TUSKEGEE UNIVERSITY
ANIMAL CARE AND USE PROTOCOL FORM

In accordance with the Federal Animal Welfare Act of United States Department of Agriculture, Public Health Policy of the Office of Laboratory Animal Welfare, National Institutes of Health and Tuskegee University Guidelines, all faculty using vertebrate animals for **research**, **teaching**, **testing** and **demonstrations** must complete an "Animal Care and Use Protocol Form" and receive **prior approval** from the Tuskegee University Animal Care and Use Committee (TU-ACUC), before purchasing animals for their project.

All completed protocol form(s) must be submitted **ONLINE** to Mrs. Shakeya Tate (state@tuskegee.edu). The form will be pre-reviewed by the Director of the Comparative Medicine Resource Center or the Attending Veterinarian (or his designee) prior to submission to the TUACUC. The purpose of the pre-review is to assist investigators in preparing protocols and to make recommendations consistent with the requirements of the TUACUC. The pre-review also ensures that routine administrative procedures are completed, that there are sufficient resources available to support the project, and that the most frequently asked questions by the TUACUC are addressed. After pre-review, **the completed original signed hard copy and one electronic copy** must be submitted to (Mrs. Shakeya Tate; Tel. # 334-727-8234; Room 119, Williams- Bowie Hall, Comparative Medicine Resource Center) a minimum of 10 working days prior to the committee's regularly scheduled meeting date (last Friday of each month unless otherwise published).

If an Animal Care and Use Protocol Form is approved by the TUACUC committee, a "**Certificate of Approval**" is issued to the principal investigator by the Chairperson of TUACUC. If a research project is **not funded** or **cancelled**, the Chairperson of the TUACUC or the administrative assistant must be notified immediately.

OFFICIAL SIGNATURES

NAME OF PRINCIPAL INVESTIGATOR	**SIGNATURE** OF PRINCIPAL INVESTIGATOR	DATE

CO-INVESTIGATOR	DATE	DEPARTMENT HEAD SIGNATURE	DATE

Adequate Veterinary Care and Consultation: Investigators using vertebrate animals at Tuskegee University must consult with the Attending Veterinarian (or his designee) or the Director of the CMRC in planning a protocol. The Animal Care and Use Application Form will be signed after conducting a pre-review and prior to submission of the protocol to Mrs. Tate.

NAME OF VETERINARIAN CONSULTED	SIGNATURE OF VETERINARIAN CONSULTED	DATE

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For Office Use Only

Approval Status	Date
Protocol Received	
TUACUC Proposal #	
Approval Withheld	
Requires modifications to secure approval	
Approval Date:	
Expiration Date:	

A. **ADMINISTRATIVE DATA: Please note: If approval by other committees (Biosafety; Radiation; etc) is required for completion of any animal work, such approval must be obtained and submitted along with a completed protocol form before review by the TUACUC committee. The TUACUC will not review and approve animal care and use applications that have not received approval or conditional approval status from the appropriate committee.**

Name of Principal Investigator (P.I.) or Faculty	Application Date:
P.I. or Faculty: Department/College/ School/Other:	P.I. or Faculty: Building and Office Room Number:
P.I. or Faculty: Office or Work Phone # and email address:	P.I. or Faculty: Cell Phone #:
Name of Emergency Contact Person 1:	Emergency Contact Person 1 Cell Phone #:
Name of Co-Principal Investigator:	Co-P.I. Office or Work Phone # and email address
Co-P.I. Department/College/ School/Other: Building and Room Number:	Co-P.I. Cell Phone #:
Name of Emergency Contact Person 2: (optional)	Emergency Contact Person 2 Cell Phone #: (optional)

1. Which of the following applies to this protocol? Please select one.

☐ Initial submission ☐ Renewal ☐ Modification

2. Project Title:

3. Please check "X" where applicable below
   a. Select and check one of the following boxes below.

New proposed project ☐ or Continuous project ☐

   b. Select and check all of the boxes below that apply to this protocol.

☐ Research ☐ Teaching ☐ Demonstrations ☐ Other (Please describe)

4. Project start date: Project end date (not longer than 3 years):

5. Funding source:

6. Does this project require review by another committee? If **yes,** place an "X" on the line to all that apply

____ Radiation Safety Committee ____ Biosafety Committee

____ Human Participants Committee ____ Intellectual Property Committee

____ Research Integrity Committee ____ Not Applicable

For Office Use Only: Received Committee Confirmation Letter **Yes () or No** () **Date** _____

7. Will other individuals from either this or other institutions be involved with animal use on this project? If yes, please provide their **names** and **list** their **training** and **experience with the animal species used on this project**. If students are to be trained specify number and who will be responsible for their training.

List Names of all protocol participants	Describe training and experience with animals used on this protocol	Name of Institution where training was obtained

Underline all that apply to participants on this protocol: Faculty; Student; Staff;

B. **ANIMAL SUBJECTS AND REQUIREMENTS**.

<table>
<tr><td>Genus/Species (e.g., Mus musculus)</td><td>Strain/Stock (e.g., C57BL/6)</td><td>Common Name (e.g., mouse)</td><td colspan="3">Total Number of Animals Requested for Project Period</td></tr>
<tr><td rowspan="3"></td><td rowspan="3"></td><td rowspan="3"></td><td colspan="3">Division of animals requested over project period</td></tr>
<tr><td>Year 1</td><td>Year 2</td><td>Year 3</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>Sex:</td><td colspan="2">Age:</td><td>Weight:</td><td colspan="3">Vendor Information: (Enter below)</td></tr>
<tr><td colspan="2">Previously used for another Protocol.
(Please Check one)

() Yes () No</td><td colspan="2">If used for another Protocol, Provide Protocol #:</td><td>Vendor Name:</td><td colspan="2">Vendor Phone #</td></tr>
<tr><td colspan="4"></td><td colspan="3">Vendor Address:</td></tr>
<tr><td colspan="7">Bacteriological status at time of entry into housing facility: [e.g., germfree (axenic); defined flora (gnotobiotic); specific pathogen free (SPF); undetermined]</td></tr>
<tr><td colspan="7">Viral status at time of entry into housing facility: [e.g., simian immunodeficency virus; simian retrovirus]</td></tr>
<tr><td colspan="7">Primary housing location(s): (Include address & location)</td></tr>
<tr><td colspan="7">Special Housing Requirements: (e.g. for mice state if animals are normal or immunocompromised; # of animals per cage; filter or standard cage tops; nesting material; enrichment materials; special housing or care requirements; etc. or state N/A.)</td></tr>
</table>

Location(s) where manipulations will be conducted: (e.g. Procedure room of William Bowie Hall (Include Room#)

Please note that animals or tissues obtained from other laboratories or from non-licensed sources must be approved by the Attending Veterinarian prior to purchase. Health certificates are required for all food and companion animals including goats, sheep, cattle, horses, dogs and any other species (e.g. rabbits).

C. **LITERATURE SEARCH:** A literature search must be performed to prevent unnecessary duplication of previous experiments. Sources of information from scientific literature may include MEDLINE, GRATEFUL MED, MEDLARS, Animal Welfare Information Center, etc.)

1. Source(s) of Information:
2. Date/Number of Searches:
3. Key Words of search:
4. Search Results:

D. **OBJECTIVES AND RATIONALE FOR THE USE OF ANIMALS ON THIS PROJECT:**

1. **State the objectives of the project**: (briefly explain in lay terms why the study is important to human or animal health and the advancement of knowledge for the well-being of society):

E. **RATIONALE FOR ANIMAL USE**

1. **Explain the rationale for animal use on this protocol**. [The rationale should include reasons why it is necessary to use animals for attainment of the research/teaching objectives.]
2. **Justify the appropriateness of the species selected**. [The species selected should be the lowest possible on the phylogenetic scale.]
3. **Give the rationale for the number of animals requested**. (The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible.)

F. **EXPERIMENTAL DESIGN**

1. Use the table below to describe experimental procedures that will be used on animals in the study that are applicable to your experimental design.

Animal identification methods [e.g., ear tags, tattoos, collar, cage card, implant, etc.].
Methods of restraint [e.g., restraint chairs, collars, vests, harnesses, slings, etc.]
Experimental injections or inoculations [e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedule].

Blood withdrawals (Give the volume to be collected, frequency, withdrawal site, and methodology).
Food or fluid restriction: (Describe method for assessing the health and wellbeing of the animals. If you are seeking a departure from the recommendations of the *Guide*, provide a scientific justification).
Pharmaceutical-grade and Non-pharmaceutical-grade Compounds (consumed or injected). Provide quantity or dosage.
Other procedures [e.g., survival studies, tail biopsies].
Resultant effects (expected or unexpected), [e.g., pain or distress, ascites production, etc.]. How will the P.I. deal with unexpected outcomes?
Other potential stressors [e.g., noxious stimuli, environmental stress] **and procedures to monitor and minimize distress**.
Experimental endpoint criteria [e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity]
Veterinary care Indicate the plan of action in case of animal illness [e.g., initiate treatment, call investigator prior to initiating treatment, euthanize].

2. Describe the experimental design and specify all animal procedures to be employed in the study that were not presented on the table above. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Use diagrams, flowcharts, or schematics when possible to ensure clarity.

3. **Alternatives, reduction, replacement, and refinement:**

    b. Explain why you cannot use an **alternative** model for the animals used in this study.

    c. Explain why you cannot **reduce** the number of animals needed further than you specified.

    d. Explain why the animals used in this study cannot be **replaced** by any others.

    e. Describe methods of **refinement** for the use of animals in this study.

G. **SURGICAL PROCEDURES, POST-OP CARE AND OTHER INVASIVE PROCEDURES:**

1. List all drugs or similar compounds that will be administered to the research animals on the table below. Add as many additional rows to the table as required to complete your list.

Drug Name and Purpose: (e.g. anesthetic; analgesic; other)	Dosage Amounts	Route of administration	Needle Size, Gauge and Length

2. Describe all invasive procedures to be performed on the animals. Include preoperative procedures (*e.g., fasting, analgesic loading)*, and monitoring and supportive care during surgery. Include the aseptic methods to be used in all cases involving survival surgery.

3. Will paralytic agents be used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.

4. Is the surgery considered to be major or minor survival surgery? (Major survival surgery penetrates and exposes a body cavity exposes a bone or joint or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation). If yes, please explain.

5. Will more than one survival surgery be performed on an animal during this study? If yes, please justify. Give the room location where each procedure will be performed, the frequency and duration of the procedure.

6. Describe the post-surgical care animals will receive (Include the room location where the care will be provided and the frequency of observation). Identify the individual(s) responsible and the location(s) where care will be provided (building(s) and room(s)). Include how detection and management of postoperative complications will be managed during work hours, after hours, weekends and holidays.

7. Provide the names of all persons performing surgical procedures or other invasive procedures and post-op care.

H. **ASSURANCE AGAINST ANIMAL PAIN AND DISTRESS:** ***The law defines a painful procedure as one that would "reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures."***

1. Pain Definitions:

   a) **Category C: Non-Painful and Non-Stressful** -- Studies, experiments and tests which will not cause any pain or distress in the animals or procedures causing only transitory discomfort (e.g., most injections, vein puncture, food/water deprivation for short periods).

   b) **Category D: Painful or Stressful Conducted with Analgesia/Anesthesia/Tranquilizers** -- Painful procedures carried out on anesthetized animals which do not subsequently wake up from anesthesia ("Acute Studies") or painful or stressful procedures that are carried out using appropriate anesthesia or pain-relieving medication following which the animals will be allowed to recover.

   c) **Category E: Painful or Stressful Conducted without Pain or Stress Relieving Measures** -- Painful and stressful procedures that are performed without the use of anesthetics, analgesics and tranquilizing medications or other measures to prevent and/or relieve pain and distress, or procedures that will induce

pain or stress at a later time (e.g. immunization employing Freund's adjuvant), or painful or stressful procedures not amendable to relief by therapeutic measures.

2. In the table below, estimate the total number of animals to be used during this study according to the category of pain and distress defined above. For each applicable category, list each species and record the number of animals to be used in the project. These numbers must clearly correlate with those indicated in **Section B. Add as many rows to the table as necessary to encompass all animals to be used over the period of the study.**

Common Name/Genus	Pain category: Number of animals used each year				3 years total number of animals
	Category C		Category D	Category E	

I. **STUDY ENDPOINT:** The principal investigator should ensure that unnecessary pain or distress is prevented by carefully considering "When is the experimental question answered so that the animals can be removed from the study as soon as feasible." ***Also, the principal investigator must specifically address and justify any proposed use of death as an endpoint.***

1. Is death the end point/termination of the animal subjects used in this study? Please Check One:

   Yes ( ) No ( )

2. Provide a justification(s) for using "death" as the endpoint/termination of the study.

3. Will animals be allowed to die naturally at the end of their life or will the animals be euthanized? Please check all that are applicable to animals used on this project:

   a. Natural Death ( )
   b. Euthanasia as the end of the study ( )
   c. Humane Euthanasia due to clinical signs of morbidity ( )

4. If euthanasia is the endpoint, describe the method of euthanasia that will be used. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is **not** consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used.

5. Describe two methods of determining death and describe what will be done with the animal carcass?

6. If the animals will be transported to a site off campus for euthanasia and harvesting of tissues, describe method of transportation and identify the site where euthanasia will take place.

7. If death is not the end for animals in the study state how they will be disposed of at the termination of the project.

J. **Assurances:** The law specifically requires several written assurances from the principal investigator. It states that "research facilities will be held responsible if it is subsequently determined that an experiment is unnecessarily duplicated, and that a good faith review of available sources would have indicated as much."

As the primary investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

a. **Animal Use:** The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a deviation is specifically approved by the TUACUC.

b. **Duplication of Effort: I** have made a reasonable, good faith effort to ensure this protocol is not an unnecessary duplication of previous experiments.

c. **Biohazard\Safety: I** have taken into consideration, and I have made the proper coordination regarding all applicable rules and regulations regarding radiation protection, biosafety, recombinant issues, etc., in preparation of this protocol.

d. **Training:** I verify that the personnel performing the animal procedures\manipulations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused because of the procedures\manipulations.

e. **Responsibility: As** the Principal Investigator/Faculty, I certify that the information provided in this document is accurate, and that I assume full responsibility for the health and welfare of the animals used in this study for compliance with the Federal Animal Welfare Act and Regulations and Public Health Service\ National Institutes of Health Policy, assigned to this project.

_____ _____

SIGNATURE OF PRINCIPAL INVESTIGATOR DATE

Revision #10: 01/08/2025
TUACUC