Renewal Animal Use Protocol Application

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. Original Approved Protocol #:

2. Original Project Title:

3. Were there any amendments to the original protocol?
   If yes, list the Amended Protocol #s:

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

1. Name:

2. Department:
3. E-mail:
4. Telephone:
C. Proposed Changes to Co-investigators, Assistants and Students and Training Documentation

1. Will there be any changes to the personnel involved in your study? If yes, please answer the questions below. If no, skip ahead to Part D.

2. Will any individuals no longer be involved in this study? If yes, identify them.

3. Identify and provide contact information for all new individuals to be added to 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></td>
<td>Telephone</td>
</tr>
<tr>
<td></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>
</tr>
</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

4. For each new 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.

D. Status of Past Animal Use

1. Were there any problems in your project that resulted in unanticipated animal injury or mortality? If yes, describe in detail all problems.

2. Describe any changes to your project that are needed to prevent further unanticipated animal injury or mortality.

E. Proposed Changes to Methods and Procedures

1. Will there be any minor changes to the methods and procedures? If yes, please answer the questions below. If no, skip ahead to Part F.

2. Describe any proposed changes to your study in detail. Changes to animal requirements should be noted here but details will be reported in Part F. Note: if there are major changes to the objectives and focus of the study, a new Animal Use Protocol should be submitted instead of a renewal.

3. Explain why these changes are necessary.

F. Proposed Changes to Animal Use Requirements

1. Will there be any proposed changes to the number of previously approved animals used in this study?

If yes, please fill out the table below. Add rows to the table if necessary.

<table>
<thead>
<tr>
<th>Species</th>
<th>Number Approved</th>
<th>Number to be Added</th>
<th>Number to be deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Will there be any changes to the sex, age, weight/size, source, or pain and distress category of the animals used in this study? If yes, identify these changes for each species.
3. Will there be any new species added to this study? If no, skip ahead to question 5 below.

4. Provide the following information for each new species involved in your study. Attach a separate table if numerous species will be involved.

A. Species (Scientific and Common Names):
B. Strain, breed or other identifying information:
C. Sex:
D. Age, Weight, and/or size:
E. Source:
F. # of animals for current year:
G. Total # of animals for project:
H. Will animals be captured or handled?
   If yes, location of temporary restraint or housing:
   If yes, duration of temporary restraint or housing:

I. Pain and Distress Category (B, C, D, E):

For each new species listed in question 4 of Part F, 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>
</tr>
</thead>
</table>

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

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.

5. Provide a justification for any changes in species, animal numbers or their sex, age, weight/size, source, or pain and distress category.

6. If any new procedures involve animals changing to 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.
G. Signatures. A signature page signed by the primary investigator and all co-investigators must be submitted to the IACUC chair before the amended protocol will be reviewed. The signature page may be 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 Renewal 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 my study 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:
Co-investigator’s Name (print):

Signature: ______________________________________________

Date:

Co-investigator’s Name (print):

Signature: ______________________________________________

Date:

Co-investigator’s Name (print):

Signature: ______________________________________________

Date:

Co-investigator’s Name (print):

Signature: ______________________________________________

Date:

Co-investigator’s Name (print):

Signature: ______________________________________________

Date: