|  |
| --- |
| For IACUC Use Only:Proposal Number: Approval Date: Expiration Date:  |

1. **Principal Investigator Information**First Name: Click here to enter text. Last Nam e: Click here to enter text.
Department: Click here to enter text.
Laboratory: Click here to enter text.
Mailing Address: Click here to enter text.
Phone: Click here to enter text. Fax: Click here to enter text.

Salem State Email: Click here to enter text.

Project Title: Click here to enter text.
Initial Submission [ ] Renewal [ ]  Modification [ ] Significant Change [ ]  [[1]](#footnote-1)

Co-Investigators, Students, Technicians and other Key Personnel with access to animals: [ ] Yes [ ] No

|  |  |
| --- | --- |
| Name: | Click here to enter text. |
| Department: | Click here to enter text. |
| Telephone: | Click here to enter text. |
| Fax: | Click here to enter text. |
| Email: | Click here to enter text. |
| Key Role: | Click here to enter text. |

Anticipated Start Date: Click here to enter a date. End Date: Click here to enter a date.

 **Funding Information and Source:**

Funding Source (Check any that apply).

[ ] Not funded.

 [ ] Internal funding: Type: Click here to enter text.

 [ ] Federal funding: List agency name: Click here to enter text.

 [ ] Subcontract. List organization

Name: Click here to enter text. Contact name:Click here to enter text. Telephone no: Click here to enter text. Address:Click here to enter text.

Will any aspect of this study or animal husbandry be conducted at another institution? [ ] Yes [ ] No
Location: Click here to enter text.

Please attach Memorandum of Agreement or IACUC approval with collaborating institution.

1. **Animal Species to be Used in Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Number of animals to be used:  | Year 1:Click here to enter text. | Year 2:Click here to enter text. | Year 3:Click here to enter text. |
| Genus: (e.g., Mus) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Species: (e.g., musculus) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Strain, subspecies or breed (e.g., C57BL/6) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Common Name (e.g., Black 6) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Source (if other than Salem State’s approved vendor) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Approximate Age, Weight or Size: | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Sex: | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Bacteriological Status: | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Viral Status: | Click here to enter text. | Click here to enter text. | Click here to enter text. |

 Does this proposal include the maintenance of a breeding colony? Yes [ ]  No [ ]

1. **Description of Experimental Design and Animal Procedures**
* Briefly explain all animal procedures including specific aims of the study and hypothesis to be tested including expected outcomes and contributions. All procedures to be employed in the study must be described.
	+ Explain the experimental design and specify all animal procedures. Include any procedures which involve pain or distress.
		- 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.
	+ Include the following specific information, if applicable:
		- Methods of restraint (*prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be used)*
		- Experimental injections or inoculations
		- Blood withdrawals
		- Food or fluid restriction (*If food or fluid will be restricted describe method for assessing the health and wellbeing of the animals. Daily written records for food and fluid restriction must be maintained and available for inspection. If you are seeking a departure from the recommendations of the Guide, provide a scientific justification)*
		- Other potential stressors and procedures to monitor/minimize stress
		- Experimental endpoint criteria
		- Veterinary care required

 **Click here to enter text.**

 **Objectives**: why is this study important to human or animal health, the advancement of knowledge, or the good of society? What are the overall goals of the research?

 **Click here to enter text.**

1. **Pain or Distress Classification and Consideration of Alternatives**Indicate the pain and distress category for the animals, by species, to be used. (Appendix A)
* Regulations mandate that you describe how the lack of alternative methods was verified for each potentially painful/distressing procedure. An alternatives search must be included in the form of a narrative description and include references and literature search.

|  |  |  |  |
| --- | --- | --- | --- |
| **Species (Common name)** | **Number of animals used each year** | **USDA Pain/Stress Category** | **3 years total number of animals** |
| **Year 1** | **Year 2** | **Year 3** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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1. **Rationale for Animal Use and Justification of Proposed Numbers**
* Explain your rationale for animal use including reasons why it is necessary to use animal models
* Justify the appropriateness of the species selected
* Justify the number of animals to be used. This should be the minimum number required to obtain statistically valid results.
* Provide a power calculation or evidence to support the numbers of animals proposed for use (*For example, use data from pilot studies or similar published studies to support the number of animals requested and the numbers of animals per group so that you can show statistically significant differences between groups*

**Click here to enter text.**

1. **Housing and Care**

Primary Housing Location: Click here to enter text. *PI must certify that facility has the resource capability to support the study. If animals will be housed in a lab or anywhere else outside the main location for more than 12 hours, provide building and room number*

Location where Research will be conducted: Click here to enter text.

