Xavier University of Louisiana Animal Research Protocol Application Form

The deadline for receipt of application to IACUC Chairman is the last Monday of the month for the following month's IACUC meeting.

Before entering information into the form, download this form using **FILE, SAVE AS** to your computer. **Email** this form and supporting documents to **IACUC CHAIR (Dr. Patience Obih @ poobih@xula.edu)**. **Sign and send** the assurance page to Office of Sponsored Programs, Administration Building Room 217C. Complete each item of this form or mark "Not Applicable" or "NA." Navigate the form using the arrow keys or mouse. To access links, use CTRL + clink link. If you have a problem using the form go to: Using IACUC form: Email: **poobih@xula.edu,** call 504-520-7656 or visit XULA Animal Resource Facility website: for help and links to other resources such as the Animal Welfare Act: **http://www.nal.usda.gov/awic/legislat/usdaleg1.htm** and Guide for the Care and Use of Laboratory Animals: **http://grants.nih.gov/grants/olaw/references/phspol.htm**

Application Date: Application Type: ☐New Project/Initial Submission

☐Renewal of IACUC #:

1. Principal Investigator: Degree(s):
   Title/Rank (Faculty or Staff Appointment Required):
   Department:
   Email:
   Telephones: Office: Lab: Cell/After hours:

2. Project Title:
3. Source of Funds for the Project. [Note: A separate IACUC protocol is required for each funded grant.]
   ☐Departmental ☐LA Board of Regent
   ☐NIH, specify which institute/center: ☐DOD ☐NSF [Complete Item 23.]☐ Other, Specify:

4. Summary- NON-TECHNICAL [Language understandable to a high school graduate]. Briefly summarize the specific aims and scientific purpose; include how this study may benefit human or animal health or advance the scientific understanding of biological processes. State which species will be used and describe how the animals will be used to achieve your goals. Do not use a grant abstract. Spell out any abbreviations and explain any technical words that must be used. Do not exceed 400 words. Do not include references to published work in this section or any other section of this application. Do not provide summaries of past accomplishments.

5. A) Indicate the source of animals.
   ☐Commercial Vendor
   ☐Active Breeding Protocol Number:
   ☐Submitting Breeding Colony Protocol titled: If different, indicate submitting Principal Investigator:
   ☐Other, specify source and indicate the circumstances in which the animals will arrive at Xavier University of Louisiana (i.e. health certificates, need for quarantine).
   B) Indicate animal identification method(s).
   ☐Cage Card ☐Ear tag ☐Tattoo ☐Microchip, describe method of placement; indicate if any anesthetics will be used. ☐Other, specify:

6. Vivarium Location
   ☐Xavier University of Louisiana Animal Resource Facility
   *If vivarium is outside of Xavier University of Louisiana, complete Item 24.

7. Indicate where any live animals transported from the Animal Care facility will be taken.
   [Note: Submit an amendment to report any location change; notify the IACUC office if you eliminate transporting live animals out of the Animal Care facility.]
   ☐Not Applicable
   ☐Transport Live Animals to Building: Room#:
   Describe the method and containment to be utilized for transport, include the route and use of any elevators.
   Indicate the disposition of live animals taken from Animal Care housing.
   ☐Animals will be euthanized within 12 hours.
   ☐Animals will be returned to Animal Care within 12 hours.
   ☐After consultation with the veterinarian, I am requesting the following special consideration and have included justification.

8. Environmental and Biosafety Issues
   Radiation Safety Committee (RSC) [Web Address]
   Institution Biohazard Committee Application (IBC) [Web Address]

   Depending upon the IBC risk assessment, new SOPs may be required whereby you must consult with the Animal Care Facility Veterinarians to modify or develop new SOPs specific to the procedures and/or the biosafety hazards of this study.

