

How to Submit a Continuing Review or Study Closure

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

Create a Continuing Review

1. From “My Inbox” or the IRB>Submissions screen, navigate to the appropriate protocol and click on the name to open it.
2. Click **Create Modification/CR**.

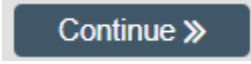


3. Select The Continuing Review radio button and hit Continue.

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

- Continuing Review ←
- Modification



4. Answer all questions. Those with a red asterisk (*) are required.

NOTE: If you wish to **close** the protocol, under the question “Research Milestones”, click all of the first four milestones

Research milestones: (select all that apply) ?

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

Submitting the Continuing Review to the IRB Office for Processing

After reaching the final page of a continuing Review submission and clicking “Finish” to exit the Continuing Review (CR), the status of the submission will still display as “Pre-Submission” and will remain visible in your “My Inbox” until submitted to the IRB Office for processing.

****TIP**** Prior to submitting the CR to the IRB Office, the PI may choose to add a Proxy. Any named Proxy has the authority to edit and submit on behalf of the PI. For more details regarding Proxy assignments, please reference the User guide called “How to Assign a Proxy”.

To submit a finished CR submission to the IRB Office for their review and processing,

1. Make sure the CR is open
2. Click the activity on the left that says “Submit”.

The screenshot shows the interface for a Continuing Review (CR) submission. At the top, a yellow box indicates the status is "Pre-Submission". Below this, the title "CR00000018: Continuing Review" is displayed. The page includes metadata such as "Last updated: 9/11/2018 1:06 PM" and details for the Principal investigator (System Administrator, IT Administrator), Submission type (Continuing Review), Primary contact (System Administrator), and Submitting Department (Huron Consulting, Inc.).

On the left side, under "Next Steps", there are buttons for "Edit Modification/CR", "Printer Version", "Submit" (highlighted with a red box and a red arrow), "Manage Ancillary Reviews", and "Add Comment".

In the center, a flowchart illustrates the review process: "Pre-Submission" leads to "Pre-Review", which can lead to "IRB Review" or "Clarification Requested". "IRB Review" can lead to "Clarification Requested" or back to "Pre-Review".

A green box at the bottom contains the note: "Note: A Pre-Submission status means the CR has not yet been submitted to the IRB Office".

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/Warning Messages" pop-up. The message reads: "This is a required field; therefore, you must provide the required information." The field name is "localSinceActivation". A red box highlights a "Jump To" button with the text "Continuing Review / Study Closure Information". A red arrow points from the "Jump To" button to the "localSinceActivation" field name.

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

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.

The status of the CR 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 CR is now in View Mode and no longer in Edit mode.

Pre-Review

Entered IRB: 9/12/2018 8:09 AM
Last updated: 9/12/2018 8:09 AM

Next Steps

- View Modification/CR**
- Printer Version


CR00000018: Continuing Review

Principal investigator: System Administrator
IT Administrator

Submission type: Continuing Review

Primary contact: System Administrator

Submitting Department: Huron Consulting, Inc.



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