



Click IACUC: Protocol Creation and Submission

The objective of this quick guide is to help Principal Investigators initiate a protocol within the Click IACUC module. This document provides an overview of the building block structure, creation, key pages, and submission of a protocol.

Protocol Planning

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Submission

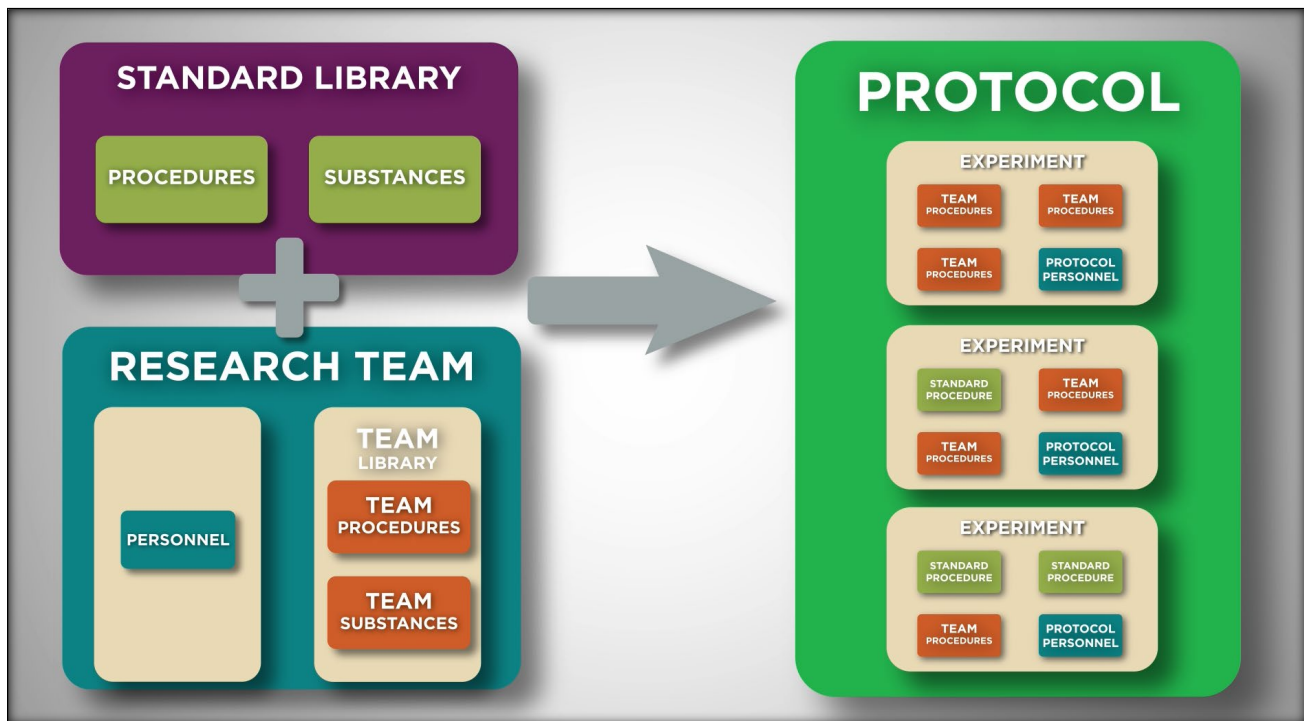
[Protocol Workspace](#)



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1. Protocol Planning – Building Blocks

Within the Click IACUC module, the protocol construction process is based on the building block approach. To create a protocol, a Principal Investigator (PI) builds experiments based on the procedures and substances, then combines the experiments into a comprehensive research protocol.



For further details about creating and managing team procedures and substances, please see additional support materials at <https://animalcare.msu.edu/click/resources.html>.

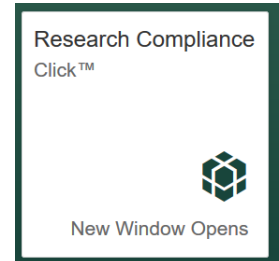


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2. Create Protocol

Click System Login

The Click system modules are part of Michigan State University’s enterprise systems, so logging in will involve use of the university’s multi-factor authentication solution (MFA or Okta Verify). A login tile is available within EBS.



My Inbox

After login, users arrive at the **Dashboard/My Inbox** page. Select the **IACUC** button or tab at the top of the page.

Page for Monique Marie Bauer

Dashboard Admin Facilities **IACUC** IRB AOPS Safety

My Inbox Assignments In Process

My Inbox

Filter by ID: %202400139 and by Name: Demonstration

ID	Name	Date Created	Date Modified	State	Coordinator	PI Last Name
PROTO202400139	Demonstration - Test Protocol	6/12/2024 9:12 AM	6/12/2024 9:12 AM	Pre-Submission		Bauer

Select the appropriate Research Team for the protocol.

Submissions

Search ?

Create Concern

Create Research Team

Create Protocol

Research Teams In-Review Active Archived All Submissions

Filter by Name: %Demonstration Research

Name	PI First Name	PI Last Name	Date Modified
Demonstration Research Team	Monique	Bauer	6/12/2024 12:53 PM



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Research Team Workspace

On the **Research Team Workspace**, the following buttons for protocol-related actions are displayed on the left side:

- Edit Research Team – allows updates to be made regarding the research team members
- Create Protocol – initiates the process of creating a protocol to submit for IACUC review
- Create Procedure/Create Substance – initiates creation of a team procedure or team substance

To create a protocol, select the **Create Protocol** button.

The screenshot shows the CLICK IACUC interface. At the top, there is a navigation bar with tabs for Dashboard, Admin, Facilities, IACUC (selected), IRB, AOPS, and Safety. Below this is a secondary navigation bar with links for Submissions, Standard Library, Concerns, Inspections, Meetings, Reports, and Help Center. The main content area is titled 'Demonstration Research Team' and includes a 'Next Steps' sidebar on the left. The 'Next Steps' sidebar contains four buttons: 'Edit Research Team', 'Create Protocol', 'Create Procedure', and 'Create Substance'. These four buttons are highlighted with a red rectangular box. The main content area also displays the principal investigator's information (Monique Bauer) and a table of submissions. The table has columns for ID, Name, Date Modified, State, Submission Type, PI First Name, and PI Last Name. One submission is listed: PROTO202400140, Demonstration IACUC Protocol, 6/12/2024 1:28 PM, Pre-Submission, New Protocol Application, Monique, Bauer.



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3. Key Pages

Basic Information

The first page of the protocol is the **Basic Information** page. All fields on this page are required.

1. **Title of protocol:** Provide an overall protocol title.
2. **Short title:** Provide a summarized identifier for the protocol (please note this phrasing will be prominently viewable on the protocol workspace).
3. **Summary of research:** Provide the lay summary of the protocol. This information should be written in a manner in which non-scientific committee members will understand the relevance to human or animal health, the advancement of scientific knowledge, and the contribution to society.
4. **Principal investigator:** This field is auto populated with the PI of the research team.
5. **What is the intention of the animal protocol:** Select 'Experimental Research' for all protocols.

The image shows a screenshot of the 'Basic Information' form. The form is divided into two main sections. The left section contains fields for: 1. Title of protocol (a large text area), 2. Short title (a small text input), 3. Summary of research (a large text area), 4. Principal investigator (a dropdown menu showing 'ra20 ra20'), and 5. What is the intention of the animal protocol? (a radio button selection). The right section is a zoomed-in view of the radio button selection for question 5. The options are: Breeding Only, Experimental Research (highlighted with a red box), Field Research, Holding Protocol, and Teaching. A 'Clear' link is also present. A red arrow points from the 'Experimental Research' option in the right section to the same option in the left section.

Once all of these questions have been answered, select the **Save** button at the bottom of the page.



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File Menu

After saving, more options appear at the left of the page. This menu allows the user to easily navigate throughout the protocol pages.

Overall, many of the protocol pages are straightforward and are modeled after questions PIs will be quite familiar with.

This remainder of this document highlights a few key pages – namely the *Experiments*, *Procedure Personnel Assignment*, and *Animal Justification* pages – and provides details about them.

CLICK

Validate Compare

Editing: PROTO202400140

Basic Information

- * Select research team:** ?
Demonstration Research Team
- * Title of protocol:** ?
Demonstration IACUC Protocol
- * Short title:** ?
Demonstration IACUC Protocol



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Experiments Page

The first key page is the **Experiments** page, where the procedures and substances will be incorporated.

To initiate experiments in the protocol, select the **Add** button located under Question 1. This will open a slide-in window where the details of each experiment are provided.

Experiments

Important! Make sure all procedures required for your protocol exist in the IACUC system before you add experiments.

If the procedure is not yet created: [Create Procedure](#)

1. * Define the experiments to be used in this protocol:

Name	Species	Is USDA	Total	Pain Category	Procedures
There are no items to display					

Answer all required questions on the experiment slide-in window. Required fields are indicated by a red asterisk (*).

