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.

   ![Create...](image)

   Create...

   - New Animal Study
   - New COMS Review
   - New Reportable Event

   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.

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**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.

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**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.
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.
      
      ![Drop-down list of response options]
      
      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.

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

**Creating a Three-Year Review**

A three-year review is a new study in the IACUC system. The easiest way to create a three-year review is to copy your approved study as a starting point.

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

![Inbox page with My IACUC tab highlighted]

2. Click the name of your approved study to open it.

3. Click **Copy Submission** on the left, and type a new short name for this continuation of your original study.
4. Click the **My Inbox** link to return to your Inbox page.
5. Refresh your browser window until the new study appears in the Inbox tab. Click the name of your new continuation study to open it.
6. Click **Edit Animal Study** on the left.
7. Answer the questions on the first form, and click **Continue** on the right.
8. On the second form in the application, answer this question **Yes**:

![Protocol Summary]

9. Answer the additional questions about the last three years, and click **Continue** to proceed through the study forms.
10. Click **Finish** on the final form.

**Important!** The PI must submit the three-year review to the ORSP by clicking **Submit Study** on the left.

**Creating an Amendment**

**Note:** Do not create an amendment within e-IACUC unless you have completed a new or 3-Year Protocol in e-IACUC.

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]

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.
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>Name</td>
</tr>
<tr>
<td></td>
<td>Add/Remove Study Staff</td>
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<tr>
<td></td>
<td>Use this option to add or remove study staff members.</td>
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<tr>
<td></td>
<td>Update Genetically Modified Animals</td>
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<tr>
<td></td>
<td>Use this option to update information on genetically modified animals.</td>
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<tr>
<td></td>
<td>Animal Housing Change</td>
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<tr>
<td></td>
<td>Use this option to update animal housing, use and transportation information.</td>
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<tr>
<td></td>
<td>Reduction in Animals</td>
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<td></td>
<td>Use this option to decrease the number of animals.</td>
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<tr>
<td></td>
<td>Change in Funding Source(s)</td>
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<tr>
<td></td>
<td>Use this option to update the funding source(s) on the protocol.</td>
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<tr>
<td></td>
<td>Amendments and other...</td>
</tr>
<tr>
<td></td>
<td>Use this option make any other changes to the study.</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.

For any questions please contact eSupport at esupport@hms.harvard.edu