

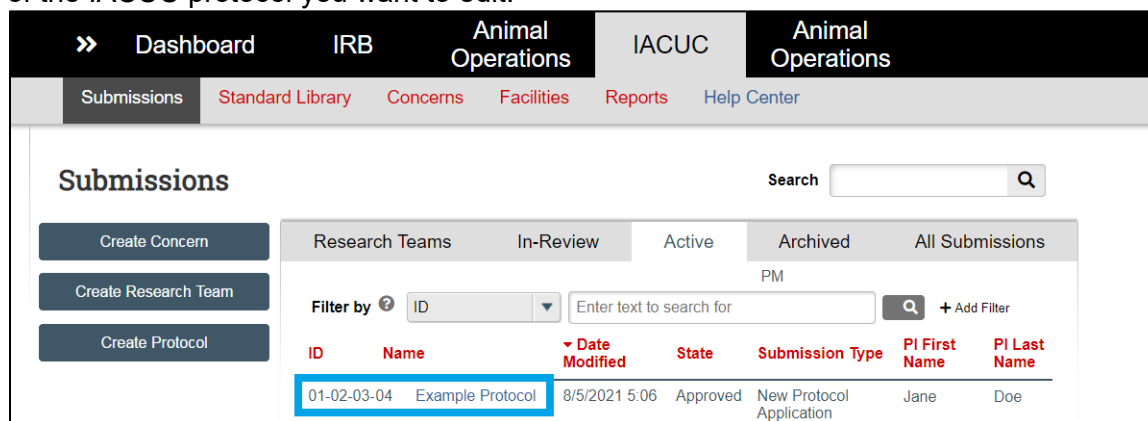
Create and Submit an IACUC Protocol Amendment

To make changes to your approved IACUC protocol, you must create and submit an amendment, which is subject to review and approval by the IACUC. We strongly recommend following these basic guidelines when editing an IACUC protocol:

- Refer to the **IACUC RAP Manual** on the [Research How 2 website](#) for:
 - instructions on how to complete each section of the protocol form
 - examples of protocol writing, preferred language, and definitions
 - instructions on reviewing the RAP Standard Library of substances and procedures before creating/copying a non-standard (team) substance and/or procedure
- All required form fields are denoted by a **red asterisk (*)**.
- Use the “Save”, “Continue”, or “Finish” buttons to save your changes. Switching sections without saving or pressing the “Exit” button will not save any changes.

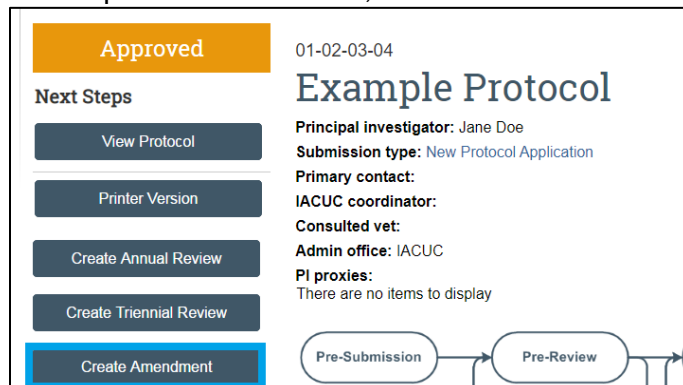
Create an IACUC Protocol Amendment

1. Log in to the IACUC section of the Research Administration Portal (RAP) website (<https://acup.uc.edu/IACUC/>) using your UC credentials. **The most compatible web browsers are Firefox or Google Chrome.**
2. Select the “IACUC” tab, then select the “Active” tab on your main workstation. Click on the ID or Name of the IACUC protocol you want to edit.



The screenshot shows the IACUC Submissions dashboard. The top navigation bar includes Dashboard, IRB, Animal Operations, IACUC, and Animal Operations. Below this, there are tabs for Submissions, Standard Library, Concerns, Facilities, Reports, and Help Center. The main content area is titled 'Submissions' and features a search bar and several filter tabs: Research Teams, In-Review, Active, Archived, and All Submissions. A 'Filter by' dropdown is set to 'ID', and a search input field contains 'Enter text to search for'. Below the filters is a table of submissions with the following columns: ID, Name, Date Modified, State, Submission Type, PI First Name, and PI Last Name. The first row in the table is highlighted with a blue box and contains the following data: ID: 01-02-03-04, Name: Example Protocol, Date Modified: 8/5/2021 5:06, State: Approved, Submission Type: New Protocol Application, PI First Name: Jane, PI Last Name: Doe.

3. On the protocol workstation, select the “Create Amendment” button on the left side of your screen.



The screenshot shows the IACUC protocol workstation for 'Example Protocol' (ID: 01-02-03-04). The protocol is in an 'Approved' state. On the left side, there is a 'Next Steps' section with several buttons: View Protocol, Printer Version, Create Annual Review, Create Triennial Review, and Create Amendment. The 'Create Amendment' button is highlighted with a blue box. On the right side, there is a summary of the protocol details: Principal investigator: Jane Doe, Submission type: New Protocol Application, Primary contact: IACUC coordinator, Consulted vet: Admin office: IACUC, and PI proxies: There are no items to display. At the bottom, there is a workflow diagram showing 'Pre-Submission' and 'Pre-Review' steps.

