

IACUC Research Administration Portal (RAP) Manual

Introduction

This comprehensive, illustrated manual details basic use of UC's IACUC protocol management website, [Research Administration Portal \(RAP\)](#). If you are viewing this document electronically, you can click any title in the Table of Contents to quickly jump to a specific section.

Table of Contents

RAP Navigation.....	3
Form Navigation.....	4
Protocol Workstation Navigation	5
Create or Edit Your Research Team.....	6
Create a New Research Team.....	7
Edit an Existing Research Team	7
Create a New IACUC Protocol	8
Basic Information	8
Experimental Research Protocol Addition	8
Protocol Team Members.....	8
Funding Sources.....	9
Scientific Aims.....	10
Experiments.....	10
Procedure Personnel Assignment.....	13
Strains.....	13
Animal Justification	14
Alternatives Searches and Duplication.....	15
Field Research Details	16
Housing.....	16
Disposition	17
Supporting Documents.....	17
Submit an IACUC Protocol for Review.....	18
IACUC Reviewer Comments	19
Submitting Responses to Reviewer Comments.....	20
Create and Submit an IACUC Protocol Amendment.....	22
Substances and Procedures.....	24
Search for Existing RAP Substances and Procedures	24
View Substance or Procedure Details	25
Create a New Team Substance	26
Create a New Team Procedure.....	26
Copy a Procedure	29
Edit a Copied Procedure.....	31
Create a New Team Procedure Version.....	31
Edit a New Version of a Team Procedure	33
Appendix 1: Protocol Writing Examples	34
Example 1: Simple Experiment	34
Example 2: Complex Pain/Behavioral Hybrid Experiment	34
Appendix 2: Preferred Language and Definitions for Procedures	35
Food and Fluid Restriction	35
Prolonged Physical Restraint	35

Imaging	35
Survival Surgery (Animals Recover/Wake Up from Anesthesia).....	35
Non-Survival Surgery (Animals Euthanized Prior to Anesthetic Recovery).....	36
Non-Surgical	36
Behavioral.....	36
Substance Administration.....	36
Euthanasia.....	37
Tissue/Blood Collection.....	37

RAP Navigation

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.**

Use the primary navigation options (black) at the top of your screen to switch to different areas of the website:

- >> (double arrow):** use this to find your location on the website, or navigate back 1 or more pages
- Dashboard:** see all pending items assigned to you that are awaiting review/action
- IRB:** human research protocol submission and management (separate log in)
- IACUC:** protocol submission and management (the focus of this tutorial)
- Animal Operations:** LAMS vivarium operations and services (separate log in)

Use the secondary navigation options (light grey) at the top of your screen to access different sections of the IACUC website:

- Submissions:** a list of all of your IACUC protocols
- Standard Library:** a list of UC IACUC pre-approved substances and procedures
- Concerns:** review all concerns relating to your IACUC protocol(s)
- Facilities:** a list of all UC facilities (including closed/retired sites)
- Reports:** administrative reports for IACUC Office use only
- Help Center:** videos and tutorials to assist you use the RAP website

Finally, there are 3 action buttons (dark grey) on the left side of your screen:

- Create Concerns:** review concerns for all of your IACUC protocols
- Create Research Team:** create a new list of researchers involved with your IACUC protocols
- Create Protocol:** create a new IACUC protocol

The screenshot shows the RAP website interface. At the top is a red header with the University of Cincinnati logo and the text "Hello, Jane Doe". Below this is a black navigation bar with buttons for "Dashboard", "IRB", "IACUC", and "Animal Operations". Underneath is a light grey secondary navigation bar with links for "Submissions", "Standard Library", "Concerns", "Facilities", "Reports", and "Help Center". The main content area is titled "Submissions" and features a search bar. On the left side, there are three dark grey buttons: "Create Concern", "Create Research Team", and "Create Protocol". The main content area displays a table with tabs for "Research Teams", "In-Review", "Active", "Archived", and "All Submissions". The "In-Review" tab is selected. Below the tabs is a filter section with a "Filter by" dropdown set to "Name", a search input field containing "Enter text to search for", and buttons for "+ Add Filter" and "x Clear All". The table shows one item: "Jane Doe Research Team" under the "Name" column and "Jane Doe" under the "Investigator" column. At the bottom of the table, it indicates "1 items" and "page 1 of 1" with a "25 / page" dropdown.

Form Navigation

Creating or editing IACUC protocols, substances, and procedures requires you to interact with different forms that use the same type of navigation and action buttons. Most forms have multiple sections, and you can use the left navigation (grey) or Continue button to move through each section of the form until you reach the end.

The screenshot shows a web interface for creating a new IACUC submission. At the top, there are tabs for 'Validate' and 'Compare', and a double arrow icon. The main title is 'Creating New: IACUC Submission'. On the right, there are 'Print' and 'Help' icons. The left navigation pane is titled 'Basic Information & Funding' and has a sub-section 'Basic Information' highlighted in orange. Below this, there are links for 'Experimental Research Protocol Addition' and 'Protocol Team Members'. The main content area is titled 'Basic Information' and contains a required field '1. * Select research team: ?' with a red 'Research Team' label. At the bottom right, there are three buttons: 'Exit' (with a close icon), 'Save' (with a save icon), and 'Continue' (with a right arrow icon).

Left Navigation (top to bottom)

≡ (three horizontal bars): displays links to all sections of the protocol form. Click a link to jump to a specific form section; and use the black arrow (▼) on the left to expand or collapse groups as needed.

Validate: shows any errors in the form so you can correct before submitting

Compare: compares different versions of a protocol (helpful when making requested clarifications, triennials, and amendments)

<< or >> (double arrows): opens or closes the left navigation pane

Right Navigation (top to bottom)

Print: print 1 section of the form, or print the entire protocol form

Help: guidelines and quick references for basic RAP functions (e.g. comparing differences, locating/submitting reviewer notes)

Exit: closes the form *without* saving changes

Save: saves changes to that specific section of the form

Continue: saves changes made to a specific section of the form, and advances the user to the next section of the form

Finish: saves changes made to a specific form and returns the user to the main workstation to proceed with form submission

Protocol Workstation Navigation

When creating or selecting an IACUC protocol for review, you will interact with the protocol workstation: a page where you can review the status of your IACUC protocol and use action buttons to edit or submit the protocol.

The screenshot shows the IACUC Protocol Workstation interface. The top navigation bar includes 'Dashboard', 'IRB', 'Animal Operations', 'IACUC', and 'Animal Operations'. Below this is a secondary menu with 'Submissions', 'Standard Library', 'Concerns', 'Facilities', 'Reports', and 'Help Center'. The main content area is titled 'Example Protocol' and shows a 'Pre-Submission' status. It includes a 'Next Steps' section with buttons for 'Edit Protocol' and 'Printer Version', and a list of actions like 'Submit', 'Assign Primary Contact', 'Assign PI Proxy', 'Manage Guest List', 'Manage Ancillary Reviews', 'Manage Related Safety Protocols', 'Add Comment', 'Discard', and 'Copy Submission'. A flowchart illustrates the review process: Pre-Submission (orange box) leads to Pre-Review, which can lead to Clarification Requested, then IACUC Review, Post-Review, and finally Review Complete. IACUC Review can also lead to Clarification Requested, and Post-Review can lead to Modifications Required. A table below the flowchart shows the activity history for the protocol.

Activity	Author	Activity Date
Protocol Created	Doe, Jane	7/12/2021 10:47 AM

Left Navigation (top to bottom)

Protocol Status: see where your IACUC protocol is in the submission-to-approval process (orange box)

Edit Protocol: make changes to any section of your IACUC protocol

Printer Version: create a printable version of your IACUC protocol in 1 of 2 layouts:

- **Default:** a simple layout of your protocol with no procedure or substance details
- **Submission Details:** a complete layout of your protocol with all procedure and substance details.

Submit: generates a popup window containing submission certification statements and areas where you can include submission comments and documents. Press the "OK" button in the bottom right corner to submit your IACUC protocol for review and close the popup window.

- **Once your protocol is submitted, you will not be able to edit it unless it is returned to you for any reason (e.g. reviewer requested clarification).**

Assign Primary Contact: DO NOT USE

Assign PI Proxy: PI proxies are individuals who are authorized to create, edit, and submit protocol amendments on behalf of the PI. The IACUC Office considers these primary protocol contacts.

Manage Guest List: DO NOT USE

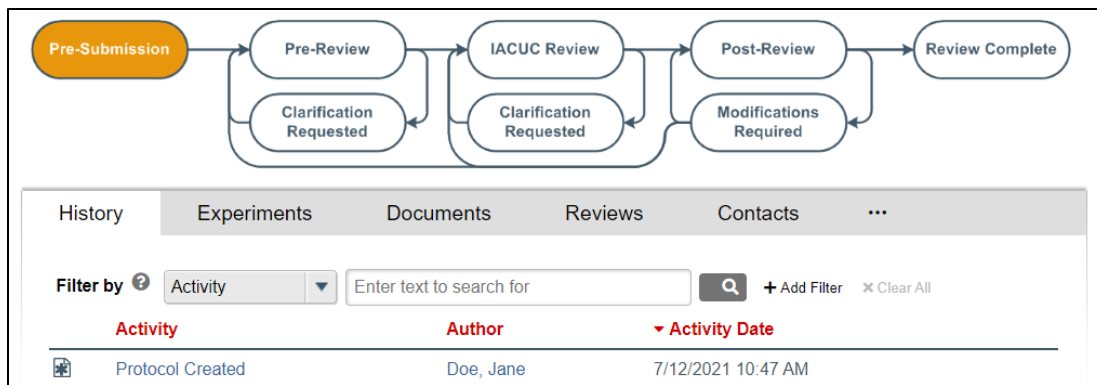
Manage Ancillary Review: DO NOT USE

Manage Related Safety Protocols: DO NOT USE

Add Comment: If you have a question for the IACUC Office about your submission, you can add that information/question using this option.

