JACKSON STATE UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
APPLICATION FOR USE OF VERTEBRATE ANIMALS

IACUC USE ONLY:	
Protocol No.: _____	Approval Date: _____
Department: _____	Expiration Date: _____

1. **Protocol Title:**

   Anticipated start date of study: _____ Anticipated end date of study:_____
   Study duration: ☐< 1 year ☐1 year ☐1-2 years ☐2-3 years
   Protocol Status: ☐New ☐ Revision ☐3rd year

2. **Principal Investigator:** _____ School/Dept.: _____
   Contact. No.: _____ E-mail Address: _____
3. **Co-Investigator(s):** _____
4. **External Funding Source:** _____ ☐Awarded ☐Pending ☐Other
5. **Will any outside contracts be used in this study?** ☐No ☐Yes If "YES" specify the outside contracts to be used: _____
6. **Is any research related to this study being conducted at another institution or facility?** NO☐ Yes☐ If "YES", list other involved institution(s), investigator(s) and their respective phone number (s).
7. **Has this protocol undergone peer review?** Has it been evaluated for scientific merit and experimental design? NO____ Yes____. If "YES", list the individuals who provided the peer review.

   Name and Title: _____; Institution: _____; Date _____

8. If supported by Departmental funds or industrial sources that do not supply external peer review or if the procedures proposed have not received a review for scientific merit, two reviewers not associated with the project must perform such a review for scientific merit. If there is no conflict of interest, one reviewer should be the department chairman/section head. The undersigned have reviewed this proposal and find it to be of scientific merit.

   Reviewer _____ Date _____
   Reviewer _____ Date _____

9. **Training**

   List all individuals involved in the study who will perform procedures in live animals, or are responsible for their welfare. State their duties. The IACUC must determine if individuals are properly trained to appropriately discharge their duties. *NOTE: The IACUC sponsors ongoing training seminars. Details regarding the seminars can be obtained by contacting the IACUC office.*

Name	Role and Duties	Description of Training

1**0.Occupational Health**

List all individuals who will be involved in the proposed study who will be exposed to animals, animal wastes, body parts, or body fluids, and/or personnel exposed (in same room/area) to aerosolized particles. These individuals must be enrolled in the Jackson University Occupational Health Program for Personnel Caring For or Using Laboratory Animals. It is the responsibility of the Principal Investigator to enroll these individuals and to ensure that the IACUC is notified of the addition of any new employees with animal exposure.

Name	Are you currently in the JSU Occupational Health Program? Yes or No

Emergency contact: List the person(s) to be contacted in case of an emergency or clinical deterioration outside of normal working hours (list at least two persons). Name/phone number(s)/pager_____
Name/phone number(s)/pager_____

11. Objectives/Hypothesis: In language that will be understood by members of the general public, state the scientific aims of the study and/or hypothesis to be tested.

12. Experimental Design and Methods: In language that will be understood by members of the general public, provide a succinct outline of the formal scientific plan and direction for experimentation. If several experimental groups or sequential studies are to be included in the protocol, a description of the experimental design for each separate experimental group should be contained in sub-parts to this section. For each experimental group, justify the number of animals required for this research project. Be specific. When an inferential statistics is used, show the result of the power calculation including values for means (or difference between means) and variance for parametric statistics used to determine the proposed number of animals. For other experiments, supply appropriate justification. Diagrams or figures may be helpful in communicating your intentions. The specialized language of grant proposals is generally not acceptable.

13. Number of animals requested and categories of manipulation: Provide the total number animals anticipated to be used for the approval term of this protocol. (3 years). Individual animals are categorized by the most severe manipulation category the animal will experience, i.e. an animal that will have injection 'B' and a non-survival surgery 'C' would be listed under 'C'. See A-E below:

[A] Live animals will: receive non-painful manipulations, be held for observation as needed in herds for agricultural research; experience no treatments, manipulations, etc., be humanely killed to obtain tissues, cells, etc., receive special diets which do not result in appreciable clinical signs of pain or distress. Dead animals or parts of animals will be obtained for study.

[B] Live animals will receive painful or stressful stimulus of SHORT duration without anesthesia, which results in a short-term response. Examples include but are not limited to: injections, field trapping/tagging, polyclonal antibody production, behavioral studies, short-term pain/stimulus tests as used in analgesic evaluation, tattooing, blood sampling, tail-tipping for genotyping, and standard agricultural husbandry practices (i.e. dehorning, branding, castration).

[C] Live animals will have significant manipulations, surgery, etc., performed while anesthetized. The animals will be killed humanely at the termination of the procedure without regaining consciousness.

[D] Live animals will have manipulations performed while anesthetized and are allowed to recover and/or animals will develop discernable clinical signs indicating pain, distress, or significant physiological changes spontaneously or as a result of specific experimental procedures. Examples include, but are not

limited to: Survival surgical procedures of any type, studies which would include tumor development (including Ascites), dietary studies resulting in discernable clinical signs of pain or distress, mother/infant separation, prolonged restraint of conscious animals for purposes other than routine clinical procedures, studies utilizing hazardous materials in live animals (Carcinogenic Agents, Radioactive Agents, Infectious Agents, Toxic Chemicals, etc.), restrictions of food/water intake for more than 12 hours, severe climatic stress, drug addiction, etc. PALLIATIVE TREATMENT MUST BE DESCRIBED AND WILL BE PROVIDED AS NEEDED OR REQUIRED BY THE IACUC.

[E] Live animals will experience significant/severe pain or distress. Examples as in [D] above, or the use of paralytic drugs, WITHOUT BENEFIT OF ANESTHETICS, TRANQUILIZERS, OR ANALGESICS. Significant scientific justification is required for using this Manipulation Category and criteria for moribundity and euthanasia must be provided.

Experimental Group	Species	Category of Manipulation	Number	Maximum Days per Animal

Justification for Category of Manipulation: Describe how the category of manipulation for each experimental group of animals was determined. Each experimental group should be categorized according to the most severe procedure that group of animals will experience.

14. Will any of the experiments described in this protocol involve the euthanasia/experimental death of pre-weanling animals (animals born/hatched, but euthanized prior to separation from parent)? No☐; Yes☐

If yes, you must report the number of pre-weanling animals used to the Animal Resource Program (ARP) on a monthly basis. The Office of Research Development will forward a reporting form to you upon approval of this protocol. The United States Department of Agriculture (USDA) and the American Association for the Accreditation of Laboratory Animal Care (AAALAC) require annual reporting of the numbers of each species of animals used in research and teaching. While the ARP keeps count of the numbers of weaned and adult animals used at JSU, it is unable to account for animals used prior to weaning.

15. RECORDS & MONITORING: State where the aforementioned records will be available for inspection by the IACUC, Attending Veterinarian, and federal officials. For daily animal monitoring, describe your record keeping system for observation of animal health and welfare.

16. HOUSING: List the location of the general housing facility: _____ .

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Will the animals be in a lab outside of the general housing facility listed above at any time? Yes No. If yes, where will the animals be? For how long and why the specified length of time? Will the alternate housing meet IACUC standards for animal care and welfare? Also, describe how the animals will be transported to/from the lab.

17. METHODOLOGY: Please check all the procedures that will be implemented and provide additional information as requested.

☐ Field Observation Only:

☐ Tissue, Organ, Device, Etc. Collection: Describe materials being collected: Items to include: Tissues/Organs/experimental devices harvested post-mortem, feces/urine/milk collectionDescribe materials being collected:

☐ Breeding: Rodent Breeding Program section of this form must be completed.

☐ Live Capture of Wild Animals: Complete section on restraint of movement.
Describe method of capture: _____.
Will animals be tagged? Method: _____.

☐ Fasting and/or Water Deprivation: Why will animals be deprived of food and/or water? What will be the duration/frequency of deprivation and describe the possible effects of deprivation.

☐ Special Diets: Detail the composition of the special diet and any special equipment needed: _____
Who will prepare the diets?_____ How often are animals fed? _____ Briefly describe the rationale for utilizing a special diet and possible affects on the animals' health_____.

☐ Restraint of freedom of movement while awake:
Why will activity be restricted?
Method of restriction:
Duration:_____ Frequency:
Frequency of monitoring during restriction:

☐ Bleeding
Frequency of bleeding: _____. Volume of blood drawn:
Method of collection: _____ Total blood draws per animal:
Will Fluids be replaced? _____.

☐ Tail-tipping
Initial the Regimen you will be following:
____Anesthesia will not be required for tail tipping under the following conditions: Less than 1cm of the intact tail has been or is being removed. It is recommended that each tail tipping should remove .5cm or less at a time. No more than 2 tail tippings per animals.
_____If more than 2 tail-tippings need to be performed on an individual mouse, complete the information below:
_____If more than 1 cm of the tail is being removed, complete the information below:

In the event that more than 2 tail-tippings need to be performed on an individual mouse and/or more than 1 cm of the tail is being removed, the investigator must provide scientific justification for utilizing these methods. Use anesthesia for the procedure: (Regimens appropriate for this procedure include administration of a topical anesthetic to the tail tip or administration of an inhalation anesthetic.

Agent:_____ Dose:_____.
Duration of Action:_____.

☐ Immunization/Antibody/Ascites Production and Collection

Monoclonal/Polyclonal antibody production:
Agent(s) used:_____. Volume injected: _____
Site of injection: _____ Frequency of injection:_____
Frequency of fluid withdrawal: _____ Volume of fluid withdrawn: _____
Maximum number of collections: _____ Frequency of observation:_____
Adjuvant(s) used:_____.

☐ Inoculation of biological materials of mammalian-origin into rodents:

Which of the following biological materials will be inoculated:

☐ tumors ☐ cell lines ☐ hybridomas ☐ embryonic stem cells ☐ blood or serum
☐ monoclonal or polyclonal antibodies ☐ other

What is the host species origin of these biological materials?
☐ mouse ☐ rat ☐ hamster ☐ rabbit ☐ human ☐ other

What species will be inoculated with the biological materials?
☐ mouse ☐ rat ☐ hamster ☐ other

Have these biomaterials been passed through rodents previously?
☐ Yes ☐ No If yes, approximately how many times have they been passed?

☐ Test Drug administration
Drugs to be administered:_____.
Amount and route of administration:_____.

☐ Palliative Therapy for Non-Surgical Protocols (Complete for all studies in section 13 of categories of animal manipulation)

Federal laws require that animals which will experience more than momentary pain and distress (such as that associated with a needle-prick) must be provided with appropriate sedatives, analgesics, and/or anesthetics. Withholding of these agents required scientific evidence that such drugs will interfere with the study or harm the welfare of the animal. Such justification must be provided in writing by the Principal Investigator. *Any change from the methods or agents listed herein must be pre-approved bythe animal care veterinarian and such approval documented in the animal's record. Permanent changes in palliative therapy must be submitted to the IACUC as an amendment to the protocol.*

Clinical signs of pain or distress that will be used to evaluate the need for palliative therapy should be listed under Section

18. SURGICAL PROCEDURES section: Surgical Procedures, Anesthetic Regimen, Peri-operative analgesics, Post-Operative Care

☐ Surgical Procedures: ☐ Survival? ☐ Non-Survival? ☐ Multiple Survival Surgery? (see below)

Site of surgical facilities that will be used in this study: ☐ Investigator Lab (bldg/room #)_____Other:

Please provide the names and qualifications of individuals participating in the surgical procedures:

☐ NPO: When should food and/or water be removed?

☐ Anesthetic Regimen
Drug:_____ Dose:_____.
Route of Administration:_____ Duration:_____.
Monitoring Processes:_____.
Tranquilizers:_____ Dose:_____.
Route of Administration:_____ Duration of Effect:_____.
Frequency of Administration:_____ Number of days administered:

Describe in detail the surgical procedures

Will any individual animal be subjected to more than one major survival surgical procedure? ☐ Yes ☐ No

Briefly describe what will occur during each surgical event, stating the interval between the surgical events.
**Provide Scientific Justification for having multiple survival surgical events.

Perioperative Analgesics: Systemic analgesics must be given to all species experiencing major survival operative procedures (defined in the AWA as surgery the penetrates and exposes a body cavity or which produced permanent impairment of function), unless justified as contraindicated for the welfare of the animal. Animals in this category must be provided analgesics for a period of at least 48 hours post surgery, with analgesics continuing as long as necessary to ameliorate clinical signs of pain and distress for the particular animal species (see IACUC Handbook pages 15-17). Additionally, local or

systemic analgesia must be considered for all other surgical procedures and scientific or animal welfare justification provided for all studies where animals will not be provided pain relief. Recent advances in animal physiology indicate that analgesic administration should begin prior to the actual surgical procedure. It is recommended that the agent be given either as part of the pre-anesthesia regimen or just following anesthetic induction. Follow-up analgesia will then be given post-surgically at the appropriate time and analgesia continued for as long as medically necessary. *Any change from the methods or agents listed herein must be pre-approved by a University Animal Care veterinarian ans such approval documented in the animal's Surgery Record. Permanent changes in analgesia must be submitted to the IACUC as an amendment to the protocol.*

Pre-Surgical Analgesia Administration

Agent:_____ Dose:
Route of Administration:_____.

If pre-surgical analgesia will not be administered, scientific justification must be provided below:

Post-Operative Care

Will intensive care be required? ☐ Yes ☐ No If yes, for how long?_____.

Who will provide Post-Operative Care?
Analgesics:_____ Dose:_____.
Route of Administration:_____ Duration of Effect:_____.
Frequency of Administration:_____ Number of days administered:_____.

If post-operative analgesia will not be provided, scientific justification must be provided below:

Antibiotics:_____ Dose:_____.
Route of Administration:_____ Duration of Effect:_____.
Frequency of Administration:_____ Number of days administered: _____.
Briefly describe post-operative monitoring procedures - Include names of participating personnel

Provide Scientific Justification for <u>not</u> providing pre- or post-operative analgesia.

PI signature:_____

19. Pain

A. Would a *non-anesthetized* animal feel more than momentary or slight pain or distress during any procedure in the protocol? No _____; Yes _____

If yes, continue below; if No, proceed to question #19.

B. Federal regulations require that the principal investigator consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals. Please provide a written narrative of the methods and sources used to determine that alternatives were not available. Sources might include Biological Abstracts, Index Medicus, the Current Research Information Service, or the Animal Welfare Information Center of the National Agriculture Library (301/504-6212).

C. Will appropriate analgesia or anesthesia be used? Yes____; No ____If no, provide justification.

20. Prolonged Restrain: Will <u>prolonged restraint</u> of unanesthetized animals be used? Yes____ No _____
If yes, provide justification.

21. Euthanasia: Describe the method used. If appropriate, give generic rather than brand names of agents used, dosage (mg/kg) and routes of administration. If euthanasia is not a scheduled part of this protocol, please describe the method to be used in the event it becomes necessary. The method of euthanasia used should be

consistent with the recommendations of the 2000 Report of the AVMA Panel on Euthanasia (JAVMA 218:669, 2001: Appendix III in the Animal Resources Program Information Manual). If method is not recommended by AVMA, provide detailed scientific justification.

22. Hazardous Agents

A. Will hazardous agents be used in live animals? Yes____ No _____If yes, answer the following:

1. Has the approval been obtained from the Biosafety Committee? Yes____ No _____
   Date of approval: _____
2. Name of agent: _____
3. Carcinogens(s): _____
4. Infectious agent(s): _____
5. Toxic chemical(s): _____
6. Transplanted tissues, cells or fluids:
   State human or animal: _____
   a. If human, will IRB (i.e. Clinical Research Practices Committee) approval be needed for the project? Yes____ No _____. Date of approval? _____

23. Radioisotopes: Will radioisotopes be used in live animals? Yes____ No _____. If yes, you must complete the form "Radionuclide Use in Animals: and obtain Radiation Safety Committee approval before receiving final approval of this ACUC application.

Signature Section

I hereby apply for a three-year approval (with annual renewal required for the second and third years) for the project described and assume responsibility for the animal care and use associated with this research. I certify that the activities listed in this protocol do not unnecessarily duplicate previous experiments. I certify that all personnel involved in the animal care, treatment and use aspects of this protocol are, or will be, adequately trained prior to participation in this study. These animal experiments conform to all policies of Jackson State University. I certify that all employees who will be in direct contact with, or exposed to animals, their wastes, body parts, or body fluids, and/or exposed (in the same room/area) to aerosolized particles from animals will be enrolled in the JSU Occupational Health Program, and I will ensure that the Animal Resources Director is notified of the addition of any new employees. In addition, if my proposal is funded, I will complete forms required by the veterinarian for facilitating the welfare of animals within my study. And, I will comply with the policy for acquiring animals for my study.

_____ _____

Principal Investigator **Date**

_____ _____

Responsible Faculty Advisor if P.I. is not faculty. **Date**