Animal Study Proposal

UNIVERSIDAD DE PUERTO RICO, ARECIBO
COMITÉ INSTITUCIONAL PARA EL CUIDADO Y USO DE ANIMALES
P.O. Box 4010 Arecibo P.R. 00614
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Date:

Please Leave Blank
Proposal #:
Approval Date:
Expiration Date:

A. ADMINISTRATIVE DATA

Department:

Principal investigator:

Mailing address:

Phone: Fax: E-mail:

Project title:

Initial submission ☐ Renewal ☐ Modification ☐

Funding Source:

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel *[e.g., co-investigator(s)]*, providing their department, telephone, fax, and e-mail:

B. ANIMAL REQUIREMENTS

Genus: *[e.g., Mus]* **Species:** *[e.g., musculus]*

Strain, subspecies, or breed: **Common name:**

[e.g., C57BL/6] *[e.g., Black6]*

Approximate

Age: **Weight or Size:** **Sex:**

Bacteriological status: *[e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free (SPF), conventional]*

Viral status: *[e.g., simian immunodeficency virus, simian retrovirus]*

Source(s): *[e.g., name of vendor or breeder, or bred in-house]*

Primary housing location(s):

[Facility manager must certify in Section S that facility has the resource capability to support the study. If animals will be housed in lab or anywhere else outside central facility for more than 12 hours, provide building and room number.]

Location(s) where manipulation will be conducted:

Number of animals to be used:

Year 1: **Year 2:** **Year 3:**

Total number of animals to be used:

C. TRANSPORTATION

Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe methods you will use to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route and elevator(s) that will be used.

D. STUDY OBJECTIVES

Briefly explain the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society in language that a layperson can understand. Please comment on whether the study unnecessarily duplicates other studies.

E. RATIONALE FOR ANIMAL USE

1. Explain your rationale for animal use. *[The rationale should include reasons why it is necessary to use animal models.]*

2. Justify the appropriateness of the species selected. *[The species selected should be the lowest possible on the phylogenetic scale.]*

3. Justify the number of animals to be used. *[The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible.]*

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

- Briefly explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. A flowchart may be an effective presentation of the planned procedure.

- A best practice is to provide an acceptable range of the specific items described below to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.

Include the following specific information, if applicable:

- **Animal identification methods** *[e.g., ear tags, tattoos, collar, cage card, implant, etc.]*.

- **Methods of restraint** *[e.g., restraint chairs, collars, vests, harnesses, slings, etc.]*. Describe how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation,

acclimation or training to be used.

- **Experimental injections or inoculations** *[substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedule]*.
- **Blood withdrawals** *[volume, frequency, withdrawal site, and methodology]*.
- **Radiation** *[dosage and schedule]***.**
- **Food or fluid restriction** If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. *[Amount earned during testing and amount freely given must be recorded and assessed to assure proper nutrition.]* If you are seeking a departure from the recommendations of the *Guide*, provide a scientific justification.
- **Pharmaceutical-grade and non-pharmaceutical-grade Compounds** Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.
- **Other procedures** *[e.g., survival studies, tail biopsies]*.
- **Resultant effects**, if any, that the animals are expected to experience *[e.g., pain or distress, ascites production, etc.]*.
- **Other potential stressors** *[e.g., noxious stimuli, environmental stress]* **and procedures to monitor and minimize distress**. If a study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.
- **Experimental endpoint criteria** *[e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity]* must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.
- **Veterinary care** Indicate the plan of action in case of animal illness *[e.g., initiate treatment, call investigator prior to initiating treatment, euthanize]*.
- **Surgical procedures** *[provide details of survival and non-survival surgical procedures in Section G.]*.

G. SURGERY

If surgery is proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures *[e.g., fasting, analgesic loading]*, and monitoring and supportive care during surgery. Include the aseptic methods to be used.
2. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.
3. Identify the location where surgery will be performed. *[building(s) and room(s)]*

4. If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided. *[building(s) and room(s)]* Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.

5. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.

6. Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.

7. Has major or minor survival surgery been performed on any animal prior to being placed on this study? *[Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)]*. If yes, please explain.

8. Will more than one survival surgery be performed on an animal while on this study?
If yes, please justify.

H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

1. Pain or distress classification for USDA covered species. See Appendix 1 for classification definitions and examples.

2. Attachment 1, Explanation for USDA Classification E, must be completed for animals listed in Classification E.

Species (common name)	**USDA Classification* B, C, D or E**	**Number of animals used each year**			**3 years total number of animals**
		Year 1	**Year 2**	**Year 3**	
				Total number of animals	

3. Consideration of Alternatives

If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate the methods and sources used in the search. Database references must include databases searched, the date of the search, period covered, and the keywords used. Alternatives include methods that:

- refine existing tests by minimizing animal distress,

- reduce the number of animals necessary for an experiment, or
- replace whole-animal use with *in vitro* or other tests.

If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system. Note that you must certify in Section Q.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not.

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS

For animals indicated in Section H.1. Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that will be used. *[A best practice is to provide an acceptable range of the specific items to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.]* Include the name of the agent(s), the dosage range, route(s) and schedule of administration. If information is provided in Section R.5., above, please cross-reference. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is **not** consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used. Indicate the method of carcass disposal if not described in Section K. below.

K. HAZARDOUS AGENTS

Use of hazardous agents requires the approval of the institutional Biosafety Office/Committee. Attach documentation of approval for the use of recombinant DNA or potential human pathogens.

Hazardous Agent	Yes	No	Agent	Date of Biosafety Approval	Tracking #
Radionuclides					
Biological Agents					
Hazardous Chemicals or Drugs					
Recombinant DNA					

Study Conducted at Animal Biosafety Level: 1 ☐ 2 ☐ 3 ☐ 4 ☐

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS

[e.g., cell lines, antiserum, etc.]

1. Specify Material:

2. Source:

3. Material Sterile or Attenuated: Yes No

   Has the material been tested for pathogens? (e.g., *MAP - Mouse Antibody Production; RAP - Rat Antibody Production; HAP - Hamster Antibody Production, PCR test)*

   Yes ☐ *[Attach copy of results]* No ☐

4. I certify that the tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

   ☐ **Initials of Principal Investigator**

M. GENETICALLY ENGINEERED ANIMALS

Describe any anticipated phenotypic consequences of the genetic manipulations to the animals. Describe any special care or monitoring that the animals will require.

N. EXEMPTIONS FROM ENVIRONMENTAL ENRICHMENT FOR NONHUMAN PRIMATES OR EXERCISE FOR DOGS

1. For nonhuman primates, are you seeking an exemption for scientific reasons from the institution's plan for environment enrichment?

   Yes ☐ No ☐

   If yes, provide the basis of the request.

2. For dogs, are you seeking an exemption for scientific reasons from the institution's plan to provide dogs with the opportunity for exercise?

   Yes ☐ No ☐

   If yes, provide the basis of the request.

O. FIELD STUDIES

If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if federal, state, and/or local permits are required and whether they have been obtained.

P. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

List any special housing, equipment, animal care or any departures from the *Guide [e.g., special caging, water, feed, waste disposal, environmental enrichment, etc.]*.

Q. PRINCIPAL INVESTIGATOR CERTIFICATIONS

1. I certify that I have attended the institutionally required investigator training course.
   Year of Course Attendance: Location:
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this proposal who are at risk are participating in the institution's Occupational Health and Safety Program.
4. I certify that the individuals listed in Section A. are authorized to conduct procedures involving animals under this proposal, have attended the institutionally required investigator training course, and received 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); and procedures for reporting animal welfare concerns.
5. For all USDA Classification D and E proposals (see section H.1.): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in Section H.2. 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.
6. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
7. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
8. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

Principal Investigator

Name: Signature: Date:

R. CONCURRENCES

PROPOSAL NUMBER _____ (leave blank)

Supervisory concurrence as applicable:

Name: Signature: Date:

Safety Office/Committee Certification of Review and Concurrence:
[Required of all studies that use hazardous agents.]

Name: Signature: Date:

Facility Management/Veterinarian certification of resource capability in the indicated facility to support the proposed study:

Facility: Name: Signature: Date:

Facility: Name: Signature: Date:

Comments:

Attending Veterinarian certification of review and consultation on proper use of anesthetics and pain relieving medications for any painful procedures:

Name:	Signature:	Date:

[IACUC Office: add any additional concurrences that are needed e.g., radiations safety, Drug Enforcement Agency licensure, select agents.]

S. FINAL APPROVAL

Certification of review and approval by the Institutional Animal Care and Use Committee:

Name:	Signature:	Date:

List any attachments here:

Appendix 1 - USDA Classifications and Examples

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.
Examples:

- Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are handled in accordance with IACUC approval, the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
- Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations.
- Animals held under proper captive conditions or wild animals that are being observed.

Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.
Examples:

- Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice [dog cephalic, cat jugular] or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
- Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.
Examples:

- Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, and laparotomy or laparoscopy.
- Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus *[e.g., guinea pigs]*.
- Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics, anesthetics, tranquilizers, or supportive care.

Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.
Examples:

- Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.
- Chairing of nonhuman primates not conditioned to the procedure for the time period used.

NOTE REGARDING CLASSIFICATION E: An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act (FOIA), and may be publicly available through the Internet via USDA's website.

Attachment 1 - Explanation for USDA Classification E

[This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.]

This document must be typed.

Name of investigator:

Animal study proposal title:

Species and number of animals listed in Classification E for each year:

Species:
Number of animals:
year 1 -
year 2 -
year 3 -
Total:

Description of project including reason(s) for species selection:

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

Signature of investigator:

Date:

Signature of IACUC Chairperson:

Date: