How to Create and Submit a Modification (Study Team Member)

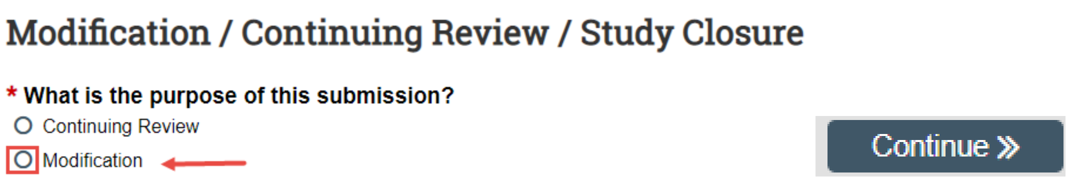
Please Note: Many of the IRB Forms have transitioned into our UVMClick online smartforms. The Key Personnel Change form has been retired and transitioned into an online smartform.

Create a Modification (Study Team Member)

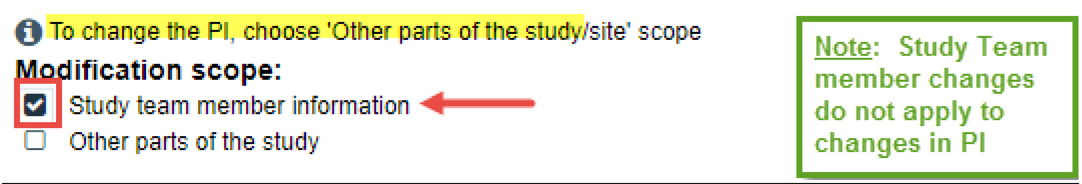
1. Navigate to the appropriate protocol and click on the name to open it. For details on this process see the user guide called "Searching for a Protocol or Submission".

2. Click **Create Modification/CR**.

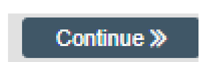
3. Select The Modification radio button and hit Continue.



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. Please note that you can only have one of these types of modifications active at one time.

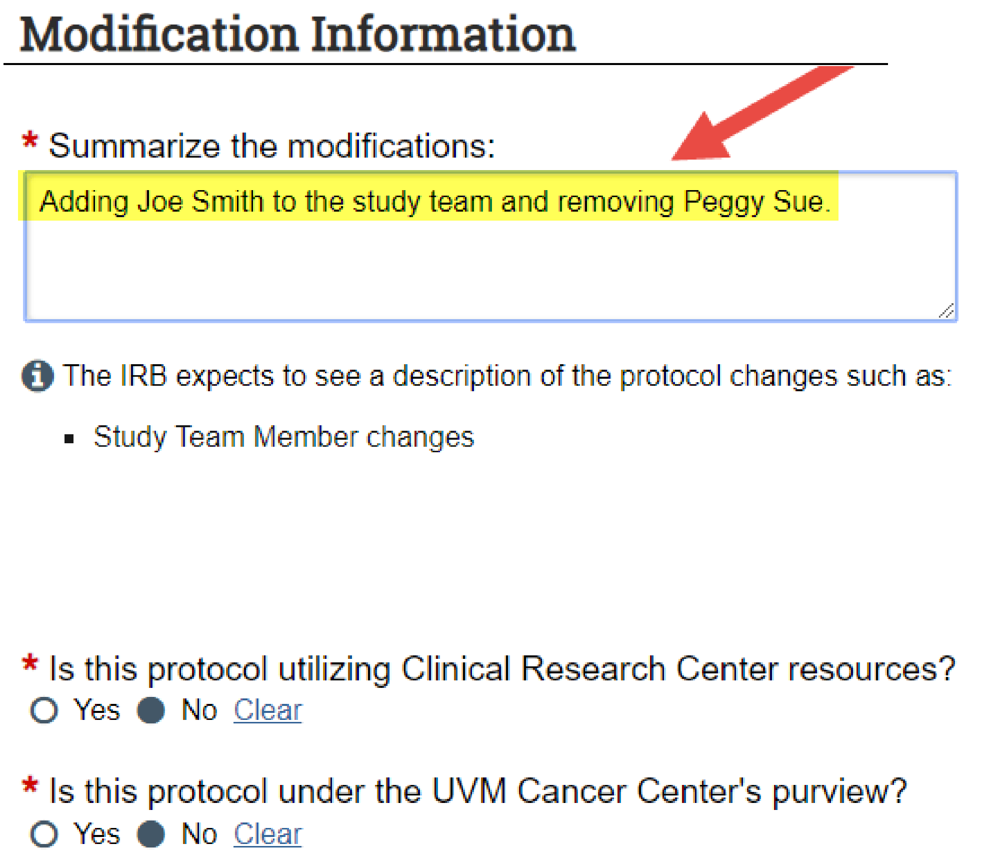


5. Click Continue (way over on the right side of the screen)



6. On the “Modification Information” view, 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 type the text carefully as there isn’t any spellcheck in UVMClick.

