

How to Create and Submit a New Protocol

You prepare a new protocol for IACUC review by entering information into a series of online smartforms. The number of smartforms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information.

The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

Before you begin, gather files and information about your protocol such as:

- Supporting information files, such as:
 - Grant documents, including JIT if applicable
 - An animal numbers table that shows animal numbers and how they are grouped
 - Other supporting documents such as SDSs (for chemical and hazards) or product instructions

NOTE: When attaching a file, name it as you want it to appear on the IACUC approval letter.

- Training and Financial interest status for each of your protocol team members
- Funding Source, including the Grants Office ID Number (starts with FP) so the grant can be linked to the protocol in the UVMClick system.
- Related study numbers

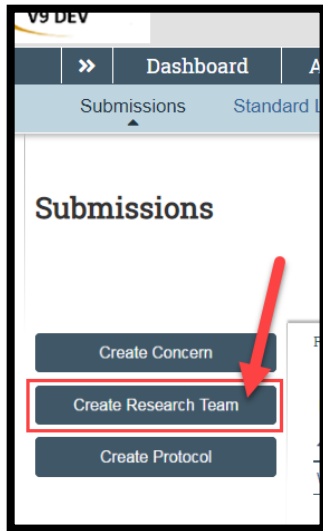
Adding a Research Team

Before you can start a new Protocol you **MUST** make sure to have at least one [Research Team](#) listed.

NOTE: If your research team is already created, you may skip to the next section called [Creating a Protocol](#).

To create a new Research Team:

1. From “Dashboard” or the IACUC > Submissions screen, Click **Create Research Team**.



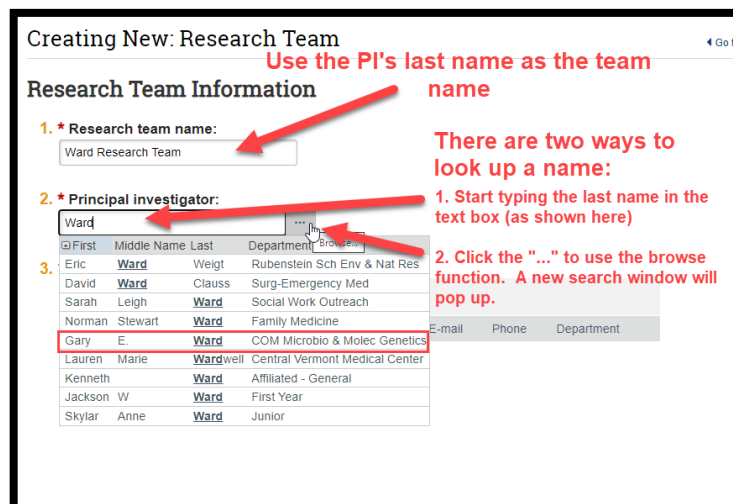
2. Fill in the applicable boxes and answer the questions on the Research Team Smartform.

Any question with a red asterisk notes that it is a required question and it must be answered to be able to save the smartform.

- **Research Team Name:** Enter a name – **we recommend using the PI name as the Research Team name** (note for coordinators creating research teams, using the PI name is helpful especially if you support more than one PI as you will likely need to create a separate Research team for each PI.)
- **Principal Investigator:** Click the button to select the appropriate PI name
- **Research Team Members:** Click the **+Add** button to add all research team members. Anyone listed here will have administrative authority to add new protocols, procedures and substances. These names are typically those who will be tasked with maintaining the protocol going forward. Key Personnel who will be working on a protocol who do not need administrative capabilities may be added later in the protocol smartform.

NOTE: These names will auto populate into the protocol personnel list and can be adjusted from there as necessary (more to come on this).

3. Clicking the +Add button will produce a new pop-up. This is where you will select the research team member name, whether they have an animal handling role and what their role is within the research activities.
4. Click OK and continue to add each person as needed.