Discard: Discards the protocol form. Discarded protocol forms are still viewable in history and cannot be edited or submitted but can be copied into new form for editing and submission.

Copy Submission/Protocol: makes a copy of the submission or protocol with a new protocol number.



Center Navigation (left to right)

The navigation does not typically display all available options at once. Press the ellipsis “...” button to display additional navigation options.

Status Map: a visual map of the IACUC protocol status in the submission-to-approval process

History: a history of all actions, comments, submissions that have occurred since the protocol was created

Experiments: a list of protocol experiments and procedures

Documents: a list of supporting protocol documents (e.g. training waivers)

Reviews: a list of all ancillary reviews performed for the protocol (e.g. safety, training)

Reviewer Notes: a list of all clarification requests from protocol reviewers (*this tab only appears once you have submitted the IACUC protocol for review*)

Contacts: list of all protocol personnel

Snapshots: an acute history of protocol activity (similar to version history)

Training: a list of training for all protocol personnel

Related Concerns: a list of all concerns for your protocol

Change Log: an extensive history of all changes made to the protocol

Create or Edit Your Research Team

A Research Team is a list of personnel who have permission to read the IACUC protocol when logged in to the RAP website. Comparatively, the Protocol Team Members is a list of personnel who are approved to perform hands on animal work and/or order animals for the IACUC protocol.

The Research Team can be edited at any time by the Principal Investigator (PI) or approved PI proxy.

However, the Protocol Team Members list can only be edited by submitting a protocol amendment, which is subject to IACUC review and approval. More information on this process can be found in the **Protocol Team Members** section of this tutorial.

Create a New Research Team

1. Click on the “IACUC” tab in the top navigation menu, then click the “Research Teams” sub-tab.
2. Click the “Create Research Team” button.
3. Answer all form questions. Research Team names usually include PI’s last name (e.g. Doe lab).
4. Select the “+ Add” button on Question 3 to add personnel. **Do not add PI to team members list.**
5. If your research group works with more than 1 species, do not add a default team species.
6. Select the “Finish” button to save your changes and close the form.

Creating New: Research Team

Go to forms menu Help

Research Team Information

1. * Research team name:

2. * Principal investigator:

3. Team members: ?

+ Add

Name	Role	Involved in Animal Handling	Authorized To Order Animals	E-mail	Phone
There are no items to display					

4. Team default species: ?

Exit Save Finish

Edit an Existing Research Team

1. Click on the “IACUC” tab in the top navigation menu, then click the “Research Teams” sub-tab.
2. Select the name of your Research Team, then select the “Edit Research Team” button.
3. Edit the Research Team name in Question 1 and add/remove Research Team members in Question 3.
4. Select the “Finish” button to save your changes and close the form.

Editing: RT-01-02-03-04

Go to forms menu Print Help

Research Team Information

1. * Research team name:

Jane Doe Research Team

2. * Principal investigator:

Principal Investigator

3. Team members: ?

+ Add

Name	Role	Involved in Animal Handling	Authorized To Order Animals	E-mail	Phone
Research Personnel #1	Study Staff	yes	no	researcher1@uc.edu	
Administrative Assistant	Study Staff	no	yes	adminasst@uc.edu	

4. Team default species: ?

Mouse

Exit Save Finish

Create a New IACUC Protocol

We strongly recommend following these basic guidelines when creating an IACUC protocol:

- Review the RAP Standard Library of substances and procedures before creating a new protocol. If the standard does not meet your research needs, you will need to create/copy a non-standard (team) substance and/or procedure prior to creating a new protocol (see **Substances and Procedures**).
- All required form fields are denoted by a **red asterisk (*)**.
- Complete each form going page by page using the “Continue” button, to ensure no section is missed.

Basic Information

The screenshot shows the 'Creating New: IACUC Submission' form. The left sidebar has a 'Basic Information' tab selected. The main content area is titled 'Basic Information' and contains five numbered questions:

1. * Title of protocol: (Text input field)
2. * Short title: ? (Text input field)
3. * Summary of research: ? (Text input field)
4. * Principal investigator: (Dropdown menu with 'Principal Investigator' selected)
5. * What is the intention of the animal protocol? ? (Radio button options: Experimental Research, Field Research, Holding Protocol, Teaching, Clear)

At the bottom right of the form are buttons for 'Exit', 'Save', and 'Continue'.

Most questions in this section of the form are self-explanatory except for:

Question 3 (Summary of research):

- Provide a short project description using non-technical/lay terms.
- Write this section as though you are providing a press release to a newspaper.
- Include the following information:
 - What central question is the protocol is answering?
 - What is the value to humans, animals, the environment, or advancement of knowledge?
 - **Triennial submissions:** provide a brief 1-3 sentence summary of project progress over the last 3 years.

Question 5: Protocol Intention

- If your protocol includes both field and experimental research, select “Experimental Research” then create a “Field Research” experiment (see **Experiments**).

Experimental Research Protocol Addition

Select “Yes” or “No” based on your research needs. **If you answer “Yes”, you must add “Animal Production” to the Experiments section to account for animals bred and culled.**

The screenshot shows the 'Editing: 01-02-03-04' form. The left sidebar has a 'Basic Information & Funding' section with 'Experimental Research Protocol Addition' selected. The main content area is titled 'Experimental Research Protocol Addition' and contains one question:

1. * Will the protocol include breeding? ? (Radio button options: Yes, No, Clear)

At the top of the form are buttons for 'Validate', 'Compare', 'Go to forms menu', 'Print', and 'Help'.

Protocol Team Members

[Research How 2 website.](#)

Add personnel to the Protocol Team Members list

1. Select the “+ Add” button to generate the Add Study Team Member form in a popup window.
2. Begin typing the first or last name of the individual you wish to add. You may also press the ellipsis “...” button to scroll through a list of personnel in the RAP database.
 - a. If you cannot locate an individual in the RAP database, send an email to animaltraining@uc.edu with the individual’s UC username (6+2) and M#.
3. Provide answers for Questions 2 through 4 based on the individual’s responsibilities on the IACUC protocol. Select “OK and Add Another” to add additional personnel. When you are finished, select the “OK” to close the popup window and return to the Protocol Team Members section of the protocol form.

The screenshot shows the University of Cincinnati IACUC protocol form. The main form is titled 'Editing: 01-' and 'Protocol Te'. The 'Protocol Team Members' section is highlighted in orange. A blue box highlights the '+ Add' button, with a blue arrow pointing to the 'Add Study Team Member' popup window. The popup window contains the following fields:

- 1. * Select the protocol team member: [Search field]
- 2. * Does the person have an animal handling role? Yes No [Clear](#)
- 3. * Is this individual authorized to order animals? Yes No [Clear](#)
- 4. * Role in research: (check all that apply)
 - Study Staff
 - Co-Investigator
 - Principal Investigator
 - Department Business Manager

Buttons at the bottom: * Required, OK, OK and Add Another, Cancel.

Funding Sources

[email the IACUC Office](#) with details.

Add funding sources to the IACUC protocol

1. Select the “+ Add” button to generate the Add Funding Agency form in a popup window.
2. Begin typing the full name (not acronym) of the funding agency. You may also press the ellipsis “...” button to scroll through a list of funding sources in the RAP database.
 - a. To perform a partial search, use % as a wildcard (takes the place of 1 or more letters in a search).
3. Select “OK and Add Another” to add additional funding sources. When you are finished, select the “OK” to close the popup window and return to the Funding Sources section of the protocol form.

The screenshot shows the University of Cincinnati IACUC protocol form. The main form is titled 'Editing: 01-02-' and 'Funding Source'. The 'Funding Sources' section is highlighted in orange. A blue box highlights the '+ Add' button, with a blue arrow pointing to the 'Add Funding Source' popup window. The popup window contains the following fields:

- 1. * Select the funding organization: [Search field]
- 2. Sponsor's funding ID: (assigned by external sponsor) [Text field]
- 3. Grants office ID: (assigned internally) [Text field]
- 4. Attach files: (including any grant applications)
 -
 - Document Name
 - Date Modified
 - There are no items to display

Buttons at the bottom: * Required, OK, OK and Add Another, Cancel.

Scientific Aims

1. **Scientific aims of the research:** goals of the research
2. **Significance and benefits of the research:** justify the benefits to society (humans, animals, the environment, advancement of knowledge) in relation to the potential detrimental impact on the animals.
 - a) This is frequently justified from an ethical cost-benefit perspective: any animal pain, morbidity and mortality must be outweighed (or at least balanced) by the potential project benefits in terms of relevance to human/animal health, advancement of knowledge, or the good of society.

The screenshot shows a web application interface for editing a form. The top navigation bar includes 'Validate', 'Compare', and 'Editing: 01-02-03-04'. The left sidebar is titled 'Experimental Design' and has 'Scientific Aims' selected. The main content area is titled 'Scientific Aims' and contains two numbered questions, each with a text input field and a help icon. Question 1 is '1. * Scientific aims of the research: ?' and Question 2 is '2. * Significance and benefits of the research: ?'. The sidebar also lists other sections like 'Experiments', 'Procedure Personnel Assignment', 'Strains', 'Animal Justification', and 'Alternatives'.

