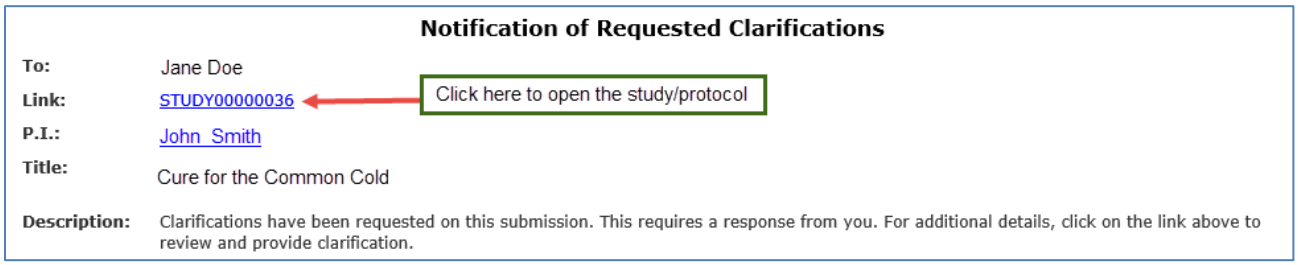
UVMClick Website	https://www.uvm.edu/ovpr/uvmclick	**Email Support**	irb@uvm.edu
UVMClick Login	https://irb.connect.uvm.edu/irb		

How to Respond to a Clarification or Modification Request

During the Pre-Review process, RPO staff may need to return the submission to researchers for clarifications or edits. The PI/contact/Proxy will receive an email notification from the IRB Regulatory Analyst asking for changes to the Click Smart form or IRB submitted protocol documents.

How do you know a clarification is required?

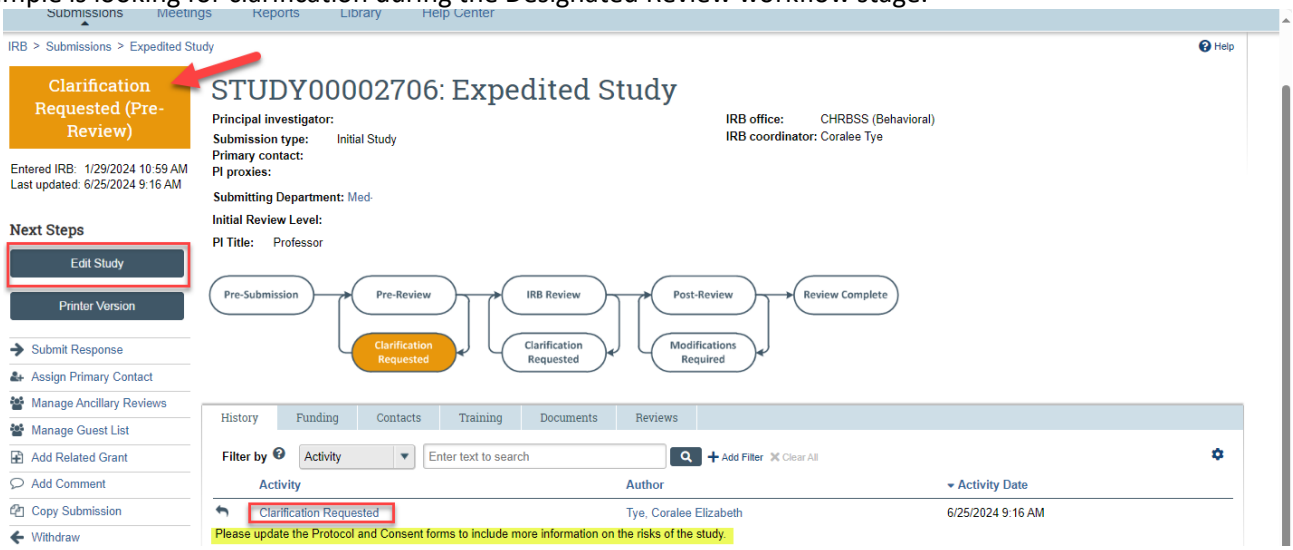
The PI (and any assigned proxy or contact) will receive an email notification requesting a clarification on a submission. An example of that email is below.



- Click on the study/protocol hyperlink. Depending on your login status at the time, the system may require your UVM NeID /password login credentials.

