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

***Northeastern University***

Institutional Animal Care and Use Committee (NU-IACUC)

**Telephone:** 617-373-3958 **Email:** iacuc-office@northeastern.edu

**Website:** <https://dlam.neu.edu/>

**ANIMAL USE PROTOCOL AMENDMENT**

*Amendments to protocols require Institutional Animal Care and Use Committee (IACUC) review and approval* ***prior*** *to initiation. The IACUC reserves the right to determine whether proposed changes require more information, full committee review, or submission of a new protocol. When submitting an amendment, the Principal Investigator is required to review all the details of the original protocol to assure the IACUC that all un-amended details remain identical to the original protocol.**Please note that certain changes to protocols may affect other aspects of the protocol. Those changes also need to be reflected in this amendment.*

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRINCIPAL INVESTIGATOR:** |  | DEGREE(S): |  |
| ACADEMIC POSITION/TITLE: |  |
| DEPT/DIV: |  |
| E-MAIL ADDRESS: |  |
| DIRECT PHONE #: |  | CELL PHONE # |  |
|  |
| **LABORATORY MANAGER or PRIMARY CONTACT:** |  | DEGREE(S): |  |
| E-MAIL ADDRESS: |  |
| DIRECT PHONE #: |  | CELL PHONE # |  |
| **PROTOCOL NUMBER & TITLE:** |  |

|  |
| --- |
| **PROPOSED MODIFICATIONS** |

**For applicable checkboxes, double-click on the box and then select “checked” to mark**,and then complete the relevant sections of the amendment form to describe changes or additions to your original protocol.

[ ]  Additional animals OR change in Pain/Distress Category

[ ]  New species

[ ]  New procedure OR change in procedure

[ ]  Change in location

[ ]  None of the above

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

Please check all that correspond to this IACUC Protocol Amendment. Double-click on a box and then select “checked” to mark your selection**.** The Principal Investigator is responsible for ensuring that the appropriate permits and approvals remain up to date. For the hazardous agents listed below, the PI must complete submit an **Animal Hazardous Materials Addendum (AHA)** along with the animal protocol amendment**. This form is to be reviewed and approved by both the IACUC and the IBC/EH&S. Include any safety plan with the AHA.**

|  |  |
| --- | --- |
| [ ]  | **Animal Hazardous Materials Addendum (AHA) has been completed and submitted with this protocol** |
| [ ]  | **Institutional Biosafety Committee (IBC)** [Scope of IBC review and responsibility](https://www.northeastern.edu/ehs/ehs-programs/biosafety/) | [ ]  | **Approval from Radiation Safety**list use of irradiator, lasers, x-rays, UV, radiation, etc.:. |
| Biohazardous Agent(s) |
| [ ]  | **Environmental Health and Safety (EHS) Chemical Hazard** Attach Animal Hazardous Materials Addendum & applicable chemical safety plan. | [ ]  | **Wildlife Permit(s)**Permit(s) issued for: |
| Chemical Hazard Name(s): |

|  |
| --- |
| **III. JUSTIFICATION FOR ADDITIONAL ANIMALS** Check here if N/A [ ]  |

|  |
| --- |
| **Provide justification for additional animals.**  Describe why additional animals are requested and explain how their use relates to the objectives, goals, and hypothesis(es) described in the main protocol. |
|  |

|  |
| --- |
| **IV. CHANGE OR ADDITION OF SPECIES** Check here if N/A [ ]  |

|  |
| --- |
| **A. Indicate NEW species being requested.** Boxes can be duplicated as needed. |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Species name |  | Species name |  |

 |
| **B. Justify the choice of NEW species.** Explain why each species was selected and any unique characteristics that make them necessary for your investigations. *If species-specific training is needed, contact the* *DLAM Office*. |
|  |
| **C. Transgenic animals.**  Will transgenic animals be used, created, or bred? If yes, continue by confirming the box below: | [ ] Yes [ ]  No |
| [ ]  | **I confirm** that neither parental transgenic rodent contains the following genetic modifications: (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.  |
| ***\*Note:*** *This confirmation means the transgenic rodents are exempt from the NIH Guidelines and IBC approval is not required. If this exemption cannot be confirmed, or the transgenic animals are not rodents*[*, IBC approval*](https://www.northeastern.edu/ehs/ehs-programs/biosafety/) *is required. Contact the* *Biosafety Office* *if you have questions about this section.* |

|  |
| --- |
| **V. REGULATORY EXCEPTIONS** Check here if NO CHANGES or N/A [ ]  |

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

|  |
| --- |
| 1. Are **multiple major survival surgeries** performed on the same animal? Major survival surgery penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection. Some surgical procedures characterized as minor may induce substantial post-procedural pain or impairment and should be similarly justified if performed more than once in a single animal.

  [ ]  No [ ]  Yes. Provide scientific justification for these multiple surgeries & the timeframes between them below. |
|  |
| 2. Are unanesthetized **animals restrained for 30 minutes or longer**? See [*IACUC Policy for Physical Restraint of Research Animals*](https://research.northeastern.edu/app/uploads/sites/5/2022/05/Physical-Restraint-Final-2022.docx)*.* [ ]  No [ ]  Yes. Provide scientific justification below: |
|  |
| 3. Are **non-pharmaceutical grade (NPG) substances** usedin live animals? See [*IACUC Policy on the Pharmaceutical and Non-Pharmaceutical Grade Compounds in Animals*](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Policy-on-the-Use-of-Non-Pharmaceutical-Grade-NPG-Substances-and-Expired-Materials-Final-2022.docx) .[ ]  No.[ ]  Yes. If NPG grade substances must be used, please identify the justification(s) below:[ ]  No pharmaceutical grade veterinary or human drug is available or consistently available.[ ]  Although a pharmaceutical grade drug is available, the NPG drug is required to replicate methods from previous studies. [x]  Although a pharmaceutical grade drug is available, a greater concentration, different formulation, or route of administration is required.[ ]  The available pharmaceutical grade formulation contains preservatives or inactive ingredients that confound the research goals of the study.[ ]  Other (provide justification below).Note: NPG substances will be the highest-grade available and formulated aseptically using sterile and biocompatible solutions appropriate for the route of administration. In addition, NPG substances administered parenterally (IV, IP, IM, SC) will be sterilized (sterile filtered, autoclaved, etc.) or justified below. |
|  |
| 4. Will **water or food be restricted** during any portion of the project? *See* [*IACUC Policy on Food/Fluid Restriction/Special Diet*](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Food-Fluid-Restriction-Final-2021.doc)for specific protocol requirements. [ ]  No [ ]  Yes. Provide scientific justification below and the time limits for the restriction or deprivation. |
|  |
| 5. Do you require an experimental exception for **single housing** of social species? See [*IACUC Policy on Single Housing of Research Animals*.](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Single-Housing-Policy-Final-2022.docx) [ ]  No [ ]  Yes. Provide scientific justification below:  |
|  |
| 6. Do you require an exception from standard **husbandry practices** or **environmental conditions** recommended in [*The Guide for the Care and Use of Laboratory Animals*](https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf) or [Animal Welfare Regulations](https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf)(e.g. prolonged cage or bedding change intervals, cage size, alteration of temperature, humidity, light level/cycle, use of wire bottom caging, removal of bedding substrate, exclusion from environmental enrichment, etc.)? [ ]  No [ ]  Yes. Describe and justify below: |
|  |
| 7. Describe and justify any other exceptions to [*The Guide for the Care and Use of Laboratory Animals*](https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf), Animal Welfare Regulations, or IACUC Policies not addressed above. |
|  |

|  |
| --- |
| **VI. NON- STANDARD ANIMAL HOUSING AND CARE** Check here if NO CHANGES or N/A [ ]  |

Describe specialized care and housing practices that do NOT constitute Regulatory Exceptions described above.

|  |
| --- |
| 1. Describe any **alterations of standard caging** or **specialized husbandry practices** that are not regulatory exemptions (e.g. use of metabolic caging, pinnacle caging, nonstandard enrichment conditions, etc.)Note: *Non-standard caging or equipment should be approved by DLAM prior to use.* |
|  |
| 2. **Non-standard drinking water:** For ANY additives placed in the drinking water, provide the following: 1) Name of additive, 2) Concentration/dose/volume, and 3) Frequency or duration treated water is provided.  |
|  |
| 3. **Non-standard diet/chow**: For ANY specialized diets used in place of the standard chow, provide the following: 1) Name of diet; 2) Dietary composition, including name & concentration of any drugs formulated into the diet, and 3) Frequency or duration.  [ ]  Confirm diet(s) are nutritionally balanced. Otherwise, provide justification below.  |
|  |

|  |
| --- |
| **VII. CHANGE IN PROCEDURE** Check here if NO CHANGES or N/A [ ]  |

|  |
| --- |
| **1. LIST PROCEDURE(S) TO BE ADDED OR CHANGED.** |
|  |

|  |
| --- |
| **2. DESCRIBE AND JUSTIFY EACH NEW PROCEDURE/EXPERIMENT.** Some details are requested in other sections (e.g. Section VIII Procedural Details, Section IX Surgery Description), so avoid unnecessary duplication.  |
|  |

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

1. **EXPERIMENTAL, THERAPEUTIC, OR OTHER ADMINISTRATIONS**  Check here if NO CHANGES or N/A [ ]

[Hypodermic and Gavage Needle Use and Injection Policy](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Hypodermic-and-Gavage-Needle-Use-and-Injection-Policy-Final-2022.docx)

|  |  |
| --- | --- |
| Provide justification for larger sized needles than recommended above:  |  |

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

|  |  |
| --- | --- |
| Name of substance  |  |
| Dosage/Concentration |  |
| Volume  |  |
| Route  | [ ]  SQ [ ]  IP [ ]  PO [ ]  IV [ ]  IM [ ]  RO (retroorbital) [ ]  Other: |

1. **ANESTHESIA/SEDATION NOT used for surgery or euthanasia.** Check here if NO CHANGES or N/A [ ]

Click link for [Recommended Doses of Anesthetics and Analgesics](https://research.northeastern.edu/animalcare/anesthesia-and-analgesia-guidelines-final-2021/) *You may copy and paste the appropriate regimen based on procedure. Additional rows can be added as necessary.*

|  |  |
| --- | --- |
| Name of procedure(s):  |  |
| **Anesthetic/Sedation Name** | **Dose** | **Route** | **Re-dose/Maintenance** |
|  |  |  |  |
|  |  |  |  |
| Methods used to monitor anesthetic/sedation (check all that apply): | [ ]  Responsiveness to stimuli  |
| [ ]  Respiratory rate/effort |
| [ ]  Other:  |
| [ ]  All animals are monitored continuously while under anesthesia.[ ] Confirm supplemental heat and eye lubricant will be provided when the animal is under anesthesia for longer than 5 mins or justify otherwise.  |

1. **IMPLANTS** Check here if NO CHANGES or N/A [ ]

Copy/paste the table below as necessary. Protocols with multiple species must identify and include species-specific details, as necessary.

|  |  |
| --- | --- |
| 1) Type and material of implant  |  |
| 2) Site(s) of implantation  |  |
| 3) Size of implant |  |
| 4) Method of sterilization for implant |  |
| 5) Length of time of implantation  |  |
| 6) Removal procedure (N/A, if post-mortem) |  |
| 7) For drugs, compounds, or other substances administered via pump or pellet, provide dosage (in mg/kg/day) and confirm how sterility of the substance will be ensured prior to loading. |
|  |

1. **SURVIVAL BLOOD COLLECTION** Check here if NO CHANGES or N/A [ ]

**Maximum Survival Blood Collection Volumes for Mice**

|  |  |  |  |
| --- | --- | --- | --- |
| Body Weight (g) | Circulating Blood Volume (CBV) (ml) | 10% CBV (ml) every 2 weeks**∇** | 15% CBV (ml) over4-week period**∇** |
| 20 | 1.26 – 1.44 | 0.13 – 0.14 | 0.19 – 0.22 |
| 25 | 1.58 – 1.80 | 0.16 – 0.18 | 0.24 – 0.27 |
| 30 | 1.89 – 2.16 | 0.19 – 0.22 | 0.28 – 0.32 |
| 35 | 2.21 – 2.52 | 0.22 – 0.25 | 0.33 – 0.38 |
| 40 | 2.52 – 2.88 | 0.25 – 0.29 | 0.38 – 0.43 |

 **Maximum total sample volume for that time period. (Based on 63-72 ml/kg TBV)**

**Maximum Survival Blood Collection Volumes for Rats**

|  |  |  |  |
| --- | --- | --- | --- |
| Body Weight (g) | Circulating Blood Volume (CBV) (ml) | 10% CBV (ml) every 2 weeks**∇** | 15% CBV (ml) over4-week period**∇** |
| 125 | 7.25 – 8.00 | 0.73 – 0.80 | 1.09 – 1.20 |
| 150 | 8.70 – 9.60 | 0.87 – 9.60 | 1.31 – 1.44 |
| 200 | 11.60 – 18.80 | 1.16 – 1.28 | 1.74 – 1.92 |
| 250 | 14.50 – 16.00 | 1.45 – 1.60 | 2.18 – 2.40 |
| 300 | 17.40 – 19.20 | 1.74 – 1.92 | 2.61 – 2.88 |
| 350 | 20.30 – 22.40 | 2.03 – 2.24 | 3.05 – 3.36 |
| 400 | 23.20 – 25.60 | 2.32 – 2.56 | 3.48 – 3.84 |

**∇ Maximum total sample volume for that time period. (based on 58-64 ml/kg TBV)**

If more than one experiment includes survival blood collections, please copy the table below as needed.

|  |  |
| --- | --- |
| Specify Experiment(s): |  |
| 1) Blood draw method and anatomical area used  |  |
| 2) Maximum volume for each blood draw  |  |
| 3) Frequency of draws |  |
| 4) Maximum number of draws/animal |  |
| If requesting larger volumes than recommended, provide scientific justification below: |
|  |

See IACUC Policy on [*Blood Collection from Common Laboratory Animals*](https://research.northeastern.edu/animalcare/blood-collection-final-2021/) for more information on blood collection.

1. **BEHAVIORAL TESTS** Check here if NO CHANGES or N/A [ ]

|  |  |  |  |
| --- | --- | --- | --- |
| Name of behavioral test | Time required for each testing and/or training session | Frequency of testing/training sessions and interval between sessions | Duration of testing/training sessions |
|  |  |  |  |
|  |  |  |  |
| **METHODS USED** |
| 1) Please describe the goals and performance expected for each test. |
|  |
| 2) Will an apparatus be used? | [ ]  No [ ]  Yes | If yes, please describe below.  |
|  |
| 3) Will aversive stimuli be used? | [ ]  No [ ]  Yes | If yes, describe the stimulus and its intensity, duration, and frequency of administration below. |
|  |
| 4) Please describe limits to deprivation or aversive stimuli if desired response does not occur. |
|  |
| 5) Will rewards be used? | [ ]  No [ ]  Yes |  If yes, please describe below. |
|  |
| 6) Please describe other techniques to be used below, if applicable. |
|  |

**F. EXPERIMENTAL TUMOR GROWTH** Check here if NO CHANGES or N/A [ ]

|  |  |
| --- | --- |
| 1) Animal Hazardous Materials Addendum Provided: | [ ]  Yes [ ]  No |
|  IBC approval must be obtained **prior to use of any tumors in animals.**  [Bio-Safety Office](http://www.northeastern.edu/ehs/ehs-programs/biosafety/).  |
| 2) Identity and source of the tumor  |  |
| 3) Is the tumor of **rodent origin** or been passaged **in rodents**?  | [ ]  Yes [ ]  No |
| If **yes**, they must be tested for contamination with adventitious agents. For more info contact DLAM. |
| 4) Is the tumor of **human origin**?  | [ ]  Yes [ ]  No |
| 5) Provide primary site(s) of anticipated tumor growth and any expected sites of metastasis, if applicable. |  |
| 6) Provide method of measuring tumor growth |  |
| 7) Provide maximum size and dimension of tumor  |  |

**G. USE OF ANTIBODY PREPARATIONS OR OTHER BIOLOGICS** Check here if NO CHANGES or N/A [ ]

|  |  |
| --- | --- |
| 1) Are antibody preparations used? If yes, continue by checking the appropriate box(es) below: | [ ]  Yes [ ]  No |
|  [ ]  Antibodies will be obtained commercially (off the shelf) *OR*  [ ]  Antibodies will be custom made. If custom made, continue below:  [ ]  in vitro tissue culture techniques used *OR* [ ]  in vivo techniques used. If live animals are used, continue below:  [ ]  in-house production (describe in Section VII) *OR* [ ]  vendor produced (see [Policy on Production of Custom Antibodies](https://research.northeastern.edu/animalcare/policy-on-production-of-custom-antibodies-final-2022/) for list of approved vendors) |
| 2) Are other biologics (e.g., blood, serum, cellular components) used? | [ ]  Yes [ ]  No |
| \*If **yes,** they must be tested for contamination with adventitious agents. For more information, please contact: DLAM - 617-373-3958 |

|  |
| --- |
| **IX. SURGERY DESCRIPTION** Check here if NO CHANGES or N/A [ ]  |

If more than one surgery is being added, please copy the table below and answer questions 1-7 for each individual surgery. See [*IACUC Policy for Rodent Surgery*](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Rodent-Surgery-Final-2022.docx) and [*Aseptic Surgery for USDA Covered Species*](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Aseptic-Surgery-for-USDA-Covered-Species-Final-2021.doc). Please note that there are additional requirements for non-rodent species. Exsanguinations/cardiac perfusions that require a skin incision to expose the vessel and perfusions need to be described as terminal surgeries.

|  |  |
| --- | --- |
| 1. **Name of surgery:**
 | Confirm if [ ]  survival or [ ]  terminal  |
| 1. **Species**
 |  |
| 1. **Check the relevant boxes for this surgery:**
 |
| The following are all required for survival surgery. Provide scientific justification to omit or change. Terminal surgeries only require continuous monitoring under anesthesia (the last box).[ ]  Disinfection of the surgical area/table. [ ]  Surgeon is properly prepared for each surgery. At a minimum, sterile gloves, mask, and gown. Disposable or  clean lab coats may only be used for non-USDA species.[ ]  Surgical instruments are sterilized prior to use and in between animals.[ ]  Animal is appropriately prepped for surgery by the following steps:1. Provision of eye lubricant2. Removal of the fur/hair3. Disinfectant/ethanol wipe of the skin (3x for each scrub).[ ]  Supplemental heat is provided while the animal is under anesthesia. [ ]  All animals are monitored continuously while under anesthesia. |
| 1. **Anesthetic details:** Click link forcommonly used anesthetics:[Anesthesia/Analgesia Formulary](https://research.northeastern.edu/animalcare/anesthesia-and-analgesia-guidelines-final-2021/)

*You may copy and paste the appropriate regimen based on surgery type. Additional rows can be added as necessary.*   |
| Anesthetic/Sedation Name | Dose | Route | Re-Dose/Maintenance |
|  |  |  |  |
|  |  |  |  |
| **Methods used to monitor anesthetic depth** (check all that apply): | [ ]  Tail/Toe Pinch |
| [ ]  Respiratory rate/effort. |
| [ ]  Other: |
| Methods used for intraoperative monitoring (USDA species only) |  |
| [ ]  All animals are monitored continuously while under anesthesia.[ ] Thermoregulation is provided while the animal is under anesthesia.  |
| 1. **How are the surgical instruments sterilized for each animal (for survival surgery)?**
 |
|  |
| 1. **Describe the surgery in detail including skin incisions, manipulations, closures, and suture information.**

*Do not repeat details confirmed in Part 2 and 3 above.*[ ]  Confirm initial dose of analgesia will be given prior to making the incision OR provide justification below. [ ]  Confirm sutures/wound clips will be removed 7-14 days post-operatively OR provide justification below*.* |
|  |
| 1. **Analgesic regimen:** Click link forcommonly used analgesics: [Anesthesia/Analgesia Formulary](https://research.northeastern.edu/animalcare/anesthesia-and-analgesia-guidelines-final-2021/)

*Multiple analgesics may be added to provide flexibility. When multiple analgesics are selected, indicate and/or below. Additional rows may be added if necessary* |
| Analgesic Name | Dose | Route | Duration of Treatment |
|  |  |  |  | [ ]  and [ ]  or [ ]  +/- |
|  |  |  |  | [ ]  and [ ]  or [ ]  +/- |
|  |  |  |  | [ ]  and [ ]  or [ ]  +/- |
| 1. [ ]  Confirm that a DLAM Surgical Card will be placed on the animal’s cage and that it is completely filled out.
 |

|  |
| --- |
| **X. ANIMAL CARE AND MONITORING** Check here if NO CHANGES or N/A [ ]  |

In animal health emergencies, animals may be treated or euthanized by the veterinary staff to relieve suffering. When possible, veterinary staff will make reasonable efforts to contact investigative staff prior to diagnostic testing, therapy, or euthanasia. However, you MUST notify veterinary staff of any therapeutic restrictions for your research in advance, in case they are unable to make contact during a health emergency.

|  |
| --- |
| **A. Adverse Effects:** Describe expected experimental effects, distress, pain, significant discomfort, or morbidity that may occur because of the experiments, procedures, genetic phenotypes, or from surgery (including infection, inflammation, erosion, or accidental removal of implants). Indicate how adverse effects will be alleviated (e.g., with analgesia, nursing care, nutritional support, etc.) or provide justification for Category E procedures below |
|  |
| **B. Justification for Category E procedures:** Please provide **scientific justification** if pain and/or distress is an unavoidable part of the research/procedures and why it cannot be alleviated. |
|  |
| **C. Health Monitoring:** Indicate the frequency and length of the time that ALL animals will be observed to evaluate pain/distress. This includes observation of animals on and off studies, as well as post-operative care and monitoring. When necessary, explain how monitoring will change if health status changes. Protocol personnel are responsible for this monitoring. Routine health checks by veterinary staff does NOT fulfill this requirement. |
| **Procedure or Experiment name(s)** | **Frequency of observations/monitoring** |
|  |  |
|  |  |
| **D. Humane Endpoints**: List the criteria used to determine when euthanasia will be performed for humane reasons, even if prior to the experimental endpoint (e.g., tumor size, and/or necrosis, % body weight gain/loss, body condition loss, inability to eat or drink, behavioral abnormalities, clinical symptoms, signs of toxicity, etc.) |
|  |
| **E. Documentation for Medical Records:** Check which criteria will be documented for Health Monitoring (described in Part C) and Humane Endpoint determination (Part D). Records must be made available to IACUC or veterinary staff upon request. Medical records are required to be maintained for all USDA covered species (either dedicated record or part of cage card). |
| [ ]  | Body weights  |
| [ ]  | Tumor measurements |
| [ ]  | Blood, urine, or other laboratory tests  |
| [ ]  | Other: indicate other scoring systems or measurable criteria used (e.g., EAE, seizure scale, etc.):  |
|  |

|  |
| --- |
| **XI. LOCATION OF ANIMALS** Check here if NO CHANGES or N/A [ ]  |

The use and/or housing of animals outside the centralized animal facility must be approved by the IACUC prior to initiation. Once approved, animals can only be outside of the centralized facility for less than 12 hours (for USDA species) or less than 24 hours (for other species), unless the location is approved as a satellite facility.

|  |  |
| --- | --- |
| **1. Are live animals ever used outside of the centralized facilities?** | [ ]  Yes [ ]  No [ ]  Other location  |

If you answered **yes** above, please complete question 1. If you answered **other location**, please complete question 2.

|  |  |  |  |
| --- | --- | --- | --- |
| **1A. Type of procedure or housing**  | **Building and** **Room Number** | **Is room currently approved by the IACUC?** | **Longest time frame animals Will Be present** |
| [ ]  Euthanasia/tissue harvest |  | [ ]  Yes [ ]  No |  |
| [ ]  Survival surgery |  | [ ]  Yes [ ]  No |  |
| [ ]  Non-survival surgery |  | [ ]  Yes [ ]  No |  |
| [ ]  Satellite housing\*\* |  | [ ]  Yes [ ]  No |  |
| [ ]  Other:  |  | [ ]  Yes [ ]  No |  |

|  |
| --- |
| **1B. Provide justification for removing animals from central facilities.** |
|  |

|  |
| --- |
| **2. Provide description(s) and justification for field studies and use of other locations.**  |
|  |

\*\* Investigators housing their animals in satellite housing must provide the IACUC and DLAM a detailed SOP on the housing and care of the animals housed in their facility.

|  |
| --- |
| **XII. DISPOSITION OF ANIMALS FOLLOWING STUDY** Check here if NO CHANGES or N/A [ ]  |

Provide details of euthanasia for each species. **Even if the experimental plan does not include euthanasia, protocols must include an emergency plan in case euthanasia becomes necessary.**No animal may be adopted, reused, or given away without advance permission from DLAM. See [IACUC Policy on Euthanasia and Secondary Method of Euthanasia in Animals](https://research.northeastern.edu/app/uploads/sites/5/2022/04/Euthanasia-and-Secondary-Methods-Final-2021.doc).

* Copy and paste the chart below for each different species, if necessary.
* If an inhalant is used for euthanasia, a secondary method of euthanasia is required.
* Methods of euthanasia must be consistent with the [AVMA Guidelines](https://www.avma.org/sites/default/files/2020-01/2020-Euthanasia-Final-1-17-20.pdf) or otherwise scientific justification must be provided below.
* Physical methods without anesthesia or sedation must be justified below (i.e., conscious cervical dislocation or decapitation). See *IACUC Policy for Maintenance of Blades for Use in Conscious Decapitation*.

|  |  |
| --- | --- |
| **Species name** |  |
| **Primary euthanasia method** |  |
| **Confirm secondary method is used when required** | [ ]  Cervical dislocation, [ ]  Decapitation, [ ]  Thoracotomy, [ ]  Exsanguination, [ ]  Major organ removal will be performed following the primary method  |
| **Other euthanasia methods:** |  |

|  |
| --- |
| [ ]  **A physical method of sacrifice will be used without prior anesthesia or sedation** (i.e., conscious cervical dislocation or decapitation). Please provide justification below. |
|  |
| [ ]   | **Euthanasia is not expected or required. Emergency only.** |

|  |
| --- |
| **XIII. ANIMAL NUMBER JUSTIFICATION** Check here if NO CHANGES or N/A [ ]  |

|  |
| --- |
| **1. EXPLANATION FOR THE NUMBER OF ANIMALS REQUESTED.** Identify the experiments the same way they are organized in Section VII and explain how many animals are needed for each. Include justifications for group sizes, the number of groups/experiments, the number of conditions, timepoints, repetitions, etc. The number of animals must be the minimum number required to meet the goals of the study. Tables or flowcharts are encouraged. |
|  |

.

|  |
| --- |
| **2. TOTAL NUMBER OF ANIMALS USED FOR BREEDING.** Provide the total number of animals bred under this protocol. Please provide a clear distinction between which of the animals bred will be used in the experiments above and which are used for maintenance or culled only. |
| Mouse |  | Rat |  | Other |  |
| Total number includes adult breeders plus offspring generated. All animals born must be accounted for, even if not used in experiments*.* A table or chart that organizes the number expected from breeding is suggested. Estimate litter size, litters per female, and number of offspring that may be culled based on Mendelian genetics or other methods. If average litter size is unknown, estimate 10 pups per pregnancy for rodents. *.* |
|  |

|  |
| --- |
| **3. TOTAL NUMBER OF ANIMALS.** Calculate the total number of animals required during the 3-year approval period by species. All animals used in experiments, used for maintenance breeding, or culled *must* be accounted for.Indicate how many animals are utilized in each [Pain/Distress Category-P/D](https://research.northeastern.edu/app/uploads/sites/5/2022/05/IACUC-Pain-and-Distress-Category-Descriptions-2022.docx) (Updated 2022):**CAT C:** Animals that underwent study-related procedures that involved *no more than slight or momentary* pain, distress, and no use of pain-relieving drugs. **CAT D:** Animals that underwent study-related procedures that involved more than momentary pain or distress which was *alleviated* with anesthetics, analgesics, or tranquilizers.**CAT E:** Animals that experienced more than slight or momentary pain or distress that could *not be relieved* for study-related reasons. |
| **Species name** |  |  |  |
| **Category C** |  |  |  |
| **Category D** |  |  |  |
| **Category E** |  |  |  |
| **Total number requested** |  |  |  |

|  |
| --- |
| **XIV. SEARCH FOR ALTERNATIVES** Check here if NO CHANGES or N/A [ ]  |

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

|  |
| --- |
| **A. SOURCE FOR ALTERNATIVE SEARCHES** |
| The database(s) searched |  |
| The date that the search was conducted |  |
| The years covered by the search |  |
| **B. METHODS & NARRATIVE DESCRIPTION FOR EACH SEARCH** Suggested search strategy: “procedure” + “species” + “alternative” [e.g.: skin incision + mouse + alternative] Provide a written narrative of the methods and sources used for each alternative search. The Committee must be able to assess if the search was appropriate and sufficiently thorough. Note: You are no longer required to provide the number of references retrieved or the alternative search for “anesthesia.”  |
|  |

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

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

|  |  |
| --- | --- |
| [ ]  | The information contained in this protocol is true and accurate, and that, to the best of my knowledge, it conforms to Northeastern University’s IACUC, NIH, and USDA policies on the use of animals in research and teaching. |
| [ ]  | I have considered alternatives to the biological models used in this project and have found these other methods unacceptable on scientific or educational grounds. |
| [ ]  | I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research. |
| [ ]  | I accept responsibility for ensuring that all personnel involved in this project will be trained regarding any potential biological, chemical, and radiological hazards, relevant safety practices, and emergency procedures (splashes, needle sticks, animal bites, etc.). If applicable, I confirm that all relevant institutional regulatory requirements (e.g., Chemical Safety Plan, IBC Registration, Radioactive Materials Permit, etc.) will be followed. |
| [ ]  | *I will complete all IACUC personnel requirements, as described in* [*the IACUC Requirements for Personnel Working with Animals*](https://research.northeastern.edu/animalcare/nu-iacuc/working-with-animals/)***prior*** *to working with animals* ***OR*** *within 2 months of the approval of my protocol,* ***whichever comes first****.* |
| [x]  | *All personnel involved in this project will be added to the protocol using a* [*Supplement P*](https://research.northeastern.edu/app/uploads/sites/5/2018/08/Supplement-P-8-2018.docx)*. All personnel named above have agreed to participate in this study and are aware of procedures that are approved. All individuals who will be involved with the animals used in the project have been instructed in the humane care, handling, and use of animals, and I have reviewed their qualifications. I will also ensure that all personnel are properly trained in the euthanasia procedures as described in this protocol* |
| [ ]  | All individuals involved will be instructed in the humane care, handling, and use of animals and I will review their qualifications and competency. |
| [ ]  | I will properly assure the training of all individuals performing euthanasia  |
| [ ]  | No change will be made to procedures, care, or housing without prior written notification to and approval by the Institutional Animal Care and Use Committee (IACUC). |
| [ ]  | I understand that it is non-compliant to provide an IACUC approval date to a funding agency without documentation of a congruency comparison conducted by the IACUC Office. For more information, see the [Policy on Requiring a Congruency Comparison Prior to Release of IACUC Approval Dates](https://research.northeastern.edu/app/uploads/sites/5/2022/05/Policy-on-Requiring-a-Congruency-Comparison-Prior-to-Release-of-IACUC-Approval-Dates-Final-2022.docx). |
| [ ]  | *I accept responsibility for complying with Material Transfer Agreement requirements. For more information, please see Material Transfer guidance on the NU-RES website.* |
| [ ]  | I understand that failure to comply with IACUC policies and procedures will jeopardize Northeastern University’s Animal Welfare Assurances on file with the NIH and may lead to revocation of my privileges to conduct animal research at this institution. |

|  |  |  |
| --- | --- | --- |
|       |   |       |
| Principal Investigator (*Type in name or* *provide* *electronic signature*) |  | Date |

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