How to Create and Submit an Update Study Details for an External IRB Study

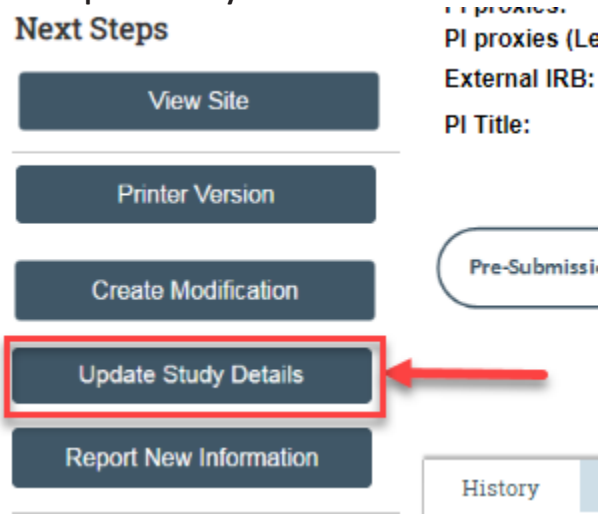
Tip Not all External IRB studies will have the option to "Create Modification," but this should be used whenever available (see corresponding User Guide) to update site-specific pages such as Basic Site Information, Local Site Documents, Study Team Members and Research Locations.

Following the UVMClick V10 upgrade, certain older protocols are classified in a way that only allows for "Update Study Details" to be used. This option will allow you to modify the Basic Study Information page (including the protocol), External IBR page, Funding Sources page, Study Scope, Drugs or Devices page, and on some studies, the Study Team Members, Research Locations, Basic Site Information and Local Site Documents page (though these last 4 will only be available using this method if "Create Modification" is not available).

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 "**Update Study Details**".



3. Complete the question "**Summarize the Updates**" by listing all modifications to the Study Team or other parts of the study/site including documents, and justifications for the required revisions. Keep in mind the UVM requirements for ongoing submissions in External IRB studies. Note that this is required field entry as it is prefixed with a red asterisk.

Study Team Members or Research Locations Update

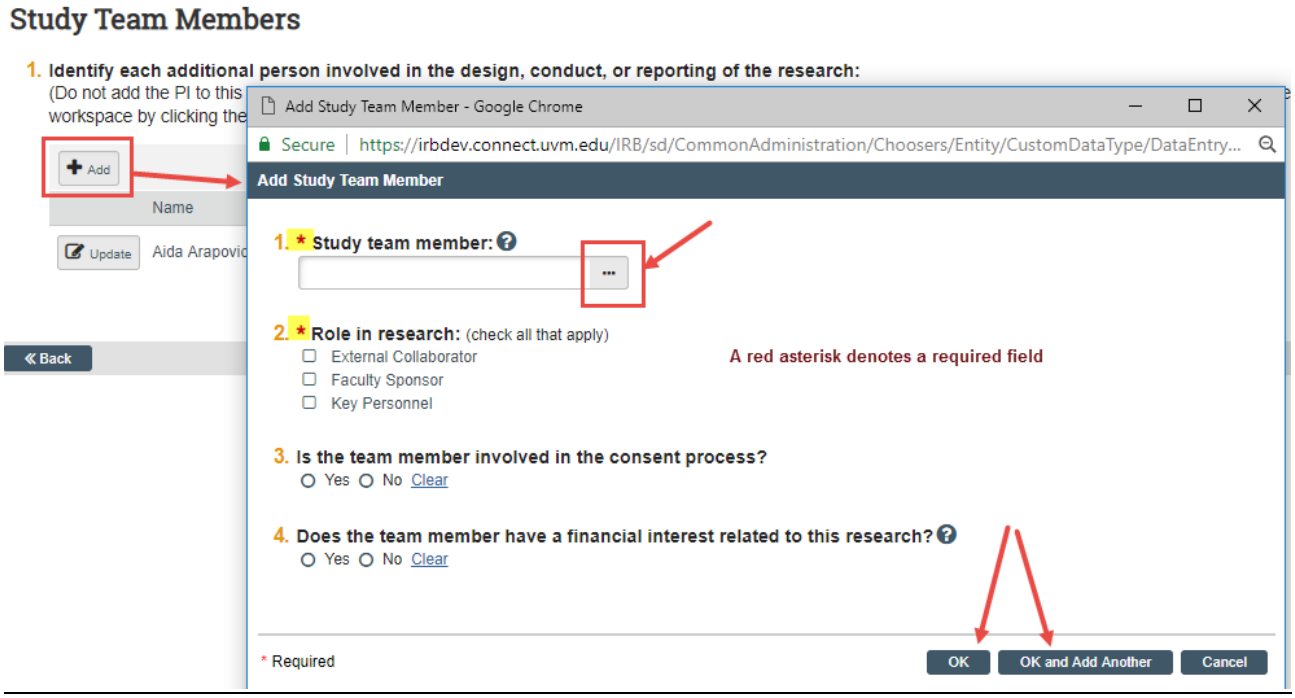
Adding a new study team member

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:**

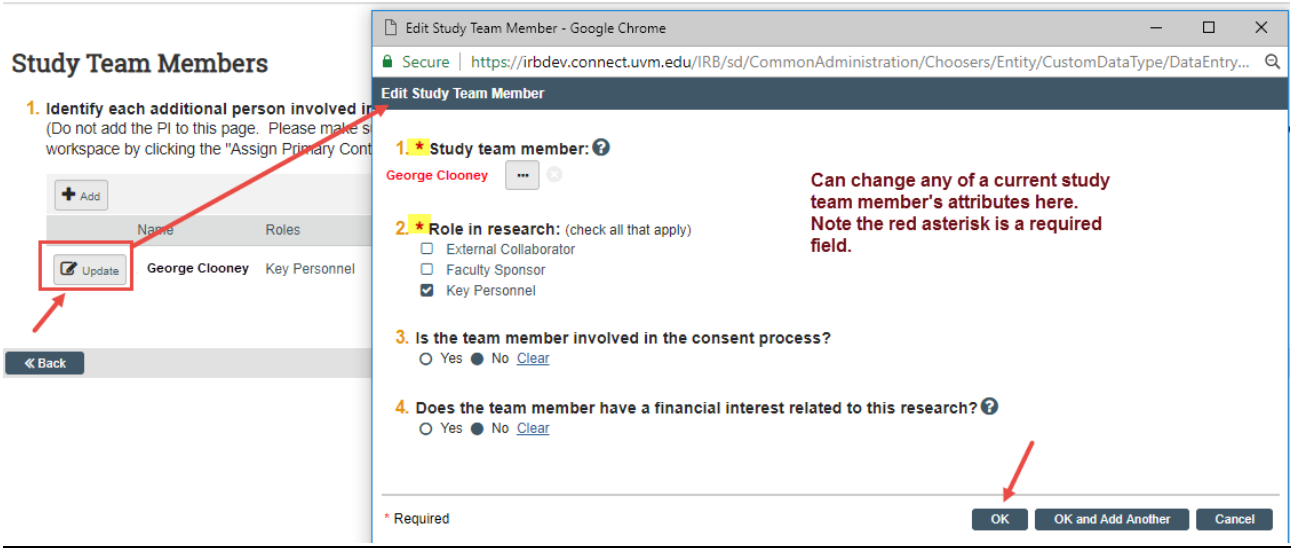
- Students will not appear in UVMClick unless they have allowed the UVM Directory to share their data. Please reference the User Guide: "UVM Students Conducting Research at UVM/UVMMC"
- External study team members that are not employed by UVM nor affiliated with UVM through the affiliation agreement (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.

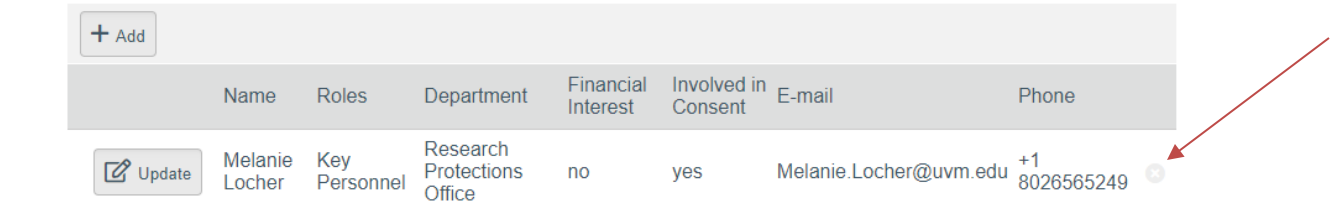
Updating an Existing Study Team Member

- 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

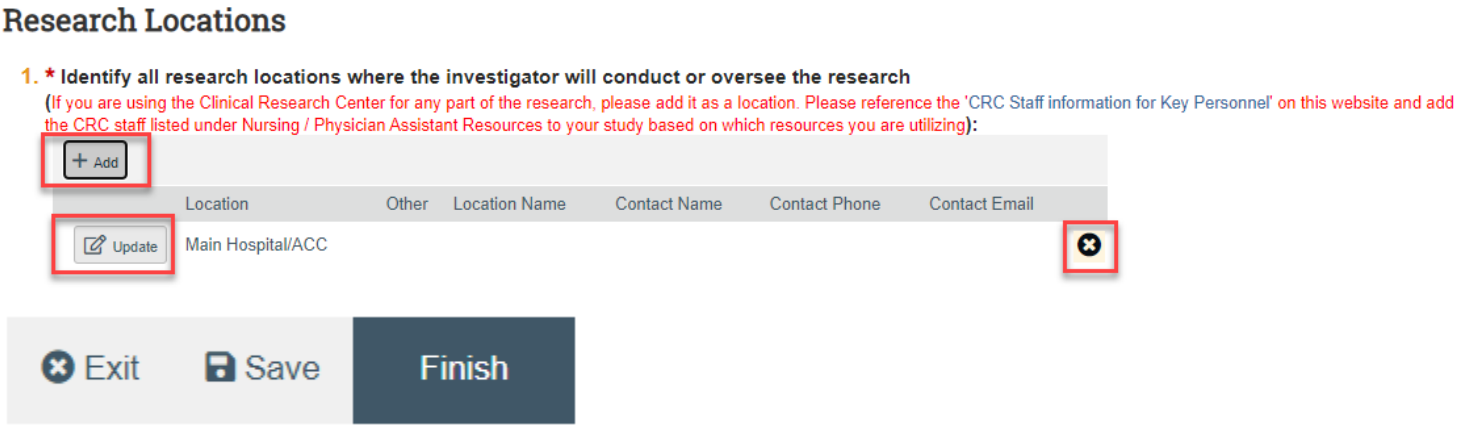
- Click the  icon to the right of the name of the person you wish to remove.
- Click **OK**



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.

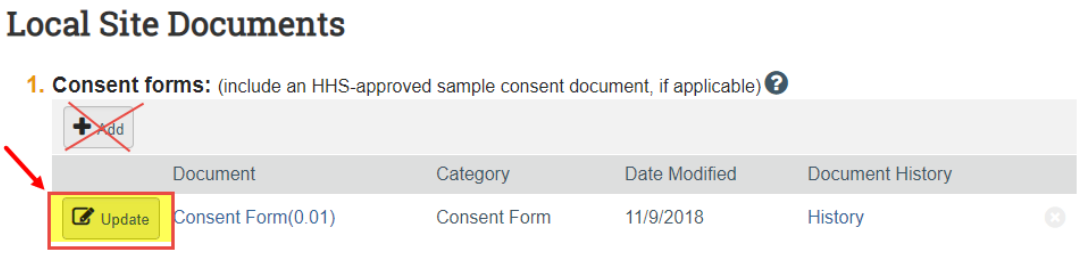


Other Parts of Site Update

1. Make any and all changes directly to the Click pages that you noted in the "Summarize the Updates" text box. "**Continue**" to move through the Click pages making changes as needed, and click "**Finish**" on the last page.

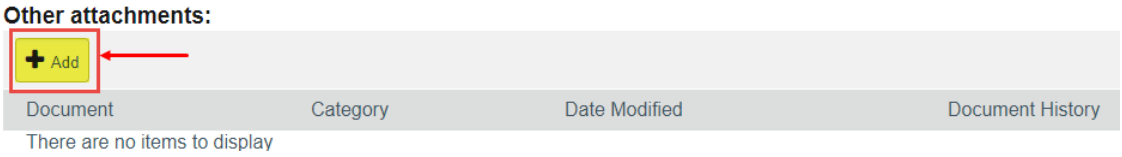
****TIP****If you want to REVISE a previously uploaded document, click the UPDATE button, not the +Add button. Do not hit "x" to delete the previous version at any time. It must remain in the Document History.

