How to Create and Submit a Modification for an External IRB Study

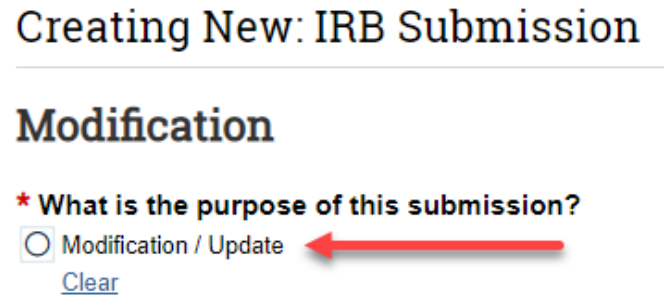
Tip Not all External IRB studies will have the option to "Create Modification." Following the UVMClick V10 upgrade, certain older protocols are classified in a way that only allows for "Update Study Details" to be used (see corresponding User Guide). When available, the "Create Modification" option should be used for ongoing External IRB submissions required by UVM, including key personnel, study closures, and amendments that affect required consent language. This option will allow users to update Study Team Members and Research Locations and other site-related pages such as Basic Site Information and Local Site Documents.

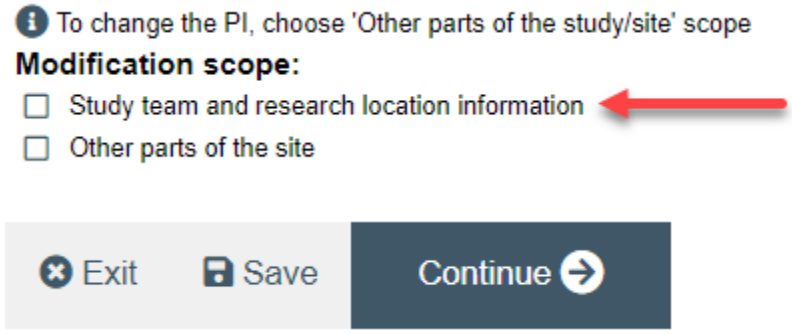
Tip **If you have any questions about which type of submission to make, please contact the IRB Reliance Administrator for guidance.**

1. From the Dashboard tab > "My Inbox" or the IRB tab > "All Submissions" screen, *navigate to the appropriate protocol and click on the name to open it*. For more details about this process, please see the User Guide called "Searching for a Protocol or Submission".

2. Click "**Create Modification"**.

3. Select The Modification / Update radio button, check the Modification scope option you wish to use, and then hit "**Continue"**.





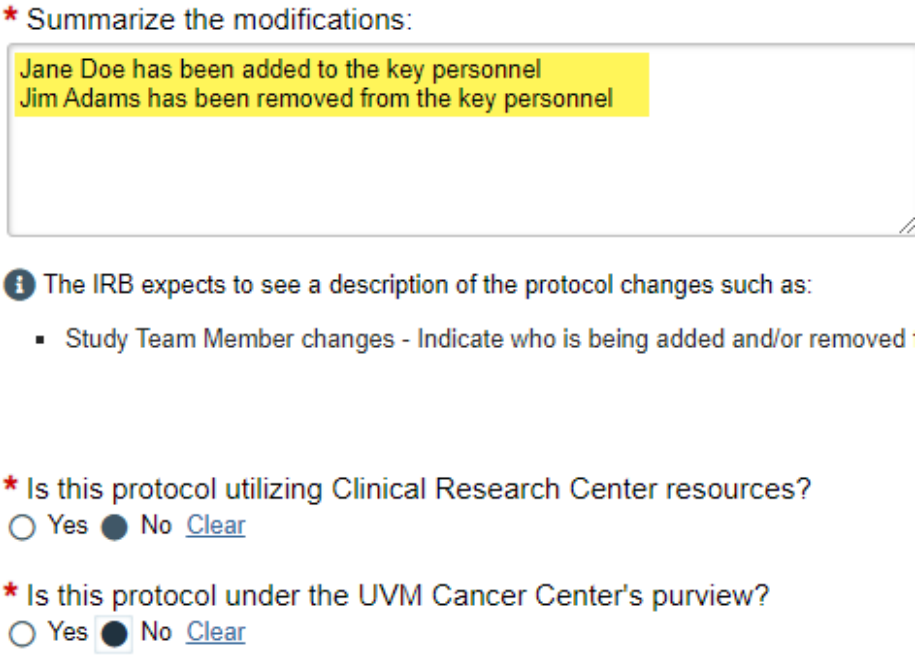
Tip Selecting "Other parts of the site" allows modification of the Basic Site Information page (description of activities this site will perform) and Local Site Documents. If you need to modify the Basic Study Information page (including the protocol), External IRB page, Funding Sources page, Study Scope, Drugs or Devices page, you will have to submit an "Update Study Details" (see corresponding User Guide).

Tip Not all External IRB studies will have the "Other parts of the site" option. On these studies, if you are trying to edit something other than Study Team Members or Research Locations, you will have to use the "Update Study Details" option. Please see the corresponding User Guide.

Study Team Members or Research Locations Modification

Complete the question "**Summarize the Modifications**" by listing the study team members you wish to add, update or remove. Note that this is required field entry as it is 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 include full names of key personnel being modified, and type the text carefully.



Adding a new study team member

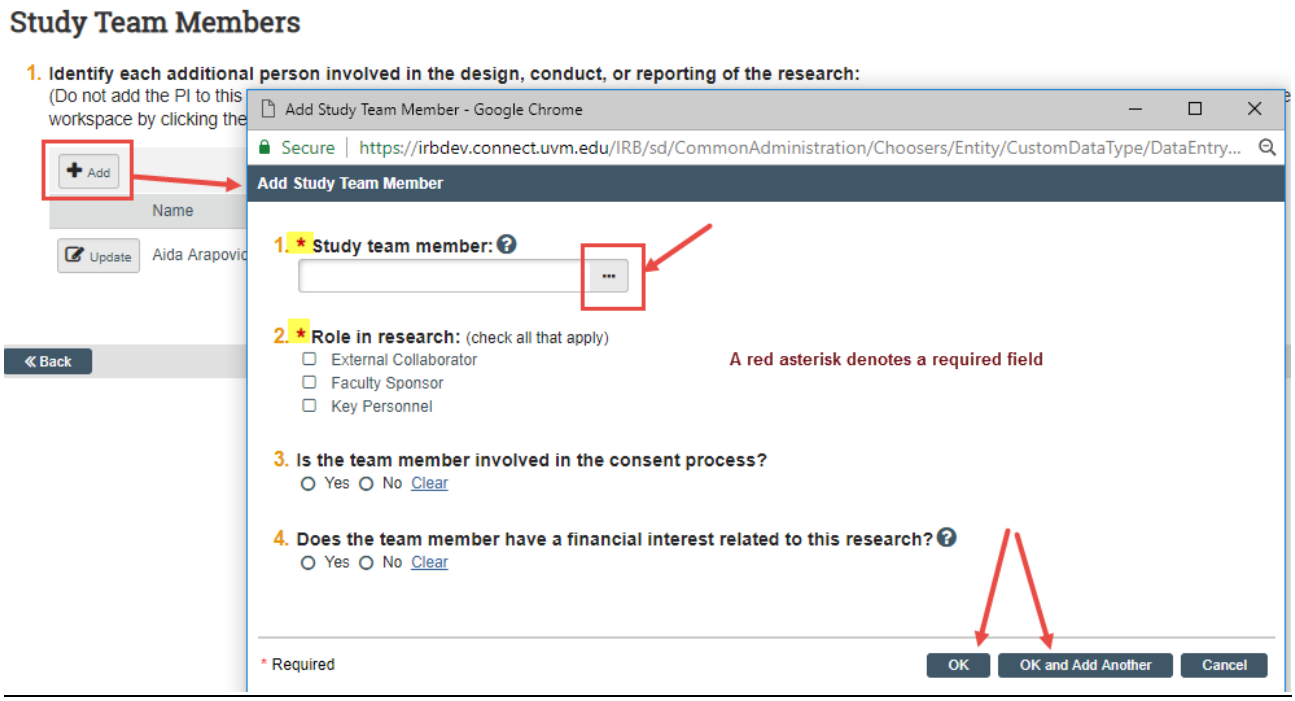
Add new study team members via the +Add button.

- Do not add the PI to this page

- If you are not the PI, add yourself as a study team member.
- If the PI is a student, please assign the role of Faculty Sponsor to the appropriate study team member. Only one person can be listed as faculty sponsor.
- Required Human Subject training (and Good Clinical Practice training if applicable) should be completed prior to adding a new study team member. Approvals will not be released until all key personnel have updated CITI training.
- Make sure that the study team member names you are adding were noted in the previous question "**Summarize the Modifications**".

****Tip**** **If a study team member is not showing up as an option to add:**

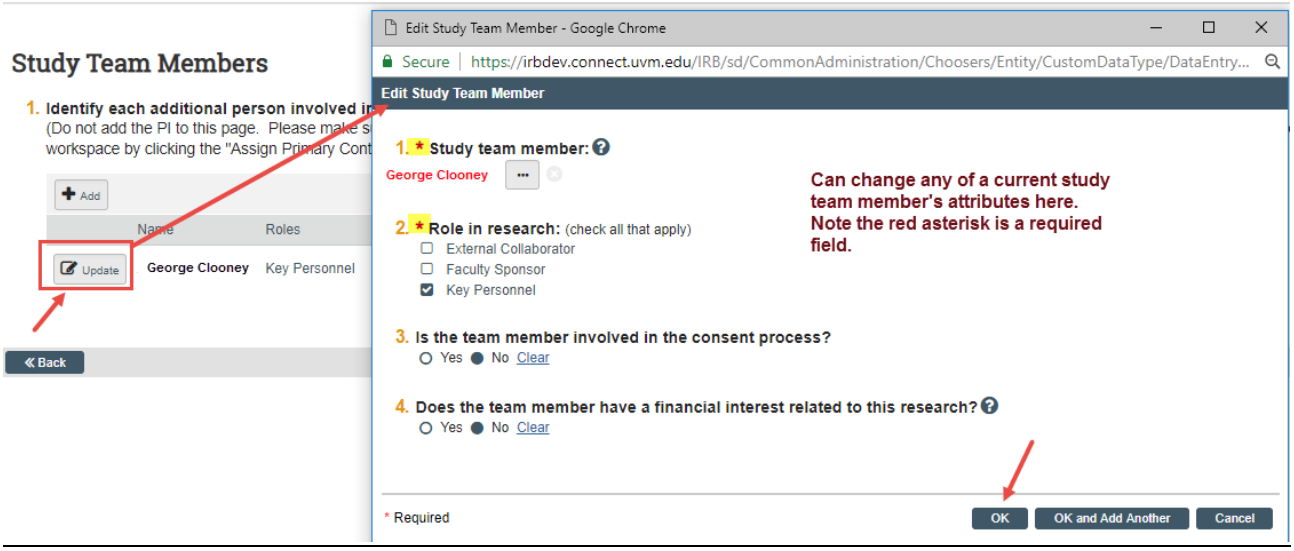
- Students will not appear in UVMClick unless they have allowed the UVM Directory to share their data. Please reference the User Guide: "UVM Students Conducting Research at UVM/UVMMC"
- It may take up to 24 hours for the profile to become available in UVMClick.
- External study team members that are not employed by UVM nor affiliated with UVM through the affiliation agreement (e.g. UVM Health Network), must have approval from the department, Dean and Provost levels to conduct research on behalf of UVM. These individuals must be added to the protocol as External Study Team Members following Collaborations with External Investigators and contact the IRB Reliance Administrator to determine if an Individual Investigator Agreement is required.



NOTE: If you are not able to find the team member name you wish to add after confirming that they have a NetID and are opted into research in the Directory (for students), contact the IRB Office for assistance via irb@uvm.edu.

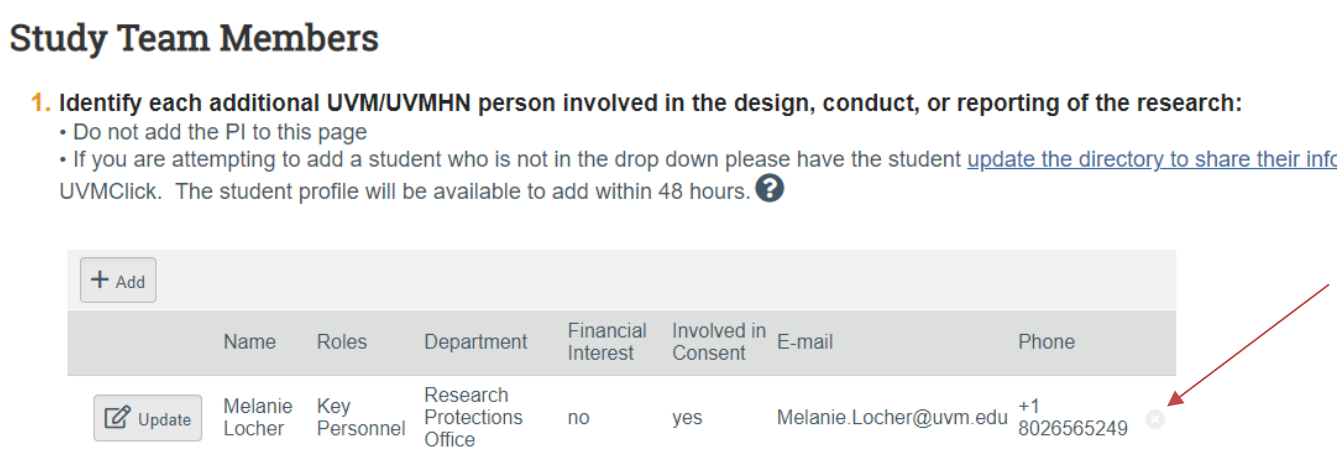
Updating an Existing Study Team Member

- Click the **UPDATE** button next to an existing study team member's name to update their team member information.
- Click **OK**



Removing an Existing Study Team Member

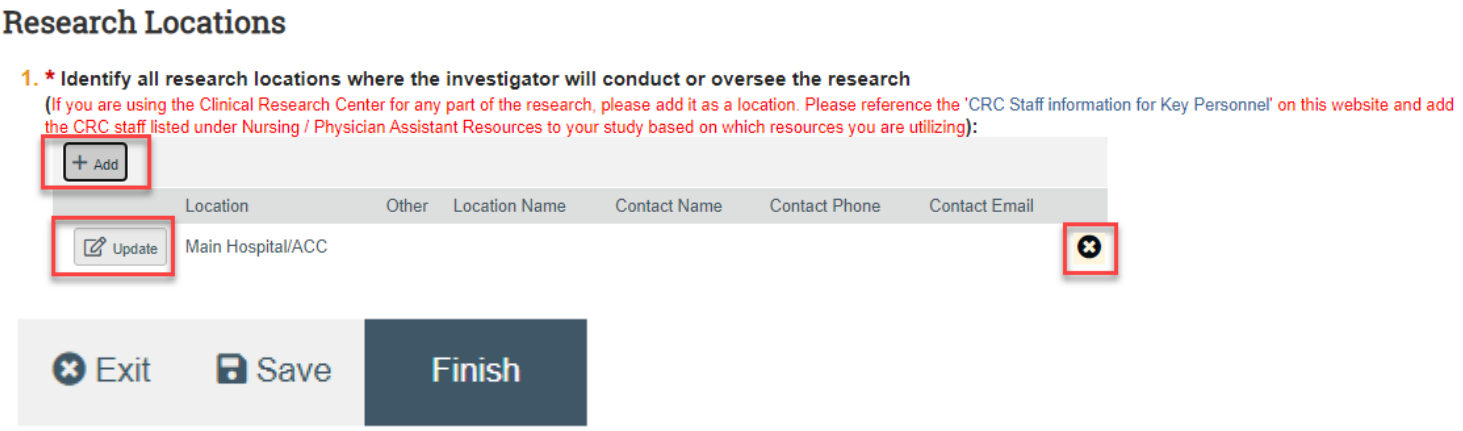
- Click the  icon to the right of the name of the person you wish to remove.
- Click **OK**



