

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

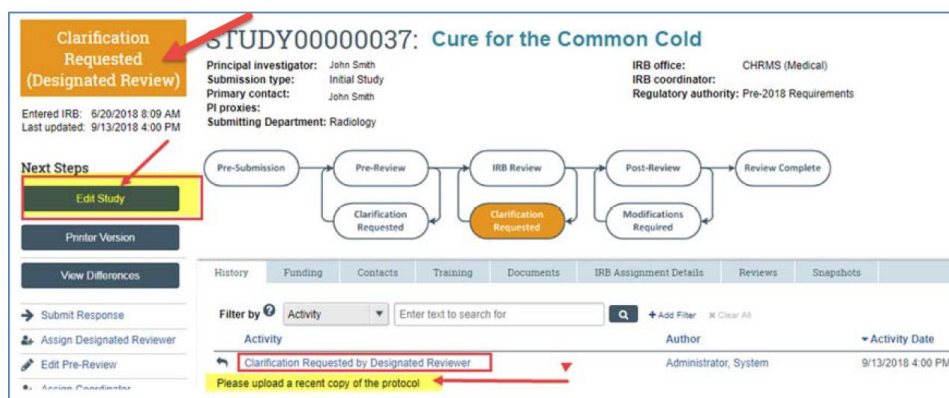
P.I.: [John Smith](#)

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 study/protocol hyperlink. Depending on your login status at the time, the system may require your UVM NeID /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 Designated Review workflow stage.



Clarification Requested (Designated Review)

STUDY00000037: Cure for the Common Cold

Principal investigator: John Smith
Submission type: Initial Study
Primary contact: John Smith
PI proxies:
Submitting Department: Radiology

IRB office: CHRMS (Medical)
IRB coordinator:
Regulatory authority: Pre-2018 Requirements

Entered IRB: 6/20/2018 8:09 AM
Last updated: 9/13/2018 4:00 PM

Next Steps

- Edit Study
- Printer Version
- View Differences

Submit Response
Assign Designated Reviewer
Edit Pre-Review
Assign Proxy

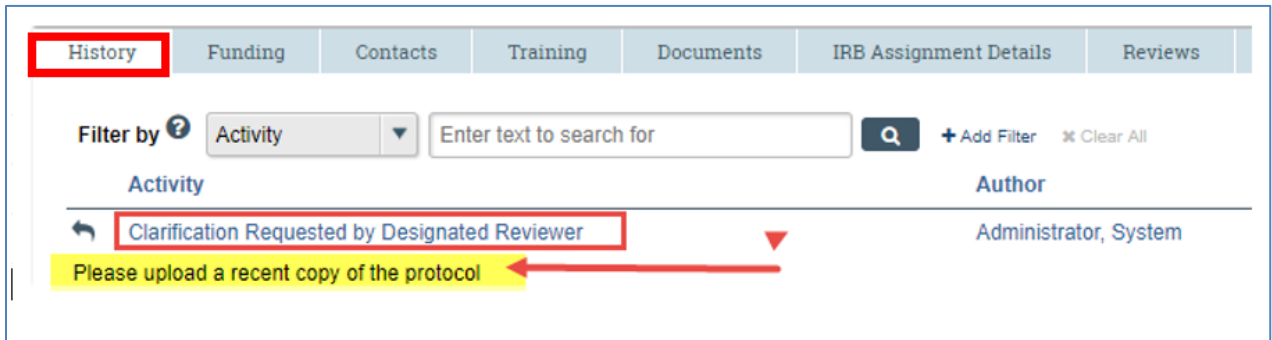
History Funding Contacts Training Documents IRB Assignment Details Reviews Snapshots

Filter by Activity Enter text to search for + Add Filter X Clear All

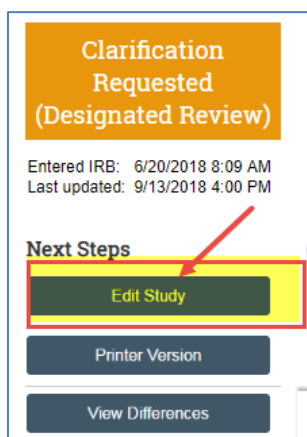
Activity	Author	Activity Date
Clarification Requested by Designated Reviewer	Administrator, System	9/13/2018 4:00 PM
Please upload a recent copy of the protocol		

To Respond to Request for Clarifications

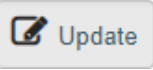
1. On the History tab, you may see a recent entry that says “Clarification Requested” or “Letter Sent” or “Required Modifications Reviewed”. Directly underneath, you will see comments and/or attached files. Review the comments and the content of any attachments (if applicable). The comments and attachments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



2. Click the dark grey button called “Edit Study” to open your forms.

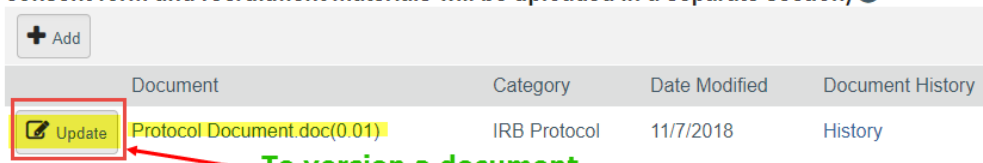


****Tip**** If you need to upload a new version of a previously uploaded document:

- Click the UPDATE  button. Not the +Add button.

Example:

11. * Attach the protocol:
(e.g. industry protocol, human subjects protocol, exempt form, or not human subjects form consent form and recruitment materials will be uploaded in a separate section) ?



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 IRB Office for review.

Submitting the Clarification back to the RPO Office

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

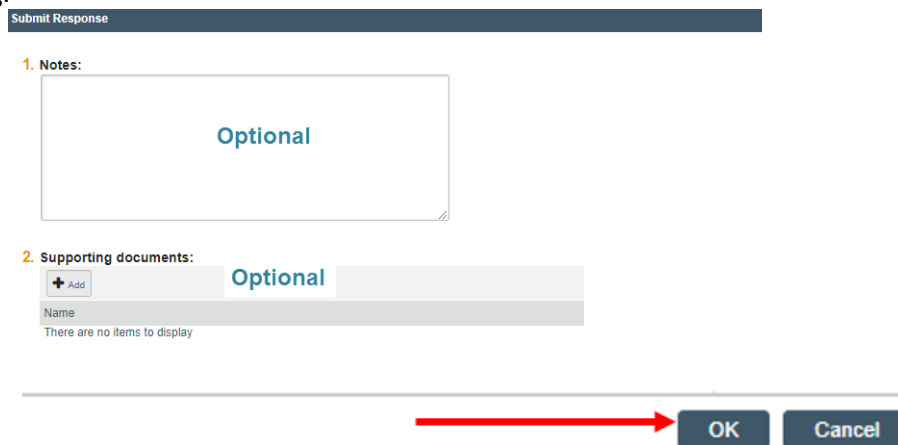


If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop-up to Jump To those particular screens quickly and enter the missing data.

Error/Warning Messages		Refresh
Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Drug Involved	Study Scope
⊖ This is a required field; therefore, you must provide the required information.	Device Involved	Study Scope

NOTE: These Errors/Warning Messages only appear if 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.



Note: The bubble will change from “Clarification Requested” to “IRB Review”.

