Animal Use Protocol Application for Initial Review

Institutional Animal Care and Use Committee (IACUC)
College of Liberal Arts and Sciences
Kutztown University

Instructions: Complete the application by typing answers directly into the Word file. Provide detailed and complete information using terms that the general public can understand. Incomplete applications will be sent back to the primary investigator which will delay the review process. If a question does not apply to your project, indicate “NA” (Not Applicable). Please see the IACUC policy, website, or contact the IACUC Chair, if you have any questions about this form. Completed forms must be submitted electronically as a Word document to the acting IACUC Chair, Dr. Todd Underwood, Dept. of Biology, (underwoo@kutztown.edu). The signature page may be scanned and sent electronically or sent as a hardcopy via campus mail.

A. Basic Information

1. Project Title:

2. Primary Objective:
   Please check only one.
   ___ Student Teaching
   ___ Student Research
   ___ Faculty Research
   ___ Public Display

3. Type of Study/Activity:
   Please check only one.
   ___ Field Work
   ___ Lab Work
   ___ Maintaining Display Population
   ___ Maintaining Breeding population
   ___ Combination of Field and Lab Work

3. Proposed Project Start Date:
4. Proposed Project End Date:

5. Project Funding:
   Please check and identify all that apply. If funding is under review, indicate “pending”.
   ___ External Grant Agency name:
   ___ Internal Grant/Funding Source name:
   ___ Non-funded
   ___ Other Source Source name:

B. Principal Investigator Information (must be a faculty member)

1. Name:
2. Department:
3. E-mail:
4. Telephone:

**Online Training Completion** - *Must have been completed within the past three years.*

5. Working with the IACUC (AALAS). Date Completed:
6. Laboratory Safety Training (KU Environmental Health & Safety or D2L). Date Completed:
7. Field Work Training (D2L). Date Completed:
8. Other relevant training and date completed:

**Investigator Experience**

9. Please describe your experience working with the specific animals listed for this project and the type of procedures involved in this project.
C. Co-investigators, Assistants and Students and Training Documentation.

1. Identify and provide contact information for individuals involved in the project in the table below. If role is student, no contact information is needed. Also, list the dates of training completion for all individuals involved. *Add rows to the table if necessary.*

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>Dates Training Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name(s)</td>
<td>E-mail</td>
</tr>
<tr>
<td>Telephone</td>
<td>Role in Project</td>
</tr>
<tr>
<td></td>
<td>IACUC</td>
</tr>
<tr>
<td></td>
<td>Field Work</td>
</tr>
<tr>
<td></td>
<td>Lab Safety</td>
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</tbody>
</table>

*Documentation of training for all researchers listed on the protocol must be submitted to the IACUC chair before protocol applications will be reviewed by the committee.*
Co-Investigator and Assistant Experience

2. For each co-investigator and assistant, please describe their experience working with the specific animals listed for this project, the type of procedures involved in this project, and any other relevant training with dates of completion. If novices, describe training and oversight they will receive from the primary investigator. For class teaching projects, describe student experience overall not individually.

D. Animal Use Requirements

Provide the following information for each species involved in your project. *Attach a separate table if multiple species will be involved.*

1. Species (Scientific and Common Names):
2. Strain, breed or other identifying information:
3. Sex:
4. Age, Weight, and/or size:
5. Source:
6. # of animals for current year:
7. Total # of animals for project:
8. Will animals be captured or handled?
   If yes, location of temporary restraint or housing:
   If yes, duration of temporary restraint or housing:

*Note: Kutztown University does not maintain an animal housing facility and cannot currently accommodate the housing of any vertebrates except small fishes.*

E. Special Permits

1. Are permits to work with the species listed in Part D required by any state or federal agencies?

2. If yes, list the permits/agencies below and their expiration dates or their application submission dates.

F. Project Description

1. Objectives and Purpose. Briefly identify the purpose and specific objectives of your study, activity or teaching exercise.
2. Background. Explain the rationale for your study, activity or teaching exercise. Based on previous knowledge, why is this work important to your field? What will students or others learn from this work? (Do not repeat the objectives and purpose here.)

3. Methods and Animal Procedures. Explain the methods of your study that will be used to achieve your objectives in detail. The animal procedures should be described from the entry of animals into the study until their endpoints. Any surgical procedures should be noted here, but details of surgical procedures will be described in Part H below. Be sure to describe early experimental endpoint criteria that will minimize further potential pain or distress. Scientific justification must be provided if animal death is the endpoint of an experiment.

4. Is this study completely novel or does it repeat previously published research? If your study is novel, provide documentation of your study’s novelty by reporting the database(s), keywords, and time period covered for a literature search as well as the date the search was conducted. Or if this study repeats other work, provide a detailed justification indicating its necessity in teaching, undergraduate research training, or to verify another study’s conclusion.

G. Animal Use Justification

1. Explain why this project requires the use of animals (without repeating the entire objectives and purpose). Could animals be replaced by computer simulations or other non-animal models?

2. Explain the need to use the particular species identified above.

3. Provide a justification for the number of animals requested for each species in this project. Explain in terms of the minimum number required to achieve a valid sample or statistically relevant results.

4. What will happen to animals used in this project upon its completion (i.e. released back into the wild or euthanized)? If animals are to be euthanized, you must complete Part J.

