Submitting a Continuing Review + Modification (CR-MOD) in eIRB+

1. Go to the main page for eIRB+ and log-in.

2. Once in the system you will be brought to your inbox.

3. On the left side of the page toward the top select "IRB”.

4. Once the page populates, select “Active” in the middle of the page and then filter for the study using the criteria available.

5. Once you have filtered, select the study, which will then take you to the main page of the study.

6. Before starting the Continuing Review submission, you will want to click on the “Study Team Training” tab of the main study page and scan the list for expired personnel training. If CITI

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training date is expired (in red), you will want to notify the personnel to update their CITI training and send their email irbtraining@northwestern.edu as soon as possible. The IRB will not re-approve a study if personnel has expired training on file.

7. On the left side of the page toward the bottom select “Create Modification/CR; or Close”.

8. Once in the submission select “Modification and Continuing Review”.

Modification / Continuing Review / Study Closure

- What is the purpose of this submission?
  - Continuing Review
  - Modification
  - Modification and Continuing Review

9. You will then also select the scope of the modification.

Modification scope:

Other parts of the study
Study team member information

10. Then select continue.

11. The beginning of the page states Continuing Review/Study Closure Information and there are 4 questions in total to respond to and then a section to upload any pertinent documents for the
continuing review.

a) **Question 1:** This question requests information for the total number of subjects enrolled at this site and then study-wide. Subjects enrolled refers to the total number of subjects who consented minus screen failures. Even if the study is only conducted at this site please include the overall enrollment number listed in the above question. You will also need to indicate the number of subjects enrolled since the last continuing review if this is not the initial CR for the study.

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Continuing Review / Study Closure Information

1. *Specify enrollment totals:*  
<table>
<thead>
<tr>
<th>Enrollment (Participants/Charts/Specimens)</th>
<th>Total to Date</th>
<th>Added Since Last CR</th>
</tr>
</thead>
<tbody>
<tr>
<td>At the investigator's site:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-wide:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
```

b) **Question 2:** The next question will request information for the current status of the study, which should be confirmed with the study coordinator or main contact for the study. Select all that apply. (Update the screenshot because it now includes a box and language to acknowledge closure when the study is being closed. In addition, the language associated with the red note has changed also.)

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Research milestones: [Select all that apply]  
- Study has been closed to enrollment OR was never open for enrollment  
- All participants have completed all study-related interventions (if applicable) or have been withdrawn (if applicable)  
- Collection of private identifiable information is complete OR not applicable (if participants were enrolled)  
- Analysis of private identifiable information is complete OR not applicable (if participants were enrolled)  
- Reviewing study activities are limited to data analyses only  
- Study remains active for long-term follow-up of participants*  

* Note: Long-term follow-up includes research activities that involve no more than minimal risk to subjects (e.g., sample collection), and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a patient for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long-term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.
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c) **Question 3:** Select all that apply on the lists that are applicable for the study.
d) Under number 4 you are requested to upload any supporting documents, which may include DMC letters not previously submitted, publications, etc. including any additional information about subject withdrawals.

12. Once all the questions are completed select “Continue”.

13. The beginning of the next page states **Modification Information** and will ask questions regarding the status of the study and what modification is being requested. There will be 2 questions where there are pre-populated selections then a 3rd question where you will state the exact nature of the modification.

   a) **Question 1:** Select which of the following criteria are applicable for the current enrollment for the study.

   1. Study enrollment status:
      - [ ] 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

   b) **Question 2:** Select who should be informed of the requested change. (Only make a selection if this is applicable to the revision, i.e. changes in Study Team Members, with the exception of the PI. would not have any items selected)
2. **Notification of subjects:** (check all that apply)
   - [ ] Current subjects will be notified of these changes
   - [ ] Former subjects will be notified of these changes

This needs to be updated. There are now three available options.

c) **Question 3:** In the top section of the box provide a description of the exact modification that is being requested, so the IRB coordinator can reference this when generating the approval letter. Then if necessary make a space and provide a more detailed description of the changes being made or the rational for them, including any reference to summary of changes documents.

   If there are updates to the IB (Investigator Brochure), please indicate if the updated IB:
   1. affects the risk-to-benefit ratio of the study thereby requiring a change to the study documents;
   2. affects alternatives available to study participants; and/or
   3. represents new information that should be provided to participants.

Example: Other Parts of Study Modification.

Because of the IRB’s added language related to IB submissions, it may be ideal to supplement the language in the description used to follow the three IB related items above.

3. **Summarize the modifications:**

Example: Study Team Member Information

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Example: Study Team Member Information

14. If the modification was for "Other Parts of the Study" then when you select **Continue** you will then be taken to the main page of the study application and allowed to navigate through to make
the necessary updates. (The screenshot used to populate this needs to be updated because this screen has an additional note on it. See pasted example below.

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**Basic Information**

1. Title of study:
   - [Enter Title]

2. Short title:
   - [Enter Short Title]

3. Brief Description:
   - [Enter Brief Description]

4. Which subsection best describes your study?
   - [Select option]

5. Principal investigator:
   - [Enter Name]

6. Will an external IRB act as the IRB of record for this study? Note: Once you answer this question and save/continue past this page, you will NOT be able to change this answer.
   - [Select Yes/No]

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15. If the modification was for “Study Team Member Information” then you will be taken directly to that page of the study application and then you can make the necessary updates. Once completed you will select **Finish** and then will be taken to the main page of the submission.
16. Once on the main page for the submission, you can then notify the PI to submit using the template language described at the end of the “COMPLETING A NEW STUDY SUBMISSION IN EIRB+” section (If you have Proxy permission for the study, you will then also be able to submit.)

   Notify PI to Submit

17. Type in a message to notify the PI that the submission is complete and ready to submit and select OK.

18. The submission process is complete and an email will be sent to the PI to submit.