Add Experiment

1. Display order:

2. * Experiment name:

3. * Species:

4. * Explain the design of the research or teaching activity and sequence and frequency of procedures. Your target audience is an external inspector and/or faculty member from a discipline that may be unrelated to yours.

For experiment name, it is recommended to number the experiments to better arrange their display; this organization will also assist the IACUC reviewers.



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The total numerical value of animals in Question 7 and Question 8 must match. Please note if a non-USDA species is used, select category C for Question 8.

7. * Total number of animals used in this experiment:

8. Number of animals by category (if animal is non-USDA, list all animals in category C):

B:

C:

D:

E:

9. * Provide scientific justification for how you determined the number of animals needed for this procedure/experiment/activity.

For guidance see: Scientific Justification for the Number of Animals to be used in Research, Teaching or Testing (RD001).

After completing necessary questions on the Experiments slide-in, select the **Ok** button at the bottom of the page.

OK

OK and Add Another

Cancel

Select the **OK and Add Another** button to add another Experiment.



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Experiments

Important! Make sure all procedures required for your protocol exist in the IACUC system before you add experiments.

If the procedure is not yet created: [Create Procedure](#)

1. * Define the experiments to be used in this protocol:

Name	Species	Is USDA	Total	Pain Category	Procedures
+ Add Mouse Experiment	Mouse	no	5	B: 0, C: 5, D: 0, E: 0	<ul style="list-style-type: none"> ✓ Blood, Tail Prick (Standard - Sample Collection (Non-Surgical)) ✓ Isoflurane (Anesthesia) (Standard - Substance Administration) Copy

Another experiment can also be added by selecting the **Add** button. Or if the experiment is similar, the previously created experiment may be copied and elements of the new experiment that are different can be edited.

Procedure Personnel Assignment

The second key page is the **Procedure Personnel Assignment** page, where the system lists procedures from the **Experiments** page.

Procedure Personnel Assignment

1. The following procedures have been identified in the experiments. Review the team member training at the bottom of this page to ensure protocol team members have the necessary training:

Procedure	Species	Is USDA Species
Sample Collection (Non-Surgical): Blood, Tail Prick, ver. 1 (Standard)	Mouse	no
Substance Administration: Isoflurane (Anesthesia), ver. 1 (Standard)	Mouse	no

Additionally, the **Procedure Personnel Assignment** page lists IACUC-relevant training for all protocol team members under Question 3. This information is not editable within the Click system. For information about required training, please visit the training page on the MSU Animal Care website <https://animalcare.msu.edu/>.



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Example:

3. Team member training:

First Name	Last Name	Training	Date Completed
Monique	Bauer	Basics for Working with Fish	1/11/2016
		Basics for Working with Swine	5/4/2018
		IACUC Tutorial	5/25/2021
		Working within CAR for Rodent Users	10/11/2017
Sandra	Wilkins	Basics for Working with Amphibians	6/15/2016
		Basics for Working with Beef Cattle	5/4/2018
		Basics for Working with Cats	6/20/2007
		Basics for Working with Dogs	6/20/2007
		Basics for Working with Fish	6/15/2016
		Basics for Working with Horses	12/3/2018
		Basics for Working with Rabbits	5/4/2018
		Basics for Working with Sheep	5/4/2018
		Basics for Working with Swine	5/4/2018
		Biosafety Refresher	3/2/2023
		IACUC Tutorial	4/13/2009
		Non-Traditional Species	9/23/2020
		Working within CAR for Rodent Users	8/8/2016

Animal Justification Page

The third key page is the ***Animal Justification*** page.

After defining the number of animals within each experiment, the system lists the total animals by species and USDA category on this page.



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Animal Justification

- Click Update to adjust the number of animals to be used or produced for this protocol. These values should include reconciliation of animal reuse and/or breeding if applicable. Please contact the IACUC Office with questions, iacuc@msu.edu and 517-432-8103.**

Species	USDA Covered Species	Pain Category	Animals Identified in Experiments	Actual Animal Count	
Mouse	no	Pain Category B	0	0	
Mouse	no	Pain Category C	5	5	
Mouse	no	Pain Category D	0	0	
Mouse	no	Pain Category E	0	0	
Rat	no	Pain Category B	0	0	
Rat	no	Pain Category C	10	10	
Rat	no	Pain Category D	0	0	
Rat	no	Pain Category E	0	0	

The system will generate an error message (upon selection of the Submit button on the protocol workspace) if **No** is selected (Question 3).

