Creating an Amendment

You create an amendment by starting from your approved study. Only one amendment can be active at a time, so plan your protocol changes accordingly.

1. Log in to https://eSupport.hms.harvard.edu/comsiauc.
   Note: If you are not on your My Inbox page, click the My Inbox link in the top right corner.

2. From the My Inbox page, click the My IACUC tab.

3. Click the name of your approved study to open it.
   Tip: You can filter the list to find your study. Next to Filter by (as shown above), select State from the drop-down, and then type “Approved” and click Go.

4. Click New Amendment on the left.

The amendment request application form opens.

   Tip: If the New Amendment button is not visible, there may already be an amendment that has not been approved or withdrawn. You will see the link to this amendment under Current Amendment.

5. In the first page of the form, select one or more types of changes to make to the study.

   Note: The first two amendment types can be selected in combination and are treated as a single expedited amendment. The last type is a full amendment, which lets you change any
part of the study. A full amendment cannot be selected in combination with any other type and requires you to input your existing protocol information.

For question 2.0, briefly list the changes you are making in this amendment in lay language.

6. Answer the questions and click Continue to proceed through the forms. 
   Note: For a full amendment, you will be prompted to click the link to the modified study. This enables you to edit any part of the study. Only edit items that you will be changing. Do not remove substances, procedures, etc. that you wish to remain approved for. When you exit the modified study or click Finish on its final form.

   Important: Do not change your response to “Is this a three year review?” on the Protocol Summary and Flowcharts page.

   1.0  * Is this a three year review?
       ☐ Yes  ☐ No  Clear

7. Make any changes needed, and click Exit.
   
   Note: For a full amendment you will be returned to the screen with the full amendment link. Click Exit again to be returned to the workspace from where you can submit your amendment.

Next Steps
   • Important! You must submit the amendment (follow-on submission) to the OOTI by clicking Submit Amendment on the left.