

Creating an Amendment in the eACUC system differs depending on what type of amendment you are submitting.

Procedural Amendment

Adding New Procedures to an Approved Protocol:

- If you are adding a brand new procedure to the protocol, begin by adding that procedure, including all substances used during the procedure, to the PI Library via the “Create Procedure” button (If you need to add new substances, add them before creating the procedure).

The screenshot shows the top navigation bar with 'My Home', 'PI Labs', 'Committee', 'Researcher Profiles', and 'Class Training'. Below it is a breadcrumb trail 'PI Labs >'. On the left, under 'Manage:', there are buttons for 'Edit Lab Members', 'Create Personnel Amendment(s)', 'Create Substance', 'Create Procedure' (highlighted with a red box), and 'Create IACUC Study'. On the right, under 'Lab PI:', there are tabs for 'Members', 'Substances', 'Procedures', 'Protocols', and 'Member Training'. Below the tabs is a 'Lab Members' section with a table containing one entry: 'Lab Member' with the name 'Funk, Jesse'.

- After the procedure has been created and completed, navigate to the home page of the protocol you are amending. If you are amending multiple protocols, you will need to repeat this step for each protocol.
- Once on the homepage, click “Create Amendment” button on the left-hand side of the screen.

The screenshot shows the top navigation bar with 'My Home', 'PI Labs', 'Committee', 'Researcher Profiles', and 'Class Training'. Below it is a breadcrumb trail 'PI Labs >'. On the left, under 'Current State', there is a yellow box labeled 'Approved' and buttons for 'View IACUC Study', 'Print Preview', 'View Differences', and 'Create Amendment' (highlighted with a red box). On the right, under 'Study:', there is a text input field and a table with the following information:

PI:	
Date Modified:	12/17/20
Original Approval Date:	12/15/20
Expiration Date:	12/14/20

Below the table is a workflow diagram showing the following steps: Pre-Submission, Veterinarian Pre-Review, Coordinator Review, Changes Required, and Designated Review. Arrows indicate the flow between these steps, with a dashed arrow between Pre-Submission and Veterinarian Pre-Review, and a solid arrow between Veterinarian Pre-Review and Coordinator Review. A solid arrow points from Coordinator Review to Changes Required, and another solid arrow points from Changes Required to Designated Review. A curved arrow also points from Designated Review back to Pre-Submission.

At the bottom left, there is a section labeled 'My Activities'.

- This will bring up the “Amendment Request” screen, which is very similar to the old paper amendment form. Just click the type of change you want (in this case, it would be “Experimental Procedure Addition(s)/Removal(s)”) and type in a brief summary of the proposed changes.

Amendment Request

- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created

1.0 * Type of change this amendment is making (check all that apply):

- Fellowship/Salary Award
- Project Title Change
- Funding Change
- Species Replacement or Addition
- Change in Scope/Animals Numbers/Project Aims
- Experimental Procedure Addition(s)/Removal(s)
- Change in Laboratory Location
- Satellite Facility Request
- Personnel Change
- Other Changes

2.0 * Description of Changes - briefly summarize the changes:

- Click “Continue” when you have filled in the required information to see a summary of the requested changes. Click “Finish” to continue after that. Your amendment is now created, but you will need to add the new procedure to the protocol before submitting it to the IACUC for review.
- Back on the home page of the protocol you are amending, you will now see a “View Amendment Workspace” link under the “History” tab.

The screenshot shows the IACUC system interface. At the top, there are navigation tabs: My Home, PI Labs, Committee, Researcher Profiles, and Class Training. Below this is a breadcrumb trail: PI Labs >. The main content area is divided into two columns. The left column contains a 'Current State' section with a yellow 'Approved' button and three links: 'View IACUC Study', 'Print Preview', and 'View Differences'. Below this is a 'My Activities' section. The right column shows a summary of the protocol with a search bar containing 'IS0000468'. Below the search bar are fields for 'PI:', 'Date Modified: 1/15/2015 3:56 PM', 'Original Approval Date: 7/8/2014', and 'Expiration Date: 7/7/2017'. A workflow diagram follows, showing steps: Pre-Submission, Veterinarian Pre-Review, Coordinator Review, Changes Required, Designated Review, Coordinator Determination, Returned for Modifications, and Review Complete. At the bottom, there is a 'Copy Submission' button and a 'History' tab which is highlighted with a red box. Below the 'History' tab, there are sub-tabs: Attachments, Reviewer Notes, Amendments, and Reviewers. Under the 'History' tab, there is an 'Activity' section with 'Amendment Opened' and a link 'View Amendment workspace' which is also highlighted with a red box.

