Job Aid Title	Respond to IRB Decision
Relevant Users	Principal Investigator (PI), Additional Contact, Study Staff
Covered Topics	o Where to find the IRB correspondence after Non-Committee or Committee Review o How to Respond to IRB Decision

1. **Notification of IRB Determination**

   o After the IRB has reviewed a submission by Non-Committee or Committee Review, a notification of the determination is sent to the PI and the additional contact.

   o The notification email will be sent to the email address on file in the eIRB system and will include a link to the corresponding submission. Please click this link.

   o If you are already in the eIRB system, go to the **Inbox** and select the study that requires a response.

   o The IRB office will provide any annotated documents directly to the PI and additional contact via email.

2. **Review the IRB correspondence letter**

   o Look for the IRB determination letter at the top of the submission workspace.

   o To view the document, click on the link to open the document.

   o Review the IRB correspondence. Edit the study submission, making sure to upload new and/or revised study documents in Section 7.0 Attachments. Prepare any response attachments accordingly, including a point-by-point response letter. ***Please avoid attaching response documents in Section 7.0 Attachments.*** Provide them to the PI to include with his or her response.

   ! Note: Refer to the How to Manage Files in eIRB Job Aid that describes how to edit study documents in Section 7.0 Attachments (PI and Study Staff only).

- **If you are the PI, skip to Step 3: Respond to IRB Decision.**
- Active study staff and the additional contact may select **Ready for PI Review** to send a notification to the PI. **However, the PI is the only study team member who can Respond to IRB Decision.**

! Note: If a response is not received within 30 days, the submission's state will change to 'Modifications Timed Out'. Ready for PI Review is **not** available in Modifications Timed Out. If modifications have timed out, you must contact the PI directly outside of the eIRB system. However, the PI will retain the ability to Respond to IRB Decision.

3. **Respond to IRB Decision (PI ONLY)**
   - When you are ready to tell the IRB that you have responded, on the left side under **My Current Actions,** click **Respond to IRB Decision**.

- Once the **Respond to IRB Decision** window pops open, select the **Add** button to upload a point-by-point response letter shown below. Should you experience any trouble uploading a response document, please contact the IRB office for assistance. If your response is urgent and are you not able to upload the document, you may email the point-by-point response letter directly to the IRB Owner.

Respond to IRB Decision

Instructions:
- Use this activity to respond to the decision. This will send it back to the IRB Office for further review.

Comments:

Respond To IRB Decision Documents:
Add

Document	Description
There are no items to display	

Select Add to attach a point-by-point response letter. Follow the instructions in the popup page to upload the document.

You must click 'OK' here

OK   Cancel

- o You **must** click on the **OK** button to submit your response to the IRB.
- o Once you have successfully completed the above steps, the state will change to **Responded to IRB Decision** and the IRB will review the response.

! Note: Responding to a clarification request from the IRB office is a different process than responding to an IRB decision. Refer to the [How to Respond to Clarifications Requested](#) Job Aid which describes how to respond to a request for clarifications.