Appendix 9: IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

The following protocols are included in Appendix 9:

1. Annual renewal form
2. Personnel update form
3. Protocol form: Three different versions of the IACUC protocol form exist due to an ongoing transition from a paper-based application to an electronic application.
    a. Protocol form (a) (in use until 2016-to be phased out by end of 2019)
    b. Protocol form (b) (to be phased out within 3 years)
    c. Electronic protocol form (c) (implemented in July, 2019; most protocols expected to be transitioned within 3 years).
4. Importation protocol
5. Holding protocol
6. Off-site protocol
7. Unanticipated Adverse Event(s) Form

Appendix 9: IACUC/OB Protocol Form

1. Annual Renewal of Animal Use Protocols

ANNUAL RENEWAL OF ANIMAL USE PROTOCOL

Complete this form at the end of **year 1 and year 2** of the approved protocol. Complete the form as soon as the IACUC Office sends you a reminder.
Submit completed-signed form to Casey Moran in the Office of Research and call **508-856-5384** with questions regarding this form.
==========

1) Docket #: PI:

2) Phone: Department:

3) Primary Contact Person:

Phone: Campus/Building

4) Title of Protocol:

5) Date of your last full-protocol approval (new or 3 year renewal):

6a) Please **indicate the total number of animals used** (including those **NOT** used in experiments, but euthanized) in the **last year** of approval. Contact Eva Miele (508-856-4409) in the Department of Animal Medicine, if you have questions about animals ordered or transferred during the past year.

Species	Number of animals used in each pain category				Total number
	B (breeding)	C	D	E	

6b) If you have transferred animals from a UMMS breeding protocol in the past year to this protocol, please indicate the following:
Protocol number: Species/no of animals transferred:

7a) Have there been any **adverse reactions**, **spontaneous deaths**, or any other problems with the animal model over the past year
Yes No
If "yes", please explain:

7b) Has the frequency of serious, but expected, adverse reactions been greater than predicted?
Yes No
If "yes", please explain:

8) Does this protocol have previous Institutional Biosafety Committee (IBC) approval? Please indicate with an "X"

Appendix 9: IACUC/OB Protocol Form

Approved:	**IBC Docket Number**
Not Approved	Not Required

Please call the IBC Office (508-856-1572), if you have any questions.

8) Are you using **areas/satellite labs <u>outside</u>** one of the main animal facilities?
Yes No

If "**yes**", please list:
(a) Campus/Building (location):
(b) Floor/Room #'s:

9) Have there been any changes in **personnel** during the year?
List omissions of personnel not previously reported to IACUC via amendment(s)

<u>Note:</u> Additions of personnel should have been done prior to start working with animals. It is a violation of UMMS IACUC policy, if someone started working with animals without IACUC approval. If you are adding new personnel at this time, please use a minor amendment form.

10) <u>PROGRESS REPORT</u>: Use the space below to write a very brief summary of the progress of the research thus far. This should not be a technical report – **use language understandable at a high school level.**

Signature: I certify that, to the best of my knowledge, the information provided is complete and accurate, and the research study is proceeding in accordance with the **previously approved protocol**.

Principal Investigator Date

For IACUC Use Only)

Reviewed and Approved by the IACUC

Chair/Vice-Chair, IACUC Date

Rev. 1/09

Appendix 9: IACUC/OB Protocol Form

Appendix 9: IACUC/OB Protocol Form

2. Personnel update form

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
PERSONNEL REQUEST FORM

To add personnel to an approved IACUC protocol, please complete this form and email to: IACUC@umassmed.edu. Please note that the personnel must complete the following before they can be added to an approved protocol:

- *Receive Health Clearance from Employee Health and Safety* (Complete this form and email to EmployeeAnimalHealth@umassmemorial.org)
- *Complete online training through AALAS Learning Library (Module 1, Module 2 and the species-specific training for all species listed on the protocol; Link for AALAS)*

If you have any questions, please email the IACUC office inbox (IACUC@umassmed.edu)

Docket #:

Project title:

Name of the PI:

Department:

Name (new personnel):

- **Email:**
- **UMMS user ID** (i.e. SmithA):
- **Summary of experience** (Format: Experience with [enter species] since [enter date] (repeat as needed). This includes performing [enter complex procedure, such as surgery] since [date] (repeat asneeded)):

Species to be used:

List procedures to be conducted (e.g. Euthanasia, breeding, survival surgery):

Personnel responsible for training:

Additional hands-on training received which may be required, please see notes below:

Introduction to Aseptic Techniques (if conducting survival surgery), **date completed:**

Herpes B Virus Training (if working with Macaques), **date completed:**

Q Fever Training (if working with Sheep), **date completed:**

Animal Medicine Rodent Euthanasia Training (personnel with less than one year of experience), **date completed:**

Personnel Removal:

PRINCIPAL INVESTIGATOR'S SIGNATURE : DATE:

Appendix 9: IACUC/OB Protocol Form

3a. Protocol

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Animal Study Protocol

PI: Docket # A-

Instructions for IACUC Animal Study Protocol application:

1. Complete the Animal Study Protocol application form if you are applying for a new, 3-year renewal or *major amendment.
2. If you need assistance in developing an Animal Study Protocol or have any questions, please contact IACUC@umassmed.edu
3. Save your file as [Your last name-IACUC] and e-mail the completed document as an attachment to IACUC: IACUC@umassmed.edu
4. Print a copy and collect signatures where appropriate: send the hard copy to IACUC, Office of Research, S1-859

All Principal Investigators are required to fill out the application face page (next page) and the sections I through X of the Animal Study Protocol. In addition, please complete appropriate forms and check the boxes below.

Forms: Double click on checkboxes to mark		
A	☒	Transporting animals for use outside of or to another area of the animal facilities
B	☐	If animals are going to bred for the use in this protocol
C	☒	Using anesthesia
D	☐	Doing survival surgery
E	☒	Administering substances other than anesthetics (therapeutic agents, toxins, cells, cell lines, cell/tissue extracts, viruses and other infectious agents, purified biological products, etc.)
	☐	Will rodent cell lines, serum, or tissues be introduced into live animals?
F	☒	Food or water restriction, prolonged physical restraint or animal care done by lab staff
G	☐	If using radioactive agents, hazardous chemicals, recombinant DNA, breeding transgenic animals carrying viral genes or synthetic nucleic acids (see form G for details), infectious agents, biotoxins, human or non-human primate materials and live non-human primates
H	☒	To indicate adverse effects of procedures and experiments/monitoring and managements
I	☐	If using any of the UMMS Core Facilities
J	☒	If using sites or vendors outside UMMS
K	☐	If you are conducting a training course
Worksheet 1	☒	Animal number worksheet
Worksheet 2	☐	Breeding worksheet

*Major amendment: Any change that could affect the well being of animals (addition of surgical procedures, use of hazardous agents as infectious agents or radioisotopes), change of animal species.
Please send a cover letter indicating what part of the protocol you are changing, and justify the reason for requesting the change. In the protocol-form use a *different font* or different color for the section that you wish to amend or to change.

Appendix 9: IACUC/OB Protocol Form

Docket No. A-

APPLICATION TO USE VERTEBRATE ANIMALS IN RESEARCH OR INSTRUCTION

UMMS Institutional Animal Care and Use Committee

Principal Investigator	Name and Highest Academic Degree(s)	
	Faculty Title	
	Department \ Division or Company Name	
	Mailing Address or UMMS Building	
	E-mail Address	
	Contact Phone Numbers	Office: Home: Pager #:
Faculty Sponsor (if required) or co-investigator	Name and Degree	
	Faculty Title	
	Department/Division	
Primary Contact Person	Name	
	Telephone No.	Office Home
	Mailing Address Building	
Project Title		

☐ New ☐ 3-Year Renewal ☐ Major Amendment (state changes in a cover letter)

Check this box if you like to receive an informal technical review and feedback from the IACUC office. The intent of this service is to assist investigators in improving the protocol and minimizing concerns during the formal review (veterinary pre-review and IACUC committee review). You may not require this option, if you are experienced in writing IACUC protocols.

USE OF THIS APPLICATION FORM

- DO NOT change formatting of this document. Forms submitted to IACUC MUST include shading. If attachments are used, they should be minimum and not replace answers to any section.
- If you have questions regarding the completion of this form, please contact the IACUC office (508.856.5384).
- Please note that upon request the University may be required by law to release a copy of this application to the public

Signature of Department Chair Date	Name (Please Print or Type)

For IACUC USE ONLY:

Approved: Yes No

Approved with conditions: Yes No

Date Chair/Vice Chair, IACUC

Appendix 9: IACUC/OB Protocol Form

Section I. OBJECTIVES OF PROPOSED RESEARCH OR INSTRUCTION

a. Check the box below that describes the type of animal use being proposed.

☐ Basic Research ☐ Service (Cores, Sentinels, etc.) ☐ Instruction or Training

☐ Field Research Testing (Biologicals, Toxicity, etc.) Applied Research

Other_____

b. Lay Summary: In clear, concise, *non-technical,* language (i.e., that could be understood by someone at a high school level), summarize the background and objectives of your studies involving animals.

c. Scientific Summary: Include an abstract of the study briefly describing the specific aims and scientific approaches to achieve these specific aims. This should serve as a scientific summary of the proposed study. Please note that the detailed procedures need not be included here.

d. Briefly explain the relevance of the proposed research or instruction to human or animal health and/or to the advancement of scientific knowledge.

e. Has this project undergone scientific peer-review?

☐ Yes ☐ No

Section II. RATIONALE FOR USING ANIMALS AND ALTERNATIVES TO THE USE OF ANIMALS

a. Briefly explain why animals are required for your studies.

b. Briefly explain why the species you propose to use is/are the most appropriate.

c. Describe the steps you have taken to reduce the usage of animals and to minimize the lethality of procedures in your experiments (e.g., using cell culture, computer simulations, or non-living models; doing pilot studies, using most specific assays possible).

Section III. NUMBER OF ANIMALS REQUESTED: PAIN / DISTRESS LEVEL

a. List the number of animals you will use over the duration (to a maximum period of 3 years) of this protocol.

By NIH policy, you will still have to renew your protocol every 3 years. *This requirement is independent of the need for the IACUC to initially review all animal activities described in your grant proposal, irrespective of the grant's time period.*

All animals must be accounted for, including E-17+ embryos (rats and mice) and neonates. The total for each row should equal the sum of the values in that row.

The total should include all animals bred for use in experiments listed in categories C, D, and E in section IIIa plus all animals generated by breeding that are discarded due to the wrong genotype and/or sex, (Category C).

Species	Number in Pain / Distress Level B (to be used only for USDA - covered species)	Number in Pain / Distress Level C	Number in Pain / Distress Level D	Number in Pain / Distress Level E	Total (should agree with numbers in worksheets I and II, if used.)

Pain / Distress level indicates maximum pain or distress level to be experienced by animal(s):
B = being bred but not used in testing, teaching or experiments (USDA covered species only)
C = negligible;
D = pain / distress relieved by appropriate drug use;
E = pain / distress not relieved by appropriate drug use. See the IACUC Instructions for definitions and examples.

- No Category B is to be used for rodents. Rodents that were once considered to be Category B should be listed under Category C.
- Induction of tumors is Category C if no distress is anticipated or if you monitor the status of animals and euthanize sick animals when detected.
- *Mice used for Ascites Production are always Category "E".*

b. If you have animals in category E, use this space to provide a description of the procedures producing pain or distress, and list the reasons why pain-relieving drugs cannot or will not be used to relieve pain or distress. If pain/distress relief would interfere with test results, justify why that is true.

c. Are you planning to reuse animals that were previously used for any other experiments or procedures under a different animal protocol?

Yes No If the answer is "yes," please provide more details (number of animals, protocol number, what previous procedures done in these animals)

d. If there are federal guidelines or regulations that *require* the use of laboratory animals then use this space to cite the agency, CFR title, number and specific section (e.g., Food and Drug Administration, 21:CFR1030.110).

Section IV. JUSTIFICATION OF THE NUMBER OF ANIMALS REQUESTED

NIH rules require that animal use must be kept to the minimum consistent with a sound scientific outcome. Please use the space below to justify that the number of animals requested is appropriate for the goals of the experiments.

a. Write a brief description of experimental design. In a table below (for large number of animals, please attach an animal number worksheet in the appendix), show all of the experimental groups and the number of animals per group. Be sure that the totals in the table match the totals shown in section III (Number of Animals Requested). Provide a science-based justification for why you chose the number of animals needed per group or other division of your research.

b. Describe, in general terms, the statistical tests required for the study.