   A) Before being introduced into the Animal Care facility, the following items must be tested and certified free of pathogens. Consult with the veterinarian to determine if testing is required or if exempt. Check all that apply.
      ☐Not applicable
      ☐Cell lines and their products (includes antibodies and ATCC cell line)
      ☐Tissues and body fluids or rodent origin (or had passage through rodents that had not been documented free or murine pathogens)
      ☐Cell lines grown on or exposed to Matrigel
      ☐Primary cell lines coming directly from a source with a current certificate of health.
      ☐Other, specify:

   B) For projects requiring investigator to have a Xavier University of Louisiana Radiochemical Certification, provide certification number.
      ☐Not applicable ☐Radiochemical certification approval number

   C) Indicate Xavier University Institutional Biosafety Committee (IBC) status for this project.
      IBC approval number: [Enter "pending" if initial IBC application is begin processed}
      Last IBC approval date:
      Check the biosafety rating for the work described in this protocol conducted in
      Animal Care facility: ☐ABSL-1 ☐ABSL-2 ☐ABSL-3 ☐ABSL-4 ☐Not applicable
      Investigator's lab: ☐BSL-1 ☐BSL-2 ☐BSL-3 ☐Not applicable

   D) Check the appropriate boxes if any animal or personnel will be exposed to any of the following.
      ☐Not Applicable ☐Radioactive compound ☐Suspected chemical carcinogens
      ☐Recombinant DNA ☐Other potential safety hazard (i.e. chemical poisons specific to your experiments)
      If any of the above boxes were checked, specify the potential hazard, the location in the facility where exposure is present and what safety precautions should be taken by personnel.

9. Describe and provide an explanation of any special care, handling or housing of animals that Xavier University of Louisiana Animal care personnel will need to provide.

10. Describe any possible adverse effects (e.g., seizures, post-operative infections) that may occur as a result of your study manipulations. You must include how you intend to address these effects, how often animals experiencing these adverse effects will be monitored and define the criteria* for making determinations.

    *Note: you must have an established plan of action for adverse effects. Prior to submitting this application, consult with the veterinarians to formulate an appropriate treatment and management plans and the ultimate disposition of an animal. The veterinarians are authorized to make the final diagnostic, treatment or euthanasia decisions.

11. Will food and/or fluid be restricted in this project for a period longer than 24 hours?
    ☐No (Go to item 13) ☐Yes (Complete parts A through E)

A) List restriction(s) for each species

Species	**Restriction type** Fluid	Food	**Duration of Restriction**	**Frequency of Restriction**
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

B) Provide justification for the restriction(s).

C) Specify which variables are monitored to insure animal health during restriction period and specify the threshold/criteria of well-being used for each variable for each species.

Species			
Body Weight (e.g., % ad lib)			
Urine/ Fecal Output (e.g., vol. monitored daily)			
Food/Fluid Consumed (e.g., vol. monitored daily			
Other criteria: (e.g., vet. Evaluation for dehydration)			
Other criteria:			

D) Describe steps to insure adequate nutrition/hydration during the restriction period.

E) If animals develop physiological or behavioral abnormalities, will the animals be removed from restrictions? Check appropriate box.

☐Animals will be permanently removed from restrictions and/or the study

☐Animals will be temporarily removed from restrictions.

Describe the criteria for returning an animal to the restrictions.

12. Will any un-anesthetized animal be restrained for a period longer than 10 minutes?
☐No (Go to Item 14) ☐Yes (Complete parts A through C)

A) List restraint(s) for each species.

Species	Method/Type of Restraint	Duration of Restraint	Frequency of Restraint

B) Provide justification for the restraint.

C) Briefly describe physical restraint acclimation procedures.

13. A major operative procedure is defined as (a) any surgical intervention that penetrates and exposes a body cavity or (b) any procedure which produces permanent impairment of physical or physiological functions.

A) Identify any initial procedure in which an animal is allowed to recover from a major operative procedure as defined above.

B) Identify any subsequent major operative procedure followed by recovery and provide a scientific justification for this requirement

C) Although highly discouraged, does this proposal involve a major operative procedure on an animal that had experienced a major operative procedure in another protocol? ☐No ☐Yes, provide a scientific justification for the use of these animals and consult with the veterinarians prior to submitting this protocol to determine applicable APHIS requirements.

