How to Create and Submit a Modification (Amendment)

How to prepare for this submission:

Make readily available:

- Protocol (with tracked changes)
- Consent form (with tracked changes)
- Drug or Device Brochure (if applicable)
- Data Safety and Monitoring Reports not affecting risk (if applicable)
- Any new documents pertinent to your modification

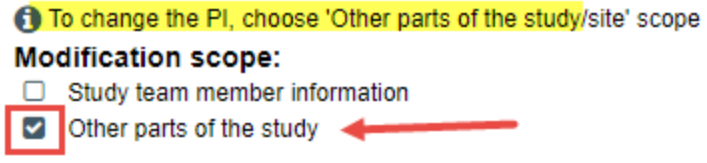
Create a Modification (Amendment)

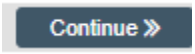
1. Navigate to the appropriate study and click on the name to open it.
2. Click **Create Modification/CR**.

3. Select the **Modification/update** radio button.

4. Check the option "Other Parts of the Study". This includes making a change to any part of an approved study (except study team members) or a change in PI

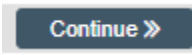
   Note: You can only have one of these types of modifications active at one time.



5. Click Continue (way over on the right side of the screen) 

6. Complete all questions. Required questions will be prefixed with a red asterisk.

   Note: When filling in the question "**Summarize the Modifications**" this text will appear on the future approval letter. Please make sure to type the text carefully. List all modifications to the protocol/consent or other documents and justifications for the required revisions.

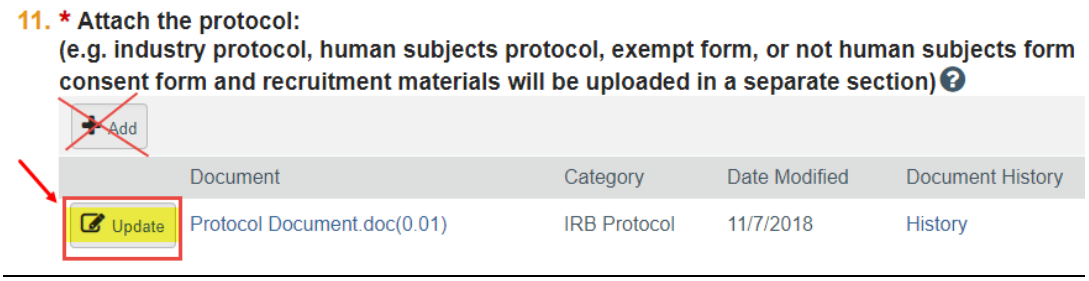
7. Click Continue (way over on the right side of the screen) 

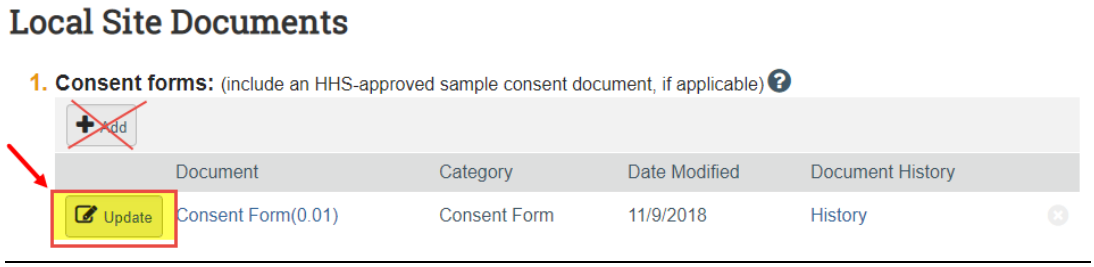
8. Make any and all changes directly to the Click Study screens that you noted in the "Summarize the Modifications" text box. For example – if you are requesting an increase in your study accrual numbers, make sure you list the new accrual number, the justification for the increase and then change question #11 on the Study Scope page.

9. **Continue** to move through the Click pages making changes as needed and click **Finish** on the last page.

! **TIP :** If you want to REVISE a previously uploaded document, click the UPDATE button, not the +Add button.