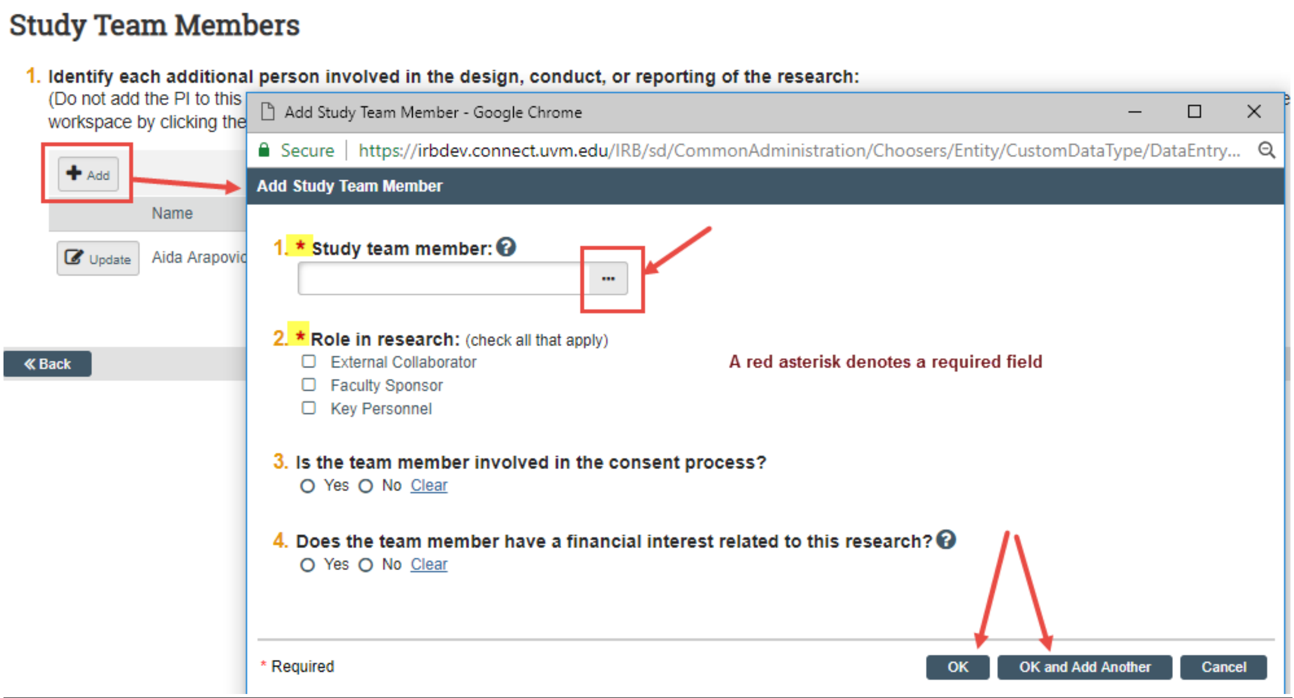


Add a new study team member

Add new study team members via the +Add button.

Important!

