

**FOR OFFICE USE ONLY IACUC APPLICATION FORM**

Date Submitted:

Date Approved:

Protocol Number:

**INSTRUCTIONS:**

Please complete, sign, and submit to the IACUC office by e-mail to: iacuc@umb.edu

Please answer all questions carefully and completely so that the committee can minimize unnecessary delay, and review and approve submissions quickly. The IACUC is required by law to ensure that all animal care and use proposals are reviewed for specific information, and are approved prior to inception of any proposed animal use activity.

**SECTION 1: ADMINISTRATIVE INFORMATION**

PI Name:       PI Department:

PI Phone Number:       PI Alternate Phone Number:

Submission Type: [ ]  New Application [ ]  Triennial Review [ ]  Modification

Protocol Type: [ ]  Holding [ ]  Research [ ]  Teaching

Protocol Title:

Protocol Number (if applicable):

Funding Source: [ ]  PHS (Includes NIH) [ ]  NSF [ ]  OTHER:

**MODIFICATION:**

If this is a modification of an approved protocol, please comply with the following: If you are requesting a modification or a change to an IACUC approved protocol, please provide a concise description of all of the changes that you are proposing in the following block. Additionally, please highlight the proposed changes in the body of the protocol where appropriate, so that it is clearly discernible to the IACUC reviewers what and where the proposed changes are. This will help the committee and facilitate the review.

**SECTION 2: HOUSING, HUSBANDRY, AND TRANSPORTATION**

1. **SPECIAL CONSIDERATIONS**

The protocol involves the following (please check all that apply):

[ ] Animal Exercise – [Section 7](#DRP)

[ ] Ascites or Antibody Production – [Section 10](#AAP)

[ ] Tumor implants or growth – [Section 11](#TM)

[ ] Induced Disease – [Section 7](#DRP)

[ ] Death as an endpoint studies (i.e. LD50) – [Section 8](#CEE)

[ ] Moribund as an endpoint – [Section 9](#MM)

[ ] Burns or Trauma– [Section 7](#DRP)

[ ] Breeding – [Section 7](#DRP)

[ ] Device evaluation – [Section 7](#DRP)

[ ] Restraint (using conventional or novel devices) of any duration – [Section 7](#DRP)

[ ] Anesthetic Agents (either injectable or inhalants) – [Section 14](#AR)

[ ] Survival Surgical Procedure – [Section 16](#PS)

[ ] Multiple survival operative procedures – [Section 16](#PS)

[ ] Procedures including minor manipulations, injections, nonsurvival surgery, behavior observations, etc. – [Section 16](#PS)

[ ] Paralytic agents – [Section 12](#P)

[ ] Food or water deprivation other than required for pre-op – [Section 7](#DRP)

[ ] Special diet (high fat, low fat) – [Section 7](#DRP)

[ ] Study of pain, distress or stress – [Section 5](#PPD) and [Section 7](#DRP)

[ ] Unalleviated pain or distress – [Section 5](#PPD) and [Section 7](#DRP)

[ ] Other:

1. **HOUSING/ TRANSPORTATION LOCATIONS**

Please check all applicable areas where animals.

 [ ] Animal Resources Core Facility

 [ ] Classroom If yes: Building and Room Number:

 [ ] Laboratory If yes, Building and Room Number:

 [ ] Other:

Please mark this box if procedures will only be done in the animal facility [ ]

1. **SPECIAL HUSBANDRY REQUIREMENTS**

Will the animals on this study require any special handling or husbandry requirements? This includes anything outside of normal routine husbandry/handling services (i.e. alterations in bedding types, cage change frequencies, housing densities, special diets/fluids, deviations from currently approved IACUC policies, etc).

 [ ] YES [ ] NO

If yes, please describe the special husbandry requirements:

**SECTION 3: NON-TECHNICAL SUMMARY**

*Please limit your answers to 2 to 3 sentences.* Using non-technical terms understandable to non-scientist IACUC members, provide a brief answer to each of the following questions.