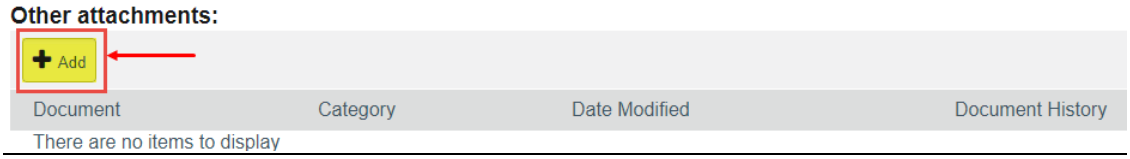
Examples:



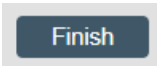


! **TIP :** If you want to ADD new materials, click the +Add button, not the Update button.

Example:



Submit the Modification to the IRB Office for Processing

After exiting the online SmartForm by clicking 

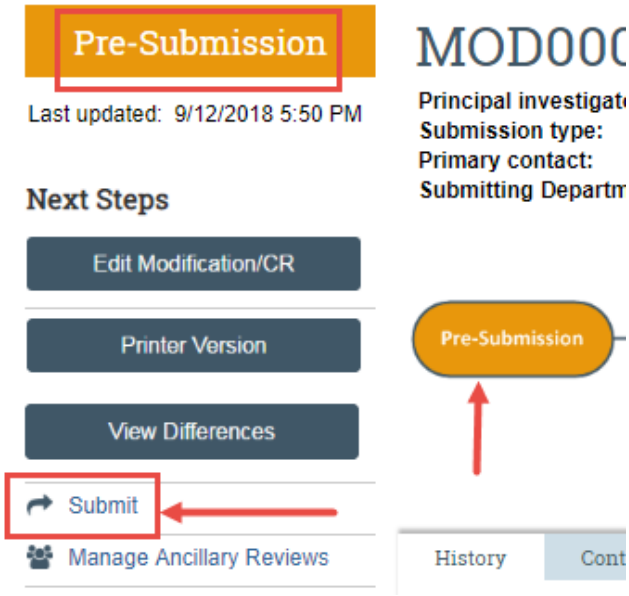
, the status of the submission will still display as "Pre-Submission" and will remain visible in your in-box until submitted to the IRB Office for processing.

REMEMBER: Click the activity on the left that says "**Submit**". If you do not see an activity called "Submit" that means that you are not designated as the PI or the Proxy.

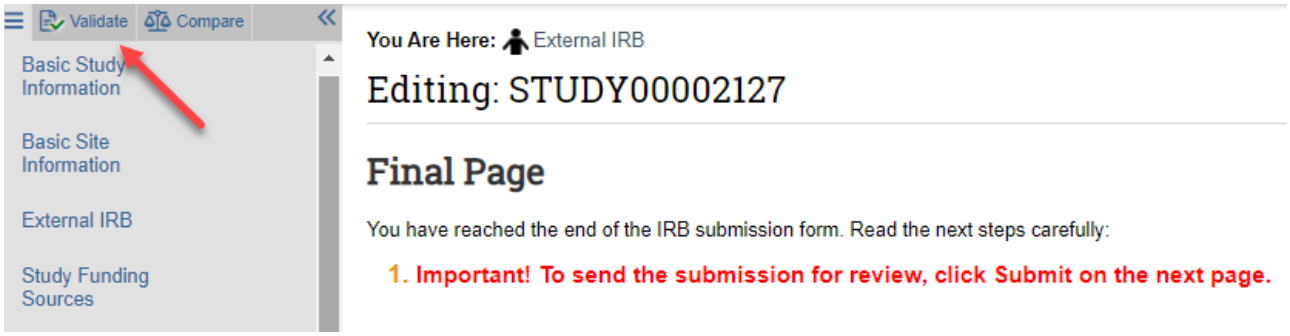
Submission Rules:

- Only the PI and any assigned Proxies have the authority to submit requests to the IRB office. And therefore, they are the only ones who will have the "Submit" activity.
- Only the PI is able to assign a new Proxy. See the user guide called "How to Assign A Proxy" on the UVMClick-IRB website.
- A Proxy must be a member of the study team and have completed the required HS training

After clicking the **Submit** activity, certification text will appear. Read the text and click **OK**.



When you reach the Smart Form called "Final Page," click "**Validate"** at the top, left corner of the page. This will search the submission for errors, specifically incomplete required fields.