Section V. ANIMAL SPECIFICS

a. Describe the age/weight, sex, and source of each animal species/strain.

SPECIES / STRAIN	AGE / WEIGHT	SEX	*VENDOR

*Note that the UMass Transgenic Core should be listed as a vendor if animals are produced there for you. If you are receiving animals from another investigator, indicate the name of the PI and protocol number.

b. If any of your animals have special needs, use the space below to list needs for special handling or housing. If animals cannot be socially housed, please explain why

Appendix 9: IACUC/OB Protocol Form

c. Specify what parameters you will assess to ensure that the animals are healthy before your experiments begin. Check all boxes that apply.

Activity		Appearance		Appetite		Behavior	
Excreta		Respiratory Pattern		Temperature		Weight	
Laboratory tests or other observations (specify)							

Section VI. EXPERIMENTAL PROCEDURES: (*except* any survival surgery and procedures that may lead to a permanent physical or physiological handicap)

IACUC reviewed procedures

a. Basic chronology (please use a flow chart or a sequential list of activities)

b. Detailed description of procedures (do not include details of in vitro procedures): Describe in narrative form all procedures to be carried out on living animals from initial contact to euthanasia.

c. Indicate how you will identify animals

d. Will the studies result in adverse effects on animal health or well being?

Yes No If yes, please complete form H

Section VII. TERMINATION OF STUDY / EUTHANASIA

Unless specified otherwise by the Principal Investigator, Department of Animal Medicine personnel who are euthanizing animals on behalf of the Principal Investigator will do so using any method listed as acceptable for the species in the most recent edition of the euthanasia guidelines of the American Veterinary Medical Association. Neonatal and pregnant rats and mice will be euthanized using methods approved by the UMMS IACUC and posted on the IACUC intranet site.

a. Is death used as an endpoint in this study? Death as an endpoint means that the animal is permitted to die as a result of experimental manipulation, i.e. exclusive of planned euthanasia. If yes, explain why an earlier end point is not acceptable. (Studies using death as an endpoint are Category E)	Yes	No

b. What criteria will be used to perform euthanasia earlier than planned?

c. Other Use – Will animals be available for further use by other investigators? Link to the Animal Medicine Exchange Board at http://i.umassmed.edu/ExchangeBoard/messagepage.aspx

d. Describe the method(s) of euthanasia for each species or procedure. For injectable drugs, give name, dose and route below. US Government policy requires the use of pharmaceutical grade drugs[1].
Must comply with the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia.

Species	Method/Drug	Dose (mg/kg body wt.)	Route

e. Current rules require that after euthanasia, death be confirmed by using a second method. For example bilateral pneumothorax is done after euthanasia using CO_2. Indicate below how you will double kill your animals.

Section VIII. DATABASE SEARCHES

In the space below, document that you have searched databases

1. To determine that you are not unnecessarily duplicating previous experiments,
2. To determine that alternatives to animal use are either not available or not appropriate,
3. To determine that procedures involving animals will avoid or minimize discomfort, distress and pain, AND

Appendix 9: IACUC/OB Protocol Form

[1]A pharmaceutical grade compound is 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 (BP).

Appendix 9: IACUC/OB Protocol Form

4. To determine that alternatives to procedures that may cause more than momentary or slight pain or distress to the animals have been considered

Sources of information regarding possible duplication and alternatives include:

- Medline (http://www.ncbi.nlm.nih.gov/pubmed)
- Animal Welfare Information Center (awic.nal.usda.gov/)
- UMMS veterinarians (508.856.3151)
- National Agricultural Library (www.nal.usda.gov/)
- WWW Virtual Library of Veterinary Medicine (http://netvet.wustl.edu/vetmed.htm)
- Altweb (http://www.jhsph.edu/~altweb)

a. Dates of Searches:
b. Name of the database(s) you searched:
c. Years Covered by Searches:
d. Keywords Searched:
e. Other Sources of Information:

Appendix 9: IACUC/OB Protocol Form

Section IX. PARTICIPATING PERSONNEL (including PI)

a. Identify all personnel working with animals at the time of this application.

Name	UMMS Phone	Emer-gency Phone	What are this person's responsibilities with animals on this study?	Years of experience with the technique to be used	Years of experience with the technique in species to be used	[2]First time animal user at UMMS (Yes/NO)	[3]On-line training courses completed (Yes/No)	[4]Occupational health requirements completed (Yes/No)

b. Briefly describe how the individuals with less than one year of experience with the technique(s) in species will be trained and/or supervised. Identify the individual(s) who would be responsible for training and/or supervising new or inexperienced personnel. Note that hands-on training can be given by an experienced personnel or designated Department of Animal Medicine staff. Those who perform survival surgery must receive aseptic Survival Surgery Training from the Department of Animal Medicine before approved as a surgeon. Please contact Van Gould (extension 66811) or Suzanne Wheeler (extension 62363) for training.

ADDITIONAL NOTES ON PARTICIPATING PERSONNEL:

IACUC training webpage IACUC new personnel webpage

- Before other new personnel perform any procedures, a written minor amendment request must be submitted to and approved by the IACUC. All personnel new to UMMS or those who never worked with animals will have to complete all the Training and Occupational Health and Safety Requirements before added on an IACUC protocol.
- The principal investigator is responsible for ensuring that all personnel adhere to the conditions approved by the IACUC.

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Section X. APPLICANT'S CERTIFICATION

IACUC is charged with carrying out the rules and regulations of the Federal Government's Animal Welfare Act governing the care and use of animals in research and instruction. The Act stipulates that (a) Principal Investigators must give written assurance that the activities do not unnecessarily duplicate previous experiments; (b) procedures involving animals must avoid or minimize discomfort, distress, and pain to the animals; (c) Principal Investigators must consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals and give a written description of methods used to determine that alternatives are not available; and (d) paralytic agents cannot be used in unanesthetized animals. Accordingly, the Applicant, who must be a member of the faculty holding Principal Investigator status, is required to read and sign the following certification:

BY SIGNING BELOW, I CERTIFY THE FOLLOWING:

1. I am thoroughly familiar with the literature in the field of research proposed in this application, and I have determined that the research does not unnecessarily duplicate experiments, that appropriate non-animal models are not available, and that the research must be conducted on living animals.
2. I will abide by all UMMS policies and procedures regulating use of animals in instruction and research, by the provisions of the PHS/NIH Guide for the Care and Use of Laboratory Animals, and by all other applicable laws, policies, and regulations governing the use of animals in instruction and research.
3. I will supervise all experiments involving live animals. Furthermore, I will ensure that all listed participants are qualified or will be trained in proper procedures, including animal handling, anesthesia, surgery, post-procedural management, and euthanasia. Also, I will ensure that individuals not listed in the application will not have responsibility in experiments involving animals.
4. All listed personnel will read the IACUC-approved Application to Use Vertebrate Animals in Research or Instruction before undertaking any procedures on laboratory animals.
5. Survival surgery will be performed using standard aseptic procedures.
6. Animal Medicine clinical veterinary staff will be consulted as needed to ensure satisfactory veterinary care.
7. In the event of an animal health emergency, my staff or I will contact the Department of Animal Medicine. We will not attempt animal treatment by ourselves, unless it is a life-threatening emergency.
8. If I cannot be contacted, and animals in this project show evidence of illness or pain, emergency care, including euthanasia, may be administered at the discretion of the Animal Medicine veterinary staff.
9. Significant changes in study objectives and procedures require IACUC approval.
10. Unanticipated adverse events will be reported to the IACUC as required by UMMS IACUC policy
11. This application meets all animal use and care requirements of the funding agencies that have been asked to support the research.
12. By signing below, I certify that all animal studies described in grant proposals using this protocol are described in this animal use application.

PI's Signature: Date:

GRANTS ASSOCIATED WITH THIS ANIMAL PROTOCOL

Sponsor	Funding period	Grant ID #

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A1. Will animals be used in areas, e.g., laboratories, outside one of the general animal facilities? (A Level, BioTech II, BNRI 1st floor, LRB 1st floor, Rose Gordon, ASC Facility)	Yes	No
If "yes", list the building and room number(s) where animals will be housed or used outside the animal facility.		
A2. Indicate which of the following procedures will be used outside of the animal facility:		
☐ Fluid Collection/Tissue Harvesting ☐ Non-Surgical Procedure ☐ Non-Survival Surgery ☐ Survival Surgery ☐ Irradiation ☐ Core Service/Imaging ☐ Other:		
A3. Will animals be held, housed, and/or used in study areas outside of the animal facility for more than 12 hours for USDA regulated species or 24 hours for non-USDA regulated species? If "Yes", in the space below list the building and room number(s), and justify scientifically the need to hold animals.	☐ Yes	☐ No
A4. Use this space to describe how you will transport animals from the animal facility to a study area outside of the animal facility		
A5. Is a patient procedural area to be used for animal studies? If "Yes", use the space below to provide room number and/or location of patient area. If animals are to be transported to the patient area, you will require the approval of the Infectious Disease Committee (ICC). Please fill out the ICC Approval form and send to Mack, Deborah Ann (Infection Control) (UMMHC) DeborahAnn.Mack@umassmemorial.org. Contact Deborah Ann Mack at 508-856-5843, if you have questions.	Yes	No
A6. If "Yes", describe any special animal transport or facility procedures that will be followed to assure health and safety of both animals and patients.		
A7. Will animals for your use be transported to a different area of the animal facility or to a different UMMS animal facility? Yes. If yes see below.		
I agree to use the Web Animal Ordering System for all transfers within the animal facility, except as noted below. Our work requires that we transport of animals to different areas of the animal facility for activities approved by the IACUC e.g. irradiator, biocontainment suite. Explain very briefly below.		

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FORM B
BREEDING

Use this section if you are breeding animals for this project.

B1. Describe the species, strain, and source of each animal that you plan to breed

SPECIES / STRAIN	AGE	WEIGHT	VENDOR

B2. Specify what parameters you will assess to ensure that the animals are healthy. Check all boxes that apply.

Activity		Appearance		Appetite	
Excreta		Respiratory Pattern		Temperature	
Laboratory tests or other observations (specify)					

B3. In this space describe how many animals you anticipate breeding over the next 3 years. Briefly explain your calculations below.

☐

B4. Anticipated health problems in the animals being bred. If there are known health or well being issues associated with the animals you are proposing to breed, or their offspring, please describe them in detail.

☐

B5. Male:Female Ratio

☐ A ratio of 1:1 will be used. No continuous breeding

☐ A ratio of 1:1 with continuous breeding will be used. See below

A ratio of 1:2 or 1:3 will be used (harem breeding). See below

I have read the IACUC Mouse Breeding Policy that prohibits more than one litter per cage. I agree to separate pregnant females to other cages prior to their giving birth in harem breeding and to wean continuously bred litters at day 21 if the female is pregnant.

Mouse Breeding Policy

B6. If your animals have special needs, use the space below to list needs for special handling or housing.

B7: Describe how you will identify your animals (e.g. ear tags):

B8. Use this space to describe what will be the disposition of retired breeders or any excess animals.

B9. Will you require special caging? (If so it is your responsibility to provide it)

B10. How often will each male and female be bred?

B11. If you will be using inbred or outbred animals, describe how you will ensure that they remain in- or outbred:

B12. Describe any special handling that you anticipate:

B13. Will males be removed from cages before birthing?

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Yes No (if no, explain why not)
B14. What nesting materials will you use? (For rodents, consider Nestlets or similar material)

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B15. At what age will the young be weaned?
☐ ☐
B16. Will the offspring be genotyped, and if so, at what age and by what method?
B17. Will mice be bred and transferred to other investigators? YES NO
If yes please check the attestation I agree that all transfers to another investigator whether within the Animal facility or directly to a laboratory must use electronic Web Animal Ordering system. I understand that failure to do so represents unapproved animal use under the donating investigator's (my) protocol and I will be responsible for all regulatory issues, violations, etc arising from such use. Use of animals not on the recipient's protocol also represents a protocol violation of his/her protocol.

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FORM C
ANESTHESIA
Anesthesia and Analgesia

C1. PRE-ANESTHETIC AGENTS (e.g., tranquilizers, narcotics) and ANESTHETIC AGENTS: Describe how these agents will be used in your studies. If none will be used, enter "none" in the "Agents" column.

Frequency of administration	Species	Pre-anesthetic Agents & Anesthetic Agents	Dose	Route/Volume

C2. MONITORING OF ANESTHESIA: Describe (a) what will be monitored (e.g., corneal reflex, heart rate, respiration, response to noxious stimulus) and (b) how frequently each of these variables will be monitored.

A form (suggested template) for recording Rodent Anesthesia and Analgesia can be obtained from the IACUC website: RODENT ANESTHESIA RECORD FORM.

C3. Use of Isofluorane: It is IACUC policy to ensure that animals do not contact liquid isofluorane. Please see the IACUC policy on isoflurane use.

C4. Describe the anesthetic gas scavenging system you will use to eliminate waste anesthetic gas. Follow the link for the policy on scavenging anesthetic gas.

☐ ☐

C5. Are any of the anesthetic or pre-anesthetic agents listed in C1 non-pharmaceutical grade? A pharmaceutical grade compound is 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 (BP).

Yes No If the answer is "yes," please explain

US government policy requires the use of pharmaceutical grade drugs especially for anesthetics or analgesics. Exceptions include unavailability of pharmaceutical grade drug and lack of a suitable alternative. Exceptions require scientific justification.

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FORM D

SURVIVAL SURGERY INCLUDING LAPAROSCOPY, ENDOSCOPY, and any procedure that has a *reasonable* potential of causing a permanent physical or physiological handicap.

Complete this section if any animals will recover from local or general anesthesia after a surgical or other major operative procedure.

D1. In the space below, explain why it is necessary for the animals to recover from surgery/anesthesia.

D2. In the space below, describe pre-operative care (including physical examinations, lab tests, and any preconditioning apparatus). All anesthetic agents and pre-operative medications should be listed in Form C.

D3. Use the space below to describe in detail the surgical procedure(s)/other major procedure to be used.

Animal pre-surgical preparation:

Instrument pre-surgical preparation:

Surgeon's pre-surgical preparation:

Details of Techniques:

D4. List all participating surgeons and assistants, and indicate the number of years of experience with the particular species and surgical or other major operative procedures to be used. Those who perform survival surgery must receive Surgery Training from the Department of Animal Medicine and submit individual form (download). Please contact Van Gould (extension 66811) or Suzanne Wheeler (extension 62363) for training.
Policy for Survival Surgery Training

Name	Role in surgery	Are you performing survival surgery?	Years of experience with the role

D5. Describe immediate postoperative care, and provide dosage, route, and frequency of administration of specified analgesics (pain relieving drugs) for the first 48 hours.

Note that "As needed" or "PRN" do not constitute an acceptable schedule for analgesia.

Species	Analgesic Agents	Dose	Route/Volume	Frequency of Administration

Describe the immediate postoperative care for the animal until it is able to maintain a sternal position (e.g., maintaining body temperature, fluid administration, bandaging, vital signs monitoring and monitoring frequency).	

Appendix 9: IACUC/OB Protocol Form

D6. List the names of individual(s) who will check animals during recovery.	
Name	AREA CODE/TELEPHONE#

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D7. In the space below describe any expected or potential postoperative complications and describe how you will handle them.	
D8. Where will surgery/procedure be performed?	Rm
D9. Where will animals be housed during recovery?	Rm
D10. Where will animals be housed after recovery?	Rm
D11. ARE MULTIPLE SURVIVAL SURGERIES PERFORMED ON THE SAME ANIMAL?	
Yes No	
D11a: Justify the need for multiple survival surgeries	
D11b: Give the species and number of animals that will have multiple survival surgeries.	
D11c: Specify the time intervals between the surgical procedures	

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FORM E
ADMINISTRATION OF SUBSTANCES OTHER THAN ANESTHETICS
Non-Anesthetic Agents

List all 1) Therapeutic , 2) Cell lines or Cell/Tissue extracts and 3) Other Experimental/Study non-anesthetic agents that will be administered to the animals, including but not limited to: 1) drugs such as antibiotics, analgesics or local anesthetics used to minimize post-procedural pain, distress, or discomfort, 2) isolated cells, cell lines, cell or tissue/cell extracts and 3) drugs, infectious agents such as viruses or other substances under study. For drugs under study in the experimental component of your protocol, drug type or group (e.g., non-steroidal anti-inflammatory agents, α-adrenergic receptor blockers) will suffice; however specific drugs should be indicated if known.

E1. Therapeutic agents:

Species receiving the agent	Agent Name	Dose	Route	Volume	Frequency & Total Duration

E2. Cells or Cell/Tissue Extracts (do not include purified cell products here) Rodent cell lines, serum and cell/tissue products can only be used in animals after confirming the absence of rodent infectious agents by MAP or PCR testing.
Please review the IACUC policy on cell line testing.

Species receiving the agent	Cells or Cell/Tissue extracts		Dose	Route	Volume	Frequency and Total Duration
	Name of cell line or tissue type	Species of origin				

E3. Experimental / Study Agents

Species receiving the agent	Agent/Substance Name	Dose Range	Route	Volume	Frequency & Total Duration

E4. Are any of the therapeutic agents listed in E1 or drugs listed in E3 are non-pharmaceutical grade? A pharmaceutical grade compound is 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 (BP).
More information for the use of non-pharmaceutical compounds.

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Yes No If the answer is "yes", please explain.
US government policy requires the use of pharmaceutical grade drugs especially for anesthetics or analgesics. Exceptions include unavailability of pharmaceutical grade drug and lack of a suitable alternative. Exceptions require scientific justification.

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FORM F
PROLONGED PHYSICAL RESTRAINT OR STRESS OF CONSCIOUS ANIMALS; FASTING; FOOD RESTRICTION; ANIMALS UNDER THE CARE OF THE INVESTIGATORS STAFF RATHER THAN ANIMAL MEDICINE PERSONNEL

Complete this section if any unanesthetized animals will be restrained, except when the restraint is for a brief examination, sample collection, or injection. Also complete if noxious stimuli will be administered, if food or water will be withheld, etc.

F1. Explain rationale for use of restraint or induction of stress:

F2. Describe device, dimensions, etc.:

F3. Duration and frequency animal will be confined to device:

F4. Observation intervals during confinement:

F5. Qualified faculty or staff making observations:

Name	AREA CODE/TELEPHONE#		
		☐	☐
		☐	☐

F6. Will pain or discomfort be induced? If yes, describe in detail using the space below.	Yes	No
	☐	☐
F7. Will stimulation, including light and sound, be used to modify animal behavior? If yes, describe in detail.	Yes	No
F8. Will animals be fasted (food, approx. 24 hours and/or water, approx. 12 hours) or placed on a diet deficient in one or more nutrients? If yes, provide the details below. How long animals will be restricted? How will the general well-being of the animal be determined How often will the animal be weighed? I have read the IACUC policy on fasting and agree to label all cages with start dates, stop dates, and telephone contacts.	Yes ☐	No ☐
F9. Animal medicine staff will be restricted from caring for animals I have read the IACUC policy on investigators caring for their animals and agree to label all cages with start dates, stop dates, and telephone contacts. Please explain why the restrictions are required below:	Yes ☐	No ☐
F10. Will analgesics, sedatives, or tranquilizers be used to provide additional restraint? If yes, make sure that the agent(s) are listed in Form C.: ANESTHESIA	Yes	No

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FORM G: HAZARDOUS AGENT INFORMATION		
Protocol may require ancillary reviews by the Institutional Biosafety Committee (IBC), the Environmental Health and Safety (EH&S), the Radiation Safety Office prior to the IACUC approval. IACUC will notify you if ancillary reviews are required based on the information provided in the protocol. Omission of appropriate information may delay the approval process.		
G1. Will this project require the use of infectious biological agents? (pathogenic to man or animal) If Yes, IBC approval is required.	☐ Yes	☐ No
G2. Will this project require the use of recombinant DNA technology in live animals? If Yes, IBC approval is required.	☐ Yes	☐ No
G3. Will this project require creation of new transgenic animals in any UMMS laboratory or transgenic core facility? If yes, IBC approval is required	Yes ☐	No ☐
G4. Will this project require the breeding of transgenic animals that contain transgene encoding more that 50% of the genome of an exogenous eukaryotic virus from a single family or express transgene under the control of gammaretroviral long terminal repeat? If Yes, IBC approval is required.	☐ Yes ☐	☐ No ☐
G5. Will this project require the use of materials of human origin? If Yes, IBC approval is required.	☐ Yes	☐ No
G6. Will this project require working with live non-human primates or materials of non-human primate origin (tissues, cells, etc.)? If Yes, IBC approval is required.	☐ Yes	☐ No
G7. Will this project require the use of biotoxins? If Yes, IBC approval is required. Please see examples of biotoxins that require IBC approval:	☐ Yes	☐ No
G8. Will this project require IBC approval for the use of synthetic nucleic acids (e.g. siRNA, synthetic DNA)? Please see the footnote below for synthetic nucleic acids which require IBC approval[1].	Yes ☐	No ☐
G9. Will your research activities potentially expose humans, other than researchers and Animal Medicine personnel, to zoonotic infections (e.g., Q fever from sheep) [2]? If yes, IBC approval is required.	Yes	No
G10. Will this project require the use of ionizing radiation in live animals? If Yes, Radiation Safety approval is required	Yes	No
G11. Will this project require the use of hazardous chemicals in live animals? If Yes, Chemical Safety Review is required. Please see the footnote below for Occupational Health and Safety Administration (OSHA) definition of a hazardous chemical[3].	☐ Yes	☐ No
G12. If you will be using any of the above agents, use this space to describe briefly what you will be doing.		

[1] Synthetic nucleic acids

If the answer to ANY of the following questions is "yes," IBC approval is required for synthetic nucleic acids:

1. Will synthetic nucleic acid molecules be modified, or used in a vehicle that is intended to enhance cell membrane penetration *in vivo* (e.g. bound to nanoparticles)?
2. Will synthetic nucleic acid molecules have ANY of the following characteristics?
   - *Able to express a transgene*
   - *Able to replicate in vivo*
   - *Able to integrate in cellular genome or modify genomic sequences*
   - *Prolonged (not transient) biologic effects if introduced into cells*

[2] The researchers and Animal Medicine personnel are required to be knowledgeable about the Occupational Health and Safety hazards of the animal species they will be working with. However, if there is the possibility of untrained individuals (e.g., if animals and patients are using the same imaging equipment) contracting serious zoonotic diseases by coming into contact with animals directly or indirectly , IBC has to review and approve procedures used for transporting, experimentation, decontamination, disposal of animal waste, etc.

[3] Chemical Safety Review

Purpose: Many chemicals used in conjunction with animals in research as part of the experimental test system have the potential to adversely affect the health and safety of researchers as well as animal care personnel. These 'hazardous chemicals' are broadly defined in the OSHA Hazard Communication Standard as chemicals that pose either a physical hazard or a health hazard to humans.

Definition: Among the chemicals that pose a 'physical hazard' are those that are combustible or flammable liquids, compressed gases, organic peroxides, oxidizers, and unstable or water-reactive. Chemicals that pose a 'health hazard' are those that may have acute or chronic health effects in exposed employees. Among these chemicals are carcinogens, toxic or highly toxic agents, reproductive toxins, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. See 29 CFR

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1900.1200(c) for the complete definition.
Process: Chemicals used with animals that are considered to be potentially 'hazardous' according to OSHA need to be listed in the IACUC Animal Study Protocol application, and their use reviewed by EH&S. Material Safety Data Sheets may be consulted for guidance regarding whether or not a given chemical may pose a chemical or physical hazard to researchers and/or animal care personnel. You may contact EH&S for additional information.