1. **What is the overall objective of the study?**

1. **Why is this work important/significant?**

1. **How will the animals be used to accomplish the goals of the study? Very briefly describe the general experimental plan.**

1. **How does this work build upon prior work with animals?**

1. **What are the study endpoints for the animals and what are the expected results?**

**SECTION 4: ADDITIONAL INFORMATION**

1. **ANIMAL INFORMATION**

Total number of animals are approved for three years; therefore, the number of animals requested should be the total number of animals needed for the entire project over the three-year period. The total number here must be the same as listed in the Section 5: Potential pain or distress section as well as in Section 7: Detailed Research Plan #1.

|  |  |  |
| --- | --- | --- |
| **Species** | **Source** | **Total # Animals**  |
| **Use tab key to insert more lines as needed** |  |  |

**Please enter any special characteristics of the selected species:** Example: If this is a rodent study, indicate the strain(s)/stock(s) including any abnormal phenotypes or behaviors exhibited. i.e. Strain- NOD, C57Bl, Transgenic, i.e. Stock- Swiss Webster, Sprague Dawley, i.e. Phenotype- animals will appear obese, exhibit tremors, grow spontaneous tumors and have respiratory difficulties as part of an induced genetic mutation

1. **If the experimental goals of the proposed studies are accomplished with fewer animals than the number approved, any "EXTRA" animals ARE NOT to be used.**

The number of animals requested must be based on the amount needed to answer a specific scientific question. Animals are not to be justified on the basis of how many experiments can be physically performed by a certain number of researchers in a given period of time.

Does the number of animals requested include extra animals to cover anticipated failures or to familiarize the staff with the procedures described?

 [ ] YES [ ] NO

1. **Provide the sample size calculation or other justification for sample and group size.** Be sure to confirm the numbers with your flow chart and double check the math.

EXAMPLE 1: Sample size needed to study differences in the means of two or more populations. Indicate expected variability, mean, "p-value", and power level supporting requested group/sample size.

EXAMPLE 2: Sample size needed to study difference in frequency of an event. Indicate expected frequency, "p-value", and power level supporting requested group/sample size.

EXAMPLE 3: Sample/group size needed to perform a pilot study or to provide procedural training. Justify the number requested.

EXAMPLE 4: If the number of animals requested is based upon the need for detailed analyses of certain tissues, provide a detailed breakdown of assays to be performed, amount of material needed for each assay and amount of material available from each animal.

1. **Please indicate what method(s) of identification will be used to track these animals (select all that apply)**

[ ] Ear tag or notch [ ] Cage card

[ ] Tattoos [ ] Other:

[ ] Implant

1. **The species selected is appropriate because:**

[ ] The process resembles that in humans.

[ ] Prior research has been done in this species.

[ ] Tissues or other substances to be harvested require an animal of this size.

[ ] The size or anatomy of this species is best or uniquely suited to the procedure to be done.

[ ] Tissues or substances needed are best or uniquely provided by this species.

[ ] Species lower on the phylogenetic scale cannot be used.

[ ] Other:

**SECTION 5: POTENTIAL PAIN AND DISTRESS (USDA CATEGORIES)**

A painful procedure in an animal is defined as any procedure that would be reasonably expected to cause more than slight or momentary pain and/or distress in a human. The IACUC is responsible for ensuring that investigators have appropriately considered alternatives. It is necessary for PIs to assure the IACUC that alternatives to procedures that cause more than momentary or slight pain or distress have been considered.

Each animal must be assigned to a pain category based on the most invasive procedure or procedure that has the greatest potential to cause pain or distress. The total number of animals assigned in all categories must equal the total number of animals requested.

The [USDA Policy #11](https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf) considers prolonged restraint and food restriction to be stressful and potentially painful. The UMass Boston IACUC considers prolonged restraint to be greater than 30 minutes.

Note: See here for examples of for IACUC guidelines on [Assigning Animals to USDA Pain and Distress Categories](https://www.umb.edu/editor_uploads/images/orsp/Assigning_Animals_to_USDA_Pain_and_Distress_Categories_1.pdf)

1. USDA Pain **category B** is defined as Animals being bred, conditioned, or held for use in teaching, testing, experiments, research or surgery, but not yet used for such purposes).

Does this protocol involve teaching, research experiments or tests that involve only breeding or housing of animals with no planned euthanasia?

 [ ]  YES [ ]  NO

**How many animals will be assigned to Category B?**

1. USDA Pain **category C** is defined as animals upon which teaching, research, experiments, or tests will be conducted involving no pain or only momentary pain, distress, or do not require the use of pain-relieving drugs.

Does the protocol involve teaching, research experiments or tests conducted that potentially induce no more than momentary pain or distress and do not involve the use of pain relieving drugs.

For example: routine injections or imaging, euthanasia by compressed CO2 gas for rodents.

 [ ]  YES [ ]  NO

**How many animals will be assigned to Category C?**

1. USDA Pain **category D** is defined as animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

 Does the protocol involve teaching, research experiments or test conducted that potentially induce more than momentary pain or distress, and for which appropriate anesthetic, analgesic or tranquilizing drugs will be used. For example: studies including prolonged restraint with pain relief administered; retroorbital blood draw, tail snips after day 21, euthanasia by exsanguination under general anesthesia, survival and non-survival surgical procedures,

 [ ]  YES [ ]  NO

**How many animals will be assigned to Category D?**

1. USDA Pain **category E** is defined as animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Does the protocol involve teaching, research experiments, surgery or tests that involve PAIN or DISTRESS, and for which appropriate anesthetic, analgesic or tranquilizing drugs are NOT used because they would adversely affect the results or interpretation of the data. For example: studies including prolonged restraint; LD50 studies, observing an animal until a moribund condition is reached, creating a debilitating condition or phenotype, pain studies

 [ ] YES [ ]  NO

Restraint is any method, cage or device that will not allow the animal to make normal postural adjustments. UMass Boston’s IACUC perceives prolonged restraint greater than 30 minutes to be prolonged and within category E. Is prolonged restraint proposed in this study?

 [ ] YES [ ] NO

If yes, will the animals be anesthetized/sedated during the restraint?

 [ ] YES [ ] NO

If NO, please provide justification:

**How many animals will be assigned to Category E?**

*If this study includes procedures that fall under Category D or E please complete SECTION 6. If not, skip to SECTION 7.*

**SECTION 6: LITERATURE SEARCH REFINE (CAT D & E ONLY)**

1. **PAIN AND/OR DISTRESS REFINEMENTS:** A literature search for alternative procedures must be performed for each procedure that has the potential to cause pain or distress, including prolonged restraint devices.

[ ]  The literature search conducted indicates that there are no alternative procedures that would involve less pain or distress

[ ]  There are alternative procedures, however they cannot be used for these experiments (If checked, please describe):

1. **DETAILS OF LITERATURE SEARCH**

|  |  |  |
| --- | --- | --- |
|  | Database 1  | Database 2 |
| Name of Database searched \*  | Click here to enter text. | Click here to enter text. |
| Date of search (must be within 6 months of protocol submission) MM/DD/YY | Click here to enter text. | Click here to enter text. |
| Years covered by search (YYYY – YYYY) |  |  |
| Search strategy (must show how keywords were combined)  |  |  |
| Other sources consulted. Provide individuals’ name, qualifications, date and summarize content |  |

\* *Suggestions for acceptable database(s): Medline, Agricola, Biosis, Pubmed, ALTWEB, Animal Welfare Institute*

1. **ALTERNATIVE ANIMAL MODELS:** The scientific reliance on live animals should be minimized. Alternative models, such as mathematical, computer simulation or in vitro biological systems can sometimes be used to replace animals. Explain why the use of animals is necessary for this experiment.

[ ] Mathematical models are not a suitable alternative to live animals

[ ] Computer simulation is not a suitable alternative to live animals

[ ] In vitro biological systems are not a suitable alternative to live animals

[ ] Other, please explain:

1. **UNNECESSARY DUPLICATION OF RESEARCH:** Unnecessarily duplicative research should be avoided for scientific and ethical reasons. Have the results fulfilling the experimental goals of this study been published in medical or veterinary journals?

 [ ]  YES [ ]  NO

If yes:

**SECTION 7: DETAILED RESEARCH PLAN**

Please answer all questions completely (do not merely duplicate grant language). A grant application is not considered a protocol. Limit the discussion of methods to experiments involving animals or animal tissues.

1. **FLOW CHART:** Provide a flow chart(s) or bulleted list that depicts the sequence of all animal procedures or manipulations (step by step) to be performed in this protocol. This should incorporate animal numbers including culled animals.

1. **STUDY GOALS:** State the broad long-term objectives and concisely describe the hypothesis to be tested.

1. **BACKGROUND AND SIGNIFICANCE:** Briefly sketch the background to the present proposal (include a summary of any preliminary findings). State concisely the importance of the research.

1. **EXPERIMENTAL DESIGN AND METHODS:** Describe the methods and procedures to be used on the animals. Describe the overall research plan, outline the time-course of the project indicating each activity and any potential adverse effects. Describe each step of the project and how it relates to an animal enrolled in this study. There is not a need to include surgical and nonsurgical procedure description here.

**SECTION 8: CLINICAL SIGNS, ENDPOINTS, AND EUTHANASIA**

1. **FOLLOW UP CARE:** Describe the investigator’s responsibilities during the post-surgical and/or post-experimental period, including frequency of examination and monitoring.

1. **HEALTH STATUS:** Describe the health status of the animals during the study period. If the health of an animal is to be compromised by a surgical procedure, the introduction of disease, tumor, or by administration of a toxic agent (including biologic and hazardous material), describe the course of the disease or expected response.

1. **PAIN MANAGEMENT:**  Note: If a controlled substance is used, item should also be indicated in Section 17: Use of Controlled Substances and Hazardous Agents. Unless scientifically justified, means for alleviating animal pain, distress or discomfort must be instituted. In general, conditions that cause more than momentary pain, distress or discomfort in humans will have the same adverse effects on animals. Such conditions that may cause pain or discomfort include; surgery, excessive inflammation, necrosis, drug, noxious stimuli without escape, functional impairments. Such conditions that may cause distress include; restraint of the unadapted animal, restraint for more than 4-8 hours, abnormal diet or environment.

Analgesia should be provided to all animals undergoing surgical procedures. Methods that can be used include; infiltration of the incision site and/or regional nerve block with long-acting anesthetics, and/or systemic analgesics. By administering analgesics pre-operatively, the agents block or suppress the pain cycle and in many cases, minimize the need for analgesics post-operatively.

Investigators are required to use pharmaceutical grade drugs and compounds whenever commercially available, even in terminal procedures. If non-pharmaceutical grade drugs/compounds are proposed for live animals list the drugs and/or compounds and explain why pharmaceutical grade drugs cannot be used (Please note - cost alone cannot justify use.

|  |  |  |  |
| --- | --- | --- | --- |
| Substance Administered | Route/volume administered | Dose/Concentration | Frequency/Duration of administration |
| Use tab key to insert more lines as needed |  |  |  |
|  |  |  |  |

1. **ENDPOINTS**

What clinical criteria will be used to remove animals from the study for euthanasia?

1. **EUTHANASIA METHOD**

How will euthanasia be performed (include agent(s), route of administration and dose). A method must be indicated even if the procedure is not terminal, in the event of an emergency. See [AVMA Guidelines for the Euthanasia of Animals](https://www.avma.org/KB/Policies/Documents/euthanasia.pdf)

**SECTION 9: MORBIDITY AND MORTALITY**

1. The IACUC acknowledges that while it is preferable to use the earliest endpoints compatible with the scientific requirements of each study, there are studies that may require moribundity or mortality as an endpoint. The committee recommends that consideration be given to surrogate markers that can be utilized for a more humane endpoint (i.e. moribund condition-defined as a clinically irreversible condition leading inevitably to death) rather than allowing the animal to proceed to death. The use of death as an endpoint is strongly discouraged and requires scientific justification.

Will the protocol include Death as an Endpoint?

 [ ] YES [ ] NO

If yes, please provide the strong justification that the use of death as an endpoint is scientifically necessary to achieve the research goals.

1. Please describe what alternatives were considered, why morbidity as an endpoint cannot be used, and how these alternatives will be used whenever possible.

