|  |  |
| --- | --- |
| FOR IACUC OFFICE USE ONLY | |
| **PROTOCOL #:** | |  |
| **APPROVAL DATE:** | |  |
| **EXPIRATION DATE:** | |  |

***Saint Anselm College***

Institutional Animal Care and Use Committee (IACUC)

**Telephone:** 603-641-7156 **Email:** [egreguske@anselm.edu](mailto:egreguske@anselm.edu)

**ANIMAL CARE AND USE PROTOCOL**

|  |
| --- |
| **I. GENERAL INFORMATION** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Principal Investigator: | |  | | Degree(s): | PhD  MD  DO  DVM  Other: |
| Academic position/title: | |  | |
| E-mail address: |  | | | | |
| Office phone #: | 603- | | Emergency phone #: |  | |
| Protocol title: |  | | | | |
| Proposal type: | Initial Submission  Renewal  Modification (with tracked changes) | | | | |

|  |
| --- |
| **II. VERIFICATION OF OTHER REGULATORY APPROVALS** |

Check the boxes that correspond to this IACUC protocol.

The **Principal Investigator** is responsible for ensuring the appropriate permits and approvals remain up to date.

|  |  |
| --- | --- |
|  | **All investigators, students, and staff will complete:**  Medical questionnaire (required)  CITI IACUC Training (required)  Laboratory Safety Training  Other: |
|  | Hazardous or Controlled Chemical(s): List if applicable |
|  | Radiation Safety |
|  | Wildlife Permit(s): List if applicable |

|  |
| --- |
| **III. PROJECT OBJECTIVES AND JUSTIFICATION** |

Federal regulations mandate this section is written using **lay terms. Simplify** or **define** all field-specific terms and phrases so they are understandable at an *8th grade reading level*. The target audience includes non-scientists that must understand the objectives and importance of the proposed project.

|  |  |
| --- | --- |
| **A. Specific OBJECTIVES of this project.** State the hypothesis(es) to be tested and provide the explicit goals. | |
|  | |
| **B. Describe the potential CONTRIBUTIONS AND SIGNIFICANCE OF THIS PROJECT** to human and/or animal health and to the advancement of knowledge. | |
|  | |
| **C. Justify the** **USE OF ANIMALS.** Select the applicable justification(s) that explain why live animals are required to accomplish the objectives of the proposed study. If none apply, choose “Other” and provide rationale. | |
|  | The complexity of the processes or mechanisms being studied cannot be duplicated with in vitro models (e.g. cell culture), computer simulation, or with simpler species (e.g. invertebrates). |
|  | There is not enough information about the processes being studied to design in vitro/non-living models. |
|  | Animal tissues are required for the development of an in vitro system. |
|  | Methods have already been tested in vitro and must now be performed in live animals; or preclinical studies in living animals are necessary prior to human testing. |
|  | This is a behavioral, learning, or developmental study which must be performed in live animals. |
|  | Participants/students must interact with live animals to develop competence in animal handling and performing procedures (i.e. teaching and training protocols). |
|  | Other: |

|  |
| --- |
| **IV. SPECIES INFORMATION** |

Copy the tableas needed for each species.

|  |  |
| --- | --- |
| **A. Describe the study animals.** | |
| 1. **List the species, with the common name, to be used:** *Genus species* (common name) 2. **Bacteriological status:**  Conventional SPF  Defined flora  Axenic (microbe free) 3. **Viral status:**  No Yes. If yes, list: | |
| **B. Source.**  Bred in-house  Vendor, breeder, gifted. Provide company/lab/breeder. If from off-campus, provide transportation or  shipping method in space below.  Collected from the field. Provide collection information and transportation method in space below. | |
|  | |
| **C. Primary location(s):** Include building and room number. | |
| **Housing** |  |
| **Experimental** |  |
| **Transportation Method, if applicable** |  |
| **D. Justify the choice of species.** Explain why each species was selected and any unique characteristics that make them necessary for your investigations in space below. | |
|  | |
| **E. Transgenic animals.**  Will transgenic animals be used, created, or bred?  No  Yes. If yes, describe any phenotypic consequences of the genetic manipulations to the animal. Include  any special care or monitoring that the animals will require in space below. | |
|  | |

|  |
| --- |
| **V. NON-STANDARD AND REGULATORY EXCEPTIONS FOR ANIMAL HOUSING AND CARE** |

Describe any specialized care and housing practices.

|  |  |
| --- | --- |
| 1. **Will non-standard animal housing or care be used?** | No. If no, skip to Section VI. Yes. |
| B. Do you require an exception from standard **husbandry practices** or **environmental conditions** recommended in the [*Guide for the Care and Use of Laboratory Animals*](https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf) or [*Animal Welfare Regulations*](https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf)(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.)?  No  Yes. Describe and justify in space below. | |
|  | |
| C. Will **water or food be restricted** during any portion of the project?  No  Yes. Provide rationale and limits for the restriction below. Weights **must** be checked at least once a week,  otherwise, justify as a departure from the  [*Guide for the Care and Use of Laboratory Animals*](https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf)below. | |
|  | |
| D. **Non-standard drinking water**: For ANY additives placed in the drinking water, provide the following: 1) Name of additive, 2) Concentration/dose/volume, and 3) Frequency or duration treated water is provided. | |
|  | |
| E. **Non-standard diet/chow**: For ANY specialized diets used in place of the standard chow, provide the following: 1) Name of diet; 2) Dietary composition, including name & concentration of any drugs formulated into the diet, and 3) Frequency or duration. | |
| Confirm diet(s) are nutritionally balanced. Otherwise, provide justification. | |
| F. Do you require an experimental exception for **single housing** of social species?  No  Yes. Provide scientific justification in space below. | |
|  | |
| G. Describe and justify any other exceptions to the [*Guide for the Care and Use of Laboratory Animals*](https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf) *, or* [*Animal Welfare Regulations*](https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf), not addressed above. | |
|  | |

|  |
| --- |
| **VI. EXPERIMENTAL DESIGN** |

Explain the experimental design addressing the bulleted items below. Some details are requested in other sections (e.g. Section VIII Procedural Details, Section IX. Surgery Description), so avoid unnecessary duplication.

* Organize each experiment by number or letter and use the same system in Section VII. Animal Number Justification.
* Outline the experimental design sequentially. Flow charts add clarity and are highly recommended.
* Describe all procedures and time intervals between them.
* Include information on study duration and scientific endpoints.

|  |
| --- |
|  |

|  |
| --- |
| **VII. ANIMAL NUMBER JUSTIFICATION** |

|  |  |  |  |
| --- | --- | --- | --- |
| **A. JUSTIFICATION FOR THE EXPERIMENTAL NUMBER OF ANIMALS REQUESTED.**  Identify the experiments in the **same way they are organized in Section VI** and explain how many animals are needed for each. The number of animals **must** be the minimum number required to meet the goals of the study. Tables or flowcharts are encouraged. | | | |
|  | | | |
| **B. NUMBER OF ANIMALS USED FOR BREEDING.** Number includes adult breeders plus offspring generated. | | | |
|  | | | |
| **C. TOTAL NUMBER OF ANIMALS.** Calculate the total number of animals required during the 3-year approval period by species. All animals used in experiments, used for maintenance breeding, or culled *must* be accounted for.Indicate how many animals are utilized in each [Pain/Distress Category](https://tufts.box.com/s/8cbfluqnluvaxgeg8k2s8bf0j6wdvh4i):  **CAT B:** Animals being bred or held for future use. Wild animals held under proper captive conditions, or briefly observed and then released.  **CAT C:** Animals that used for teaching or study-related procedures that involved *no more than slight or momentary* pain, distress, and no use of pain-relieving drugs.  **CAT D:** Animals that underwent study-related procedures that involved more than momentary pain or distress which was *alleviated* with anesthetics, analgesics, or tranquilizers.  **CAT E:** Animals that experienced more than slight or momentary pain or distress that could *not be relieved* for study-related reasons. | | | |
| **Species name** |  |  |  |
| Category B |  |  |  |
| Category C |  |  |  |
| Category D |  |  |  |
| Category E |  |  |  |
| **Total number requested** |  |  |  |

Federal regulations require investigators consider alternatives for procedures that may cause more than momentary pain or distress. You must provide a written narrative description of the methods and sources that were used to determine that alternatives were not available. This only applies to **Category D** and **Category E** procedures. Category C procedures do not require an alternative search.

|  |  |
| --- | --- |
| **D. SOURCE FOR ALTERNATIVE SEARCHES** | |
| The database(s) searched |  |
| The date that the search was conducted |  |
| The years covered by the search |  |
| **E. METHODS & NARRATIVE DESCRIPTION FOR EACH SEARCH**  Suggested search strategy: “procedure” + “species” + “alternative” [e.g.: skin incision + mouse + alternative]  Provide a written narrative of the methods and sources used for each alternative search. The Committee must be able to assess if the search was appropriate and sufficiently thorough. Note: You are not required to provide the number of references retrieved or the alternative search for “anesthesia.” | |
|  | |

|  |
| --- |
| **VIII. PROCEDURAL DETAILS** |

1. **EXPERIMENTAL, THERAPEUTIC, OR OTHER ADMINISTRATIONS**

Copy/paste the table below as necessary. Protocols with multiple species must identify and include species-specific details, as necessary. Do not include anesthetics, analgesics, or water/diet provisions addressed in other sections.

|  |  |
| --- | --- |
| Name of substance |  |
| Dosage/Concentration |  |
| Volume |  |
| Route | SQ  IP  IM  IV  Other: |

1. **ANESTHESIA/SEDATION NOT USED for surgery or euthanasia.**

Add additional rows for Anesthetic/Sedation as needed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of procedure(s): |  | | | |
| Species: |  | | | |
| Anesthetic/Sedation Name | Dose | Route | Re-dose/ Maintenance | |
|  |  |  |  | and  or  +/- |
|  |  |  |  | and  or  +/- |
| Monitoring Methods: | | | | |
| All animals are monitored continuously while under anesthesia. (required) | | | | |
| Methods used to monitor anesthetic/sedation  (check all that apply): | | Responsiveness to stimuli | | |
| Respiratory rate/effort | | |
| Other: | | |
| Confirm supplemental heat and eye lubricant will be provided when the animal is under anesthesia for longer than 5 mins, or justify otherwise. | | | | |
| Recovery Assessment: Describe how recovery will be assessed in box below. | | | | |
|  | | | | |

1. **SURVIVAL BLOOD COLLECTION**

Protocols with multiple species and/or multiple experiments that include blood collection must clearly be identified below. Copy/paste the table as necessary.

|  |  |  |
| --- | --- | --- |
| Specify Experiment(s): |  | |
| Method of blood collection & site used | |  |
| Maximum volume for each sample | |  |
| Frequency of draws | |  |
| Maximum number of draws per animal | |  |
| If requesting larger volumes than recommended, provide scientific justification in box below: | | |
|  | | |

1. **BEHAVIORAL TESTS** Copy the tableas needed for each test.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of behavioral test |  | | |
| Frequency of testing/training sessions |  | | |
| Duration of testing/training |  | | |
| **METHODS USED** | | | |
| 1. Describe the goals and performance expected for each test. | | | |
|  | | | |
| 1. Will an apparatus be used? | | No Yes | If yes, describe below. |
|  | | | |
| 1. Will aversive stimuli be used? | | No Yes | If yes, describe the stimulus and its intensity, duration and frequency of administration below. |
|  | | | |
| 1. Describe limits to deprivation or aversive stimuli if desired response does not occur. | | | |
|  | | | |
| 1. Will rewards be used? | | No Yes | If yes, describe below. |
|  | | | |
| 1. Describe other techniques to be used below, if applicable. | | | |
|  | | | |

1. **USE OF** **ANTIBODY PREPARATIONS OR OTHER BIOLOGICS**

|  |  |
| --- | --- |
| 1. Are antibody preparations used? If so, check the appropriate box(es) below. | No  Yes |
| Antibodies will be obtained commercially (off the shelf) *OR*  Antibodies will be custom made. If custom made, continue below:  in vitro tissue culture techniques used *OR*  in vivo techniques used. If live animals are used, continue below:  in-house production (describe in Section VII) *OR*  vendor produced | |
| 2. Are other biologics (e.g. blood, serum, cellular components) used? If yes, describe below. | No  Yes |
|  | |

|  |
| --- |
| **IX. SURGERY DESCRIPTION** |

If more than one surgery will be performed, copy the table and answer all questions for each surgery.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **A. Name of surgery:** |  | | | | | | | Confirm  survival or  terminal | | |
| **B. Species:** |  | | | | | | | | | |
| **C. Check the relevant boxes for this surgery:** | | | | | | | | | | |
| The following are all required for survival surgery. Provide scientific justification to omit or change. Terminal surgeries only require continuous monitoring under anesthesia (the last box).  Disinfection of the surgical area/table.  Surgical instruments are sterilized prior to use and in between animals.  Supplemental heat is provided while the animal is under anesthesia.  All animals are monitored continuously while under anesthesia. | | | | | | | | | | |
| **D. Anesthetic details:** *Additional rows can be added as needed.* | | | | | | | | | | |
| **Anesthetic/Sedation Name** | | **Dose** | | | **Route** | | **Re-dose/ Maintenance** | | | |
|  | |  | | |  | |  | | | and  or  +/- |
|  | |  | | |  | |  | | | and  or  +/- |
| **Methods used to monitor anesthetic depth** (check all that apply): | | | Tail/toe pinch | | | | | | | |
| Respiratory rate/effort | | | | | | | |
| Other: | | | | | | | |
| **E. Describe the surgery.** *Do not repeat details confirmed in Part 2 and 3 above.* | | | | | | | | | | |
|  | | | | | | | | | | |
| **F. Analgesic regimen:**  *Additional rows can be added as necessary. Multiple analgesics may be chosen to provide flexibility. When multiple analgesics are selected, indicate and/or below.* | | | | | | | | | | |
| **Analgesic Name** | **Dose** | | | **Route** | | **Duration of Treatment** | | | | |
|  |  | | |  | |  | | | and  or  +/- | |
|  |  | | |  | |  | | | and  or  +/- | |

|  |
| --- |
| **X. REGULATORY EXCEPTIONS** |

In accordance with federal regulations, the items listed below must be approved by the IACUC. Check the correct box and provide the justification in the text box.

|  |
| --- |
| 1. Are **multiple major survival surgeries** performed on the same animal? Major survival surgery penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection. 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.     No  Yes. Provide scientific justification for these multiple surgeries in the box below. |
|  |
| B. Are unanesthetized animals **restrained** for **more than 30 minutes**?  No  Yes. Provide scientific justification in box below. |
|  |
| C. Are **non-pharmaceutical grade (NPG) substances** usedin live animals?  Check these references for availability of [animal pharmaceuticals](https://animaldrugsatfda.fda.gov/adafda/views/" \l "/search) or [human pharmaceuticals](http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm).  No  Yes. If NPG grade substances must be used, identify the justification(s) below:    No pharmaceutical grade veterinary or human drug is available or 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 that confound the research goals of the study.    Other: (provide justification in box below). |
|  |

|  |
| --- |
| **XI. DISPOSITION OF ANIMALS** |

Provide details of euthanasia for each species. Even if the experimental plan does not include euthanasia, protocols must include an emergency plan in case it becomes necessary.

* Methods of euthanasia not consistent with *[AVMA Guidelines](https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf)* must be justified below.

|  |  |
| --- | --- |
| **Species name:** |  |
| **Euthanasia:** | During the experiment  Upon completion of entire experiment  Euthanasia is not expected or required. **Emergency euthanasia only.** |
| **Euthanasia method(s):** |  |
| **Secondary method:** | Cervical dislocation  Decapitation  Thoracotomy  Exsanguination  Refrigeration/freezing (embryos, reptiles and fish only)  Other: |
| **Humane Endpoints**: List the criteria used to determine when euthanasia will be performed for humane reasons, even if prior to the experimental endpoint in space below. | |
|  | |

|  |
| --- |
| **XII. PRINCIPAL INVESTIGATOR ASSURANCE OF COMPLIANCE** |

**Protocol personnel must be added via IACUC Personnel Form.** All personnel must complete their IACUC requirements **prior** to being approved protocol personnel.

**As the individual responsible for this project, I confirm the following:**

|  |  |
| --- | --- |
|  | The information contained in this protocol is true and accurate, and to the best of my knowledge conforms to IACUC and NIH policies on the use of animals in research and teaching. |
|  | I certify that I will notify the IACUC regarding any unexpected or unanticipated study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC. |
|  | I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research. |
|  | I accept responsibility for ensuring that all personnel involved in this project will be trained regarding any potential biological, chemical, and radiological hazards, relevant safety practices, and emergency procedures. |
|  | I will complete all IACUC personnel requirements prior to working with animals OR within 2 months of the approval of my protocol, whichever comes first. |
|  | All personnel involved in this project, other than myself**,**will be added to the protocol using an IACUC Personnel Form. |
|  | All individuals involved will be instructed in the humane care, handling, and use of animals and I will review their qualifications and competency. |
|  | No change will be made to procedures, care, or housing without prior written notification to and approval by the Institutional Animal Care and Use Committee (IACUC). |
|  | **I understand that failure to comply with IACUC policies and procedures** will jeopardize Saint Anselm College Animal Welfare Assurances on file with the NIH and may **lead to revocation of my privileges to conduct animal research at this institution**. |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Principal Investigator (*provide* *electronic signature*) |  | Date |

*By typing your name, you are submitting an electronic signature that confirms your understanding and adherence to the above statements and IACUC policies. This is considered legal documentation and confirmation of your agreement to execute all activities as approved.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| IACUC Chair (*provide signature*) |  | Date |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| IACUC Veterinarian (*provide* *signature*) |  | Date |