Add Study Team Member

1. * Select the protocol team member:

2. * Does the person have an animal handling role?
 Yes No [Clear](#)

3. * Role in research: (check all that apply)

Veterinarian
 Key Personnel
 Animal Emergency Contact
 Primary Contact
 Faculty Sponsor
 Administrative Support
 Principal Investigator
 Oversight Designee

Search by typing in a last name or using the "..."
 browse function

When all research team members have been added, click the **Finish** Button found on the rightside of the screen.

Getting Ready to Create a Protocol

STEP 1

Prior to creating a new protocol, check out the Procedure/Substance Standard Library to see if any of the procedures and substances you will be being using are already listed.

Check both tabs to see if any of the IACUC-approved procedures or substances can be used in your protocol

Standard Library

Search

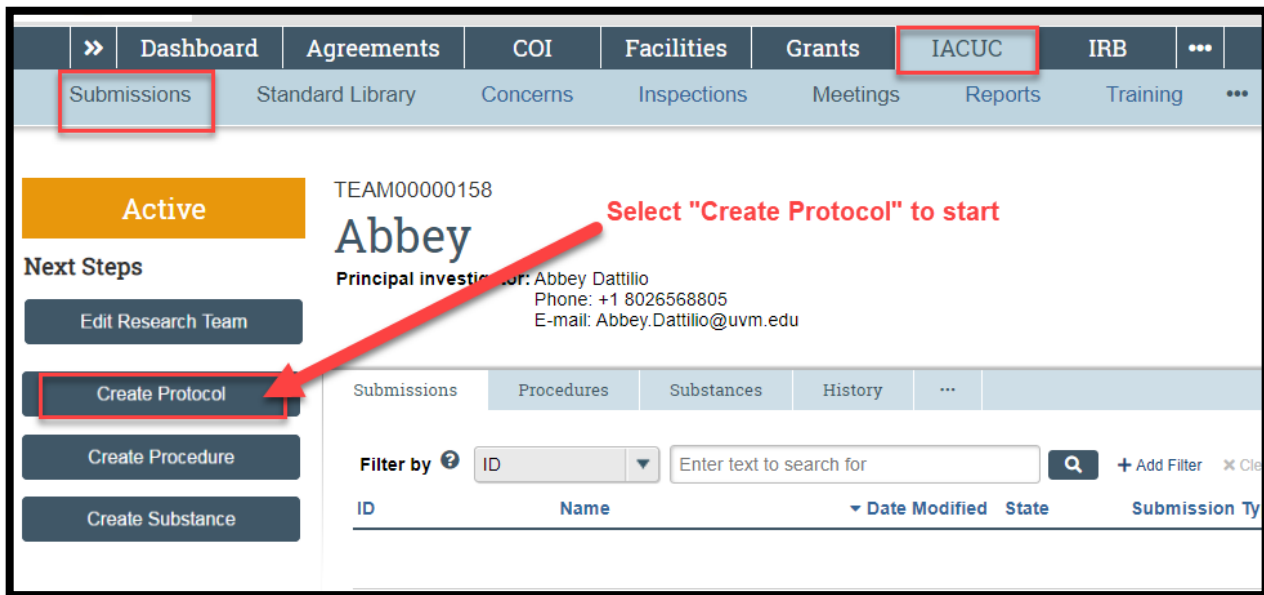
Name	SmartForm	Execute Activity	Date Modified	State	Version	Species	Procedure
Mouse Euthanasia CO2 9/22/21	[Edit or View]	Actions	8/29/2022 1:27 PM	Active	1	Mouse	Imaging
Rat Euthanasia CO2 - 9/22/21	[Edit or View]	Actions	12/9/2021 11:50 AM	Active	1	Rat	Euthanasia
Euthansia Decapitation Under Anesthesia	[Edit or View]	Actions	7/31/2020 12:57 PM	Active	1	Rat	Euthanasia
Stereotaxic Surgery	[Edit or View]	Actions	1/23/2020 10:18 AM	Active	1	Mouse	Survival Su

STEP 2

If they are not listed in the Standard Library, **you can either create procedures and substances prior to starting your protocol record or create them later from within the protocol.** Please see "How to Create Procedures and Substances" for guidance.

Creating a Protocol

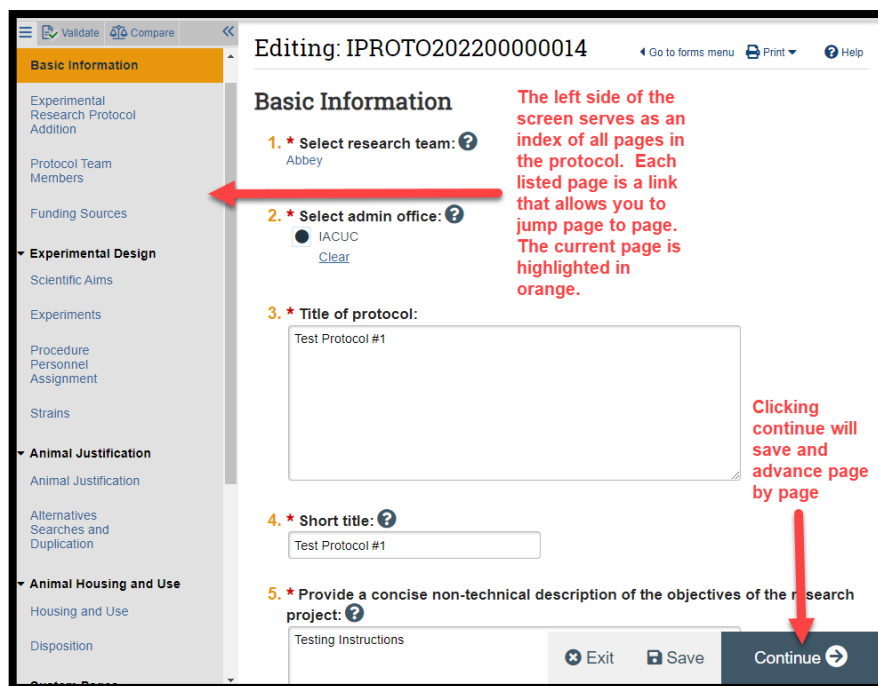
1. While you can start a protocol from the “Submissions” tab, we recommend first selecting your new Research Team.
2. Click “Create Protocol”



3. Fill in the applicable boxes and answer the questions on the protocol smartforms.

Note: New UVMClick protocols will have a new numbering scheme. Example: “IPROTO202200001”

****Tip**** After completing the Basic Information smartform page, hit Save and take a few minutes to peruse the other eform pages (via the index on the left) before completing the remaining questions. This will give you a sense of where it is most appropriate to enter information about your work in order to avoid redundancies.



Targeted Smartform Guidance

- Click **Continue** to move to the next form.

****Tip**** A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, click the SAVE button. You must return and answer it before you can submit the protocol for review.

- When you reach the final page, click **Finish** to exit the protocol.

You can continue to edit the protocol until you submit it for review.

Important! The protocol has not yet been submitted for review. For instructions, see [Submitting the Protocol for Review](#) below.

Entering the Protocol, Page by Page

Helpful hints:

When looking for a name/species/room in a text box:

For any field in which you want to enter a specific location, name, or species, there are two options. The easiest way is to start typing the last name, room number (not the building), or species in the text box and after just a second some options will appear below for you to choose from. You can also click the “...” to the right of the text box to open the search function in a new window.

- Basic Information page:**

The title and the short title MUST be the same. UVMClick will use the short title to list your protocol in the system.

- Experimental Research Protocol Addition page:**

Indicating “Breeding” here will open a breeding page later in the protocol.

- Protocol Team Members page:**

One person on the roster must have the assigned role of “Animal Emergency Contact”.

The PI must be listed on the roster.

People on the roster may be assigned to more than one role.

