable.

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(NCI) Central Institutional Review Board (CIRB))			The research team can add additional submissions to the study.