


## 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.


### Modification / Continuing Review / Study Closure

\* What is the purpose of this submission?

- Continuing Review  
 Modification ←



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.

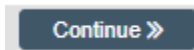
 To change the PI, choose 'Other parts of the study/site' scope

#### Modification scope:

- Study team member information ←  
 Other parts of the study

**Note:** Study Team member changes do not apply to changes in PI

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.

## Modification Information

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\* 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](#)

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## 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**”

## 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

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)

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

A red asterisk denotes a required field

**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](mailto: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**

**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 page. Please make sure to include the Primary Contact (if the Primary Contact is not the PI). The Primary Contact will also need workspace by clicking the "Assign Primary Contact" activity.)

+ Add

Name	Roles
George Clooney	Key Personnel

Update

<< Back

**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

Can change any of a current study team member's attributes here. Note the red asterisk is a required field.


## 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 person involved in the design, conduct, or reporting of the research:

(Do not add the PI to this page. Please make sure to include the Primary Contact (if the Primary Contact is not the PI). The Primary Contact will also need workspace by clicking the "Assign Primary Contact" activity.)

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone	
+ Add							
Update	Melanie Locher	Key Personnel	no	no	Melanie.Locher@uvm.edu	+1 802-656-5040	

## 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**”.

The screenshot shows a web interface for a modification. At the top left, a yellow box highlights the text "Pre-Submission". Below it, it says "Last updated: 9/12/2018 5:50 PM". To the right, the word "MOD000" is displayed in large blue letters. Below that, there are labels for "Principal investigator:", "Submission type:", "Primary contact:", and "Submitting Department:". On the left side, under the heading "Next Steps", there are four buttons: "Edit Modification/CR", "Printer Version", "View Differences", and "Submit". The "Submit" button is highlighted with a red box and a red arrow points to it from the right. Below the "Submit" button is a "Manage Ancillary Reviews" button. On the right side, there is a yellow oval labeled "Pre-Submission" with a red arrow pointing up to it. At the bottom, there are tabs for "History" and "Cont".

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: 9/13/2018 9:10 AM  
Last updated: 9/13/2018 9:10 AM

### Next Steps

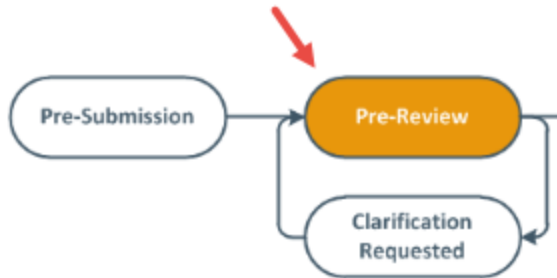
[View Modification/CR](#)

[Printer Version](#)

[View Differences](#)

# MOD00000055: Mod

Principal investigator: Christopher Morris  
Submission type: Modification  
Primary contact: Christopher Morris  
Submitting Department: Radiology



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