

How to Respond to a Clarification Request

During the Pre-Review process, RPO staff may need to return the submission to you for clarifications or edits that are needed. The PI/contact/Proxy will receive an email notification if RPO staff does request clarification.

How do you know a clarification is required?

You (and any assigned proxy or contact) will receive an email notification requesting a clarification on a submission. An example of that email is below.

Notification of Requested Clarifications

To: Jane Doe

Link: [STUDY00000036](#) Click here to open the study/protocol

P.I.: [John Smith](#)

Title: Cure for the Common Cold

Description: Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.

- Click on the protocol hyperlink. Depending on your login status at the time, the system may require your UVM Net ID /password login credentials.
- The submission will appear with a status of “Clarification Requested” or “Required Modifications” along with the step it relates to.

The below example is looking for clarification during the Pre-Review workflow stage.



Clarification Requested (Pre-Review)

PROTO201900010
test ws 2

Principal investigator: Catherine Weiss
Submission type: New Protocol Application
Primary contact: Letter:
IACUC coordinator: PI Department: Experi
Consulted vet: Huron C
PI proxies:

Next Steps

- Edit Protocol
- Printer Version
- View Differences
- Submit Response
- Submit Ancillary Review
- Assign Admin Office
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Manage Guest List
- Manage Ancillary Reviews

Workflow Diagram: Pre-Submission → Pre-Review → IACUC Review → Post-Review → Review Complete. Clarification Requested (orange) is shown as a branch from Pre-Review and IACUC Review. Modifications Required is shown as a branch from Post-Review.

Activity Log:

Activity	Author
Clarification by Pre-Reviewer Requested	Tracy, Lynn R
Please add this that and the other thing	

To Respond to Request for Clarifications

1. On the History tab, you may see a recent entry that says “Clarification Requested” or “Letter Sent” or “Required Modifications Reviewed”. Directly underneath, you will see comments and/or attached files. Review the comments and the content of any attachments (if applicable). The comments and attachments (if applicable) should provide you with the additional information or changes that are required.



History	Experiments	Documents	Reviews	Reviewer Notes	Contacts	Snapshots	Training	...
Filter by Activity <input type="text" value="Enter text to search for"/> + Add Filter × Clear All								
Activity	Author	Activity Date						
Clarification by Pre-Reviewer Requested Please address the following concerns.	Dattilio, Abbey L.	11/29/2022 10:54 AM						

2. Click the dark grey “Edit Protocol” button to open your protocol:

Clarification Requested (Pre-Review)

Next Steps

[Edit Protocol](#)

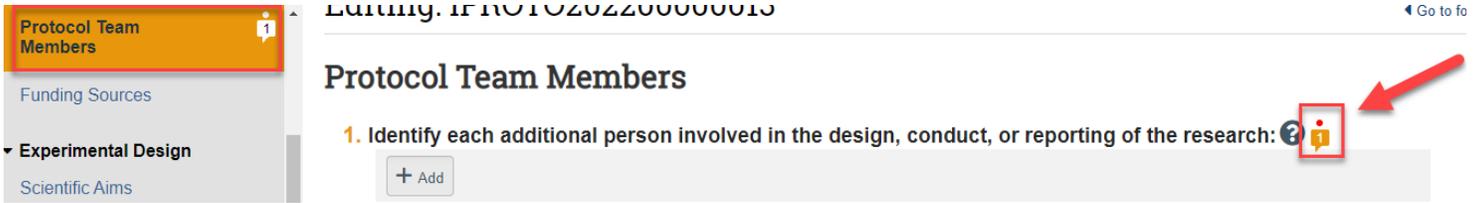
[Printer Version](#)

NOTE: For clarifications in specific parts of the protocol, an orange message icon with a red dot above it will denote the specific part of the protocol for you to address:

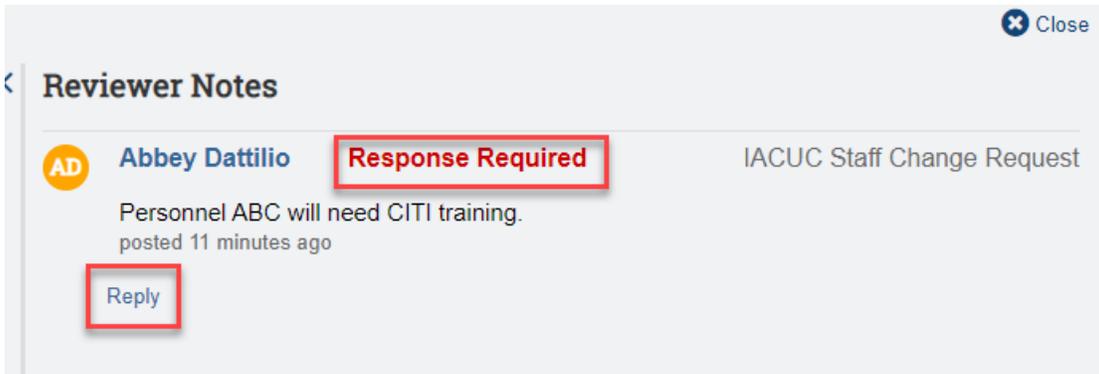
Protocol Team Members

Funding Sources

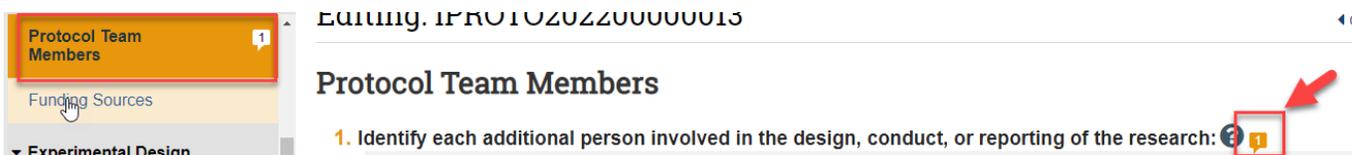
3. Click on the orange message icon, you will be brought to the exact location to address the reviewers' concerns:



This will open a new window with the reviewers' notes, where a response may be required. Please note if a response is required, you **must** address the concern by clicking on the "Reply" button and entering your comments:



Once you have addressed any required comments, the orange message icon will no longer have the red dot above it, indicating it is complete:

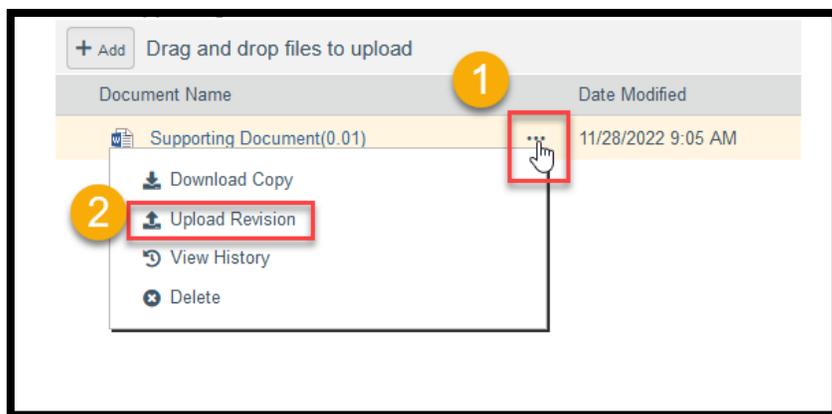


4. Scroll down the left-hand side of the menu to go through any additional required comments:



****Tip**** If you need to upload a new version of a previously uploaded document:
To replace the document, click the “...” and choose “Upload Revision”.

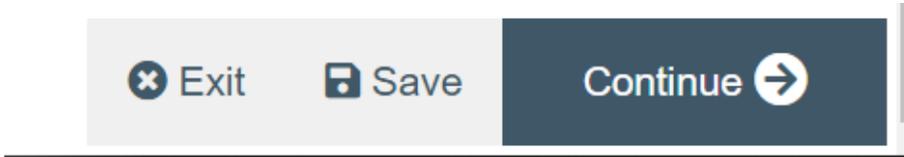
***Do not delete any document.**



To add a new document, click the “+ Add” button at the top.



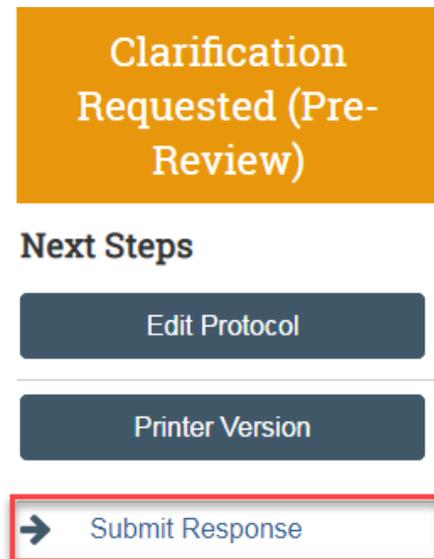
5. Once you have addressed all the required comments, click “Save”, then “Exit”:



Important! The response has not yet been submitted back to the IRB Office for review.

Submitting the Clarification back to the RPO Office

6. Click the activity on the left that says “Submit Response” to send this submission back to the RPO Office for review and processing:



If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop up window to Jump To those particular page quickly and enter the missing data:

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Aims and Significance of Research	Scientific Aims
⊖ This is a required field; therefore, you must provide the required information.	Animal Counts	Holding Details
⊖ This is a required field; therefore, you must provide the required information.	Departure Request	Departures From Animal Welfare Standards

These Errors/Warning Messages only appear if a required field entry was missed.

- When submitting a response, you have the opportunity to optionally add notes and/or upload supporting documents. Clicking OK will remove this submission from your “My Inbox,” and place it in the RPO Office “My Inbox” for processing.

Submit Response

1. Notes:

Optional

2. Supporting documents:

+ Add
Optional

Name
There are no items to display

→
OK
Cancel

NOTE: Example below shows the bubble will change from “Clarification Requested” to “Pre-Review”.