- * Do you confirm the values in the Actual Animal Count column?**

Yes No [Clear](#)

Error/Warning Messages

[Refresh](#)

Message	Field Name	Jump To
You must review personnel assignments on the Procedure Personnel Assignment page.	Procedure Team Members	SF: Procedure Personnel Assignment

If the Animal Count is not correct, navigate to the Experiments page and make the necessary adjustments.



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Submission – Protocol Workspace

Once the remaining pages on the protocol are completed, the protocol will be submitted to the IACUC Office for processing. From the protocol workspace, select the **Submit** activity along the left side menu.

The screenshot shows the CLICK IACUC Protocol workspace. The navigation menu includes: Dashboard, Admin, Facilities, IACUC, IRB, AOPS, Safety, Submissions, Standard Library, Concerns, Inspections, Meetings, Reports, and Help Center. The main content area displays the following information:

- Pre-Submission** (highlighted in a red box)
- Next Steps**: Edit Protocol, Printer Version, **Submit** (highlighted in a red box), Assign Coordinator, Assign Primary Contact, Assign PI Proxy, Manage Guest List, Manage Ancillary Reviews.
- Protocol ID**: PROTO202400140
- Protocol Title**: Demonstration IACUC Protocol
- Principal investigator**: Monique Bauer
- Letter:**
- Submission type**: New Protocol Application
- Primary contact:**
- Protocol type**: Experimental Research
- IACUC coordinator:**
- Consulted vet:**
- PI proxies:** There are no items to display
- Admin office:** IACUC
- Grace period:** -

The workflow diagram shows the following steps: Pre-Submission (orange oval) → Pre-Review (white oval) → IACUC Review (white oval) → Post-Review (white oval) → Review Complete (white oval). There are also two 'Clarification Requested' (white oval) and 'Modifications Required' (white oval) boxes that branch off from the main flow and loop back to the previous step.

A pop-up window will open with the PI attestation – by selecting the **Ok** button you are agreeing to these institutional and regulatory requirements.



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Submit

As the principal investigator, I certify that:

- I agree to abide by all federal and state regulations, Michigan State University (MSU) policies and Institutional Animal Care and Use Committee (IACUC) guidelines concerning the use of animals.
- I agree that all use of vertebrate animals will be covered by a protocol that has been reviewed and approved by the MSU IACUC and that IACUC approval must be obtained before ordering animals and/or performing any animal procedures described in this form.
- I will promptly notify the Attending Veterinarian or designee regarding any unexpected study results that negatively impact the animals, including any unanticipated pain or distress and/or morbidity or mortality.
- I agree that any proposed changes to this protocol will be requested by sending an amendment outlining the changes. IACUC approval must be obtained before performing the revised animal procedures described therein.
- I will maintain appropriate animal records (e.g., census, health, veterinary care, euthanasia, surgery, diagnostic, anesthesia, etc.).
- I will do everything within my power to safeguard the health and well-being of each animal under this protocol.
- I accept responsibility that all personnel working on this project are aware of and will follow the approved procedures outlined in this form. I assure personnel are adequately trained and have demonstrated competence in the animal procedures.
- I understand that approval of projects is for a maximum of three years from the date of approval. I understand that the IACUC can call for a complete re-review of the project as needed.
- By submitting this form, I agree to protocol-related activities including post approval monitoring, equipment maintenance, and communications with representatives of the IACUC at least annually.

1. Comments: ?

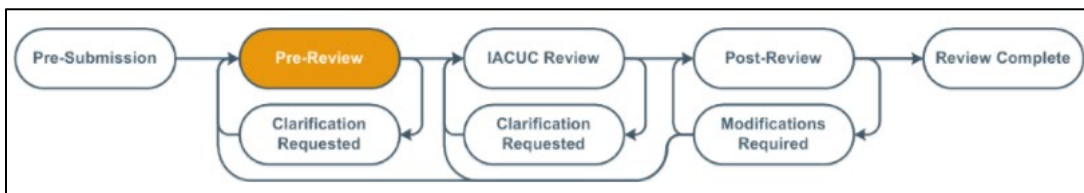
2. Supporting documents: ?

+ Add

Document Name	Date Modified
There are no items to display	

OK Cancel

After selecting the **Ok** button, the protocol moves to the Pre-Review workflow step and has been received by the IACUC Office for processing.



For further support within the Click IACUC Module, please contact the IACUC Administrative Office (iacuc@msu.edu, 517-432-8103) or the Click Help Desk (clickhelpdesk@msu.edu, 517-355-2000).