14. Complete the information below for all anesthetics (local and general), analgesics and sedatives used in live animals before (pre-op), or after (post-op painful procedures and/or euthanasia). [Pharmaceutical grade drugs must be used for live animal work, including survival surgery. Guidelines on the use of drugs are available. On Animal Care Website:

Species	Drug-if given combined, list as combination, i.e., Ketamine/Xylazine		Pre OP	O P	Post OP	Euthanasia	Dose (mg/kg)	Route SQ, IV, IP, IM	Frequency/Duration of Administration (e.g., every 4 hrs for 2 days, once)
			☐	☐	☐	☐			
			☐	☐	☐	☐			
			☐	☐	☐	☐			
			☐	☐	☐	☐			
			☐	☐	☐	☐			
			☐	☐	☐	☐			
			☐	☐	☐	☐			
			☐	☐	☐	☐			

15. Provide at least two methods of monitoring the appropriate depth of anesthesia during painful procedure(s) and/or surgery.
    ☐Not Applicable ☐Toe Pinch Reflex ☐Web Pinch Reflex ☐Blood Pressure ☐
    ☐Palpebral (Eye) reflex ☐Tail Pinch Reflex ☐Heart and Respiratory Rate ☐Other, Explain:

16. Complete the information below for all other experimental drugs or therapeutic agents (e.g. antibiotics, steroids) to be used in live animals.

Species	Drug/Agent	Use	Dose (mg/kg)	Route	Frequency/Duration of Administration

17. A) What method of euthanasia will be used for each species? [Guidelines concerning these issues are available at the Xavier University of Louisiana Animal Resource Facility website or located at American Veterinary Medical Association]
    :http://www.avma.org/issues/animal_welfare/euthanasia.pdf

Species	Specify group of multiple methods used	Compressed CO_2	Drug, Dose(mg/kg), Route	Cervical Dislocation, Decapitation *or Specify other method	Is anesthesia used prior to euthanasia? (list anesthesia in Item 14)
		☐			☐Yes ☐No**
		☐			☐Yes ☐No**
		☐			☐Yes ☐No**
		☐			☐Yes ☐No**
		☐			☐Yes ☐No**

*Identify the equipment used for decapitation and the maintenance procedures for the equipment used (e.g. contracted services, when and how blade is sharpened).

**For cervical dislocation or decapitation without the prior use of anesthesia provide information on the training of each person(s) utilizing the technique.

**In accordance with AVMA guidelines, decapitation or cervical dislocation is conditionally acceptable. Provide justification to euthanize by cervical dislocation or decapitation without prior use of anesthesia.

B) Indicate method to confirm death:

☐Decapitation

☐Thoracotomy

☐Other, specify:

C) Are all methods and/or apparatus being used consistent with current recommendations of the panel on Euthanasia of the American Veterinary Medical Association?

☐Yes ☐ No, provide scientific justification why the proposed method must be used.

D) Will all animals in this protocol be euthanized?
☐Yes ☐ No, describe the plan for disposition of any animals at the completion of the experiment

18. Enter the total number of animals of each species needed for the duration of this protocol approval period. (If using non-human primate, specify species, e.g., rhesus macaques). Indicate under the appropriate USDA Category for which the experiments fall. Count the animal only once. If an animal is subject to multiple categories, count the animal in the highest category.

USDA Category C: [USDA AWA, 2.36(b)(5)] No pain, distress or use of pain-relieving drugs (e.g., studies experiments, test or procedures where animals do not experience pain or distress but may have only transitory discomfort such as venipuncture, injection, tattooing).

USDA Category D: [USDA AWA, 2.36(b)(6) painful or Distressful with use of Analgesia/Anesthesia/Sedatives/Tranquilizers (e.g., painful or stressful experiment, test or procedures that are conducted with the use of appropriate anesthetic, analgesics, and sedative drugs that will prevent pain or distress; also includes procedures performed on anesthetized animals that are not allowed to regain consciousness). Complete Item 15 and/or Item 16.