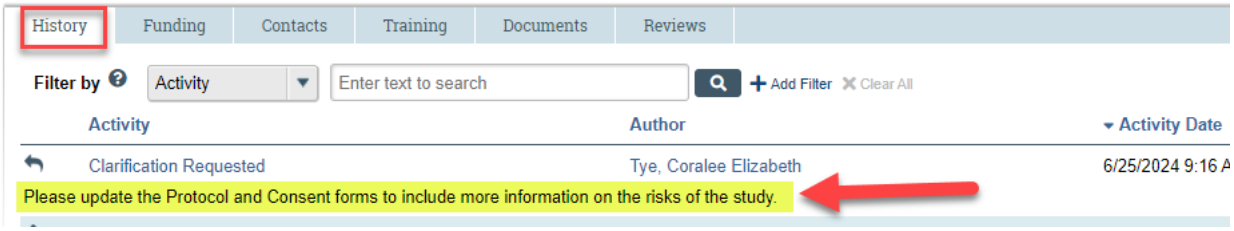
- The submission will appear with a status of “Clarification Requested” or “Required Modifications” along with the step it relates to.

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

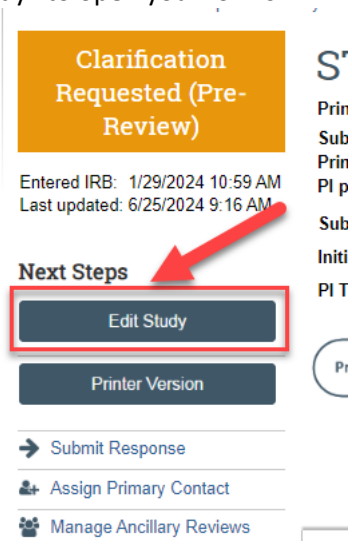


To Respond to Request for Clarifications

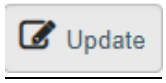
1. On the History tab, you may see a recent entry that says, “Clarification Requested” or “Letter Sent” or “Required Modifications Reviewed”. Directly underneath, you will see comments and/or attached files. Review the comments and the content of any attachments (if applicable). The comments and attachments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



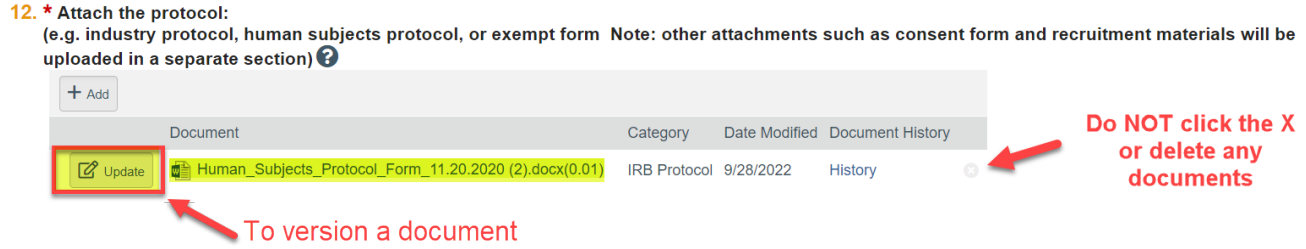
2. Click the dark grey button called “Edit Study” to open your forms.



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

- Click the UPDATE  button. Do not delete previous document versions (do NOT click the x). Do not click the +Add button unless you are adding a new document type.

  Example:

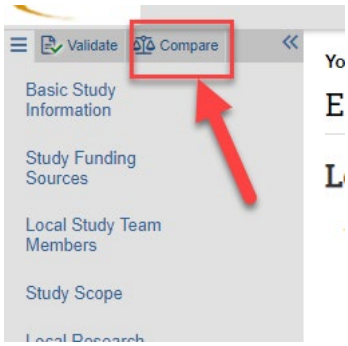


3. Depending upon the requested change, you will be required to modify the specific fields or uploaded documents in your form. Once you have edited the applicable fields, select “Save”. Then select “Exit”.

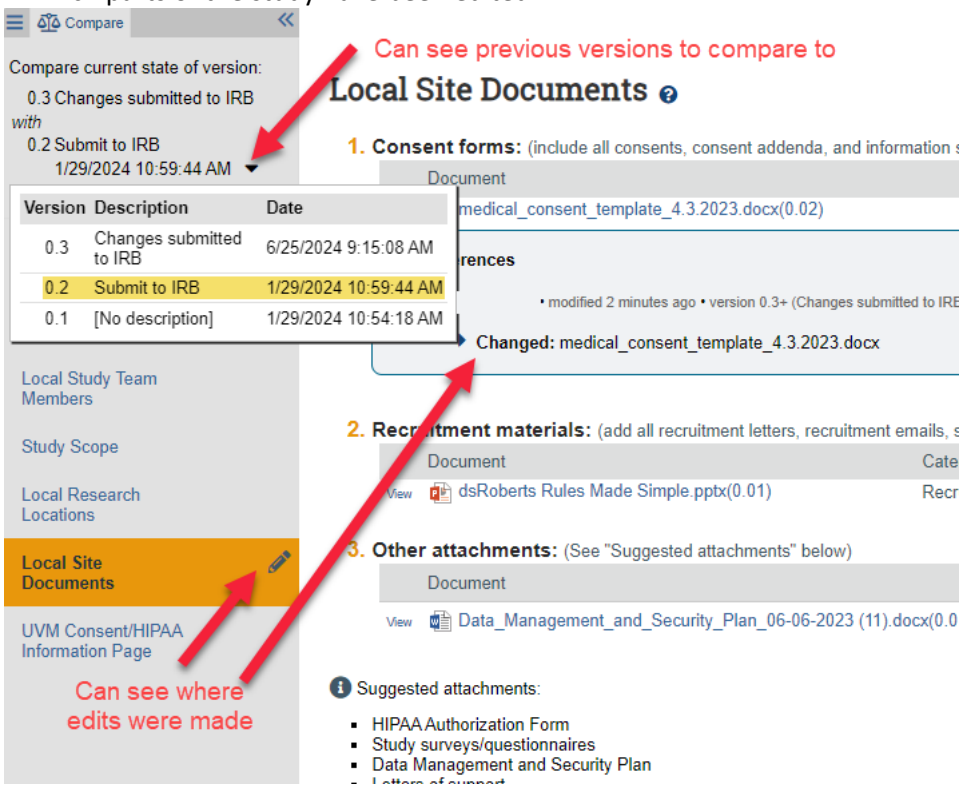
Important! The response has not yet been submitted back to the IRB Office for review.

Comparing your Updated Submission to Previous Versions

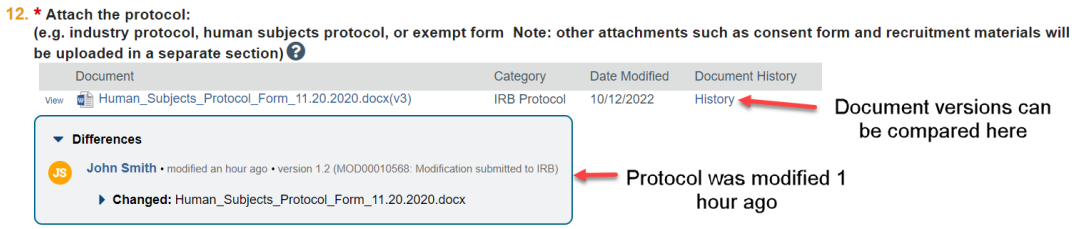
4. To see the modifications made to your study please use the Compare function.



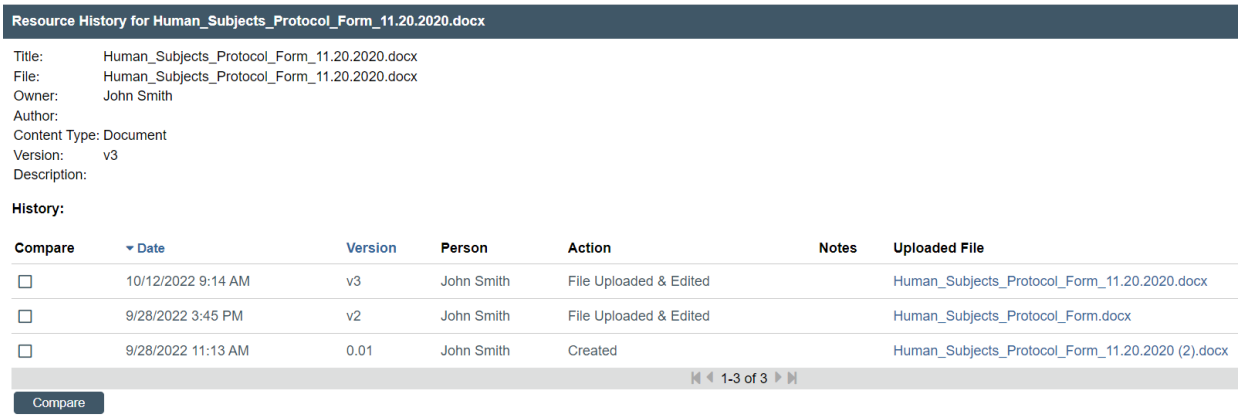
5. On the comparison page, you can select the previous version of the submission for comparison. The pencil icons will show which parts of the study have been edited.



