

How to Create and Submit a Modification (Amendment)


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)
- Any new documents pertinent to your modification

Create a Modification (Amendment)

1. Navigate to the appropriate study and click on the name to open it.
2. Click **Create Modification/CR**.



3. Select the **Modification/update** radio button.

Modification / Continuing Review / Study Closure


* What is the purpose of this submission?

- ☐ Continuing Review
☐ Modification / Update

[Clear](#)

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

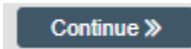
Note: You can only have one of these types of modifications active at one time.

 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. List all modifications to the protocol/consent or other documents and justifications for the required revisions.

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

Continue »

8. Make any and all changes directly to the Click Study screens that you noted in the “Summarize the Modifications” text box. For example – if you are requesting an increase in your study accrual numbers, make sure you list the new accrual number, the justification for the increase and then change question #11 on the Study Scope page.

9. **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.

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) ?

<div>+ Add</div>				
Document	Category	Date Modified	Document History	
<div>Update</div> 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) ?

<div>+ Add</div>				
Document	Category	Date Modified	Document History	
<div>Update</div> 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:

<div>+ Add</div>			
Document	Category	Date Modified	Document History
There are no items to display			

Submit the Modification to the IRB Office for Processing

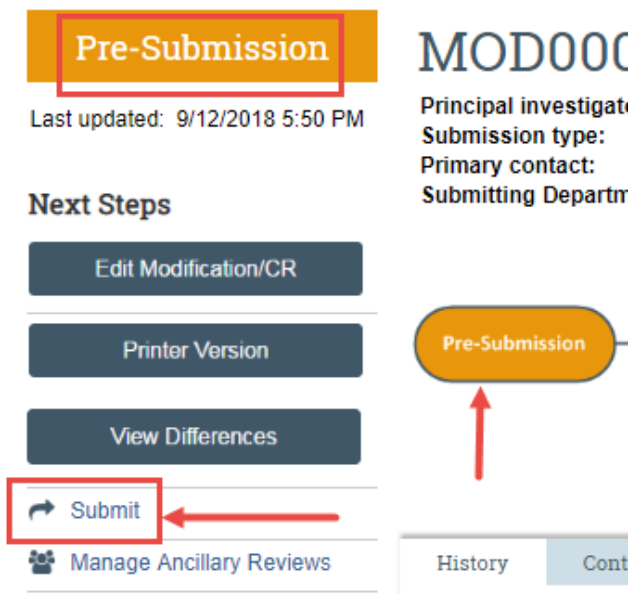
After exiting the online SmartForm by clicking  , the status of the submission will still display as “Pre-Submission” and will remain visible in your in-box until submitted to the IRB Office for processing.

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.

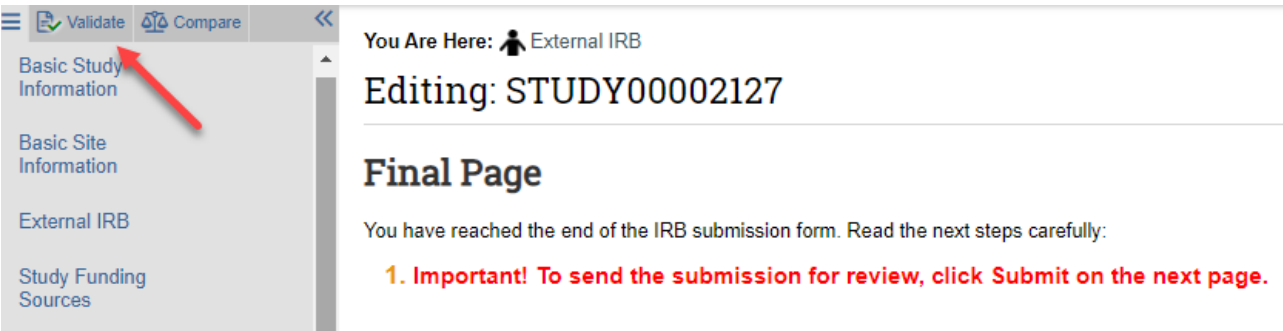
Submission Rules:

- 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 and have completed the required HS training


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



When you reach the Smart Form called “Final Page,” click “**Validate**” at the top, left corner of the page. This will search the submission for errors, specifically incomplete required fields.



****Tip**** Pages without errors will display a green check “”

Pages with errors will display a red error sign “” and will include a blue hyperlink. You can click on this link to take you directly to the error, which will briefly be highlighted in blue.

By Clicking on the “compare” button, you will be able to see changes you have made to the Click form, ensure the changes match the description of the modification.

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 changed 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: 10/21/2022 10:56 AM
Last updated: 10/21/2022 10:56 AM

Next Steps

View Modification/CR

Printer Version

Manage Ancillary Reviews


Add Comment

Withdraw

Discard

MOD00010571: Modification / Example Study Title
Principal investigator: John Smith
Submission type: Modification / Update
Primary contact: John Smith
Submitting Department: Med-General

IRB office:
IRB coordinator:
Regulatory:
Modification:
Study:



History

Contacts

Training

Documents

Reviews

(IRB - Mod/CR - In-Review)

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