- Click the “View Amendment Workspace” link, then “Edit Modified Study” on the left-hand side (see below). This will allow you to add the new procedure on the “Experimental Groups” page and any other Sequence and Timing, animal number, or pain category information that will relate to the new procedure.

- After you have completed adding your new procedure, click “Save” and “Exit” to return to the main protocol homepage. Then click the “View Amendment Workspace” link one last time, and click the “Submit” button on the left-hand side to send the amendment to the IACUC for review:



Amending an Existing, Approved Procedure:

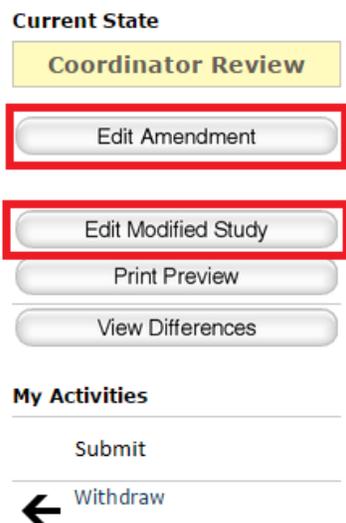
If you are editing an existing procedure, you can begin the amendment one of two ways:

Editing Via the Procedure

- 1) Go to the procedure itself within the PI Library and click the “Amend Procedure” button on the left-hand side.



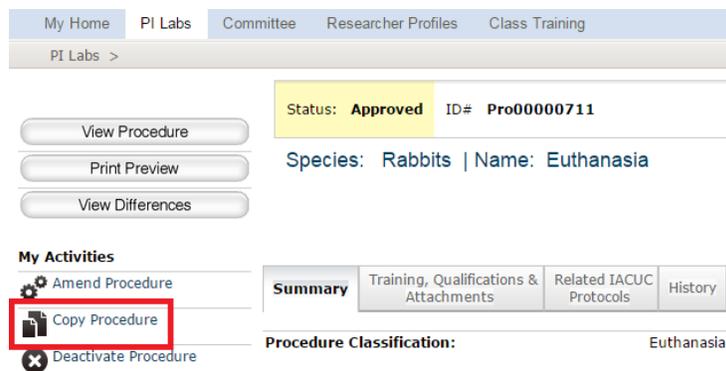
- 2) A pop-up box will appear asking which protocols you would like to amend. Click all that apply. It will also allow you to name the amended procedure, which is usually the procedure name then “2.0” – so this will essentially be version 2.0 of your original procedure.
- 3) After clicking “OK,” go back to your procedures tab within the PI Library. Your Version 2.0 procedure will now exist, allowing you to edit what needs to be changed within the new procedure.
- 4) After you have edited the Version 2.0 procedure, navigate to the homepage of the protocol you are amending and click the “View Amendment Workspace” link under the “History” tab (pictured above on page 2). You can edit the Amendment Form via the “Edit Amendment” link and edit any information within the protocol via the “Edit Modified Study” link:



- 5) You will not need to replace your original procedure (Version 1.0) with Version 2.0 as this is done automatically since the amendment was started via the “Amend Procedure” button. You will need to click “Edit Modified Study” if your modified procedure changes anything else within the protocol (animal numbers, pain category, sequence and timing information, etc.). You will also need to attach the personnel who will perform the procedure on the “Define Procedure Personnel” page.
- 6) When the protocol has been edited to your satisfaction, click the “Submit” button within the “View Amendment Workspace” link. This sends the amendment to the IACUC for review.

Editing Via “Copy Procedure”

- 1) You can also copy the procedure you want to amend on your own and replace the original manually in the protocol. This method is used when amending more than one procedure per amendment.
- 2) Click on the procedure you want to amend, then click the “Copy Procedure” button:



- 3) You will be able to name the copy whatever you like; usually the procedure name then “2.0” is handy for keeping versions in chronological order.
- 4) After the procedure is copied, you can edit the copy the same way as in the #3 instructions above.
- 5) Then follow the instructions above the same way until #5. Using this method, you WILL need to go inside the protocol via the “View Amendment Workspace” link, then the “Edit Modified Study” link. You’ll then need to navigate to the “Experimental Groups” page and replace your original procedure(s) with the new, Version 2.0 procedures manually. You can also edit any pain category, sequence and timing, or other pertinent information at this time. You will also need to attach the personnel who will perform the procedure on the “Define Procedure Personnel” page.
- 6) After you are done editing the protocol, “Save” and “Exit,” navigate back to the “View Amendment Workspace” link, then click the “Submit” button on the left-hand side to send the amendment to the IACUC for review.