UVMClick

IACUC

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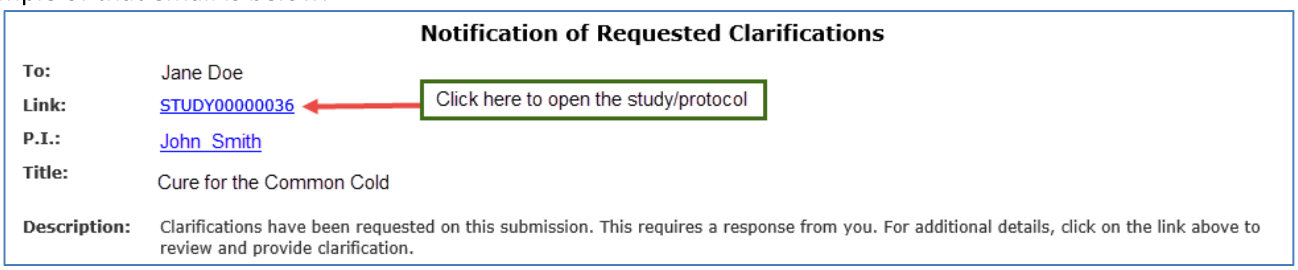
How to Respond to a Clarification Request

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

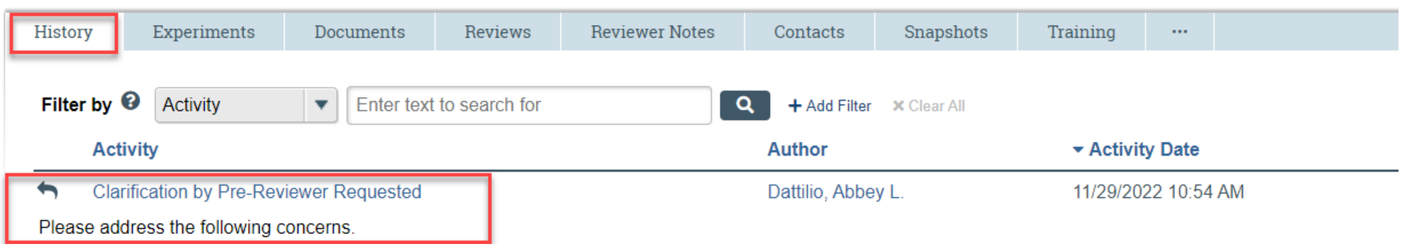
To: Jane Doe
Link: STUDY00000036
P.I.: John Smith
Title: Cure for the Common Cold
Description: Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.

- 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.

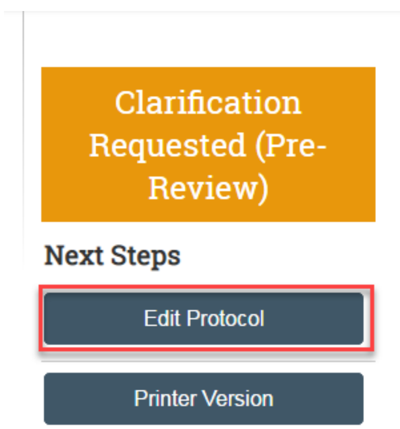
The below example is looking for clarification during the Pre-Review workflow stage.

To Respond to Request for Clarifications

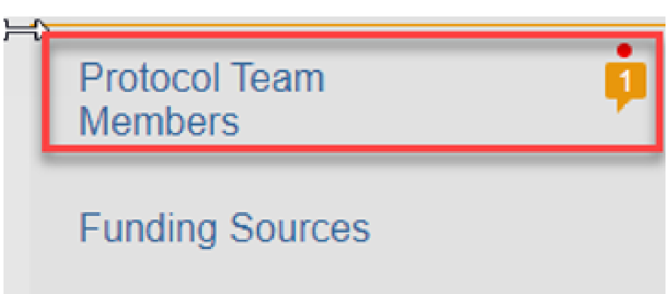
1. On the History tab, you may see a recent entry that says “Clarification Requested” or “Letter Sent” or “Required Modifications Reviewed”. Directly underneath, you will see comments and/or attached files. Review the comments and the content of any attachments (if applicable). The comments and attachments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



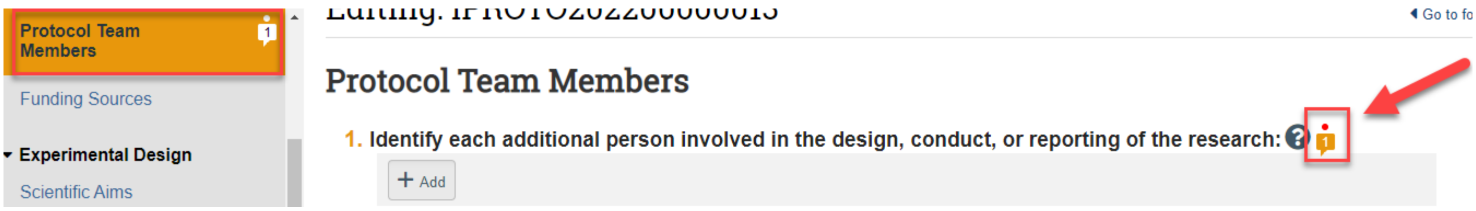
2. Click the dark grey “Edit Protocol” button to open your protocol:



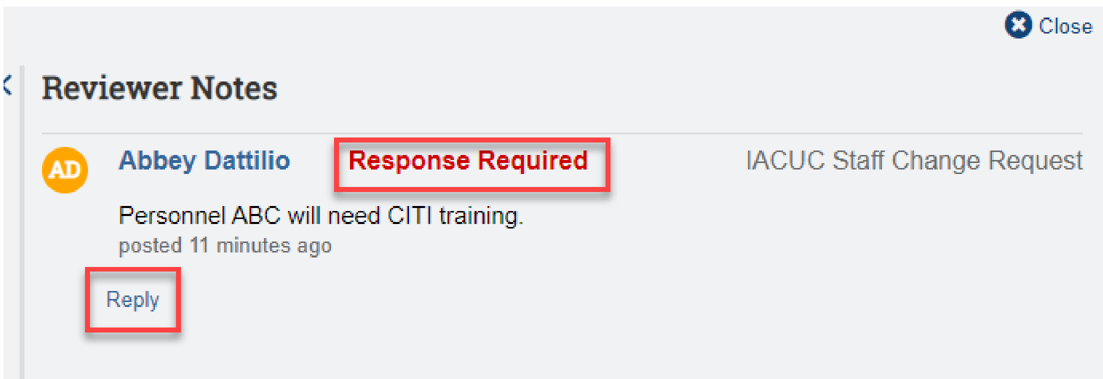
NOTE: For clarifications in specific parts of the protocol, an orange message icon with a red dot above it will denote the specific part of the protocol for you to address:



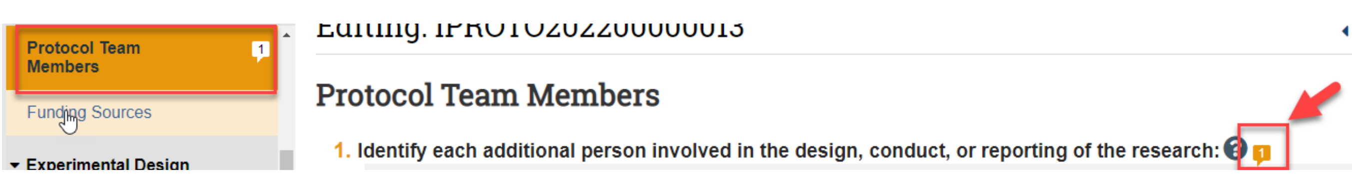
3. Click on the orange message icon, you will be brought to the exact location to address the reviewers' concerns:



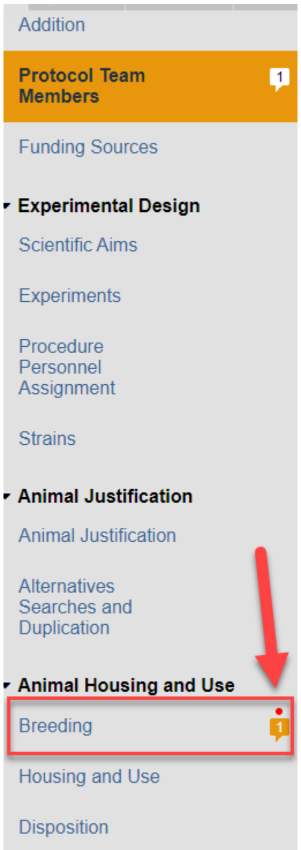
This will open a new window with the reviewers' notes, where a response may be required. Please note if a response is required, you **must** address the concern by clicking on the "Reply" button and entering your comments:



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



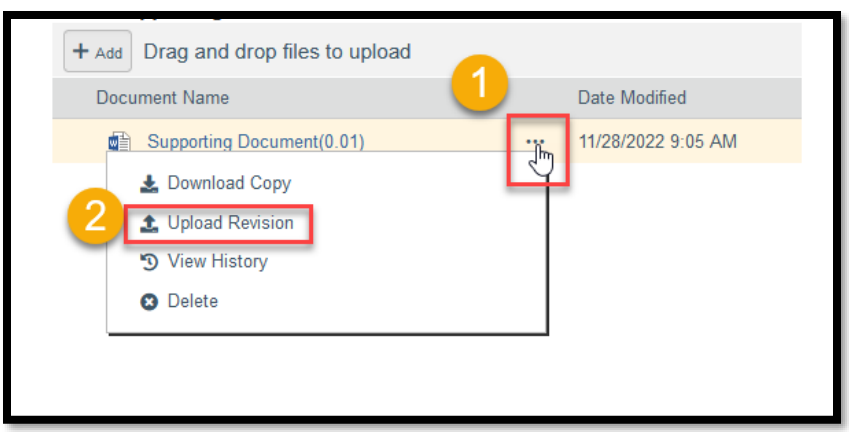
4. Scroll down the left-hand side of the menu to go through any additional required comments:



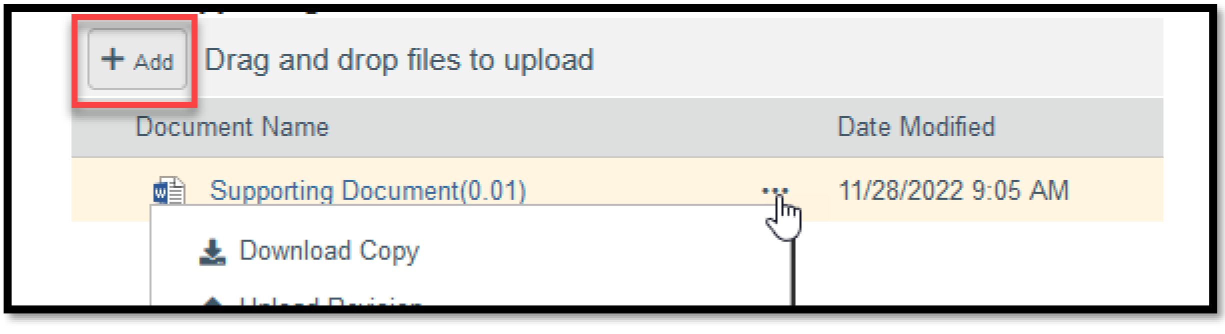
Tip If you need to upload a new version of a previously uploaded document:

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.

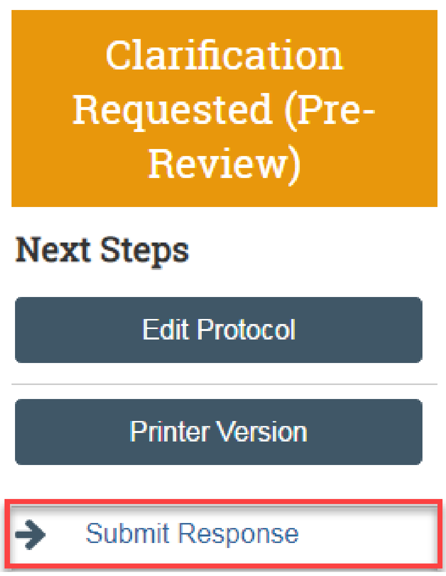


5. Once you have addressed all the required comments, click “Save”, then “Exit”:

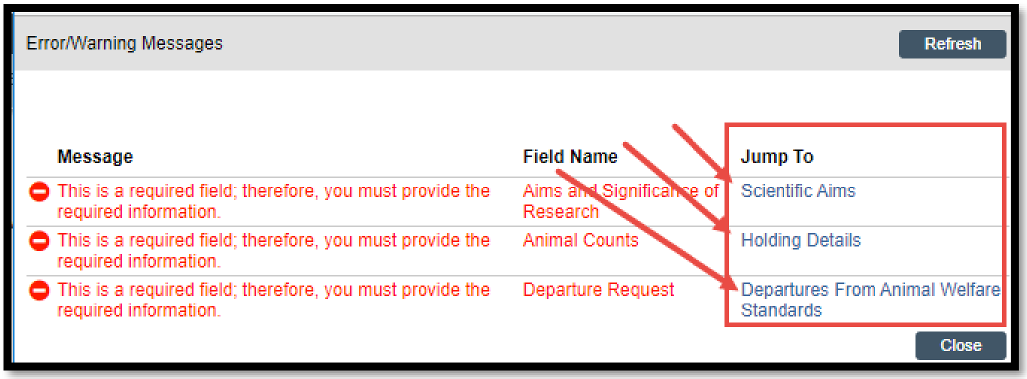
Important! The response has not yet been submitted back to the IRB Office for review.

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:

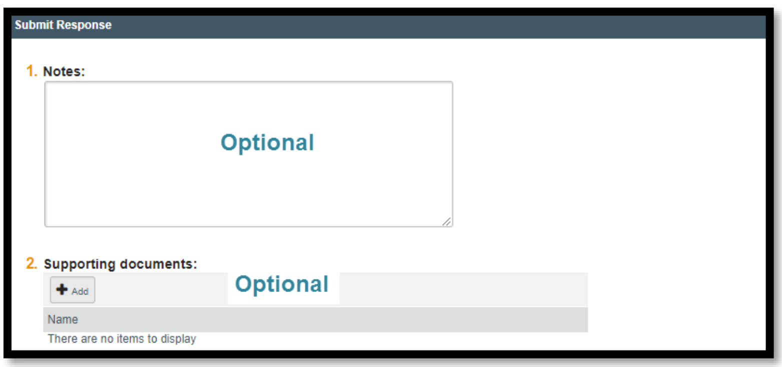


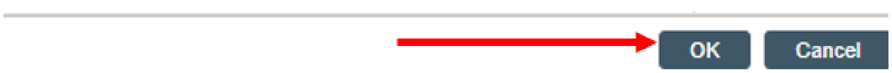
If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop up window to Jump To those particular page quickly and enter the missing data:



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

7. 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.





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