G13. If you have IBC approval for the studies described in the protocol, please check the box below and fill in the requested information	
I (PI of this IACUC protocol) have reviewed the IBC protocol and verified that all the hazardous biological agents used in live animals under this protocol have IBC approval. There is an IBC approved animal addendum for use of animals at animal biosafety level >ABSL-1.	IBC protocol number _____ PI of the IBC protocol _____

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☐

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FORM H
ADVERSE EFFECTS OF PROCEDURES AND EXPERIMENTS/MONITORING AND MANAGEMENT

H1. What will be monitored to assess the presence of pain, discomfort, or other potential adverse effects caused by your studies? NOTE: This period includes the time from initiation of experiments until the animals are removed from the study; for surgically operated animals, this includes the time after anesthesia recovery until animals are removed from the study. Check all that apply.

Activity		Appearance		Appetite		Behavior	
Excreta		Grooming		Guarding		Heart rate	
Licking, biting		Posture		Respiratory rate		Temperature	
Vocalizing		Weight loss		Wound site		Other	
Laboratory tests or other evaluation (specify)							

H2. Indicate the frequency with which you will monitor your animals during and after all procedures. Please indicate both monitoring interval and total length of time.

H3. Describe the conditions and complications that would lead to removal of an animal from the study and how this will be accomplished (e.g., stopping treatment and/or euthanasia).

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FORM I PROCEDURES DONE IN UMMS CORE FACILITIES			
For use a UMMS core facility for this study, you need to get the approval for those animals used in the core facility under this protocol. However, you do not need to list details of the specific procedures performed in the core facility by its staff if the procedures are part of an IACUC approved core protocol.			
I1. List below the UMMS core facility services you will be using for this protocol.			
Name of the core facility	Name of the PI of the core facility	Protocol # (if applicable)	Briefly describe the procedures/services provided by the core facility
			☐ ☐
I2. Is any of the procedure(s) performed by personnel other than the core facility personnel?			
If the answer is "Yes" please name the individuals performing the procedures under this protocol in the core facility and identify the procedure(s) by core facility SOP# or by other means.			
I3. If any of the procedure(s) used in the core facility is different from the IACUC approved core facility protocol, please describe below the procedure deviations.			
I4. Use this space to describe how you will transport animals between the animal facility and the study area			

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FORM J ANIMAL WORK DONE OUTSIDE UMMS			
Please fill out this form, if a UMMS investigator is going to perform animal studies in collaboration with a non-UMMS collaborator or commercial vendor. This includes production of antibodies by an outside company. According to Federal Regulations, UMMS, being the grantee institution, is responsible to verify that all animal work done outside UMMS has been reviewed and approved by a PHS assured institution, and approved by an IACUC.			
J1. List below the details of animal work done outside UMMS			
Name of institution or company	Name of the PI or contact (if a company), & contact information (phone # or email address)	IACUC Protocol number, if applicable	Animal Species used in the study
J2. Provide a brief description of the animal work done at the non-UMMS site below:			
☐ ☐			
J3. List below the supporting documents provided with this application. UMMS IACUC may require one or more of the following documents to attached to this application: Evidence of collaboration or service (letter from the collaborator or company indicating willingness for doing the animal work) Copy of the IACUC approval from the non-UMMS institution to indicate that this work has been reviewed and approved by an IACUC. If this approval letter is in a foreign language, please provide an English translation along with a copy of the original Approval Letter. Evidence for PHS Assurance of the non-UMMS institution (A copy of the Assurance Letter from NIH to the institution or company will be sufficient). This is not required if the Assurance number and period of validity is indicated in the IACUC Approval Letter) A copy of the protocol (translation into English, if in another language), if the collaborating institution or company is from outside United States, or non-human primates are used in the protocol. Memorandum of Understanding (requested by the IACUC)			

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FORM K IF ANIMALS ARE USED FOR TRAINING COURSES (TO TRAIN STUDENTS, RESIDENTS, FELLOWS AND OTHERS)	
Please fill out this form, if this application is designed for training courses. The trainees should be under the supervision of a trained UMMS investigator during any contact with live animals. Please note that the trainees are not permitted to work independently with live animals; to do so, they have to be listed as personnel in the protocol (please see section IX). According to Federal Regulations, the IACUC is to ensure the occupational health and safety of personnel working with animals, and that all individuals working with animals receive appropriate training. Because the training participants are not known at the time of protocol submission, IACUC recommends the following options to meet the Occupational Health and Safety and Training requirements, and requests that a list of participants submitted to the IACUC Office before the training session(s).	
K1. Occupational Health Evaluation of the trainees; please check all the choices that you are planning to recommend the training participants. Each participant has to full fill this requirement by full filling one the choices below.	
a. Are the participants UMMS student, resident, employee or volunteer? Please submit an Initial Health Evaluation form to the Employee Health Service for obtaining Health Clearance.	☐ Yes ☐ No
b. Are the participants going to receive clearance for working with animals from a qualified physician? Health Clearance from a qualified physician is acceptable, if the participant is not affiliated with UMMS. The physician must review and accept the criteria established by the UMMS Occupational Health and Safety Policy. The UMMS Occupational Health and Safety Policy and Health Clearance Forms are available from the IACUC office.	Yes No ☐ ☐
c. Are the participants going to sign the "Informed Consent Form?" (Participants who are not affiliated with UMMS) In lieu of obtaining health clearance from a qualified health care practitioner participant may submit a signed Informed Consent form indicating that they are aware of and understand the risks of working with animals . and participate at his/her own risk. This option is only allowed if the trainees are only attending one or two training session(s).	Yes No ☐ ☐
K2. Training options: please check the option(s) below for participant training	
a. Are you planning to provide an instructional lecture on working with animals? The PI or his designee can provide training in a lecture format (the lecture should include an overview of Federal Regulations, ethical guidelines for using animals, hazards and risks associated with the use of animals, species-specific information, humane techniques for animal procedures, and other appropriate information relevant to the experimental procedures being used). IACUC could provide the PIs with PowerPoint slides on the UMMS IACUC Animal Care and Use Program upon request. Please note that these slides do not cover Federal Regulations, Occupational Health Hazards and Species Specific information.	Yes No ☐ ☐
b. Are the participants UMMS students, residents, staff or volunteers? The trainees may fulfill this requirement by completing the online Training courses available to the New Animals Users at UMMS to meet all the training requirements.	☐ Yes ☐ No
K3. Are the trainees going to perform SURVIVAL SURGERY? If the trainees are going to perform survival surgery, they are required to complete Survival Surgery Training provided by the Dept of Animal Medicine.	Yes No

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The PIs are required to provide a list of trainees on or before the day of training to the IACUC office. Please see next page for a template for listing trainees. The list should include the names, affiliation and contact information, and evidence for completion of the above requirements (K1 to K3). Failure to submit a list of participants prior to the training session may be considered a protocol violation.

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TRAINING PARTICIPANT LIST (template; make additional copies if necessary)

Note: Do not have to fill this out at the time of protocol submission; to be submitted to the IACUC Office (hardcopy or pdf) on or before the day of training

PI Name:	
Docket Number:	
Name of personnel conducting the training session if other than PI:	
Date of training:	

TRAINING PARTICIPANTS

Name	Indicate if affiliated to UMMS, OR provide the name and address of the non-UMMS affiliation	Contact information (Email and phone number)	Occupational Health Evaluation and clearance to work with animals, OR Informed Consent singed (check applicable box below)			Training (check applicable box below)		
			By the Employee Health Service	By a qualified physician[1]	Informed Consent Form[2]	Online training courses	Classroom instruction	Surgery Training (if performing survival surgery)

[1] Please submit copies of Heath Clearance certificate to the IACUC Office
[2] Please submit copies of the Informed Consent Form to the IACUC Office

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WORKSHEET 1 (Optional)

Animal number worksheet (addendum to section IV)-*add on more rows as needed*
Use this worksheet to show the details of animal numbers to be used for 3 years

Species ----------(please use one sheet/species)

A	B	C	D	E	F	G	H			I			
#	Experiment or procedure[1]	Number of animals per group[2]	Number of groups, including replicates	Total number of animals per experi-ment or procedure	Estimated number of additional animals to compen-sate for possible death or protocol failure	Total number of animals requested (Sum of E and F)	Source of animals			Pain level			
							To be bred	To be purchased	To be transferred from another protocol	B	C	D	E
Grand total													

[1] The specific experiment(s) and procedure(s) listed here should be referenced in the Experimental Design (section IV)
[2] Should be based on justification (power analysis, previous publications, etc.) for the number of animals as described in section IV

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WORKSHEET 2 (Optional)

Breeding worksheet (add more rows if needed)

Species ---------- (please use one sheet/species)

A	B		C	D	E	F	G	H	I	J
#	Animal strain, genotype, phenotype, etc.		Number of animals from outside source used in mating [1]	Number of matings	Expected litter size	Total number of pups expected	Number of pups expected to be used in experiments	Number of pups which may not be used in experiments	Number of pups to be used for continued breeding	Total number of animals (sum of columns C and F)
	Offspring	Parents								
Grand total				Not applicable						

[1] Animals purchased or obtained from other investigators used in breeding, do not use animals bred in house used for breeding in this column

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3b. Protocol

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL ANIMAL CARE AND USE COMMITTEE Animal Study Protocol

PI Name:	**Docket Number: A-**
PART 1: ADMINISTRATIVE QUESTIONS	
1.0 Study Type*	☐ New ☐ 3-Year ☐ Amendment (summarize below)
1.1 Docket #	
1.2 PI Name *	
1.3 Faculty Title * If *"other" describe:*	Choose an item.
1.4 Email Address *	
1.5 Phone Number *	
Telephone type	☐ OFFICE ☐ CELL ☐ OTHER
1.6 Academic Degree *	Choose a degree
1.7 Department/Division or Company Name *	Select a Department.
1.8 Emergency Phone Number *	
1.9 Faculty Sponsor (if required)	
1.10 Co-investigator	
1.11 Primary Contact Person *	
1.12 Primary Contact Email *	
1.13 Primary Contact Phone Number *	
1.14 Project Title *	

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1.15 Grants Associated with this Animal Protocol		
Grant Sponsor	Grant ID	Grant PI
Choose an item.		
Choose an item.		
Choose an item.		
Choose an item.		
1.16 Has the study undergone peer-review? *	☐ YES ☐ NO	

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PART 2: BACKGROUND QUESTIONS		
2.1 Lay summary: Briefly summarize the background and goals of your animal studies using non-technical terms that could be understood by individuals with high school level education. *		
2.2 Scientific Summary: Briefly describe the specific aims and scientific approaches to achieving these aims. Detailed procedures should not be entered here. This section will help the committee understand the rationale and goals of your study. The IACUC does not use this section to conduct a scientific merit review. Limit to 5,000 characters. *		
2.3 Describe the potential scientific benefit of the proposed study to human or animal health, the advancement of scientific knowledge, or the good of society. *		
2.4 Dates of Searches: Years covered by the search (From - To) *	From: -select date-	To: -select date-
2.5 Keywords searched: Keywords must include procedures that may generate more than momentary pain or distress. If not enter N/A. *		
2.6 Databases searched to determine: • That you are not unnecessarily duplicating previous experiments, • that alternatives to animal use are either not available or not appropriate, • that procedures involving animals will avoid or minimize discomfort, distress and pain, AND • that alternatives to procedures that may cause more than momentary or slight pain or distress have been considered.	*☐ PubMed/Medline *☐ Scopus *☐ Web of Science *☐ Agricola *☐ AltWeb *☐ Animal Welfare Information Center *☐ UMMS Veterinarians *☐ Other Sources of Information (explain below)	
2.7 Did the search identify less painful alternatives, previous studies that would be unnecessarily duplicated or alternative approaches that would not require animals? *	☐ YES ☐ NO	
2.8 If you answered YES to the above question, please explain why the proposed studies are required.		

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2.9 Why are vertebrate animals required for your study? *
*☐ The complexity of the processes being studied cannot be duplicated or modeled in simpler systems
*☐ There is not enough information known about the processes being studied
*☐ Preclinical studies in living animals are necessary prior to human testing.
*☐ This is a behavioral, learning or developmental study
*☐ Other. Please explain:
2.10 Why are the proposed species the most appropriate for your studies? Check all that apply. *
*☐ The anatomy, genetics, physiology or behavior of this species is uniquely suited to the study.
*☐ This is the phylogentically lowest species that provides adequate size, tissue, or anatomy.
*☐ This species provides a particularly good model for duplicating the human situation.
*☐ Previous studies using this species formed the background of this project.
*☐ This species has the following unique features that make it the best choice available for this study.
*☐ Other. Please explain:
2.11. Briefly explain your selection(s) from 2.10.*

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PART 3: EXPERIMENTAL DESIGN

3.1 List the number of animals you will use over the duration (to a maximum of 3 years) of this protocol. Include mouse and rat fetuses ≥17 days of gestation. The total should include all animals bred for use in experiments AND all animals generated by breeding that are discarded due to the wrong genotype and/or sex.

