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| BROOKHAVEN NATIONAL LABORATORY  **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**    **ANIMAL USE PROTOCOL** | | |
| *The protocol must be typed and all questions must be answered. Answers must be written in English and in lay terms understandable to all IACUC members.* | | |
| **PROTOCOL #** |  |



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| **Title** |  | | |
| **Principal Investigator\*** |  | | |
| **Institution** |  | | |
| **Street Address** |  | | |
| **Phone** |  | | |
| **Fax** |  | | |
| **E-mail** |  | | |
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| **Key Investigators\*** |  | | |
| *\* Note - if no investigators are BNL employees, please list a BNL employee contact* |  | | |
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| **Funding Source**  ***Submit animal methods section of grant*** |  |  |  |
| **Home Institution IACUC Approval # and dates** | |  | |

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| **A. OVERVIEW** |
| **A.1 Please provide a brief description of the proposed studies in lay terms.** |
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| B. PERSONNEL AND TRAINING |
| B.1 In each box, list all personnel working directly with animals and indicate number of years of experience for each procedure for each species. |
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***Note: Any personnel with less than one year experience in any of the above categories must take the applicable training listed below.***

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| **B.2 Indicate which training courses apply to this protocol.** Use A to indicate all personnel or put initials of those required to take the training. *All courses are located at http://www.bnl.gov/training* |
| |  |  |  | | --- | --- | --- | | Required | COURSE TITLE | PROCEDURES COVERED | | A | Basic Overview of Laboratory Animal Care and Use | Overview required by all animal users | | A | Regulated Medical Waste Management | Required if regulated medical waste (animal carcasses, needles, syringes) will be generated as a result of the work | | The courses below are for BNL employees or guest researchers who have less than one year of training. Guest researchers must have appropriate training from their home institution. | | | |  | Biomethodology of the Mouse | Restraint, handling, identification, sexing, husbandry, behavior of mice | |  | Biomethodology of the Rat | Restraint, handling, identification, sexing, husbandry, behavior of rats | |  | Experimental Techniques in Rodents | Injections, blood sampling, oral gavage, euthanasia | |  | Post-Procedure Care of Mice and Rats: Reducing Pain and Distress | Analgesia, pain & distress recognition and alleviation, post-operative care | |  | Anesthesia in Laboratory Animals | Anesthesia techniques | |  | Survival Surgery in Rodents | Aseptic surgical techniques | |

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| **C. PROCEDURES** |
| **C.1 Concisely describe all manipulations and experimental procedures performed on animals.** *Everything done to the live animal at BNL must be detailed here, including the timing of shipment to/from BNL. A short description of experimental procedures done at collaborating institutions (if applicable) should be included. Include the end point of the experiment and timing of euthanasia, if applicable. Flow diagrams or charts are helpful.* |
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| **C.2 Does the work duplicate previous experiments/activities?**  *If yes, justify.* |
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| D. ANIMAL DESCRIPTION | |
| D.1 Species |  |
| D.2 Strain/Breed |  |
| D.3 Sex |  |
| D.4 Supplier |  |
| *If not a commercial vendor, a recent health report (no older than three months) from the animal facility must be submitted to the BLAF Manager at least two weeks before the planned experiment or shipment of animals. Please contact the BLAF Manager at (631) 344-3620 to make arrangements for the receipt of the animals. Rodents less than three weeks old must be received with their dams.* | |

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| **D.6 Justify that the work is appropriate to be done in an animal model.** *Indicate why a computer or non-animal model is not a viable alternative.* |
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| **D.7 Justify species to be used and why a lower phylogenetic species cannot be used.** |
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| **D.8 List total number of animals to be used.** |
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| **D.9 Justify number of animals.** Indicate design of study groups and statistical methods and include power calculations. Include steps taken to minimize the number of animals required. Flow diagrams or charts are helpful. |
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| E. PAIN/DISTRESS |
| E.1 List total number of animals at applicable levels of stress/discomfort |
| LEVEL A: No Pain or Distress: Animals will be euthanized without any treatments or manipulations; OR animals will undergo irradiation with minimally restricted movement and no anesthesia and without anticipated subsequent effects while at BNL.  Level B: Relieved or momentary pain or distress: Momentary pain or potential pain or distress relieved by pharmacologic, behavioral or other means, e.g., injection of any substance including anesthetics, post- procedural analgesics, behavioral conditioning, restraint or minor pain/distress and medical treatment of disease states.  Level C: Unrelieved or sustained pain or distress: Any procedure that would cause more than momentary or slight pain or distress, e.g., chronic untreated disease states, pain research. |

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| Species | LEVEL A | LEVEL B | LEVEL C |
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| Include scientific justification for any animals in Level C. | | | |

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| **E.2 For animals used in Level B or C, perform a literature search for alternatives to pain/distress**.  Use this link for search tips: <https://www.nal.usda.gov/awic/awic-tips-searching-alternatives-animal-research-and-testing> | |
| **List procedures that may cause pain/distress (e.g. imaging, surgery, injection, behavioral testing, food restriction, etc.) and perform a search using the procedure terms.** *Procedures that have pain eliminated by the use of anesthetics and/or analgesics are still considered painful even though the animal is not expected to experience any pain/distress.* | |
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| **Date of Search** |  |
| **Databases Searched** |  |
| **Key Words Searched.** *Include the word “alternatives”* |  |
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| **Provide a narrative of Search Results.** *List how many “hits” were obtained for key words used. If alternative procedures are discovered, identify them and justify why those procedures are not being considered*: | |
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| **E.3 For animals used in Level B or C, indicate how procedures have been refined to reduce the amount of potential pain, distress or morbidity.** |
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| **E.4 Describe if animals are subjected to food/water deprivation or prolonged and/or unusual restraint and provide justification.** *Describe how animal health is monitored during deprivation/restraint.* |
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| **E.5 Is death used as a study endpoint wherein animals must die without intervention such as pain relief and/or euthanasia?** *If yes, explain why an earlier end point is not acceptable.* |
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| **F. ANIMAL CARE** |
| **F.1 Describe additional requirements for other than routine animal care (e.g. housing, feeding, hazardous waste bedding disposal).** |
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| **F.2 Scientifically justify if animals must be singly-housed (excluding male mice).** |
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| **F.3 Scientifically justify if animals will not be provided with environmental enrichment.** |
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| **G. PROCEDURE SPECIFICS** | | | | | |
| **G.1 List all chemical agents (Sedatives, analgesics, anesthetics, paralytics, euthanasia, study drugs, radiotracers) administered to the animals.** *For ketamine anesthesia, please use intraperitoneal (ip) injections, not intramuscular (im). Ketamine/xylazine may be stored for up to 28 days after mixture.* | | | | | |
| Type | Agent | Dose | Route | Frequency | Controlled Substance (Y/N) \* |
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\*Note: Controlled Substance Awareness training and a DEA background Check will be required for anyone using controlled substances.

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| **For any non-pharmaceutical grade drugs/substances, the preparation and use of the drug must be scientifically necessary, appropriately justified and approved by the IACUC, taking into consideration the side effects, stability, sterility and aseptic handling, storage requirements and other considerations associated with the preparation of this agent.** *Please provide information in the box below for all non-pharmaceutical grade substances listed above.* |
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| G.1.a List the name(s) of the individual(s) administering the above agents. |
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| G.1.b If paralytic agents are used in conjunction with surgical manipulations, indicate the means by which absence of pain is monitored and/or determined, and who is responsible. |
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| **G.2 Is surgery involved?** *If yes, indicate whether surgery is survival or non-survival.* |
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| **G.2.a Describe monitoring and supportive care provided during surgery** *(who, what and how will this be done?)* |
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| **G.2.b Describe indications for analgesic therapy to be administered before, during, and/or following surgery.** |
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| **G.2.c Describe post-operative and supportive care (***who, what and how often).* ***Please use Surgery and Recovery Record (link to document)*** |
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| **G.2.d Who will maintain surgical and post-operative records and where will they be maintained?** *Records must be accessible for inspection and originals for USDA covered species must remain at BNL.* |
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| **G.3 Is anesthesia involved?** |
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| **G.3.a Describe monitoring and supportive care provided during anesthesia** *(who, what, and how will this be done?).* ***Please use Surgery and Recovery Record (link to document)*** |
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| **G.3.b Who will maintain anesthetic records and where will they be maintained?** *Records must be accessible for inspection and originals for USDA covered species must remain at BNL.* |
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| **G.4 Are animals to be used in more than one major surgical procedure from which they are allowed to recover?** *If yes, please describe and justify.* |
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| **G.5 For euthanasia performed at BNL (planned or unplanned), what method and by whom will animals be euthanized and how will death be confirmed? If a chemical agent is used, please list it in Section G.1.** *For euthanasia involving CO2, please use 100% CO2 at a 60% air replacement per minute rate. Justification must be provided for any physical method, such as decapitation, without anesthesia.* |
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| **G.6 List criteria for intervention and/or removal of animals from study or unplanned euthanasia.**  *• Examples are severe ataxia, rapidly increased heartrate or respiratory rates, oral, nasal or vaginal discharge such as pus or blood, wound dehiscence, marked swelling, tumor(s) greater than 2 cm or ulcerating, inability to eat or drink or loss of weight greater than 15%.*  *• Unless otherwise noted, 100% CO2 at a 60% air replacement per minute rate will be used for early euthanasia for rodents.* |
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| **H. SPECIAL CONSIDERATIONS** | | | |
| **H.1 Check materials used in this study that are hazardous to personnel.** | | | |
| **Human cells or fluid** | **Microorganism/Virus** | **Chemicals including fixatives** | **Recombinant DNA** |
| **Nanoparticles** | **Radioactivity (isotopes)** | **Irradiation** | **Other (Specify)** |
| **For each agent listed above, please ensure that it is covered under an approved ESR.** | | | |

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| **H.2 Indicate if animals will be shipped from BNL.** *If yes, indicate that BNL’s preferred shipping procedures will be followed. If other arrangements are necessary, please describe.* |
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| **H.3 If not shipped from an approved vendor, detail how animals will be transported to BNL.** |
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| **I. INVESTIGATOR ASSURANCE** | | | |
| I affirm to the best of my knowledge that all the above information is complete and accurate and agree to accept responsibility for this project in accordance with applicable Federal and State of New York regulations, USDA guidelines and established BNL policies and procedures.  **No changes will be implemented without approval from the IACUC.**  In order to reduce risk to all personnel and laboratory animals, I agree to:   1. Follow BNL procedures for aspects of the animal care and use such as preoperative care, anesthesia, surgical technique, postoperative care, sampling techniques, euthanasia, and disposal of contaminated carcasses and waste. 2. Ensure that my instructions to project personnel are implemented.   c. Ensure that all project personnel complete all required training before handling animals.  d. Instruct all personnel in my laboratory that they should inform me if they believe that the treatment of any research animal is inappropriate. If the situation is not resolved, the employee should contact the Attending Veterinarian, the IACUC Chair and/or Institutional Official.  e. Ensure that all research outlined under this protocol shall be carried out under approved Experimental Safety Review(s) (ESR). | | | |
| **PRINCIPAL INVESTIGATOR** |  | **DATE** |  |
| *Your Department Safety Coordinator will be notified of your IACUC approval.* | | | |
| **BNL DEPARTMENT** |  | **DATE** |  |

Please review the attached Principal Investigator Roles/Responsibilities/Accountabilities /Authorities and detach the page before submission to the IACUC.**Principal Investigator Roles/Responsibilities/Accountabilities/Authorities**

### Role

**•** Design and conduct properly approved research studies involving animals.

### Responsibilities

* Know and adhere to federal and BNL rules and regulations governing research involving animals.
* Submit research protocols and addenda to approved protocols to the IACUC for approval prior to start of work.
* Retain copies of all correspondence with the IACUC.
* Submit substantive annual reports of the results of research conducted under IACUC protocols.
* Identify in the IACUC protocol all personnel working on the protocol, including other investigators, technicians, etc.
* Direct the work of staff members conducting research under IACUC protocols.
* Ensure that all protocol personnel are appropriately qualified and that training is kept up to date, including facility-specific training.
* Follow all Brookhaven Laboratory Animal Facility (BLAF) policies and procedures.
* Ensure that animals are properly handled and monitored during a procedure or surgery, as defined in the IACUC approved protocol, and ensure that research procedures that are followed are those defined in the IACUC approved protocol.
* Ensure that animals receive appropriate post-procedure care and monitoring.
* Ensure that animals are transported, on and/or off-site, by proper methods.
* Ensure that all approved protocols, addenda, and terminations are distributed to all protocol personnel, and that such personnel have read and understand the documents.
* Promptly report animal distress or unexpected death to Attending Veterinarian and/or BLAF staff.
* Report any unusual or adverse event or unanticipated problem to the IACUC.
* Maintain records according to Sponsor’s requirements or for at least three years following completion of research.
* Make records available for inspection by the IACUC, the United States Department of Agriculture (USDA) or other federal or state government agencies as required.

### Accountabilities

* To the IACUC
* To the Department Chair
* To the Department Training Coordinator

### Authorities

* Stop or interrupt an animal research study upon evidence of a hazard to the safety of study personnel
* Stop or interrupt an animal research study if an issue of animal welfare and/or protocol compliance arises