**NATIONAL INSTITUTES OF HEALTH ANIMAL STUDY PROPOSAL [ASP]**

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PROPOSAL # APPROVAL DATE

EXPIRATION DATE

(6/22/2018)

1. **ADMINISTRATIVE DATA:**

Institute or Center

Principal Investigator

Building/Room \_E-Mail Telephone FAX

Emergency Treatment and Animal Care instructions shall be provided on the attached form at the end of this document.

Division, Laboratory, or Branch

Project Title

Initial Submission [ ] Renewal [ ] or Modification [ ] of Proposal Number List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., Co-investigator(s)): A brief summary of the training and/or experience for procedures each individual will be expected to perform in this ASP must be documented and available to the ACUC. The name(s) of the supervisor, mentor, or trainer who will provide assurance each individual is/has achieved proficiency in those procedures shall be included in that documentation.

1. **ANIMAL REQUIREMENTS:**

Species Age/Weight/Size Sex

Stock or Strain

Source(s) Holding Location(s)

Animal Procedure Location(s)

Estimated Number of Animals:

= Year 1 Year 2 Year 3 TOTAL

1. **TRANSPORTATION:** Transportation of animals must conform to all NIH and Facility guidelines/policies. Describe the methods and containment to be utilized if animals will be transported between facilities. Also include the route and elevator(s) to be utilized if animals will be transported within the Clinical Center.
2. **STUDY OBJECTIVES:** Provide no more than a 300 word summary of the objectives of this work. Address why this work is important and how it might benefit humans and/or animals. This should be written so that a non-scientist can easily understand it. Acronyms should be defined and only used when necessary. Please eliminate or minimize abbreviations, technical terms, and jargon.
3. **RATIONALE FOR ANIMAL USE:** 1) Explain your rationale for animal use. 2) Justify the

appropriateness of the species selected. 3) Justify the number of animals to be used. 4) If applicable, justify why this study uses only animals of the same sex in all experimental groups. (Use additional sheets if necessary)

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1. **DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES**: Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following: (Use additional sheets if necessary.)

**Injections, Inoculations or Instillations** (substances, e.g., infectious agents, adjuvants, medications, drugs, etc.; dose, sites, volume, route, diluent, and schedules). ACUCs will address non-pharmaceutical grade compounds IAW [Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals](http://oacu.od.nih.gov/ARAC/documents/Pharmaceutical_Compounds.pdf)

**Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology)

**Non-Survival Surgical Procedures** (Provide details of survival surgical procedures in Section G.)

**Radiation** (dosage and schedule)

**Methods of Restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)

**Animal Identification Methods** (e.g., ear tags, tattoos, collar, cage card, etc.)

**Other Procedures** (e.g., survival studies, tail biopsies, etc.)

**Potentially Painful or Distressful Effects**, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.) For Column E studies provide: 1) a description of the procedure(s) producing pain and/or distress; 2) scientific justification why pain and/or distress cannot be relieved.

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

1. **SURVIVAL SURGERY** - If proposed, complete the following:

None

Major\_

Minor

* 1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized. (Use additional sheets if necessary):
  2. Who will perform surgery and what are their qualifications and/or experience?
  3. Where will surgery be performed, Building and Room?
  4. Describe post-operative care required, including consideration of the use of post-operative analgesics, and identify the responsible individual:
  5. Has survival surgery been performed on any animal prior to being placed on this study? Y/N

If yes, please explain:

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

If yes, please justify:

1. **RECORDING PAIN OR DISTRESS CATEGORY *-*** *The ACUC is responsible for applying U.S. Government*

*Principle IV.: Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.* Check the appropriate category or categories and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

IF ANIMALS ARE INDICATED IN COLUMN E, A SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED. FOR USDA REGULATED SPECIES, PLEASE COMPLETE THE EXPLANATION FOR COLUMN E LISTINGS FORM AT THE END OF THIS DOCUMENT. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO THE USDA. FOR ALL OTHER SPECIES, THE JUSTIFICATION FOR SUCH STUDIES MUST BE PROVIDED IN SECTION F. NOTE: THIS COLUMN E FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT

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| **NUMBER OF ANIMALS USED EACH YEAR** | | | Year 1 | Year 2 | Year 3 |
|  | **USDA Column C** | Minimal, Transient, or No Pain or Distress |  |  |  |
|  | **USDA Column D** | Pain or Distress Relieved By Appropriate Measures |  |  |  |
|  | **USDA Column E** | Unrelieved Pain or Distress |  |  |  |

Describe your consideration of alternatives to procedures listed for Column D and E, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. **Database references must include the databases (2 or more) searched, the date of the search, period covered, and keywords used.**

1. **ANESTHESIA, ANALGESIA, TRANQUILIZATION:** For animals indicated in Section H, Column D, specify

the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route, and schedule of administration. ACUCs will address non-pharmaceutical grade compounds IAW [Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals.](http://oacu.od.nih.gov/ARAC/documents/Pharmaceutical_Compounds.pdf)

**NONE** (check if none)

1. **METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY:** Indicate the

proposed method, and if a chemical agent is used, specify the dosage and route of administration. If the method(s) of euthanasia include those not recommended by the AVMA Guidelines on Euthanasia, provide justification why such methods must be used. Indicate the method of carcass disposal if not as MPW.

**NONE** (check if none)

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| **K. HAZARDOUS AGENTS: NONE**\_\_\_\_(check if none)  Use of hazardous agents requires the approval of an IC safety specialist. |

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| **Biological Agents with Pathogenic Potential: NONE** (check if none) For guidance, see [ORS/DOHS Biological Safety and Compliance**.**](http://www.ors.od.nih.gov/sr/dohs/BioSafety/Pages/Registrations.aspx) Include the NIH Institutional Biosafety Committee’s  risk-assessment language or attach a copy of the registration documents. | | |
| Agent: | PRD #: | ABSL: |
| Additional occupational health and/or animal facility handling safety considerations: | | |

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| **Recombinant DNA: NONE** (check if none)  For guidance, see [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules FAQs.](http://osp.od.nih.gov/sites/default/files/Experiments_that_are_Exempt_from_the_NIH_Guidelines.pdf)  Include the NIH Institutional Biosafety Committee’s risk-assessment language or attach a copy of the registration documents. | | |
| Recombinant DNA: | RD #: | ABSL: |
| Additional occupational health and/or animal facility handling safety considerations: | | |

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| **Ionizing Radiation: (Radionuclides & radiation producing equipment)**  NONE\_\_\_\_\_ (check if none)  For guidance, see [ORS/DRS/Policies/Radiation Safety Protocols Animal Studies Proposal Requirements](http://drs.ors.od.nih.gov/policies/protocols/Pages/Animal-Studies-Proposal-Requirements.aspx) |

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| Yes, I will use radionuclides or radiation producing equipment as part of the experimental procedures on the ASP and all operators will be registered with Division of Radiation Safety. If an irradiator is to be used, then all individual users must comply with Division of Radiation Safety requirements for irradiator training, and all individual accessors will comply with applicable security requirements for escorts and proxy card access approval. |
| List of Radionuclides: |
| Radiological safety considerations: |

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| **Hazardous Chemicals or Drugs:**  **NONE\_\_\_\_\_**(check if none)  For guidance, see NIH Policy Manual 3034 – [Working with Hazardous Chemicals](http://oma1.od.nih.gov/manualchapters/intramural/3034/)  Material safety data sheets for hazardous chemicals and drugs must be maintained readily accessible to laboratory and animal facility employees ([Title 29, Part 1910.1200(b)(3)(ii), CFR](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&amp;p_id=10099)) |
| List of Agents: |
| Additional occupational health and/or animal facility handling safety considerations: |

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| **L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS: NONE** (check if none)  List cells/tissues, sera/antibodies, viruses/parasites/bacteria, and non-synthetic biochemicals that will be introduced into research animals. | | | |
| Material: | Source: | Sterile? | |
| Y | N |
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| If derived from rodents, has the material been tested, e.g. MAP/RAP/HAP/PCR? (If Yes, attach copy of results) | |  |  |
| Have the tested materials been passed through rodents outside of the animal facility in question? | |  |  |
| Is the material derived from the original MAP/RAP/HAP/PCR tested sample? | |  |  |
| I certify that to the best of my knowledge that the above is complete and correct, and that the material remains uncontaminated with rodent pathogens. | |  |  |

1. **SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY**: **NONE** (check if none)

List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.). Include justification for exemption from participation in the environmental enrichment plan for nonhuman primates or exercise for dogs.

1. **PRINCIPAL INVESTIGATOR CERTIFICATIONS**:
   1. I certify that I have attended an approved NIH investigator training course.

Month/Year of Initial Course Completion: ; Month/Year(s) of Refresher Training:

* 1. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
  2. I certify that all individuals working on this proposal who have animal contact are participating in the NIH Animal Exposure Program (or equivalent, as applicable, for contract personnel).
  3. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal, have completed the course "Using Animals in Intramural Research: Guidelines for Animal Users" will complete refresher training as required, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns. I further certify that I am responsible for the professional conduct of all personnel listed in Section A.
  4. **FOR ALL COLUMN D AND COLUMN E PROPOSALS (see section H):** I certify that I have reviewed the pertinent scientific literature and the sources and/or databases (2 or more) **as noted in section H,** and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
  5. I will obtain approval from the ACUC before initiating any significant changes in this study.

**Principal Investigator:**

Signature Date

1. **CONCURRENCES: PROPOSAL NUMBER (LEAVE BLANK)**

**Laboratory/Branch Chief:** (certification of review and approval on the basis of scientific merit and sex as a biological variable. Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief)

Name Signature Date

**NIH Safety Representative:** (signature represents certification, compliance and concurrence for use of material listed in the Hazardous Material Section)

**DOHS Safety Representative DRS Safety Representative**

**Facility Manager:** (certification of resource capability in the indicated facility to support the proposed study) Facility Name Signature Date Facility Name Signature Date Facility Name Signature Date Facility Name Signature Date

COMMENTS:

**Facility Veterinarian: Certification of Review**

Name Signature Date

**Attending Veterinarian: Certification of Review**

Name Signature Date

1. **FINAL APPROVAL:**

Certification of review and approval by the Animal Care and Use Committee Chairperson

Chairperson Signature Date\_\_\_\_\_\_\_\_\_\_