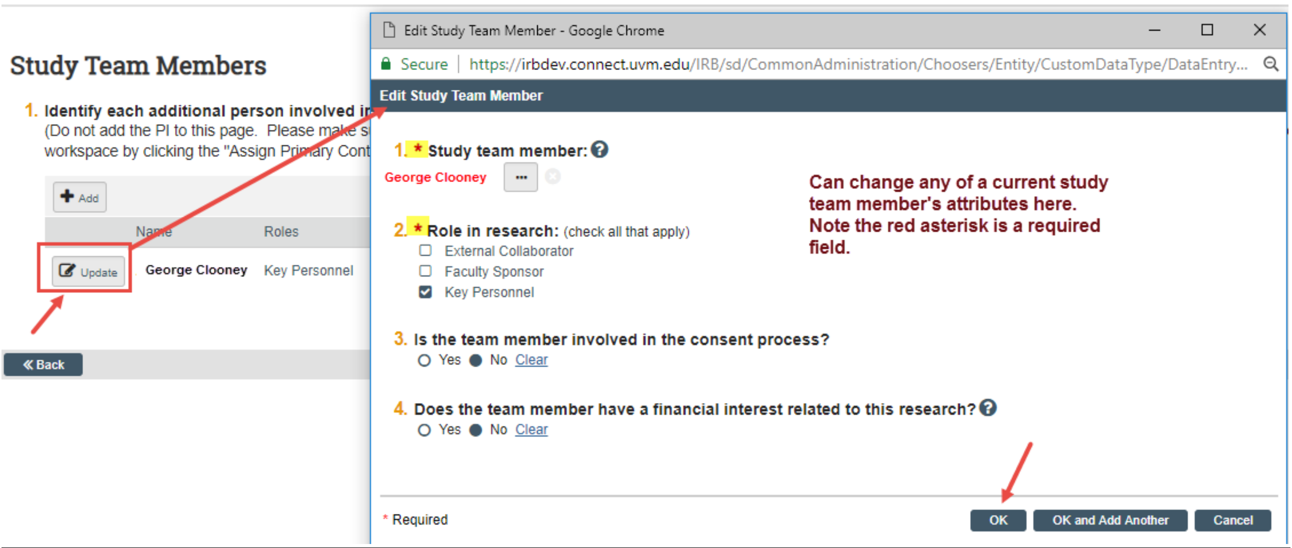
- Any Study with a student PI **must** have a Faculty Sponsor listed on the Study Team
- Required Human Subject training (and GCP training if applicable) should be checked before adding a new study team member.
- Make sure that the study team member name you are adding was noted in the previous question "**Summarize the Modifications**"



NOTE: If you are not able to find the team member name you wish to add, contact the IRB Office for assistance via UVMClick@uvm.edu or 656-5040.

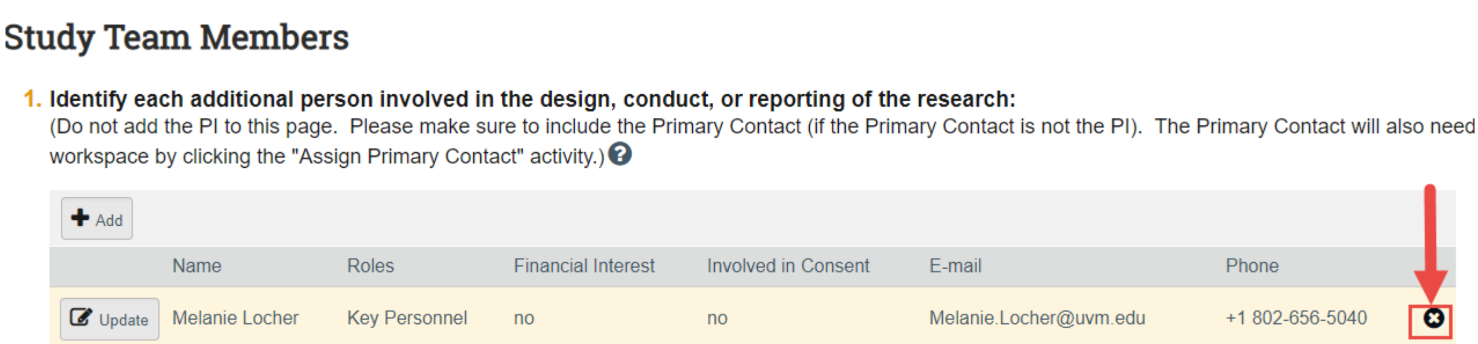
Updating an Existing Study Team Member

- 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 way over on the right side associated with the name of the person you wish to remove.
- Click **OK**

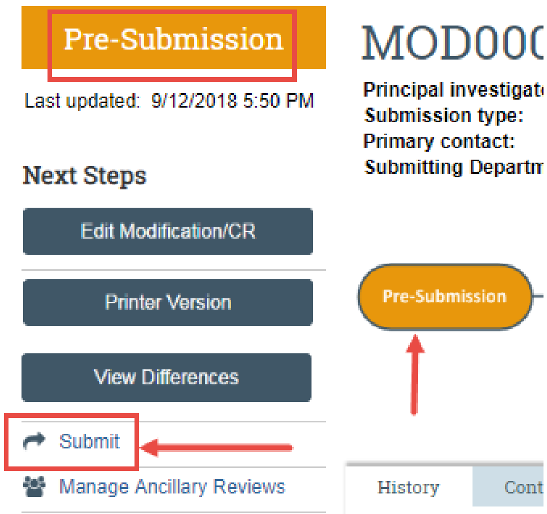


Submit the Modification to the IRB Office for Processing

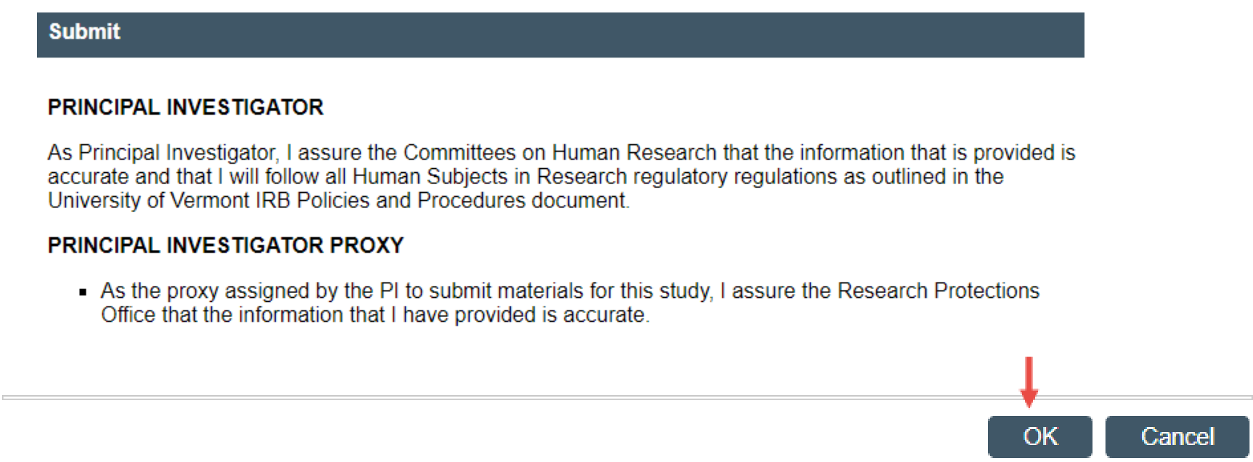
After clicking “Finish” to exit the Modification, the status of the submission will continue to still display as “Pre-Submission” and will remain visible in your in-box until submitted to the IRB Office for processing.

To submit a finished Modification submission to the IRB Office for their review and processing,

1. Make sure the Modification is open
2. Click the activity on the left that says “**Submit**”.

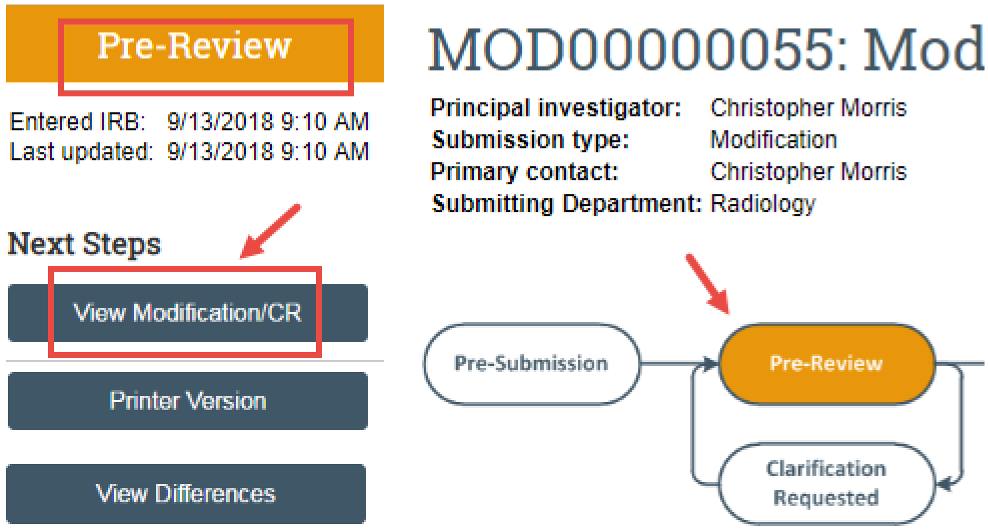


When clicking the **Submit** activity, certification text will appear. Read the text and click **OK**.



Once submitted, the status of the Modification is no longer “Pre-Submission”. It has changes 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 In-Box. It now displays in the In-Box for the IRB Office.