Pain/distress level indicates maximum pain or distress level to be experienced by animals:

- B=USDA covered species only being bred but not used in testing, teaching or experiments (do not include mice/rats)
- C=negligible pain/distress
- D=pain/distress relieved by appropriate drug use
- E=pain/distress not relieved by appropriate drug use

Species	Category B	Category C	Category D	Category E	Total
Choose species.					
Choose species.					
Choose species.					
Choose species.					
Choose species.					
Choose species.					

Note: This table will not automatically total columns. Please enter the total for each row.

3.2 Category E Justification: If you have animals in category E, briefly refer to the procedures producing pain or distress and/or a timeline of disease progression, and list the reasons why pain-relieving drugs cannot or will not be used to relieve pain or distress. If pain/distress relief would interfere with test results, justify why that is true.

3.3 Are you planning to reuse animals that were previously used for other experiments or procedures under a different protocol? *	☐ YES ☐NO

3.4 If the answer is "yes" to question 3.3 please provide more details (number of animals, what previous procedures done in these animals)

3.5 If there are federal guidelines or regulations that require the use of laboratory animals then please cite the agency, CFR title, number and specific section (e.g., Food and Drug Administration, 21:CFR 1030.110).

3.6 The number of animals requested for this protocol is based on the following. Guidance on animal number justification can be found on the UMMS IACUC web site. (select all that apply) *	*☐ A statistical estimate of the number required to achieve statistical significance *☐ The estimated minimum number necessary to achieve the goals of the study in the absence of a statistical estimate

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	*☐ The number necessary to obtain sufficient tissue or other material for testing or analysis *☐ The number required to provide sufficient technical training or practice for the number of trainees expected *☐ The expected or established mortality associated with this procedure *☐ The number of animals generated from breeding that cannot be used due to the wrong genotype or gender *☐ Other (*explain below*)
3.6.a. Please provide details of the number of animals requested based on experimental design, including the experimental groups and the number of animals per group. Be sure that the total number of animals based on experimental design match the total # of animals in table 3.1.	
3.7 Write a brief description of experimental design using a chronological list of activities to be carried out on living animals from initial contact to euthanasia *	
3.8 If using an approved standard procedure from the UMMS IACUC website without modification please check the appropriate check box (s) below. Deviations to standard procedures should be described in section 3.10.	*☐ Facial Vein Blood Collection *☐ Lateral Tail Vein Blood Collection *☐ Retro-Orbital Bleeding *☐ Use of Freund's Complete Adjuvant (FCA) *☐ Ascites Production for Monoclonal Antibodies *☐ Tail Snipping of Mice up to 21 days of age *☐ Tail Snipping of Mice between 22-28 days of age *☐ Tail Snipping of Mice > 28 days of age *☐ Ear Punching as Alternative to Tail Snipping for Isolating DNA *☐ Intramuscular injections in rabbit *☐ Pearl Imaging *☐ IVIS Imaging

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3.9 If using an approved procedure from a UMASS Research Core Facility please check the appropriate check box(s) below. If procedures and/or species are not covered under the core protocol(s) please provide a detailed description of the procedures for each species in narrative form in section 3.10.
*☐ Advanced MRI Core *☐ Transgenic Animal Modeling Core *☐ Metabolism Core *☐ Micro CT *☐ Radio Labeling Small Animal Translational Imaging Core
3.10 Please provide a detailed description of the procedures for each species in narrative form. Do not include procedures done post mortem. Do not include survival surgery. Please use Form D to describe details of survival surgical procedures.

3.11 Indicate how you will identify animals. *	*☐ Animal identification is not necessary for this protocol. Cage cards will be used. *☐ Ear tagging/notching *☐ Tattoo *☐ Dye or ink marking *☐ SQ radio *☐ Tag (microchip) *☐ Vendor-placed tag or tattoo *☐ Other

[If "Other" is selected in 3.11, please explain the method you will use]
3.12 List any special housing, handling, husbandry or care that animals may need. Check all that apply. Please provide a description and justification for each box checked above:
*☐ Single housing for social species. Provide a description and justification below.

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*☐ Cage density exceeding limit. Provide a description and justification below.	
*☐ Modified Cage change frequency exception. Provide a description and justification below.	
*☐ Animal husbandry done by research staff. Provide a description and justification below.	
*☐ Deviation from standard housing condition (cold exposure, light/dark cycle, standard enrichment plan). Provide a description and justification below.	
*☐ Food/water manipulation (e.g. Medicated food and/or water, increase/decrease food, special diet)	
*☐ Other: Please describe and provide a justification below.	
3.13 Is death used as an endpoint in this study? *	☐ YES ☐NO
3.14 If you answered "YES" to 3.13, explain why an earlier end point is not acceptable. (Studies using death as an endpoint are Category E)	
3.15 Will there be the presence of pain, discomfort, or other adverse events caused by disease models, surgery, or other procedures used in your studies? *	☐ YES ☐NO
3.16 If you answered "YES" to 3.15, please indicate what will be monitored. Check all that apply.	
*☐ Activity	*☐ Licking, biting
*☐ Appearance	*☐ Posture
*☐ Appetite	*☐ Respiratory rate
*☐ Behavior	*☐ Temperature

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*☐ Excreta	*☐ Vocalizing
*☐ Grooming	*☐ Weight loss
*☐ Guarding	*☐ Wound site
*☐ Heart rate	*☐ Other (describe below)

3.17 Animal monitoring is required for progressive disease models and painful/distressful procedures. Please describe frequency of monitoring during disease progression or procedures causing pain or distress (written documentation of ongoing monitoring will be required once protocol is approved). Do not include post-operative monitoring in this section.

3.18 What criteria will be used to perform euthanasia earlier than planned? Please include conditions and complications that would lead to removal of an animal from the study.

3.19 Describe the method(s) of euthanasia for each species or procedure. *

Unless otherwise specified by the principal investigator, Department of Animal Medicine personnel who are euthanizing animals on behalf of the principal investigator will do so using any method listed as acceptable for the species in the most recent edition of the euthanasia guidelines of the American Veterinary Medical Association. Neonatal and pregnant rats and mice will be euthanized using methods approved by the UMMS IACUC.

Species	Primary Method	Dose	Route	Secondary Method	Comments
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	
Select Species	Select Primary			Select Secondary	

Appendix 9: IACUC/OB Protocol Form

UMASS

FORM A: TRANSPORTING ANIMALS FOR USE OUTSIDE OF OR TO ANOTHER AREA OF THE ANIMAL FACILITIES	
A1 Will animals be used in areas, e.g. laboratories, outside one of the general animal facilities? *	☐ YES ☐NO

A2 If you answered yes to A1, list the building and room number(s) where animals will be housed or used outside the animal facility. Please check 'yes' for extended housing if animals will be kept in this area for greater than 24 hours (mice and rats) or 12 hours (all other species).

Building	Room #	Species	Survival Surgery	Terminal Surgery	Non-Surgical Procedure	Extended Housing
Choose location			☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO
Choose location			☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO
Choose location			☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO
Choose location			☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO
Choose location			☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO

A3 If animals will be held, housed and/or used in an area outside of the animal facility for an extended period of time, please describe the duration and reason.

A4 How will you transport animals from the animal facility to a study area outside of the animal facility? *

A5 When moving animals from one Department of Animal Medicine managed housing room to a different animal housing room, do you agree to use the Web Animal Ordering System. *	☐ YES ☐NO

Appendix 9: IACUC/OB Protocol Form

FORM B: BREEDING	
B1 How many animals do you expect to breed for each species? *	
Species	Number of animals to be breed
B2 Male / Female standard ratio: check all that apply *	*☐ a ratio of 1:1 will be used. No continuous breeding. *☐ a ratio of 1:1 with continuous breeding will be used. *☐ a ratio of 1:2 or 1:3 will be used (Harem breeding). *☐ Non-standard ratio
B3 Explain non-standard ratios:	
B4 I have read the IACUC Mouse Breeding Policy that prohibits more than one litter per cage. I agree to separate pregnant females to other cages prior to their giving birth in harem breeding and to wean continuously bred litters at day 21 if the female is pregnant. *	☐ YES ☐NO
B5 At what age will the offspring be weaned (if applicable)? *	
B6 Please justify exceptions to the IACUC policies on rodent breeding and overcrowding.	

Appendix 9: IACUC/OB Protocol Form

FORM C: ANESTHESIA AND ANALGESIA

C1 Pre-anesthetic Agents (e.g. tranquilizers, narcotics) and Anesthetic agents. Please refer to IACUC website for specific policies on the use of ketamine/xylazine, isofluorane or avertin.

Species	Agent	Dose	Route	Frequency & Duration	Procedure

C2 Please describe secondary anesthetic dosing, if applicable.

C3 If anesthetizing animals with isoflurane using the open drop method, will IACUC policy 4.04 (hyperlink) Use of Isoflurane: drop method be followed? *	☐ YES ☐ NO
C4 List any non-pharmaceutical grade anesthetic or pre-anesthetic agents listed in C1.	☐ YES ☐ NO ☐ NA
C5 If using non-pharmaceutical grade anesthetics or pre-anesthetic agents, please justify	☐ YES ☐ NO ☐ NA
C6 I agree to follow IACUC policy 3.01 on handling and storage of drugs/chemicals to maintain sterility. *	☐ YES ☐ NO
C7 Monitoring of Anesthesia: Describe what will be monitored.	* ☐Palpebral reflex * ☐Heart rate * ☐Respiration * ☐Temperature

Appendix 9: IACUC/OB Protocol Form

	* ☐Toe Pinch * ☐Other: describe below
C8 Describe how frequently each of the signs listed in C7 will be monitored.	
C9 Describe the anesthetic gas scavenging system you will use to eliminate waste anesthetic gas.	* ☐Building vacuum system * ☐Non-recirculating fume hood or externally hard-ducted hood * ☐Activated charcoal canisters (e.g. F/air canister) * ☐Other: describe below

C10 Please describe analgesic agents (must be USP grade).

Species	Agent	Dose	Route	Frequency & Duration	Procedure

Appendix 9: IACUC/OB Protocol Form

FORM D: SURVIVAL SURGERY INCLUDING LAPAROSCOPY, ENDOSCOPY	
(and any procedure that has a reasonable potential of causing a permanent physical or physiological handicap.)	
D1 Explain why it is necessary for the animals to recover from surgery/anesthesia. *	
D2 Describe pre-operative care (including physical examinations, lab tests, and any preconditioning apparatus) Note: All anesthetic agents and pre-operative medications should be listed in Form C. *	
D3 Animal pre-surgical preparation. If using small animals, will you follow pre-surgical animal preparation as described in IACUC policy 6.12 for Basic Survival Surgical Preparation? If no, please describe. *	☐ YES ☐ NO
D4 Instrument pre-surgical preparation. If using small animals, will you follow pre-surgical instrument preparation as described in IACUC policy 6.10 for Autoclave Sterilization of Surgical Instruments? If no, please describe. *	☐ YES ☐ NO
D5 Surgeon's pre-surgical preparation. If using small animals, will you follow pre-surgical surgeon preparation as described in IACUC policy 6.12 for Basic Survival Surgical Preparation? If no, please describe. *	☐ YES ☐ NO
D6 Describe each surgical procedure in detail. *	

Appendix 9: IACUC/OB Protocol Form

D7 Describe post-operative monitoring until fully recovered. *	
D8 Describe any expected or potential post-operative complications. *	
D9 Will animals undergo more than a single survival surgical procedure? If yes, please explain. *	☐ YES ☐ NO

Appendix 9: IACUC/OB Protocol Form

FORM E: ADMINISTRATION OF SUBSTANCES OTHER THAN ANESTHETICS/ANALGESICS						
E1 Biologics: Cells or Cell/Tissue Extracts or Blood Products (do not include purified cell products here).						
Agent	**Species of Origin**	**Species**	**Dose**	**Volume**	**Route**	**Frequency & Duration**

Appendix 9: IACUC/OB Protocol Form

E2 Agents/Drugs (excluding analgesics and anesthetics)						
Agent	**Species**	**Dose**	**Volume**	**Route**	**Frequency Duration**	**USP (Y/N)**

E3 Rodent-derived materials must be tested for pathogens prior to use according to UMMS policy. If using rodent-derived materials, do you agree to submit pathogen testing results prior to use? *	☐ YES ☐ NO ☐ N/A
E4 Please justify use of non-USP grade for agents listed:	* ☐ USP is not available in suitable formulation * ☐ Other: describe below
E5 I agree to follow IACUC policy 3.01 on handling and storage of drugs/chemicals to maintain sterility. *	☐ YES ☐ NO

Appendix 9: IACUC/OB Protocol Form

FORM F: PROLONGED PHYSICAL RESTRAINT OR STRESS OF CONSCIOUS ANIMALS	
F1 Will animals undergo: *	*☐ Prolonged physical restraint of conscious animals beyond routine handling *☐ Electric Shock *☐ Other: describe below
F2 Why are restraints or adverse conditions required? *	
F3 Describe condition(s) and/or device: *	
F4 For animals confined to a device, please describe the duration and frequency animals will be confined. Please include how the general well-being of the animals will be determined and observation interval during confinement.	
F5 For animals confined to a restraint device, describe the acclimation to device, if applicable.	

Appendix 9: IACUC/OB Protocol Form

FORM G: HAZARDOUS AGENT INFORMATION		
G1.a Will this project require the use of any of the following agents in live animals:		
G1.a Infectious biological agents (pathogenic to man or animal)? *	☐ YES	☐ NO
G1.b Recombinant nucleic acids (e.g., recombinant plasmids, lentivirus, adenovirus, AAV)? *	☐ YES	☐ NO
G1.c Synthetic nucleic acids? *	☐ YES	☐ NO
G1.d Materials of human origin (tissues, cells, etc.)? *	☐ YES	☐ NO
G1.e Materials of non-human primate origin (tissues, cells, etc.)? *	☐ YES	☐ NO
G1.f Biotoxins (e.g., LPS)? *	☐ YES	☐ NO
G2 List below the hazardous agents that require housing of animals in animal biocontainment ABSL-2 or ABSL-3 per the IBC-approved animal addendum. These agents must also be listed in form E.		
G3 Will this project require creation of new transgenic, knockout, knock-in or other mutations in the genome of animals in any UMMS laboratory or transgenic core facility? *	☐ YES	☐ NO
G4 Will this project require the breeding of transgenic animals that contain transgene encoding more that 50% of the genome of an exogenous eukaryotic virus from a single family or express transgene under the control of gammaretroviral long terminal repeat? *	☐ YES	☐ NO
G5 Will your research activities potentially expose humans, other than researchers and Animal Medicine personnel who are already trained, to zoonotic infections (e.g., Q fever from sheep)? *	☐ YES	☐ NO
G6 If checked yes to G3-G5, please describe briefly		
G7 Will your research involve working with nonhuman primates? *	☐ YES	☐ NO
G8 If you have IBC approval for the studies described in this protocol please fill in the requested information below. NOTE: Only individuals listed and approved in the IBC and IACUC protocols are authorized to work with hazardous biological agents in live animals.		
G8.a IBC protocol number		
G8.b Principle Investigator of the IBC protocol		
G9 Will this project require the use of ionizing radiation in live animals? If Yes, Radiation Safety approval is required*	☐ YES	☐ NO
G10 If checked "yes" for G9, identify the name of the agent(s) below		
G11 Will this project require the use of hazardous chemicals in live animals? *	☐ YES	☐ NO

Appendix 9: IACUC/OB Protocol Form

G12 If checked "yes" for G11, identify the name of the agent(s) below

Appendix 9: IACUC/OB Protocol Form

FORM H: USE OF ANIMALS IN A TRAINING COURSE

This form is designed for PIs conducting training courses. Training participants are not permitted to work independently with live animals and must be under the supervision of a trained UMMS investigator during any contact with live animals. According to federal regulations, the IACUC must ensure the occupational health and safety of all individuals working with animals, and that all individuals working with animals receive appropriate training. Because the training participants may not be known at the time of protocol submission, the PI must provide assurance that Occupational Health and Safety and training requirements will be met before trainees participate in the course. Below outlines requirements for participants.

FOR PARTICIPANTS AFFILIATED WITH UMMS (students, residents, employees or volunteers must complete the following requirements before beginning the course):

1. ***Occupational Health and Safety Requirements:*** health clearance by Employee Health Services. An initial health clearance form must be submitted to Employee Health Services and approved before participating in the course.

2. ***Regulatory training requirements:*** Training through the AALAS Learning Library: Module 1, Module 2 and species-specific training. Information on accessing the AALAS Learning Library is available on the IACUC website.

3. Submission of an amendment to add the participant and an approval letter from the IACUC Office.

FOR PARTICIPANTS NOT AFFILIATED WITH UMMS:

1. ***Occupational Health and Safety Requirements:***
   - If the participant is NOT a UMMS student, resident, employee or volunteer, Initial Health Clearance and Visiting Researcher forms may be submitted to Employee Health Services.
   - If trainees are only attending a single training session, in lieu of obtaining health clearance, the participant may submit a signed Informed Consent form indicating they are aware of and understand the risks of working with animals and agreeing to participate at his/her own risk. The PI is required to submit the consent forms to the IACUC office along with the participant roster.

2. ***Regulatory training requirements:***
   - Training through the AALAS Learning Library: Module 1, Module 2 and species-specific training. Information on accessing the AALAS Learning Library is available on the IACUC website.
   - In lieu of the AALAS Learning Library, the PI or his designee can provide training in a lecture format (the lecture should include an overview of Federal Regulations, ethical guidelines for using animals, hazards and risks associated with the use of animals, species-specific information, humane techniques for animal procedures, and other appropriate information relevant to the experimental procedures being used)

3. Submission of the participant roster (below) to the IACUC office, as training sessions occur, including the name of participants and method of health clearance for each individual.

UMASS

Appendix 9: IACUC/OB Protocol Form

Participant Name	Date of Training Course	Health Clearance	Regulatory Training
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library
		☐ Informed Consent ☐ Health Clearance from EHS	☐ Instructional lecture ☐ AALAS Learning Library

Appendix 9: IACUC/OB Protocol Form

PART 5: PARTICIPATING PERSONNEL

First	Last	Phone	Emergency Phone	Responsibilities	Years experience with technique	Years experience with species	First time user (Y/N)

Briefly describe how the individuals with less than one year of experience with the technique(s) in species will be trained and/or supervised. Identify the individual(s) who would be responsible for training and/or supervising new or inexperienced personnel. Note that hands-on training can be given by an experienced personnel or designated Department of Animal Medicine staff. Those who perform survival surgery must receive aseptic Survival Surgery Training from the Department of Animal Medicine before approved as a surgeon. Please contact Van Gould (extension 66811) or Suzanne Wheeler (extension 62363) for training.

ADDITIONAL NOTES ON PARTICIPATING PERSONNEL:

IACUC training webpage IACUC new personnel webpage

- Before other new personnel perform any procedures, a written minor amendment request must be submitted to and approved by the IACUC. All personnel new to UMMS or those who never worked with animals will have to complete all the Training and Occupational Health and Safety Requirements before added on an IACUC protocol.
- The principal investigator is responsible for ensuring that all personnel adhere to the conditions approved by the IACUC.

Appendix 9: IACUC/OB Protocol Form

APPLICANT'S CERTIFICATION

IACUC is charged with carrying out the rules and regulations of the Federal Government's Animal Welfare Act governing the care and use of animals in research and instruction. The Act stipulates that (a) Principal Investigators must give written assurance that the activities do not unnecessarily duplicate previous experiments; (b) procedures involving animals must avoid or minimize discomfort, distress, and pain to the animals; (c) Principal Investigators must consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals and give a written description of methods used to determine that alternatives are not available; and (d) paralytic agents cannot be used in unanesthetized animals. Accordingly, the Applicant, who must be a member of the faculty holding Principal Investigator status, is required to read and sign the following certification:

BY SIGNING BELOW, I CERTIFY THE FOLLOWING:

1. I am thoroughly familiar with the literature in the field of research proposed in this application, and I have determined that the research does not unnecessarily duplicate experiments, that appropriate non-animal models are not available, and that the research must be conducted on living animals.

2. I will abide by all UMMS policies and procedures regulating use of animals in instruction and research, by the provisions of the PHS/NIH Guide for the Care and Use of Laboratory Animals, and by all other applicable laws, policies, and regulations governing the use of animals in instruction and research.

3. I will supervise all experiments involving live animals. Furthermore, I will ensure that all listed participants are qualified or will be trained in proper procedures, including animal handling, anesthesia, surgery, post-procedural management, and euthanasia. Also, I will ensure that individuals not listed in the application will not have responsibility in experiments involving animals.

4. All listed personnel will read the IACUC-approved Application to Use Vertebrate Animals in Research or Instruction before undertaking any procedures on laboratory animals.

5. Survival surgery will be performed using standard aseptic procedures.

6. Animal Medicine clinical veterinary staff will be consulted as needed to ensure satisfactory veterinary care.

7. In the event of an animal health emergency, my staff or I will contact the Department of Animal Medicine. We will not attempt animal treatment by ourselves, unless it is a life-threatening emergency.

8. If I cannot be contacted, and animals in this project show evidence of illness or pain, emergency care, including euthanasia, may be administered at the discretion of the Animal Medicine veterinary staff.

9. Significant changes in study objectives and procedures require IACUC approval.

10. Unanticipated adverse events will be reported to the IACUC as required by UMMS IACUC policy

11. This application meets all animal use and care requirements of the funding agencies that have been asked to support the research.

12. By signing below, I certify that all animal studies described in grant proposals using this protocol are described in this animal use application.

PI's Signature: Date:

Appendix 9: IACUC/OB Protocol Form

University of Massachusetts Medical School

Print Close

View: SF: Basic Information

Basic Information

1. * Select research team:

2. * Title of protocol:

3. * Short title:

4. * Summary of research:

5. * Principal investigator:

6. * What is the intention of the animal protocol?

Appendix 9: IACUC/OB Protocol Form

View: SF: Experimental Research Protocol Addition

Experimental Research Protocol Addition

1. * **Will the protocol include breeding?**
   ● Yes ○ No

Appendix 9: IACUC/OB Protocol Form

View: SF: Protocol Team Members

Protocol Team Members

1. **Identify each additional person involved in the design, conduct, or reporting of the research:**

2. **External team member information:**

Appendix 9: IACUC/OB Protocol Form

View: SF: Funding Sources

Funding Sources

1. Identify each organization supplying funding for the protocol:

Funding Organization	Sponsor's Funding ID	Grants Office ID	Documents

2. Indicate the protocol team members who have a financial interest in this research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Scientific Aims

Scientific Aims

1. * **Scientific aims of the research:**

2. * **Significance and benefits of the research:**

View: SF: Experiments_custom

Experiments

1. * Define the experiments to be used in this protocol:

Name	Species	USDA	Count	Count by Pain Category	Common Procedures	Variable Procedures	Variable Description
				B: 0 C: 0 D: 0 E: 0			

Appendix 9: IACUC/OB Protocol Form

2. If the experiments include survival surgery, will any single animal undergo more than one survival surgery? (include any animal that underwent surgery prior to use on this protocol)

3. *Describe the order of and time interval between surgical procedures on a single animal:

   * Provide scientific justification for multiple survival surgical procedures on a single animal:

   * Specify how many animals will undergo multiple survival surgeries:

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Personnel Assignment_custom

Procedure Personnel Assignment

1. **Describe a training plan for research team members with less than 1 year of species-specific experience with a procedure(s). Training records must be maintained by the laboratory to document completion of training:**

2. *** Select the team members who will be performing each procedure:**

Procedure	Species	Is USDA Species	Team Members

Appendix 9: IACUC/OB Protocol Form

3. Team member training:

First Name	Last Name	Training Course	Category	Source	Stage	Completion date	Expiration date	Experience

Appendix 9: IACUC/OB Protocol Form

View: SF: Strains_custom

Strains

1. **Identify strains or genotypes associated with this protocol that are expected to have a phenotype(s) adversely affecting animal health and/or welfare:**