USDA Category E: [USDA AWA, 2.36(b)(7)] Painful or Distressful without Pain and Stress Relieving Measures. Consultation with the veterinarian is required. (e.g., painful and stressful procedures performed without the use of appropriate analgesics, anesthetics and sedative drugs or other measures to prevent and relieve pain or distress; painful and stressful procedures not amenable to relief by therapeutic measures).

Species	Strain	Gender: M=male F=female M/F=both	Age Range	Check if Transgenic	Check if using Recombinant DNA	Category C (No pain/distress)	Category D (provide relief)	Category E*(without relief, justify)	Total # Animals (C+D+E)
				☐	☐				
				☐	☐				
				☐	☐				
				☐	☐				
				☐	☐				
				☐	☐				
				☐	☐				
				☐	☐				
				☐	☐				

For multiple strains of a species, recap the total animals requested by each species.

Species	Total # per Species

*If USDA Category E is indicated, provide justification for each procedure/experiment when not using appropriate analgesics, anesthetics, sedative or other measures to prevent pain or distress. Indicate your search criteria for alternatives to these procedures in Item 20. [This information will be included in the USDA Annual Report for protected species.]

19. In support of your certification to (1**) reduce**, (2) **refine and 3**) **replace** the use of animals, you must demonstrate that the number of animal used is minimized and that these activities do not unnecessarily duplicate previous experiments, alternatives to pain categories "D" and "E" procedures that may cause pain and/or distress to the animals were considered and any occurrences of pain/ distress are minimized and non-animal alternatives were considered.

A) To address all of the above points more than one set of key words and multiple searches may be necessary. Provide the following information of your web base searches. Retain a copy of your searches for future use or audit purposes. Search help is available on websites:

Animal Welfare Information Center (AWIC):

Alternatives Searches Index:

Search Engine [e.g. PubMed. CRISP, BIOSIS Google is not acceptable]	Type of Search		Search Criteria/Keywords	Inclusive years of search	Date search was conducted (mm/dd/yy)
	Duplication	Alternatives: Non-animal, minimize pain			
	☐	☐			
	☐	☐			
	☐	☐			
	☐	☐			

B) Based upon your search, explain your rationale for the use of animals and consideration of alternative to reduce, refine and replace animal use.

1. Identify non-animal alternatives that you have considered and explain why these alternatives are unacceptable. Indicate what other alternative procedures, methods or techniques were considered to minimize pain and/or distress. (e.g., mathematical models, computer simulation, in vitro biological systems, modified restraint, housing modifications, less invasive procedure, early humane endpoints.)

2. Provide and explanation of the experimental requirements for the selection of each species involved. (e.g. uniqueness of model anatomic, physiologic, genetic, etc.), comparable models or previous experience, comparability to human disease)

3. Explain how you determined the number of animals to be used in each group (e.g., statistical variability, specific experimental needs, power analysis). Comparable models or previous experience, comparability to human disease)

20. Describe the distribution of the number of animals requested throughout the study (show group assignments according to experimental variable or list each animal according to use). All animals must be represented and must be consistent with the total number of animals requested in Item 19 and justified in item 20. [A series of tables may be useful in presenting this information; tables, charts and pictures can be copied and pasted into this section.]

21. Beginning with the entry of an animal into the experiment to the endpoint of the study, describe the proposed use of the animals which will allow the IACUC to understand the experimental course. Provide a chronological description of all procedure/experiments to be used on the animals.

When describing surgical procedures, indicate how long the procedure will last and who will perform the pre-op, anesthesia, the surgery, recovery and post-op monitoring.

If multiple categories were listed in Item 19, indicate which experiment/procedure is considered Category C, D, or E.

[Do not include methodological detail or methods not related to animals. Do not substitute this section with the methods section of a grant].