Experiments

- If you have multiple similar experiments, save time by creating 1 experiment, copying the experiment, and making changes to the resulting copy.
- If you answered “Yes” to the breeding question in the Experimental Research Protocol Addition section, you must add an “Animal Production” experiment to account for animals bred/culled.
- If your protocol includes both field and experimental research, you must select “Experimental Research” for Question 5 in the Basic Information section, and add a “Field Research” experiment that answers the following 3 questions:
 1. Where will these studies take place?
 2. Describe your plan if animals become injured during procedures. Include the anesthetic, analgesic or euthanasia procedures in the associated question.
 3. List the required permits to conduct the field research. Include permit number/oversight agency.

Adding an Experiment

Select the “+ Add” button in Question 1 to generate the Add Experiment form in a popup window.

The screenshot shows a web application interface for adding an experiment. The top navigation bar includes 'Validate', 'Compare', and 'Editing: 01-02-03-04'. The left sidebar is titled 'Basic Information & Funding' and has 'Experiments' selected. The main content area is titled 'Experiments ?' and contains a link 'If the procedure is not yet created: Create Procedure' and an important note: 'Important! Make sure you assign your new procedures to the appropriate experiments.' Below this is a question: '1. * Define the experiments to be used in this protocol:' followed by a '+ Add' button. At the bottom, there is a table with the following columns: Name, Species, Is USDA, Total, Pain Category, Common Procedures, Variable Procedures, and Variable Description. The table is currently empty, with the text 'There are no items to display' below it.

Experiments Question 1: Add an Experiment to an IACUC Protocol

There are 12 questions within the Add Experiment form:

1. **Experiment name:** provide a short title of the experiment
2. **Species:** select the species involved in the experiment
3. **Describe the experiment (Include justification of the purpose of the experiment):** You must provide enough information so that protocol reviewers understand what is happening to each animal.
 - See **Appendix 1: Protocol Writing Examples** for well-written study design examples.
 - Specific details of the individual procedures should be provided in the procedure form.

This section must include the following study design information:

- Rationale for the number of animals to be used
 - List of experimental groups and the number of animals per group
 - Outline of the procedures/manipulations performed on each experimental group and the number of groups per study
 - Maximum duration of animals or groups on the study
4. **Justify the number of animals to be involved in this experiment (justify each group size using literature citation or power analysis).** Justify each group size using literature citation or power analysis. Justify quantity of tissue used and/or need for pilot study (the "N").
 - <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/ceah-toolbox/animal-sample-size-calculator>
 - <https://www.taconic.com/taconic-insights/quality/animal-research-sample-size-calculation.html>
 5. **Select common procedures:** apply to ALL animals in the experiment. Begin typing the procedure name to generate a list of available options. You may also press the ellipsis "...” button to scroll through a list of procedures in the RAP database. **Examples of each procedure type are located in Appendix 2: Preferred Language and Definitions.**

Each procedure is categorized into 1 of the following types:

- Behavioral
- Euthanasia
- Food and Fluid Restriction
- Non-Surgical
- Non-survival surgery
- Physical Restraint
- Substance Administration
- Survival surgery-major/minor
- Tissue/Blood Collection

If a procedure does not appear in the list, go back to the Experiments page, and select the "Create Procedure" button at the top to add it (see **Substances and Procedures** section for details).

6. **Variable procedures:** apply to some animals or differently across animals in the experiment.
 - **Select variable procedures**
 - **Describe the variables of the experiment**
7. **Describe the maximum number of procedures an animal will experience.** Provide the maximum number of procedures per procedure type (Questions 5 and 6 above) to be performed on each animal.
 - Example: each animal may undergo up to 5 behavioral procedures, 1 major and 2 minor survival surgeries, 6 tissue collections, and 1 euthanasia.
8. **Describe expected adverse clinical signs/symptoms, frequency of monitoring, and criteria for removal from the experiment and/or euthanasia.** Include a detailed description of ALL humane endpoints for each experiment, including procedures within the experiment. If none, state "none expected".
9. **Total number of animals used in this experiment:** provide a total count.

10. Number of animals by pain category:

- **USDA species:** report each animal into the highest pain category of all performed procedures
 - e.g. an animal undergoing both category C and E procedures is reported in category E, but is not counted in both categories
- **Non-USDA species:** report all animals in the highest pain category listed on the protocol
 - e.g. if a protocol lists 2 experiments (pain categories D and E respectively), then all protocol animals are reported in category E regardless of performed procedures

11. Identify husbandry exceptions:

- Include the exception type, description, and justification.
- Satellite locations that store special diets must be listed in this section.
- Some behavioral procedures/stressors (e.g. chronic stress paradigms) exceptions can be combined (e.g. non-standard caging can include large, small, tilt, wet, empty, etc.).
 - Altered Light Cycle Duration
 - Enrichment Policy Waiver
 - Non-standard Caging
 - Sanitation Frequency
 - Wire Bottom
 - Special Diet
 - Altered Room Temperature
 - Medicated Water
 - Observation Frequency
 - Social Housing Policy Waiver
 - Solid Bottom Cage (no bedding)
 - Other

12. Supporting documents: Add any information specifically related to the experiment. These documents will be automatically added to the Documents tab of the main protocol workspace.

- After completing an experiment form, select “OK and Add Another” to add additional experiments.
- When you are finished adding experiments, select the “OK” button to close the Add Experiment form and return to the Experiments section of the new protocol form.

Experiments Question 2: Momentary Pain/Distress

You must tie unrelieved pain and distress to the associated procedures and experiments. Refer to **Appendix 1: Protocol Writing Examples** for additional details.

Describe and justify momentary pain and distress if your protocol:

- withholds analgesics, anesthetics, or tranquilizers,
- contains any pain category E procedures, or
- has chronic/persistent clinical symptoms or conditions that persist instead of euthanizing the animals.



Experiments Questions 3 & 4: Multiple Survival Surgeries

Editing: 01-02-03-04

Go to forms menu Print Help

Experiments

3. If the experiments include survival surgery, will any single animal undergo more than one survival surgery? (include any animal that underwent surgery prior to use on this protocol)

Yes No [Clear](#)

Survival surgery includes both minor and major procedures. Surgical procedure examples include:

- **Major** survival surgery: myocardial infarction, ovariectomy
- **Minor** survival surgery: cannulation, minipump implantations

If an animal will undergo more than 1 survival surgery (minor or major), select Yes for Question 3.

The form will update to display Question 4, where you must provide the following information:

- Describe the order of and time interval between surgical procedures on a single animal.
- Provide scientific justification for multiple survival surgical procedures on a single animal.
- Specify how many animals will undergo multiple survival surgeries.

Procedure Personnel Assignment

This section should automatically prefill with all team members performing all procedures. The IACUC Office does not currently track or regulate this section of the protocol form – as such, it is acceptable to assign any personnel or leave the default assignments in this section. **Question 2 (Team member training): do not add or edit any automatically populated information.**

Editing: 01-02-03-04

Go to forms menu Print Help

Procedure Personnel Assignment

1. Select the team members who will be performing each procedure:

Procedure	Species	Is USDA Species	Team Members
Substance Administration: Analgesia Moderate – Mouse, ver. 2 (Standard)	Mouse	no	<input checked="" type="checkbox"/> John Smith <input type="checkbox"/>

2. Team member training:

Strains

Only list a strain if it has an adverse phenotype that requires special care or observation (e.g. strain that spontaneously develops tumors, or spontaneously develops multiple sclerosis). Select the “+ Add” button in Question 1 to generate the Add Background Strain form in a popup window.

Editing: 01-02-03-04

Go to forms menu Print Help

Strains

1. Identify background strains:

Species	Is USDA Species	Strain	Genetically Modified Strain	Phenotype
There are no items to display				

Add Background Strains Form

There are 5 questions within the Add Background Strain form:

1. **Strain:** leave first field blank and skip to next 2 fields
 - **If other, identify here:** type strain information in the text box (e.g. B6SJL.SOD1-G93A)
 - **Species:** select applicable species
2. **Genetically modified strain:** select “Yes” or “No”
3. **Phenotype:** provide an ID or description
4. **Percent of animals with the phenotype:** consider using Punnett squares or Hardy-Weinberg equilibrium calculators to assist with completing this field
5. **Describe how animals will be managed if the phenotype causes welfare issues.** Include information regarding monitoring frequency, what will be monitored, and endpoints. Details should be provided relative to the impact of the phenotype on animal welfare – small impacts require few details, and large impacts require extensive details.

Animal Justification

Species	USDA Covered Species	Pain Category	Animals Identified in Experiments	Adjusted Animal Count
Mouse	no	Pain Category B	1	1

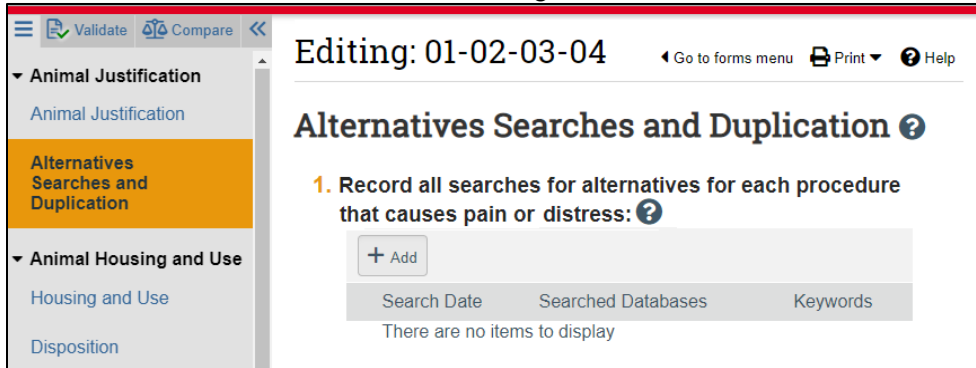
1. **Adjust animal numbers:** section is prefilled by the number of animals that are in your experiments.
2. **Explain animal number adjustment:** leave this question blank
3. **Rationale for animal use:** explain why computers, *in vitro* systems, invertebrates, or human subjects cannot be used in place of the animal experiments in this protocol.
4. **Animal number justification:** write “See Q4 of associated experiment for animal number justification”
5. **Animal species justification:** justify the use of each specific species listed on the protocol
6. **Supporting documents:** provide any related information

Alternatives Searches and Duplication

For each procedure listed on your protocol that causes pain or distress, you must document a recent literature search. If your procedure does not cause pain or distress, you may still be asked to complete this section by the IACUC or Attending Veterinarian in some circumstances. The search should look for animal alternatives, ways to reduce pain/distress, and methods to reduce the number of animals needed for the study.

