LSU Health NEW ORLEANS
School of Medicine

School of Medicine Research Cafe

Date March 10
Noon - 1:00 pm
CSRB 366

Preparing IACUC Applications

Learning Objectives:

- Describing the process for IACUC application submission and review.
- Ensuring compliance with animal research ethics and federal guidelines.
- Recognizing elements of a well-justified animal use

Join via Zoom

Paul Fidel, PhD
Chair of IACUC
School of Dentistry

Taylor Fuselier , PhD
Research Compliance
Analyst 2 IACUC/IBC

IACUC and Division of Animal Care (DOAC) Contacts :

- **IACUC Chairperson**
  - Paul Fidel, PhD
- **IACUC Compliance** **(Office of Research Services)**
  - Taylor Fuselier, PhD
  - Remi Landry, MPH, PhD
- **DOAC**
  - Adam Caro, CPIA, DVM, DACLAM (Director of DOAC)
  - Carol Baker, DVM, PhD (Clinical Veterinarian)

Overview of Presentation

1. Overview of Federal Guidelines for PHS-funded Animal Research Projects
   - Animal Welfare Act
   - PHS Policy
   - The Guide for the Care and Use of Laboratory Animals

2. How to Submit an IACUC Protocol
   - Submitting initial IACUC protocol and design considerations
   - Submitting IACUC amendments
   - Submitting *de novo* 3-year renewals

3. How to Manage IACUC Protocols Within Kuali
   - Using status updates, filters and "Manage Columns"

How was the Institutional Animal Care & Use Committee (IACUC) established?

Federal Regulations

Animal Welfare Act (Amended 1985)

National Institute of Health (NIH)

- Office of Laboratory Animal Welfare (OLAW)
  - Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy)
  - The Guide for the Care and Use of Laboratory Animals (the *Guide*)
    - "…*assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate.*"
    - Contains guidelines for animal care and use program, environmental, housing and management to animal facility design

The PHS Policy and the IACUC

The IACUC shall perform the following duties:

1. Review concerns involving the care and use of animals at the institution
2. Review and approve, require modifications to secure approval (MRSA), or withhold approval of animal activities according to Sections IV.C. of the Policy
3. Review and approve, require modifications to secure approval (MRSA), or withhold approval of significant changes (amendments) to animal activities
4. Authorized to suspend an activity involving animals according to Sections IV.C.6 of the Policy
5. Review the institution's program for humane care and use of animals via the Guide at least once per 6-month interval.
6. Inspect the institution's animal facilities via the Guide at least once per 6-month interval.
7. Prepare reports of IACUC evaluations and submit reports to the Institutional Official (IO) (VCAA here at LSUHSC-NO, Dr. Porche)
8. Make recommendations to the Institutional Official (IO) on any aspects of the institution's animal program, facilities, or personnel training

The PHS Policy and the IACUC

PHS supported projects require the IACUC to review the following from researchers' IACUC protocols:

1. Procedures with animals should avoid or minimize discomfort, distress, and pain to animal given sound research design
   a. Procedures should be performed with appropriate sedation, analgesia or anesthesia
      i. If animals cannot be provided with pain management, justification **must be** provided by researcher
      ii. Animals that experience severe or chronic pain/distress not able to be relieved **must be** painlessly euthanized at end of procedure or when morbidity criteria are met
2. Appropriate housing conditions for animals (housing, feeding, non-medical care directed by vets).
3. Personnel listed on IACUC protocol have appropriate trainings
4. Methods of euthanasia are consistent with American Veterinary Medical Association (AVMA).

The PHS Policy, the IACUC, and Your Protocols

PHS supporte IACUC protocols:

1. Identificatic r numbers.
2. Description
   1. Assuran esthetics and trai
3. Euthanasia

These pecies add th the

- unnecessary duplication of experiments
- nonstandard housing and husbandry requirements
- impact of the proposed procedures on the animals' well-being
- appropriate sedation, analgesia, and anesthesia (indices of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, Anesthesia, Pain, and Surgery)
- conduct of surgical procedures, including multiple operative procedures
- postprocedural care and observation (e.g., inclusion of post-treatment or postsurgical animal assessment forms)
- description and rationale for anticipated or selected endpoints
- criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated
- method of euthanasia or disposition of animals, including planning for care of long-lived species after study completion
- adequacy of training and experience of personnel in the procedures used, and roles and responsibilities of the personnel involved
- use of hazardous materials and provision of a safe working environment.

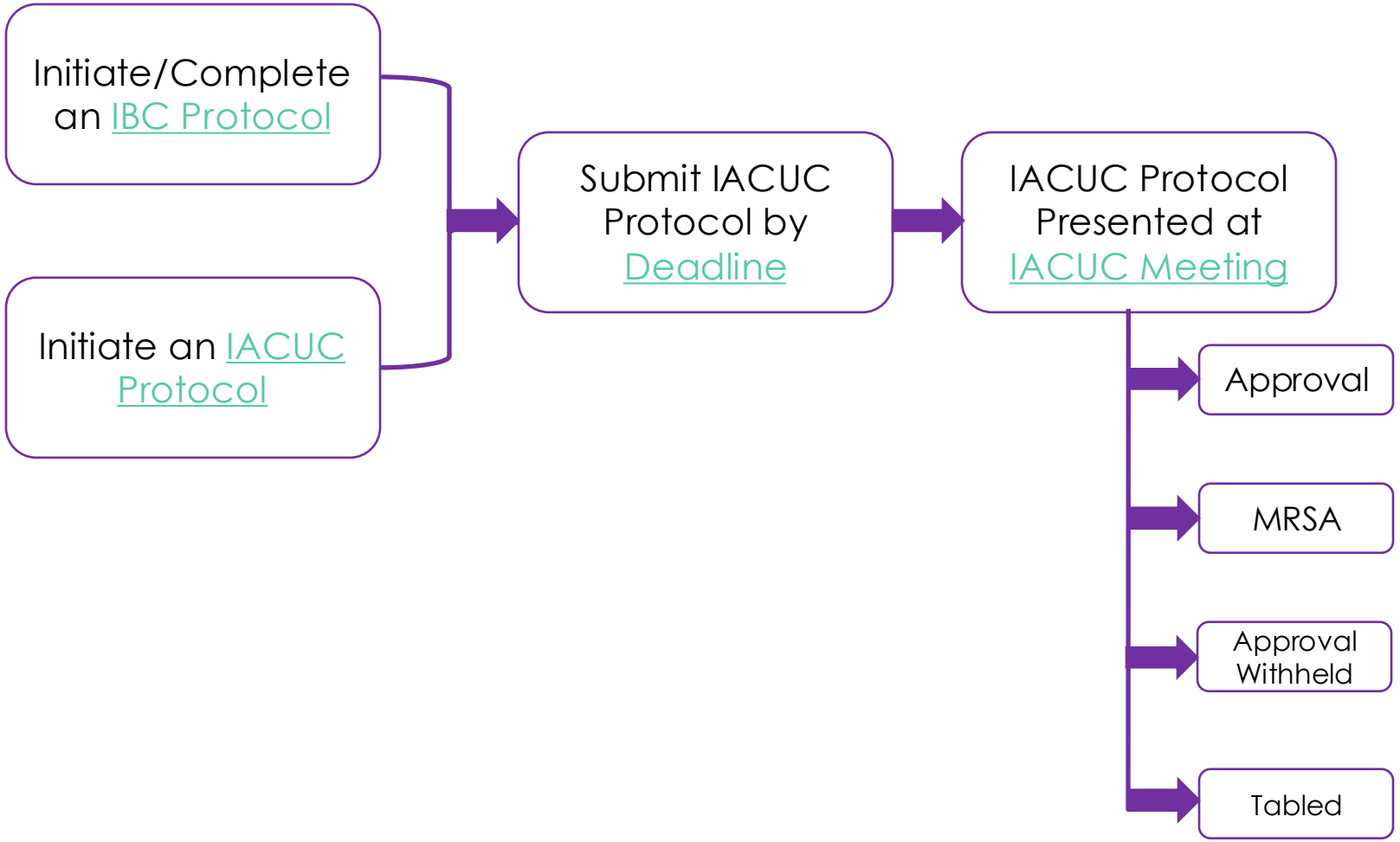
LSUHSC-NO's IACUC

Make-up of the IACUC

- 11 voting members
  - 7 scientists (who conduct vertebrate animal research)
    - 3-year appointments with option of another 3-year appointment (avg. 1-2 rotating off/year)
  - 2 veterinarians
  - 1 non-scientist
  - 1 non-affiliate (layperson)
- 2 office staff from the Office of Research Services
  - Taylor Fuselier, PhD
  - Remi Landry, MPH, PhD
- Monthly meetings held every 3rd Monday of the month
  - Quorum of >50% of voting members required
- Deadline for submissions last Monday of the month

LSUHSC-NO IACUC Policies and Procedures

The IACUC website contains our Policies and Procedures



Submitting An IACUC Protocol

Initiate/Complete an IBC Protocol

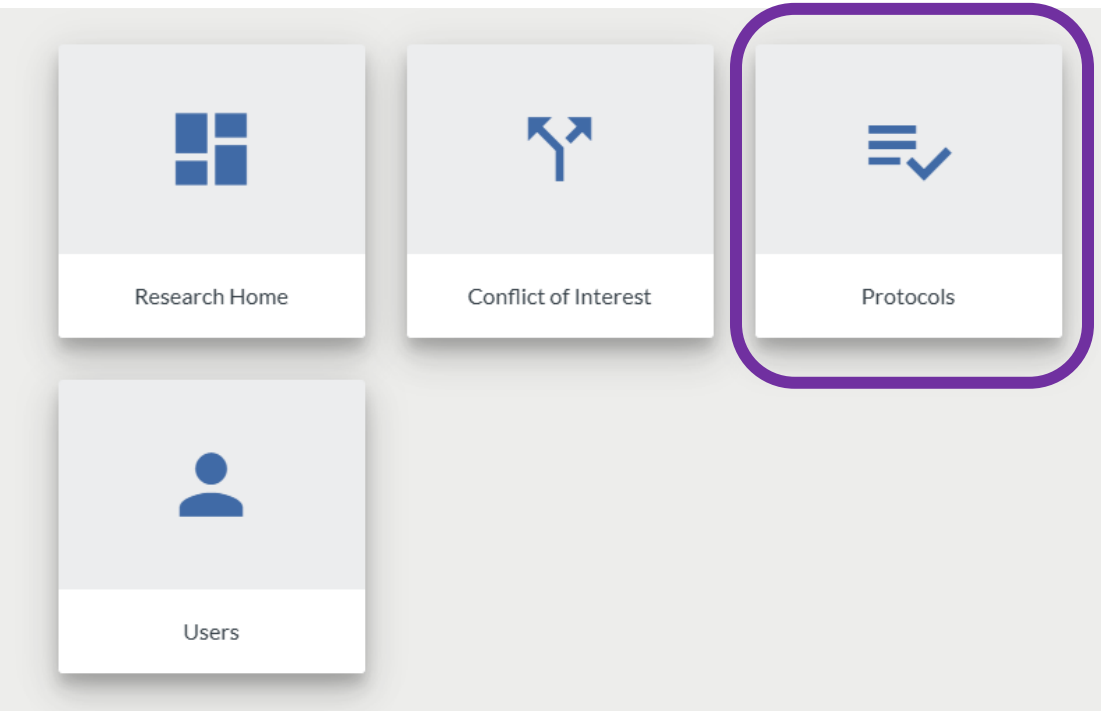
Researchers With an LSUHSC Email Account

kuali

Click to Login

Kuali Quickguides for Creating & Submitting

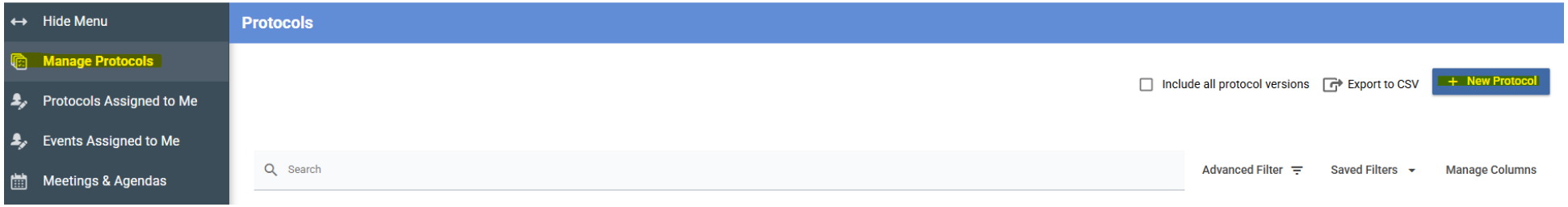
Initiate an IACUC Protocol

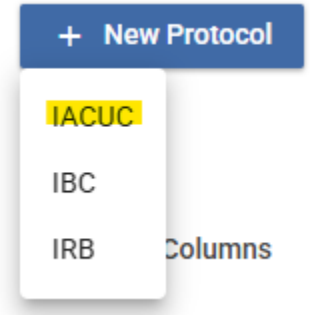


Submitting An IACUC Protocol

Initiate/Complete an IBC Protocol

Initiate an IACUC Protocol





IACUC - General Information

Cancel

Next

* 1A1. **Project Title:**

Type here

* 1A2. **Principal Investigator:**

Start typing the name of the individual and select from the drop down list.

* 1A3. **Department:**

Click on the down arrow and select the department.

* 1A4. **PI Office and Mobile Phone Numbers:**

Please provide a cell phone number to ensure DOAC staff can contact PI during all hours in case of emergency.

Click Here to Add Text

* 1A5. **Projected start date:**

1A6. **Estimated Duration of Project (months or years):**

Type here

1A7. **If desired, designate a person whom Animal Care staff should initially contact for animal welfare issues within the vivarium before contacting the PI:**

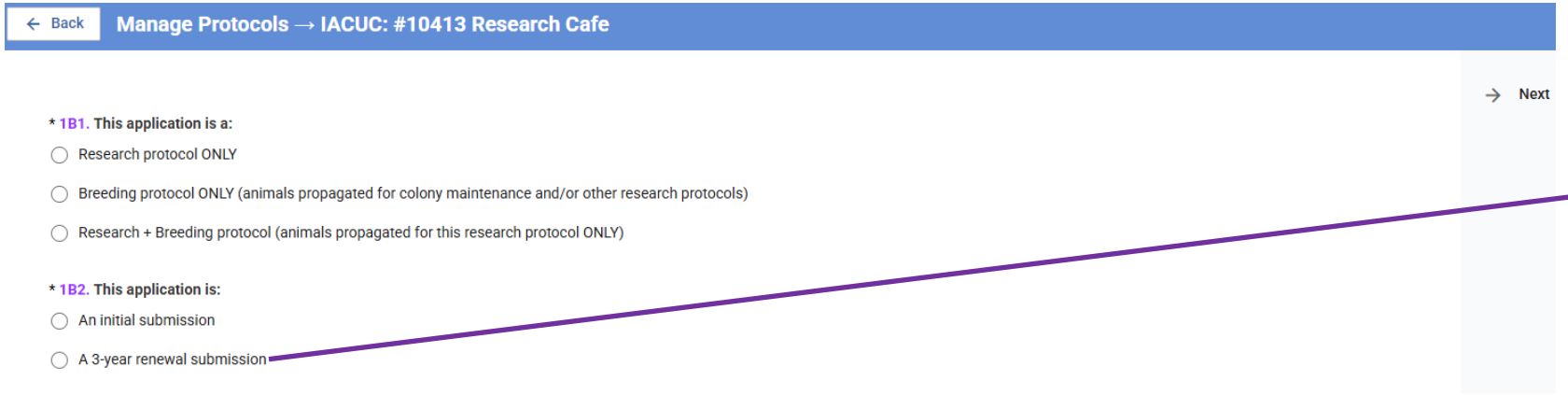
This person must be listed in the Project Personnel table below. ***Please provide both an office/lab and cell phone numbers for the selected person in Question 1A8.***

1A8. **If applicable, please provide the office/lab AND cell phone numbers for the Animal Care Contact Person listed in Question 1A7:**

A mobile (cell) number is needed in case of emergencies with research animals during non-work hours.

Click Here to Add Text

Submitting An IACUC Protocol



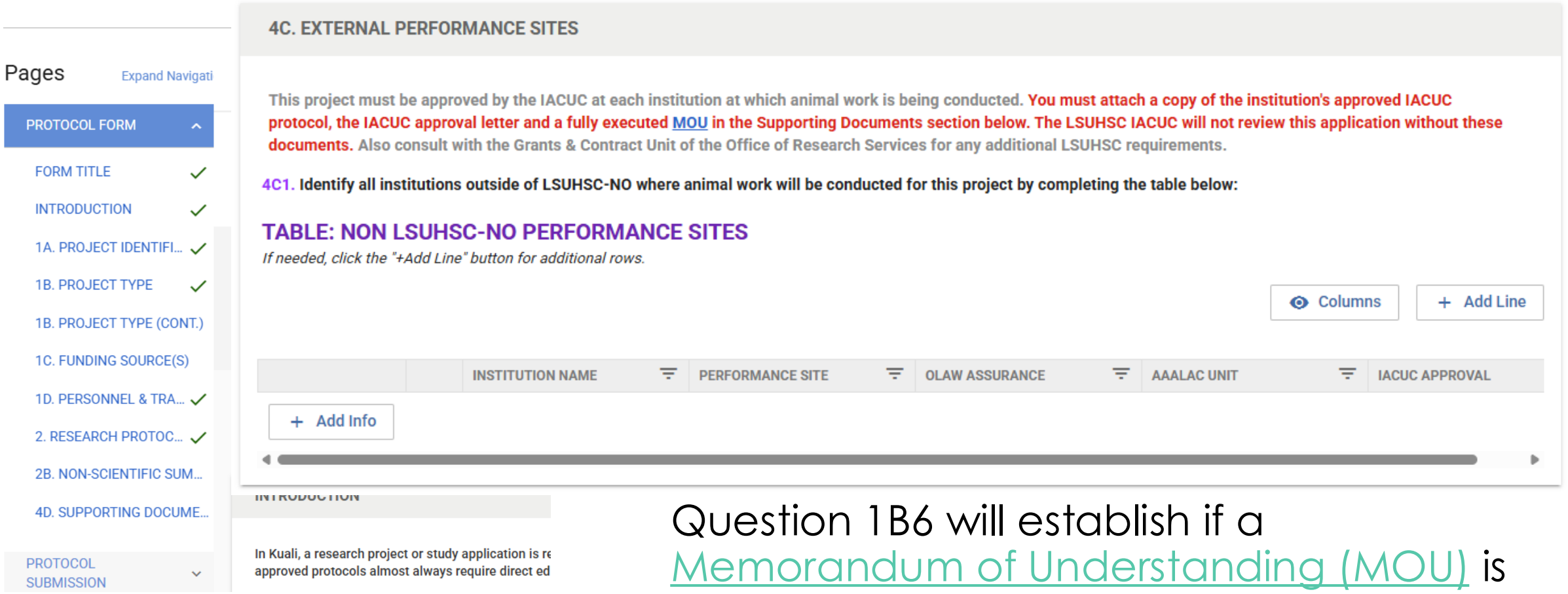
PHS Policy states at most, a protocol can be approved for 3-year interval, after, a *de novo* protocol review must occur.

LSUHSC-NO policy requires **annual continuing review** for USDA species

1B1. Three Considerations:

