**IACUC RESEARCH PROTOCOL FORM**

****

(ORI use only)

IACUC protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Submitted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NO ITEM IN THIS FORM MAY BE DELETED FOR ANY REASON**. This form must be submitted to the Institutional Animal Care and Use Committee (IACUC) via the Office of Research Integrity at UNCG. **Applications should be emailed to** **ori@uncg.edu** **and must include signatures and all other applicable documents related to the study.**

***STOP:* Consultation with the Attending Veterinarian and/or the Animal Facilities manager is highly recommended to take place ahead of this submission, please contact the ORI office at (336)-256-0253 for their contact information.**

**Instructions:** **PLEASE SUBMIT THIS FORM AS A WORD DOCUMENT WITH YOUR ELECTRONIC SIGNATURE.** This application must be completed for each separate research project. A significant change in an approved protocol requires new application. Attach a copy of the original approval and complete only those items on this form for which there are changes. Ensure the PI’s name and Protocol Title are on the header of each page. Double click on check boxes to activate the check mark.

1. **Principal Investigator:**

 Telephone #:       Email:

 Position:       Department/Unit:

 Co-Investigator(s):

 Position:       Department/Unit:

 Dates of research:       to

1. **Project Title:**

 [ ]  New Protocol **OR** [ ] Replacement for Protocol #

 (Check here if you are submitting a new protocol to replace an existing 3 year old protocol.)

1. **Project Support:**

[ ]  Grant: Agency [ ]  Pending [ ]  Funded

[ ]  \*Departmental Support:

[ ]  \*Teaching – Course Number(s), Year(s), Semester(s) offered:

[ ]  \*Other – Specify:

\*Requires Department head signature on final page.

1. **Collaborating Institutions (if applicable)**

Are there any collaborating institutions? Yes [ ]  No [ ]  Institution’s name:

Approved by institution? Yes [ ]  No [ ]  Protocol Number:            Approval date:

Institution’s FWA #:                 USDA Registration #:            PHS Assurance #:

Last approval date:

1. **Scientific Merit Review is required to take place before IACUC review.
Has this application had a Scientific Merit Review? Yes [ ]  No [ ]**

Departmental Scientific Merit Reviewer:

Name:

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(signature is required)*

1. **Relevant Training/Experience of all Professional and Technical Personnel**
2. List all individuals involved in the study who will be handling animals, performing procedures using live animals or are responsible for their welfare; state their duties and relevant training/experience. By **signing** below, each individual acknowledges his/her role and willingness to participate in the proposed project. By **signing** below, you also acknowledge that you have read and understand the study protocol.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | **Signature** | Duties & Animal Related Procedures Performed by Each Individual: (Add space if necessary.) | Training: List relevant experience and CITI modules completed | Animal handling? | Initials |
|       |  |       |       | [ ]  Yes [ ]  No |  |
|       |  |       |       | [ ]  Yes [ ]  No |  |
|       |  |       |       | [ ]  Yes [ ]  No |  |
|       |  |       |       | [ ]  Yes [ ]  No |  |
|       |  |       |       | [ ]  Yes [ ]  No |  |

1. **CITI Training Module “Working with the IACUC: Investigators, Staff and Students” plus appropriate species-specific modules *are* *required base modules for all investigators***. CITI Training is verified with the Office of Research Integrity.

[ ]  Check this box to confirm that all staff have completed the required modules or will do so prior to handling animals.

1. **Other Individuals**

List all ***other*** individuals in your laboratory who may be inadvertently exposed to animals (living or dead), animal wastes, body parts, or body fluids. These individuals (and the individuals listed in question 5 above) must be enrolled in the UNCG Occupational Health Program for Personnel Caring For or Using Laboratory Animals. It is the responsibility of the Principal Investigator to enroll these individuals and to ensure that the Office of Research Integrity is notified of the addition of any new personnel with animal exposure.

Training on Allergy Prevention, Zoonotic disease, etc. is performed in consultation with the Veterinarian and animal facility manager. Associated training records are maintained in the animal facility.

|  |
| --- |
| Name |
|       |
|       |
|       |
|       |

1. **Will all members of the research team receive an Occupational Health Screening prior to work?**

[ ]  Yes [ ]  N**o If no, why not?**

1. **Purpose**

BRIEFLY (no more than 250 words) describe in non-scientific terms (as if it were to appear as a newspaper article) the purpose and importance of this animal use activity.

1. **Benefit**

Describe the potential scientific benefit of the proposed study with respect to human or animal health, the advancement of knowledge, or the good of society (250 words or less):

1. **Classification of Animals into USDA Pain Categories:**

Federal agencies require animals be classified into pain and distress categories. If any procedures fall into Category D or E, describe your consideration of alternatives and your determination that alternatives to procedures causing pain or distress are not available. ENTER numbers in all columns.

**Number of animals projected on study in each category (see descriptions below table):**

|  |  |  |
| --- | --- | --- |
| Category C(non-painful procedures) | Category D(procedures with analgesia/ anesthesia to alleviate pain)**If zero is not entered, a literature search is required** | Category E(Painful or distressful procedures without anesthesia/analgesia)**If zero is not entered, a literature search is required** |
|  |  |  |

**Examples and Definitions of Categories:**

**Category C**—Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs. *Examples include: simple injections or microchipping, behavior observation, peripheral injections or blood collection, studies with no expected systemic toxicity based on prior data, retro-orbital bleeding (mouse).*

**Category D**—Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animal and upon which appropriate anesthetic, analgesic, or tranquilizing drugs will be used to relieve the pain/distress. *Examples include: Surgery (terminal or recovery), retro-orbital bleeding (rat), exsanguination and/or perfusion under anesthesia.*

**Category E**—Animals upon which teaching, experiments, research, surgery, or tests will be conducted that involve accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will not be used because they would adversely affect the procedures, results, or interpretation of teaching, research, experiments, surgery, or tests. *Examples include: Studies which require death as an endpoint; toxicological or microbiological testing, cancer research or infectious disease research that requires continuation after clinical symptoms are evident without medical relief or euthanasia; Toxicology studies with expected systemic toxicity that will not be relieved by euthanasia; Genetically engineered phenotypes that causes pain or distress that will not be alleviated.*

1. **Provide below a brief narrative description of the methods and sources that were used to determine that the proposed activities do not unnecessarily duplicate previous experiments or involve the unnecessary use of animals. (Computer software programs, videos, etc.) The following link is to assist investigators in their searches:** <http://www.nal.usda.gov/awic/alternatives/searches/altwksht.pdf>

Narrative:

1. Literature search for alternatives
2. Which databases were searched?

(Sources might include Biological Abstracts, Index Medicus [PubMed or Ovid databases], Agricola, ISI Web of Science, Chemical Abstracts)

1. Provide the most recent date that a full search was performed:
2. Range of dates searched:
3. Keywords should include those likely to yield information on alternatives to the potentially painful or distressful procedures or conditions that are part of this protocol. As such, one of the keywords included in your search terms should be either “alternative” or “alternatives.”

**Note on Keywords: Multiple searches using a variety of keywords are required.** Use as many synonyms as possible such as "cardiac" and "heart". Include acronyms and complete spellings (ie "GH" and "growth hormone"). Also include all possible spellings of words. For example, "anesthesia", and "anesthetic", and "anaesthesia". Include words that make the study different from other studies. This will help detect unintentional duplication as well as limit the scope of the search if the number of citations from a broader search is more than 200.

Keywords/Keyword combinations used:

Number of results returned:

1. Other methods or sources used (briefly describe):
2. Summarize how the above methods and sources have helped you identify alternatives or determine that alternatives are not available, or are not appropriate for this protocol.
3. **Experimental Design and Methods**

Provide a summary of the overall experimental design.

* The description should define animal groups, group sizes, anticipated or established mortality for these procedures, and how each group will be tested or used, and if pain will be transient or more than minimal.
* Describe the anticipated sequence of experimental events (timeline) such as receipt, breeding, preparation of animals, surgery, testing procedures, collection of tissues, euthanasia, duration of study for each group, etc.
* Include a table of your research design and if helpful, a timeline graphic.
* *This section should NOT include a detailed review of surgery or other activities, but should include the use of any unique drugs or practices. All procedures and surgeries should be listed; however, specific surgical information will be requested in #20 and procedures performed on tissues after harvest need not be described in detail. (Definitions of major surgery, minor surgery, and procedures are listed in question #20.)*

1. **Animal Use Justification**

The justification for using live vertebrate animals rather than alternative means of achieving the research goal is: (check all that apply.)

[ ]  The complexity of the processes being studied cannot be duplicated or modeled in simpler systems because:

[ ]  There is not enough information known about the processes being studied to design nonliving models. Explain:

[ ]  Other (explain):

1. **Species/Strain Justification (address each species individually)**
2. Species/Strain:

This species/strain was selected for the study because of the following attributes (select all that apply):

|  |  |  |
| --- | --- | --- |
| [ ]  | A large database exists allowing comparisons with previous data. | Explain:       |
| [ ]  | The anatomy or physiology is uniquely suited to the study proposed. | Explain:       |
| [ ]  | This is the lowest species on the phylogenetic scale that is suitable for the proposed study. | Explain:       |
| [ ]  | Other attributes. (details required). | Explain:       |

1. Will genetically altered animals be used? [ ]  No [ ]  Yes If Yes, continue below; if No, proceed to question #14.
2. Briefly describe the genetic alteration of interest
3. Will genotyping be performed under this protocol? [ ]  No [ ]  Yes: Describe
4. Describe the monitoring plan that will be used for early detection of potential impairments caused by the genetic change:
5. Describe how the phenotypic expression of this genetic alteration may impact the animals’ health and/or survival:
6. **Animal Use and Justification for numbers of animals requested**

In the table below, enter the animal groups and quantities that will be used in this protocol. Be sure to give the total number that will be used in the entire duration of the protocol.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species/Strain** | **Treatment Group(s)** | **Total # of Animals****per Group** | **Sex** | **Age/Weight** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|  Total number of animals to be used in this protocol:       |

1. Indicate how you arrived at the number of animals to be used for each group size, and total number of animals proposed for three-year period.

Supporting information:

[ ]  Indicate if a statistical analysis was performed to ascertain you have enough power to demonstrate significance

[ ]  The estimated minimum number necessary to achieve the goals of study in the absence of a statistical estimate

[ ]  The number is necessary to obtain sufficient tissue or other material for testing or analysis

[ ]  The number required to provide sufficient technical training or practice for the number of trainees expected

[ ]  Other:

1. What is your plan for keeping track of your usage of animals?

1. Have any of the animals to be used on this protocol been previously used on a different protocol?

[ ]  Yes [ ]  No

If **YES**, you must distinguish new animals to be acquired from animals already “in house” that were acquired using a different protocol. List the total number of animals that will be “transferred” from other protocols (list by species/strain and previous protocol number):

1. Where will animals be obtained and how will they be transported? Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If 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 method, route and elevator(s) that will be used

1. **Pain/Distress**

 Please indicate criteria and frequency of monitoring for pain and distress. The [Mouse Grimace Scale](http://integrity.uncg.edu/wp-content/uploads/2012/08/Mouse-Grimace-Scale.pdf) may be referenced.

If an animal in this study were ***not anesthetized***, would the animal feel more than momentary or slight pain or distress if exposed to the proposed procedures ? [ ]  Yes [ ]  No

If **Yes**, continue below; if **No**, proceed to question #16.

 **Will analgesia be used?** [ ]  Yes [ ]  No

 **Will anesthesia be used?** [ ]  Yes [ ]  No

If No to either, provide justification.

1. **Humane endpoints for adults and juveniles.** Complete a description of the proposed humane endpoints (i.e., the objective criteria used to determine whether animals will be euthanized or removed from study in order to minimize pain and distress). **(Check all that apply):**

|  |
| --- |
| [ ]  Infection unrelated to the protocol[ ]  Signs of moderate to severe pain or distress that was not anticipated by the study plan[ ]  Abnormal body weight loss exceeding 15% of free-feeding body weight relative to an aged-matched reference[ ]  Self-mutilation, or mutilation of an operative site [ ]  Neurological disorders (e.g., seizure, blindness, ataxia) that were not anticipated by the study plan (describe): [ ]  Cardiopulmonary disorders (e.g., sudden weakness, vascular collapse, coma) that were not anticipated by the study plan[ ]  Abnormal feeding or defecation for 48 hours (e.g., decreased feed or water intake and/or decreased fecal production) that is unrelated to the study plan[ ]  Non-weight bearing for >12 hours (e.g., difficulty walking, inability to maintain upright posture)[ ]  Dystocia[ ]  Hypothermia[ ]  Open wounds or ulcers[ ]  Recumbant (inability to ambulate)[ ]  Labored breathing that was not anticipated by the study plan[ ]  Other (describe):  |
|  **Humane endpoints for neonates.**[ ]  Not applicable[ ]  Mutilation[ ]  Moribund (e.g., cold, pale/gray, labored breathing)[ ]  Other (describe):  |

1. **Literature Search for Alternatives to Painful Procedures**

Provide below a brief narrative description of the following items:

* Methods and sources that were used to determine that the proposed activities do not unnecessarily duplicate previous experiments or involve the unnecessary use of animals (Mannequins, computer software programs, videos, etc.)
* Justification on why alternative procedures to eliminate or reduce the animals are not being implemented.

Narrative:

(Sources might include Biological Abstracts, Index Medicus [PubMed or Ovid databases], Agricola, ISI Web of Science, Chemical Abstracts)

Databases Searched (The minimum is two databases. Check all databases searched.):

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | AGRICOLA Data Base ATLA (Alternatives to Lab. Animal J.) | [ ]  | Quick Bibliography Series (AGRICOLA) Laboratory Animal Welfare Bibliography |
| [ ]  | MEDLINE Toxline | [ ]  | CAB Abstracts Biosis |
| [ ]  | Animal Welfare Information Center UC Davis / Johns Hopkins Web Search | [ ]  | Other (define):       |
| Number of results returned:       |

1. **Prolonged Restraint:**

Will prolonged restraint of unanesthetized animals be used? *Prolonged restraint is ≥ 15 minutes where the animal will be unable to perform normal postural adjustments, and/or temporary housing in spaces smaller than recommended by the Guide for the Care and Use of Laboratory Animals)*

[ ]  Yes [ ]  No

If yes, provide justification.

1. **Individual Animal Identification \***

[ ]  Individual animal identification is not necessary for this protocol.

[ ]  Individual animal Identification is necessary for this protocol.

Specify method(s) below (check all that apply):

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Ear Tagging with a unique numbered tag | [ ]  | Temporary Dye / Ink Marking |
| [ ]  | SQ Radio Tag | [ ]  | Ear Punch or notch |
| [ ]  | Collar | [ ]  | Tattoo |
| [ ]  | Other Methods: Please describe:       |

\*Regardless, each cage must be labeled, however this refers to the individual labeling of different animals within one cage.

1. **Drugs Administered**

Consult the UNCG Attending Veterinarian concerning the types of analgesics and anesthetics, proper dosages (in mg/kg), and routes of administration before completing this part of the application. If the answer to Question 15 was Yes, please describe the drugs proposed in the spaces below.

**Table 20-1 Pre-surgical sedation and analgesic drugs administered to live animals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug (generic name)** | **Dose (mg/kg)** | **Route** | **Frequency****of Administration** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

**Table 20-2** **Anesthetic drugs (including neuromuscular blocking agents) administered to live animals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug (generic name)** | **Initial Dose (mg/kg)** | **Additional****Maintenance Dose (mg/kg)** | **Route** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

1. What is the estimated total time period the animal will be anesthetized?
2. Neuromuscular blocking agents require specific justification for use; describe the equipment which will be used and how you will monitor anesthesia to ensure animals are properly treated.

**Table 20-3 Post Surgical/Post Procedural Analgesic or Tranquilizing Drugs**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug (generic name)** | **Dose (mg/kg)** | **Route** | **Frequency****of Administration** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

**Table 20-4 List all Drugs requiring DEA License**

|  |  |
| --- | --- |
| **Drug (generic name)** | **DEA License Holder Name** |
|       |       |
|       |       |

1. **List all other Agents administered to animals (e.g. excipients (vehicles), saline, solvents, compound agents, materials injected, fed, or applied that are NOT used to alleviate pain)**
2. Complete the following table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **/ Agent** **(generic name)** | **Dose (mg/kg)** | **Route** | **Frequency** | **Estimated Duration of Treatment** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

1. Are all of the agents listed above pharmaceutical grade materials (USP, NF, etc.) obtained from commercial sources? E.g. saline, sterile water, drugs, test materials. [ ]  Yes [ ] No

Note: Food grade materials administered orally do not need to be USP grade.

If No, please provide justification. Include information from certificates of analysis, if applicable:

1. **Dietary/Environmental Manipulations:**

***If animals will require dietary or environmental manipulations, please contact the Animal Facility Manager prior to submission to ensure manipulations are feasible and to learn the Facilities’ policies and procedures.***

1. Will animals be fed experimental diets? [ ]  Yes [ ] No

If yes, describe unique features of the experimental diets, who will be monitoring the animal’s intake, and any potential adverse consequences related to the diets.

1. Does the protocol involve restriction of food or water? [ ]  Yes [ ] No

If yes, which? [ ]  Food [ ]  Water

If yes, complete the following questions to describe the procedures involving food or water restriction and the methods used to monitor the health of animals.

* 1. Describe the method of restriction:
	2. Describe the duration of restriction:
	3. How will daily food or water consumption be measured?
	4. Animals must be weighed at least weekly and documents retained for IACUC/veterinary inspection, describe the schedule for weighing:
	5. Describe any additional methods for monitoring health, and criteria used for determining when supplementation or ad-lib feeding or watering will be performed.
	6. If you or a member of your research team will be responsible for providing food or water, please provide names of the individuals responsible for daily monitoring of these animals.
1. Will the protocol involve environmental alterations (e.g. reversed light-dark cycle, rat /mouse temperatures ≤ 68 or ≥79, etc.) during housing [ ]  Yes [ ]  No or during experimentation? [ ]  Yes [ ]  No

If yes to either, describe the alterations and provide scientific justification for doing this.

1. Will the protocol involve non-standard housing (e.g. custom caging, caging without solid bottom, single housing of social species, no enrichment, etc.) during housing [ ]  Yes [ ]  No
or during experimentation? [ ]  Yes [ ]  No

If yes to either, describe the alterations. If alterations disagree with the recommendations within the Guide for the care and use of laboratory animals, provide scientific justification for doing this.

1. **Will chemical restraint be used (anesthesia or sedation) solely for the purpose of immobilizing animals for transport or nonsurgical procedures that are expected to cause little or no pain (e.g., simple injections, percutaneous blood sampling, and physical measurements)?** Do not use this section to describe the use of anesthesia, sedatives, or other agents for pain management.

[ ]  Yes [ ]  No If Yes, proceed to A; if No, skip to Question 24.

1. Indicate below the reason for using chemical restraint:

[ ]  Chemical restraint will be used to permit safe handling and/or transport of animals.

[ ]  Chemical restraint will be used for blood collection and/or the administration of drugs or test agents.

[ ]  Chemical restraint will be used for painless data collection procedures (e.g., body measurements, magnetic resonance imaging [MRI], X-ray).

[ ]  Other chemical restraint purpose.

1. Please provide the details for the chemical restraint agent(s) below (address each species separately). Chemical restraint agents must be labeled for use in animals or humans.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Chemical Restraint Agent** | **Dose (mg/kg and Approx Volume)** | **Route of Administration** | **Frequency of Administration (Include Supplemental Dose Information, if Necessary)** | **Duration of Chemical Restraint** |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Surgical Procedures:**
2. Does the protocol involve surgery? [ ]  Yes [ ]  No **If Yes, proceed to B; if No, skip to Question 25.**
3. State whether the procedure is survival or terminal. (Check one or both as applicable.)

[ ]  Survival (major/minor surgical procedure from which animal is allowed to recover)

[ ]  Terminal (major/minor surgical procedure conducted in an anesthetized animal; animal is euthanized prior to recovery)

 *If terminal, go to Section C. If survival, go to Section D.*

1. Terminal Surgery:

**Provide a brief description of the surgical procedure.** At minimum, the surgical site must be clipped, the surgeon must wear gloves, and the instruments and surgical area must be clean.

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

Identify the location where surgery will be performed. [e.g. inside the animal facility or identify laboratory locations including building(s) and room(s)].

1. Survival Surgery

**Provide a brief description of the surgical procedures. Do not exceed one page.**

Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures [e.g., fasting, analgesic loading], 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. [e.g. inside the animal facility, or identify laboratory locations including building(s) and room(s)]

Note that survival surgery (including that done on rats and mice) must be performed using aseptic surgical technique, as per the PHS [*Guide for the Care and Use of Laboratory Animals*](http://www.nap.edu/books/0309053773/html/index.html) and NIH recommendations (e.g. http://oacu.od.nih.gov/ARAC/documents/Rodent\_Surgery.pdf )

**List the number/type of surgeries**\* **proposed.**

|  |  |  |
| --- | --- | --- |
| Experimental Group | No. of Major Survival Surgeries per Animal | No. of Minor Survival Surgeries per Animal |
|       |       |       |
|       |       |       |
|       |       |       |

\*Definition: Major survival surgery is any surgical intervention into a body cavity or having the potential for producing a permanent handicap in an animal that is expected to recover. The body cavity involved may be cranial, vertebral, thoracic, abdominal, peritoneal or joint. Less invasive surgical procedures (e.g. peripheral blood vessel cannulation, subcutaneous fat biopsy, muscle biopsy, etc.) are generally considered “minor” surgery. DNA collection (ear punch or tail snip), blood sample collection, microchip implantation, and tagging are considered “procedures” and need not be listed as surgery.

1. Post-Surgical Care

1. Describe post-surgical care, including:

1. Name(s) of individual(s) responsible for providing post-surgical care.

Note that for all survival surgeries, animals must be monitored daily, including weekends and holidays, records of animal condition must be maintained until the animals are fully recovered. Individuals responsible for post-surgical care must be listed.

1. Describe the type and frequency of animal monitoring (immediate post-surgical period and thereafter). Post-surgical monitoring of animals should occur at least every 30 minutes throughout recovery, and then at least twice daily until fully recovered.

1. Signs of distress monitored

1. Describe the plan for animals which show pain or distress even when appropriate analgesia has been provided.

2. If more than one major survival surgery is planned, provide scientific justification and list interval between procedures.You must also consider major surgery that has been performed prior to an animal’s inclusion in this protocol.

1. **Euthanasia:**

Describe the method used and how death will be verified ( a second method of death such as cervical dislocation or thoracic puncture is recommended). If appropriate, give generic rather than brand names of agents used, dosage (mg/kg) and routes of administration. **If euthanasia is not a scheduled part of this protocol, please describe the method to be used in the event it becomes necessary.** The method of euthanasia used should be consistent with the recommendations of the [latest guidelines from AVMA](https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx). If the method is not recommended by the AVMA, provide a detailed scientific justification.

Method:

|  |  |
| --- | --- |
| **Name of person performing euthanasia** | **Training credentials** |
|       |       |
|       |       |

1. **Hazardous Agents:**

Please list all chemical agents to be used. For each agent listed, indicate location of Material Safety Data Sheet (MSDS) and describe precautions needed for each substance.

|  |  |
| --- | --- |
| **Chemical Agent** | **Precautions** |
|       |       |
|       |       |
|       |       |
|       |       |

**Will EPA hazardous waste be produced? [ ]  Yes [ ]  No**

If yes, please identify disposal procedures to be followed.

**Will any regulated radioactive materials be used? [ ]  Yes [ ]  No**

If yes, secure approval from your Radiation Safety Officer.

**Radiation Safety Officer Signature (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Will any infectious materials be used in this protocol? [ ]  Yes [ ]  No**

If yes, explain and secure approval from the Institutional Biosafety Committee.

