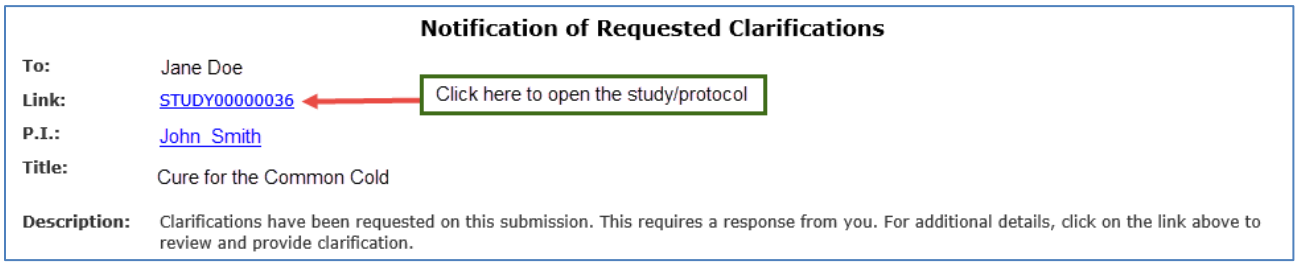
How to Respond to a Clarification Request During Initial Local Context Review of External IRB Studies

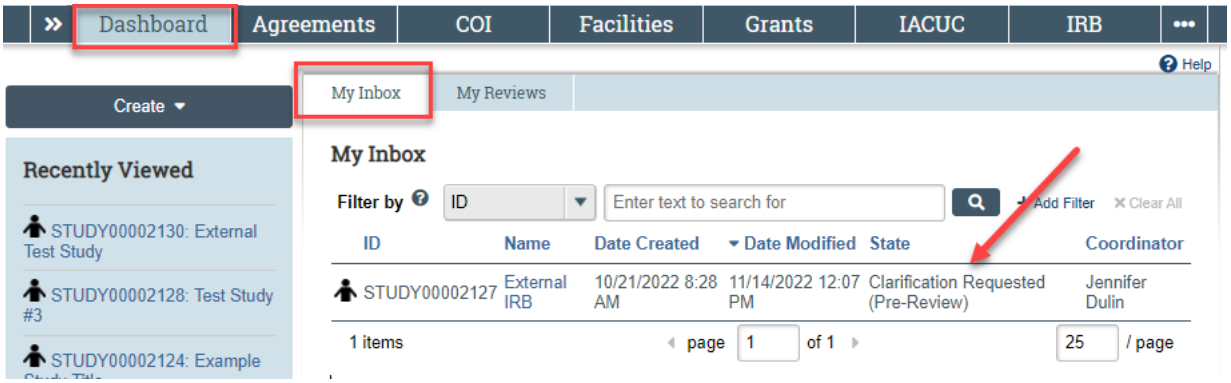
When relying on an External IRB, the UVM IRB needs to conduct local, institutional reviews in UVMClick prior to releasing approval to begin local research activities (see "How to Request Reliance on an External IRB" user guide). The required documentation will be requested through a clarification as needed. The PI/Contact/Proxy will receive an email notification from the IRB Reliance Administrator asking for changes to the Click smart forms or submitted documents.

How do you know that the UVM IRB is waiting for a clarification?

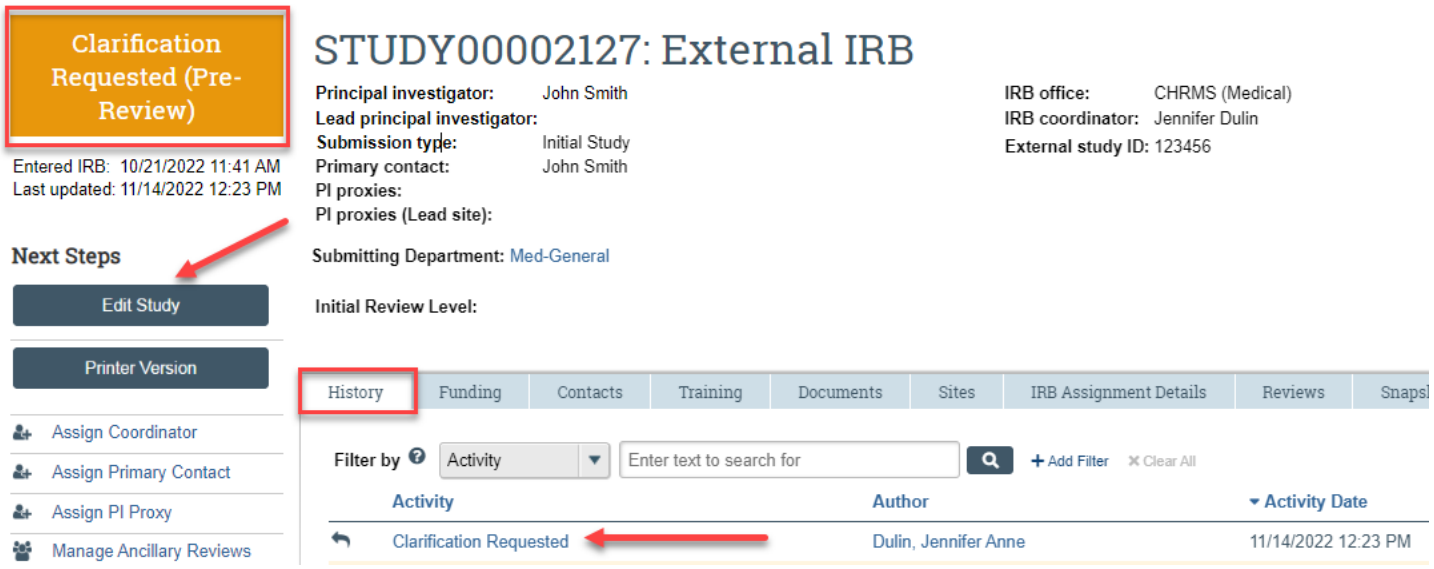
The PI (and any assigned proxy or contact) will receive an email notification requesting the required clarifications. An example of that email is below.



The submission will also appear in your "Dashboard > My Inbox" with a status of Clarification Requested or Modifications Required, and the step of review. An example is shown below.



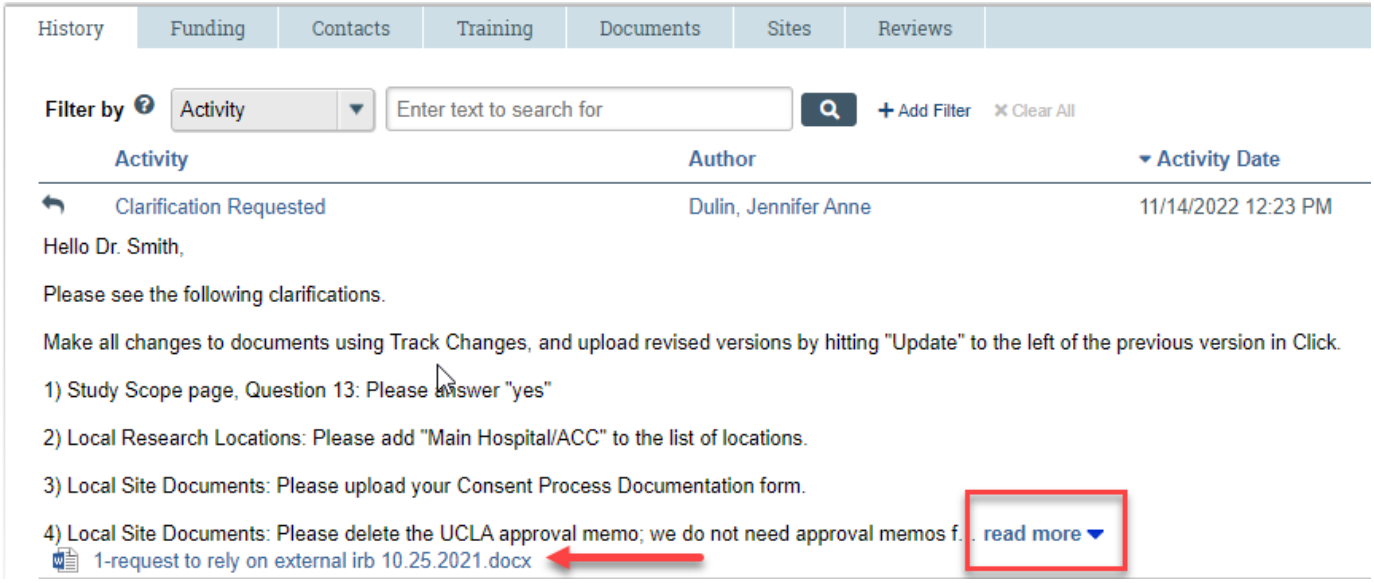
- Click on the study hyperlink. Depending on your login status at the time, the system may require your UVM NetID/password login credentials.
- The submission will appear with a status of Clarification Requested or Modifications Required, along with the step of review. The example below shows Clarification Requested during Pre-Review.



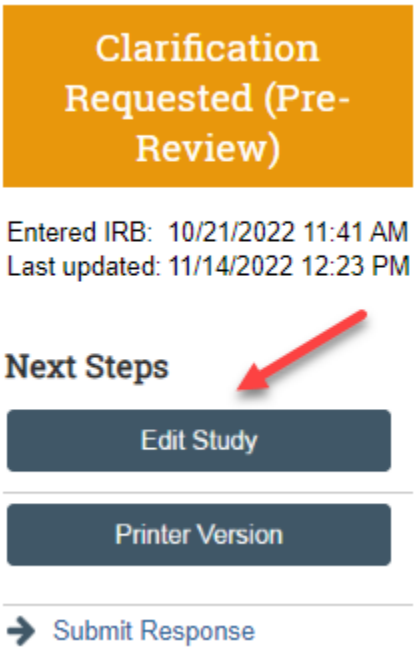
To Respond to Request for Clarifications

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

   Tip If the clarification comments are longer than a few lines, you will see blue text in the bottom right corner that says “read more.” Click on this link to expand the entry and see all required clarifications.



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

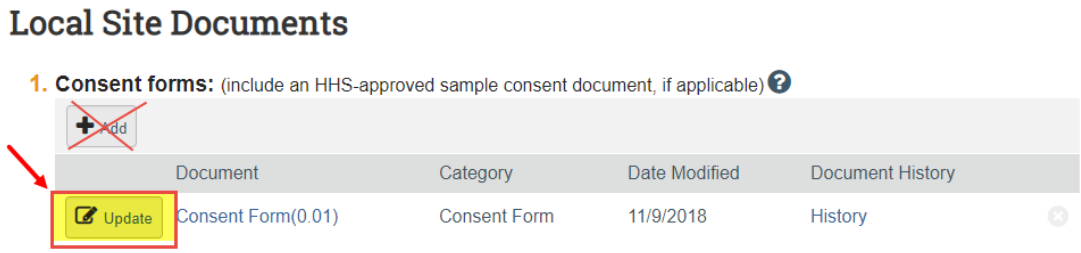


3. Depending upon the requested change, you may be required to modify specific fields or upload documents.

****Tip** When uploading any document:**

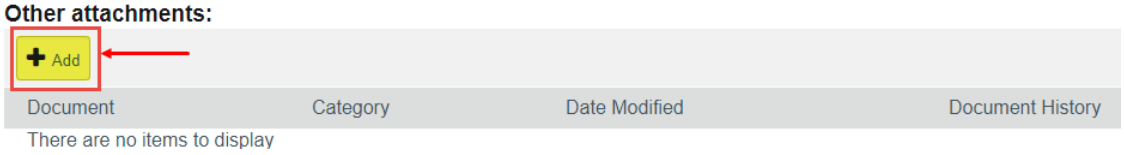
****TIP****If you want to REVISE a previously uploaded document, click the UPDATE button, not the +Add button. Do not hit “x” to delete the previous version at any time. It must remain in the Document History.

Example:



****Tip****If you want to ADD new materials, click the +Add button, not the Update button.

Example:

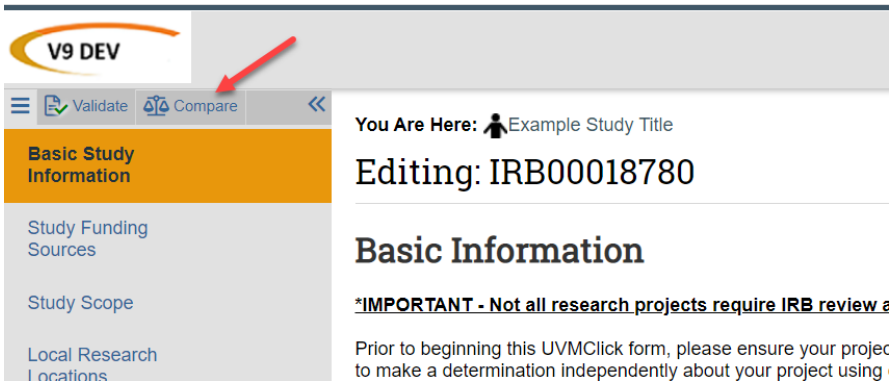


4. Once you have edited the applicable fields, select “Save”. Then select “Exit”.

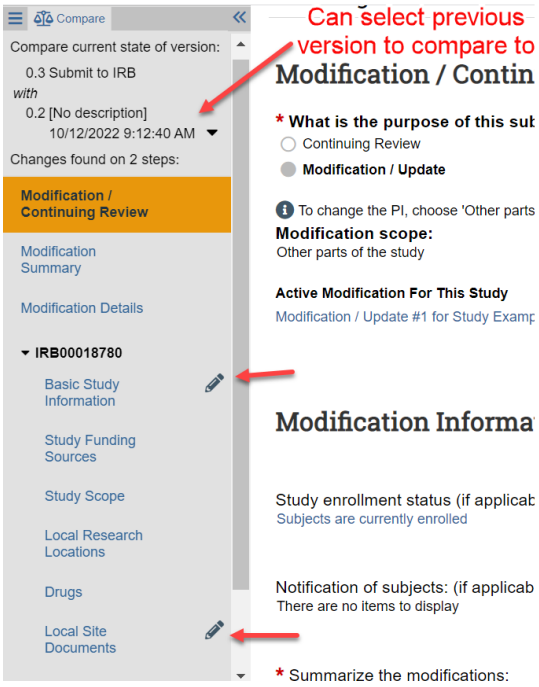
Important! The response has not yet been submitted back to the IRB for review.

Comparing your Updated Submission to Previous Versions

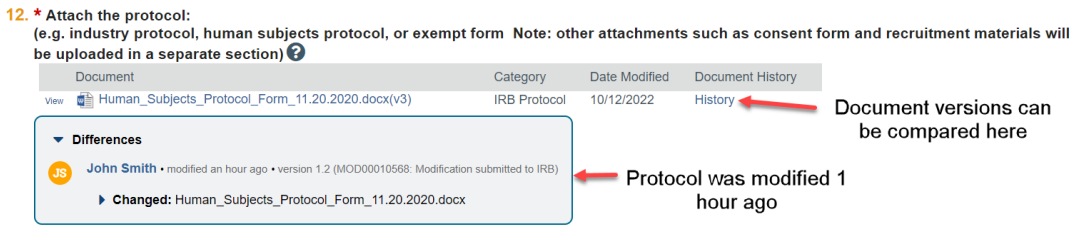
1. To see the modifications made to your study please use the Compare function.



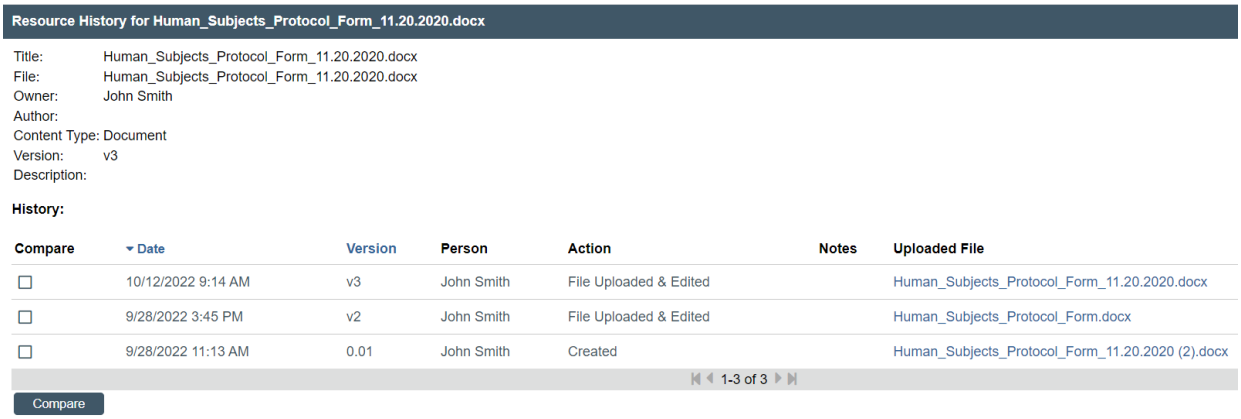
2. On the comparison page, you can select the previous version of the submission for comparison. The pencil icons will show which parts of the study have been edited.



3. Differences can be viewed by clicking on the pencil icon to take you to that section.



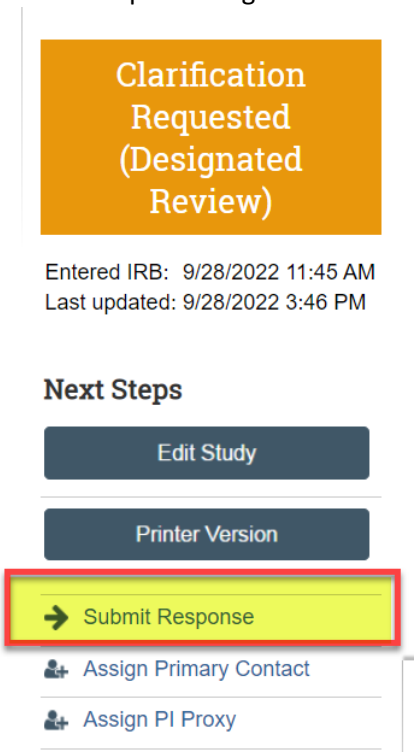
By clicking on the document history, you can compare document versions.



4. To exit the comparison view, click EXIT on the bottom right-hand side of the screen.

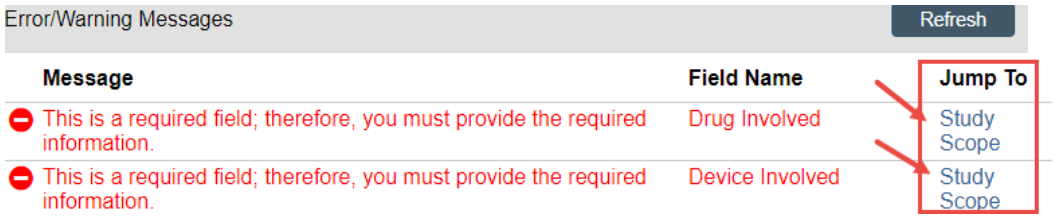
Submitting the Clarification back to the RPO Office

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



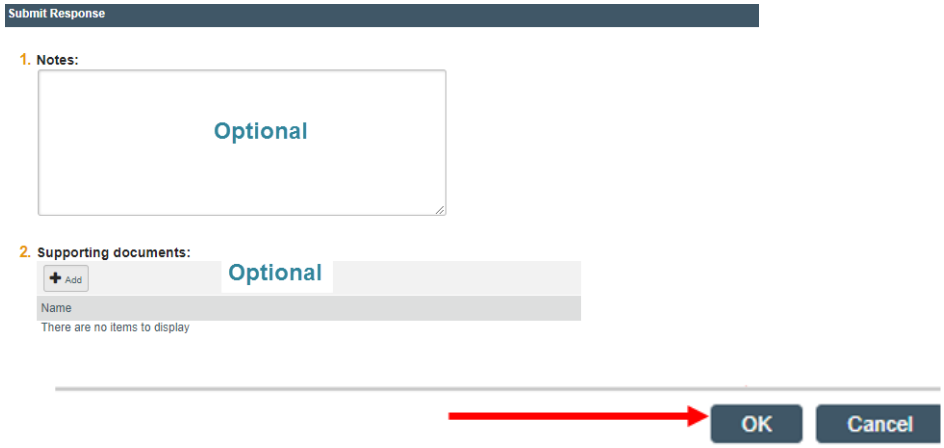
If there are any required fields that you forgot to enter, the Submit process will display them. You can use

the pop-up to Jump To those particular screens quickly and enter the missing data. Click on blue hyperlinks.



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

6. When submitting a response, you have the opportunity to optionally add notes and/or upload supporting documents (do not use this to upload documents required to be in the Smart Forms). These are not required fields. Clicking OK will remove this submission from your "My Inbox," and place it in the IRB Reliance Administrator's "My Inbox" for processing.



Note: The status will change from "Clarification Requested" or "Modifications Required" to an IRB Review status.

Approval to Begin Local Activities

Once the IRB has all of the required documentation, including the site approval memo from the External IRB, approved local consent(s), and all local Ancillary Reviews are completed, you will receive a memorandum that states that you are approved to begin local activities and the IRB review status will be "Review Complete".