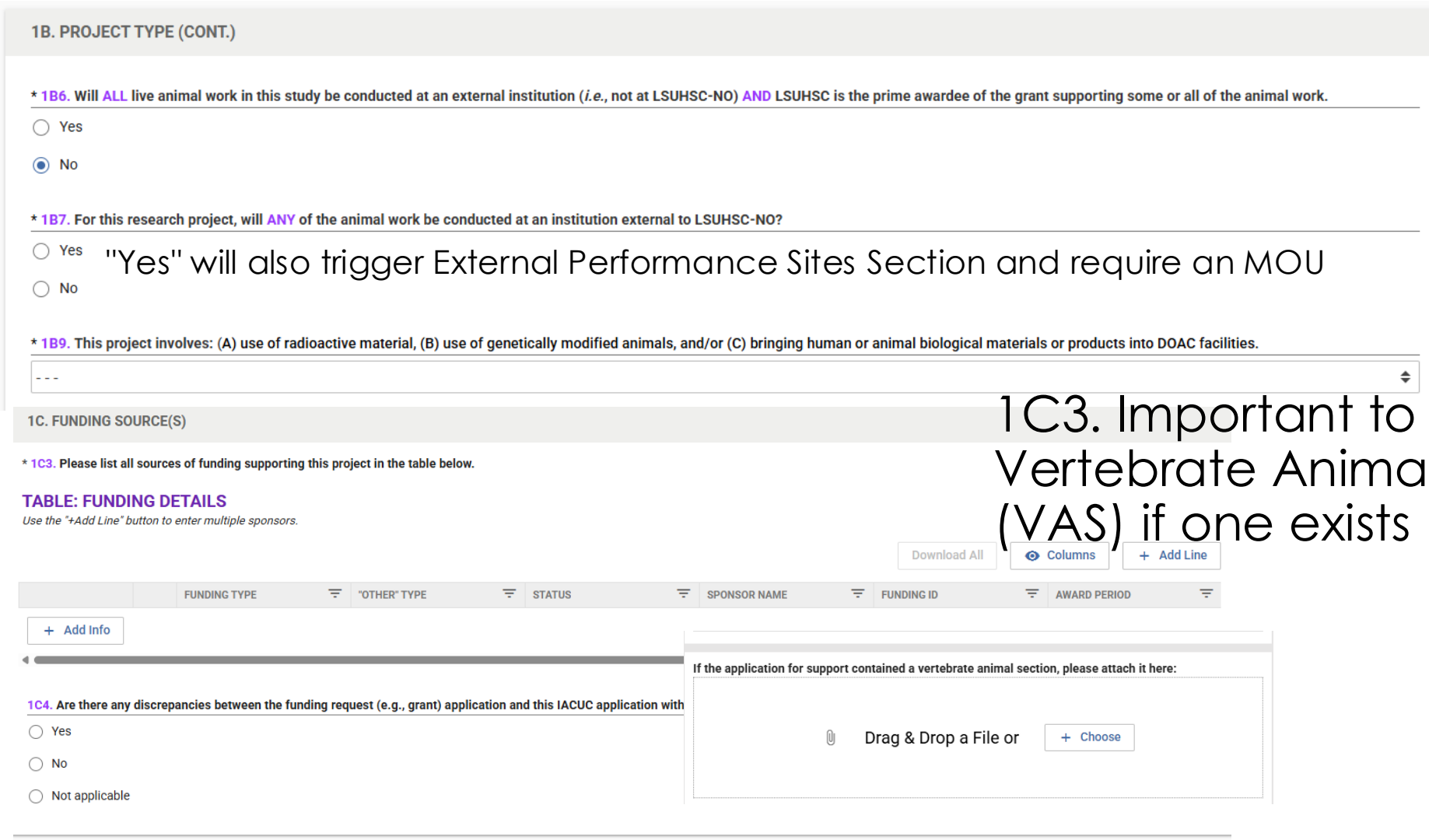
1. Research protocol ONLY
   - Choose this if you will strictly purchase* animals for your project
2. Breeding protocol ONLY
   - Choose this if you will strictly only breed animals for several "Research protocol ONLY"
   - *an approved Breeding protocol can supply a "Research protocol ONLY" application
3. Research + Breeding protocol
   - Choose this if one or more strains will need to be bred for this specific IACUC protocol.

Submitting An IACUC Protocol

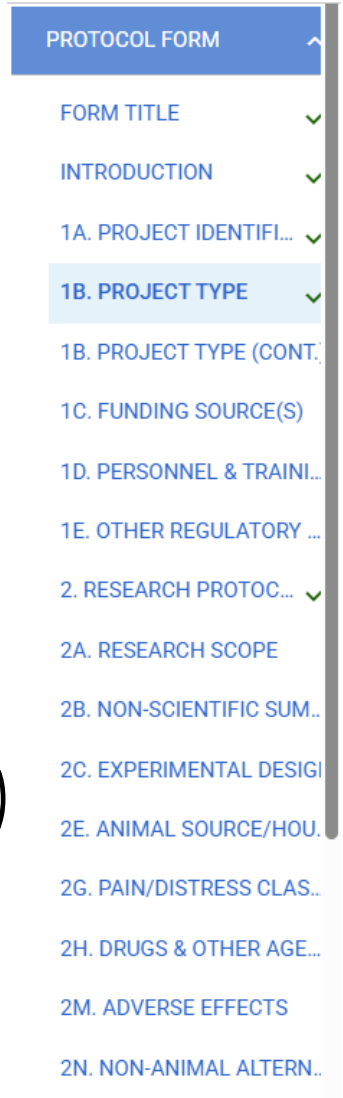


Question 1B6 will establish if a Memorandum of Understanding (MOU) is required between LSUHSC-NO and external institution (by selecting "Yes")

Submitting An IACUC Protocol

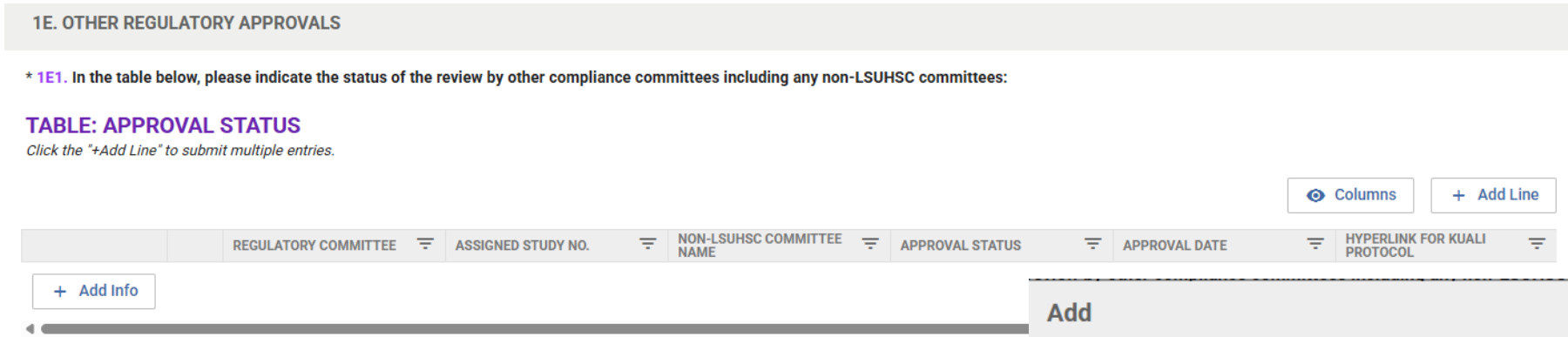


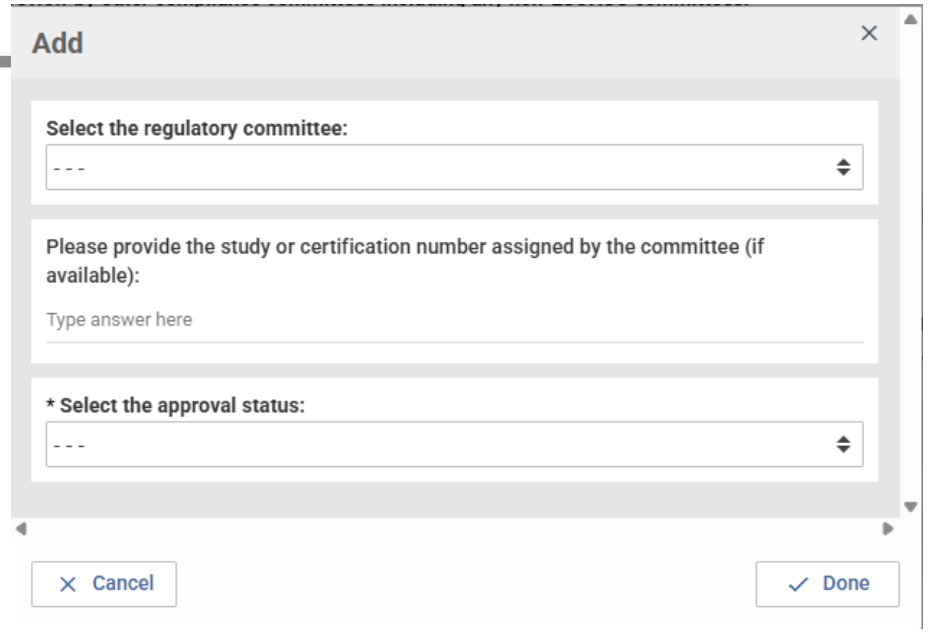
1C3. Important to upload Vertebrate Animal Section (VAS) if one exists (i.e., NIH)