Guidance and literature search strategies: https://www.nal.usda.gov/sites/default/files/altwksht_jan2020.pdf

Click the “+ Add” button in Question 1 to generate the Add Procedure Search Details form in a popup window.



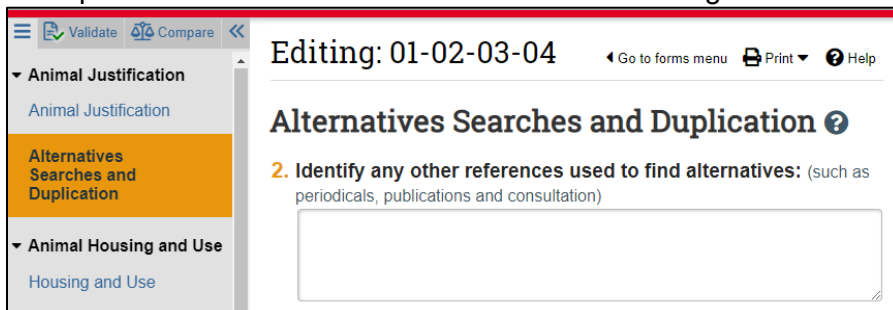
Alternatives Question 1: Add an Alternatives Search to an IACUC Protocol

There are 6 questions within the Add Procedure Search Details form:

- 1. Procedures causing pain or distress:** select 1 or more procedures that you are performing the literature search for. Begin typing the procedure name to generate a list of available options. You may also press the ellipsis “...” button to scroll through a list of procedures found in the Experiments section of your IACUC protocol that cause pain or distress.
- 2. Date of search**
- 3. Databases searched:** check all that apply
- 4. Keywords used:** words likely to be found in the title, abstract, and descriptor fields of the publication.
 - Use words included in specific aims, species, anatomy, and systems studied.
 - Use Boolean search strategies (e.g. cardiac AND rat OR mouse AND myocardial infarction)
- 5. Summarize your search for an alternative procedure**
- 6. Time period covered by search:** each search must cover a minimum span of the last 10 years

Alternatives Question 2: Identify Other References

Examples of other references include scientific meetings and outside collaborators.



Alternatives Question 3: No Unnecessary Duplication of Previous Experiments

Confirm that the activities described in the protocol do not unnecessarily duplicate previous experiments, and that you will not unnecessarily duplicate other animal research by selecting the “Yes” option.

Field Research Details

This section contains 3 questions and only displays if you selected “Field Research” for Question 5 in the **Basic Information** section.

If your protocol includes both field and experimental research, you should instead select “Experimental Research” for Question 5 in the **Basic Information** and create an experiment in the **Experiments** section called “Field Research” that includes answers to the following 3 questions:

1. **Where will these studies take place?**
2. **Describe your plan if animals become injured during procedures:** Include the anesthetic, analgesic or euthanasia procedures in the associated question.
3. **List the required permits to conduct the field research.** Include permit numbers/oversight agency.

Housing

Include all satellite locations where you are housing animals, using live animals, and/or storing diet outside of the vivarium.

1. **Identify vivarium housing/procedural locations:** leave this area blank (LAMS will complete)
2. **Identify non-vivarium housing/procedural locations:** click the “+ Add” button in Question 2 to generate the Add Animal Housing and Use Location form in a popup window.

Editing: 01-02-03-04

Go to forms menu Print Help

Animal Housing and Use

Housing and Use

Disposition

Supporting Documents

Supporting Documents

Housing and Use

1. Identify each vivarium location where animals will be housed or used:
+ Add
Name Species Hours
There are no items to display
2. Identify each non-vivarium location where animals will be housed or used:
+ Add
Name Species Hours Reason
There are no items to display

Housing Question 2: Add Animal Housing and Use Locations

There are 6 questions within the Add Animal Housing and Use Location form:

1. **Identify the location where animals will be housed or used outside the vivarium:** Begin typing the room number to generate a list of available options. You may also press the ellipsis “...” button to scroll through a list of existing satellite locations found in the RAP database.
2. **What species will be housed or used in this location?**
3. **How many hours will animals be kept?** Areas in which non-USDA covered species (e.g. mice, rats, ectotherms, avian) are held 24 hours or longer, or USDA covered species (e.g. guinea pigs) are held 12 hours or longer are considered housing areas. Use of a satellite housing location requires the PI to include a standard operating procedure (SOP) detailing animal husbandry and care with their protocol.

4. **Describe how this location will be used.**
5. **Justify why the animals must be removed from the vivarium:** provide justification, for example- research equipment cannot be moved
6. **Describe how animals will be transported to and from this location, including container and route:** If you are following ACUP Policy 108 (Animal Transportation), then state “as per policy”. If you are not following ACUP Policy 108, describe specific details regarding safe animal transportation.

Disposition

If you intend to transfer animals to LAMS for training purposes, be sure to check the box indicating that animals will be transferred to another approved protocol by another investigator. For example, investigators with a breeding colony may choose to transfer animals to LAMS instead of culling.

Editing: 01-02-03-04 Go to forms menu Print Help

Disposition

1. **Disposition plans for the animals when this research is complete:**
(check all that apply)

- Other (describe below).
- The animals will be euthanized according to the procedures described in this protocol.
- The animals will be transferred to another approved protocol by another investigator.
- The animals will be transferred to another approved protocol held by this investigator.
- The animals will remain with their owners.
- Field study: Animals will be returned to their habitat.

2. **If other, provide an animal disposition description:**

Supporting Documents

In this section, you may attach any relevant protocol documentation to help with IACUC review.

This is the last section of a new protocol form. Press the “Finish” button in the bottom right corner of your screen to save your changes and return to the main protocol workstation, where you can **Submit an IACUC Protocol for Review.**

Editing: 01-02-03-04 Go to forms menu Print Help

Supporting Documents

1. **Attach supporting files:**

+ Add

Document Name	Date Modified
There are no items to display	

Exit Save Finish

Submit an IACUC Protocol for Review

As you create content in your draft IACUC protocol, the status will display as “Pre-Submission”. Use the following process to submit your protocol draft for IACUC review:

1. On the protocol workstation, click the “Submit” button on the left side of the screen to generate a popup window.

The screenshot shows a web interface for a protocol workstation. At the top left, there is a yellow box with the text "Pre-Submission". To its right, the date "01-02-03-04" is displayed. The main heading is "Example Protocol". Below this, there are several fields: "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". On the left side, under the heading "Next Steps", there are four buttons: "Edit Protocol", "Printer Version", "Submit" (highlighted with a blue border), and "Assign Primary Contact".

2. Carefully review each confirmation statement and provide comments or supporting documents if necessary. Press the “OK” button to submit the protocol for review and close the popup window. The protocol status will change from “Pre-Submission” to “Pre-Review” on the protocol workstation.

The screenshot shows a browser window titled "Execute 'Submit' on 01-02-03-04 - Google Chrome". The address bar shows the URL "rcp-qa.uc.edu/IACUC_Candidate/sd/ResourceAdministration/Activity/form?A". The main content area is titled "Submit" and contains the following elements: "As the principal investigator, I certify that:" followed by three horizontal lines for text entry. Below this is a section titled "1. Comments: ?" with a large text area. Underneath is a section titled "2. Supporting documents: ?" with a "+ Add" button and a table with columns "Document Name" and "Date Modified". The table is currently empty, with the text "There are no items to display" below it. At the bottom right, there are "OK" and "Cancel" buttons, with the "OK" button highlighted in blue.

IACUC Reviewer Comments

Submitted IACUC protocols and 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 or 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. The navigation bar includes 'Dashboard', 'IRB', 'Animal Operations', 'IACUC', and 'Animal Operations'. The 'Submissions' section is active, showing a table of submissions. The first row is highlighted with a blue box, containing 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'.

2. For protocol reviewer comments, press the “Edit Protocol” button on the left side of your screen. If you want to see amendment reviewer comments, see step 3 (next). If not, advance to step 4.

The screenshot shows the 'Example Protocol' workstation. The title is 'Example Protocol' and the ID is '01-02-03-04'. The status is 'Clarification Requested (Vet Consult)'. The principal investigator is Jane Doe, and the submission type is 'New Protocol Application'. The 'Edit Protocol' button is highlighted with a blue box.

3. For amendment reviewer comments, locate and click on the amendment ID in the “History” tab to open the amendment workstation. Press the “Edit Amendment” button on the left side of your screen.

The screenshot shows the 'Add a new experiment' amendment workstation. The title is 'Add a new experiment' and the ID is 'AM01-01-02-03-04'. The status is 'Clarification Requested (Vet Consult)'. The principal investigator is Jane Doe, and the submission type is 'Amendment'. The 'Edit Amendment' button is highlighted with a blue box.

- 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.

