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Institutional Animal Care and Use Committee (IACUC)

**Animal Use Protocol**

*A completed protocol form must be submitted for review to the UF Institutional Animal Care and Use Committee (IACUC)* ***prior*** *to initiation of the project. Submitted the completed protocol with all signatures to* *iacuc@findlay.edu**. Allow at least eight weeks for the review process.*

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| Title of Project:  |       |
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| Principal Investigator: |       | Email: |       |
|  |  |  |
| Address: |       | Department: |       |
|       |  |
|       | Telephone: |       |

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| Type of research: [Double click on the check box to select it.][ ]  Faculty Research[ ]  Undergraduate Course Number:      [ ]  Graduate Course Number:      [ ]  Master Project/Thesis/Dissertation:      [ ]  Other (describe):       |

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| Anticipated Beginning and Ending Dates: |       | to |       |
|  |  mo / dy / yr  |  |  mo / dy / yr |

I hereby certify that upon approval of this proposal by the IACUC, no changes will be made without approval of the IACUC, and that any problems, adverse reaction, or unforeseen conditions encountered will be immediately reported to the Chair of the IACUC. As the Faculty Advisor/Sponsor, I certify that I have reviewed this protocol and affirm the merit of this research project and the competency of the investigator(s) to conduct the project.

Principal Investigator’s Signature Date

Student Researcher’s Signature(s) Date

Program Director’s Signature Date

Dean’s Signature Date

***The IACUC approval of the research project is for a period of one year. An annual progress report must be completed to maintain approval. A full proposal must be submitted every three years.***

For IACUC Use Only

 Approved [ ]  Not Approved [ ]

Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_
 Approval Date Expiration Date

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Chair of IACUC

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| **1. Project Introduction/Overview** *Describe in non-technical term, the scientific or educational aims of the project. Justify the project in terms of its potential value in obtaining or establishing significant information relevant to the understanding of humans or animals, maintenance and improvement of human or animal health and welfare, improvement of animal management or production, or achievement of educational objectives.* |
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| **2. Design and Methods** *Provide an outline of the formal scientific plan and direction for experimentation.* *Describe the experimental protocol in detail, including information on behavioral, dietary, environmental, pharmacologic, physiologic, surgical, etc., manipulations. Include dosages, routes of administration, and monitoring procedures employed.* |
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| **3. Justification for the use of animals** *Explain why animals are needed for this project. Include a brief discussion of the use of animals vs. non-animal alternatives, the choice of species (why this is the most appropriate species/strain to use in these studies), non-animal alternatives considered and why these cannot be utilized, and how consideration of the “3 Rs” (Replacement, Reduction, Refinement) was incorporated into the proposed protocol.* **Methods used to investigate alternatives MUST be described in the last section of this proposal if any Category B or above procedure is proposed***.*  |

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| **4. Duplication**  |
| Does the proposed activity duplicate any previous experiments using animals? [Double click on the box to select it.][ ]  No [ ]  Yes. If yes, provide the rationale for duplication: |
| **5. Animal Number and Species Information**  |
| a. Animal Species, Numbers and Sources. *List all animal species (and strain) and indicate numbers to be used. Add additional lines if necessary.* |
| Species/strain | Total # to be used | Age/Weight and Purpose | Pain/Distress Category |
| M | F |
|  |  |  |  | A | B | C | D | E |
|  |  |  |  | A | B | C | D | E |
|  |  |  |  | A | B | C | D | E |
|  |  |  |  | A | B | C | D | E |
| Category A: Experiments involving either no living materials or use of plants, bacteria, protozoa, or invertebrate animal species.Category B: Experiments on vertebrate animal species that are expected to produce little or no discomfort.Category C: Experiments that involve some minor stress or pain (short-duration pain) to vertebrate animal species.Category D: Experiments that involve significant but unavoidable stress or pain to vertebrate animal species.Category E: Procedures that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals.*The USDA requires documentation from an attending or consulting veterinarian regarding veterinarian involvement in the planning of studies in the Pain/Distress Categories C, D and E. Please attach documentation to the proposal. Procedures that cause unrelieved pain or distress (Category E) must be justified in the Regulatory Exceptions section below.* |
| b. Identify the source(s) of animals (name, address, and phone # of vendor) |
| c. Rationale for appropriateness of species/strain |
| d. Rationale for numbers requested |
| e. Location of Animal Procedures and/or Housing. *List all locations where animal procedures will be performed, on- and off-campus. If new on-campus facilities are to be used for housing or procedures, attach memo from Facilities Director, Program Director, or Dean as appropriate describing and confirming the availability and suitability of facilities listed. Add additional lines if necessary.* |
| Location | Species | Activity *(housing, surgery, euthanasia, etc.)* |
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| Specify any special requirements for animal housing, diet, environment, etc. needed for any part of the study: |

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| f. Permits  |
| Are permits required for importation, collection or maintenance of animals? [Double click on the box to select it.][ ]  No [ ]  Yes. If yes, list agencies that require permits, and permit status below. Submit a copy of the permits to the IACUC with each application.

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| 1. | Agency |       |

Permit Application: [ ]  Approved [ ]  Pending [ ]  To be submitted

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| 2. | Agency |       |

Permit Application: [ ]  Approved [ ]  Pending [ ]  To be submitted |

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| **6. PERSONNEL**  |
| A. List below all persons, other than the PI, who will have contact with the animals in this project. (Add more lines if needed.) |
| Name | Nature of Involvement (co-investigator, graduate assistant, undergraduate, staff, etc) | Procedures to be performed |
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| B. Training of Principal Investigator(s)Describe the relevant qualifications and experience, including number of years’ experience, and the current status of the PI's training in the following:a) The biomethodology proposed (handling, surgical procedures, nutrition, etc.) of the animal species being used.b) The humane care and use of animals and alternatives to the use of animals. |
| C. Training and Experience of Other Project PersonnelFor each individual listed above, describe relevant qualifications and experience in the procedures to be performed and the species being used. If the individual has limited or no experience working with animals, describe how training will be provided. All personnel must complete required training prior to working with animals including the use of animals in research, relevant Occupational Health and Safety requirements, and any necessary in-person training related to the species used and procedures to be performed. |

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| **7. MATERIALS**  |
| A. Will biological, chemical, or physical agents to be administered to the animals? [Double click on the box to select it.][ ]  No [ ]  YesIf YES, identify agents to be used. Add more lines if necessary. |
| Agent | Amount/Dosage/Frequency | Route\* | Purpose |
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| *\* Identify the location and number of injection sites.* |
| B. Will any hazardous materials/agents be administered to the animal? [Double click on the box to select it.][ ]  No [ ]  YesIf YES, list hazardous materials (biohazardous materials, hazardous chemicals, radioactive materials) in the proposed study and their purpose. Add more lines if necessary. |
| Agent | Risk | Safety Procedures |
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| C. Do any materials listed require federal or state **licensure**? [Double click on the box to select it.][ ]  No [ ]  Yes If yes, list the agent, the name of the individual holding appropriate credentials (must also be listed in personnel list), and the licensure information (including licensing agency and credential number) below.  |
| D. Do any materials listed require **enhanced biosafety precautions** or exceed CDC Biosafety Level 1? [Double click on the box to select it.][ ]  No [ ]  Yes If yes, explain risk and safety procedures to be followed by laboratory and animal facility personnel. For infectious agents, indicate the appropriate CDC biosafety level.  |

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| **8. STRESS, PAIN, and ADVERSE CONSEQUENCES** |
| **A. Are there any potentially painful procedures being proposed?** [Double click on the box to select it.] [ ]  No [ ]  Yes. If YES, identify procedures that may cause discomfort, distress and pain to the animals at any point in this protocol and describe methods used to minimize pain and discomfort for each. Describe procedures for monitoring levels of pain and discomfort and steps to be taken if extreme. |
| **B. What adverse effects may occur as a result of the experiments and/or from surgery?** Describe expected experimental effects, distress, pain, significant discomfort, morbidity, etc. and how animals will be monitored for adverse effects. |
| **C. Humane endpoint criteria.** When the experimental manipulations could cause significant distress or pain, adverse effects, or are potentially lethal, criteria for humanely ending the animal’s suffering must be specified.Clearly list the criteria used to determine when euthanasia will be performed even if prior to the experimental endpoint. |
| **D. Will animals be deprived of food or water in preparation for or as part of experimental treatment?** [Double click on the box to select it.] [ ]  No [ ]  Yes. If YES, describe the deprivation, its degree, and how the animal's health will be monitored during the period of deprivation.  |
| **E. Will the animals be subject to other forms of stress, such as sleep deprivation, aggression, maternal deprivation, prolonged restraint, social isolation, etc.?** [Double click on the box to select it.] [ ]  No [ ]  Yes. If YES, describe the stress, its degree, and how the animal's health will be monitored during the procedure. Indicate whether the stimuli are warned or unwarned, escapable, or avoidable. |

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| **9. EUTHANASIA**  |
| [ ]  No [ ]  Yes **Are animals to be euthanized at the end of this study?** [Double click on the box to select it.]Euthanasia must comply with 1993 AVMA recommendations.  |
| A. If YES, describe method(s) of euthanasia.  |
| B. If NO, describe the disposition of the animals at the conclusion of the study. |
| C. What method of euthanasia will be used for an animal meeting the humane endpoint criteria specified above or if other adverse consequences require ending an animal’s suffering? |

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| **10. REGULATORY EXCEPTIONS** Regulations require that some procedures receive special consideration by the IACUC.  |

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| 1. **Will any animals experience unrelieved pain or distress?** *Procedures that involve accompanying greater than slight of momentary pain or distress to the animals for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.* [Double click on the box to select it.]  [ ]  No [ ]  Yes. If animals will experience painful/stressful procedures WITHOUT pain or stress relieving measures, provide references and scientific justification showing that all available or any particularly prescribed anesthetics, analgesics or tranquilizers will interfere with the specific measurements that are proposed in this protocol. Documentation from an attending or consulting veterinarian must also be included as an attachment. |
| 2. Are **multiple major survival surgeries** performed on the same animal? According to *the Guide*, major survival surgery “penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection.” Please note that some surgical procedures characterized as minor may induce substantial post-procedural pain or impairment and should be similarly justified if performed more than once in a single animal below. [Double click on the box to select it.]  [ ]  No [ ]  Yes. Provide scientific justification for the use of multiple survival surgeries and include the  timeframe between the surgeries below: |
| 3. Are unanesthetized animals **restrained** for **more than 30 minutes**? [Double click on the box to select it.] [ ]  No [ ]  Yes. Provide scientific justification below: |
| 4. Will **water or food be restricted** during any portion of the project? [Double click on the box to select it.] [ ]  No [ ]  Yes. Provide scientific justification below and the time limits for the restriction or deprivation |
| 5. Does experiment require **single housing** of social species? [Double click on the box to select it.] [ ]  No [ ]  Yes. Provide scientific justification below:  |
| 6. Does experiment require an exception from standard **husbandry practices** or **environmental conditions** recommended in *the Guide* or Animal Welfare Regulations(e.g. prolonged cage or bedding change intervals, cage size, alteration of temperature, humidity, light level/cycle, use of wire bottom caging, removal of bedding substrate, exclusion from environmental enrichment, etc.)? [Double click on the box to select it.] [ ]  No [ ]  Yes. Describe and justify below: |
| 7. Are **non-pharmaceutical grade (NPG) substances** usedin live animals? [Double click on the box to select it.] [ ]  No. [ ]  Yes. If NPG grade substances must be used, please identify the justification(s) below:[ ]  No pharmaceutical grade veterinary or human drug is consistently available.  [ ]  Although a pharmaceutical grade drug is available, the NPG drug is required to replicate methods from previous studies. [ ]  Although a pharmaceutical grade drug is available, a greater concentration, different formulation, or route of administration is required.[ ]  The available pharmaceutical grade formulation contains preservatives or inactive ingredients which confound the research goals of the study.[ ]  Other (provide justification below). |
| 7. **Other.** Describe and provide a rationale for any other exceptions to *the Guide*, Animal Welfare Regulations, or IACUC Policies not addressed above. |

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| **11. Alternatives to the use of animals (*Required if any Category B-relieved pain/distress or above procedures are proposed, regardless of species.)*** *Animal welfare regulations require documentation that the principal investigator has considered alternatives to the use of animals and to procedures that may cause more than momentary or slight pain or distress to the animals. Provide a written narrative description of the methods (including keywords) and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available. See* [*https://grants.nih.gov/grants/olaw/links.htm*](https://grants.nih.gov/grants/olaw/links.htm) *for links to databases and policies.* |
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**Institutional Animal Care and Use Committee (IACUC)**

**Principal Investigator Certification**

**I certify the following:**

A. This protocol provides a complete and accurate description of all proposed uses of live animals or animal products in this research activity. I will obtain approval from the IACUC prior to starting any of the work proposed.

B. This project is being conducted in accordance with all applicable laws, policies and regulations, including the Animal Welfare Act, the NIH Guide for the Care and Use of Laboratory Animals, all regulations governing the importation, collection and/or maintenance of wild species, and all UF policies and procedures regulating the humane use of vertebrate animals or animal products in instruction and research. I will ensure that students, fellows and staff under my supervision have access to and are familiar with these policies and will comply with the procedures described.

C. This protocol meets all animal care and use requirements of the funding agency (or agencies) supporting this project. The procedures listed accurately reflect those described in the funding application/awards.

D. All experiments involving live animals will be performed under my supervision. Listed personnel will perform only those procedures for which they have received adequate training.

E. Any problems, adverse reaction, or unforeseen conditions encountered will be immediately reported to the IACUC for review.

F. I will submit a written amendment to this protocol for any changes, including but not limited to changes to species, numbers, procedures, animal care, or personnel. I understand that no changes may be implemented until formal approval is obtained.

Signature of PI Date