4. Answer 3 questions in the “Amendment Summary” form, then press the “Continue” button to advance.

- **Amendment short title:** change title to reflect a summary of the amendment
- **Describe the changes:** provide a brief description of your change request.
- **Describe the rationale for the changes:** provide a reason for your change request.

5. You now have the ability to edit each section of your IACUC protocol. After saving all changes, press the “Exit” or “Finish” button to close the form and return to the amendment workstation.

6. On the amendment workstation, select the “Submit” button on the left side of your screen to generate a popup window. *IACUC processing cannot begin until the amendment is submitted.*

IACUC Reviewer Comments

Submitted IACUC protocol amendments are subject to review by the IACUC prior to approval. During the review process, IACUC reviewers may leave comments on the amendment summary and/or specific sections of the protocol form for many reasons, including requesting clarification or edits to your protocol amendment. **Remember that you may use your Dashboard button on the primary navigation bar to quickly see all pending items assigned to you that are awaiting review/action.**

1. Select the "IACUC" tab, then select the "In Review" tab on your main workstation. Click on the ID or Name of the IACUC protocol to open the protocol workstation.

The screenshot shows the IACUC Submissions dashboard. At the top, there are navigation tabs: Dashboard, IRB, Animal Operations, IACUC, and Animal Operations. Below these are sub-tabs: Submissions, Standard Library, Concerns, Facilities, Reports, and Help Center. The main content area is titled "Submissions" and includes a search bar. On the left, there are three buttons: "Create Concern", "Create Research Team", and "Create Protocol". The main table has tabs for "Research Teams", "In-Review", "Active", "Archived", and "All Submissions". A filter section shows "Filter by" set to "ID" with a search input field. The table has columns for ID, Name, Date Modified, State, Submission Type, PI First Name, and PI Last Name. One row is highlighted with a blue border: ID 01-02-03-04, Name Example Protocol, Date Modified 8/5/2021 5:06, State Clarification Requested (Vet Consult), Submission Type New Protocol Application, PI First Name Jane, and PI Last Name Doe.

This screenshot shows the "Example Protocol" workstation. It features a yellow box with the text "Clarification Requested (Vet Consult)" and the ID "01-02-03-04". The title "Example Protocol" is prominently displayed. Below the title, the "Next Steps" section includes a blue button labeled "Edit Protocol". To the right of the "Next Steps" section, the following information is listed: "Principal investigator: Jane Doe", "Submission type: New Protocol Application", and "Primary contact:".

This screenshot shows the "Add a new experiment" workstation. It features a yellow box with the text "Clarification Requested (Vet Consult)" and the ID "AM01-01-02-03-04". The title "Add a new experiment" is prominently displayed. Below the title, the "Next Steps" section includes two buttons: "Edit Amendment" (highlighted with a blue border) and "Printer Version". To the right of the "Next Steps" section, the following information is listed: "Principal investigator: Jane Doe", "Submission type: Amendment", "Primary contact:", and "IACUC coordinator:".

- To locate reviewer comments, look for a numbered textbox icon on the left navigation panel. When you click and open the specific section, you will see the textbox icons next to specific questions on the form, indicating there are comments available for review.

Example: in the image below, there are 2 reviewer comments in the Amendment Summary section. When the section is opened, there are 2 reviewer comments made to Question 2 of this form.

Substances and Procedures section of this manual.

Submitting Responses to Reviewer Comments

- Click on the numbered textbox icon next to a specific question on the protocol form to open the comment in a textbox-shaped popup window. The comment popup window has 2 sections:
 - Change History (left side):** a history of changes made to the protocol form as a result of this comment.
 - Reviewer Notes (right side):** includes a history of requested changes or clarifications.
- Make the requested changes to the protocol form. Press “Save” to save your changes.
- On the “Reviewer Notes” side of the popup, press the “Reply” button to open up a textbox where you can type a response to the reviewer. Press the “OK” button to save your comment response.

4. Once all changes have been made and saved, press the “Exit” button to leave the protocol form and return to the protocol or amendment workstation. Press the “Submit Response” button on the left side of the screen to generate a popup window.

The screenshot shows a web interface for a protocol. On the left, an orange box contains the text "Clarification Requested (Designated Review)". Below this is a "Next Steps" section with buttons for "Edit Protocol", "Printer Version", "Submit Response" (highlighted with a blue border), and "Assign Primary Contact". On the right, the protocol details are listed: "01-02-03-04", "Example Protocol", "Principal investigator: Jane Doe", "Submission type: New Protocol Application", "Primary contact:", "IACUC coordinator:", "Consulted vet:", "Admin office: IACUC", and "PI proxies: There are no items to display". A flow diagram at the bottom right shows "Pre-Submission" leading to "Pre-Review".

The screenshot shows a "Submit" popup window. It contains a text area for "Comments" and a table for "Supporting documents". The table has columns for "Document Name" and "Date Modified" and currently displays "There are no items to display". At the bottom, there are "OK" and "Cancel" buttons, with "OK" highlighted in blue.