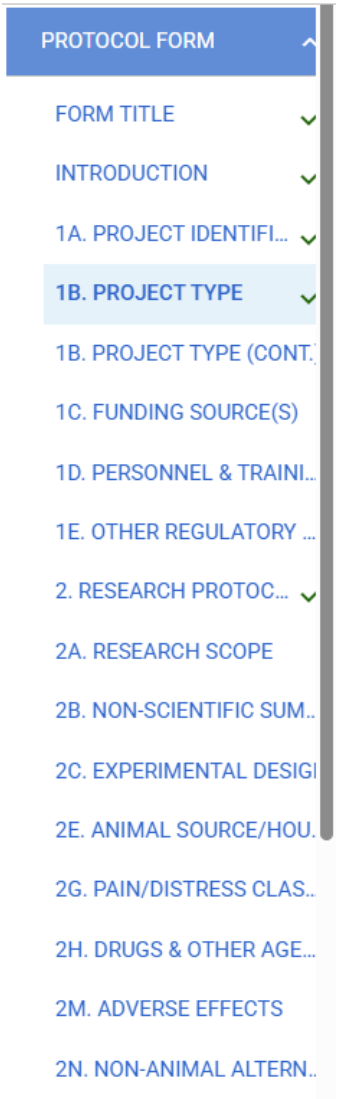


Initiate/Complete an IBC Protocol

Submitting An IACUC Protocol



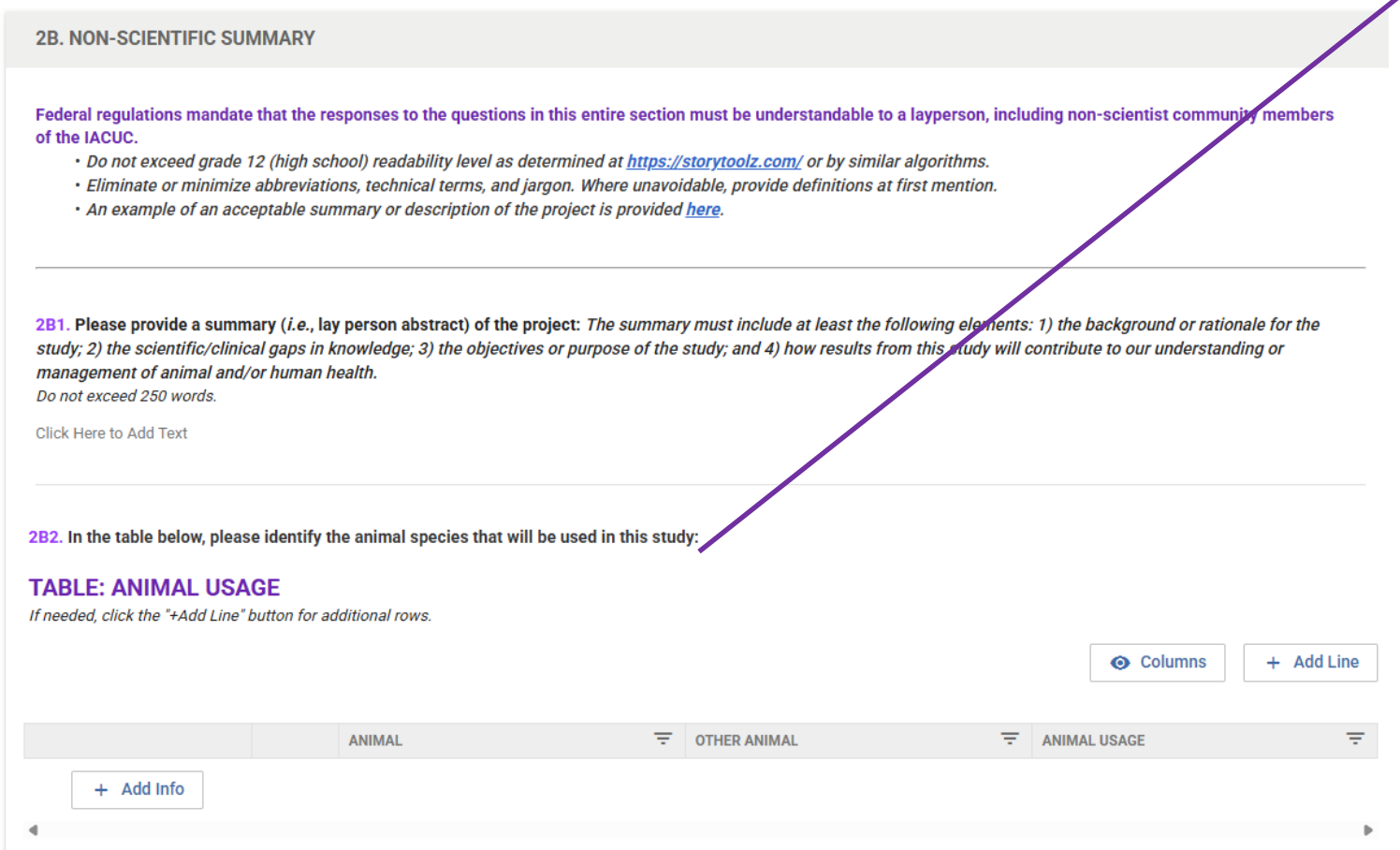




It is LSUHSC-NO policy to have an approved IBC protocol for IACUC approval. ***However, not having an approved IBC <u>does not</u> prevent*** *you from submitting an IACUC protocol to be reviewed.*

Submitting An IACUC Protocol

Highly Suggested to "Skip" to Section 2B. Non-Scientific Summary
Reasoning: You know your project! Describe it as if to a layperson!



2B. NON-SCIENTIFIC SUMMARY

Federal regulations mandate that the responses to the questions in this entire section must be understandable to a layperson, including non-scientist community members of the IACUC.

- *Do not exceed grade 12 (high school) readability level as determined at https://storytoolz.com/ or by similar algorithms.*
- *Eliminate or minimize abbreviations, technical terms, and jargon. Where unavoidable, provide definitions at first mention.*
- *An example of an acceptable summary or description of the project is provided here.*

2B1. **Please provide a summary (*i.e.*, lay person abstract) of the project:** *The summary must include at least the following elements: 1) the background or rationale for the study; 2) the scientific/clinical gaps in knowledge; 3) the objectives or purpose of the study; and 4) how results from this study will contribute to our understanding or management of animal and/or human health.*
Do not exceed 250 words.

Click Here to Add Text

2B2. **In the table below, please identify the animal species that will be used in this study:**

TABLE: ANIMAL USAGE

If needed, click the "+Add Line" button for additional rows.

Columns | + Add Line

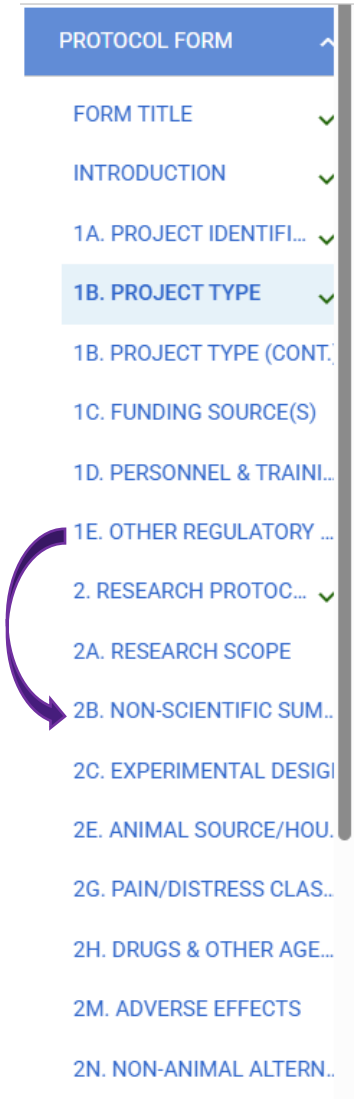
	ANIMAL	OTHER ANIMAL	ANIMAL USAGE

+ Add Info

2B2. Defines what species this protocol will utilize as succinct as possible.

"Animal Usage" Column

In 1-3 sentences, please describe how each type of animal will be used in this study (*i.e.*, which procedures/experiments to which these animals will be subjected):
Do not exceed 150 words.

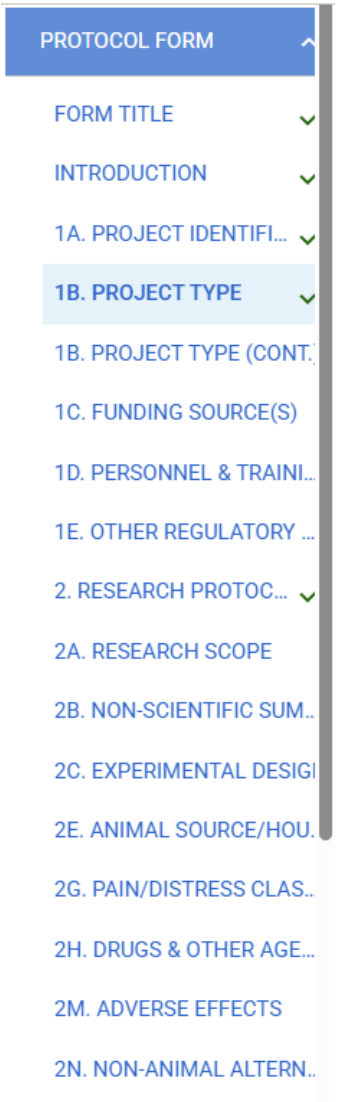


LSU Health NEW ORLEANS
INSTITUTIONAL ANIMAL CARE & USE COMMITTEE

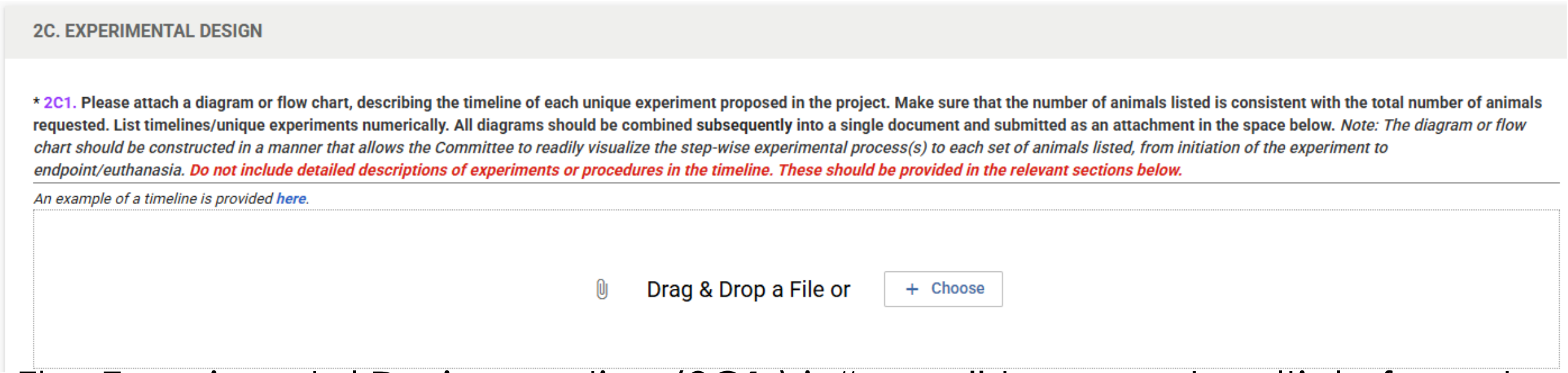
Submitting An IACUC Protocol

Experimental

- unnecessary duplication of experiments
- nonstandard housing and husbandry requirements
- impact of the proposed procedures on the animals' well-being
- appropriate sedation, analgesia, and anesthesia (indices of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, Anesthesia, Pain, and Surgery)
- conduct of surgical procedures, including multiple operative procedures
- postprocedural care and observation (e.g., inclusion of post-treatment or postsurgical animal assessment forms)
- description and rationale for anticipated or selected endpoints
- criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated
- method of euthanasia or disposition of animals, including planning for care of long-lived species after study completion
- adequacy of training and experience of personnel in the procedures used, and roles and responsibilities of the personnel involved
- use of hazardous materials and provision of a safe working environment.



Submitting An IACUC Protocol



The Experimental Design section (2C1.) is "open" to accept multiple formats (i.e. PDF, JPEG, etc.), but constraints do exist for this section!

1. Make this section as visual as possible to represent your project (i.e. flowchart, hierarchical branching, timelines, groups/number of animals, etc.)
2. Use concise experimental identification ("Experiment Number 1, Experiment Number 2, etc.) that will ***need to be congruent*** *with* subsequent sections below (Sections 2C2-table and 2C4-narrative)
3. Include ***animal numbers (by sex) and strain*** per exp. number and include all treatments, procedures (surgical and non-surgical) and potential equipment needed (stereotaxic mount, behavioral equipment (i.e. running wheel, balance beam, mazes, etc.)

Submitting An IACUC Protocol

Example of a **great** Experimental Design Section from 2C1. to 2C4.

4. Examine how the Sulfs regulates macrophage phenotype in vitro.

Please note that in this experiment, alveolar and bone marrow derived macrophages (BMDMs) will be isolated from 8-12 weeks old mice, and then the rest of the experiment will be performed in vitro. There is no experimental manipulation in these mice, thus diagram or flowchart is not necessary.