To ensure all reviewer comments are addressed, it is recommended to start at the top of the form and work your way down each section of the form, saving changes made to each section of the protocol form and responding to reviewer comments before switching between sections. To edit substances and procedures in response to a reviewer comment, refer to the **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 workstation. On the left, there is a large orange box with the text "Clarification Requested (Designated Review)". Below this, under "Next Steps", are buttons for "Edit Protocol", "Printer Version", and "Submit Response" (which is highlighted with a blue border and a red arrow). At the bottom left is an "Assign Primary Contact" button. On the right, the protocol details are displayed: "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".

5. Provide comments or supporting documents if necessary. Press the “OK” button to submit the protocol for review and close the popup window. The protocol status will no longer contain “Clarification Requested” on the protocol workstation.

The screenshot shows a "Submit" popup window. At the top, it says "Execute 'Submit' on 01-02-03-04 - Google Chrome". The URL is "rcp-qa.uc.edu/IACUC_Candidate/sd/ResourceAdministration/Activity/form?A". The main content area has a dark header "Submit". Below it, the text "As the principal investigator, I certify that:" is followed by three horizontal lines for a signature. Then, there are two sections: "1. Comments: ?" with a text area, and "2. Supporting documents: ?" with an "+ Add" button and a table. The table has columns "Document Name" and "Date Modified" and contains the text "There are no items to display". At the bottom right, there are "OK" and "Cancel" buttons, with "OK" highlighted in blue.

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.

1. 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 navigation bar includes Dashboard, IRB, Animal Operations, IACUC, and Animal Operations. The Submissions section is active, showing a search bar and tabs for Research Teams, In-Review, Active, Archived, and All Submissions. A filter dropdown is set to 'ID'. The table below lists one protocol:

ID	Name	Date Modified	State	Submission Type	PI First Name	PI Last Name
01-02-03-04	Example Protocol	8/5/2021 5:06	Approved	New Protocol Application	Jane	Doe

2. 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'. The protocol is in an 'Approved' state. The left sidebar contains buttons for 'View Protocol', 'Printer Version', 'Create Annual Review', 'Create Triennial Review', and 'Create Amendment' (highlighted in blue). The main content area displays protocol details:

- Principal investigator: Jane Doe
- Submission type: New Protocol Application
- Primary contact:
- IACUC coordinator:
- Consulted vet:
- Admin office: IACUC
- PI proxies: There are no items to display

Additional details include: Letter: Correspondence_for_01-02-03-04.doc(0.01) ... Protocol type: Experimental Research, Approval date: 5/28/2021, Effective date: 5/28/2021, Last day of annual review period: 5/14/2023, Last day of triennial approval period: 5/14/2023. A workflow diagram at the bottom shows stages: Pre-Submission, Pre-Review, IACUC Review, Post-Review, and Review Complete.

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

The screenshot shows the 'Creating New: IACUC Submission' form. The 'Amendment Summary' section includes the following text and fields:

Only one amendment can be active at one time.
Active follow-on submissions for this protocol:

ID	Name	Date Modified	State
There are no items to display			

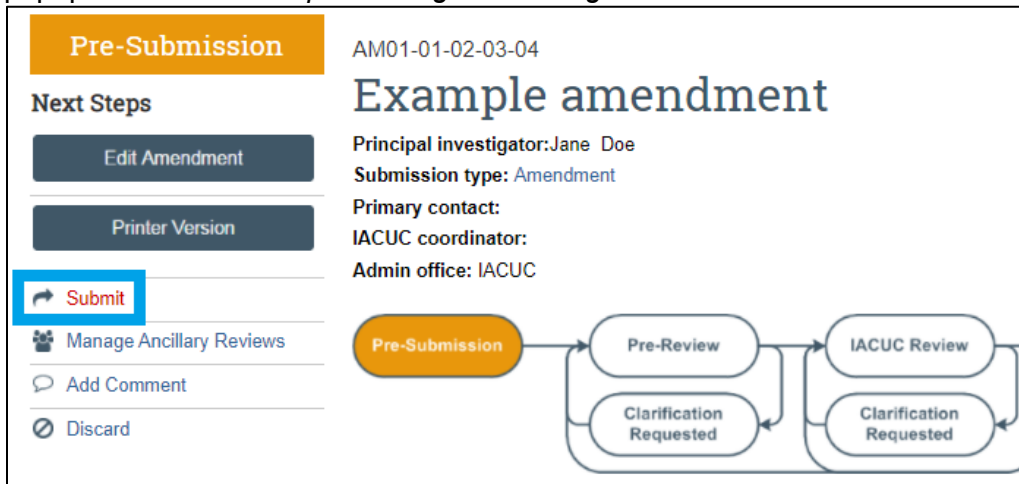
1. * Amendment short title: ?
2. * Describe the changes: ?
3. * Describe the rationale for changes:

- **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.

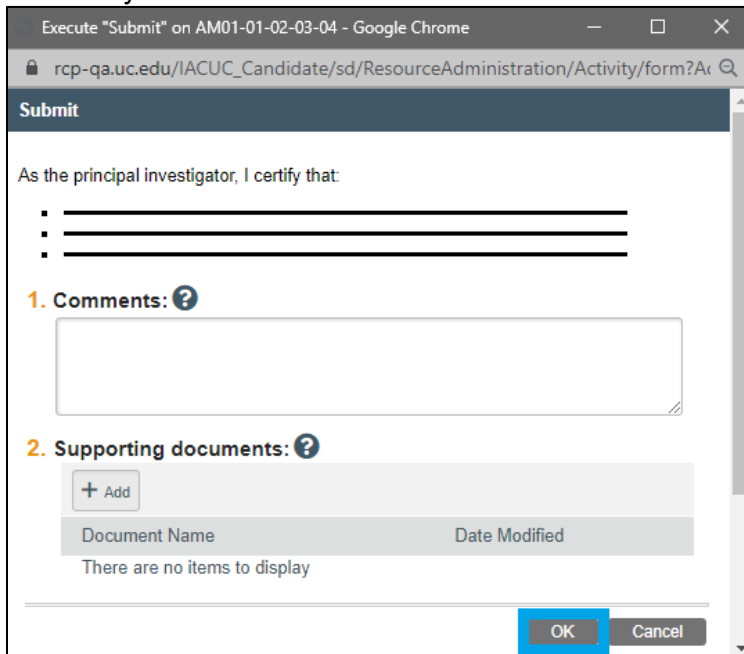
4. You now have the ability to edit each section of your IACUC protocol. After saving all changes, press the “Exit” or “Finish” button to close the form and return to the amendment workstation.
 - Refer to the **Create a New IACUC Protocol** section of this manual for information on how to complete each section of the protocol form.
 - Refer to **Appendix 1: Protocol Writing Examples** and **Appendix 2: Preferred Language and Definitions** for helpful examples and resources.
 - Refer to **Create a New Team Procedure Version** to amend procedures.

We strongly recommend following these basic guidelines when editing an IACUC protocol:

- Review the RAP Standard Library of substances and procedures before creating/copying a non-standard (team) substance and/or procedure (see **Substances and Procedures**).
 - All required form fields are denoted by a **red asterisk (*)**.
 - **You must 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.**
5. 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.*



6. Carefully review each confirmation statement and provide comments or supporting documents if necessary. Press the “OK” button to submit the amendment and close the popup window.



Substances and Procedures

There are 2 types of substances and procedures found in the [Research Administration Portal \(RAP\) website](#).

- **Standard:** these have been pre-approved by the appropriate safety office(s) and IACUC
- **Team:** these are subject to review and approval by the appropriate safety office(s) and IACUC

When creating an experiment for your IACUC protocol, you should always use existing RAP substances and procedures if they meet your research needs. You can perform a **Search for Existing RAP Substances and Procedures to View Substance or Procedure Details** and compare them to your research needs.

If a substance or procedure does not meet your research needs, you must **Create a New Team Substance or Create a New Team Procedure**.

Search for Existing RAP Substances and Procedures

1. Select the “IACUC” tab in the top navigation menu, then select the “Research Teams” tab.
2. Select the name of your Research Team to open the Research Team workstation.

The screenshot shows the University of Cincinnati IACUC Research Teams workstation. The top navigation bar includes Dashboard, IRB, IACUC, and Animal Operations. The IACUC section has sub-tabs for Submissions, Standard Library, Concerns, Facilities, Reports, and Help Center. The main content area is titled "Submissions" and features a search bar, a "Create Concern" button, a "Create Research Team" button, and a "Create Protocol" button. The "Research Teams" tab is selected, showing a list of teams. The "Jane Doe Research Team" is highlighted in a blue box. The team details show the investigator as Jane Doe. The page indicates 1 item and is on page 1 of 1.

3. By default, the Research Team workstation opens with the “Submissions” tab displaying.
 - a. select the “Procedures” tab to view a list of all RAP procedures
 - b. select the “Substances” tab to view a list of all RAP substances

The screenshot shows the University of Cincinnati IACUC Research Team workstation for the "Jane Doe Research Team". The top navigation bar includes Dashboard, IRB, IACUC, and Animal Operations. The IACUC section has sub-tabs for Submissions, Standard Library, Concerns, Facilities, Reports, and Help Center. The main content area is titled "Jane Doe Research Team" and features a "Next Steps" section with buttons for "Edit Research Team", "Create Protocol", "Create Procedure", and "Create Substance". The "Procedures" tab is selected, showing a search bar and a filter by "Name" dropdown. The page indicates 1 item and is on page 1 of 1.

Use the Filter to Search for Specific Criteria

Almost every tab on the Research Team workstation has a filter to search for specific criteria or view specific results. To perform a partial search, use % as a wildcard (takes the place of 1 or more letters in a search).

