***Western Carolina University***

***Institutional Animal Care and Use Committee***

**Animal Use Protocol**

**for Laboratory Animal Research or Teaching**

This form is used for studies which involve housing or experimental interventions on animals in a laboratory environment.

**The Principal Investigator must be a full-time faculty or staff member.**

Return the completed form and any necessary permits to IACUC@wcu.edu

**PLEASE SINGLE CLICK ON SHADED BOXES TO TYPE**

1. **Administrative Information**

|  |
| --- |
| Project Title:      |
| Type of Project: Laboratory Animal Research  Teaching  |
| If this application is a continuation of a currently or previously approved AUP, what is the old AUP number? |
| Project Period (cannot exceed 3 years): Start date: End date: |

|  |  |
| --- | --- |
| Principal Investigator:  | Work phone:  Lab phone: |
| Title: | Email: |
| Department: | Office location: |

1. **Project Funding, if applicable**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Agency** |  **Grant No.** |  **Start Date** |  **End Date** |  **PI** |
|  |  |  |  |  |
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1. **Project Summary for Lay Person (not to exceed 500 words):**

In lay language, briefly summarize the overall intent/objectives of the study. The target audience for this summary is a non-scientist.

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**Harm/Benefit Analysis**: In 2-3 sentences and using lay language, compare the potential harm to participating animals with the potential benefits of the research for humans, animals and/or the advancement of science.

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1. **Transportation:** *Transportation must conform to all local and federal regulations*. Will animals be transported on public roads for between facilities? If yes, describe the methods of transport, and locations.

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1. **Experience and Training**

List all persons working on this AUP. All individuals listed must obtain training from Laboratory Animal Resources personnel BEFORE beginning work with animals. Please include years of experience conducting techniques and working with species proposed in his proposal.

|  |  |
| --- | --- |
| Name:Title: Department:Office Location: Email:  | Check (XX) if: PI Office phone:Lab phone:     Training approval dates: |

Experience:

|  |  |
| --- | --- |
| Name: Title:Department: Office Location:Email: | Check (XX) if: Co-PI  Contact Person Office phone:Lab phone:Training approval dates: |

Experience:

|  |  |
| --- | --- |
| Name: Title:Department: Office Location:Email: | Check (XX) if: Co-PI  Contact Person Office phone:Lab phone:Training approval dates: |

Experience:

1. **Study Objectives**
	1. In scientific language, provide a project summary describing the purpose of the experiments(s). If this is a triennial resubmission, include summaries of findings during the previous 3 years of work and how these data will be expanded upon in the next 3 years.

* 1. List the specific aims or objectives for the project:

* 1. Please check (XX) the applicable boxes below and follow related instructions:

|  |  |  |
| --- | --- | --- |
| **Yes** | **Procedure** | **Instructions** |
|  | Animal identification methods | Describe details of ear tags, tattoos, collars, etc. in **part 5d** below. |
|  | Breeding | Describe the need for breeding and methodology in **part d** below.  |
|  | Blood collection | Describe volume, frequency, collection site, needle size, methodology in **part 5d** below |
|  | Anesthesia | Describe **briefly in part d** below and provide **details in part 6**.  |
|  | Non-survival surgery | Describe procedures in detail in **part 5d** below.  |
|  | Animal pain or distress | Describe briefly the expected adverse effects on animals in **part 5d** below and provide details in **part 9**. |
|  | Devices for prolonged restraint | Describe briefly in **part 5d** below and provide details in **part 9**.  |
|  | Animal work done at another institution | Describe how the work at the other institution fits into the project in **part 5d** below. Include the **Animal Welfare Assurance Number** for the other institution. Attach the **completed proposal form** and **IACUC approval number** from the other institution. |
|  | Survival surgery | Describe briefly in **part 5d** below and attach **Supplemental Section II**. |
|  | Illness, induced disease or pathological condition | Describe briefly in **part 5d** below and attach **Supplemental Section III**. |
|  | Special diets and/or food orwater restriction | Describe briefly in **part 5d** below and attach **Supplemental Section IV**. |
|  | Immunizations | Describe briefly in **part 5d** below and attach **Supplemental Section V**. |
|  | Hazardous Materials (exogenous tumors, cells lines, hybridomas, biohazards, isotopes, etc.) | Describe briefly in **part 5d** below and attach **Supplemental Section VI**. |

* 1. Provide a **detailed description** of the use of animals (similar to Section F “vertebrate animals” for NIH/PHS 398, Section D5 of NSF or similar). 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. Cover all items checked above as instructed in the table.

1. **Anesthesia and Euthanasia agents**
	1. Specify in the table below the anesthetic agent for each procedure. Where anesthetic combinations are called for, list each drug separately.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Experiment or** **Procedure**  |  **Drug** |  **Dose** |  **Route** | **Expected Duration** **of Anesthesia** |
|  |  |  |  |  |
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* 1. Volatile (gas) anesthetic agents.
		1. Are you using a volatile anesthetic (e.g. isoflurane)? **Yes**  **No**
		2. How will this be vented (e.g., fume hood) or scavenged (e.g. charcoal canister)?
		3. List the location of the venting or scavenging equipment.
	2. List who will administer the anesthesia and the qualifications of each person listed.

1. **Animals**

Complete a separate column for each species or rodent strain to be used. If more than 3 species or strains are to be used, duplicate this page and insert appropriately. Please include all information that applies to the animals you propose to use in this proposal.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  **A** |  **B** |  **C** |
| 1. Species (common name)
 |  |  |  |
| 1. Strain
 |  |  |  |
| 1. Gender
 | M  Both  F  | M  Both  F  | M  Both  F  |
| 1. Age range
 |  |  |  |
| 1. Weight range
 |  |  |  |
| 1. Number of animals/year
 |  |  |  |
| 1. Vendor/Source
 |  |  |  |
| 1. Animal facility where housed
 |  |  |  |
| 1. Building and room number where experiment will be performed
 |  |  |  |
| 1. If different from animal facility where housed, are animals housed overnight in this experimental area?
 | Yes  No N/A  | Yes  No N/A  | Yes  No N/A  |
| 1. Does this project require breedingof animals?
 | Yes  No  | Yes  No  | Yes  No  |

1. **Justification for Animal Use**
	1. Describe the number of animals to be used for each experiment in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Experiment or Procedure** | **Animals/Group** | **Groups/Experiment** | **Experiments/Year** | **Animals/Year** |
|  |  |  |  |  |
|  |  |  |  |  |

* 1. You arrived at these numbers by (check [XX] all that apply).

 Power analyses indicate that the proposed number of experiments is required for statistically valid tests of the hypothesis.

 The experiments will compare the effects of several independent variables and therefore require many groups or cohorts.

 The outcome measures or phenomena being measured are variable and large sample sizes are necessary for statistically valid sampling.

 Differences from controls are expected to be small, and large sample sizes are necessary to distinguish differences reliably.

 The experiments are technically difficult and multiple attempts will be needed to obtain satisfactory data from each experiment.

 Other (explain):

* 1. What is the rationale for using animals in this study? Check (XX) all that apply.

 This research requires behavioral measurements from living animals.

 This research requires biological measurements or tissue samples from living animals.

 Computer or other models cannot be used to replace animals in this research.

 The research cannot be done in vitro.

 This research is a direct extension of previous work on this species.

 This research seeks to extend previous findings from other species specifically to this species.

 Nothing is known about the physiological/behavioral phenomena of interest in this species.

 More is known about related aspects of the physiological/behavioral phenomena of interest in this species than any other.

 This species represents the best compromise between the simplest (lowest) organism that can be used and the most relevant model system for human physiology/behavior.

 This species is the most cost-effective for the proposed research.

 Other (explain):

* 1. Search for **alternatives to the use of live animals**.

A literature search for alternatives to the use of live animals must be conducted and you will be requested to provide detailed results.

* + 1. List a minimum of 2 data bases consulted (e.g. PubMed, Agricola, Toxline, Biological Abstracts, etc.).

(1)

(2)

Additional databases:

* + 1. Date of search:
		2. Years covered by search:
		3. Key words or search strategies used (e.g., models, in vitro, pilot, tissues, etc.):

* + 1. Provide a brief summary of your search results:

1. **Experimental Stress and Pain**
	1. Prolonged Restraint
		1. Does this proposal involve prolonged restraint (e.g. animals held in slings or small confinement apparatus)? *Note: brief restraint, for the purpose of performing routine clinical or experimental procedures need not be described.* **Yes**  **No**
		2. If YES, indicate frequency and duration of restraint and describe the method of restraint and the rationale for its use.

* 1. Experimental Stress:
		1. Will the animals be subjected to stressful conditions such as high intensity light or noise, water immersion or electrical shock: **Yes**  **No**
		2. Describe the stressor, its level and frequency, and the rational for its use.

* 1. Indicate the appropriate pain and distress category(ies) and the number of animals in each. Sums should equal the total animals from Part 7 above.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  **Pain and Distress Category  (based on USDA categories)** |

|  |  |
| --- | --- |
| Number of animals per year |  |
| Year 1 | Year 2 | Year 3 | TOTALS |

 |
| Pain and distress category **B** – holding or breeding |  |  |  |  |
| Pain and distress category **C** – minimal, transient, or no pain or distress |  |  |  |  |
| Pain and distress category **D** – pain or distress relieved by appropriate measures |  |  |  |  |
| Pain and distress category **E\*** - unrelieved pain or distress |  |  |  |  |

\*For **category E** animals, a scientific justification is required to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressful procedures is contraindicated.

For **category D and E animals**, the results of a **targeted literature** search **for alternatives to painful and distressful procedures** must be provided below and you will be requested to provide detailed search results.

* + 1. List a minimum of 2 data bases consulted (e.g., PubMed, Agricola, Toxline, Biological Abstracts, etc.).

(1)

(2)

Additional databases:

* + 1. Date of search:
		2. Years covered by search:
		3. Key words or search strategies used (e.g., analgesics, reduce pain, non-invasive, training):

* + 1. Provide a brief summary of your search results:

1. **Euthanasia and Final Disposition of Animals**
	1. If animals **will not** be euthanized, check (XX) disposition:

 Return to colony flock, or herd

 Adoption

 Experimental animals may be transferred to another AUP for non-survival procedures. Breeders and non-experimental animals may be transferred to another AUP.

 Other:

* 1. If animals **will be** euthanized, check (XX) method(s) of euthanasia:

 Carbon dioxide (CO2)-induced hypoxia followed by a secondary mechanical means of euthanasia

 Exsanguination under anesthesia. Specify anesthesia in Part 6, Anesthesia Table.

 Perfusion under anesthesia. Specify anesthesia in Part 6, Anesthesia Table.

 Injectable agent overdose. Specify anesthesia in Part 6, Anesthesia Table.

 Decapitation. If used without prior anesthesia, you must provide scientific justification below\*

 Cervical dislocation. If used without prior anesthesia, you must provide scientific justification below\*

 Other method of euthanasia. Please specify:

\*Provide scientific justification for decapitation or cervical dislocation without anesthesia here:

* 1. Who will be responsible for carrying out the final disposition of the animals?

* 1. Where will the final disposition take place?
1. **Use of Drug Enforcement Agency (DEA) Regulated Controlled Substances**
	1. Will this project involve any DEA regulated controlled Substance? **Yes**  **No**

If you answered **YES** :

1. The PI will have a DEA license (or have applied for a license) BEFORE use of controlled substances under this AUP.
Provide name on license and license number or the application confirmation number.

1. The PI will include the proposed use of controlled substances at appropriate doses.
2. The PI will provide appropriate security (anchored cabinet with a minimum of 2 separately keyed doors and limited access to keys or lock combinations) for controlled substances.
3. The PI will be responsible for keeping records of controlled substance use on forms provided by WCU.
	1. Are the controlled substances to be used listed in either the anesthesia, euthanasia, or analgesia sections of this AUP? **Yes**   **No**

**Note:** You must be individually licensed or have applied for a license with the DEA to use controlled substances at Western Carolina University. By signing this animal use protocol you agree to abide by all WCU policies and procedures for use of controlled substances. Unauthorized use of DEA controlled substances may result in suspension of the Protocol.

1. **Principal Investigator’s Statement**

I certify (check [XX] box) that the statements made in this request are accurate and complete and that the animal usage in this proposal does not unnecessarily duplicate previous experiments.

 If I receive approval for this project, I agree to inform the IACUC in writing of any emergent problems. I further agree not to proceed with the project until the problems have been resolved.

 I will not make significant procedural changes to procedures involving animals without submitting a written amendment to the IACUC and will not undertake such changes until the IACUC has reviewed and approved them.

 All photographs and videotapes of research animals and/or personnel will be for documentation of my research and for scientific purposes only.

 It is my responsibility to ensure that every person working with animals is appropriately trained.

 I will not begin work on the procedures described in this proposal until I receive notice of approval from the IACUC.

 I will keep a copy of this proposal and all subsequent correspondence.

*By submitting this request, the Principal Investigator (and responsible faculty member if the PI is a student) I declare that I have reviewed this report which provides a complete and accurate description of the event and that upon receipt of the IACUC’s review, I will fully and immediately implement any corrective actions required by the IACUC.*

*The parties (the IACUC, the Principal Investigator, and responsible faculty member if the PI is a student) have agreed to conduct this application process by electronic means, and this application is signed electronically by the Principal Investigator and by the responsible faculty member if a student is the PI.*

*My name and email address together constitute the symbol and/or process I have adopted with the intent to sign this application, and my name and email address, set out below, thus constitute my electronic signature to this application.*

Date

PI Name PI Email Address

Responsible Faculty Name if PI is a Student Responsible Faculty Email Address if PI is a Student