|  |  |
| --- | --- |
|  | PROTOCOL NUMBER: |
|  |  |
| APPROVAL DATES: | MODIFICATION DATE(S): |
|  Date Filed: |  |
|  Approval: |  |
|  1st Renewal: |  |
| 2nd Renewal: |  |

1. Protocol Summary

# 1.1 Protocol Title

|  |
| --- |
|  |

# 1.2 Principal Investigator (PI) Name and Address

|  |  |  |  |
| --- | --- | --- | --- |
| First Name: |  | Department: |  |
| Last Name: |  | Phone Number: |  |
| Email Address: |  |  |
| Campus Address: |  |

# 1.3 Project Personnel

|  |  |
| --- | --- |
| **Name(s)** of all individuals involved in project | **Role in Project** (Indicate who will do euthanasia, anesthesia, surgery, and any other non-surgical procedure). |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  | YES | NO |
| Are all personnel trained on the procedures they will be performing? |  |  |

# 1.4 Type of Submission (Check One) and Provide Related IACUC Numbers

Standard Operating Procedures (SOPs) are available in the Vivarium, Vivarium Managers and the IACUC Administrative Assistant’s office.

In addition, IACUC reference materials are available outside GP3010.

|  |  |  |
| --- | --- | --- |
|  | New Protocol | (Not applicable for new protocols) |
|  | Year 3 Renewal of IACUC Protocol # |  |
|  | Pilot Study  |  |
| 1.4.1 Teaching / Training Protocol | YES | NO |
| Is this protocol for teaching / training / or education? (If YES, complete below) |  |  |
|  Check all that apply: |
|  |  | Undergraduate students |
|  |  | Graduate students |
|  |  | Course # / Title  |  |
|  |  | Only dead animals or tissues obtained through euthanasia by the PI |
|  |  | Non‑survival surgery (complete the section titled “Animal Surgery Information”) |
|  |  | Demonstration only by PI |
|  |  | Student involvement ‑ live animal observation and handling |
|  |  | Student involvement ‑ exposure to research |
|  |  | Student involvement ‑ gain skills, more than just handling (Explain below) |
|  |  | Other (Explain below) |
|  |  |

# 1.5 Funding Source(s):

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1.6 Project Start Date: |  | Project End Date: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1.7 Species |  | **Est. Proj.** | **Procedures:** Check ALL that apply(See below for corresponding *List of Procedures*) | **Pain** |
|  | Common Name and Strain | **#/Yr** | **Tot.** | a | b | c | d | e | f | g | h | i | j | k | l | m | z | Level |
| 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **List of Procedures**: | h. Food / Water Deprivation |
| a. Survival Surgeryb. Non-survival Surgery | i. Biohazard (i.e. Radioisotopes, Infectious Agents, Toxin/Mutagen/Carcinogen, Recombinant DNA) |
| c. Multiple Survival Surgery | j. Burns or Trauma |
| d. Prolonged Restraint | k. Drugs |
| e. Collection of Cells, Tissues, or Organs | l. Antibody production |
| f. Aversive Conditioning | m Diagnostic X-rays |
| g. Special Diet | z. Other (Specify:) |  |
| **\* Pain Levels:** **1** = negligible, **2** = pain/distress avoided/treated by appropriate drug use, **3** = pain/distress NOT avoided/treated by appropriate drug use. (Level 3 procedures require appropriate documentation and justification) |

# 1.8 Facility and Room # Where Procedures Will Take Place (If Multiple, so Indicate)

|  |
| --- |
|  |

# 1.9 Proposed Facility where Animals will be Housed (Must be an IACUC Approved Facility)

|  |
| --- |
|  |
| Special Conditions / Situations | YES | NO |
| **Housing Outside of the Central Animal Facility for More than 12 Hours** (in a Study Area) |  |  |
| **Will animals require care above the standard care levels (i.e. frequent cage changing; autoclaved caging, frequent monitoring, special bedding, etc.) Consult with the Vivarium Director to determine if additional costs are associated with this level of care.** |  |  |

1. Drug USE Summary

# 2.1 Analgesics / Anesthetics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Generic Name** | **Species** | **Dose (mg/kg)** | **Route** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

# 2.2 Sedatives / Tranquilizers

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Generic Name** | Species | **Dose (mg/kg)** | **Route** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

# 2.3 Antibiotics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Generic Name** | Species | **Dose (mg/kg)** | **Route** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

# 2.4 Miscellaneous and Other Drugs (Including IV Fluids)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Generic Name** | Species | **Dose (mg/kg)** | **Route** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |

# 2.5 Euthanasia Method(s) / Drug(s)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Euthanasia Method / Generic Drug Name** | Species | **Dose (mg/kg)** | **Route** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| 2.6 Will all drugs used be USP grade? (if not, please justify below) | YES | NO |
|  |  |
|  |

Note: All drugs used on animals before, during, or after an experiment or surgical procedure must be obtained from legal sources. All controlled substances should be kept in a double-locked compartment. Records should be kept documenting each use of a controlled substance. USE ONLY DRUGS THAT ARE WITHIN THEIR EXPIRATION DATE. All drugs should be disposed of properly when out of date or no longer needed. This applies to IV fluids as well.

1. Principal Investigator’s Assurance

# Read Carefully, then Sign and Date Below

I have provided an accurate description of the proposed animal care and use protocol and agree to the following conditions:

|  |
| --- |
| All experiments involving live animals will be performed under my supervision or that of other qualified individuals as indicated on this form. The personnel involved have been, or will be, trained prior to any animal work in proper procedures of animal handling, administration of anesthetics and analgesics, and the AVMA recommended methods of euthanasia to be used in this project. |
| No animal will be used in more than one major operative procedure from which it is allowed to recover, unless scientifically justified or required as a veterinary procedure. Paralytics will not be used without appropriate anesthesia. Medical care for animals will not be withheld and will be available and provided or supervised as necessary by a veterinarian. Animals that would otherwise experience severe or chronic pain/distress that cannot be relieved will be euthanized at the end of the procedure or, if appropriate, during the procedure. |
| I agree to report all animal purchases to the WPI Institutional Animal Care and Use Committee (IACUC) and to purchase only those animals approved for use and only up the maximum allowed by the IACUC. I understand that a failure to report all animal purchases to IACUC or to exceed the maximum number allowed is a violation and may result in the suspension of my approved protocol. |
| All personnel will be informed that any concerns for inhumane care and treatment of animals or unlawful acts involving animals should be reported to the IACUC and that anyone reporting such concerns cannot be discriminated against or be subject to any reprisal for reporting their concerns. Contact information for reporting, including names and telephone numbers, can be found at http://www.wpi.edu/Admin/Research/IACUC/.  |
| I agree to abide by governmental regulations and WPI policies concerning the use of animals. |
| I will ensure that veterinary care is provided to animals showing evidence of pain or illness. |
| I agree to give consideration to tissue sharing and will do so whenever possible. |
| I certify that any animal use proposed in a grant or contract proposal to support this research corresponds to the information provided herein. |
| If the procedures concerning animal use in this research activity are to be revised or changed, I will so notify the IACUC of these changes before the change is implemented. I understand that failure to request an amendment for changes in animal use may place WPI and myself in violation of Federal regulations and the Animal Welfare Act. |
| As required by Federal regulations, I assure that the activities described do not unnecessarily duplicate previous experiments and I assure the animal models proposed are the most appropriate for achieving the objectives of this project and have provided justification for each model used in the protocol (Animal Research Plan Rationale). |
| **Principal Investigator Signature:** |  | **Date:** |  |

1. CONFIRMATION OF SCIENTIFIC / INSTRUCTIONAL MERIT REVIEW

Before any project utilizing animals can be initiated, it must be reviewed and approved based on scientific or instructional merit. To assure the IACUC that this review is in place, the following information is needed regarding the review process that is applicable for this protocol. (**check one of the two boxes below far left**).

|  |  |
| --- | --- |
|  |  |
|  | This project will only be initiated after it has been peer‑reviewed outside of WPI (e.g. NIH, NSF, etc.)  |
|  | or within WPI by a formal *inter*departmental review group. If so, identify which group, agency or board has reviewed or will review this project for scientific or instructional merit. (Note: a signature is not required if you checked this box) |
|  |  |
|  | Name of Review Agency, Committee, or Board: |
|  |  |
|  |  |
| OR |  |
|  | This project is 1) ONLY being reviewed *within* a department or the project is for teaching/training purposes. |
|  |  |
|  |  | Departmental Committee |
|  |  |  |
|  |  | Name of Committee |
|  |  |  |
|  |  |  |
|  |  | Name of Committee Chairperson or Official Designee |
|  |  |  |
|  |  |  |
|  | Department Chairperson Signature: |  | **Date:** |  |
|  |  |  |
| **OR** |  |  |
|  |  |  |
|  |  | The Project is 2) you would like to initiate the project prior to receipt of an extramural award notice. If so, the chairperson of your department must attest to the scientific or instructional merit of this project. Please have him/her sign below on the signature line and indicate who conducted the review  |
|  |  |  |
|  |  | Describe Review Process |
|  |  |  |
|  |  |  |
|  |  | Name of Department Chairperson |
|  |  |  |
|  |  |  |
|  | Department Chairperson Signature: |  | **Date:** |  |

1. Animal Research Plan

The IACUC is responsible for ensuring that investigators have appropriately considered alternatives to animal use as well as test materials and procedures that may cause unnecessary pain and distress (USDA Pain Category D or E). Please keep the “Three R’s of Animal Research” in mind when completing this section of the form:

**Replacement** – refers to methods which avoid or replace the use of animals in an area where animals would otherwise be used. This includes both absolute replacements (i.e. replacing animals with inanimate systems, such as computer programs) and relative replacements (i.e. replacing more sentient animals, such as vertebrates, with animals that current scientific evidence indicates have a significantly lower potential for pain perception, such as some invertebrates).

**Refinements** – refers to the modification of husbandry, experimental or surgical procedures to minimize pain and distress, and to enhance the welfare of an animal used in science from the time it is born until its death.

**Reduction –** refers to any strategy that will result in fewer animals being used to obtain sufficient data to answer the research question or in maximizing the information obtained per animal and thus potentially limiting or avoiding the subsequent use of additional animals, without compromising animal welfare.

# 5.1 Project Overview / Objective

|  |
| --- |
|  |

# 5.2 Protocol Synopsis / Experimental Plan

|  |
| --- |
|  |

# 5.3 Rationale, Appropriateness, Alternatives, and Numbers

|  |
| --- |
| 5.3.1 Very briefly state the objective(s) and potential significance of the activities involving animal use (Explain why animals are required for your studies) |
|  |  |
| 5.3.2 List each species selected and discuss its appropriateness |
|  |  |
| 5.3.3 Discuss the appropriateness of the NUMBER of animals to be used |
|  |  |
| 5.3.4 Summarize the experimental design in a simple table or other form that clarifies how the groups, time frames, and totals of animal used are broken down |
|  |  |
| 5.3.5 Describe how you will prevent or minimize pain or discomfort to the animals through the use of anesthetics, analgesics, supportive care, or refinement of invasive techniques |
|  |  |
| 5.3.6 Discuss how have you determined that your proposed research does not unnecessarily duplicate previous experiments (For Pain Level 2 or 3, additional justification is required in the section titled “Judicious Use of Animals”) |
|  |  |

# 5.4 Judicious Use of Animals

|  |  |  |
| --- | --- | --- |
| 5.4.1 Does this project involve procedures that may cause more than momentary or slight pain or distress to animals? (Pain Level 2 or 3. If YES, complete below) | YES | NO |
|  |  |
|  5.4.2 Database(s) searched, INCLUDING the date range of the search and the date search was done |
|  |  |  |  |
|  Keywords Used |
|  |  |  |  |
|  Brief narrative description of search that led you to believe that no alternative was available |  |  |
|  |  |  |  |
| 5.4.3 Are "whole live animals" required for this project rather than alternatives, such as cultured cells? (If YES, provide a brief explanation of why below) | YES | NO |
|  |  |
|  |  |  |  |

# 5.5 Animal Tracking (Purchase, Housing, Usage, and Outcome)

## 5.5.1 Animal Purchase

|  |  |  |
| --- | --- | --- |
| Source or vendor used for animal purchase or acquisition: |  |  |
|  |  |  |  |
| Evidence or assurances of animal’s health status: |  |  |
|  |  |  |  |

## 5.5.2 Animal Housing in the Central Animal Facility

|  |  |  |
| --- | --- | --- |
| Will animals be housed for more than 12 hours in the Central Animal Facility (Gateway Vivarium)?(If YES, complete below) | YES | NO |
|  |  |
| How long is the quarantine period? |  |  |
|  |  |  |  |
| How long is the stabilization period? |  |  |
|  |  |  |  |
| How long will the animals be housed (estimate)? |  |  |
|  |  |  |  |

## 5.5.2.1

**Social Housing and Enrichment**

[ ]  Environmental Enrichment Devices/Food Supplementation will be provided as described in the IACUC approved SOPs, polices and guidelines.

[ ]  An exemption from enrichment is requested.

Please justify and detail which enrichment will not be provided below:

|  |  |  |
| --- | --- | --- |
|  |  |  |

[ ]  Social housing (full/periodic commingling) will be provided as described in the IACUC approved SOPs, polices and guidelines.

[ ]  Full [ ]  Periodic, please describe below:

|  |  |  |
| --- | --- | --- |
|  |  |  |

[ ]  An exemption from social housing is requested.

Please justify and detail the circumstances of this exemption below:

|  |  |  |
| --- | --- | --- |
|  |  |  |

## 5.5.3 Location of Animal Use

|  |  |  |
| --- | --- | --- |
| Will animals be used in the Central Animal Facility (Gateway Vivarium)? (If YES, skip forward to section titled “Animal Outcome”)  | YES | NO |
|  |  |
| Will animals be used (but not housed) in a laboratory outside of the animal facility? (If YES, complete below and then skip forward to section titled “Animal Outcome”) | YES | NO |
|  |  |
|  Building: |  |
|  |  |  |
|  Room: |
|  |  |  |
|  Duration: |
|  |  |  |
|  Frequency: |
|  |  |  |
|  Method of transportation (include safety precautions for animals and personnel): |  |
|  |  | YES | NO |
|  |
| Will animals be housed (more than 12 hours) and used in a study area? (If YES, complete below) |  |  |
|  Building: |  |  |
|  |  |  |
|  Room: |
|  |  |  |
|  Duration: |
|  |  |  |
|  Frequency: |
|  |  |  |
|  Method of transportation (include safety precautions for animals and personnel): |  |
|  |  |  |  |
|  Who provides husbandry: |  |
|  |  |  |  |

## 5.6 Animal Outcome YES NO

|  |  |  |
| --- | --- | --- |
| 5.6.1 Will the animal survive the research with no harm (#1)? (If YES, complete below) |  |  |
|  |  | Yes | No |  |
|  Will the animals be used in another protocol? (If YES, indicate protocol number and PI) |  |  |  |  |
|  | Protocol #: |  | PI:  |  |  |  |
|  Will the animals be adopted? (If YES, indicate arrangements that have been made, including the use of appropriate animal adoption forms) | Yes | No |  |  |
|  |  |  |  |
|  |  |  |  |
|  STOP: Skip forward to section titled “Anesthesia” | YES | NO |
| 5.6.2 Will animal be euthanized at the end of the research (#2)? (If YES, complete below) |  |  |
|  Describe and justify the procedure for euthanasia: |  |  |
|  |  |  |  |
|  How will death be determined: |  |  |
|  |  |  |  |
|  STOP: Skip forward to section titled “Anesthesia”. |  |  |
| **5.6.3 Will death be the endpoint, i.e. animal will be in experiment until its death (#3)?** (If YES, complete below) | YES | NO |
|  |  |
|  Briefly justify why death is the end point rather than euthanasia: |
|  |  |  |  |
|  Will euthanasia ever be considered or is there any other condition or stage (such as "moribund") at which euthanasia will be performed? (If YES, explain below) | Yes | No |  |  |
|  |  |
|  |  |  |  |
|  What sign is the animal expected to exhibit as it goes through the terminal stages? |  |  |
|  |  |  |  |
|  What measures can be taken to alleviate pain (e.g. analgesics)? (If NONE, please justify) |  |  |
|  |  |  |  |
|  Who will observe the animal during the terminal stages? |  |  |
|  |  |  |  |
|  What will be the frequency of observation? |  |  |
|  |  |  |  |

## 5.7 Anesthesia YES NO

|  |  |  |
| --- | --- | --- |
| Will animals be anesthetized? |  |  |
| (If NO, explain why not below) |  |
|  |  |  |
| (If YES, complete below) |  |  |
|  Who will administer the anesthesia: |  |  |
|  |  |  |
|  What anesthetic will be used and how: |  |  |
|  |  |  |
|  Who will fill out the anesthesia record: |  |  |
|  |  |  |
|  Who will monitor recovery (if allowed to recover): |  |  |
|  |  |  |
|  Explain anesthetic recovery monitoring (if applicable): |  |  |
|  |  |  |

## 5.8 Disposition of Sick or Injured Animals YES NO

|  |  |  |
| --- | --- | --- |
| Should the PI be called? (If YES, complete below) |  |  |
| Work Phone |  | Home/Cell Phone |  |  |  |
| Alternate person is |  | Home/Cell Phone |  |  |  |
| **In case of an emergency, should the Veterinarian or staff treat the animals?** (If NO, information and justification must be included above in section titled “Animal Outcome“. If YES, explain any restrictions on treatment below.) |  |  |
| YES | NO |
|  |  |
|  |  |  |  |

## 5.9 Disposition of Dead Animals / Tissues YES NO

|  |  |  |
| --- | --- | --- |
| Call investigator? |  |  |
|  Comments: |  |  |
|  |  |  |  |
| Necropsy special instructions (All unexpected deaths require necropsy) |  |  |
|  |  | YES | NO |
|  |
| Refrigerate carcass? |  |  |
| Freeze carcass? |  |  |
| Bag for disposal? |  |  |
| Other? (If YES, explain below) |  |  |
|  |  |  |  |

# 5.10 Pain, Distress, and Suffering

## 5.10.1 Consideration of Pain, Distress, and Suffering

|  |
| --- |
| What pain or distress is anticipated? (Be explicit and include potential for pain or distress while under anesthesia) |
|  |  |
| The PI, the project personnel, and the IACUC must observe for the following signs of pain or distress: \* Loss of appetite \* Restlessness \* Loss of weight \* Teeth grinding \* Failure to groom, causing an unkempt \* Licking, biting, scratching, or shaking a appearance particular area \* Loss of mobility \* Vocalizing \* Guarding (protecting the painful area) \* Failure to show normal patterns of \* Abnormal resting postures in which the animal inquisitiveness appears to be sleeping or is hunched up YES NO |
| Are there other signs that will be used to assess pain and distress? (If YES, explain below) |  |  |
|  |  |  |  |

## 5.10.2 Pain / Distress Care

|  |  |  |
| --- | --- | --- |
| All animals must be observed on a daily basis in the animal care facilities and laboratories. | YES | NO |
| 5.10.2.1 Does this protocol require special observation? (If YES, complete below) |  |  |
|  Frequency: |  |  |
|  |  |  |  |
|  By whom: |  |  |
|  |  |  |  |
|  Beginning: |  |  |
|  |  |  |  |
|  Ending: |  |  |
|  |  |  |  |
| 5.10.2.2 Will the WPI Veterinarian NOT be notified if UNANTICIPATED pain, distress, or suffering occurs? (If YES, explain below) | YES | NO |
|  |  |
|  |  | YES | NO |
|  |
| 5.10.2.3 Will other actions be taken? (If YES, complete below) |  |  |
|  What actions will be taken: |  |  |
|  |  |  |  |
|  By whom: |
|  |  |  |  |
|  When: |  |  |
|  |  | YES | NO |
|  |
| 5.10.2.4 Will drugs or other pain relieving methods be used for the relief of pain or distress? |  |  |
|  | If YES, list on the Drug Use Summary page. If NO [i.e. drugs WILL NOT BE USED for one or more procedures involving potential pain], provide a brief statement describing the painful procedure(s) and explain and fully justify why pain‑relieving methods, including administration of analgesics, are believed to be inappropriate. |   |   |
|  |  |  |  |
| 5.11 Animal Surgery Information | YES | NO |
| 5.11.1 Does this protocol involve ANY type of surgical procedure(s)? |  |  |
|  | Surgical procedures include non-survival, single-survival, and multiple-survival surgeries. If YES, complete below. (Anesthetic induction is NOT normally considered a surgical procedure)If NO, skip forward to section titled “Animal Use Procedures” |  |
| Where: |  |
|  |  |  |

## 5.11.2 Pre-Operative Procedures

|  |  |  |
| --- | --- | --- |
| Describe how animals will be prepared for surgery: |  |  |
|  |  | YES | NO |
|  |
| Do you plan to use specially modified animals (e.g. diabetics)? (If YES, complete below) |  |  |
|  Justify: |  |
|  |  |  |
|  Who is the person responsible for evaluating the health status of these animals: |  |  |
|  |  | YES | NO |
|  |
| Pre‑operative anesthetics? (If YES, list both below and in the “Drug Use Summary” section) |  |  |
|  |  | YES | NO |
|  |
| Will food be withheld? (If YES, complete below) |  |  |
|  Explain: |  |
|  |  |  |
|  How long: |  |  |
|  |  |  |
|  Why: |  |  |
|  |  |  |

## 5.11.3 Operative Procedure

|  |
| --- |
| Approach: |
|  |  |  |
| Procedure: |
|  |  |  |
| Closure: |
|  |  |  |
| List any organ(s) or tissue(s) involved: |  |
|  |  |  |
| Who will fill out the Operative Report: |
|  |  |  |

## 5.11.4 Post-Operative Procedures / Survival Surgery YES NO

|  |  |  |
| --- | --- | --- |
| Will the animal survive the surgical procedure? (If YES, complete below) |  |  |
|  Who will keep the post-operative record: |  |  |
|  |  |  |  |
|  Veterinarian / Individual who will monitor care: |  |  |
|  |  |  |  |
|  Who will observe and care for the animal daily: |  |  |
|  |  |  |  |
|  Who will administer post-operative analgesia: |  |  |
|  |  |  |  |
|  What analgesia will be given: |  |  |
|  |  |  |  |
|  When will post-operative analgesia begin: |  |  |
|  |  |  |  |
|  How often will post-operative analgesics be given (specify times): |  |  |
|  |  |  |  |
|  When will sutures be removed: |  |  |
|  |  |  |  |
| Will an individual animal be subjected to more than one survival surgery? (If YES, explain below how surgeries are related and justify the scientific need for more than one surgery per animal) | YES | NO |
|  |  |
|  |  |  |

# 5.12 Animal Use Procedures

## Collection of Cells, Tissues, and Organs YES NO

|  |  |  |
| --- | --- | --- |
| 5.12.1 Blood Sampling? (If YES, complete below) |  |  |
|  Technique: |  |  |
|  |  |  |  |
|  Site: |
|  |  |  |  |
|  Volume: |
|  |  |  |  |
|  Frequency: |
|  |  | YES | NO |
|  |
| 5.12.2 Urine/Feces Sampling? (If YES, complete below)  |  |  |
|  Method: |  |  |
|  |  |  |  |
|  Frequency: |
|  |  |  |  |
|  Duration: |
|  |  | YES | NO |
|  |
| 5.12.3 Collection of tissue(s) BEFORE euthanasia? (If YES, complete below)  |  |  |
|  Tissues: |
|  |  |  |  |
|  To Protocol No.: |
|  |  |  |  |
|  By Whom: |
|  |  |  |  |
|  Method of Disposal: |
|  |  | YES | NO |
|  |
| 5.12.4 Collection of tissue(s) AFTER euthanasia? (If YES, complete below) |  |  |
|  Tissues: |
|  |  |  |  |
|  To Protocol No: |
|  |  |  |  |
|  By Whom: |
|  |  |  |  |
|  Method of Disposal: |
|  |  |  |  |

## 5.13 Behavioral / Restraint / Dietary YES NO

|  |  |  |
| --- | --- | --- |
| 5.13.1 Behavioral testing of animals? (If YES, complete below) |  |  |
|  Describe the procedure, including any use of noxious stimuli: |  |  |
|  |  | YES | NO |
|  |
| 5.13.2 Brief physical OR prolonged restraint of animals? (If YES, complete below) |  |  |
|  | Brief physical restraint or induction of stress in animals for examination, collection of samples, and a variety of other clinical and experimental manipulations can be accomplished manually or with devices such as restraint stocks or squeeze cages. It is important that such devices be suitable in size and design for the animal and operated properly to minimize stress and avoid injury to the animal. Prolonged restraint or induction of stress in any animal, including the chairing of non‑human primates, should be avoided unless essential to the research objectives. |  |
|  Explain rationale for use of restraint or induction of stress: |
|  |  |  |
|  Describe the device and include dimensions or other specific features. Include pictures or diagrams if available (May be attached separately): |
|  |  |  |
|  Duration the animal will be confined to the device each time: |
|  |  |  |
|  Frequency animal will be confined to the device: |
|  |  |  |
|  Observation intervals during confinement: |
|  |  |  |
|  Qualified faculty or staff making the observations: |
| Name: |  | Phone: |  | YES | NO |
|  |
| 5.13.3 Will pain or discomfort be induced? (If YES, describe in detail below) |  |  |
|  |  |  |
| 5.13.4 Will analgesics, sedatives or tranquilizers be used to provide additional restraint? (If YES, describe in detail below) | YES | NO |
|  |  |
|  |  |  |  |
| 5.13.5 Will electrical or other forms of stimulation, including light and sound, be used to modify animal behavior? (If YES, describe in detail below) | YES | NO |
|  |  |
|  |  | YES | NO |
|  |
| 5.13.6 Will food be withheld for 24 hours or more? (If YES, describe in detail below) |  |  |
|  |  | YES | NO |
|  |
| 5.13.7 Will water be withheld for 12 hours or more? (If YES, describe in detail below) |  |  |
|  |  | YES | NO |
|  |
| 5.13.8 Will a special diet or water be used (nutritional deficit / supplementation)? (If YES, complete below)  |  |  |
|  Describe anticipated nutritional deficit/supplementation: |  |  |
|  |  |  |  |
|  Reason for and treatment of deficit/supplementation: |
|  |  |  |  |
|  How long will the diet be used: |  |
|  |  |  |
|  How will the general well‑being of the animal be determined: |  |
|  |  |  |
|  How often will animals be weighed: |  |  |
|  |  |  |  |
|  How much weight change will be permitted before the study is terminated: |  |  |
|  |  |  |  |

**A. Feed to be provided:**

[ ]  Standard, commercially available diet

[ ]  Special diet is requested.

[ ]  Other. Please list below:

Please describe the diet below, including regimen, any special storage conditions or husbandry practices required for administration (Please include diet formulation):

|  |  |  |
| --- | --- | --- |
|  |  |  |

**B. Water to be provided (check all that apply):**

[ ]  Tap water [ ]  Autoclaved water

|  |  |  |
| --- | --- | --- |
|  |  |  |

[ ]  Other (describe below)

Please describe the water below, including regimen, any special considerations or husbandry practices required for administration (Please include water formulation).

|  |  |  |
| --- | --- | --- |
|  |  |  |

## 5.14 Procedures and Implants

|  |  |  |
| --- | --- | --- |
| 5.14.1 Administration of agents, other than anesthetics or analgesics, such as: drugs / reagents / cells, etc.? (If YES, complete below and in the “Drug Use Summary” section) | YES | NO |
|  |  |
|  Agent: |
|  |  |  |  |
|  Route: |
|  |  |  |  |
|  Frequency: |
|  |  |  |  |
|  Side Effects: |
|  |  |  |  |
|  Treatment: |  |  |
|  |  |  |  |
|  Needle Size: |
|  |  |  |  |
|  Volume of Injection: |
|  |  | YES | NO |
|  |
| 5.14.2 Indwelling catheters or implants? (If YES, complete below) |  |  |
|  Size: |
|  |  |  |  |
|  Type: |
|  |  |  |  |
|  Maintenance: |
|  |  |  |  |
|  Duration: |
|  |  | YES | NO |
|  |
| 5.14.3 Tumor Transplantation? (If YES, complete below) |  |  |
|  Anticipated functional deficit: |  |  |
|  |  |  |  |
|  Treatment: |
|  |  |  |  |
|  Monitoring: |
|  |  |  |  |
|  End Point: |
|  |  | YES | NO |
|  |
| 5.14.4 Other procedures not covered above? (If YES, explain below) |  |  |
|  |  |  |  |
|  |
| * 1. **Rationale for Number of Animals**

**5.15.1 Does this protocol involve breeding?**[ ]  YES [ ]  NO If yes, provide the breeding scheme and estimated number of offspring produced per year below including the percentage of animals that will be used for study:

|  |
| --- |
|  |

**5.15.1.1 Are you requesting spare animals?** [ ]  YES [ ]  NO **5.15.2 . Is the percentage of additional animals needed as spares > 10% of the proposed number of study animals?**[ ]  YES [ ]  NO If yes, justify in the text box below.

|  |
| --- |
|  |

**5.15.3. Grouping of animals to be used:**Insert study design table below:**5.15.4.**  **The proposed numbers of animals, and group size should be based on one or more of the following: supporting historical data, regulatory requirements, published literature, *in vitro* requirements, and biometric analysis.**Rationale for appropriateness of number of animals obtained for the study, including additional animals bred/procured:

|  |
| --- |
|  |

 |

1. Hazardous Agents

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| 6.1 Will hazardous agents be used? (If YES, complete all information below) |  |  |
|  Study Involves (Check ALL that apply): |  |  |
|  |  | Radioactive Materials |  |  |
|  |  | X-ray machines |  |  |
|  |  | Infectious Agents (pathogenic to human or animal) |  |  |
|  |  | Acute Toxins |  |  |
|  |  | Known or suspect chemical carcinogens or mutagens |  |  |
|  |  | Recombinant DNA/RNA |  |  |
|  |  | Allergens |  |  |
|  |  | Corrosives |  |  |
|  |  | Irritants |  |  |
|  |  | Neurotoxins |  |  |
|  |  | Teratogens |  |  |
|  |  | Other (Describe) |  |  |
|  |  |  |
| STATUS OF REVIEW by the appropriate Hazards Committee(s) (Attach approval(s)) |
|  (If pending approval, a copy must be submitted as soon as approval is obtained) |  |  |
|  Committee Name(s) |  | Approval date(s) |  |  |  |
| 6.1.1 Identify Agent(s) |
|  Agents(s): |
|  |  |  |  |
|  Species: |
|  |  |  |  |
|  Dose (Volume): |
|  |  |  |  |
|  Route: |
|  |  |  |  |
|  Needle Size: |
|  |  |  |  |
|  Frequency: |
|  |  |  |
|  | Yes | No |  |  |
| 6.1.2 Are there risks to humans? (If YES, complete below) |  |  |  |  |
|  Method of exposure: |  |  |
|  |  |  |
|  Signs/Symptoms: |  |  |
|  |  |  |
|  Treatment: |  |  |
|  |  |  |
|  Protection: |  |  |
|  |  |  |
| 6.1.3 Are there risks to other animals in the room or animal facility? (If YES, complete below) | Yes | No |  |  |
|  |  |
|  Method of exposure: |  |  |
|  |  |  |
|  Signs: |  |  |
|  |  |  |
|  Treatment: |  |  |
|  |  |  |
|  Protection: |  |  |
|  |  |  |
| 6.1.4 Describe experimental procedures involving hazardous agents |  |  |
|  |  |  |
| 6.1.5 Is the duration of use of hazardous agents the same as the total project duration? (If YES, complete below) | Yes | No |  |  |
|  |  |
| Start Date |  | Stop Date |  |  |  |
| 6.1.6 Is there special animal care required relating to the use of hazardous materials? (If YES, describe below) | Yes | No |  |  |
|  |  |
|  |  |  |
| 6.1.7 Are there special containment facility requirements? (If YES, describe below) | Yes | No |  |  |
|  |  |
|  |  |  |
| 6.1.8 Are there waste and animal disposal requirements? (If YES, describe below) | Yes | No |  |  |
|  |  |
|  |  |  |

Antibody Information

Complete this section only if antibodies will be produced.

## Polyclonal Antibodies YES NO

|  |  |  |
| --- | --- | --- |
| Will polyclonal antibodies be produced? (If YES, complete below) |  |  |
|  Explain: |  |
|  |  |  |
|  Animal(s) to be used (list all species): |  |  |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Approximate number of antibodies per year: |  |  |  |
| Approximate number of animals needed per antibody: |  |  |  |
| TOTAL number of animals requested per year: |  |  |  |
|  Statistical justification of the TOTAL number: |
|  |  |  |

## Monoclonal Antibodies YES NO

|  |  |  |
| --- | --- | --- |
| Will monoclonal antibodies be produced? (If YES, complete below) |  |  |
|  Explain: |  |
|  |  |  |
|  Animal(s) to be used (list all species): |  |  |
|  |  |  |
| Approximate number of antibodies per year: |  |  |  |
| Approximate number of animals needed per antibody: |  |  |  |
| TOTAL number of animals requested per year: |  |  |  |
|  Statistical justification of the TOTAL number: |
|  |  |  |

## Immunization Procedures YES NO

|  |  |  |
| --- | --- | --- |
| Will you immunize animals? (If YES, complete below) |  |  |
|  Explain the procedure: |  |  |
|  |  |  |  |
|  | Yes | No |  |  |
| Will Freund’s Complete Adjuvant be used? (If YES, complete below) |  |  |
|  Justify: |  |  |
|  |  |  |
|  Site: |  |  |
|  |  |  |  |
|  Site preparation: |  |  |
|  |  |  |
| Number of sites: |  |  |  |
| Route: |  |  |  |
| Total volume: |  |  |  |
| How many times: |  |  |  |
|  | Yes | No |  |  |
| Will Freund’s Incomplete Adjuvant be used? (If YES, complete below) |  |  |
|  Justify: |  |  |
|  |  |  |
|  Site: |  |  |
|  |  |  |  |
|  Site preparation: |  |  |
|  |  |  |
| Number of sites: |  |  |  |
| Route: |  |  |  |
| Total volume: |  |  |  |
| How many times: |  |  |  |
| Will media other than Freund’s Complete Adjuvant be used, such as Ribi or Hunter TiterMax? (If YES, complete below) | Yes | No |  |  |
|  |  |
|  Name: |  |  |
|  |  |  |
|  Site: |  |  |
|  |  |  |  |
|  Site preparation: |  |  |
|  |  |  |
| Number of sites: |  |  |  |
| Route: |  |  |  |
| Total volume: |  |  |  |
| How many times: |  |  |  |

## Antibody Post-Procedure Care YES NO

|  |  |  |
| --- | --- | --- |
| Will post‑procedure care be required? (If YES, complete below) |  |  |
|  Who will provide care: |  |  |
|  |  |  |
|  What post‑procedure care is required: |  |  |
|  |  |  |
|  When will post‑procedure care be given: |  |  |
|  |  |  |
|  What analgesics will be given? (If none, explain) |  |  |
|  |  |  |
|  What will be the endpoint: |  |  |
|  |  |  |

## Antibody Collection Procedures YES NO

|  |  |  |
| --- | --- | --- |
| Will a chemical restraint be used? (If YES, complete below) |  |  |
| Generic name of drug: |  |  |  |
| Dose: |  |  |  |
| Route: |  |  |  |
| Frequency: |  |  |  |
| Who: |  | YES | NO |
|  |
| Will blood be collected prior to death? (If YES, complete below) |  |  |
| Method: |  |  |  |
| Frequency: |  |  |  |
| Total number of collections: |  | YES | NO |
|  |
| If ascites occurs, will fluids be removed from the abdomen prior to death? (If YES, complete below) |  |  |
| Method: |  |  |  |
| Frequency: |  |  |  |
| Total number of collections: |  |  |  |
| Describe and fully justify what anticipated unalleviated pain, stress, or discomfort may be expected to be associate with antibody production and collection |  |
|  |  |  |