

How to Create and Submit a Modification (Amendment)

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

How to prepare for this submission:

Make readily available:

- Protocol (with tracked changes)
- Consent form (with tracked changes)
- Drug or Device Brochure (if applicable)
- Data Safety and Monitoring Reports not affecting risk (if applicable)

Create a Modification (Amendment)

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

Note: You can only have one of these types of modifications active at one time.

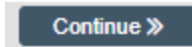
 To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information

Other parts of the study ←

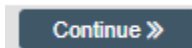
5. Click Continue (way over on the right side of the screen)



6. 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.

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

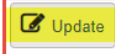


8. Make any and all changes directly to the Study screens that you noted in the “Summarize the Modifications” text box. **Continue** to move through the pages and **Finish** on the last page.

! TIP : If you want to REVISE a previously uploaded document, click the UPDATE button, not the +Add button.

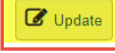
Examples:

11. * Attach the protocol:
(e.g. industry protocol, human subjects protocol, exempt form, or not human subjects form consent form and recruitment materials will be uploaded in a separate section) ?

Document	Category	Date Modified	Document History
 Protocol Document.doc(0.01)	IRB Protocol	11/7/2018	History

Local Site Documents

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

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

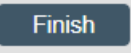
! TIP : If you want to ADD new materials, click the +Add button, not the Update button.

Example:

Other attachments:

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

Submit the Modification to the IRB Office for Processing

After exiting the online smartform by clicking , the status of the submission will still display as “Pre-Submission” and will remain visible in your in-box until submitted to the IRB Office for processing.

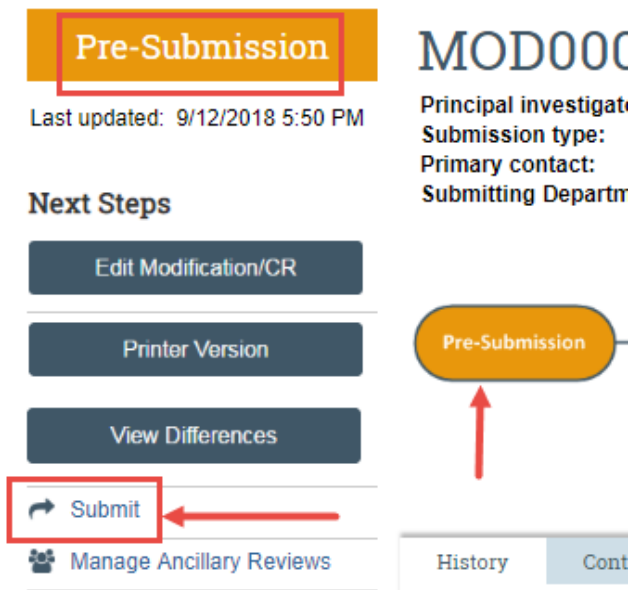
REMEMBER: Click the activity on the left that says “**Submit**”. If you do not see an activity called “Submit” that means that you are not designated as the PI or the Proxy.

Submission Rules:

- Only the PI and any assigned Proxies have the authority to submit requests to the IRB office. And therefore, they are the only ones who will have the “Submit” activity.
- 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 membership list and have completed the required HS training

Click the **Submit** activity

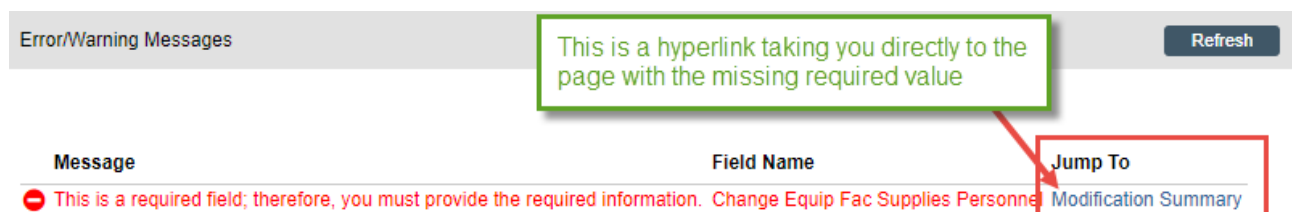
After clicking the **Submit** activity, certification text will appear. Read the text and click **OK**.



The screenshot shows a web interface for a modification. At the top left, a yellow box labeled "Pre-Submission" is highlighted with a red border. Below it, the text "Last updated: 9/12/2018 5:50 PM" is visible. To the right, the title "MOD000" is displayed, followed by fields for "Principal investigator:", "Submission type:", "Primary contact:", and "Submitting Department:". Below these fields, a yellow pill-shaped button labeled "Pre-Submission" is shown with a red arrow pointing up to it. On the left side, there is a vertical list of buttons: "Edit Modification/CR", "Printer Version", "View Differences", "Submit" (highlighted with a red box and a red arrow pointing to it), and "Manage Ancillary Reviews". At the bottom, there are tabs for "History" and "Cont".

If there are any required fields that you forgot to enter, the Submit process will display them.

You can use the pop-up to Jump To those particular screens quickly and enter the missing data.



The screenshot shows an error message pop-up. At the top left, it says "Error/Warning Messages" and at the top right, there is a "Refresh" button. The main message text is: "This is a required field; therefore, you must provide the required information. Change Equip Fac Supplies Personnel". A green box highlights the text: "This is a hyperlink taking you directly to the page with the missing required value". Below the message, there is a table with two columns: "Message" and "Field Name". The "Message" column contains the error text, and the "Field Name" column contains "Change Equip Fac Supplies Personnel". To the right of the table, there is a "Jump To" button with a red border, which is linked to the "Field Name" column. Below the "Jump To" button, the text "Modification Summary" is visible.

NOTE: These Errors/Warning Messages only appear if required field entry was missing.

When clicking the **Submit** activity, once all required field entry is complete, 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

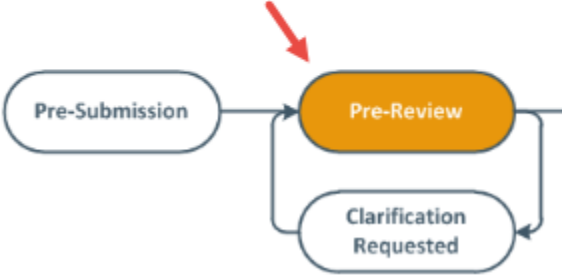
Entered IRB: 9/13/2018 9:10 AM
Last updated: 9/13/2018 9:10 AM

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



```
graph LR; A([Pre-Submission]) --> B([Pre-Review]); B --> C([Clarification Requested]); C --> B;
```

The Modification has now been submitted and removed from your “My Inbox.” It now displays in the IRB Office “My Inbox.”