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

Updated 11.24.2020
7. Once in the submission select “Continuing Review”.

[Image]

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? (Select Continuing Review to close a study)
- Continuing Review
- Modification
- Modification and Continuing Review

8. Then select continue.

[Image] Continue »

9. 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 request information for the total number of subjects enrolled at this site and then study-wide, which should be confirmed with the study coordinator. 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.

   b) **Question 2**: The next question will request information for the current status of the study, which should also be confirmed with the study coordinator or main contact for the study. Select all that apply. *(Since this is a termination the first 4 choices should be applicable)*
c) **Question 3:** Select all that apply on the lists that are applicable for the study.

<table>
<thead>
<tr>
<th>c)</th>
<th>Question 3: Select all that apply on the lists that are applicable for the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Research milestones. (select all that apply)</td>
</tr>
<tr>
<td>Note: The first four checkboxes are sequential and describe the milestones of the overall study. If the first four milestones have been met and are checked, then the study will be closed.</td>
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</tr>
<tr>
<td>☐ Study is permanently closed to enrollment or was never open for enrollment</td>
<td>☐ Study is permanently closed to enrollment or was never open for enrollment</td>
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<tr>
<td>☐ All participants have completed all study-related interventions or are not applicable (e.g., study did not include interventions, no participants were enrolled)</td>
<td>☐ All participants have completed all study-related interventions or are not applicable (e.g., study did not include interventions, no participants were enrolled)</td>
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<tr>
<td>☐ Collection of private identifiable information is complete or not applicable (no participants were enrolled)</td>
<td>☐ Collection of private identifiable information is complete or not applicable (no participants were enrolled)</td>
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<td>☐ Analysis of private identifiable information is complete or not applicable (no participants were enrolled)</td>
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<tr>
<td>☐ Remaining study activities are limited to data analysis only</td>
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</tr>
<tr>
<td>☐ Study remains active only for long-term follow-up of participants*</td>
<td>☐ Study remains active only for long-term follow-up of participants*</td>
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</tbody>
</table>

* Note: Long-term follow-up includes research interactions that involve no more than minimal-risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a participant 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.

*d) Under number 4 you are requested to upload any supporting documents, which may include Sponsor Close-out letters or reports, DMC letters not previously submitted, publications, etc. including any additional information about subject withdrawals.

4. Attach supporting documents. (For each item left unchecked, include an explanation or document. You may upload supporting documents explaining other situations even if all boxes are checked, such as a reason why there have not been any DSMB reports.)

<table>
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<tr>
<th>Add</th>
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There are no items to display

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

11. You will be taken to the Final Page of the submission and then select **Finish** and you will be taken to the main page of the submission.

12. Once on the main page for the submission, you can then notify the PI to submit. (If you have Proxy permission for the study, you will then also be able to submit.) **(Make sure that the RSS**
indicates “Completed” before notifying the PI to submit)

.Notify PI to Submit

13. Type in a message to notify the PI that the submission is complete and ready to submit using the template language described at the end of the “COMPLETING A NEW STUDY SUBMISSION IN EIRB+” section and select **OK**.

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