

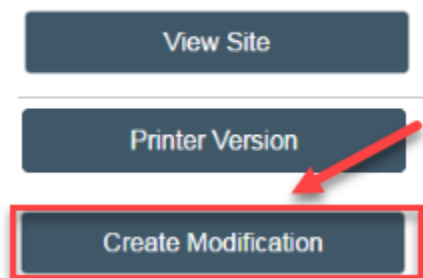
How to Create and Submit a Modification for an External IRB Study

****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”.

Next Steps




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

Creating New: IRB Submission


Modification


*** What is the purpose of this submission?**

☐ Modification / Update
[Clear](#)


 To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

- ☐ Study team and research location information 
- ☐ Other parts of the site

 Exit

 Save

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.

* Summarize the modifications:

Jane Doe has been added to the key personnel
Jim Adams has been removed from the key personnel

 The IRB expects to see a description of the protocol changes such as:

- Study Team Member changes - Indicate who is being added and/or removed

* Is this protocol utilizing Clinical Research Center resources?

☐ Yes ☒ No [Clear](#)

* Is this protocol under the UVM Cancer Center's purview?

☐ Yes ☒ No [Clear](#)

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.

Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:
(Do not add the PI to this workspace by clicking the

Add Study Team Member

1. **Study team member:** ...

2. **Role in research:** (check all that apply)

☐ External Collaborator

☐ Faculty Sponsor

☐ Key Personnel

3. **Is the team member involved in the consent process?**

☐ Yes ☐ No [Clear](#)

4. **Does the team member have a financial interest related to this research?**

☐ Yes ☐ No [Clear](#)

* Required

[OK](#) [OK and Add Another](#) [Cancel](#)

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**

Study Team Members

1. Identify each additional person involved in the research (Do not add the PI to this page. Please make sure the person is added to the workspace by clicking the "Assign Primary Contact" button.)

Update

Edit Study Team Member

1. Study team member: ?
George Clooney

2. Role in research: (check all that apply)
☐ External Collaborator
☐ Faculty Sponsor
☒ Key Personnel


3. Is the team member involved in the consent process?
☐ Yes ☒ No [Clear](#)

4. Does the team member have a financial interest related to this research? ?
☐ Yes ☒ No [Clear](#)

* Required

OK **OK and Add Another** **Cancel**

Removing an Existing Study Team Member

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

Study Team Members

1. Identify each additional UVM/UVMHN person involved in the design, conduct, or reporting of the research:
- Do not add the PI to this page
 - If you are attempting to add a student who is not in the drop down please have the student [update the directory to share their information](#) with UVMClick. The student profile will be available to add within 48 hours. ?

+ Add							
	Name	Roles	Department	Financial Interest	Involved in Consent	E-mail	Phone
Update	Melanie Locher	Key Personnel	Research Protections Office	no	yes	Melanie.Locher@uvm.edu	+1 8026565249

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.

Research Locations

1. *** Identify all research locations where the investigator will conduct or oversee the research**
(If you are using the Clinical Research Center for any part of the research, please add it as a location. Please reference the [‘CRC Staff information for Key Personnel’](#) on this website and add the CRC staff listed under Nursing / Physician Assistant Resources to your study based on which resources you are utilizing):

+ Add

Location	Other	Location Name	Contact Name	Contact Phone	Contact Email
<div><div>Update</div></div>		Main Hospital/ACC			<div><div>X</div></div>

X

 Exit

Save

Finish

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.

****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:

Local Site Documents

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable) ?

+ Add

Update

Document	Category	Date Modified	Document History
Consent Form(0.01)	Consent Form	11/9/2018	History

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

Example:

Other attachments:

Document	Category	Date Modified	Document History
There are no items to display			

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”**

Pre-Submission

Last updated: 11/14/2022 2:37 PM

Next Steps

Edit Modification

Printer Version

Submit

Manage Ancillary Reviews

Correspond with sIRB

Add Comment

Discard

MOD000

Principal investigator

Submission type:

Primary contact:

Submitting Department

Institution:

Pre-Submission

History

Content

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.”**

Submit

PRINCIPAL INVESTIGATOR

As Principal Investigator, I assure the Committees on Human Research that the information that is provided is accurate and that I will follow all Human Subjects in Research regulatory regulations as outlined in the University of Vermont IRB Policies and Procedures document.

PRINCIPAL INVESTIGATOR PROXY

- As the proxy assigned by the PI to submit materials for this study, I assure the Research Protections Office that the information that I have provided is accurate.

OK

Cancel

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.

Pre-Review

Entered IRB: 11/14/2022 3:01 PM
Last updated: 11/14/2022 3:01 PM

MOD00010574: Mo

Principal investigator: John Smith
Submission type: Modification / Update
Primary contact: John Smith
Submitting Department: Med-General
Institution: WCG IRB (previously

Next Steps

View Modification

Printer Version

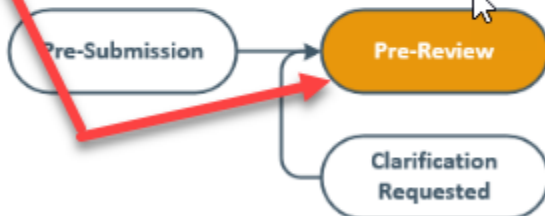
 [Manage Ancillary Reviews](#)

 [Correspond with sIRB](#)

 [Add Comment](#)

 [Withdraw](#)

 [Discard](#)



History

Contacts

Training