- **Example:** searching for %glu will result in a list of results with “glu” anywhere in the name e.g. glucose, L-glutamine, monosodium glutamate, fluoro-2-deoxyglucose

RT-01-02-03-04

Jane Doe Research Team

Principal investigator: Jane Doe
Phone:
E-mail: jane.doe@uc.edu

Submissions | Procedures | Substances | History | Research Team Contacts ...

Filter by [?] Name

ID	Name	Date Modified	State	Submission Type
01-02-03-04	Example Protocol	7/13/2021 5:05 PM	Approved	New Protocol Application

View Substance or Procedure Details

1. In your search results, select the name of the substance or procedure you want to view details for.

RT-01-02-03-04

Jane Doe Research Team

Principal investigator: Jane Doe
Phone:
E-mail: jane.doe@uc.edu

Submissions | Procedures | Substances | History | Research Team Contacts ...

Filter [?] Name

Name	Execute Activity	Date Modified	State	Version	Species	Procedure Type	Scope
Adrenalectomy - Mouse	Actions ▾	7/8/2019 10:18 AM	Active	1	Mice	Survival Surgery	Standard
Agents Administration - Mice	Actions ▾	3/22/2021 4:10 PM	Active	1	Mice	Substance Administration	Team

2. Select the “View Procedure” or “View Substance” button on the left side of your screen for details. Scroll through and review the entire procedure and to check if it meets your needs.

Active

PROC00001328

Adrenalectomy - Mouse

Next Steps

Procedure type: Survival Surgery
Surgery type: Major
Procedure scope: Standard
Species: Mouse
Version: 1
Approval date: 7/8/2019

Active

SUBST00001966

PLX-5622

Next Steps

Substance types: Standard Housing Area
Substance Housing and Containment: Standard Housing Area
Substance scope: Team

If the standard procedure or substance meets your needs, then no further action needed. The standard will be available when you need to add it to the experiment. If the procedure or substance does not meet your needs, you must **Create a New Team Substance** or **Create a New Team Procedure**.

3. When you are done viewing procedure or substance details, click the “Exit” button on the bottom right of your screen to close the form.

Create a New Team Substance

From the Research Team workstation, select the “Create Substance” button on the left side of your screen to open a “Create New Substance” form. There are 4 questions within this form:

1. **Name:** follow the guidance below for substance name requirements
 - use generic name instead of trademarked name
 - e.g. “acetaminophen” instead of “Tylenol®”
 - add substance abbreviations in parenthesis
 - e.g. “dimethyl sulfoxide (DMSO)”
 - if radiological agent, identify the radionuclide
 - e.g. “uridine triphosphate S-35 (UTP S-35)”
 - use the compound class to group similar substances together (must provide 1 or 2 examples)
 - e.g. “topical antibiotics (e.g. neomycin, bacitracin)”
2. **Substance Types:** select all that apply, including at least 1 of the following types
 - Biological Agent
 - Chemical Agent
 - Radioactive Agent
3. **Substance Housing and Containment:** select all that apply to the housing and containment of animals after administration of this substance.
 - Non-hazardous substances are typically used in a “Standard Housing Area”.
 - Hazardous substances must typically be used in at least 1 of the following areas:
 - Biocontainment Room (biohazards)
 - Chemical Containment Room (chemicals)
 - Radiation Commissioned Room (radioactive agents)
4. **Is this a hazardous agent?** Select “Yes” or “No”. You can confirm the hazard status of a substance with the appropriate safety office:
 - a. Biological agents: UC Biosafety Office
 - b. Chemical agents: UC Environmental Health & Safety (EH&S)
 - c. Radioactive agents: UC Radiation Safety Office

Select the “Finish” button to finish creating the new team substance and close the form.

Create a New Team Procedure

From the Research Team workstation, select the “Create Procedure” button on the left side of your screen to open a “Creating New Procedure” form. If multiple species on your protocol undergo similar procedures, use the **Copy a Procedure** technique to quickly duplicate a procedure and change the species.

There are 5 questions on the first page of this form:

1. **Name:** create a name for the procedure with enough detail so that you can easily search for and add this procedure to a protocol experiment later on (e.g. administering inflammatory agents, TAC surgery).
2. **Procedure Type:** choose 1 of the categories below. Your answer to this question will determine the questions populated on the next page of the form. Each category is defined in **Appendix 2: Preferred Language and Definitions**.
 - Survival Surgery (major/minor)
 - Non-Surgical
 - Substance Administration
 - Physical Restraint
 - Food and Fluid Restriction
 - Non-survival Surgery
 - Behavioral
 - Tissue/Blood Collection
 - Euthanasia

3. **Species:** select 1 species per procedure.
4. **Admin office:** defaults to IACUC
5. **Will administering this procedure cause any more than momentary pain and distress?**
Consider both the immediate procedure and intended, downstream effects of this procedure in your answer. For example, you should answer “Yes” for a procedure administering Lipopolysaccharide (LPS), bacteria, or tumor cells with the intention of making the animal sick, grow tumors, cause inflammation, etc.

Another example: you should answer “No” for a substance administration procedure where a substance that does not cause pain/distress (e.g. insulin, saline) is administered by a route that does have associated pain/distress (e.g. surgical minipump implant). In this example, the pain/distress description is provided in the surgical implant procedure instead of the substance administration procedure, because the surgery is the source of the pain/distress.

If yes, provide the following response to the following questions:

- a. **Identify expected symptoms from administering this procedure:** write “See Q8 of associated experiment.”
- b. **Identify criteria under which animals will be removed from research:** write “See Q8 of associated experiment.”

Press the “Continue” button to move forward to the next page(s) of the form. Use the following guidelines to complete the remaining procedure form pages.


- Textbox questions: if there is no appropriate response, type “N/A” (do not leave field textbox blank).
- Use the word “animal” instead of the species name when providing descriptions (facilitates the **Copy a Procedure** technique).
- See **Appendix 2: Preferred Language and Definitions** for writing examples and specific details.
- Forms for all procedure types EXCEPT Substance Administration will ask you to identify substances administered during the procedure. This includes anesthesia and/or analgesics administered.
 - **Add related substance administration procedures for all non-variable substances.** For example, for a Survival Surgery you would include analgesics and anesthetics, but would not include experimental substances (e.g. LPS, biological and chemical agents).
 - **Leave the “Describe each substance” textbox blank.**

4. Select the substance administration used (include anesthesia and analgesia):

Name	Type	Version	Scope
There are no items to display			

Alternatively, if you cannot find the procedures in the list above, enter the information here:

Describe each substance and the step-by-step procedure to be used: (include route, dose, volume, concentration, and whether substance is pharmaceutical grade) ?



Substance Administration Team Procedure

If you selected “Substance Administration” as the procedure type, this is the second page of the form. Group substances based on use.

- **Example:** if you have an induction of tumor substance administration that would include all of your tumor cells, and a separate treatment of tumor substance administration that includes all of the agents that you would use to stop tumor growth.

1. **Substances.** Click the “+ Add” button to add substances using a “Add Substance to Procedure” form with the following questions:

a) **Substance.** Use the filter feature to search for a substance. You can use % as a wildcard (takes the place of 1 or more letters in a search) to perform a partial search.

Name	Scope
<input type="radio"/> 17-Alpha-Estradiol	Standard
<input type="radio"/> 3-Aminobenzoic Acid Ethyl Ester (Ms22)	Standard

b) **Route.** Select the route of administration from the dropdown menu. If using multiple routes of administration OR the route of administration is not listed, select “Other” from the dropdown menu, and describe in the provided textbox:

2. Route:

If you indicated Other, specify the route:

c) **Dose.** Provide a dose and units of measurement.

- Units of measurement can be specific (e.g. mg/kg) or general (e.g. number of cells).
- Provide a dose range or use flexible language (e.g. up to 5 mg/kg).
- Distinguish between multiple administration routes (e.g. 5 mg/kg PO, 2-6 mg/kg IP).

d) **Frequency of dosage.** Distinguish between multiple routes of administration if applicable (e.g. PO administered 1x/week, IP administered 2x/month).

- If 1 substance has several administration routes and frequencies, consider adding the substance with a different administration route and frequency multiple times, instead of adding too many details to 1 substance. **Information must be clear to the reviewer.**

e) **Concentration.** Typically provided in mg/mL. This field is not required if your provided adequate details in the “Dose” question.

f) **Volume.** Provide the maximum volume/route.

g) **Purpose.** Provide a reason for substance administration (e.g. induce inflammation, treatment, antibiotic).

h) **Is substance pharmaceutical grade?** Answer using 1 of the following options.

Note: most biological agents are not pharmaceutical grade.

- Yes
- No (not available)
- No (incorrect formulation)
- No (other) – *provide a description/justification*

Select either the “OK” (closes form) or “OK and Add Another” (keeps form open) button to finish adding your substance.

2. **Describe step by step the procedure for administering the substances.** See **Appendix 1: Protocol Writing Examples** to see examples of responses to this question.
3. **Describe any anticipated adverse reactions to administering the substances.** Do not leave this question blank. If no adverse reactions are expected, you must state this.
4. **Are all substances being administered in this procedure pharmaceutical grade?**
If you listed multiple substances, be very clear about which specific substances are non-pharmaceutical grade and provide detailed responses to subsequent questions. For details and definitions, see ACUP Policy 105: Use of Expired Materials, Non-Pharmaceutical Grade Substances and Labelling Requirements (located on [Research How 2 website](#)).

If you answer “No”, the following questions will display:

- a) **If you answered "No-other" above, please provide justification for not using pharmaceutical grade.** Otherwise state "N/A".
 - b) **For each non-pharmaceutical grade substance, describe the procedures to be used to ensure the sterility, purity, stability, and physiologic pH of the compound.**
Include formulation information, including sterile filtration through 0.22 micron filter if applicable.
 - c) **For each non-pharmaceutical grade substance, describe storage method, if any.**
e.g. substance frozen at -80°C, then thawed at room temperature for before administration
5. **Select the anesthesia and analgesia procedures to be used.** Add ONLY if required for the act of substance administration (e.g. retroorbital injections). Anesthesia and analgesia administered during surgery must be listed in the surgical procedure (e.g. craniostomy, minipump) and should not be included here.
 6. **Describe the monitoring of the animal during the procedure.**
 7. **Describe post-procedural care and monitoring.**

Press the “Finish” button in the lower right corner of your screen to finish creating your new team procedure.

Copy a Procedure

Copying a procedure is a quick and easy technique to use similar language, descriptions, and substances. Standard or team procedures can be copied from a research team or from the procedure workstation.

Examples of why you might want to copy a procedure include:

- Modifying a standard procedure to meet your research needs
- Applying similar procedures to multiple species

When you copy a procedure, it may take a few minutes before the copied procedure associated with your research team displays in RAP. You may need to refresh your page a few times.

Copy Procedure from a Research Team

1. Select the “IACUC” tab, then click on the name of your Research Team.
2. Select the “Procedures” tab and locate the procedure you want to copy.
3. In the Execute Activity column, select the small arrow to the right of “Actions” to display a dropdown menu. Select “Copy Procedure” from the dropdown menu to generate a new popup window.

The screenshot shows the 'Jane Doe Research Team' page. On the left, there is a 'Next Steps' sidebar with buttons for 'Edit Research Team', 'Create Protocol', 'Create Procedure', and 'Create Substance'. The main content area has tabs for 'Submissions', 'Procedures', 'Substances', and 'History'. The 'Procedures' tab is active, showing a table of procedures. A dropdown menu is open over the 'Execute Activity' column for the 'Neonatal Euthanasia - Mouse' procedure, with 'Copy Procedure' highlighted. The table has columns for Name, Execute Activity, Date Modified, State, and Version.

Name	Execute Activity	Date Modified	State	Version
Neonatal Euthanasia - Mouse	Actions	7/8/2019 10:18 AM	Active	1
Agents Administration - Mice	Create New Version		Active	1
Barnes Maze Test-Mouse	Add Comment		Active	1
	Copy Procedure			
	Archive Procedure			

4. Alternatively, you can click the procedure name to navigate to the procedure workstation. Select the “Copy Procedure” button from the left navigation menu to generate a new popup window.

The screenshot shows the 'Neonatal Euthanasia - Mouse' procedure workstation. The page title is 'PROC00003551 Neonatal Euthanasia - Mouse'. It displays details for the procedure type (Euthanasia), scope (Standard), species (Mouse), version (1), coordinator (Rebecca Jones), and approval date (6/8/2020). On the left, there is a 'Next Steps' sidebar with buttons for 'View Procedure' and 'Printer Version'. At the bottom left, there is an 'Add Comment' button and a 'Copy Procedure' button, which is highlighted with a red box.

5. The “Copy Procedure” form will display in a popup window. Provide a name for the copied procedure (Question 1) and assign it to the applicable research team (Question 2). Press the “OK” button to create a procedure copy. **When copying a standard procedure: to avoid confusion, please do not use similar naming strategies as the standard.**

The screenshot shows the 'Copy Procedure' popup form. It has a title bar 'Copy Procedure' and a subtitle 'Euthanasia Procedure: Neonatal Euthanasia - Mouse'. Below the subtitle, there is a warning message: 'This procedure will be copied to the selected research team when you click OK. Any associated team substances will not be copied if you assign the copy to a different research team.' The form contains two main sections: '1. * New procedure name:' with an empty text input field, and '2. * New research team:' with a table of radio buttons and team names. At the bottom, there is a 'Clear' link, a warning message 'Depending on the size of the procedure, copying may take some time.', and 'OK' and 'Cancel' buttons.

Name	PI
<input type="radio"/> Jane Doe Research Team	Jane Doe
<input type="radio"/> Smith Cardiovascular Research Team	John Smith

Edit a Copied Procedure

1. Select the “IACUC” tab, then click on the name of your Research Team.
2. Select the “Procedures” tab and use the filter feature to search for a procedure using specific criteria. Once you locate the copied procedure you want to edit, click on the procedure name.
3. Select the “Edit Procedure” button on the procedure workstation to review and make edits/changes.

PROC00005732

Neonatal Euthanasia - Mouse (Doe lab)

Procedure type: Euthanasia Euthanasia method: Physical
Procedure scope: Team
Species: Mouse
Version: 1

History Documents Related Protocols ...

Filter by ? Activity + Add Filter

Activity	Author	Activity Date
<i>i</i> Procedure Created	Doe, Jane	7/20/2021 12:53 PM

Copied from Standard Procedure: PROC00003551 Neonatal Euthanasia - Mouse

You can edit the procedure to meet your needs – for example, you may need to change the species the procedure applies to or change the type of substance administered as part of this procedure. Like other forms, press the “Continue” button to save your changes and proceed to the next section of a form. Press the “Finish” button to save your changes and close the form.

Create a New Team Procedure Version

If you have a team procedure that is approved on your protocol or approved on another protocol you may want to create a new version of the procedure. Benefits of creating a new procedure version include:

- Historical tracking of procedural changes over time (allows you to keep the historical procedure in use but allows you to make changes to a new procedure version).
- Automatic archiving of previous procedure versions (will cause the system to flag archived procedures for update/replacement during triennial review). **Old versions must be replaced by the newest versions during triennial. Each procedure has an associated version number visible on the procedure workstation.**
- Designated reviewers can focus on changes between previous and new procedure versions, instead of reviewing an entirely new procedure from start to finish (decreases reviewing turnaround time).

Create a New Version of a Team Procedure from a Research Team

1. Select the "IACUC" tab, then click on the name of your Research Team.
2. Select the "Procedures" tab and locate the procedure you want to create a new version of.
3. In the Execute Activity column, select the small arrow to the right of "Actions" to display a dropdown menu. Select "Create New Version" from the dropdown menu to generate a new popup window.

The screenshot shows the IACUC system interface. At the top, there are navigation tabs: Dashboard, IRB, IACUC, and Animal Operation. Below these are sub-tabs: Submissions, Standard Library, Concerns, Facilities, Reports, and Help Center. The main content area is for the 'Jane Doe Research Team' (RT-01-02-03-04). It includes a 'Next Steps' section with buttons for 'Edit Research Team', 'Create Protocol', 'Create Procedure', and 'Create Substance'. A 'Send Training Expiration Reminder' button is also present. The 'Procedures' tab is selected, showing a table of procedures. The 'Neonatal Euthanasia - Mouse (Doe lab)' procedure is highlighted, and a dropdown menu is open over it, with 'Create New Version' selected. Other options in the menu include 'Add Comment', 'Copy Procedure', and 'Archive Procedure'.

4. Alternatively, you can click the procedure name to navigate to the procedure workstation. Select the "Create New Version" button from the left navigation menu to generate a new popup window.

The screenshot shows the IACUC system interface for the 'Neonatal Euthanasia - Mouse (Doe lab)' procedure (PROC00005732). The 'Active' status is shown. The 'Next Steps' section includes buttons for 'Edit Procedure', 'Printer Version', 'Create New Version', 'Add Comment', 'Copy Procedure', and 'Archive Procedure'. The 'Create New Version' button is highlighted. The main content area shows the procedure details: Procedure type: Euthanasia, Euthanasia method: Physical, Procedure scope: Team, Species: Mouse, Version: 1. Below this is a table with columns for Activity, Author, and Activity Date. The table shows one entry: 'Procedure Created' by 'Doe, Jane' on '7/20/2021 12:53 PM'. A note at the bottom states 'Copied from Standard Procedure: PROC00003551 Neonatal Euthanasia - Mouse'.

- The “Create New Version” form will display in a popup window. Select “Yes” for Question 1, then press the “OK” button to create a new version of the team procedure. **This action will archive the prior version of the procedure and activate the new version of the procedure.**

Create New Version

This activity creates a new version of this procedure. The older version will be archived, meaning it can no longer be selected in protocol experiments. The older procedure must be replaced in any active protocol referencing it before the next triennial review can be submitted.

- * Are you sure you want a new version of this procedure? (The current version will be archived. It can no longer be selected in experiments and must be updated in existing protocols.)** Yes No [Clear](#)
- Comments:**
- Supporting documents:**

+ Add

Document Name	Date Modified
There are no items to display	

Edit a New Version of a Team Procedure

- Select the “IACUC” tab, then click on the name of your Research Team.
- Select the “Procedures” tab and use the filter feature to search for a procedure using specific criteria. Once you locate the copied procedure you want to edit, click on the procedure name.
- Select the “Edit Procedure” button on the procedure workstation to review and make edits/changes.

Active

Next Steps

Edit Procedure

Printer Version

Create New Version

Add Comment

Copy Procedure

Archive Procedure

PROC00005732

Neonatal Euthanasia - Mouse (Doe lab)

Procedure type: Euthanasia Euthanasia method: Physical
 Procedure scope: Team
 Species: Mouse
 Version: 1

History

Documents

Related Protocols

...

Filter by ? Activity Enter text to search for Q + Add Filter

Activity	Author	▼ Activity Date
i	Procedure Created	Doe, Jane 7/20/2021 12:53 PM

Copied from Standard Procedure: PROC00003551 Neonatal Euthanasia - Mouse

Like other forms, press the “Continue” button to save your changes and proceed to the next section of a form. Press the “Finish” button to save your changes and close the form.

