e-IACUC Investigator Guide

Instructions for understanding your Inbox, creating, editing, and submitting a new animal study, responding to requests for changes, copying a study, submitting an amendment, and creating an annual renewal (for USDA-covered species only).

Log in to https://eSupport.hms.harvard.edu/comsiacuc to access the e-IACUC system and your Inbox.

- The Inbox page contains studies or other submissions that require you (or your team members) to take action. The Inbox tab should be visible on your personal page when you first log in.
- **Note:** If you are not on your personal page, click the My Inbox link in the top right corner.

Creating a New Animal Study

1. Click **New Animal Study** on the left.

This opens the animal study application.

2. Answer the questions and click **Continue** to proceed through the study forms.

3. Click **Finish** on the final form.
Note: You can continue to make changes to a study or other submission until you submit it for ORSP review. Click on the title of the study you wish to edit from My Inbox. Click on Edit Animal Study, and make changes as appropriate.

Submitting a Study for Review

Note: Only the PI can submit the study to the ORSP for review. Other study team members can check the study for errors in advance.

1. From My Inbox, click the name of the study to open it.
2. Click Submit Study on the left.

Tip: If any errors are shown, click the link in the Jump To column to go to the form containing the problem. When all errors are corrected, perform the steps to submit again.

3. Check the box and click OK to agree to the statement presented on the screen.

The study is submitted to the ORSP for review.

Copying a Study

A study’s PI can copy the study and then edit it to create a similar study.

1. Open the study by clicking its name when you find it in the Inbox tab or on another tab.
2. Click **Copy Submission** on the left.

3. Type a new short name for your new study, and click **OK**.
4. Click the **My Inbox** link to return to your personal page.
5. Refresh your browser window until the new study appears in the Inbox tab.
   **Tips:**
   - Copying can take several seconds or more. Continue refreshing until the study appears.
6. Click the study name to open it and make necessary changes.

**Responding to Requests for Changes**

The PI and Contact Person receive an e-mail any time the ORSP or the Vet Reviewer recommends or requires changes to a study. All study team members see the study in My Inbox while the ORSP or Vet Reviewer staff awaits a response.

1. From My Inbox, click the name of the study to open it.
2. Click the **Reviewer Notes** Tab to get a summary of the requested changes.
3. To address changes, click on **Edit Animal Study**. From within the submission, you can click Previous and Next on the Reviewer Note bar to navigate to pages that contain reviewer notes. You can also hide/show the reviewer notes by clicking the arrow on the left of the Reviewer Note bar.
4. As needed, make changes WITHIN STUDY FORMS to address the notes.

**NOTE:** Requested changes may require you to edit study documentation. It may not be sufficient to simply respond with a comment.
5. For each Reviewer Note, when you have changed the study or have an alternate response:
   a. Click the **Click here to respond** link at the bottom of the note.

   ![Response Required! Click here to respond.]

   Select a response from the drop-down list.

   ![Change Request Completed, Change Request Completed, Change Request Not Completed, Reviewer Information Only]

   b. Explain your response in the text box and click **OK**.

6. When you have made all appropriate changes to your study and responded to each required Reviewer Note, save and exit the forms.

7. Click **Submit Changes** on the left to return the study to the ORSP.

![Submit Changes]

8. Add an explanation, and click **OK**. The study is sent back to the ORSP or Vet for continued review.

**Creating an Amendment**

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

1. From your My Inbox page, click the **My IACUC** tab.

   ![My IACUC tab]

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Date Created</th>
<th>Date Modified</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>123</td>
<td>Compound effects on EAE development in C57BL/6 mice</td>
<td>2/25/2014 11:41 AM</td>
<td>3/4/2014 11:14 AM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

   ![Filter by State: Approved]

2. 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**.

3. Click **New Amendment** on the left.

   ![New Amendment]

   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. Click the Amendments tab to see any amendments.

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

<table>
<thead>
<tr>
<th>1.0</th>
<th>Choose the type of change this amendment will be making (check all that apply):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Description</td>
</tr>
<tr>
<td>☐</td>
<td>Add/Remove Study Staff</td>
</tr>
<tr>
<td>☐</td>
<td>Update Genetically Modified Animals</td>
</tr>
<tr>
<td>☐</td>
<td>Animal Housing Change</td>
</tr>
<tr>
<td>☐</td>
<td>Reduction in Animals</td>
</tr>
<tr>
<td>☐</td>
<td>Change in Funding Source(s)</td>
</tr>
<tr>
<td>☐</td>
<td>Amendments and other...</td>
</tr>
</tbody>
</table>

Note: The first several 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.

5. 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.

6. Make any changes needed, and click Finish on the final form.

7. Important! You must submit the amendment to the ORSP by clicking Submit Amendment on the left.

Creating an Annual Renewal

You create an annual renewal (for USDA-covered species only!) by starting from an approved study.

1. From your My Inbox page, click the My IACUC tab.
2. Click the name of your approved study to open it.
3. Click New Annual Renewal on the left.

The annual renewal application opens.

4. Answer the questions and click Continue to proceed through the forms.
5. Click Finish on the final form.
6. Important! You must submit the annual renewal to the ORSP by clicking Submit Annual Renewal on the left.