**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) PROTOCOL**

**FOR THE USE OF LIVE VERTEBRATES**

Principal Investigator (faculty/staff):

Campus Address: Email: Phone:

Phone Contact for Emergencies:

Type of Research: Faculty/Staff Undergraduate Graduate Masters Graduate Doctoral

Co-PI(s):

*(Please note that undergraduate and master's students cannot be added as co-PIs to a protocol, they should be listed under Other investigators below)*

Campus Address: Email: Phone:

Phone Contact for Emergencies:

Other Investigators not working with live animals:

Other Investigators working with live animals:

*If you collaborate with an individual from another institution who is also working with live animals on the project, the research must be submitted to that institution’s IACUC as well and a copy of the approval letter must be filed with SCSU’s IACUC.*

Project Title or Course Title:

Projected Start Date: Projected End Date:

Facility Where Research will be Conducted: ISELF Vivarium WSB291 Aquatics Lab WSB9 Fish Room

N/A Field Study Other:  (may require inspection of facility(ies) prior to protocol approval)

**As Principal Investigator, I verify that (all must be completed prior to protocol submission):**

I am familiar with and will comply with the Animal Welfare Act Regulations, Public Health Service Policy, Guide for the Care and Use of Animals and Guide for Care and Use of Agricultural Animals in Agricultural Research and Teaching

I agree to request approval in writing of any significant changes prior to their implementation and will notify the IACUC regarding any unexpected study results which impact the health and well-being of the animals

As the Principal Investigator, I will be responsible for all work conducted under this protocol

I certify the research proposed herein is not unnecessarily duplicative of previously reported research

As Principal Investigator, I and all other investigators have completed the required IACUC training upon protocol submission. I will verify all students involved with the research have completed the required IACUC training prior to their involvement with the animals and submit proof of training upon request.

Other (specify)

If submitting electronically, I hereby acknowledge this serves as my signature.

**Principal Investigator Signature:**\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**\_\_\_\_\_\_\_\_\_\_

**Dr. Nancy Cowardin;** [nlcowardin@gmail.com](mailto:nlcowardin@gmail.com); **cell 320-291-2689**

Backup Veterinarian: Dr. Jennifer Schurrer; [jschurrer10@gmail.com](mailto:jschurrer10@gmail.com); cell 763-333-6336

**Brian Lorenz;** [**balorenz@stcloudstate.edu**](mailto:balorenz@stcloudstate.edu)**; phone: 320-308-4911; emergency phone: 320-249-9686**

**A. FUNDING SOURCE**

Is there potential or confirmed external funding source(s) for this research project: Yes No

If yes, funding agency:  Account #:

**B. ANIMAL REQUIREMENTS**

Lab and farm animals or field studies\* where animals are held more than 12 hours:

Species (use common and scientific name):

Breed or Strain:

Animal Source(s) [e.g. vendor name or breeder; bred –inhouse]:

If captured from the wild, attach copy of permit or verify below when the required permitting will be obtained:

Primary Housing Location(s) [i.e. 291d, etc.):

Location(s) where manipulation will be conducted:

Number of animals to be used – Year 1:  Year 2:  Year 3:  Total:

Describe special housing needs:

Describe specialized husbandry needs:

Field studies\* where animals are held less than 12 hours:

Species (use common and scientific name):

Breed or Strain:

Location(s) where manipulation will be conducted:

Number of animals to be used – Year 1:  Year 2:  Year 3:  Total:

Capture/trapping methods:

\*Field studies

If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if federal, state, and/or local permits are required and whether they have been obtained.

If the endpoint is survival, what is the plan to care and house the animals?

What precautions will be taken to reduce non-target captures and what will happen to these animals after capture?

**C. TRANSPORTATION**

Transportation of animals must conform to all institutional guidelines/policies and applicable federal regulations. If regulated animals will be transported on public roads or out of state, describe methods you will use to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route and elevator(s) that will be used.

N/A If yes, explain in detail:

**D. STUDY OBJECTIVES**

Briefly explain the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society in language a layperson can understand.

Does the proposed research duplicate any previous work (respond to one of the following)?

If no, what procedures or sources did you use to determine this?

If yes, provide justification for duplication:

**E. RATIONALE FOR ANIMAL USE**

Please explain your rationale for animal use. *Include reasons why it is necessary to use animal models.*

Justify the appropriateness of the species selected. *Describe characteristics of the animal model that make it appropriate for use in your studies. This might include consideration of body size, comparative data from prior studies, or unique physiological features. Cost alone is not an acceptable justification for selection of the animal model.*

Justify the number of animals to be used. Provide statistically valid documentation to justify use of sample size (own previous work, published work, power calculations, etc.) *Should be minimum number required to obtain statistically valid results.*

**F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES**

**Briefly explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. *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.***

**Best practice is to provide an acceptable range of specific items to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol. For example:**

**Animal identification methods – ear tags, tattoos, collar, cage card, implant, etc.**

**Methods of restraint – restraint chairs, collars, vests, harnesses, slings, etc.**

**Experimental injections or inoculations – substances: infectious agents, adjuvants, etc.; dose, sites, volume, route and schedule**

**Blood withdrawals – volume, frequency, withdrawal site and methodology**

**Radiation – dosage and schedule**

**Food or fluid restriction – if restriction(s), describe method for assessing the health and wellbeing of the animals**

**Pharmaceutical-grade and non-pharmaceutical-grade compounds – identify any drugs, biologics, or reagents that will be administered to the animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.**

**Other procedures – survival studies, tail biopsies, etc.**

**Resultant effects – pain or distress, ascites production, etc.**

**Other potential stressors (noxious stimuli, environmental stress) and procedures to monitor and minimize distress. If study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.**

**Experimental endpoint criteria (tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.**

**Veterinary care – indicate the plan of action in case or animal illness (initiate treatment, call investigator prior to initiating treatment, euthanize)**

**Surgical procedures – provide details of survival and non-survival surgical procedures**

**G. SURGERY – Complete if applicable**

Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures (fasting, analgesic loading), procedures to assure antinociception (lack of response to noxious stimuli) and monitoring and supportive care during surgery. Include the aseptic methods to be used.

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

Identify the location where surgery will be performed (building, room #). If surgery is not performed in the surgical suite in ISELF, provide sufficient justification for the location:

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, room #). Include detection and management of postoperative complications during work hours, after hours, weekends and holidays. Verify the surgery will be conducted in a sterile environment.

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

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

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.

Will more than one survival surgery be performed on an animal while on this study? ☐ No

If yes, please explain:

**H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATIONS**

**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 as an attachment to the protocol. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the internet via the USDA’s website.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Species  (Common and Scientific Name) | USDA Classification  B, C, D or E | | | Number of Animals Used Each Year | | | | | | Total # of Animals |
| Year 1 | | Year 2 | | Year 3 | |
|  | |  |  | |  | |  | |  | |
|  | |  |  | |  | |  | |  | |

***Consideration of alternatives – If any procedures fall into USDA’s Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate the methods and sources used in the search:***

* ***Database references must include databases searched or other sources used, date performed (within the last six months prior to protocol submission), period covered, keywords used, search results, and alternatives.***
* ***Alternatives include methods that: refine existing tests by minimizing animal distress, reduce the number of animals necessary for an experiment, or replace whole-animal use with in vitro or other tests.***

If Classification D or E, literature search attached (be as current with literature as possible) and description provided as follows:

For all USDA Classification D and E proposals, I certify that I have reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether relieved or not. Yes I certify

If any procedures are USDA Classification E, Attachment 1-Explanation for USDA Classification E is attached.

If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system.

For animals in USDA 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. Include the name of the agent(s), the dosage range, route(s) and schedule of administration.

Describe tracking and security of controlled drugs (Drug Enforcement Agency [DEA] registration number; primary registrant or authorized user and name; how will the controlled drug(s) be tracked, stored and secured).

**I. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY**

Indicate the proposed method of euthanasia appropriate to the species. If a chemical agent is used, specify the dosage range and route(s) of administration. Describe method(s) to be utilized to assure death after euthanasia. If the method(s) of euthanasia include those NOT recommended by the AVMA Guidelines on Euthanasia (e.g. decapitation or cervical dislocation without anesthesia), provide scientific justification as to why such methods must be used. See the [www.avma.org](http://www.avma.org) website for more information. Indicate the method of carcass disposal. This section must be completed for every protocol even though your study does not involve planned euthanasia. The method outlined may be used in the event of unanticipated animal injury or illness.

NOTE: Only personnel with euthanasia training may conduct euthanasia.

**J. HAZARDOUS AGENTS**

Use of hazardous agents requires institutional approval; therefore, complete Attachment 2-Use of Potentially Hazardous Agents in Animals if applicable.

Are you using any hazardous agents for this project? Yes No

Are you receiving any hazardous donated agents?  Yes  No

For more information, contact:

Risk Management, Safety Administrator, 320-308-2145

**K. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS**

Not Applicable

Specify material (e.g. cell lines, antiserum, etc.):

Source:

Material sterile or attenuated: Yes No

Has the material been tested for pathogens? (e.g. Mouse Antibody Production (MAP), Rat Antibody Production (RAP), Hamster Antibody Production (HAP), PCR test) Yes No

I certify that the tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original tested sample. To the best of my knowledge, the material remains uncontaminated with rodent pathogens. Yes No Not Applicable

**L. EXEMPTION FROM EXERCISE FOR DOGS**

Are you seeing an exemption for scientific reasons from the institution’s plan to provide dogs with the opportunity for exercise? No Yes, then provide the basis of the request:

**M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY**

List any special housing, equipment, animal care or any departures from the Guide (e.g. special caging, water, feed, waste disposal, environmental enrichment, etc.)

Not Applicable

**N. REPORTING MISTREATMENT OR NON-COMPLIANCE**

The university is committed to the humane treatment of all vertebrate animals used in research and teaching activities. The privilege to use live animals for the advancement of science and medicine carries with it the responsibility to follow applicable laws, policies, and procedures established to promote the well-being and ethical treatment of animals. Concerns or complaints regarding the care and use of animals at the university should be directed to any member of the IAC UC or the Institutional Official. See [www.stcloudstate.edu/iacuc/members](http://www.stcloudstate.edu/iacuc/members).