Purdue Animal Care and Use Committee (PACUC)
APPLICATION TO USE VERTEBRATE ANIMALS
IN RESEARCH, TEACHING, OR TESTING

Principal Investigator/Project Director: 

Protocol Title: 

Coeus Protocol Number: 

IACUC Protocol Electronic Submission Instructions:

1. Justification for Animal Use and Species

1.1 How was it determined that alternatives (e.g., less painful/distressful animal procedures, use of phylogenetically lower species or non-animal procedures) could not be substituted (i.e., why live animals must be used)? "Alternatives" refers to methods, models, and approaches that result in the reduction of the number of animals used, that incorporate refinements of procedures which result in the lessening of pain or distress to animals, or that provide for the replacement of animals with non-whole animal systems or the replacement of one animal species with another, particularly if the substituted species is non-mammalian or invertebrate. There must be a written narrative description of the methods and sources which were consulted to determine the availability of alternatives (reduction, refinements, replacement).


Note: ANY POTENTIALLY PAINFUL/DISTRESSFUL PROCEDURES IN THIS PROJECT MUST BE ADDED AS A KEYWORD USED IN YOUR LITERATURE SEARCH in the Protocol Details - Alternative Search Tab in the Coeus record.

1.2 Briefly state the objective(s), including the rationale for using vertebrate animals. Use terminology that can be understood by someone with minimal knowledge of the specific scientific area.
1.3 Indicate the scientific rationale for the number of animals to be used. How did you determine the number of animals required? Your explanation should include the numbers per group, number of groups, power analysis used, number of animals needed for training, etc. THE TOTAL NUMBER OF ANIMALS LISTED IN THIS SECTION MUST MATCH THE NUMBER GIVEN IN THE COUNT COLUMN IN THE SPECIES/GROUPS TAB OF COEUS.

1.3a Will you be maintaining a breeding colony as part of this protocol? YES ____ NO ____
If yes, please answer the following questions. If no, continue to question 1.4.

a. How will the colony contribute to the overall objectives of your research and/or teaching activity?

b. Please provide an explanation as to why animals from commercial vendor sources are not appropriate and this breeding colony is necessary.

c. If breeding is proposed solely to maintain a line for future use, include a discussion about why cryopreservation techniques are not appropriate.

1.3b PACUC Policy states that animals must be weaned at 21 days (see Mouse Housing and Cage Density Policy at http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/policies-guidelines.php). Will the animals on this protocol be weaned at 21 days? YES ____ NO ____*

*If no, please state what day animals will be weaned and provide an explanation as to why animals cannot be weaned on day 21.

1.4 Enter the following information for all applicable protocol locations:
*If you will need to transport animals between buildings during the course of this protocol or keep animals in your laboratory for greater than 12 hours, please refer to the PACUC policies below.
Adequate Animal Care in Animal Study Areas: http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/Adequate%20Animal%20Care%20in%20Study%20Areas.pdf

1.5 Are Aquatic species being used on this protocol? YES _____ NO _____

1.5a If yes, what water quality parameters will be monitored and how frequently will the monitoring be done?

1.6 Are genetically modified animals (GMA’s) being generated? YES* _____ NO _____
*Must obtain Institutional Biosafety Committee (IBC) approval. Contact 41496 or rwgolden@purdue.edu.

1.6a If yes, how will the new lines generated be monitored for conditions that could negatively affect the well-being of the animals?

1.7 Are the animals on this protocol considered critical or irreplaceable? YES___ NO____

1.7a If yes, how do you plan to preserve the line of this irreplaceable animal (e.g., cryopreservation, etc.)?

1.8 Will you be fluid and/or food restricting any animals on this protocol (not for surgery purposes)? YES _____ * NO _____
http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/Food%20and%20Water%20Restriction-Deprivation.pdf

1.8a *If yes, describe in detail the amount and duration of such restriction. Body weight on fluid/food restricted animals must be recorded weekly by study personnel. Written records should be maintained for each animal to document daily food and fluid consumption, hydration status, and any behavioral and clinical changes used as criteria for temporary or permanent removal of an animal from a protocol.
See PACUC Policy on Use of Non-pharmaceutical Grade Compounds at www.purdue.edu/animals.

Please acknowledge by checking the box below:

The FDA publishes the Green Book (veterinary) and the Orange Book (human) databases of approved drugs. Substances listed in these databases are recognized as pharmaceutical-grade. Please use the links to aid in your search. Also, you may determine whether a particular drug is available by consulting the FDA database.