Example:



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

Example:



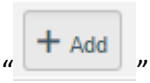
Submit the Update on an External Study

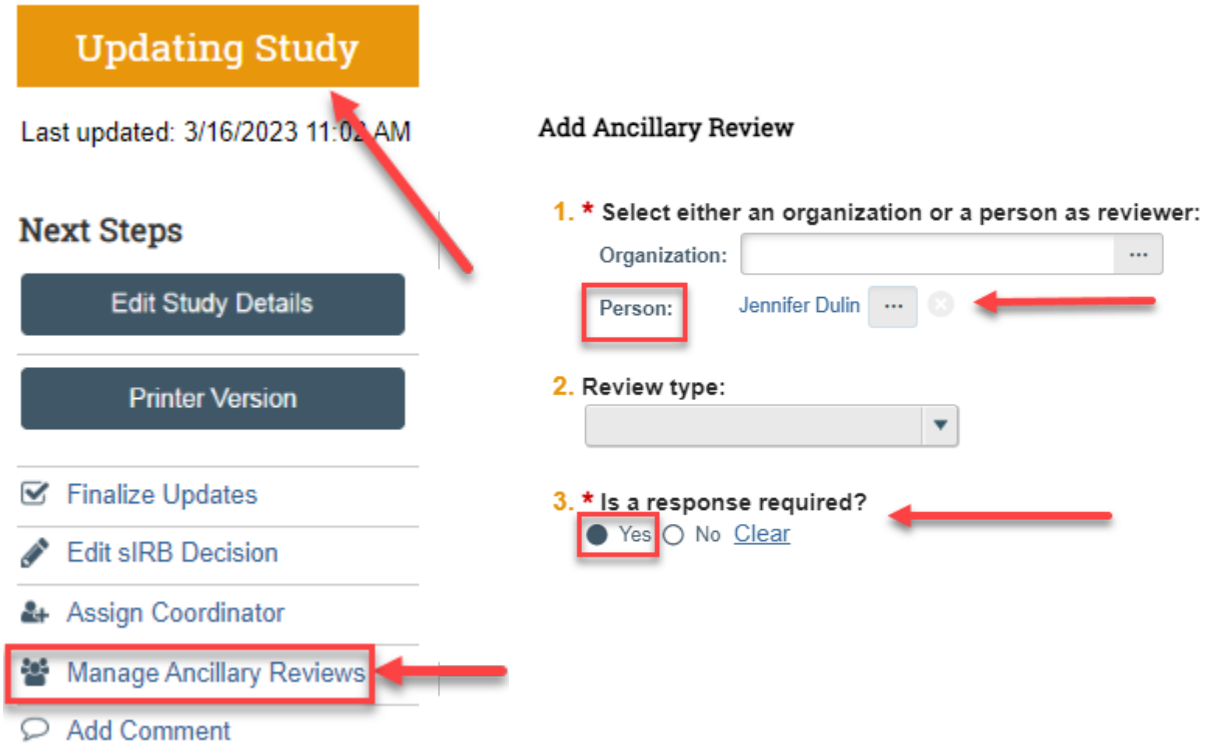
After clicking "**Finish**" to exit the Update Study Details, the status of the submission will display as "**Updating Study**" and will remain visible in your My Inbox. There is no submit function on an Update Study Details submission. To route the submission to the IRB Reliance Administrator for review and finalization, follow these steps:

1. If you are not already in the update, from the Dashboard tab > "My Inbox" or the IRB tab > "All Submissions" screen, *navigate to the appropriate External IRB protocol and click on the name to open it. From the "History" tab, select the appropriate EXTUPDATE to open.*

2. **IMPORTANT: Do not select "Finalize Updates." This will be completed by the IRB Reliance Administrator.**

3. Assign the IRB Reliance Administrator as an Ancillary Reviewer to route review of the Update to the IRB. Click the activity on the left side of the page that says "**Manage Ancillary Reviews."**

4. Then, hit the "  " button. A new window will pop up; complete Question 1 with the name of the current IRB Reliance Administrator under the Person field. Question 2 can remain unanswered. Question 3 should be answered "yes." Then hit "**OK**" at the bottom right of the pop-out window AND "**OK**" at the bottom right of the Manage Ancillary Reviews window.



The Update Study Details (EXTUPDATExxxxxxxx) has now been routed to the IRB. Any required clarifications will be communicated from the IRB to the study team via a Comment on the submission. The Update remains in an editable state. Any clarifications should be addressed by the study team, and then the study team should use "**Add Comment**" on the left side of the main page to alert the IRB Reliance Administrator that the clarifications have been addressed. When all clarifications are complete, the IRB Reliance Administrator will "**Finalize Updates**," incorporating the changes into the External IRB record.