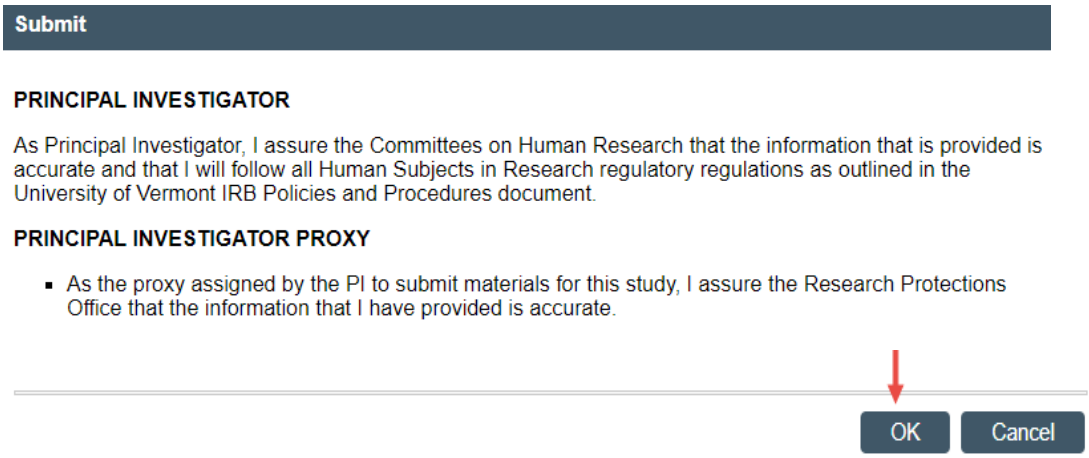


****Tip**** Pages without errors will display a green check "  "

Pages with errors will display a red error sign "  " and will include a blue hyperlink. You can click on this link to take you directly to the error, which will briefly be highlighted in blue.

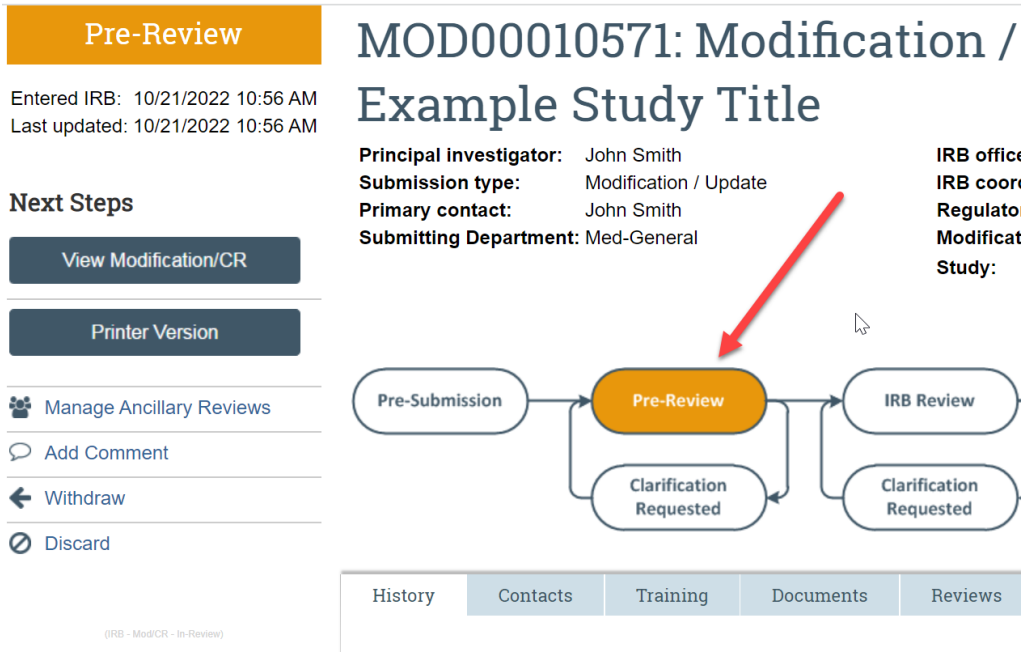
By Clicking on the "compare" button, you will be able to see changes you have made to the Click form, ensure the changes match the description of the modification.

When clicking the **Submit** activity, once all required field entry is complete, certification text will appear. Read the text and click **OK**.



Once submitted, the status of the Modification is no longer "Pre-Submission". It has changed to "Pre-Review" indicating it is in the hands of the IRB Office for processing.

You will also note that the Modification is now in View Mode and no longer in Edit mode.



The Modification has now been submitted and removed from your "My Inbox." It now displays in the IRB Office "My Inbox."