Submitting an Amendment

This guide will instruct you on how to make changes to an approved eIACUC protocol. Only one amendment can be created at a time, so plan protocol changes accordingly. Contact the Office of the IACUC for suggestions if one is already under review (IACUC@hms.harvard.edu).

Generating the Amendment:

1. Access eIACUC (esupport.hms.harvard.edu/COMSIACUC/). This will take you to your Personal Page.

   Note: You can always select the My Inbox link to return to this page.

2. Select the My IACUC tab to display the protocols with which you are associated.

3. Select the approved protocol you wish to amend. This will take you to its workspace.

4. Select the New Amendment button. This will generate and open the amendment application, known as a Follow-On Submission.

   Note: The New Amendment button is not visible if an amendment is already in progress. Pending amendments will be displayed underneath the Current Amendment section of the protocol’s workspace.
5. For the first page of the Follow-On Submission, outline the changes to your animal study:

i. **Title your amendment** to help identify it. This will also appear on approval letters.

ii. **Select the ‘type’ of change you are making** to the protocol.
   a. The first two ‘types’ may be selected jointly. These changes are reviewed administratively and are considered ‘expedited amendments’.
   b. The last ‘type’ is a ‘full amendment’ and allows you to alter any part of the approved protocol. If your amendment involves all three ‘types’ of changes, then choose this option.

iii. **In lay language, enumerate the changes being made and for each change briefly explain why they are needed**. Specific details should be described within the ‘modified study’.
6. Select **Continue** to proceed to the next page of the Follow-On Submission.

7. This next page is dependant on the ‘type’ of change you selected.
   - **A ‘full amendment’** generates a copy of your approved protocol, known as the modified study. Select the link to enter the modified study. This is where you must describe your study changes.
   - **An ‘expedited amendment’** simply provides the appropriate page(s) that need to be answered.

   *Note: The modified study will replace your existing protocol upon approval. So, only edit areas that need to be changed. Do NOT delete any information you wish to remain on your protocol. For example, do NOT change your response to the question “Is this a three year review?” when updating the “Protocol Summary and Flowcharts” page of the modified study.*

8. Fill out the rest of the application.
   - **For ‘full amendments’,** make the necessary updates to the modified study.
   - **For ‘expedited amendments’,** fill out the remainder of the Follow-On Submission.

   *Note: Select **Continue** to move across pages of the Follow-On Submission or modified study. You may also use the **Jump To** drop-down menu to navigate to a specific page.*

9. **Save** and **Exit** the Follow-On Submission. This will take you to the amendment’s workspace.
   - **For ‘full amendments’,** save and exit the modified study first, and then again to exit the Follow-On Submission.

   *Note: Exiting the Follow-On Submission does NOT submit the amendment for review. You may continue editing the amendment as needed. You can access the amendment through your eIACUC inbox, or through a link on your approved protocol’s workspace as seen in the example on the right.*
10. From the amendment’s workspace, select the **Submit Amendment** activity.

*Note: The system will verify if all of the mandatory fields have been answered. For help, read the E-IACUC Investigator Guide: Checking the Study for Errors.*

Once the amendment is submitted, the current state will change from Pre Submission to ORSP Review, indicating the beginning of the review process. Work involving this amendment can only begin after IACUC approval.