1. What information is to be gained in the interval between moribundity and death?

1. Will the protocol include Moribund as an endpoint?

 [ ] YES [ ] NO

If yes, the following will be checked:

[ ] Body condition score of 2 or less [ ] Abnormal breathing

[ ] Abnormal posture or stance [ ] Difficulty with ambulation

[ ] Rough hair coat [ ] Decreased food or water intake

[ ] Head tucked into abdomen [ ] Weight loss

[ ] Exudate around eyes or nose [ ] Self-mutilation

[ ] Skin lesions [ ] Other: Click here to enter text.

**SECTION 10: ANTIBODY & ASCITES PRODUCTION**

1. Does the protocol include the production of antibodies?

 [ ] YES [ ] NO

If yes, indicate the adjuvant to be used. Be sure to include the volume and the route of administration:

1. Please select the technique used to collect the needed blood samples.

 [ ] Lateral tail vein [ ] Marginal Ear vein

 [ ] Facial vein [ ] Cardiac puncture

 [ ] Orbital sinus [ ] Jugular vein

 [ ] Saphenous vein [ ] Other: Click here to enter text.

1. Please indicate how much blood will be withdrawn for each collection, the amount of collection points and the interval between blood draws:

1. Does the protocol include the production of ascites?

 [ ] YES [ ] NO

1. Provide justification for the in vivo production of ascites rather than using an in vitro method. Be sure the justification addresses the following points: What are the goals of the study that require antibodies? Has there been an adequate attempt to expand the hybridoma in vitro? Have all attempts at in vitro production been carried out without an acceptable product? Might in vivo pilot studies be appropriate? Are the mouse strain and number of animals appropriate? Is the priming appropriate in terms of type of chemical, amount, and length of time prior to inoculation of hybridoma?

1. Indicate the adjuvant to be used. Be sure to include the volume and the route of administration.

1. How frequently will the animals be tapped? The IACUC recommends a three-tap maximum, e.g. two survival taps and one following euthanasia. Also consider a one-tap limit to minimize the occurrence of unrelieved discomfort.

1. List the staff responsible for monitoring the animals involved in ascites production.

1. Describe the monitoring plan that will be used including the frequency of observations (must be at least daily while producing ascites fluid). What are the clinical signs that constitute criteria for euthanasia?

1. Describe the method of euthanasia:

**SECTION 11: TUMOR MODEL**

Please note: completion of this section requires concurrent completion of section 9.

1. A tumor model is cells, tissues, or animals used to study the development and progression of cancer. Is a tumor model proposed in this study?

 [ ] YES [ ] NO

1. Identify the method used to generate tumor models:

[ ] Implantation

If so, indicate the site of implantation and whether the cancer cells are of the same species as the host organism or if a xenograft is to be used. Note: A detailed description of the route of administration, and any surgical procedures and injections should all be described in detail in Section 16: Procedures and Surgeries

[ ] Genetically Engineered

If genetically engineered tumor models are to be used this should be indicated. All schedules and protocols for breeding and maintaining genetically engineered animals should be described in Section 7: Detailed Research Plan #4

[ ] Chemically Induced

If so all procedures for administration of carcinogenic reagents should be described in Section 16: Procedures and Surgeries. The use of any hazardous agents should also be indicated in Section 17: Use of Controlled Substances and Hazardous Agents

1. What is the maximum tumor burden allowed per animal? How will tumor burden be addressed? Note: See here for IACUC guidelines on [Spontaneous and Induced Tumor Production in Rodents](https://www.umb.edu/editor_uploads/images/orsp/Guidelines_Induced_Tumor_in_Rodents.pdf).

**SECTION 12: PARALYTICS**

1. Muscle paralyzing agents must only be used in animals that are anesthetized. Is paralytics proposed in this study?

 [ ] YES [ ] NO

If yes, provide the justification for using a paralytic agent for this study.

1. Please indicate the agent, route of administration and dose to be used.

1. Please describe the monitoring methods to be used to ensure that an adequate level of anesthesia is maintained during paralysis.

**SECTION 13: PHARMACOLOGICAL AGENTS**

A pharmaceutical grade compound is defined as a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary (USP-NF), or British Pharmacopeia. Reagents are not drugs.