Is standard food and housing to be used? Yes [ ]  No [ ]

Are any special conditions required? Yes [ ]  No [ ]

|  |  |
| --- | --- |
| [ ] Special Diet or Food Restriction | [ ] Medications/Treatments |
| [ ] Non-standard Light Cycle Requirements | [ ] Water Restrictions |
| [ ] Non-standard Caging | [ ] Other, please specify Click here to enter text. |

For each special condition checked above, specify who will be responsible to oversee daily treatment or condition including weekend, holiday and other periods when University may be closed. **Click here to enter text.**

How will animals be identified: Ear punching: [ ]  Cage card: [ ] Other: [ ]  Please specify: Click here to enter text.

Will animals be transported to/from campus facilities by a non-approved vendor? Yes [ ]  No [ ]
*Transportation of animals must conform to federal regulations. If animals will be transported describe methods you will use to comply with USDA regulations.*

Will procedures be conducted on animals outside of the main facility? Yes [ ]  No [ ]
**Note:** IACUC approval is required to house animals outside the main facility

1. Why do animals need to be housed or taken outside the main facility? Click here to enter text.
2. How will environmental conditions be maintained? Click here to enter text.
3. Who will be responsible for the oversight and daily care of animals outside the facility? Click here to enter text.
4. What is the emergency care plan? Click here to enter text.
5. What is the euthanasia plan at the offsite location? Click here to enter text.
6. **Surgery, Anesthesia, Analgesia, Tranquilization or other Agents**

Does this proposal include?

* Surgical methods Yes [ ]  No [ ]
* Anesthesia Yes [ ]  No [ ]
* Analgesia Yes[ ]  No [ ]
* Tranquilization Yes [ ]  No [ ]
* Other Agents Yes [ ]  No [ ]  Please specify Click here to enter text.

Additional documentation is required for any of the above. Please refer to Appendix B and C

1. **Other Considerations**

Does this proposal include the use of any hazardous agents? Yes [ ] No [ ]
Describe the practices and procedures required for the safe handling and disposal of contaminated animals and materials associated with this study. Also describe methods for removal of waste and any additional safety concerns.

**Click here to enter text.**

Does this proposal include genetically engineered animals? Yes [ ] No[ ]
Describe any anticipated phenotypic consequences of the genetic manipulations to the animals.

**Click here to enter text.**

Describe any special care or monitoring that the animals will require.

**Click here to enter text.**

List any special housing, equipment, animal care or any departures from the *Guide* such as special caging, water, feed, waste disposal, environmental enrichment, etc.

**Click here to enter text.**

1. **Scientific and Humane Endpoints**
* **Scientific Endpoints:** Provide the scientific endpoints for this study (*The scientific endpoint of a study is when the PI’s scientific aims and objectives are met. The protocol should clearly state what will happen to the animals when the scientific endpoints are reached)*

Click here to enter text.

* **Humane Endpoints:** Provide the humane endpoints for this study (*A humane endpoint is the point in which an experimental animal’s pain and/or distress is terminated, minimized, or reduced. Describe when it is time to either:*
	+ *Euthanize the animal to prevent suffering;*
	+ *Discontinue a painful procedure;*
	+ *Remove an animal from the study*

Click here to enter text.

* Project personnel **must** observe for the following signs of pain and/or distress and evaluate if an animal has reached a human endpoint:
	+ Change in water/food intake and body weight
	+ Change in physical appearance (failure to groom, appearance, tremors)
	+ Measureable clinical signs
	+ Change in behavior (lethargic, aggressive, vocalization)
	+ Behavioral changes to external stimuli (excitability)

Personnel responsible for monitoring animals: Click here to enter text.

1. **Euthanasia**

Will animal(s) be euthanized at end of experiment? Yes [ ] No [ ]
Indicate method of euthanasia Click here to enter text.

If a chemical agent is used, specify the dosage range and route(s) of administration. If the method(s) of euthanasia differs from the AVMA Guidelines on Euthanasia (Appendix C), provide scientific justification for alternative methods.

 Click here to enter text.

If animal(s) will NOT be euthanized, indicate their final disposition:

* Transferred live to another protocol Yes [ ]  No [ ]  Protocol Number Click here to enter text.
* Transferred, other Click here to enter text.
1. **Principal Investigator Assurance and Signature**

*Please check each box and provide an original signature below. Form should be scanned and emailed to* *iacuc@salemstate.edu* *for submission*

|  |
| --- |
| [ ] I certify that all animal species, numbers and procedures proposed in this project have been completely described on this application. I, the undersigned, accept responsibility for assuring that all personnel involved in this study have met training requirements, are aware of and will not deviate from the approved procedures outlined on this form, and are in accordance with the Animal Welfare Act, the *Guide* *for the Care and Use of Laboratory Animals*, and applicable federal and state laws, regulations and policies of Salem State University with regard to the human care and use of animals involved in this study.[ ] I have attached certification of applicable documented training. (See appendix E)[ ] These activities do not unnecessarily duplicate previous experiments.[ ] I understand that if I or my designated representative cannot respond within 24 hours and animals on this project show evidence of illness or pain, emergency care including euthanasia may be administered by the Attending Veterinarian as appropriate, after consulting with the IACUC Chair. [ ] I have received and reviewed the Salem State University Facilities Description, IACUC Policy, and Standard Operating Procedures.[ ] I understand that I may not begin any research activities until I have received official notification of approval from the IACUC, the proposed facilities have been approved by the Attending Veterinarian, and that my signature has been received by the IACUC on this application.  |

|  |
| --- |
| **Principal Investigator Signature** |
| PI Signature:  | Date: Click here to enter a date. |
|  Print Name: Click here to enter text. |  |

[[2]](#footnote-2)

**Appendix A - USDA Classifications and Examples**

**Classification B:** Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

**Examples:**

* Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are handled in accordance with IACUC approval, the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
* Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations.
* Animals held under proper captive conditions or wild animals that are being observed.

**Classification C:** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

**Examples:**

* Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice [dog cephalic, cat jugular] or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
* Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

**Classification D:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

**Examples:**

* Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, and laparotomy or laparoscopy.
* Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus *[e.g., guinea pigs]*.
* Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics, anesthetics, tranquilizers, or supportive care.

**Classification E:** Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

**Examples:**

* Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
* Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
* Negative conditioning via electric shocks that would cause pain in humans.
* Chairing of nonhuman primates not conditioned to the procedure for the time period used.

**NOTE REGARDING CLASSIFICATION E:** An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act (FOIA), and may be publicly available through the Internet via USDA’s website.

**Attachment 1** - **Explanation for USDA Classification E**

*[This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.]*

This document must be typed.

Name of investigator:Click here to enter text.

Animal study proposal title:Click here to enter text.

Species and number of animals listed in Classification E for each year:

 Species:Click here to enter text.

 Number of animals:Click here to enter text.

 Year 1:Click here to enter text.

 Year 2:Click here to enter text.

 Year 3:Click here to enter text.

 Total: Click here to enter text.

Description of project including reason(s) for species selection:Click here to enter text.

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

**Click here to enter text.**

Signature of investigator: Click here to enter text.

Date:Click here to enter a date.

Signature of IACUC Chairperson:Click here to enter text.

Date:Click here to enter a date.

**APPENDIX B: ANIMAL SURGERY INFORMATION**

If surgery is proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures *[e.g., fasting, analgesic loading]*, and monitoring and supportive care during surgery. Include the aseptic methods to be used.

**Click here to enter text.**

1. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.

Name: Click here to enter text. Training: Click here to enter text. Qualifications: Click here to enter text. Experience: Click here to enter text.

1. Identify the location where surgery will be performed. *[building(s) and room(s)]*

Building: Click here to enter text. Room: Click here to enter text.

1. If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided. *[building(s) and room(s)]* Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.

**Click here to enter text.**

1. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.

**Click here to enter text.**

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

**Click here to enter text.**

* 1. Has major or minor survival surgery been performed on any animal prior to being placed on this study? *[Major survival surgery penetrates and exposes a body cavity 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.

#### Click here to enter text.

* 1. Will more than one survival surgery be performed on an animal while on this study?

If yes, please justify.