At the bottom of the Protocol Team Members page, question #2 allows for external members to be added to the protocol. External members are individuals that are not affiliated with UVM. This section requires a completed and signed visitor waiver to be uploaded. Please contact RPO at IACUC@uvm.edu for a waiver form.

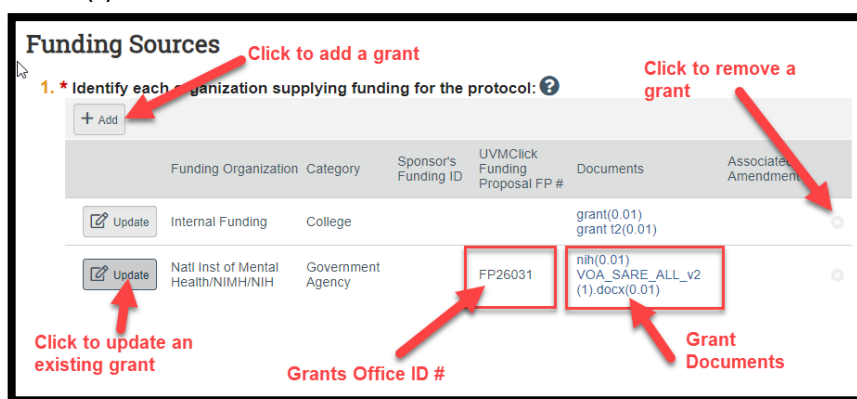


4. Funding Sources page:

Please be sure to include the grant document(s) that include the vertebrate animals section as an upload in this section.

Please include the Grants Office ID Number (starts with “FP”) so the RPO Analyst can link the grant to the protocol. Internal Funding will not have a Grants Office ID Number.

Departmental funds/funds from UVM should be entered as “internal funding”. An entry of “Internal Funding” will prompt you to enter the name(s) of scientific merit reviewers to provide the IACUC assurance that the proposed work has been reviewed based on scientific merit. Either the PI or the RPO Analyst can assign the scientific merit review to the named reviewer(s).



5. Scientific Aims page:

Ensure that this section is brief, it should just include just a few sentences.

6. Experiments page:

For each experiment, the description (question #5) should be well detailed and must clearly narrate how all of the procedures included come together in the timeline of the experiment. Procedures should be added to question #4 and must be inclusive of all work done on the animals, including surgery, behavior, substance administration, tissue/blood collection, euthanasia, etc. See separate instructions for “creating Substances and Procedures.”

Helpful tips:

- You can group substances together by route of administration into one Substance Administration Procedure. For example, create a substance administration for “IP Injections for Acute Bladder Surgery” and pull in all substances you will be giving IP in that particular experiment. It is helpful to clearly name this type of group administration procedure in a way that you can recognize it in your library and distinguish it from any other IP administration procedures that may contain drugs that do not apply to this particular experiment.
- If you are using a drug in a procedure (such as euthanasia or anesthesia) you must also create a substance administration for that drug.
- Breeding experiments should be pain level B only.
- Experiments for Mouse pups only should be pain level C as unused pups may undergo euthanasia.
- If you are adding a new experiment that is similar to an existing experiment, you can use the “copy” button to the right of the experiment name. This will make an exact copy of the first experiment and you can make changes to the copy.

To do so, click the Experiment name:

Experiments ?

Click experiment name to open it and view details

This copy function will make a second copy of the experiment. This will save you time if you are creating another experiment that is very similar to the current one.

1. * Define the experiments to be used in this protocol: **REMEMBER TO CLICK SAVE ABOVE AFTER YOU HAVE ADDED A NEW EXPERIMENT**

Name	Species	USDA	Count	Count by Pain Category	Procedures
1 mouse experiment	Mouse	no	25	B: 0 C: 5 D: 20 E: 0	<ul style="list-style-type: none"> Laparotomy (Standard - Survival Surgery) food fluid restriction (Team - Food or Fluid Restriction) Isoflurane Anesthesia (Team - Substance Administration) CO2 Euthanasia 7-3-22 (Team - Euthanasia)
name	Pig Biomedical	yes	200	B: 100 C: 50 D: 0 E: 50	<ul style="list-style-type: none"> procedure (Team - Imaging)

Clicking procedures will open them in a separate window

A new window will open with the experiment Information:

Edit Experiment

Editing: IPROT

Experiments &

1. * Define the exper

2. * If the experimen

1. If there is a specific order in which experiments will be completed, identify the sequence number below: **Numbering experiments will put them in a certain order on the experiments page. This is OPTIONAL**

2. * Experiment Name: mouse experiment

3. * Species: ? Mouse

4. Select all the procedures that will be performed in this experimental group: ?

Name	Type	Version	Scope
CO2 Euthanasia 7-3-22	Euthanasia	1	Team
food fluid restriction	Food or Fluid Restriction	1	Team
Isoflurane Anesthesia	Substance Administration	1	Team
Laparotomy	Survival Surgery	1	Standard

5. * Describe the experiment: (This narrative should convey a clear sense of what will actually happen to the animals and a timeline of when each attached procedure will be performed. An upload space is provided at the bottom of the page if needed)

Demd for software update

Team= Created by your Team
Standard= Created by RPO/ACUC

The bottom of the Experiments page:

8. * Total number of animals required in this experiment: (including all the animals to be produced)

25

9. For USDA-covered animals, indicate the actual pain category. For non USDA-covered animals, indicate the highest pain category:

B: 0

C: 5

D: 20

E: 0

Animals should be added by pain category. The number in question 8 should equal the total in question 9

10. Supporting documents: (include relevant timelines) ?

7. Strains page:

Phenotype characteristics and ordering information should be completed as this is helpful to OACM.

8. Animal Justification page:

Section #1 automatically updates- these numbers should never be changed manually.

Species	USDA Covered Species	Pain Category	Animals Identified in Experiments	Adjusted Animal Count
Mouse	no	Pain Category B	0	0
Mouse	no	Pain Category C	200	200
Mouse	no	Pain Category D	50	50
Mouse	no	Pain Category E	0	0

Question 7 at the very bottom of the page is a required upload. You will need to create a table that clearly shows animal groups and numbers to help clarify this section for reviewers.

9. Alternatives and Duplication Searches page:

This search is required for protocols with a designated USDA pain level D or E only. Level B and C can skip this page.

NOTE: All USDA covered species are required to search AT LEAST two databases on this page.

10. Breeding page:

Only included if you indicated breeding on the protocol.

If you indicate that animals will be used on any other protocols (question #5), please be sure to include the protocol number on the Protocols/Registrations page (see #13 below).

11. Housing and Use page:

Add all non-vivarium rooms that animals will enter.

List all procedures that will take place within each room. Please be specific as semiannual inspections are based on your responses (some procedures do not require regular inspections).

If you use controlled substances, please ensure the location of your lock box is correct.

12. Disposition page:

Please select all boxes that apply (some animals may be transferred to another protocol).

13. Departures and Exceptions from Animal Welfare Standards page:

Enter all departure types. If you are unsure whether your protocol includes departures, please contact your IACUC Analyst for help.

Provide clear justification for the departure.

* Departure Type:

- Analgesic / Pain Management
- Aseptic Technique
- Euthanasia
- Floor Space
- Housing Density
- Prolonged Physical Restraint
- Social Housing
- Use of Non-Pharmaceutical-Grade Chemicals / Drugs
- Weaning
- Other
- Environmental Enrichment

14. Protocols/Registrations page:

Add any IRB, IBC, or IACUC protocols/registrations that are related to this study. Be sure to include any protocols that animals will be transferred to.

15. Additional Information:

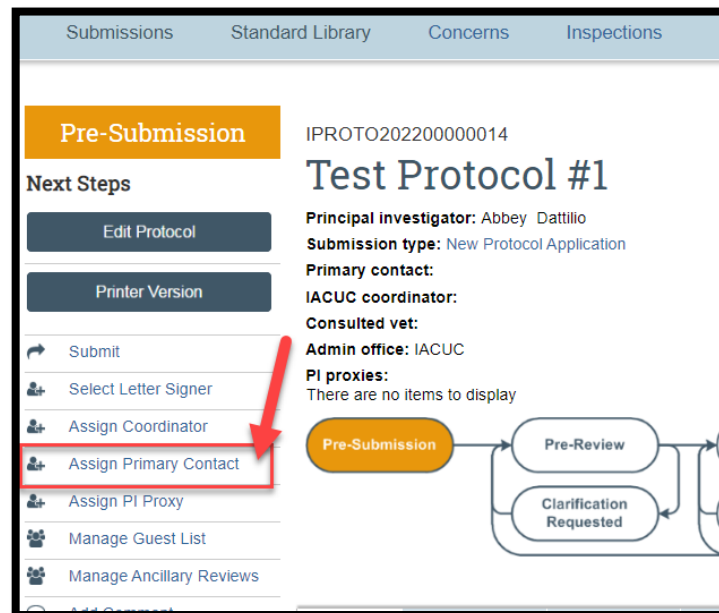
Death is considered an endpoint when death without the assistance of euthanasia is an expected/measured data point. If the planned outcome of the experiment is euthanasia, the answer is “no”. If animals are expected to die without the option of intervention of euthanasia, the answer is “yes”.

16. Supporting Documents page:

Add any related documents that should be included or reviewed with your submission, such as SOPs, product inserts, drug information.

****Tip**** When you create a protocol, if you are not the PI, you may wish to assign yourself as the primary contact who receives all communications from the IACUC on behalf of the protocol team. (The principal investigator you specified also receives the communications.)

You must do this outside of the protocol smartform with the activity on the left called “Assign Primary Contact”.

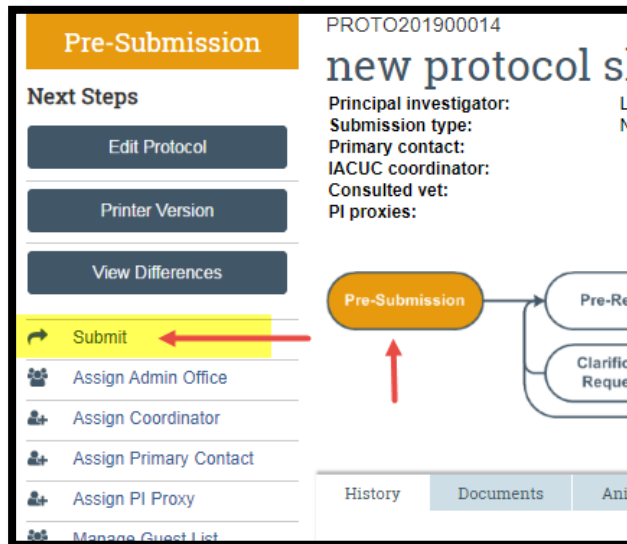


Submitting the Protocol for Review

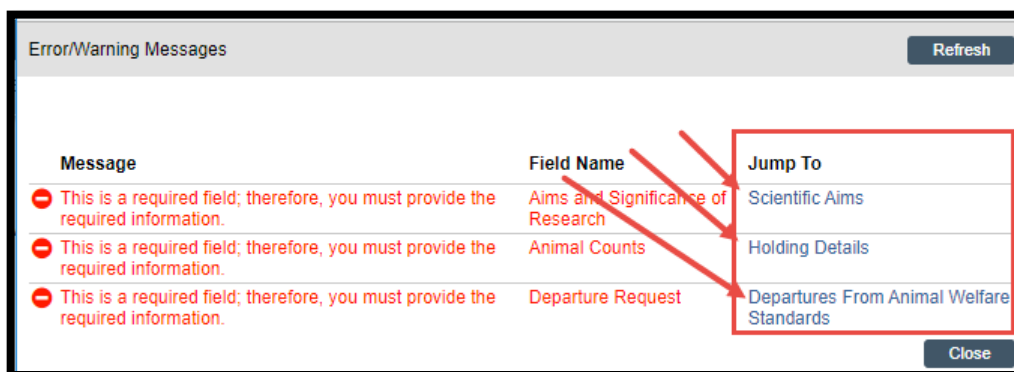
After reaching the final page of a new protocol and clicking “Finish” to exit the protocol, the status of the protocol will still display as “Pre-Submission” and will remain visible in your “Dashboard” until submitted to the IACUC Office for processing.

