Making Decisions Using Full Board review procedures

Purpose of this resource: To show SHSU IRB members how to make decisions on IRB submissions using Full Board 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 Full Board IRB submission, you will see a task called **Complete IRB Review** beneath My Tasks.

My Tasks		
<u>IRP 2018-36</u> Дру	Complete IRB Review	

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**.

Name	Organization	Address	Pho				
Penny Principal	Biological Chemistry						
Collapse Comments							
B I <u>U</u> 5- ∷≣ ∷≣ ⊘							
I ne primary contact cannot be the s	ame as the principal investiga	ator.					
···· · · · · · · · · · · · · · · · · ·							
SAVE COMMENT							

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

Annetta Analyst	Today at 5:25 PM	Visibility: Restricted 🖌
The primary conta	act cannot be the	same as the principal investigator.
Edit Reply		

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**.

* 1.	Primary Contact				
	Name	Organization			
	Penny Principal	Biological Chemistry			
	Collapse Comments				
	Annetta Analyst Today at 5:25 PM	Visibility: Restricted			
	Edit Reply	Anyone with access to study can see			
		Restricted () Researchers can not see comment			

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 Full Board review are:

- Approved
- Deferred
- Disapproved
- Exempt
- Minor Stipulations
- No Engagement in Research
- No Human Subjects Research
- Not Reviewed
- 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.

Today

2. Click the "Today" button to the right of the Result Date:

3. Internal Notes: If a reviewer needs the IRB Analyst to know anything about the review/decision (e.g., this submission should go back to full board, this submission needs to be review by the IBC, etc.), include those notes under Internal Notes section of the decision panel.

Internal Notes

¶	В	I	U	÷	F	≔	▦	GĐ	×Ħ	

- 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 Expiration Date, typically one year from the result date.
 - 4. **Categories:** There are currently no categories to choose from for this type of review. The determination is built into the approval letter template.
 - 5. **Internal Notes:** If a reviewer needs the IRB Analyst to know anything about the review/decision, include those notes under Internal Notes section of the decision panel.

Internal Notes



7. Click **Review Complete** on the Submissions Details page.