Click **"Save"** and then "**Continue"** after making all changes to key personnel.

Adding, Updating, or Removing a Research Location

Using the same instructions for adding, updating, or removing as described above, edit research locations if applicable. If no change to the research locations is required, simply hit "**Finish"** on the bottom, right corner of the screen.



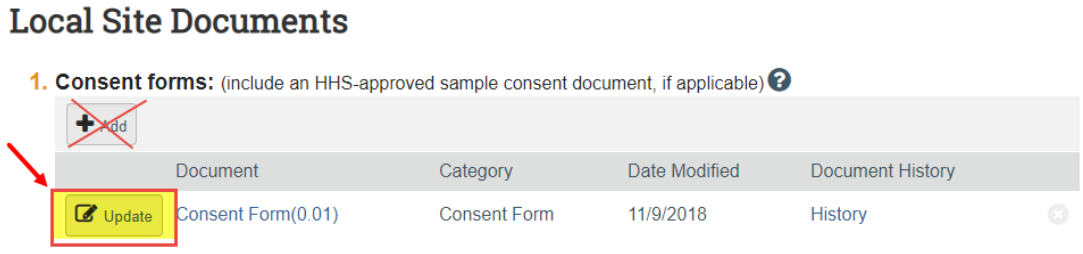
Other Parts of Site Modification

1. Selecting "Other parts of the site" allows modification of the Basic Site Information page (description of activities this site will perform) and Local Site Documents page. If you need to modify the Basic Study Information page, External IRB page, Funding Sources page, Study Scope, Drugs or Devices page, you will have to submit an "Update Study Details" (see corresponding User Guide).
2. 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. Keep in mind the UVM requirements for ongoing submissions in External IRB studies.
3. Make any and all changes directly to the Click pages that you noted in the "Summarize the Modifications" text box. "**Continue**" to move through the Click pages making changes as needed, and click "**Finish**" on the last page.

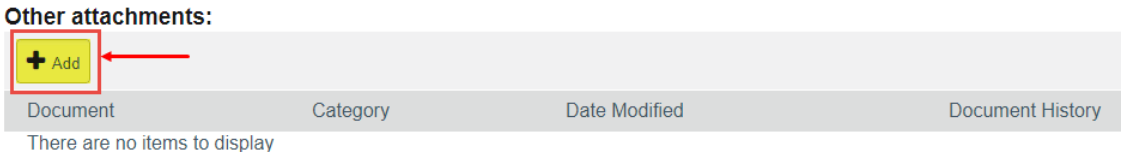
TIPIf you want to REVISE a previously uploaded document, click the UPDATE button, not the +Add button. Do not hit "x" to delete the previous version at any time. It must remain in the Document History.

Example:



TipIf you want to ADD new materials, click the +Add button, not the Update button.

Example:



Submit the Modification on an External Study

After clicking "**Finish**" to exit the Modification, the status of the submission will continue to display as "Pre-Submission" and will remain visible in your My Inbox until submitted to the IRB for review.

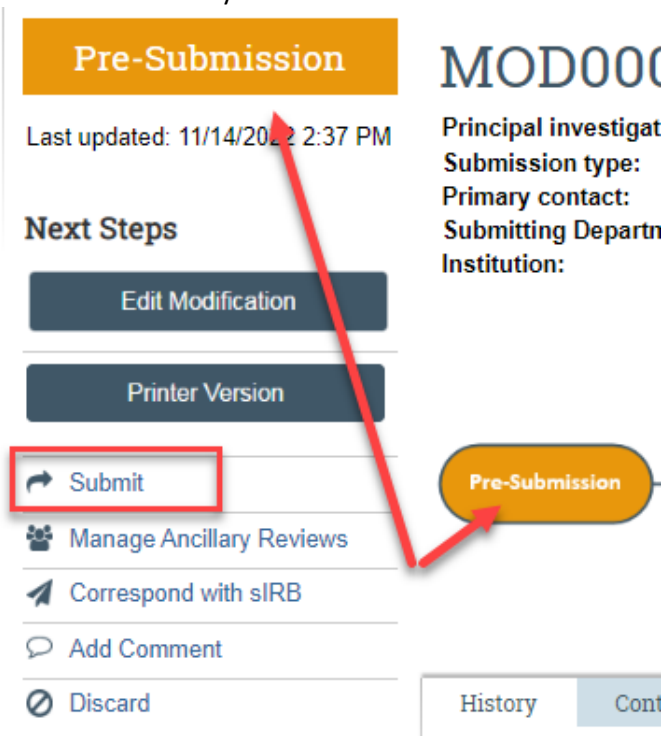
Submission Rules:

- Only the PI and assigned Proxies have the authority to submit to the IRB office. Therefore, they are the only ones who will have the "Submit" activity. If you do not see an activity called "Submit" that means that you are not designated as the PI or the Proxy.
- 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

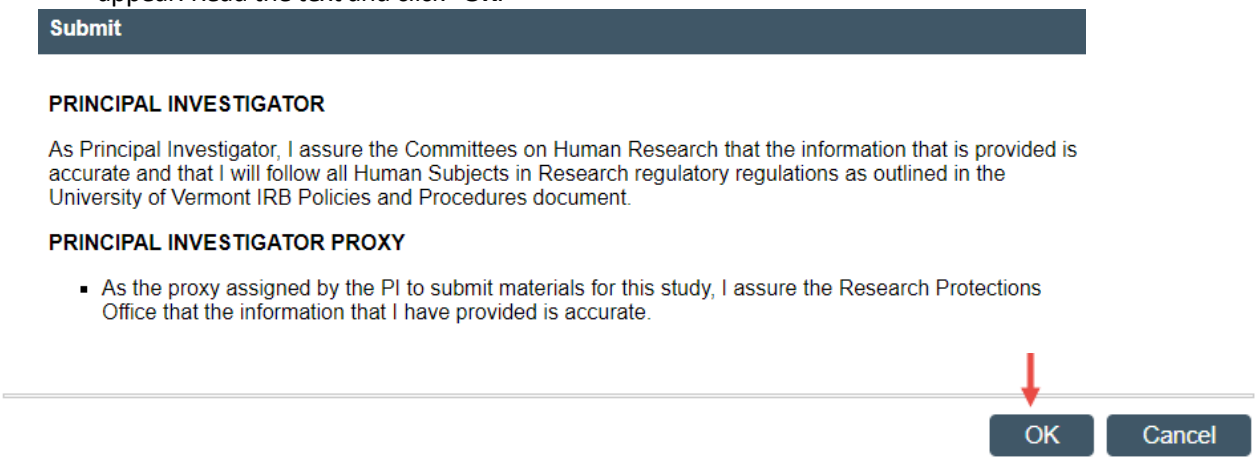
To submit a completed Modification to the IRB for review:

1. From the Dashboard tab > "My Inbox" or the IRB tab > "All Submissions" screen, *navigate to the appropriate Modification and click on the name to open it*.

2. Click the activity on the left side of the main Modification page that says "**Submit"**



3. After clicking the "**Submit"** activity, UVMClick will check for errors in the submission and then a verification text will appear. Read the text and click "**OK**."



The Modification has now been submitted and removed from your "My Inbox." The status of the Modification is now "Pre-Review" indicating it is in the hands of the IRB for review. You will also note that the Modification is now in View Mode and no longer in Edit mode.