Appendix 1: Protocol Writing Examples

Example 1: Simple Experiment

Animals will be exposed to an allergen (papain, ovalbumin, or house dust mite extract). Once the allergen administration is completed the animals will be infected. We will assess fungal burden, immune response, and pathology for up to 3 weeks after infection. Conversely, we will infect animals and 2-4 weeks later we will administer the allergen for up to 3 weeks. Fungal burden, immune response, and pathology of visceral and lymphoid organs will be assessed up to 3 weeks after the administration of an allergen.

6 animals/group x 2 sexes x 3 allergens x 3 time points x 3 doses of allergen x 2 inocula = 648 animals

Example 2: Complex Pain/Behavioral Hybrid Experiment

Aim 1. Role of abnormal spontaneous activity.

In this experiment, we study how spontaneous activity including clustered firing of the sensory neurons affects the chronic pain state. After inflammation or injury, one of the first abnormalities to appear is spontaneous activity – the neurons begin to fire without any appropriate stimulus. We will stimulate the sympathetic nervous system, apply different therapeutic regimens (pharmacological, surgical, and genetic), assess behavioral responses to injury/therapy/pain and then euthanize and collect tissues/samples for analysis. The maximum duration of study is up to 4 months. Injury models for these experiments include 1 back pain model, 1 neuropathic pain model, and the postoperative pain model.

Behavioral measurements:

1. Adhesive removal test (motor)
2. Conditional place preference/aversion (spontaneous pain)
3. Facial grimace scale (spontaneous pain)
4. Grip strength assay (motor)
5. Heat Sensitivity Assay (evoked pain)
6. Cold Plantar Assay (evoked pain)
7. Open field test (motor and pain-related)
8. Spontaneous Observation (may involve cold platform and predator smell)
9. Two-temperature choice assay (evoked pain)
10. Von Frey Mechanical sensitivities test (evoked pain)

Any given animal will only undergo a subset of these tests, which may be repeated several times a week. The above test listed as "motor" tests, are only needed to verify particular manipulations have not affected motor function and are used less often than pain measurements.

Pain models:

1. Acute pain: paw formalin injection test
2. Chronic inflammatory pain (includes low back pain models): DRG inflammation (LID); DRG chronic compression; CFA or carrageenan injection into the paw
3. Postoperative pain: paw incision model
4. Neuropathic pain models: spared nerve injury (SNI), spinal nerve ligation (SNL), chronic constriction of sciatic nerve (CCI)

An animal receives at most 1 pain model or modified pain model. In some cases these models are modified (e.g. by local drug implantation or perfusion of the DRG or injury site, or molecular manipulations).

Experimental endpoints:

1. Behavioral: repeated measurements and after euthanasia to isolate tissues
8 animals/group x 2 groups x 3 pain models x 5 therapeutic interventions = 240 animals
2. Molecular: expression of genes and proteins in nerve tissues or isolated macrophages)
6 animals/group x 2 groups x 3 pain models x 5 therapeutic interventions x 3 time points = 540 animals
3. Microscopy: expression and localization of specific proteins, degree of inflammation)
6 animals/group x 2 groups x 3 pain models x 5 therapeutic interventions x 3 time points = 540 animals
4. Electrophysiological: nerve activity in ex vivo preparations or cultured neurons
4 animals/group x 2 groups x 3 pain models x 5 therapeutic interventions x 2 time points = 240 animals

Appendix 2: Preferred Language and Definitions for Procedures

Food and Fluid Restriction

Separate procedure is required for 16 or more hours of food restriction and 8 or more hours of water restriction. Otherwise, the restriction must be described in its associated procedure.

Prolonged Physical Restraint

Separate procedure is required for physical restraint greater than 10 minutes. Otherwise, the restraint must be described in its associated procedure.

Imaging

Separate procedure is only required if you will be performing the imaging or irradiation. Separate procedure is not required if the procedure is performed via temporary transfer.

Question 4 (Purpose): Include a description of the imaging or irradiation procedure and the reason the procedure is needed.

Question 6 (Describe post-procedural care and monitoring): Animals will be returned to their home cage following the procedure.

Survival Surgery (Animals Recover/Wake Up from Anesthesia)

Question 2 (Describe the surgical procedure): choose 1 of the following description styles

- Incisions are closed in 2 layers - inner layer with absorbable suture, and skin with wound clips or non-absorbable suture.
- The skin incision is closed with wound clips (or non-absorbable suture).

Question 3 (Describe how the animal, surgeon, & instruments will be prepared for aseptic surgery):

- ACUP survival surgery guidelines will be followed.
- Animal Prep: hair removal followed by alternating scrubs of povidone iodine or chlorhexidine and 70% ethanol repeated 3 times.
- Surgeon Prep: clean lab coat, surgical scrubs, or disposable gown; mask; sterile surgical gloves. Hair bonnet/cap is recommended.
- Instrument Prep: Instruments will be steam (e.g. autoclave) or gas (e.g. ethylene oxide) sterilized initially. Some items may come sterile from the manufacturer or may require chemical sterilization according to directions from the manufacturer.
- If batch surgeries are performed, instruments will be sterilized between animals via glass bead sterilization. A new surgical pack will be used following the 5th animal.

Question 5 (Describe the anesthetic monitoring): Anesthesia monitoring details are in the Substance Administration Anesthesia form.

Question 6 (Describe post-operative care and monitoring): Include descriptions for immediate post-operative care and daily care thereafter.

- During and immediately following surgery, animals will receive supplemental heat (e.g. circulating warm water blanket or equivalent to prevent thermal injury) until they regain consciousness.
- Animals will be continuously monitored until sternal.
- Wet chow or hydrogel may be provided post-operatively.
- Animals will be checked for at least 3 days following surgery to monitor (and document) the surgical site, behavior, and analgesic administration.
- The animal will receive analgesics as described in the Substance Administration-Analgesia form.
- Suture or wound clips will be removed in 10-14 days.

Non-Survival Surgery (Animals Euthanized Prior to Anesthetic Recovery)

Question 3 (Describe how the animal, surgeon, and instruments will be prepared for aseptic surgery):

- Animal Prep: hair will be removed
- Surgeon Prep: clean lab coat and gloves.
- Instrument Prep: Instruments will be clean.

Question 6 (Describe post-operative care and monitoring): N/A

Non-Surgical

Non-surgical procedures may have a behavioral component, but animal does not have a conscious choice to participate (e.g. forced exercise, Hargreaves, burn).

Question 2 (Describe any apparatus you will use and provide details of sanitization between uses):

Apparatus may be cleaned with 70% ethanol (or equivalent) after each animal. At the end of the study, the apparatus is sanitized with a disinfectant (e.g. zepamine, peroxigard, clidox).

Question 6 (Describe post-procedural care and monitoring): Animals will be returned to their home cage following the procedure.

Behavioral

Behavioral procedures are those in which animals have a conscious choice to participate (e.g. CPP, open field, running wheel without forced exercise).

Question 2 (Describe any apparatus you will use and provide details of sanitization between uses):

Apparatus may be cleaned with 70% ethanol (or equivalent) after each animal. At the end of the study, the apparatus is sanitized with a disinfectant (e.g. zepamine, peroxigard, clidox).

Question 3 (Indicate how animals will be monitored for stress during procedure, including criteria for prematurely ending the session): This procedure may be used as part of a stress paradigm. However, the procedure does not result in distress to the animal.

Question 6 (Describe post-procedural care and monitoring): Animals will be returned to their home cage following the procedure.

Substance Administration

Question 2 (Describe the procedure for substance administration, including route if "Other"):

- SQ/SC or IP: Animal is gently restrained, and injection is given.
- IV (tail vein): Animal will be manually or mechanically restrained, and the injection is given. Following injection, pressure is applied to the injection site with sterile gauze until bleeding stops.
- IV (retroorbital under anesthesia): Animal is anesthetized, and the injection is given. Following injection, pressure is applied to the injection site with sterile gauze until bleeding stops.
- Oral gavage: Animal is gently restrained, the oral gavage needle/tube is inserted, the substance is administered, and needle/tube removed.
- Substance administered during a procedure (e.g. minipump): Substance administration description is provided in the associated surgical procedure.

Question 6 (Describe the monitoring of the animal during the procedure): Animal will be continuously monitored during the administration.

Question 7 (Describe post-procedural care and monitoring): Animals will be returned to their home cage following the procedure.

Euthanasia

Question 3 (Describe how death will be confirmed): A secondary physical method (listed below) will be performed:

- Bilateral thoracotomy
- Decapitation
- Removal of vital organ
- Cervical dislocation (mouse only)

Tissue/Blood Collection

Only required for survival procedures. Tissue/blood collection post-euthanasia does not require a separate procedure.

Question 2 (Describe timing and frequency of collection and amount to be collected):

- ACUP Blood and Fluid Guidelines will be followed.
- Provide maximum blood volume for each collection and maximum volume in a particular timeframe.
 - Example: Blood samples will be taken up to 6 times, with 15-minute intervals, 50 uL (not to exceed 7.7 mL/kg every 2 weeks)

Question 5 (Describe post-procedural care and monitoring): Animals will be monitored to ensure that bleeding has stopped and will be returned to their home cage.

Question 7 (Describe any potential complications from collection):

- Tail Vein: If tail becomes damaged/unsheathed, notify LAMS veterinary staff.
- If too much blood is taken/lost, subcutaneous or intraperitoneal injection of sterile 0.9% sodium chloride or lactated ringers (0.5-1 mL mouse/1-3 mL rat) depending on size of animal and amount of blood loss.