

## How to Respond to a Clarification Request

During the Pre-Review process, RPO staff may need to return the submission 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:** [REG201900001](#) Click here to open the lab registration link ←

**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 lab registration live Link.  
NOTE: Depending on your login status at the time, the system may require your UVM NetID /password login credentials.
- The submission will appear with a status of “Clarification Requested” or “Required Modifications” along with the step it relates to.

This example is looking for clarification during the Specialist Review workflow stage.

**Clarification Requested (Specialist Review)**

SAMEND202200000003  
**Amendment for REG202200013**

**Principal Investigator:** Margaret Vizzard  
**Specialist:** Abbey Dattilio  
**Primary Contact:**  
**Admin office:** Safety  
**PI proxies:** Aubrie Clas  
**Submitting Department:** Neurological Sciences

**Submission Type:** Amendment  
**Safety Review Type:** Biosafety  
**Letter:**  
**Last day of continuing review period:** 11/26/2023  
**Approval Date:**  
**Biocontainment Level:** BSL-2  
**Exempt from NIH Guidelines:**

**Amendment Type:**  
Protocol team member information  
Other parts of the protocol  
**Registration:** New Registration

**Workflow:** Pre-Submission → Specialist Review → Committee Review → Post-Review → Review Complete. A 'Clarification Requested' box is shown between Specialist Review and Committee Review.

**History Table:**

Activity	Author	Activity Date
Clarification Requested by Specialist Please add the name(s) of the personnel being added to question #3 on the amendment form. The storage location for tissues was updated with the new room but the usage location was not. Please confirm that the new room is for storage only.	Dattilio, Abbey L.	11/27/2022 5:12 PM
Submitted	Vizzard, Margaret A.	11/27/2022 5:10 PM
Amendment Created	Vizzard, Margaret A.	11/27/2022 5:07 PM

## To Respond to Request for Clarifications

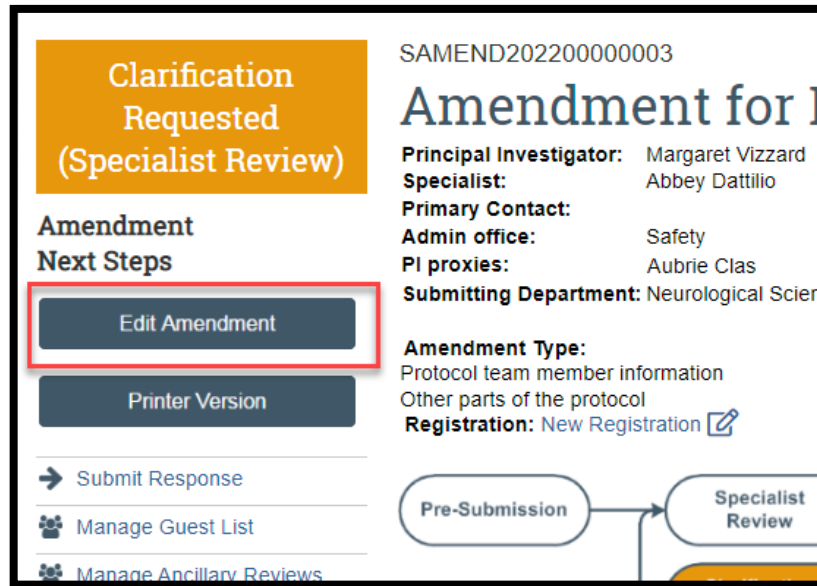
1. On the History tab, you may see a recent entry that says “Clarification Requested” or “Letter Sent” or “Required Modifications Reviewed”. Directly underneath, you will see comments and/or attached files. Review the comments and the content of any attachments (if applicable). The comments and attachments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

**History** Documents Reviews Contacts CITI Training Related Projects ...

Filter by Activity [Enter text to search for]

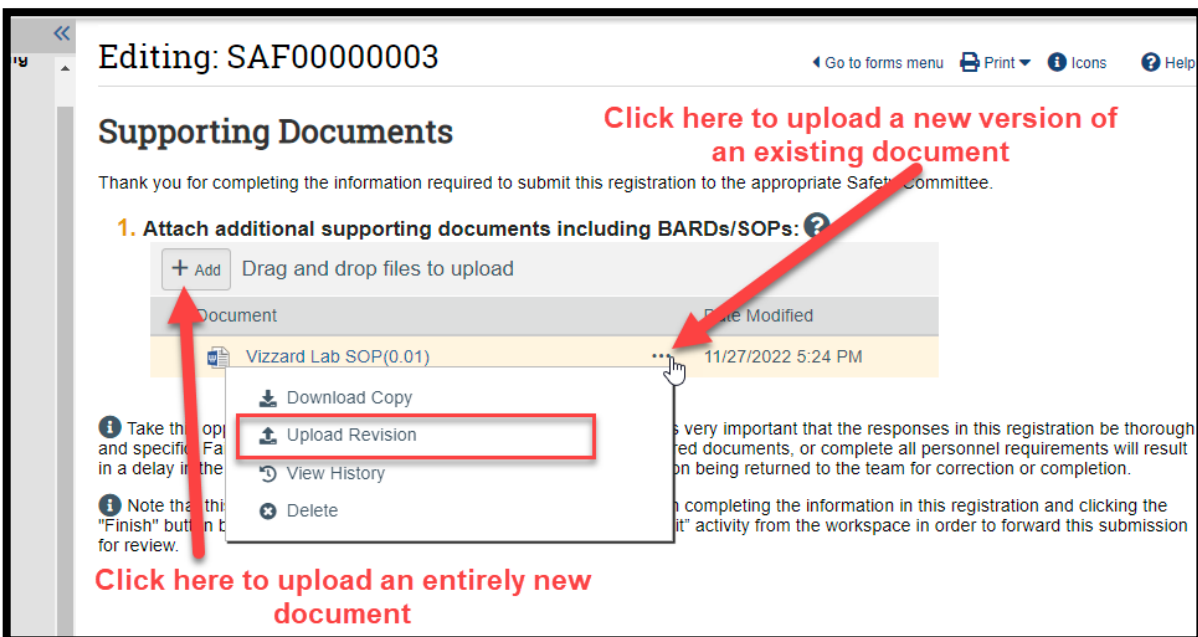
Activity	Author	Activity Date
Clarification Requested by Specialist Please add the name(s) of the personnel being added to question #3 on the amendment form. The storage location for tissues was updated with the new room but the usage location was not. Please confirm that the new room is for storage only.	Dattilio, Abbey L.	11/27/2022 5:12 PM
Submitted	Vizzard, Margaret A.	11/27/2022 5:10 PM
Amendment Created	Vizzard, Margaret A.	11/27/2022 5:07 PM

2. Click the dark grey button called “Edit Amendment” or “Edit Protocol” to open your registration forms.

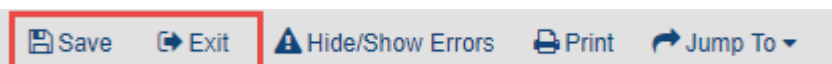


Go through page by page and make the corrections requested. If you have questions, please contact the Research analyst.

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



3. Depending upon the requested change, you will be required to modify the specific fields or uploaded documents in your form. Once you have edited the applicable fields, select “Save”. Then select “Exit”.



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

## Submitting the Clarification back to the RPO Office

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

The screenshot shows a web interface for an amendment. On the left, under 'Amendment Next Steps', there is a list of actions: 'Edit Amendment', 'Printer Version', 'Submit Response' (highlighted with a red box and arrow), 'Manage Guest List', 'Manage Ancillary Reviews', 'Add Comment', and 'Withdraw'. The main content area displays the amendment ID 'SAMEND202200000003' and the title 'Amendment for REG2022'. It lists contact information: Principal Investigator: Margaret Vizzard, Specialist: Abbey Dattilio, Primary Contact: Safety, Admin office: Safety, PI proxies: Aubrie Clas, and Submitting Department: Neurological Sciences. The Amendment Type is 'Protocol team member information' and 'Other parts of the protocol'. The Registration is 'New Registration'. A flowchart on the right shows the process: Pre-Submission -> Specialist Review -> Clarification Requested -> Commitment -> Clarification Requested.

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

The screenshot shows an 'Error/Warning Messages' pop-up with a 'Refresh' button. The message is: 'This is a required field; therefore, you must provide the required information.' Below the message is a table with two columns: 'Field Name' and 'Jump To'. The 'Field Name' is 'Funding Sources' and the 'Jump To' is 'Funding Sources'. A red arrow points to the 'Jump To' button.

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Funding Sources	Funding Sources

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

5. 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 “Dashboard,” and place it in the RPO Office “Dashboard” for processing.

1. Comments:

Optional

2. Supporting documents:

+ Add Optional

Document Name	Date Modified
There are no items to display	

OK Cancel

**Note:** The bubble will change from “Clarification Requested” to “Specialist Review” (or the related “Committee Review”, or “Post Review”)