H. Surgery

Will surgery be conducted as part of this study or exercise? If yes, please answer the following questions.
1. Describe in detail the procedures to be performed from preoperative preparation through postoperative care. Include details of the administration of anesthesia or any other drugs before, during, or after the surgery.

2. Identify the person who will perform the surgery and his/her qualifications.

3. Where will the surgery take place?

4. Is this a non-survival surgery? If yes, describe the details of Euthanasia in Part J below.

5. Is surgery to be conducted more than once on each animal? If yes, please provide a justification.

I. Pain or Distress Classification

1. For each species listed in Part D, fill out the following table using the pain and distress classifications below, which are based on USDA guidelines. *Add rows to the table if needed.*

<table>
<thead>
<tr>
<th>Species Name</th>
<th>Classification Category (B, C, D, or E)</th>
<th># of animals used in current year</th>
<th>Total # of animals for project</th>
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</table>

*Any projects involving animals in Category D or E must consult with the IACUC’s veterinarian before submitting an Animal Use Protocol.*

2. If procedures involve animals in Category D or E, explain alternatives you have considered and why these were not appropriate or chosen. Provide documentation of your search for alternatives by reporting the database(s), keywords, and time period covered for the literature search as well as the date the search was conducted.

Pain and Distress Categories

**Category B.** Animals held in captivity or studied in the wild that are involved in observational studies only. These studies involve no experimental manipulations and no pain or distress to animals. This category applies to animals held for breeding purposes that may be used in future experiments.
**Category C.** Animals involved in experimental procedures or restraint that cause no pain or distress or momentary, minor pain or distress. These procedures include routine blood collection, capture of animals in the wild, restraint for individual marking, radiography, injection of fluids or non-irritating substances, behavioral experiments, and euthanasia by approved methods.

**Category D.** Animals involved in experimental procedures that involve moderate pain or distress but are accompanied by appropriate anesthetic or analgesic drugs. These procedures include surgery, invasive methods of blood collection, live predator prey interactions, behavioral aggression between individuals, and the administration of substances that cause pain or distress. This category requires that the pain or distress of animals must be alleviated with appropriate drugs.

**Category E.** Animals involved in experimental procedures that involve moderate pain or distress but cannot be accompanied with appropriate anesthetic or analgesic drugs because they will alter the results of the study. These procedures include toxicity, disease, or physiological studies that produce unrelieved pain, negative behavioral conditioning via electric shocks, or other procedures producing unrelieved pain.

**J. Euthanasia**

1. Describe the intended method of euthanasia. Provide the details of the drugs, dosages, and route of administration that will be used in this process.

2. Is the intended method of euthanasia approved by the American Veterinary Medical Association? If not, provide a scientific justification for the need to use this method.

3. Identify the final destination of the carcass (i.e. museum collection) or the method of carcass disposal.

**K. Hazardous Substances**

1. Will your study involve the use of any of the following hazardous substances? Fill out the table below.

<table>
<thead>
<tr>
<th>Hazardous Substance</th>
<th>Yes</th>
<th>No</th>
<th>Specific Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radioactive substances</td>
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<tr>
<td>Biological agents</td>
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<tr>
<td>Hazardous chemicals</td>
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<tr>
<td>Carcinogens</td>
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<tr>
<td>Controlled Drugs</td>
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<tr>
<td>Recombinant DNA</td>
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</tbody>
</table>
2. If you answered yes to any of the above, describe the procedures for the safe use and proper disposal for each of the hazardous materials or contaminated animals/carcasses.

3. Has Kutztown University’s Lab Safety Committee approved of the use of any radioactive substances, biological agents of biosafety level 2 or higher, and any hazard level 4 chemicals?
L. Signatures. A signature page signed by the primary investigator and all co-investigators must be submitted to the IACUC chair before the protocol will be reviewed. The signature page may submitted via hardcopy or be scanned and sent via e-mail as a pdf document. Note: for teaching projects, student participants are not required to sign this form.

By signing and submitting this Animal Use Protocol application, all investigators certify that they have read and agree with/to the following statements.

The information submitted in this application is an accurate and complete representation of the proposed project and all investigators’ experience and training.

I will abide by all Kutztown University policies and applicable federal, state, and local laws while conducting the project proposed in this application and have or will obtain the permits necessary prior to conducting this project.

I understand that I am responsible for protecting the welfare of animals involved in my study. I agree to adhere to the ethical standards adopted by my profession for the specific group of vertebrate animals I will use in my project.

I understand that I cannot order animals or begin any research involving animals until I have received a letter of approval from the IACUC. I understand that approval of Animal Use Protocols will be for a period of one year. If further research is intended, I will submit a Renewal Animal Use Protocol application before the year is complete and any further work is conducted with animals.

I understand that if any changes are to be made to this project, including the addition of animals or personnel, I must submit an Amended Animal Use Protocol application prior to the implementation of any of these changes.

I will report any adverse outcomes that produce unexpected pain, distress, disease, or mortality in the animals involved in this project to the IACUC Chair immediately.

As Principal Investigator, I also certify that I have read and agree with/to the following statements.

I understand that I am ultimately responsible for ensuring that all legal and ethical standards will be maintained to protect the welfare of animal subjects and human researchers involved in this project. I will ensure that all co-investigators and assistants have received proper training in research procedures and occupational health and safety issues unique to the species involved in this project before any work begins.

Project title:

Principal Investigator’s Name (print):

Signature: ___________________________________________ Date: