

How to Submit a Continuing Review or Study Closure

Create a Continuing Review


1. From "My Inbox" or the IRB>Submission's screen, navigate to the appropriate protocol and click on the name to open it. For more information about locating a protocol, please see the user guide called "Searching for a Protocol or Submission".
2. Click **Create Modification/CR**.

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 / Update

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 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

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

5. If you wish to close the study and it was funded by an external sponsor the final monitoring report must be attached to ensure the study can be closed and no further access to research data will be accessed or sent outside the entity.
6. Please review your study teams members' CITI training prior to submitting. If any member of your team has expired CITI IRB or GCP training (LCOM and clinical trials) the annual review and approval will be held until training is updated or expired team members have been removed and no longer working on the protocol.

7. If applicable, please attach:

- a copy of the last signed consent form of each type that was used on this protocol over the last year. The subject's name (only) should be blanked out leaving the date of consent for auditing purposes,
- sponsor monitoring reports,
- list of non-risk deviations
- closing study – final sponsor letter/monitoring visit

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**”.

Pre-Submission

Last updated: 9/11/2018 1:06 PM

Next Steps

- Edit Modification/CR
- Printer Version
- Submit**
- Manage Ancillary Reviews
- Add Comment

CR00000018: Continuing Review

Principal investigator: System Administrator
IT Administrator

Submission type: Continuing Review

Primary contact: System Administrator

Submitting Department: Huron Consulting, Inc.

Flowchart:

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graph LR; PS([Pre-Submission]) --> PR([Pre-Review]); PR --> IR([IRB Review]); IR --> CR1([Clarification Requested]); CR1 --> PR; PR --> CR2([Clarification Requested]); CR2 --> IR; IR --> End(( ));
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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.

Error/Warning Messages [Refresh](#)

Message

⊘ This is a required field; therefore, you must provide the required information.

Field Name	Jump To
localSinceActivation	Continuing Review / Study Closure Information

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.

OK

Cancel

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

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Pre-Submission

Pre-Review

IRB Review

Clarification Requested

Clarification Requested

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