Species	Is USDA Species	Strain	Genetically Modified Strain	Phenotype

1. **Identify strains or genotypes associated with this protocol that are expected to have a phenotype(s) adversely affecting animal health and/or welfare:**

2. **Species:**

3. *** Genetically modified strain:**

4. **Phenotype:**

5. **Percent of animals with the phenotype:**

6. **Describe the management plan for these animals, including any supportive care to be provided:**

Appendix 9: IACUC/OB Protocol Form

View: SF: Animal Justification_custom

Animal Justification

1. Adjust the number of animals to be used or produced for this protocol as needed:

Species	USDA Covered Species	Pain Category	Animals Identified in Experiments	Adjusted Animal Count
		Pain Category B		
		Pain Category C		
		Pain Category D		
		Pain Category E		

2. If you adjusted the number of animals for this protocol, explain why:

3. * Provide the rationale for using animals in this protocol:

4. * Justify why each proposed species was chosen for this protocol:

5. Identify each source of animals for this protocol:

6. Supporting documents:

Document Name	Date Modified

Appendix 9: IACUC/OB Protocol Form

View: SF: Alternatives and Duplication Searches

Alternatives and Duplication Searches

1. Record all searches for any previous research that this protocol might duplicate:

Search Date | Searched Databases | Keywords

View

Sub questions:

a. List procedures causing pain or distress:
b. Date of Search:
c. Databases Searched:
d. Keywords used:
e. Alternative and Duplicates Summary:
f. Time period covered by search:

2. Identify any other references used to find alternatives: (such as periodicals, publications and consultation)

3. Confirm that you have made every effort to ensure that this protocol is not unnecessary duplication of previous research: ☐

Appendix 9: IACUC/OB Protocol Form

View: SF: Breeding_custom

Breeding

1. * Describe the objectives and justifications for this breeding activity:

2. * Describe the methods you will use to identify the offspring:

3. Identify any other protocols to which you will supply animals bred from this protocol:

Appendix 9: IACUC/OB Protocol Form

View: SF: Housing and Use_Custom

Housing and Use

1. Identify each non-vivarium location where animals will be housed or used:

Name	Species	Hours	Reason

View

Sub questions:

a. Identify the location where animals will be housed or used outside the vivarium:
b. What species will be housed or used in this location?
c. How many hours will animals be kept:
d. Describe how this location will be used:
e. Justify why the animals must be removed from the vivarium:
f. Described how animals will be transported to and from this location, including container and route:

Appendix 9: IACUC/OB Protocol Form

View: SF: Disposition

Disposition

1. **Disposition plans for the animals when this research is complete:**
   (check all that apply)

2. **If other, provide an animal disposition description:**

Appendix 9: IACUC/OB Protocol Form

View: SF: Custom_Other Information

Other Information

1. IBC Registration Number:

Appendix 9: IACUC/OB Protocol Form

Procedures Appendix:

University of Massachusetts
UMASS. Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Core Procedure

1. *** Name of the procedure or surgery:**
   Core Procedure

2. *** Select procedure type:** Core Procedure

3. *** Species:**

4. *** Will administering this procedure cause any more than momentary pain and distress?**
   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

   ii. Identify criteria under which animals will be removed from research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Core Procedures_custom

Core Procedures

1. **List the procedure(s) being performed by the core (detailed description is not required):**
   *

Appendix 9: IACUC/OB Protocol Form

University of Massachusetts
UMASS Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Euthanasia Procedure

1. *** Name of the procedure or surgery:**
   Euthanasia Procedure

2. *** Select procedure type:** Euthanasia

3. *** Species:**

4. *** Will administering this procedure cause any more than momentary pain and distress?**
   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):
   *

   ii. Identify criteria under which animals will be removed from research:
   *

Appendix 9: IACUC/OB Protocol Form

View: SF: Euthanasia

Euthanasia

1. *** Method of euthanasia:**

2. **Describe procedure:**

3. **Describe how death will be confirmed:**

4. **If animals will be anesthetized prior to euthanasia, select the anesthesia procedures to be used:**
   There are no items to display

   Alternatively, if you cannot find the procedures in the list above, enter the information here:
   Describe each substance and the step-by-step procedure to be used:
   (include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

Appendix 9: IACUC/OB Protocol Form

University of Massachusetts
UMASS Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Behavioral Procedure

1. ***Name of the procedure or surgery:**
   Behavioral Procedure

2. ***Select procedure type:** Behavioral

3. ***Species:**

4. ***Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

   ii. Identify criteria under which animals will be removed from research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Behavioral Procedures_custom

Behavioral Procedures

1. ***Describe the procedure, including length and frequency of sessions:**

2. **Describe any apparatus you will use, and provide the details of sanitation between uses:**

3. **Indicate how animals will be monitored for stress during the procedure, include any criteria for prematurely ending the session:**

4. **Select the anesthesia and analgesia procedures to be used:**

Name	Type	Version	Scope

There are no items to display

Alternatively, if you cannot find the procedures in the list above, enter the information here:
Describe each substance and the step-by-step procedure to be used:
(include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

5. **Describe the anesthetic monitoring:**

6. **Describe post-procedural care and monitoring:**

Appendix 9: IACUC/OB Protocol Form

University of Massachusetts
UMASS Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Antibody production procedure

1. ***Name of the procedure or surgery:**

2. ***Select procedure type:** Antibody Production

3. ***Species:**

4. *** Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

   ii. Identify criteria under which animals will be removed from research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Antibody Production_custom

Antibody Production

1. ***Describe the procedure:**

2. ***Justify the use of live animals for antibody production:** *

3. **Describe your plans to monitor and alleviate pain:**
   *

4. **Select the anesthesia and analgesia procedures to be used:**

Name	Type	Version	Scope
There are no items to display			

Alternatively, if you cannot find the procedures in the list above, enter the information here:
Describe each substance and the step-by-step procedure to be used:
(include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

5. **Describe the anesthetic monitoring:**

6. **Describe post-procedural care and monitoring:**

Appendix 9: IACUC/OB Protocol Form

University of Massachusetts Medical School
UMASS

View: SF: Procedure Identification_custom

Procedure Identification

: Non-survival Surgery Procedure

1. ***Name of the procedure or surgery:**
   Blank Non-survival Surgery Procedure

2. ***Select procedure type:** Non-Survival Surgery

3. ***Species:**

4. ***Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

   ii. Identify criteria under which animals will be removed from research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Non-Survival Surgery

Non-Survival Surgery

1. ***Describe the surgical procedure:**

2. ***Describe how the animal, surgeon, and instruments will be prepared for surgery:**

3. **Describe how death will be confirmed:**

4. **Select the anesthesia and analgesia procedures to be used:**
   There are no items to display

   Alternatively, if you cannot find the procedures in the list above, enter the information here:
   Describe each substance and the step-by-step procedure to be used:
   (include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

5. **Describe the anesthetic monitoring:**

Appendix 9: IACUC/OB Protocol Form

University of Massachusetts
UMASS Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Blank Imaging Procedure

1. ***Name of the procedure or surgery:**
   Imaging Procedure

2. *** Select procedure type:** Imaging

3. *** Species:**

4. *** Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

   ii. Identify criteria under which animals will be removed from research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Imaging_custom

Imaging

1. Imaging types:

2. Frequency:

3. Duration of imaging session:

4. Purpose:

5. Will supportive care of animals be necessary?

Yes No

6. If yes, describe:

7. Select the anesthesia and analgesia procedures to be used:

Name Type Version Scope

There are no items to display

Alternatively, if you cannot find the procedures in the list above, enter the information here:

Describe each substance and the step-by-step procedure to be used: (include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

8. Describe the anesthetic monitoring:

9. Describe post-procedural care and monitoring:

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Identification_custom

Procedure Identification

: Breeding Procedure

1. ***Name of the procedure or surgery:**
   Breeding Procedure

2. ***Select procedure type:** Breeding

3. ***Species:**

4. *** Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

   ii. Identify criteria under which animals will be removed from research:

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Identification_custom

Procedure Identification

: Survival Surgery Procedure

1. *** Name of the procedure or surgery:**
   Survival Surgery Procedure

2. ***Select procedure type:** Survival Surgery

3. ***Species:**

4. ***Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):
   *

Appendix 9: IACUC/OB Protocol Form

View: SF: Survival Surgery_custom

Survival Surgery

1. * Surgery type:

2. * Describe the surgical procedure:

3. * Describe how the animal, surgeon and instruments will be prepared for aseptic surgery:

4. Select the anesthesia, analgesia, antibiotics and/or peri-operative medication to be used:

Name	Type	Version	Scope
There are no items to display			

Alternatively, if you cannot find the procedures in the list above, enter the information here:
Describe each substance and the step-by-step procedure to be used:
(include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

5. Describe the anesthetic monitoring:

6. Describe immediate post-operative care and monitoring until fully recovered:

7. Describe long-term post-operative care and monitoring:

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Documents

Procedure Documents

1. **Supporting documents:**

Document Name	Date Modified
There are no items to display	

University of Massachusetts Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Substance Administration Procedure

1. ***Name of the procedure or surgery:**
   Substance Administration Procedure

2. ***Select procedure type:** Substance Administration

3. ***Species:**

4. ***Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

Appendix 9: IACUC/OB Protocol Form

View: SF: Administration of Substances

Administration of Substances

1. *Substances:

Substance	Substance Scope	Route	Other Route	Dose	Dosage Frequency	Concentration	Volume	Complication Remediation	Substance Order for Procedure

2. *Describe step-by-step the procedure for administering the substance:

3. Describe any anticipated adverse reactions to administering the substances:

4. * Are all substances being administered in this procedure of pharmaceutical grade?

Yes **No**

a. * For each non-pharmaceutical grade substance, provide justification for not using the pharmaceutical grade:

b. * For each non-pharmaceutical grade substance, describe the procedures to be used to ensure the sterility, purity, stability and physiologic pH of the compound:

c. For each non-pharmaceutical grade substance, describe the storage method, if any:

5. Select the anesthesia and analgesia procedures to be used:

There are no items to display

Alternatively, if you cannot find the procedures in the list above, enter the information here:

Describe each substance and the step-by-step procedure to be used:

(include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

Appendix 9: IACUC/OB Protocol Form

6. Describe the monitoring of the animal during the procedure:

7. Describe post-procedural care and monitoring:

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Documents

Procedure Documents

1. **Supporting documents:**

   Document Name Date Modified

University of Massachusetts
UMASS Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Physical Restraint Procedure

1. *** Name of the procedure or surgery:**
   Physical Restraint Procedure

2. *** Select procedure type:** Physical Restraint

3. *** Species:**

4. *** Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

Appendix 9: IACUC/OB Protocol Form

View: SF: Prolonged Physical Restraint_custom

Prolonged Physical Restraint

1. ***Describe the restraint devices and how they will be used:**

2. ***Justify the use of the restraint:**

3. **Describe the acclimation procedure:** (include plan for identifying acclimation and handling failure to acclimate)

4. **Describe the monitoring frequency during restraint, including weekends and holidays:**

5. **Select the anesthesia and analgesia procedures to be used:**

Name	Type	Version	Scope

There are no items to display

Alternatively, if you cannot find the procedures in the list above, enter the information here:

Describe each substance and the step-by-step procedure to be used: (include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

6. **Describe the anesthetic monitoring:**

7. **Describe post-procedural care and monitoring:**

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Documents

Procedure Documents

1. Supporting documents:

Document Name	Date Modified
There are no items to display	

University of Massachusetts Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Tissue/Blood Collection Procedure

1. * Name of the procedure or surgery:
Tissue/Blood Collection Procedure

2. * Select procedure type: Tissue/Blood Collection

3. * Species:

4. *Will administering this procedure cause any more than momentary pain and distress?