Cohort 1: Macrophage-specific Sulf deletion Model

Group	Males	Females	# of mice
$Sulf1^{flox/flox}Sulf2^{flox/flox}$ (control)	10	10	20
$Cx3cr1\text{-}cre^{+/-}$ (control)	10	10	20
$Sulf1^{flox/flox}Sulf2^{flox/flox}Cx3cr1\text{-}cre^{+/-}$	10	10	20
Total number of mice			60

Cohort 2: Macrophage-specific hSULF2 OE Model

Group	Males	Females	# of mice
LoxP-STOP-LoxP (LSL)-hSULF2 (control)	10	10	20
$Cx3cr1\text{-}cre^{+/-}$ (control)	10	10	20
$LSL\text{-}hSULF2\text{-}Cx3cr1\text{-}cre^{+/-}$	10	10	20
Total number of mice			60

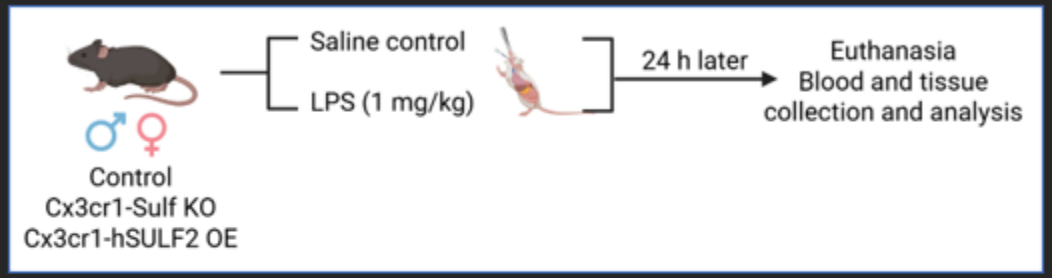
Brief description of experiment 4: Because the LysM-Sulf KO mice have defects in bone marrow hematopoiesis, Cx3cr1-cre (more specific for macrophages) will be used to induce Sulf deletion or hSULF2 overexpression. Both alveolar macrophages and bone marrow derived macrophages (BMDMs) will be isolated from control and mice with macrophage-specific deletion of Sulfs or macrophage-specific OE of hSULF2 at 8-12 weeks of age, and these cells will be analyzed *in vitro*.

LysM-hSULF2 OE mice (LSL-hSULF2-LysM-$cre^{+/-}$)	10 males 10 females	10 males 10 females	40
Total number of mice			120

Brief description of experiment 1: Mice at two different ages (8-12 weeks of age and 8-12 months of age) will be euthanized, cells from the bone marrow and the spleen will be isolated and their hematopoietic stem and progenitor cell populations will be analyzed by flow cytometry and RNA/protein analyses. An updated panel of antibodies compared to our published findings in Matrix Biology (2024 Dec;134:107-118) will be used to further dissect how myeloid deletion or overexpression of the Sulf will alter bone marrow hematopoiesis.

5. Examine how the Sulfs regulates macrophage phenotype in lung homeostasis and in LPS-induced lung injury and inflammation.

Experimental diagram:



Cohort 1: Macrophage-specific Sulf deletion Model

Group	Saline		LPS		# of mice
	Males	Females	Males	Females	
$Sulf1^{flox/flox}Sulf2^{flox/flox}$ (control)	5	5	10	10	30
$Cx3cr1\text{-}cre^{+/-}$ (control)	5	5	10	10	30
$Sulf1^{flox/flox}Sulf2^{flox/flox}Cx3cr1\text{-}cre^{+/-}$	5	5	10	10	30
Total number of mice					90

Cohort 2: Macrophage-specific hSULF2 OE Model

Group	Saline		LPS		# of mice
	Males	Females	Males	Females	
LSL-hSULF2 (control)	5	5	10	10	30
$Cx3cr1\text{-}cre^{+/-}$ (control)	5	5	10	10	30
$LSL\text{-}hSULF2\text{-}Cx3cr1\text{-}cre^{+/-}$	5	5	10	10	30
Total number of mice					90

Brief description of experiment 4: Control, macrophage-specific Sulf KO, and macrophage-specific hSULF2 overexpression mice at 8-12 weeks of age will be treated with saline (control) or LPS (1 mg/kg) via oropharyngeal aspiration. These mice will be euthanized 24 hours later followed by blood and tissue collection.

Submitting An IACUC Protocol

Example of a **great** Experimental Design Section from 2C1. to 2C4.

2C2. In the table below, indicate the distribution of animals requested throughout the study as a function of experimental group/variable. DO NOT INCLUDE BREEDERS IN THESE NUMBERS (USDA CATEGORY B ANIMALS).

Columns

		EXPERIMENT NUMBER	GROUP/VARIABLE	ANIMAL	OTHER ANIMAL	NUMBER OF ANIMALS
No Action Items		1	Control, Myeloid Sulf KO mice, and myeloid hSULF2 overexpression mice	Mouse		240

2C3. Based on the experiments listed in the previous table, calculate the total number of animals of each type to be used in this study DO NOT INCLUDE BREEDERS IN THESE NUMBERS (USDA CATEGORY B ANIMALS):

Columns

		ANIMAL	OTHER ANIMAL	TOTAL ANIMALS
No Action Items		Mouse		600

No Action Items		5	Control, macrophage-specific Sulf KO mice, and macrophage-specific hSULF2 overexpression mice	Mouse		180

Submitting An IACUC Protocol

Example of a **great** Experimental Design Section from 2C1. to 2C4.

2C4. Please provide a complete description of each unique experiment, or set of experiments, depicted in the flow chart/diagram (i.e., timeline). Start each narrative with the objective of the experiment and then describe the entire course of the experiment in chronological order. *Experimental descriptions should reference the experiments depicted in the timeline.*

Five main experiments will be performed in this study with myeloid-Sulf knockout mice (LysM-cre mediated deletion), myeloid-hSULF2 overexpression mice (LysM-cre mediated induction), macrophage-specific Sulf knockout mice (Cx3cr1-cre mediated deletion), and macrophage-specific hSULF2 overexpression mice (Cx3cr1-cre mediated induction).

1. Characterization of bone marrow and spleen hematopoietic stem and progenitor cell populations.
This experiment will tell us the role of the Sulfs in the production of myeloid lineage cells in the bone marrow and the possible compensation from the spleen. We hypothesize that LysM-cre mediated Sulf deletion or overexpression will alter the production of all myeloid lineage cells including granulocytes/monocytes, red blood cells and platelets. Cells from the bone marrow and the spleen will be isolated from both young (8-12 weeks of age) and older (8-12 months of age) mice with equal numbers of males and females (10 per group) after euthanasia. These cells will then be analyzed by flow cytometry using markers for different stem and progenitor cells to determine which step of hematopoiesis is altered. An updated panel of antibodies compared to our published report in Matrix Biology (2024 Dec:134:107-118) will be used to further dissect how myeloid deletion or overexpression of the Sulf will alter bone marrow hematopoiesis. In addition, blood will be collected at euthanasia and analyzed by a hematology analyzer, which will report numbers of white blood cells (lymphocytes, neutrophils, and monocytes), red blood cells and platelets in the peripheral blood.

2. Bone marrow transplantation.
This experiment will tell us whether bone marrow transplantation will be an effective therapy to correct bone marrow hematopoietic defects due to myeloid Sulf deletion. After euthanasia, bone marrow cells will be collected from wildtype or LysM-cre mediated hSULF2 overexpression mice (males at 2-3 months of age), which will then be transplanted into irradiated LysM-Sulf KO mice. For bone marrow cell isolation, one femur will be isolated and cleaned of soft tissue. Bone marrow cells will then be flushed out with PBS containing 2% BSA using a 10 ml syringe and 27-gauge needle. 1E+06 cells will be transplanted to the recipient mice via tail vein injection. Mice after bone marrow transplantation will be carefully observed (daily for the first week and weekly after). These mice will be euthanized at 3 months after bone marrow transplantation to allow sufficient time for the engraftment of the transplanted bone marrow cells and the production of new blood cells. Blood, bone marrow and spleen stem and progenitor cells will be analyzed as in experiment 1.

3. Role of male sex hormones in the development of bone marrow hematopoietic abnormality in the LysM-Sulf KO mice.
Male mice at 3 weeks of age will undergo bilateral orchiectomy and these mice will be examined 6 months later for changes in blood cell production as in experiment 1.

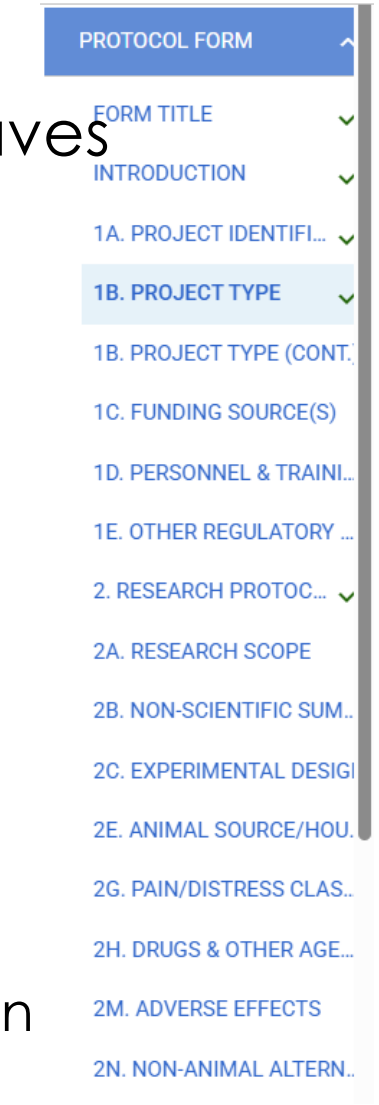
4. **Examine how the Sulfs regulate macrophage phenotype in vitro.**
In this experiment, alveolar macrophages and bone marrow derived macrophages (BMDMs) will be isolated from control, macrophage-specific Sulf KO, and macrophage-specific hSULF2 overexpression mice at 8-12 weeks of age, and these cells will be analyzed *in vitro*.

5. **Examine how the Sulfs regulate macrophage phenotype in lung homeostasis and in LPS-induced lung injury and inflammation.**
This experiment will tell us how Sulf expression in the macrophages regulate macrophage function at baseline and in LPS-induced lung injury and inflammation. Control, macrophage-specific Sulf KO, and macrophage-specific hSULF2 overexpression mice at 8-12 weeks of age will be treated with saline (control) or LPS (1 mg/kg) via oropharyngeal aspiration. These mice will be euthanized 24 hours later followed by blood and tissue collection.

Submitting An IACUC Protocol

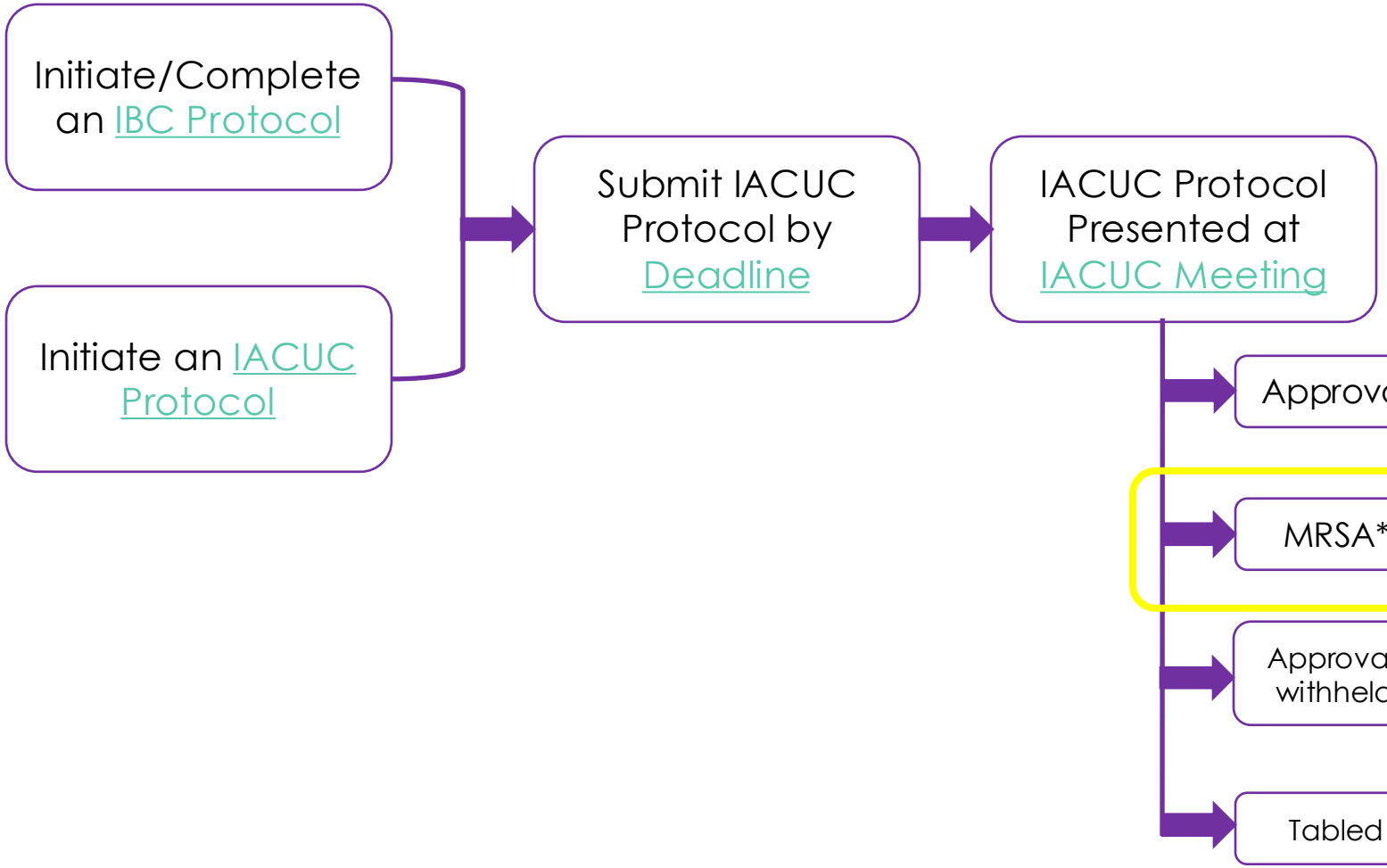
A **great** Experimental Design Section from 2C1. to 2C4. then paves the way for the rest of the protocol to be filled out.

1. List animal strains needed and numbers
   - This aids with maintaining those numbers in subsequent sections:
     - Section 2E. Animal Source/Housing (numbers per strain)
     - Section 2G. Pain/Distress Classification (numbers per strain)
2. List all procedures that will be performed
   - This aids with populating protocol with needed procedures in subsequent sections:
     - Section 2A. Research Scope (filling out if blood collections are needed, surgical/non-surgical procedure(s))
       - From Section 2A., all required sections will appear for completion
3. List all drugs and other agents that will be used
   - This aids with populating protocol with needed drugs/compounds in subsequent sections:
     - Section 2H. Drugs & Other Agents (this includes anesthetics, analgesics and tranquilizers as need in surgical section)



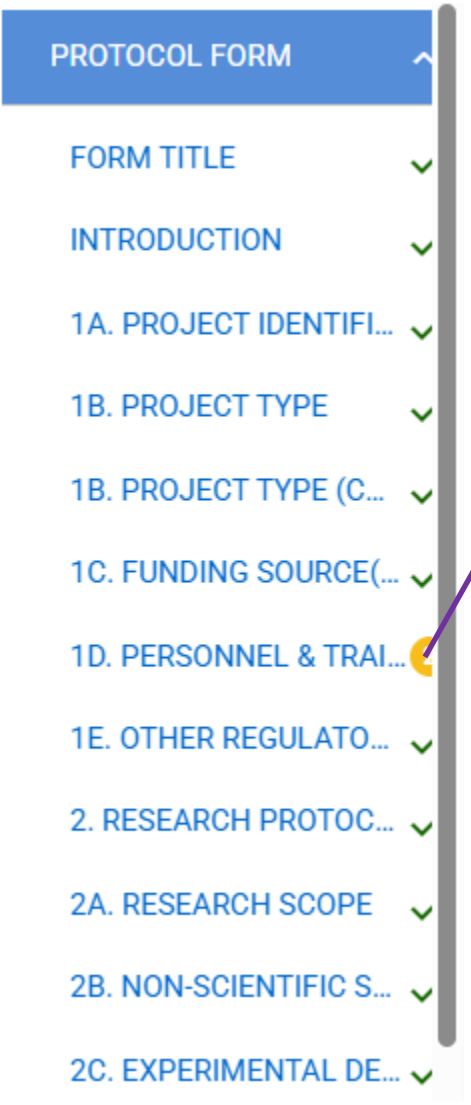
LSUHSC-NO IACUC Policies and Procedures

The IACUC website contains our Policies and Procedures

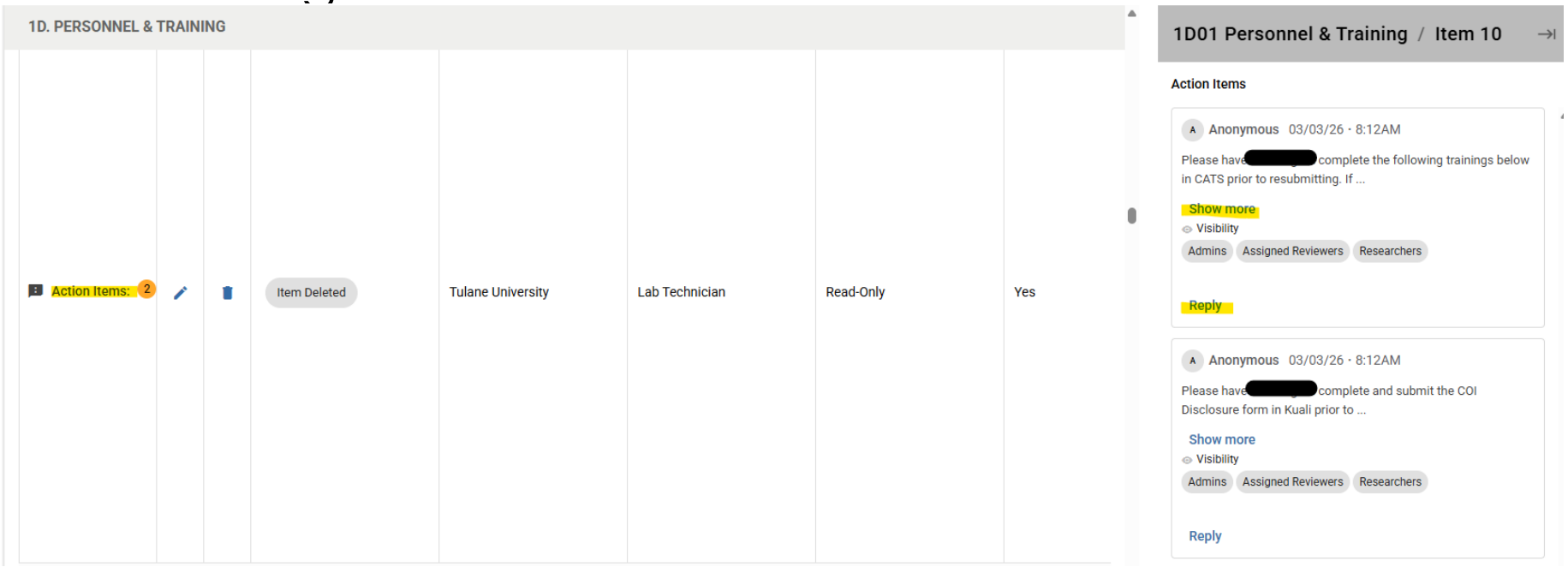


"Modifications to Secure an Approval"
*w/full committee review (FCR)

Submitting An IACUC Protocol



Action Item(s) placed throughout the protocol where a reviewer has made comments for a modification. Make modifications in the protocol and also 'reply' to the action item with a message of what was done.

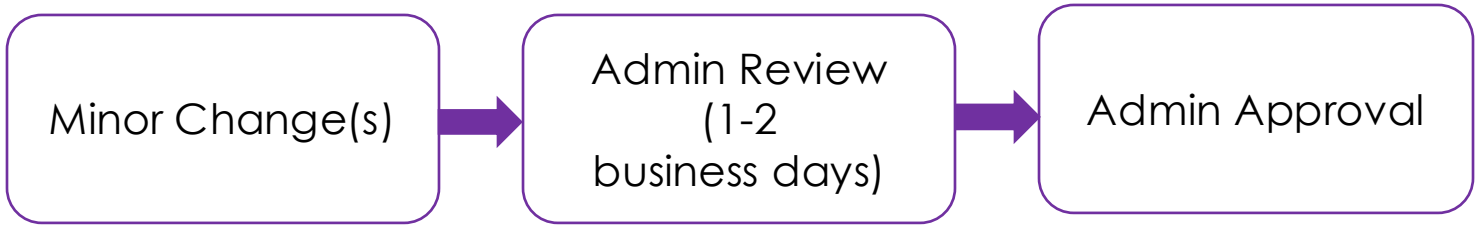


Submitting An IACUC Protocol

Additional sections that commonly delay approval:

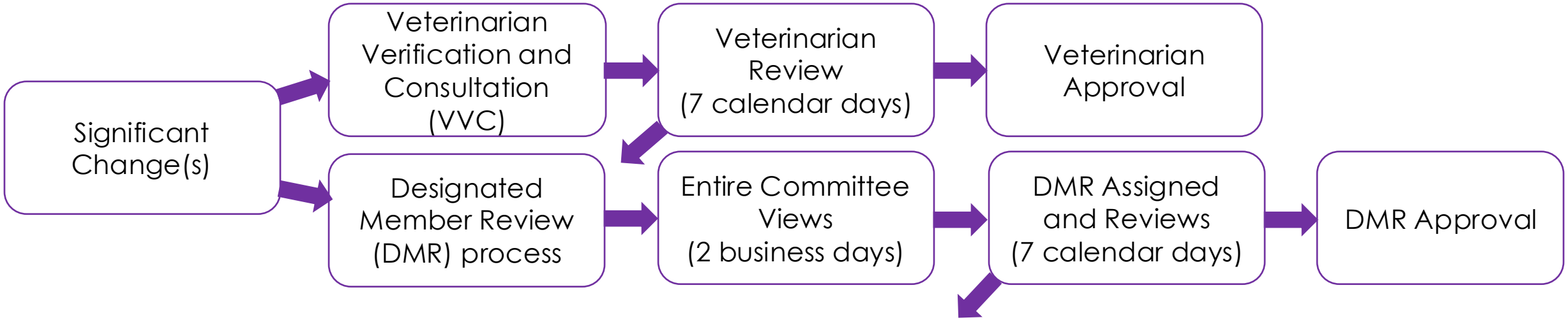
1. Required trainings are not completed for all personnel in Section 1D.(CATS, CITI and DOAC trainings)
2. 3 "R's" are not sufficiently described in Section 2N. Non-Animal Alternatives
    - The *Guide* lists a need to **reduce**, **refine** and **replace** the use of animals for research so that animal use is minimized
        - Reduce – steps taken to reduce number of animals to have the minimal amount required to obtain scientifically valid data as determined by power analysis or statistical rigor
        - Refine – how procedures producing pain and distress can be refined to reduce pain and distress on needed animals
        - Replace – justify why animals are needed to study your project
            1. Justifying why the chosen species is needed for your project
3. Not having an approved IBC protocol within scope of work of the IACUC in Section 1E. Other Regulatory Agencies
4. Animal numbers not congruent in Section 2C. Experimental Design with Section 2G. Pain and Distress Classification

Submitting An IACUC Amendment



- Change in Personnel
- Change in DOAC Animal Room
- Sub of strain of same species **without increasing animal number**
- Change in title with no change in experimental design*

Changes to previously approved anesthesia/drugs, euthanasia methods (per AVMA guidelines), or the duration, frequency, type, or number of approved animal procedures.



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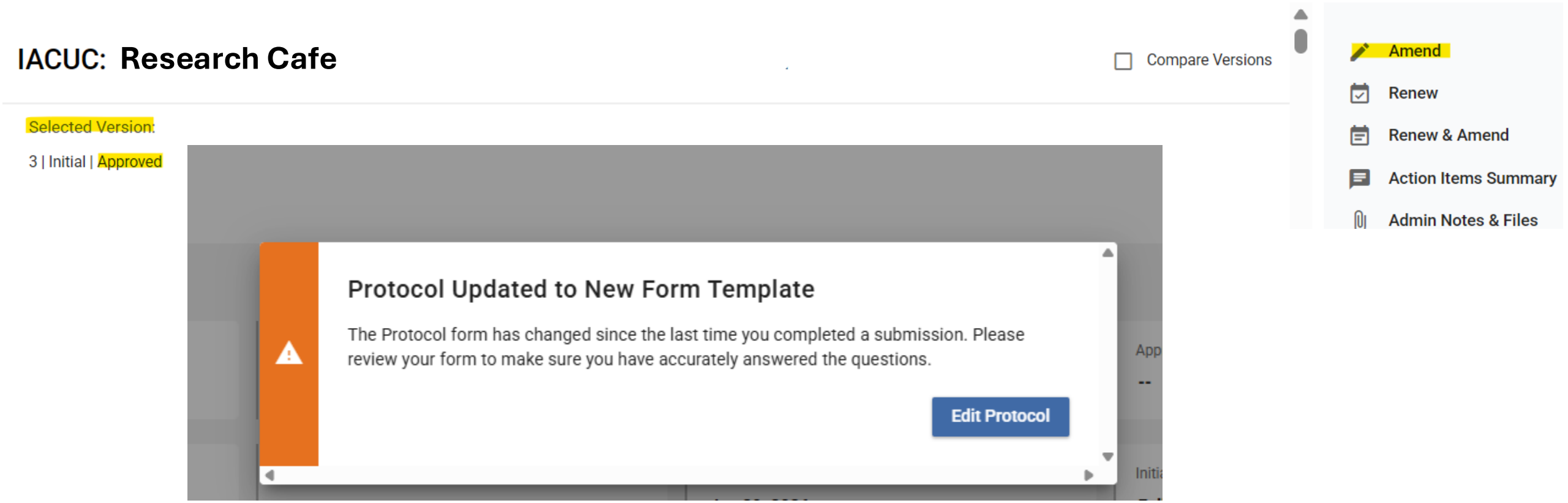


Submitting An IACUC Amendment

IACUC AMENDMENT FORM

Introduction & Instructions

All amendments to currently approved research must be approved by the IACUC prior to implementation, except when necessary to eliminate apparent immediate hazards to animals. More information is available at the IACUC website.

Please note the following:

- To request a modification to an approved study you must complete this AMENDMENT FORM **AND** edit the relevant sections of the currently approved PROTOCOL FORM that follows the AMENDMENT FORM.
- If you accessed this form by clicking on the ***Amend*** button but intend to simultaneously request annual renewal, then click the ***Abandon*** button to terminate this application. Start a new application by selecting ***Renew & Amend*** which will give you access to both the RENEWAL and AMENDMENT forms.
- Additional instructions for creating and submitting IACUC applications including ***Amendments*** are available in this document.

A. Amendment Questionnaire

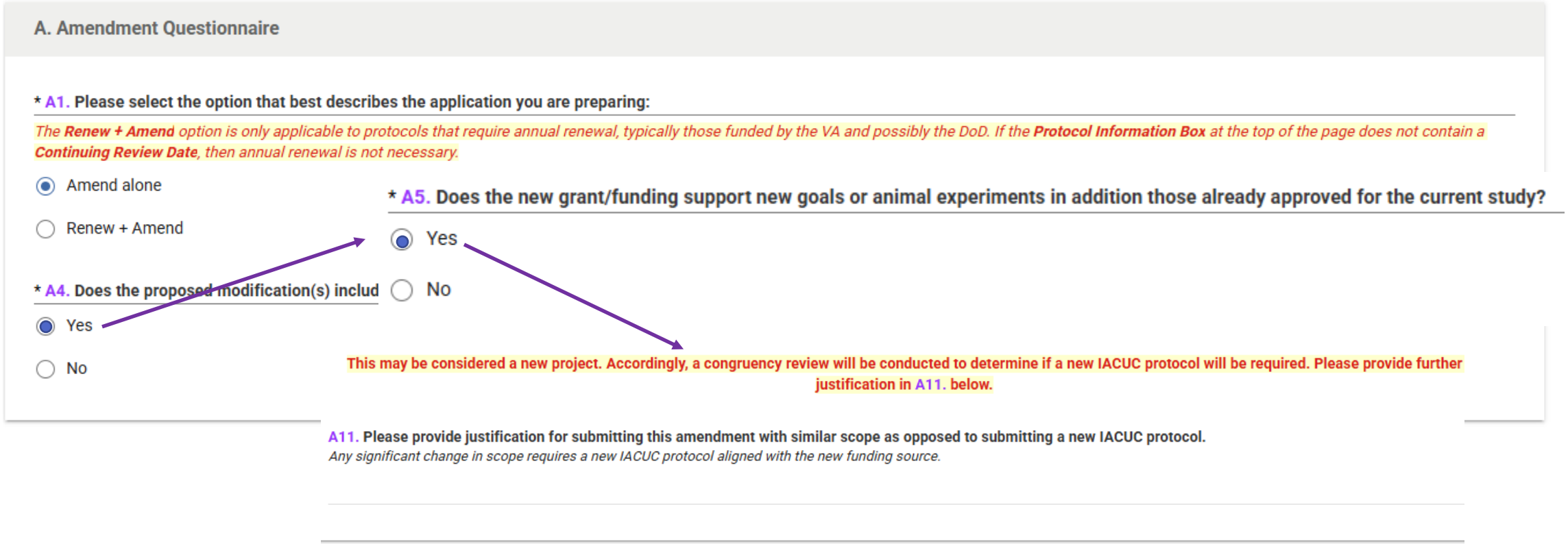
*** A1. Please select the option that best describes the application you are preparing:**

*The **Renew + Amend** option is only applicable to protocols that require annual renewal, typically those funded by the VA and possibly the DoD. If the **Protocol Information Box** at the top of the page does not contain a **Continuing Review Date**, then annual renewal is not necessary.*

- ◯ Amend alone
- ◯ Renew + Amend

END OF AMENDMENT FORM

Submitting An IACUC Amendment



Amendment will undergo congruency review/check. A new protocol **may be** required to be congruent with funding support.

Submitting An IACUC Amendment

Changes in federal funding with a reportable change in scope require a new VAS upload

*** A4. Does the proposed modification(s) include a change in funding?**

- (●) Yes
- ( ) No

*** A5. Does the new grant/funding support new goals or animal experiments in addition those already approved for the current study?**

- ( ) Yes
- (●) No

→ **Be advised, a new VAS will need to be uploaded in Section 1C3.**

*** A6. Select all modifications being proposed for this study:**

- [ ] Change of Principal Investigator
- [ ] Change in personnel (other than PI)
- [ ] Change of protocol title
- [ ] Change in animal location
- [ ] Change in animal type or number
- [ ] Change in drugs or research material being used
- [ ] Change in procedures or experiments
- [x] Change in funding (check only if you answered "Yes" to question A4)
- [ ] Use of photos, videos, and/or audio recordings of animal research that require IACUC approval (excludes publishing in manuscripts/chapters (except for visual journals (i.e. JoVE), scientific meetings, presentations, educational programs, and communication between lab personnel)

A8. Does this amendment constitute a reportable change in scope?

- (●) Yes
- ( ) No

A9. Enter the date the federal agency was notified or will be notified (*i.e.*, next annual date).

*** A7. Is the project funded by a federal agency?**

- (●) Yes
- ( ) No

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Submitting An IACUC Amendment

*** A4. Does the proposed modification(s) include a change in funding?**

- ○ Yes
- ◉ No

"Minor" Amendments

*** A6. Select all modifications being proposed for this study:**

- ☐ Change of Principal Investigator
- ☐ Change in personnel (other than PI)
- ☐ Change of protocol title
- ☐ Change in animal location
- ☐ Change in animal type or number
- ☐ Change in drugs or research material being used
- ☐ Change in procedures or experiments
- ☐ Change in funding (check only if you answered "Yes" to question A4)
- ☐ Use of photos, videos, and/or audio recordings of animal research that require IACUC approval (excludes publishing in manuscripts/chapters (except for visual journals (i.e. JoVE), scientific meetings, presentations, educational programs, and communication between lab personnel)

*** A7. Is the project funded by a federal agency?**

- ○ Yes
- ○ No

Submitting An IACUC Amendment

*** A4. Does the proposed modification(s) include a change in funding?**

- ○ Yes
- ◉ No

"Major" Amendment

*** A6. Select all modifications being proposed for this study:**

- ☐ Change of Principal Investigator
- ☐ Change in personnel (other than PI)
- ☐ Change of protocol title
- ☐ Change in animal location
- ☐ Change in animal type or number
- ☐ Change in drugs or research material being used
- ☐ Change in procedures or experiments
- ☐ Change in funding (check only if you answered "Yes" to question A4)
- ☐ Use of photos, videos, and/or audio recordings of animal research that require IACUC approval (excludes publishing in manuscripts/chapters (except for visual journals (i.e. JoVE), scientific meetings, presentations, educational programs, and communication between lab personnel)

B. Rationale/Justification

*** B2. If you are proposing modifications to, or addition of, procedures or experiments, drugs or research materials, animal type or number, and/or the PI, please provide a thorough justification of the proposed changes:**

At minimum, an acceptable justification should answer the following questions: *Why is it necessary to modify the approved protocol? If and how do the proposed modifications impact the goals and objectives of the approved project? What is the rationale for the specific modifications (i.e., specific procedure or experiment, specific drug or reagent, specific animal type or number, specific PI) being proposed?*

Click Here to Add Text

*** A7. Is the project funded by a federal agency?**

- ◉ Yes
- ○ No

A8. Does this amendment constitute a reportable change in scope?

- ○ Yes
- ◉ No

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Submitting An IACUC Amendment

D. Submission

This *Amendment* (or *Renewal + Amendment*) application may be submitted ONLY by the Principal Investigator.

- If you are not the PI, click the *Notify PI to Submit* button to alert the PI that the application is ready for review, certification and submission. Successful notification will be indicated by a gray bar across the button.
- If you are the PI, please go to the next step, PI Certification.

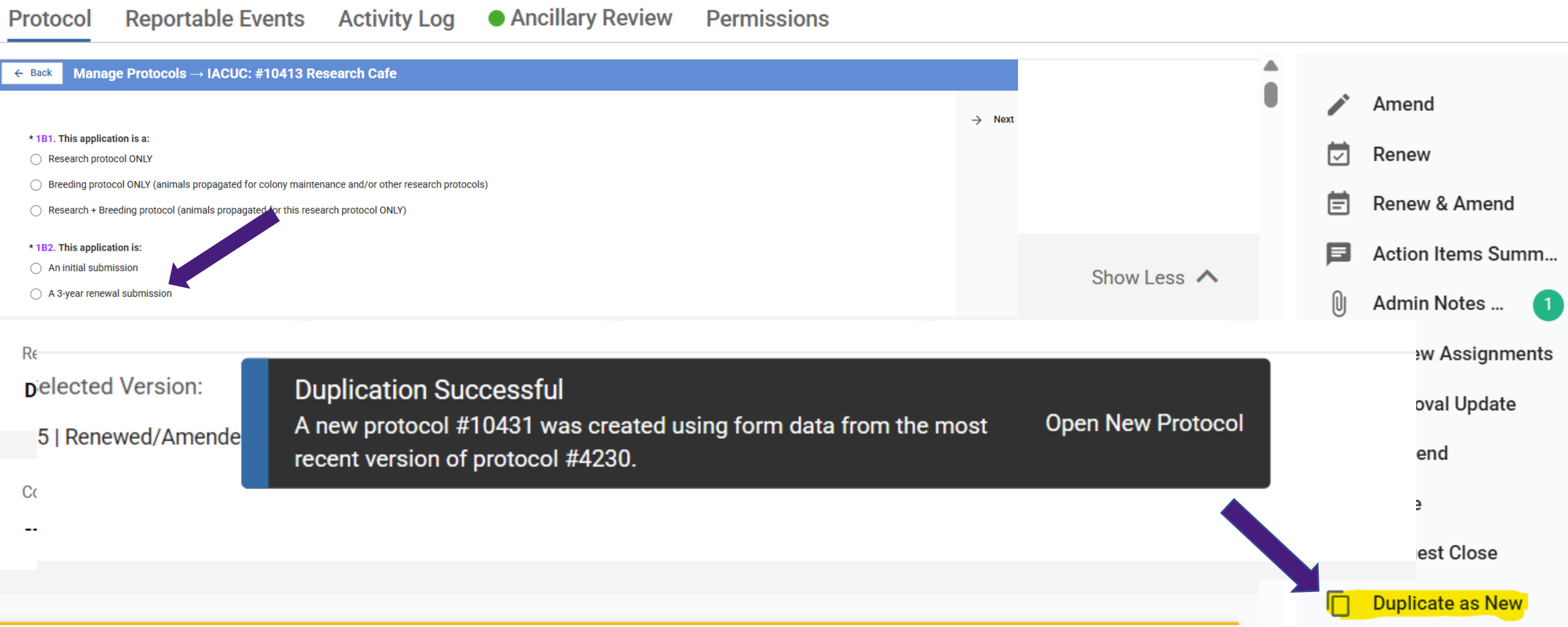
* D1. *As the Principal Investigator on this project, I certify that I am* ***responsible for the overall conduct of the research and****, to the best of my knowledge, the information included herein is accurate and complete. I also agree:*

- *that no additional change, whether minor or major, will be made without IACUC approval, except where necessary to eliminate apparent immediate hazards;*
- *that all amendments approved within the three-year protocol approval period are bound to the approval date of the protocol, which they amend;*
- *that after three years, all modifications approved via amendment(s) that are anticipated to remain as a component of the study must be incorporated into the triennial renewal application;*
- *to report to the IACUC any* ***emergent problems, serious adverse reactions, or any procedural changes*** *that may affect the status of the investigation; and*
- *to periodic review of this project by the IACUC at intervals appropriate to assure that the project is being conducted in compliance with the IACUC' s understanding and recommendation.*

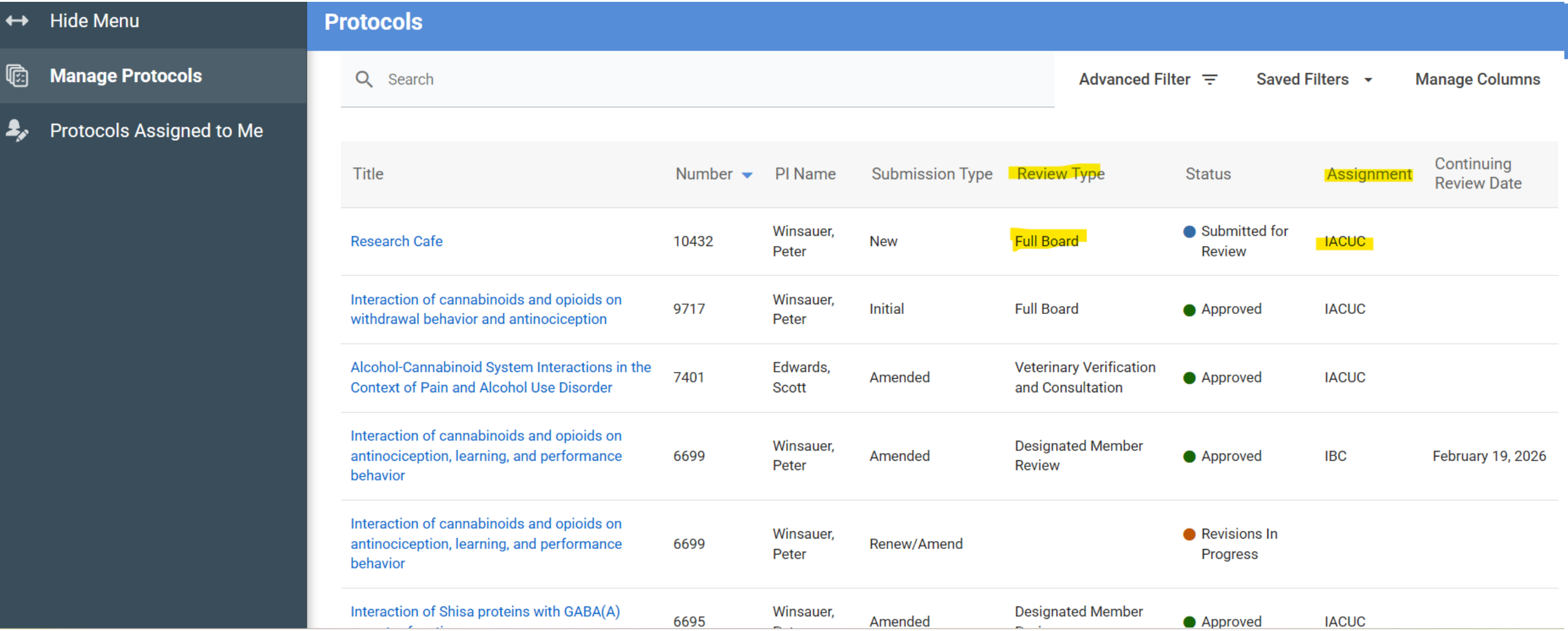
◯ I certify and agree

◯ I DO NOT certify and agree

Submitting a *de novo* IACUC Protocol ("3-year Renewal")



Using the Kuali "Manage Protocols"



Using the Kuali "Manage Protocols"

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Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date
Research Cafe	10432	Winsauer, Peter	New	Full Board	Submitted for Review	IACUC	
Interaction of cannabinoids and opioids on withdrawal behavior and antinociception	9717	Winsauer, Peter	Initial	Full Board	Approved	IACUC	
Alcohol-Cannabinoid System Interactions in the Context of Pain and Alcohol Use Disorder	7401	Edwards, Scott	Amended	Veterinary Verification and Consultation	Approved	IACUC	
Interaction of Shisa proteins with GABA(A) receptor function	6695	Winsauer, Peter	Amended	Designated Member Review	Approved	IACUC	
Protection against development of dietary non-alcoholic steatohepatitis (NASH) by Cannabinoids	4341	Ronis, Martin	Close Request	Designated Member Review	Closed	IACUC	
Interaction of cannabinoids and opioids on antinociception and conditioned behavior	2419	Winsauer, Peter	Renewed/Amended	Designated Member Review	Closed	IACUC	

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Using the Kuali "Manage Protocols"

Protocols

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Title	Number	Type	PI Name	Submission Type	Review Type	Status	Continuing Review Date	Expiration Date	Revision Due Date	Committee Date
Research Cafe	10432	IACUC	Winsauer, Peter	New	Full Board	Submitted for Review				
Interaction of cannabinoids and opioids on withdrawal behavior and antinociception	9717	IACUC	Winsauer, Peter	Initial	Full Board	Approved		September 24, 2028	October 15, 2025	September 15, 2025
Alcohol-Cannabinoid System Interactions in the Context of Pain and Alcohol Use Disorder	7401	IACUC	Edwards, Scott	Amended	Veterinary Verification and Consultation	Approved		July 22, 2027	March 31, 2025	March 17, 2025
Interaction of Shisa proteins with GABA(A) receptor function	6695	IACUC	Winsauer, Peter	Amended	Designated Member Review	Approved		March 06, 2027		August 18, 2025

Submitting IACUC protocols

Questions?