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 (TUACUC), 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) – 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).

For approved Animal Care and Use Protocol Forms, a "**Certificate of Approval**" is issued to the principal investigator by the chairperson of TUACUC. However, if a research project is **not funded** or **cancelled**, the Chairperson of 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 Ms. Mitchell.

NAME OF VETERINARIAN CONSULTED	SIGNATURE OF VETERINARIAN CONSULTED	DATE

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For Office Use Only

Date Received: _____ TUACUC PRN #: _____ Expiration Date: _____

***Approved ( ) Requires Modification(s) To Secure Approval ( ) Withhold Approval ( ) Date: _____**

A. ADMINISTRATIVE DATA: Approval or conditional approval status by other committees must be submitted to TUACUC. TUACUC will not approve completed animal care and use applications that have not received approval or conditional approval status from the appropriate committee.

Principal Investigator/Faculty:	**Date:**
Department/College/ School/Other:	Building and Room Number:
Work Phone:	Cell Phone:
Emergency Contact:	Cell Number:
Co-Principal Investigator:	Department/College/ School/Other
Department/College/School/Other:	Building and Room Number:
Work Phone:	Cell Phone:
Emergency Contact:	Cell Number:

1. **Title of Project**:

2. **Select One: New Proposed Project ( ) or Continuous/Active Project** ( )

   Place an "X" in all that apply:

   a) Research ( )
   b) Teaching ( )
   c) Demonstrations ( )
   d) Other(s):

3. Does this project require review by another committee? If **Yes,** place an "X" in 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 _____**

4. **Project Start Date for Animal Use**: **End Date for Animal Use:**

5. **Funding Source:**

6. 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**:

Name:	Training and Experience	Name of Institution

Underline all that apply: Faculty, Student, and Staff

B. ANIMAL SUBJECTS (USE A SEPARATE FORM FOR EACH SPECIES):

Genus/species	Strain/Stock	Common Name	Total Number of animals requested: ( ) Year 1 Year 2 Year 3		
Sex	Age	Weight	Vendor Source		
Previously used for another Protocol? (Please Check) ( ) Yes ( ) No	If used for another Protocol Provide Protocol #:		Name:	Phone Number:	
			Address:		

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. <u>Health certificates are required for all food and companion animals including goats, sheep, cattle, horses and dogs.</u>

C. MAINTENANCE OF ANIMALS:

Housing Facility (Include address & location)

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

1) Source (s):

2) Date/Number of Searches:

3) Key Words:

4) Results:

E. OBJECTIVES AND RATIONALE FOR USE OF ANIMALS:

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):

2. EXPLAIN WHY IT IS NECESSARY TO USE ANIMALS IN THIS PROJECT (**It is important to adequately justify that animals are necessary for attainment of the research/teaching objectives**.):

3. GIVE THE RATIONALE FOR USING THE REQUESTED ANIMAL SPECIES (**Explain why the requested animal species is being used.**):

4. GIVE THE RATIONALE FOR THE NUMBER OF ANIMAL REQUESTED (**Explain treatments used, the statistical method used to determine the experimental design to reduce the number of animals to be used, to refine the research techniques, and to replace certain procedures with others.**)

F. EXPERIMENTAL DESIGN

1. DESCRIBE TECHNICAL METHODS PLANNED FOR THIS STUDY. **The technical method should be presented in sufficient detail, documented or referenced, so that the TUACUC can adequately review the procedure and obtain a clear understanding of what is to be done, how the animals will be handled, and make a reasonable determination as to whether this proposed use of animals is in compliance with federal law and pertinent guidelines. (Use diagrams, flowcharts, or schematics when possible).**

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

   a. Explain why you cannot use an **alternative** to the use of animals.

   b. Explain why you cannot **reduce** the number of animals needed further than what you have specified.

c. **Replacement**

d. **Refinement**

G. Surgical Procedures, Post-op Care, and Other Invasive Procedures:

1. All drugs or similar compounds that will be administered to the research animals

Drug Name: Purpose: anesthetic; analgesic; other	Dosage Amounts	Route of administration	Needle Size, Gauge and Length

2. DESCRIBE ALL INVASIVE PROCEDURES TO BE PERFORMED ON THE ANIMALS (**to include surgical procedures**). GIVE THE ROOM LOCATION WHERE EACH PROCEDURE WILL BE PERFORMED, FREQUENCY AND DURATION.

3. DESCRIBE THE POST-SURGICAL CARE ANIMALS WILL RECEIVE (**Include the room location where the care will be provided**.)

4. PROVIDE THE NAMES OF 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. 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**

Common Name/Genus	Pain category	Category C	Category D	Category E	Total

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. **What is the project endpoint/termination of study? As it relates to the animal subject.**

Is death the end point/termination of the study? Please Check One: Yes ( ) No ( ) **2. If euthanasia is the endpoint: Describe two methods of determining death?**

3. Justification(s) for endpoint/termination of study using "death", and disposition of animals

4. If animals are to be removed from the study but not euthanized how will they be humanely disposed of?

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:

1. **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.

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

3. **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.

4. **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 as a result of the procedures\manipulations.

5. **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 #9: 12/15/2023
TUACUC/st