Yes No

If yes,

i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

Appendix 9: IACUC/OB Protocol Form

View: SF: Tissue/Blood Collection_custom

Tissue/Blood Collection

1. ***Identify tissues to be collected:**

2. **Describe timing and frequency of collection and amount to be collected:**

3. **Select the anesthesia and analgesia procedures to be used:**

Name	Type	Version	Scope

There are no items to display

Alternatively, if you cannot find the procedures in the list above, enter the information here:

Describe each substance and the step-by-step procedure to be used:
(include route, dose, volume, concentration, and whether substance is pharmaceutical grade)

4. **Describe the anesthetic monitoring:**

5. **Describe post-procedural care and monitoring:**

6. **Describe any potential complications from collection:**

7. *** Describe the collection procedure:**

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Documents

Procedure Documents

1. **Supporting documents:**

Document Name	Date Modified
There are no items to display	

University of Massachusetts Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Monitoring Disease Models Procedure

1. ***Name of the procedure or surgery:**
   Monitoring Disease Models Procedure

2. ***Select procedure type:** Monitoring Disease Models

3. ***Species:**

4. ***Will administering this procedure cause any more than momentary pain and distress?**

   Yes No

   If yes,

   i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

Appendix 9: IACUC/OB Protocol Form

View: SF: Monitoring Disease Models Procedures_custom

Monitoring Disease Models Procedures

1. **Describe the anticipated progression of the disease, including onset of clinical signs and expected mortality rate:**

2. **Describe frequency of monitoring upon onset of clinical signs:**

3. **Describe what will be monitored:**

4. **Described the criteria to be used to identify humane endpoints:**

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Documents

Procedure Documents

1. Supporting documents:

Document Name	Date Modified
There are no items to display	

University of Massachusetts Medical School

View: SF: Procedure Identification_custom

Procedure Identification

: Food or Fluid Restriction Procedure

1. *Name of the procedure or surgery:
Food or Fluid Restriction Procedure

2. *Select procedure type: Food or Fluid Restriction

3. *Species:

4. *Will administering this procedure cause any more than momentary pain and distress?

Yes No

If yes,

i. Identify expected or potential clinical signs from administering this procedure (include anticipated animal loss, if applicable):

Appendix 9: IACUC/OB Protocol Form

View: SF: Food or Fluid Restriction

Food or Fluid Restriction

1. * Restrictions:

2. *How many hours will the food/fluid be restricted:

3. * Describe the procedure for providing food/fluid including schedules and amounts:

4. * Describe criteria for monitoring the health of animals while on food/fluid restriction:

5. * Provide justification for restricting food/fluid to the extent defined:

6. Describe what will happen if animals fail to meet selected health criteria:

Appendix 9: IACUC/OB Protocol Form

View: SF: Procedure Documents

Procedure Documents

1. **Supporting documents:**

Document Name	Date Modified
There are no items to display	

Substances Appendix:

View: SF: Substance Information

University of Massachusetts Medical School

Substance Information

1. ***Name:**

2. ***Substance types:** (select all that apply)

3. **Is this a hazardous agent:**
   *

4. **Supporting documents:**

Document Name	Date Modified
There are no items to display	

Appendix 9: IACUC/OB Protocol Form

View: Create and Edit_custom

Experiments Appendix:

*

1. *Experiment name:

2. *Species:

3. Justify the purpose of this experiment:

4. Describe the experimental design (all animals must be counted, including experimental animals, live-born offspring, and animals that are produced in breeding colonies but cannot be used in research. Click here for guidance.)

5. Provide a justification of animal numbers, based on study type (studies requiring inferential statistical analysis, pilot study, tissue harvest required for in vitro work, teaching protocol):

6. Select common procedures: (applied to all animals in the experiment)

Name	Type	Version Scope

Appendix 9: IACUC/OB Protocol Form

7. Define variable procedures: (applied to some animals or differently across animals in the experiment)

a. Select the variable procedures:

Name	Type	Version	Scope

There are no items to display

b. Describe the variables of the experiment:

8. Describe any variations to the selected standard procedures:

9. Procedure Timing/Chronology:

10. * **Total number of animals used in this experiment:** (including all the animals to be produced)

11. Number of animals by pain category: (include each animal only once in the highest pain category)

B: 0
C: 0
D: 0
E: 0

12. If animals are listed in category E (unalleviated pain/distress), please provide a justification for why the use of appropriate anesthetic, analgesic, or tranquilizer drugs would adversely affect the procedure results, or interpretation of the results:

13. Identify husbandry exceptions:

Exception Type	Description and Justification

14. Supporting documents:

Appendix 9: IACUC/OB Protocol Form

Appendix 9: IACUC/OB Protocol Form

4. Importation protocol

Docket No. A-

APPLICATION TO IMPORT VERTEBRATE ANIMALS TO THE UMMS ANIMAL FACILITY

UMMS Institutional Animal Care and Use Committee

Principal Investigator (PI)	**Name and Highest Academic Degree(s)**	
	Faculty Title	
	Department \ Division or Company Name	
	Mailing Address or UMMS Building	
	E-mail Address	
	Contact Phone Numbers	**Office:** **Pager #:** **Home:**
Faculty Sponsor (if required) or co-investigator	**Name and Degree**	
	Faculty Title	
	Department/Division	
Protocol Title		

Name of Department Chair (Please Print or Type)

Signature of Department Chair **Date**

For IACUC USE ONLY:

Approved: Yes No

Approved with conditions: Yes No

Date **Chair/Vice Chair, IACUC**

Appendix 9: IACUC/OB Protocol Form

Section I. OBJECTIVES

a. Briefly explain why animals are kept under an importation protocol.

Section II. SPECIES, SOURCE AND ANIMAL NUMBERS

a. Describe the species, age and weight, and the number of animals being held. Note that all animals held under the importation protocol are considered to be under pain category B/C (not used in experiments, teaching or testing).

Species/strain	Age	Number of animals

b. Indicate the source of animals below.

Species/strain	Animal source (name of the commercial vendor/institution)

c. Anticipated health problems in the animals being held. If there are known health or well being issues associated with the animals under this protocol, please describe them in detail.

d. If your animals have special needs, use this space to list needs for special handling or housing.

e. Will your animals require special caging?

Section III. APPLICANT'S CERTIFICATION

IACUC is charged with carrying out the rules and regulations of the Federal Government's Animal Welfare Act governing the care and use of animals in research and instruction. Accordingly, the Applicant, holding the PI status, is required to read and sign the following certification:

BY SIGNING BELOW, I CERTIFY THE FOLLOWING:

1. I will abide by all UMMS policies and procedures regulating use of animals in instruction and research, by the provisions of the PHS/NIH Guide for the Care and Use of Laboratory Animals, and by all other applicable laws, policies, and regulations governing the use of animals in instruction and research.
2. I understand that the animals under this holding protocol will be cared for by the Department of Animal Medicine, and I or my parent Department will be charged for all the expenses.
3. If animals in this project show evidence of illness or pain, emergency care, including euthanasia, may be administered at the discretion of the Animal Medicine veterinary staff.
4. This application meets all animal use and care requirements of the funding agencies that have been asked to support the research.

PI's Signature: Date:

Appendix 9: IACUC/OB Protocol Form

5. Holding Protocol

IACUC Animal Transfer Addendum

Holding Protocol Transfer Id #:

The animals held under the IACUC Holding Protocol will be identified by a unique Holding Protocol Transfer Id # that reflects the IACUC Blanket Protocol number, 1910, followed by the original Animal Study Protocol number. For example, the Id # 1910, 1000-12 designates animals transferred from the protocol A-1000-12.

Notes to the Principal Investigator of the expired Animal Study Protocol

IACUC approved animal protocols are only valid for a maximum period of 3 years, and they cannot be extended. All Principal Investigators (PIs) are required to submit renewal applications for IACUC review and approval within 3 years. In the event that IACUC approval is not obtained before the protocol expiration date, the Department of Animal Medicine will transfer the remaining animals from the expired protocol to this holding protocol.

The animals in the holding protocol will be cared for by the Department of Animal Medicine. The PIs will be responsible for the applicable animal care charges. Animal care per diem charges during this period are not allowable costs for Federal Govt. grants. While animals are kept under this holding protocol, no animal activity (experimentation, breeding and euthanasia) is permitted. The PIs are required to transfer the animals to their IACUC approved protocols within 3 months or the animals may be euthanized by the Department of Animal Medicine at the discretion of the IACUC in accordance with the current UMMS IACUC Holding Protocol Policy.

Name of the Principal Investigator (PI) of the expired IACUC Protocol		
Expired Animal Protocol Number		
Protocol Expiration Date		
Project Title		
Details of animals transferred		
Species/strain	Age	Number of animals transferred
Anticipated health problems, special animal care or housing requests or special needs	***PI is responsible for communicating this information in writing to the Department of Animal Medicine (refer to the above Transfer Id# in your communication)***	
Effective Date:	Signature of the IACUC Chair:	
If animals are transferred to an IACUC approved protocol	PI name: Protocol number: Approval Date:	
If animals are euthanized by the Department of Animal Medicine	Number of animals euthanized: Date of euthanasia:	

Appendix 9: IACUC/OB Protocol Form

6. Off-site Protocol

APPLICATION FOR OFF-SITE ANIMAL STUDY

Docket No. A-

UMMS Institutional Animal Care and Use Committee

An off-site protocol is required for animal studies performed or animals used outside of UMMS.

Principal Investigator	Name and Highest Academic Degree(s)	
	Faculty Title	
	Department \ Division or Company Name	
	Mailing Address or UMMS Building	
	E-mail Address	
	Phone Numbers	
Primary Contact	Name	
	E-mail Address	
Project Title		

APPLICANT'S CERTIFICATION

BY CHECKING AND SIGNING BELOW, I CERTIFY THE FOLLOWING:

- ☐ I am thoroughly familiar with the literature in the field of research I am engaged in, and I have determined that the research does not unnecessarily duplicate experiments, that appropriate non-animal models are not available, and that the research must be conducted on living animals.
- ☐ All off-site animal studies will take place at NIH Assured Institutions.
- ☐ The studies has been reviewed and approved, and will be overseen by another IACUC or similar institutional oversight committees in compliance with federal laws.
- ☐ To the best of my knowledge, my collaborators at off-site facilities meet all animal use and care requirements of the funding agencies that have been asked to support the research.
- I agree to maintain IACUC approval at the outside institution as long as the project remains active.
- I will promptly inform the UMMS IACUC of any changes in the status of my off-site studies and IACUC approval associated with this project and will amend the protocol to accommodate changes.

PI's Signature: Date:

GRANTS ASSOCIATED WITH THIS OFF-SITE ANIMAL STUDY

Sponsor	Funding period	Grant ID #

Appendix 9: IACUC/OB Protocol Form

OBJECTIVES OF PROPOSED RESEARCH
Lay Summary: In a few brief sentences, concisely summarize the objectives of your animal studies, using, *non-technical*, language (i.e., that could be understood by someone at a high school level),
Scientific Summary: Briefly summarize the aims and scientific approaches to be used.

ANIMAL WORK DONE OUTSIDE UMMS			
Institution/company PI/contact Contact information	Provide a brief description of the animal work done	IACUC Protocol number PHS Assurance number, if applicable	Animal Species

For office use only:

Additional documents obtained:

Name of the institution:
☐ MOU ☐ LETTER ☐ APPROVAL ☐ PROTOCOL ☐ ENGLISH

Name of the institution:
☐ MOU ☐ LETTER ☐ APPROVAL ☐ PROTOCOL ☐ ENGLISH

Name of the institution:
☐ MOU ☐ LETTER ☐ APPROVAL ☐ PROTOCOL ☐ ENGLISH

MOU: Memorandum of understanding
LETTER: Letter from the collaborator/company
APPROVAL: Copy of the IACUC approval
PROTOCOL: Copy of the IACUC protocol
ENGLISH: English translation of the animal study protocol

Appendix 9: IACUC/OB Protocol Form

7. Unanticipated Adverse Event(s) Form

Unanticipated Adverse Event Report

Institutional Animal Care and Use Committee
University of Massachusetts Medical School

IACUC Protocol Number _____ Species _____
Principal Investigator _____
Today's Date _____

1. Date when the unanticipated adverse event was first identified:_____

2. Date when the unanticipated adverse event was reported to the Principal Investigator (or that person's designee): _____

3. Describe the unanticipated adverse event.

4. What were the circumstances that led to the unanticipated adverse event? Please check one of the following and explain:

___Drug/Device Related __Procedure Related __Other Reasons

5. If not already described above, how many animals were affected? In which experimental group were these animals? What percentage of the animals in the experimental group experienced the unanticipated adverse event?

6. Describe the corrective actions you took or will take to remedy the situation and ensure that this event will not repeat itself?

Principal Investigator's Signature:_____