****Tip**** Prior to submitting the protocol to the IACUC Office, the PI may choose to add a Proxy. Any named Proxy has the authority to edit and submit on behalf of the PI. For more details regarding Proxy assignments, please reference the User Guide called “How to Assign a Proxy”.

To submit a finished protocol to the IACUC Office for their review and processing, Click the activity on the left that says “Submit”.



If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop-up to “Jump To” those particular screens quickly and enter the missing data.



NOTE: These Errors/Warning Messages only appear if required field entry was missed.

When clicking the **Submit** activity, once all required field entry is complete, certification text will appear. Read the text and click **OK**.

NOTE: The Comments and Supporting Documents are optional.

As the principal investigator, I certify that:

I have provided an accurate description of the proposed animal use in this protocol document. If the procedures concerning animal use in this project are to be changed, I will obtain approval from the IACUC before the changes are implemented. I understand that failure to do this may place both me and the University in violation of federal regulations and the Animal Welfare Act.

In addition to the above, I agree to the following conditions;

- Correct procedures for animal handling and restraint, administration of anesthetics and analgesics, and AVMA recommended methods of euthanasia are used in this project.
- All experiments involving live animals will be performed only by the qualified individuals indicated in the personnel roster.
- Personnel involved in this project have been or will be adequately trained prior to any animal work and will be given the opportunity to participate in the University's Occupational Health Program for individuals working with animals in research or teaching.
- Veterinary care is provided promptly to any animals showing unanticipated signs of pain or distress.
- I will make animal tissue available for sharing, or use tissues shared from other protocols whenever possible.

I agree to abide by the U.S. Public Health Service Policy, the Animal Welfare Act and University policies concerning the use of animals. As required by Federal regulations, I confirm that the activities described herein do not unnecessarily duplicate previous experiments, and that the animal models proposed are the most appropriate for achieving the objectives of this project.

All personnel will be informed that any concerns about the humane care and treatment of animals or unlawful acts involving animals must be reported to the IACUC Chair, the University Veterinarian, the Research Protections Office, or to the Institutional Official using the EthicsPoint™ website. Any individual reporting such concerns cannot be discriminated against or subjected to any reprisal.

As the proxy assigned by the PI to submit materials for this study, I assure the Research Protections Office that the information that I have provided is correct, and if applicable, is congruent with the grant.

1. Comments: ?

2. Supporting documents: ?

+ Add

Document Name	Date Modified
There are no items to display	

The status of the protocol is no longer "Pre-Submission". It has changed to "Pre-Review" indicating it is in the hands of the IACUC Office for processing.

You will also note that the protocol is now in View Mode and no longer in Edit mode.

Pre-Review

PROTO201900004

Demo 8/23/19

Next Steps

View Protocol

Printer Version

View Differences

Submit Pre-Review

Principal investigator: Jamie Abaied

Submission type: New Protocol Application

Primary contact: Abbey Dattilio

IACUC coordinator: Abbey Dattilio

Consulted vet:

PI proxies: Cassandra George

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graph LR
    A(Pre-Submission) --> B(Pre-Review)
    B --> C(Pre-Review)
    B --> D(Clarification Requested)
    D --> B
    
```

The protocol has now been submitted and removed from your "Dashboard". It now displays in the IACUC Office "Dashboard".