Governors State University

Live Vertebrates in Research and Teaching Application

Instructions: This form must be completed, in lay terms, by investigators wishing to use live vertebrates or tissues harvested directly from vertebrates for research or teaching activities conducted at, or funded through, Governors State University. Once complete, the form must be submitted to the Institutional Animal Care and Use Committee (IACUC) c/o OSPR in G351.

IACUC must approve this application before live vertebrates or tissues harvested directly from vertebrates can be acquired or used in any research and teaching activity. IACUC will approve protocols for a period up to three years. For activities extending beyond three years, a new application must be submitted and approved prior to the protocol expiration date. If there are deviations from the approved protocol, a new application must be submitted to the IACUC. Annual reports are required for approved protocols.

All project personnel must have completed the appropriate CITI training and include the completion certificates with this protocol application.

If this protocol application has a related request for funding application, that application must be included with this application. The documents will be reviewed for consistency.

1 General Protocol Information

1.1 Protocol Title: Click here to enter text.

1.2 Funding source or agency: Click here to enter text.

1.3 Award or proposal number: Click here to enter text.

1.4 Identify the vertebrates or harvested tissues to be used: Click here to enter text.

1.5 Number of live vertebrates or harvested tissues to be used: Click here to enter text.

2 Personnel and Qualifications

2.1 Principal Investigator name: Click here to enter text.

2.2 Office location: Click here to enter text.

2.3 Office phone: Click here to enter text.

2.4 Email address: Click here to enter text.

2.5 Describe the Principal Investigator's experience and training with the vertebrates or harvested tissues, project methods and euthanasia.
Click here to enter text.

2.6 For each individual who will handle live vertebrates or tissues harvested directly from vertebrates, provide their **name, project role, email address, phone number, qualifications and experience**. This includes employees, students, collaborators and volunteers.
Click here to enter text.

3 Vertebrate Purpose, Rationale and Location

3.1 Provide a brief description of the project; indicate the purpose and why the study is important to human or animal health, the advancement of knowledge, and/or the good of society.
Click here to enter text.

3.2 Explain your rationale for the vertebrate used; include justification for the appropriateness of the species selected. The rationale should include reasons why non-vertebrate models cannot be used, with appropriate literature citations.
Click here to enter text.

3.3 Justify the number of vertebrates to be used. The number of vertebrates should be the minimum number needed. Indicate specific groups to be used and the number of vertebrates per group with rationale using statistical analysis, if possible. This description should clearly account for the total number of vertebrates requested over the three year period of protocol approval period.
Click here to enter text.

3.4 Describe any vertebrate phenotypic abnormalities and provisions for addressing these abnormalities that will affect vertebrate/tissue health or wellbeing.
Click here to enter text.

3.5 Identify where the vertebrates will be obtained or purchased:
Click here to enter text.

3.6 Give the facility and room number where the vertebrates will be housed:
Click here to enter text.

4 Methods for Pain and Distress to Vertebrates

4.1 Please mark the box for each listed method that will be used in the protocol. (Clicking the box will mark and unmark the boxes.)

☐ Isotopes

☐ Prolonged restraint

☐ Electric shock

☐ Water restriction

☐ Muscle paralyzing agents

☐ Potential significant debilitation

☐ Multiple surgeries on same vertebrate

☐ Terminal Surgery

☐ Survival surgery

☐ Hazardous/Infectious agents

☐ Controlled substances/chemicals

☐ Recombinant DNA

☐ Pain/distress without anesthetic/analgesic

4.2 Identify the expected vertebrate pain or distress classification. Please include the **species common name, USDA classification, number of species needed for each year and the total number of species needed** for the project.
Click here to enter text.

4.3 If a study is USDA Classification E, indicate any non-pharmaceutical methods to minimize pain and distress.
Click here to enter text.

4.4 All methods for euthanasia must be consistent with the most current version of the "American Veterinary Medical Association Guidelines for the Euthanasia of Animals" or "Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research." Describe the methods to ensure vertebrate death.
Click here to enter text.

4.5 Describe any other procedure or method that may cause harm or distress to the vertebrate that was not listed above.
Click here to enter text.

4.6 Federal regulations require a written description of methods and sources used to determine that there are neither non-vertebrate nor less painful/distressful vertebrate models/methods with which to perform work that results in pain or distress to vertebrates. Described through the following:

4.6.1 Identify search databases such as Medline, Biosis, or AWIC.
Click here to enter text.

4.6.2 Identify dates the searches were conducted.
Click here to enter text.

4.6.3 Identify the keywords used, one of which should be "alternatives" and others to include the species of animal, and the procedure likely to result in pain or distress including antibody production, ascites, tumor growth, and surgery.
Click here to enter text.

4.6.4 Describe your search results.
Click here to enter text.

5 Agents

5.1 Pharmaceutical grade compounds should be used when available. If you plan to administer non-pharmaceutical grade compounds to vertebrates, please list the compounds and provide justification for not using pharmaceutical grade agents.
Click here to enter text.

5.2 The use of hazardous and infectious agents requires the approval of the Institutional Biosafety Committee (IBC). Please attach the approval documents and provide the **agent type, agent name, IBC approval date and the IBC number**.
Click here to enter text.

5.3 Study will be conducted at biosafety level: Click here to enter text.

5.4 Describe the equipment and processes to mitigate any risks for personnel, including personal protective equipment, ventilation and engineering controls.
Click here to enter text.

6 Animal Use Procedures

6.1 Describe procedures involving vertebrates using the animal use and procedure template. The description should allow reviewers to understand the sequential use of individual vertebrates from entry into the experiment to the endpoint of the study. If field collection of vertebrates is part of this work, indicate methods of trapping and include copies of any relevant state and federal permits.
Click here to enter text.

6.2 Procedures with vertebrates should avoid or minimize discomfort, distress and pain to the vertebrates, consistent with sound research design. Please the address the following:

6.2.1 Method of marking or identification of vertebrates.
Click here to enter text.

6.2.2 Experimental injections or inoculations including infectious agents, adjuvants, test compounds; including dose, sites, volume, route, and schedules.

Click here to enter text.

6.2.3 Blood or other sample withdrawals including volume, frequency, withdrawal sites, and methodology.

Click here to enter text.

6.2.4 Methods of restraint. For periods of restraint that are longer than routine procedures like blood withdrawals, it must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be utilized.

Click here to enter text.

6.2.5 Other procedures including survival studies and tail biopsies.

Click here to enter text.

6.2.6 Resultant effects, if any, that the vertebrates are expected to experience including pain, distress and ascites production.

Click here to enter text.

6.2.7 Other potential stressors including food deprivation, water deprivation, noxious stimuli, environmental stress and procedures to monitor and minimize distress.

Click here to enter text.

6.2.8 Experimental endpoint criteria including 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 illness or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

Click here to enter text.

6.2.9 Veterinary care. Consultation with the Attending Veterinarian is highly recommended and should indicate plan of action in case of vertebrate illness, including initiate treatment and euthanize.

Click here to enter text.

7 Surgical Procedures

7.1 Identify surgical procedures to be performed. Describe preoperative procedures such as fasting, monitoring and supportive care during surgery and the aseptic methods to be utilized. Include analgesics administered before, during, and after a surgical procedure.
Click here to enter text.

7.2 Who will perform the surgical procedures and what are their qualifications and/or experience?
Click here to enter text.

7.3 Where will the surgical procedures, preoperative care and postoperative care be performed? Include the building and room.
Click here to enter text.

7.4 If survival surgery, describe postoperative care and frequency of observation. Provide the responsible individuals names and contact information in case of vertebrate emergencies.
Click here to enter text.

7.5 If paralytic agents are used during surgery, describe how the vertebrate's ventilation will be maintained and how pain will be assessed.
Click here to enter text.

7.6 If more than one major survival surgery will be performed on any vertebrate, explain the need to perform more than one surgery. Major survival surgery is that which penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions.
Click here to enter text.

8 Availability of Alternative Studies

Federal regulations require assurance from the principal investigator that the work proposed in this protocol does not unnecessarily duplicate previous studies. Provide a statement indicating that studies such as these have not been done. In this statement, include the sources used to make that determination such as database searches, attendance at meetings and conversations with colleagues. If the proposed studies are similar to those done previously, indicate how the studies differ.
Click here to enter text.

9 Certification

The principal investigator whose signature appears below agrees to comply with the NIH Guide for the Care and Use of Laboratory Animals, the Federal Animal Welfare Act, the Guidelines of the American Society of Mammalogists for the use of wild mammals in

research, and the euthanasia guidelines established by the American Veterinary Medical Association Panel on Euthanasia. The undersigned also certifies to the best of their knowledge, the activities proposed in this protocol do not unnecessarily duplicate any previous experiments.

X _____

Principal Investigator Signature Date: Click here to enter a date.
Name: Click here to enter text.
Title: Click here to enter text.

10 IACUC Review and Approval

GSU IACUC Use Only

Application Receipt Date: Click here to enter a date.

Assigned IACUC Protocol Number: Click here to enter text.
Principal Investigator Name: Click here to enter text.
Protocol Title: Click here to enter text.

Initial Protocol Review Date: Click here to enter a date.
Review Notes: Click here to enter text.

2nd Review Date: Click here to enter a date.
Review Notes: Click here to enter text.

Approval Date: Click here to enter a date.

The IACUC chair's signature indicates that the aforementioned application has been reviewed and approved in its entirety by IACUC. Any conditions of approval must be indicated below.

Conditions for Approval:

Click here to enter text.

X _____

IACUC Chair Signature

Date: Click here to enter a date.

Name: Click here to enter text.
Title: Click here to enter text.