

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

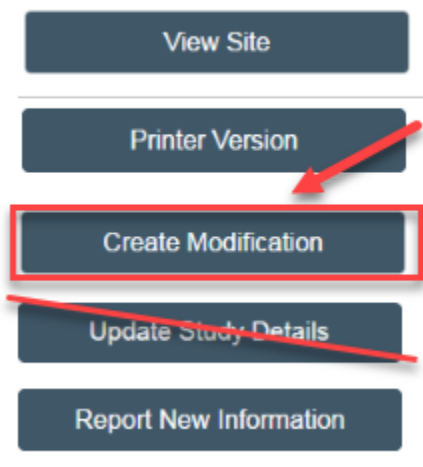
For External IRB studies, Click does not have a specific closure submission type. You will not use the Continuing Review Study Closure like other studies; you will need to submit a Modification to close the protocol.

Create a Modification to Close an External Study

1. From the Dashboard tab > “My Inbox” or the IRB tab > “External IRB” or “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”.
1. Click “**Create Modification**”.

Do not use “Update Study Details”! This function will not be used for External IRB Study Closures on most studies. (Occasionally, an older External IRB study will not have a “Create Modification” option, and in that instance you may use the “Update Study Details” to edit the Local Site Documents page.)

Next Steps



2. Select The Modification / Update radio button and then the radio button for “Other parts of the site” and then hit “**Continue**”.

Creating New: IRB Submission

Modification

* What is the purpose of this submission?

☐ Modification / Update

[Clear](#)

i 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 ➔

3. Complete the questions on the next page:

- Select the enrollment status of the study. To close an External Study, *either* the first checkbox *or* ALL three of the last checkboxes will need to be selected and true.

Study enrollment status (if applicable, check all that apply):

- ☐ No subjects have been enrolled to date
- ☐ Subjects are currently enrolled
- ☐ Study is permanently closed to enrollment
- ☐ All subjects have completed all study-related interventions
- ☐ Collection of private identifiable information is complete

- Select whether participants will require notification of study closure.

Notification of subjects: (if applicable, check all that apply)

- ☐ Current subjects will be notified of these changes
- ☐ Former subjects will be notified of these changes

- **“Summarize the Modifications”** by stating that the study is being closed. Note that this is required field entry as it is prefixed with a red asterisk. Specify whether the protocol is being closed at a study level (all sites) or just at UVM.

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.

- Answer the remaining questions, then hit **“Save”** and **“Continue.”**

Important!

- If all sites are closed, upload the study closure acknowledgement memo from the External IRB under the Local Site Documents page.
- If only UVM is closing, upload the site closure acknowledgement memo from the External IRB under the Local

Site Documents page, AND explain why the UVM site is closing.

Submit the Modification to Close 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.

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 RNI and click on the name to open it.*
2. Click the activity on the left side of the main Modification page that says **“Submit”**

The screenshot shows the 'Pre-Submission' status for a modification. The status is displayed in a yellow box at the top left. Below it, the text 'Last updated: 11/14/2022 2:37 PM' is shown. To the right, the modification ID 'MOD000' is displayed. Below the ID, the following information is listed: 'Principal investigator', 'Submission type:', 'Primary contact:', 'Submitting Department', and 'Institution:'. On the left side, under the heading 'Next Steps', there are several buttons: 'Edit Modification', 'Printer Version', 'Submit' (highlighted with a red box and a red arrow), 'Manage Ancillary Reviews', 'Correspond with sIRB', 'Add Comment', and 'Discard'. On the right side, there is a yellow button labeled 'Pre-Submission' with a red arrow pointing to it. At the bottom right, there are two tabs: 'History' and 'Cont'.

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

Next Steps

View Modification

Printer Version

Manage Ancillary Reviews

Correspond with sIRB

Add Comment

Withdraw

Discard

MOD00010574: Mo

Principal investigator: John Smith

Submission type: Modification / Update

Primary contact: John Smith

Submitting Department: Med-General

Institution: WCG IRB (previously

Pre-Submission

Pre-Review

Clarification Requested

History

Contacts

Training

The IRB will acknowledge the request to close and change the status of the study to Closed.

August 2024
Click Version 10

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