 **Biosafety Committee Approval Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **Legal Authorization:**

Is legal authorization from any state or country required for any aspect of this research (other than IACUC approval)? [ ]  Yes [ ]  No

If **YES**, please explain the nature of authorization, from whom it was obtained, and provide license/permit number and the dates covered by the permit/license. A site license is an example.

1. **Animal Housing and Enrichment**

It is the policy of the University that all laboratory animals must be housed in UNCG animal facilities maintained and managed by the Office of Research and Engagement (ORE). Exceptions to housing animals in Central Animal Facilities are made on the basis of scientific requirements of particular research projects.

1. Will ORE personnel provide the primary care (e.g. feeding, watering, cage changing) of experimental animals?

 [ ]  Yes [ ]  No

If **NO**, provide the name and signature of the investigator responsible for ensuring care of the animals. Note that current Standard Operating Procedures for the daily care of the animals must be available to a site visitor or inspector.

 Printed Name Signature

1. Will the animals be housed in a UNCG facility operated by the ORED? [ ] Yes [ ]  No

If **NO**,

1. Where will the animals be housed? Building       Room #
2. Have these facilities been previously inspected and approved to house the indicated species?

[ ] Yes [ ]  No

1. If the answer to either 27A or 27B is “no,” then provide detailed justification. State clearly why it is not possible to accommodate your experiment in facilities managed by the ORE or why personnel other than ORE staff should provide primary animal care.

1. Enrichment: All animals are required to have enrichment items in their home cage, typically nylabones, nestlets, huts, or tubes. What items will be used for animal enrichment, and if none, please identify any limitations in the type of enrichment that may be used.
2. Choose Single or Group housing: [ ]  Group [ ]  Single: If single housing is requested, please provide a scientific justification for single housing of social species (e.g. female mice, rats). No justification for single housing male mice is required.
3. Have you secured approval from the animal facilities staff that resources are available in the animal facility for your project?

 [ ] Yes [ ]  No

NOTE: Standard feed, bedding, enrichment, and water will be provided unless prior arrangements with the facility manager have been approved. The PI is responsible for providing all non-standard materials (special caging, enrichment, feed, etc.) used in the course of the study.

**PRINCIPAL INVESTIGATOR ASSURANCE STATEMENTS**

* ***I will abide by UNCG policies for the care and use of animals, the provisions of the most recent* Guide for the Care and Use of Laboratory Animals, *and all federal, state and local laws and regulations governing the use of animals in research.***
* ***I understand that emergency veterinary care will be administered to animals showing evidence of pain or illness, in addition to routine veterinary care as prescribed for individual species in the Standard Operating Procedures.***
* ***I certify that I have reviewed the applicable NIH guidelines on aseptic technique for surgery and will follow current veterinary standards for surgical procedures.***
* ***I certify that all manipulations involving live animals will be performed under my supervision or that of another qualified individual listed on this protocol.***
* ***I certify that all personnel having direct animal contact, including myself, are or will be adequately trained prior to participation in these studies.***
* ***I certify that personnel who have contact with animals or animal tissues through these studies will participate in the Occupational Health and Safety Program.***
* ***I certify that this proposed animal use does not unnecessarily duplicate previous activities.***
* ***I agree to obtain approval from the IACUC before initiating any changes in this study, including changes in personnel or location of animal use.***
* ***I will notify the IACUC and the attending veterinarian regarding any unexpected study results that adversely impact the animals, including any unanticipated pain or distress, morbidity or mortality.***
* ***I agree to follow the Animal Facility Manual guidelines and Standard Operating Procedures when conducting research on campus at UNCG.***

***I agree if at any time any member of the research team or their immediate family members have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a personal conflict of interest, the Potential Conflict of Interest in Research form must be attached to this application.***

 **I have read, understand, and will comply with the above assurance statements.**

Principal Investigator:

 Signature Date

Co-Principal Investigator:

 Signature Date

Research Assistant(s)/Other Investigator(s):

 Signature Date

Research Assistant(s)/Other Investigator(s):

 Signature Date

Research Assistant(s)/Other Investigator(s):

 Signature Date

***Any deviation from an approved protocol or violations of pertinent policies, guidelines or laws could result in immediate suspension of this project.***