☐ As the PI on the protocol I assure, that I have conducted a search on a FDA recognized pharmacopeia to see if there is a pharmaceutical grade equivalent to the compound that I am proposing to use in this protocol.

1.9 Are pharmaceutical grade drugs or chemicals used for this protocol? YES__ NO__ N/A__

1.9a Are non-pharmaceutical grade drugs or chemicals used for this protocol? YES__ NO__ N/A__

1.9a.1 If yes, please provide justification for using the non-pharmaceutical grade drug or compound (e.g., necessary to meet scientific goals, need to replicate methodology, inappropriate concentration or formulation of available pharmaceutical grade, pharmaceutical grade vehicle not appropriate for planned route of administration, non-availability of pharmaceutical grade. Note: cost savings alone is not an adequate justification)

1.9a.2 Describe the steps that will be taken during the preparation of the drug or compound to ensure sterility (e.g., use of filter, sterile diluents, sterile container if appropriate), the appropriate pH as feasible and that an appropriate non-toxic vehicle/diluents will be used. Include proposed shelf life/use by date, labeling method to include drug or compound name, date prepared, expiration date and storage method.

1.9a.3 Describe who (e.g., someone on this protocol, a pharmacist [veterinary or human], etc.) will be responsible for monitoring the drug or compound preparation and use and any relevant experience handling the drug or compound.
1.9.4 Describe the site and route of drug or compound administration. Include potential side effects and adverse reactions. Also include who will be responsible for monitoring the animals and how they have been trained to look for adverse reactions.

2.0 Will expired medical materials (see PACUC Policy at: www.purdue.edu/animals) such as fluids, sutures, catheters, implants, etc. be used in any procedures, to include acute terminal procedures? YES_______ NO_____
(Note: the use of expired anesthetics, analgesics, euthanasia solutions, emergency drugs, etc. is prohibited even if the procedure is acute/terminal.)

If yes, indicate the type of expired material to be used, the type of procedure for which it will be used (acute/terminal vs. survival), justify the usage and describe how such materials will be clearly labeled and segregated from non-expired materials.

2 Personnel Training Qualifications and Conflict of Interest Disclosure

2.1 Personnel Qualifications. List the names of all individuals (including yourself as project director) who will be conducting the procedures on animals. If no qualification number has been issued, please refer to the PACUC website for information on how to complete an Animal Use Qualification Form (http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/qualification-training.php). PERSONNEL LISTED IN THIS SECTION MUST MATCH THE PERSONNEL LISTED IN THE INVESTIGATORS/STUDY PERSONNEL TAB IN COEUS WHENEVER POSSIBLE.

<table>
<thead>
<tr>
<th>Name</th>
<th>Qualification Number</th>
<th>Specific Procedures Each Person Will Perform (e.g., surgery, injections, blood collection, euthanasia, etc.) PLEASE DO NOT LIST JOB TITLES</th>
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2.2 Conflict of Interest and/or Financial Conflict Interest. An individual financial conflict of interest in the context of research with animal subjects may occur when a specific PACUC protocol is used in research projects that are related to, or may impact, the business scope and activities of
companies/entities where Investigators/Researchers/Personnel using that protocol may have a Significant Financial Interest (i.e., an outside income from the company that exceeds $5,000 and/or ownership interest in such outside entity).

**Do you, or any other personnel listed on this protocol, have any financial interests and/or real or potential conflicts of interest related to this study? YES ___*  NO ____**

*If you responded YES, please choose the situation that best describes the disclosure and management status of any and all financial interests/conflicts of interest related to this PACUC protocol:

A. _____ I, and/or study personnel, have already disclosed relevant financial interests and/or conflicts of interest to Purdue officials in the Office of the Executive Vice President for Research and Partnerships (EVPRP) and all identified conflicts of interest are managed.

B. ______ I, and/or study personnel, are in the process of disclosing financial interests and/or managing conflicts of interest related to this protocol and/or have filed relevant Reportable Outside Activity Form(s) with the Office of the Vice President for Ethics and Compliance.

**Guidance to Investigators:** If B was chosen, please complete your Research Related Significant Financial Interest Disclosure (at [https://webapps.ecn.purdue.edu/VPR/PDD](https://webapps.ecn.purdue.edu/VPR/PDD)) and/or your relevant Reportable Outside Activity Form (https://webapps.ecn.purdue.edu/VPEC/OAD), at your earliest convenience (if you have not done so already).

3 **Surgical Procedures**

3.1 Will there be surgical procedures on this protocol? YES ___  NO ____
(If yes, complete items 3.2-3.15. If No, go to section 4)

3.2 Describe the training the surgeon has received to perform the surgical procedures listed on this protocol application.

3.3 Describe the preoperative procedures that will be performed to prepare the animal(s) for surgery (e.g., fasting of animal(s) to include length of fast, withholding of water to include length of time withheld, pre-anesthetic, analgesic or antibiotic administration [include dose in mg/kg and route of administration], catheter placement or other procedures).

3.4 Will the surgery be done aseptically? YES ____  NO ____

3.4a. If yes, describe aseptic procedures (e.g., include information regarding how instrument/equipment is sterilized; how animal is prepared such as hair clipping and skin disinfection and use of drapes; and surgeon preparation such as hand scrub, use of sterile gloves, sterile gown, cap, mask).
3.4b. If no, please provide an explanation. NOTE: Terminal surgeries greater than 6 hours should be performed using aseptic technique.

3.5 Describe any survival and/or non-survival surgical procedures in enough detail such that the PACUC reviewers can determine what procedures are actually being performed.

3.6 Specify anesthetic drugs to be used during the surgical procedures. Include dosage(s) [in mg/kg of body weight or percent concentration of gases] and route(s) of administration. THE USE OF EXPIRED DRUGS IS STRICTLY PROHIBITED FROM BEING USED IN AN ANIMAL AT PURDUE UNIVERSITY.

3.7 List the name(s) of veterinarian(s) or other sources consulted in regard to use of drugs listed.

3.8 How will you determine that the animal is adequately anesthetized throughout the procedure?

3.9 Will you be using any muscle relaxants or paralytic drugs? YES___ NO___ N/A___

3.9a. Provide the name(s), dosage(s), and route(s) of administration of these drugs and provide justification for the use of these drugs. Describe in detail the monitoring procedures (e.g., rise in heart rate, rise in blood pressure) that will be used to determine that sufficient anesthesia/analgesia is present. Paralytic agents cannot be used without anesthetics and assisted ventilation.
3.10 Describe any physical methods used to support the animal during surgery (e.g., circulating warm water heating pad, electrical heating pad, blankets, fluid administration, etc.)

3.11 Will this surgery involve recovery from anesthesia? YES___ NO___

3.11a. If yes, describe post-surgical care and monitoring. Include any physical methods used to support animal such as heating blanket and fluid administration. Include frequency of post-procedure observations, how long observation will continue and individual(s) responsible for monitoring animal in immediate postoperative period (until animal can ambulate) and thereafter including after-hours, weekends, and holidays as applicable.

3.11b. When will sutures or staples be removed from the animal?

3.12 Will postoperative analgesics be provided to relieve pain in animals? YES___ NO___

3.12a. If yes, provide the agent used, dose (mg/kg), route, frequency of administration (e.g., times per day), and duration of administration (e.g., days). NOTE: “As needed” is not an adequate response. How often will the animal be checked and what signs will be used to determine the need for analgesic administration?

3.12b. If no, provide a justification for not using postoperative analgesics.

3.13 What post-operative complications can reasonably be anticipated? How will potential complications be detected, managed, and resolved? List the specific criteria that will be used to decide when to perform euthanasia prior to completion of the study or to otherwise relieve the suffering (e.g., refusal to eat, loss of body weight, tumor ulceration or total burden, health problems refractory to medical intervention, etc.).

3.14 Describe your planned recordkeeping (pre-surgical, surgical, and post-surgical). Include the location at which such records will be maintained that will allow access to LAP, USDA, and PACUC as needed (for both survival and non-survival).

3.15 Will more than one major survival surgical procedure be performed on any one animal?  
YES ___ *  NO ___  
3.15a. *If yes, justify, in detail, the scientific necessity for performing more than one procedure on an individual animal and describe the interval between the surgeries. Cost may not be used as scientific justification.

4 Non-Surgical Procedures

4.1 Describe the proposed non-surgical use of animals, including pilot studies, using terms that can be understood by those not familiar with your area of expertise.

4.2 Please include a clear, concise, sequential description of the experimental design involving the use of animals that is easily understood.

4.3 Provide a description of the procedures to be performed on the animals including drugs and chemicals. THE USE OF EXPIRED DRUGS IS STRICTLY PROHIBITED FROM BEING USED IN AN ANIMAL AT PURDUE UNIVERSITY.

4.4 Include a description of how the procedures performed could have an impact on the animals’ health and well-being.
5 Anesthesia/Analgesia/Pain Relief for Non-Surgical Studies

5.1 Will the animal be subjected to any non-surgical procedure that might cause more than momentary or slight pain or distress (see list below)? YES____ NO____

5.1a. If yes, describe the painful/distressful condition and check all appropriate conditions that apply.

Check all that apply:

___ Toxicity or LD50 tests
___ Tumor/tumor cell implant
___ Painful/noxious stimuli
___ Tissue trauma
___ Death/mortality as an endpoint
___ Infectious agent administration
___ Behavioral or physiological changes
___ Prolonged physical restraint*
___ Study of natural disease/state
___ Other significant incapacitation

*Definition of Prolonged Physical Restraint: Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy or experimental manipulation. Prolonged physical restraint (lasting longer than 30 minutes) must be scientifically justified and requires prior approval by the PACUC. The complete PACUC-approved guideline on prolonged physical restraint may be found at: http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/Physical%20Restraint%20Guideline.pdf.

5.2 Indicate the approximate period of time animals may experience such pain or distress.

5.3 Will anesthetics, analgesics, and / or tranquilizers be used? Yes ____ No ____ (see 5.8)

5.3a. If yes, provide the agent(s) used, dose (mg/kg), route, frequency of administration (e.g., times per day) and duration of administration (e.g. days). NOTE: “As needed” is not an appropriate response for this section unless accompanied by a description of the signs that will be used to determine the need for anesthetic, analgesic, and/or tranquilizer administration. THE USE OF EXPIRED DRUGS IS STRICTLY PROHIBITED FROM BEING USED IN AN ANIMAL AT PURDUE UNIVERSITY.

5.4 Name(s) of veterinarian(s) or other sources consulted in regard to use of drugs listed.
5.5 How do you determine that the animal is adequately anesthetized throughout the non-surgical procedure?

5.6 If anesthetic gases are used, what precautions will be taken to protect personnel?

5.7 Describe the non-surgical post-anesthetic care and monitoring.

5.8 If any animals will undergo non-surgical procedures in which pain or stress is not relieved with the use of anesthetics, analgesics, tranquilizers or euthanasia, justify why pain or distress relief cannot be provided.

6 Humane Endpoints

NOTE: The attending veterinarian (AV), or designated veterinary staff for the AV, has full authority to treat or humanely euthanize animals at his/her discretion. Ideally, this will be done after consultation with the Principal Investigator or responsible member of the research and/or teaching team. However, the AV or designated staff is NOT required to seek approval from the investigator, the investigator’s department chair, or the animal care and use committee (PACUC) in order to treat or euthanize animals for humane reasons if such actions are judged prudent by the AV or designated staff for the welfare of the animal.

6.1 List the specific criteria that will be used to decide when to perform euthanasia prior to completion of the study or to otherwise relieve the suffering (e.g., refusal to eat, loss of body weight, tumor ulceration or total burden, health problems refractory to medical intervention, etc.). [http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/HumaneEndpointsforResearchandTeachingAnimals.pdf](http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/HumaneEndpointsforResearchandTeachingAnimals.pdf). Under Guidelines, “Humane Endpoints for Research, Teaching, or Testing Animals.”
6.1a What specific training has been provided to personnel responsible for assessment and recognition of the humane endpoint listed above?

7 Animal Disposition

7.1 Will animals be euthanized? YES___(complete 7.2-7.5) NO___(complete 7.6)

7.2 Briefly describe the method of euthanasia (specify agents, doses, and routes of administration) and who will euthanize the animals.

7.3 If chemical euthanasia is used, include the method that will be used to assure that the animals will not recover (e.g., monitoring vital signs, secondary physical method of euthanasia, creation of a pneumothorax, etc.). [http://www.avma.org/resources/euthanasia.pdf](http://www.avma.org/resources/euthanasia.pdf)

7.4 If you are using a physical method of euthanasia (e.g., cervical dislocation, decapitation), justify the need for use of this method.

7.5 Carcass disposition will be done by (check all that are applicable):  

___ Univ. Collection Service  
___ Rad. And Env. Management (REM)  
___ Animal Disease Diagnostic Lab  
___ Other (please specify)

Other:

7.6 Live animal disposition will be done by (check all that are applicable):

Species

_____ Return to colony  
_____ Adoption
<table>
<thead>
<tr>
<th>Option</th>
<th>Action</th>
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<tbody>
<tr>
<td>Transfer to another project</td>
<td>(Submit a PACUC Form 9 for approval to transfer animals.)</td>
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<tr>
<td>Return to wild</td>
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<tr>
<td>Sale (specify below)</td>
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<tr>
<td>Other (specify below)</td>
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**IMPORTANT:** Please be certain to upload this file into your CoeusLite Protocol submission when complete. Go to the “Attachments” screen and upload with the Document Type “Protocol Application Attachment”.