**Click here to enter text.**

**APPENDIX C: ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS**

For animals indicated in Section H.1. Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that will be used. *[A best practice is to provide an acceptable range of the specific items to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.]* If information is provided in Section R.5., above, please cross-reference. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements). Please include:

|  |  |
| --- | --- |
| Name of the agent(s): | Click here to enter text. |
| Dosage range: | Click here to enter text. |
| Route(s): | Click here to enter text. |
| Schedule of administration: | Click here to enter text. |

**APPENDIX D: TRAINING REGULATIONS**

All personnel involved in animal care, treatment, and/or use must be trained in accordance with the following guidelines to insure that several key concepts related to responsible care and use of animals are fully understood. These key concepts include:

* Humane animal care and use practices
* Research and/or test methods that minimize or eliminate animal use
* Research and/or test methods that limit animal pain and distress
* Database searches for alternative methods to reduce or eliminate pain and distress
* Procedures to report deficiencies in animal care and use
* Responsible conduct in research

Training will include, but not be limited to, instruction on the following:

* Regulations covering the humane practice of animal care and use; basic needs and proper handling and care for species used at SSU; pre- and post-procedural care of the animals; and aseptic surgical methods and procedures;
* Research or testing methods that minimize or eliminate the use of animals or limit animal pain and distress;
* Sources of information for alternatives to the use of animal research models;
* EHS lab safety training;
* Reporting of deficiencies or concern for animals;
* Instructions regarding animal ordering and receipt;
* Instructions on institutional policies and procedures.

Additional training will be offered to personnel on a regular basis and will include but not be limited to:

* Hands-on individual or group orientation sessions for newly employed personnel;
* Review of facility policies and procedures, in addition to specific SOPs before training, to inform animal care personnel about new policies, regulations or methods pertinent to animal activities;
* Individual instruction to scientists, technicians and students for specific techniques, including animal handling, surgery, anesthesia, and experimental manipulations
* Lectures from agency representatives or invited scientists on ethical, philosophical, and/or technical aspects of animal research.

Goals for training at SSU are for all staff, students, and PIs to understand and become familiar with include but are not limited to:

* State, local, and federal regulations related to animal care and use
* SSU policies and procedures regarding animal care and use and facility operations
* Occupational health and safety issues and zoonoses
* Proper use of anesthetics, analgesics, etc. to minimize pain and distress for the animals
* Instruction in aseptic surgical techniques
* Guidelines for endpoints and euthanasia
* Guidelines for alternatives to animal use, methods to reducing the number of animals used, and unnecessary duplication of studies

Online training and a Certificate of Completion is required from all PIs, students, technicians, and staff that work with animals. SSU subscribes to the Collaborative Institutional Training Initiative (CITI) at the University of Miami which includes modules for IACUC Chairs, Members and Coordinators, Investigators, Staff and Students, Working with Rats in Research Settings, Working with Mice in Research, Working with Fish in Research, Reducing Pain and Distress in Laboratory Mice and Rats, and Biosafety Security (pending). A Certificate of completion from the CITI training program is available at <http://www.citiprogram.org>. These trainings provide a good overall review of care and use of animals, research mandates, sanitation and cleanliness, occupational health issues, humane standards, EHS staff and responsibilities, right-to-know law, emergency spill response notification, blood borne pathogens and/or biohazards, personal protective equipment (PPE), hazardous waste management, fire response procedures, and laboratory practices and policies. The CITI training program curriculum fulfills federal training requirements.

All faculty, staff, graduate students, and researchers that use chemicals and/or generate hazardous waste must obtain EHS laboratory safety training. Certification must be kept current to work in any SSU laboratory. It is the responsibility of the faculty member or laboratory technician that oversees the laboratory to ensure that all workers complete the EHS laboratory safety training and maintain certification. The CITI Program’s Biosafety and Biosecurity training program fulfills federal training requirements.

The PI tracks all training events and reports the type of training offered and the participants that have successfully completed the training. The PI also maintains these records for inspection. Entries include the date of training, the procedure, and the individuals in attendance. The IACUC will review these records semiannually during their inspections.

Any personnel including faculty, staff, students, technicians, and/or principal investigators who work in the vivarium and affiliated laboratories must complete the following CITI training modules:

* Investigators, Staff and Students
* Working with Rats in Research Settings
* Reducing Pain and Distress in Laboratory Mice and Rats
* Biosafety Security (pending)

Any personnel including faculty, staff, students, technicians, and/or principal investigators who work at Cat Cove Marine Laboratory must complete the following CITI training modules:

* Investigators, Staff and Students
* Working with Fish in Research Settings
* Biosafety Security (pending)

1. Significant Change includes changes to in the objectives of a study; from non-survival to survival surgery; resulting in greater discomfort or in greater degree of invasiveness; in species or approximate number used; in anesthetic agent(s) or the use or withholding of analgesics; in euthanasia method; in duration, frequency or number of procedures performed on animal(s). [↑](#footnote-ref-1)
2. Animal Study Proposal adapted from the National Institutes of Health *Animal Study Proposal* and the University of Massachusetts Lowell *Animal Care and Use Protocol Form* [↑](#footnote-ref-2)