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



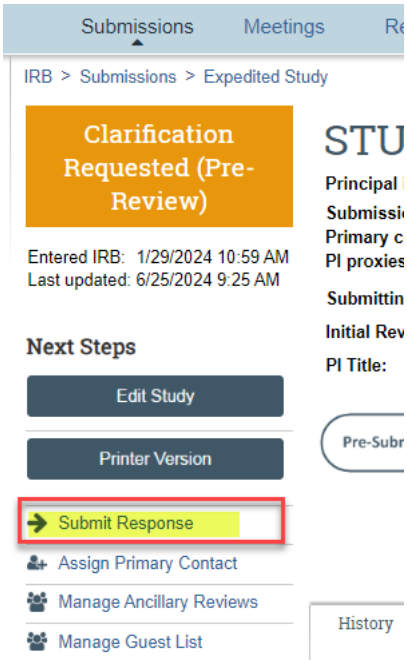
By clicking on the document history, you can compare document versions.



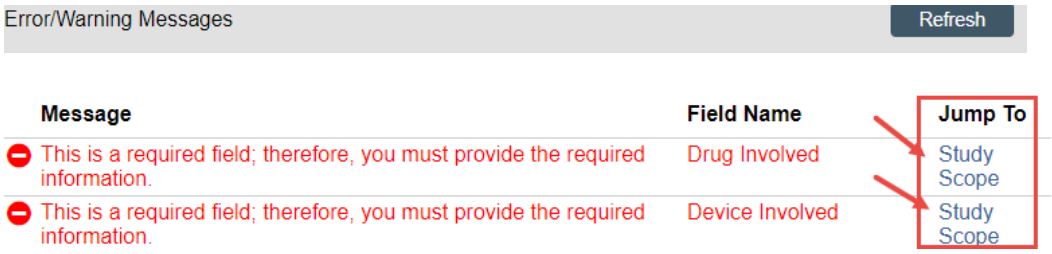
7. To exit the comparison view, click EXIT on the bottom right-hand side of the screen.

Submitting the Clarification back to the RPO Office

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

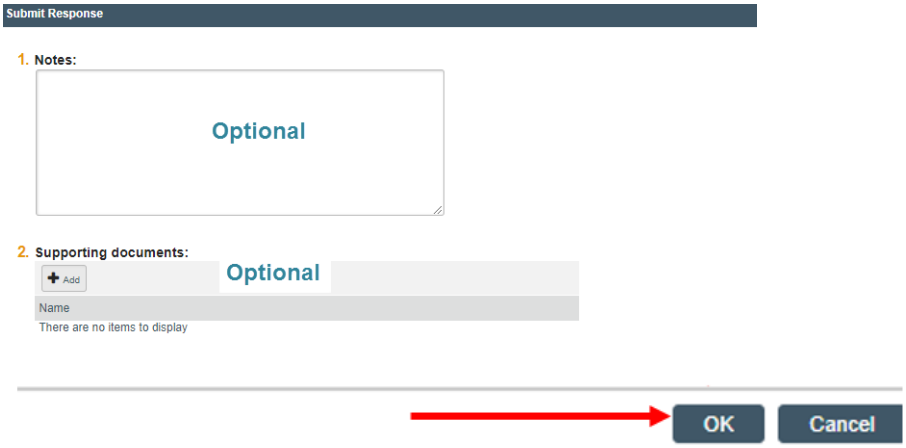


If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop-up to Jump To those particular screens quickly and enter the missing data.



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

9. 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".