Making Decisions Using Expedited review procedures

Purpose of this resource: To show SHSU IRB members how to make decisions on IRB submissions using Expedited review procedures in Cayuse IRB.

Returning a Submission for Edits

When the reviewer is not satisfied that the PI has satisfactorily met <u>all criteria for IRB approval</u>, s/he can proceed with returning the submission back to the PI via the IRB Analyst through the following steps:

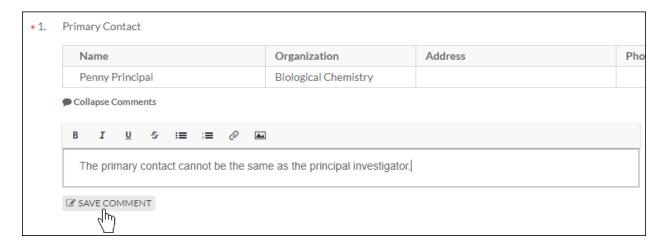
IRB Reviewer Dashboard

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

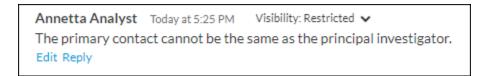
My Tasks		
IRB 2018-62	Complete Expedited Review	
IR\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Complete IRB Review	
	View All	

Commenting on a Submission

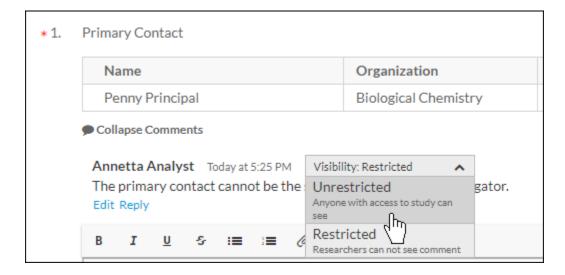
To leave a comment on a submission, click +Add Comment beneath a submission question. Type up your comment and click **Save Comment**.



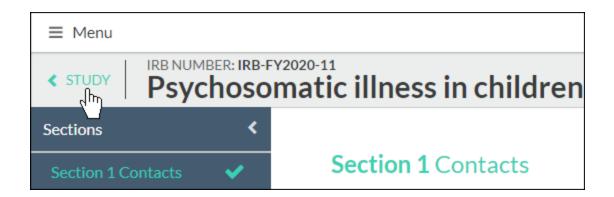
Once your comment is saved, you can **Edit** or **Reply** to the comment, or toggle the visibility of the comment.



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**.

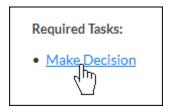


Once you're finished reviewing and commenting, click on **Study** to return to the Submission Details page.



Making a Decision

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



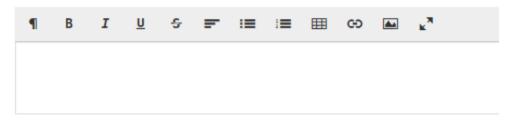
On the decision panel, you will be asked to complete a series of questions. All questions are optional with the exception of the **Decision and Result Date**. The available decisions for an Expedited review are:

- Approved
- Deferred
- Exempt
- Minor Stipulations
- No Engagement in Research
- No Human Subjects Research
- Not Expedited
- Rely on External IRB
- Rely on NCI-CIRB
- Return to PI
- A. If you need to return the application to the PI, do the following:
 - 1. Select Return to PI from the Decision dropdown list.
 - 2. Click the "Today" button to the right of the Result Date:

Today

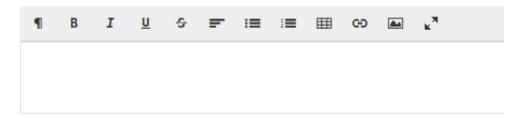
3. **Internal Notes:** If a reviewer needs me to know anything about the review/decision, include those notes under Internal Notes section of the decision panel.

Internal Notes



- 4. Click **Save** on the decision panel.
- 5. Click **Review Complete** on the Submissions Details page.
- B. When you are ready to approve the protocol as written, do the following:
 - 1. Select Approve from the Decision dropdown list.
 - 2. Click the "Today" button to the right of the Result Date:
 - 3. Select the appropriate Administrative Check-In Date, typically one year from the result date.
 - 4. **Categories:** Select the applicable categories for this decision.
 - 5. **Internal Notes:** If a reviewer needs me to know anything about the review/decision, include those notes under Internal Notes section of the decision panel.

Internal Notes



- 6. Click **Save** on the decision panel.
- 7. Click **Review Complete** on the Submissions Details page.