22. Complete the following where there is a federal government agency e.g. NIH or DOD) grant affiliation or any other granting agency (e.g., American Heart Association, Alzheimer's) requiring a vertebrate animal section and IACUCU approval.

A) Grant number (enter "pending" if not assigned):

B) Grant title:

C) Award period that this application covers:

D) If part of a program project type grant, provide the grant's Principal Investigator.

E) Are there any discrepancies between the project describe in this application and the "vertebrate animal" section of the grant proposal?

☐No discrepancy exist between IACUC and the grant proposal

☐Yes, provide an explanation for each discrepancy.

F) Attach a copy of the grant proposal's "vertebrate animal" section to this IACUC application. (e.g. Section F of the PHS 398 Forms)

23. If this project will be conducted in an institution other than Xavier University of Louisiana, provide the following information. Such projects must be approved by the IACUC at each institution. Consult with the Office of Sponsored Programs for any additional institutional requirements.

Name of other Institution:

Location where project will be conducted:

AAALAC [www.aaalac.org] Status: ☐Active member ☐Inactive or Non-member

PHS Assurance Status (OLAW): ☐Active member ☐Inactive or non-member

Check the current status of the protocol with the other institution.

☐A copy of the current IACUC approval is attached to this application.

☐ IACUC approval is pending and will be forwarded when received.

24. List all personnel participating in this protocol. List the activities/procedures described in this protocol that each person is authorized and trained to perform.

Prior to working with animals, PI and all participants must also complete all training required by Xavier University of Louisiana Animal Care Training Program, Xavier University of Louisiana IBC and CITI. A refresher course is required every three years. CITI initial and refresher courses are available on the web through CITI [https://www.citiorogram.org/]

Participant Name	Degree (MD, PhD, BS)	Role, (PI, Investigator, Research Asst., Lab Tech, Student)	Species working with in this protocol	Years of experience with species	List the activities in this protocol that the participant is trained, qualified and authorized to perform.	Indicate if Completed or scheduled for all required Xavier university Animal care Training and CITI Courses

[After initial approval, submit an amendment to authorize additional personnel.]

25. Indicate who animal Care personnel should contact for animal care concerns.

☐Always contact Principal Investigator of this protocol.

☐The following person is designated as first point of contact for animal care concerns only.

[In the event the designated person cannot be contacted, the Principal Investigator will be contacted.]

Name: Email:

Telephone: Office: Lab: Cell/After hours:

Note: your emergency contact information is maintained by the Director of Animal Care (DAC). Report any changes in your contact information to the DAC or the IACUC Coordinator.

Institutional Animal Care and use Committee (IACUC)

Principal Investigator's Protocol Assurance Statement

Title of project [from front page]:

Principal Investigator:

- I acknowledge responsibility for the work described here.
- I assure that the Faculty and Staff on the project are qualified to conduct the study in a humane and scientific manner consistent with PHS document "Guide for the Care and Use of Laboratory Animals" and the provisions of the Animal Welfare Act are knowledgeable of the procedures for reporting animal welfare concerns.
- I certify that the individuals listed in this application are authorized to conduct the listed procedures involving training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary).
- I certify that all individuals working on this proposal who are at risk were informed of the institution's occupational Health and Safety Program.
- I certify that I gave full consideration to reduce, refine and replace the use of live animals and that these experiments do not unnecessarily duplicate previous work using animals.
- I certify that I have reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
- I certify that I will notify the IACUC regarding any unexpected study results that impact the animals, and that any unanticipated pain or distress, morbidity will be reported to the attending veterinarian and the IACUC.
- I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

By signing, the Principal Investigator certifies each of the above statements.

_____

Principal Investigator Date

[Submit only this signature page to the IACUC Office after emailing this application to IACUC

*******Xavier University of Louisiana IACUC USE ONLY**********DO NOT SUBMIT TO GRANTING AGENCY*******

In the judgment of IACUC, the procedures delineated in this application conform to the pertinent federal rules and regulations regarding use and care of animals.

IACUC#

Approval Period: _____ through _____

With subsequent annual reviews.