IRB

How to Create and Submit 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 "Study Team member information". Please note that you can only have one of these types of modifications active at one time.

5. Click Continue (on the bottom 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 exact text will appear on the future approval letter. Please make sure to type the text carefully as there isn't any spellcheck in UVMClick.

Modification Information

* Summarize the modifications:

Adding Joe Smith to the study team and removing Peggy Sue.

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

- Study Team Member changes

* Is this protocol utilizing Clinical Research Center resources?
○ Yes ● No Clear

* Is this protocol under the UVM Cancer Center's purview?
○ Yes ● No Clear

Add a new study team member

Add new study team members via the +Add button.

> **Important!**
>
> - Any protocol with a student PI **must** have a Faculty Sponsor listed on the Study Team page.
> - Required Human Subject training (and GCP training if applicable) should be checked before 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 name you are adding was noted in the previous question "**Summarize the Modifications**"

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

Name

Update Aida Arapovic

« Back

Add Study Team Member - Google Chrome — □ ×

🔒 Secure | https://irbdev.connect.uvm.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry... 🔍

Add Study Team Member

1. *** Study team member:** ❓

   [............................] [...]

2. *** Role in research:** (check all that apply)   *A red asterisk denotes a required field*
   ☐ 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

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* Required   [OK] [OK and Add Another] [Cancel]

NOTE: If you are not able to find the team member name you wish to add, please ensure the person has a UVMNet ID and email.

If you are trying to add a UVM Student and cannot find their name, then the student will need to go to the [Directory](#) to update their information to be added to UVMClick. It may take up to 24 hours for the profile to become available in UVMClick. The instructions can be found in the "[User Guides](#)" as "UVM Students Conducting Research at UVM/UVMMC"

Information about accessing CITI, creating/linking a UVM NetID, and required training can be found at:

[CITI Program Training | Research Protections Office | The University of Vermont (uvm.edu)](#)

For additional assistance, please contact the IRB Office 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 way over on the right side associated with 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. ❓

	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	⊗

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**".

Pre-Submission
Last updated: 10/28/2022 11:12 AM

Next Steps

Edit Modification/CR

Printer Version

➡ Submit

👥 Manage Ancillary Reviews

When clicking the **Submit** activity, certification 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

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.

Pre-Review

Entered IRB: 10/28/2022 2:15 PM
Last updated: 10/28/2022 2:15 PM

Next Steps

View Modification/CR

Printer Version

👥 Manage Ancillary Reviews

MOD00010573: Modi #4

Principal investigator: John Smith
Submission type: Modification / Update
Primary contact: John Smith
Submitting Department: Med-General

Pre-Submission → Pre-Review

The Modification has now been submitted and removed from your In-Box. It now displays in the In-Box for the IRB Office.