Drugs are manufactured by a pharmaceutical producer under Good Manufacturing Practices and approved by the FDA. The IACUC requires that all chemical compounds administered to any animal species be of pharmaceutical grade, if that agent is available in pharmaceutical grade. Specific permission must be obtained to administer any non-pharmaceutical chemical compound. Such compounds must be sterile, maintained in a sterile container and labeled to provide the name and concentration of the compound as well as its expiration date.

1. **PHARMACEUTICAL AGENTS:**

Please identify pharmacological agents that will be used on this protocol. This includes any anesthetics, analgesics, test substances or other agents to be administered to the animal.

|  |  |  |
| --- | --- | --- |
| Substance Administered | Source |  |
| Use tab key to insert more lines as needed |  |  |

1. **NON-PHARMACEUTICAL GRADE JUSTIFICATION AND PREPARATION:**

Please identify any non-pharmaceutical agents proposed to be used on this protocol. Please provide justification for the use of those selected agent(s).

*As a reminder, cost in itself is not considered an adequate reason to use non-pharmaceutical grade compounds.* OLAW has specifically addressed the use of non-pharmaceutical grade agents in a Frequently Asked Question on their website ([Section F, Number 4](https://grants.nih.gov/grants/olaw/faqs.htm#662)).

Describe how the non-pharmaceutical grade compound(s) will be prepared, stored and disposed. Be sure to address the following: Grade/ Purity (e.g. HPLC grade, life science grade) Sterility/ Pyrogenicity (e.g. micron filtration, sterile diluent) Formulation/pH range Stability/ Compatibility Labeling/Storage (e.g. container type, temperature) Expiration/Disposal

**SECTION 14: ANESTHESIA REGIMEN**

1. Please identify the anesthetic agent(s) that will be used. Be sure to include the dose/concentration and route and frequency of administration for each agent. The IACUC approved preferred formulary for rodents can be found [here](https://www.umb.edu/editor_uploads/images/orsp/Rodent_Anesthesia_Analgesia_SOP.pdf).

1. The adequacy or depth of anesthesia will be monitored by:(check all that apply)

[ ] Respiration Rate [ ] Tail pinch

 [ ] ECG [ ] Jaw laxity [ ] Toe pinch [ ] Muscle Relaxation

[ ] Blood gas [ ] Pulse oximetry

[ ] Corneal or Palpebral reflex [ ] Respirometer

[ ] Blood pressure [ ] Other:

[ ] Heart Rate

1. How frequently will the depth of anesthesia be assessed? Please include how frequently this assessment be documented. Documentation is required for procedures that will last 20 minutes or greater. For guidance to the recommended documentation frequency, please review the IACUC preferred formulary [here](https://www.umb.edu/editor_uploads/images/orsp/Rodent_Anesthesia_Analgesia_SOP.pdf).

**SECTION 15: PROCEDURES AND SURGERIES**

A procedure is any manipulation of an animal for an experimental application, for examination purposes or for treatment of an induced or spontaneous disease or condition. For clarity of definition the IACUC uses the terms 'procedure' or 'surgery' to describe all manipulations performed.

“Procedure” is used to describe injections, bandaging or casting, imaging, antibody production, collection of blood and other clinical samples, non-invasive physiological monitoring, breeding, behavior observations, euthanasia, etc. Procedures may or may not require the use of a sedative or anesthetic, and may or may not require the use of analgesics.

"Surgery" usually involves an incision and exposure of a tissue for an operative method or the operative manipulation of physiologic or physical parameters to create a model of a clinical disease process or condition and/or treatment of a disease or condition. Surgery usually requires anesthesia, and is further sub-classified as major or minor, and survival or non-survival.

Describe the procedure or surgery, including the approach used. Describe how pain and distress will be minimized during the procedure (include name, dose, route and duration of effect of sedative, anesthetic, and/or analgesic used).

1. **Preoperative procedures**  YES NO

Describe preoperative surgical procedures planned:

1. **Procedures**

Describe surgical procedures planned:

1. **Multiple Survival Surgery Procedures** YES NO

Describe multiple surgical procedures planned:

1. **Non-survival Surgery Procedures**

Describe non-survival surgery procedures planned:

1. **Aseptic technique will be maintained by:**

 [ ] Clipping/shaving fur around incision site

 [ ] Surgical soap scrub/ alcohol rinse/ final application of solution over incision site

[ ] Draping of the animal

 [ ] Clean lab coat, masks, surgical gloves (used for rodent surgeries)

[ ] Sterile gown, hat, booties, mask, surgical gloves (required for large animals)

[ ] Pre-packed sterile blade, disposable instruments

[ ] Other If other:

1. **Sterile instruments**

Instruments will be made sterile by:

[ ] Autoclave [ ] Plasma sterilizer

[ ] Glass bead sterilizer [ ] Chemical sterilent

[ ] Ethylene oxide sterilizer [ ] Plasma sterilizer

 [ ] Prepackaged sterile instruments

 [ ] Other, If other:

1. **Surgeon Qualifications:**

**SECTION 16: USE OF CONTROLLED SUBSTANCES AND HAZARDOUS AGENTS**

For information or assistance when completing this portion of the application, contact the OEHS.

All projects involving the use of any radiological, chemical, or biological hazard must be performed in accordance with UMass Boston safety protocol(s) for hazardous materials.

If yes, please list the name, source, storage location, physical state of the agent, total amount that will be prepared, describe all manipulation(s) to be performed after the hazard(s) have been administered to the animal, including all procedures at necropsy, and if the animal will be returning to the facilities after exposure.

1. **\*Biological, Infectious or Parasitic agents**  [ ] NO [ ] YES

If yes:

1. **\*Recombinant or synthetic nucleic acid molecules** [ ] NO [ ] YES

If yes:

**C. Hazardous chemicals**  [ ] NO [ ] YES

If yes:

**D. \*\*Radioisotopes**  [ ] NO [ ] YES

If yes:

**E. Other**  [ ] NO [ ] YES

If yes:

**F. \*\*\*Controlled Substance**  [ ] NO [ ] YES

If yes:

\*If “yes” you must have a Registration Document from the Institutional Biosafety Committee. Be sure to include the Material Safety Data Sheet (MSDS) for this agent and copy of your chemical hygiene plan.

\*\* If “yes” you must have a Registration Document from the Radiation Safety Committee.

\*\*\* If yes, you must have an up to date copy of your DEA License on file with OEHS.

**SECTION 17: APPLICATION ATTACHMENTS**

## Before submitting, please ensure that the following relevant documents are included with your submission:

[ ] [Project Personnel Form](https://www.umb.edu/editor_uploads/images/orsp/Project_Personnel_4.docx?cachebuster:54) (Required)

[ ] DEA License (If applicable)

[ ] Safety Info (If applicable)

[ ] MSDS Sheet(s) (If applicable)

[ ] Chemical Hygiene Plan (If applicable)

[ ] Biological Safety Plan (If applicable)

[ ] [Field Study Plan Form](https://www.umb.edu/editor_uploads/images/ehs/Field_Research_Safety_Plan.pdf) (If applicable)

[ ] Grant Proposal Section Detailing Vertebrate Animal Research (If applicable)

[ ] Wildlife Permits (If applicable)

[ ] Other:

**SECTION 18: ASSURANCE STATEMENT & SIGNATURES**

By checking the following, you are certifying that:

[ ] I have provided accurate information on my qualifications, description of all animal activities, required documentation, personnel qualifications and training and other documentation related to the animal activities in this application

[ ] I, and the assigned personnel listed in this application, will work with the IACUC and animal care staff to ensure that all animal activities, described herein, will be performed in accordance with UMass Boston Policies and Standard Operating Procedures.

[ ] I understand that significant changes in animal activities must be approved by the IACUC before any such changes in animal activities can take place.

[ ] I acknowledge ownership of the animals to be used and accept, in part, responsibility for UMass Boston’s compliance with provisions of all Federal regulations and guidelines, including the “Animal Welfare Act,” the PHS "Policy on Humane Care and Use of Animals," and the ILAR “Guide for the Care and Use of Laboratory Animals.”

**Principal Investigator Department Chair (required for new applications and 3 YR renewals)**

**Name:**       **Name:**

**Date:** Click here to enter a date. **Date:** Click here to enter a date.

**Signature: Signature:**