Macalester College IACUC Animal Use Form

Institutional Animal Care and Use Committee Revised 2/5/2016

	Protocol Information – *Please Leave Blank*
The *Macalester College IACUC Animal Use Form* must be completed and submitted to the Macalester College IACUC Chair and approved by the IACUC prior to any research or teaching activity involving live vertebrate animals, unless otherwise indicated. Attach additional sheets as necessary.	**Protocol #:** _____ **Approval Date:** _____ **Expiration Date:** _____

Title of Project, Experiment, or Activity:
Abstract of Project, Experiment, or Activity (Describe in no more than 100 words):

Faculty or Staff Member(s) Involved:	Student Investigator(s):
Department:	**Begin Date of Study:**
Application Date:	**End Date of Study**

Review Category Criteria

The information requested on the following pages is to be used in determining the type of review appropriate for this proposal. Based on the review category criteria, indicate the type of review you are requesting in the appropriate box.

All reviews are completed by a designated reviewer (member of the IACUC). Any member of IACUC may request a full-committee review of any proposal once posted to the Moodle list. Designated reviewers generally complete reviews within 48 hours of receipt.

- **Category 1A – Extension**
- **Category 1B – Modification**
- **Category 2 – Expedited Review**
- **Category 3 – Standard Review**

☐ Category 1A – Extension

This review is appropriate if the protocol is identical to an existing approved protocol except for changes in the student participants, to increase the number of animals in the original protocol or extend the proposed dates of the study. This may not be used to extend the Protocol Expiration Date. In the box below, please write or type the number assigned to the original protocol.

Protocol #	

Names and signatures of new Student Investigator(s), if any:

Name	Signature
Name	Signature
Name	Signature
Name	Signature

How many animals do you wish to add to this protocol? _____

Rationale for additional animals, including your statement for minimizing the number of animals used in the study:

What is your revised completion date? _____

I certify that the information provided on this form is complete and correct to the best of my knowledge.

_____

Principle Investigator / Faculty Member's Signature

*This page and the cover page are all that are required for **Category 1A – Extension**.*
Please submit an original paper copy of this page and the cover page to the IACUC Chair.

☐ Category 1B – Modification

This review is appropriate if the protocol is identical to an existing approved protocol except changes in the student participants or minor changes in methods. Examples of changes include different drug dosages, different animal strains or sex within the same species, substitution of drugs within the same pharmaceutical family (mode of action), minor changes in experimental methods, minor changes in animal care, or changes in euthanasia procedures.

In the box below, please type the number assigned to the original protocol:

Protocol #	

Describe the change(s) you wish to make and the rationale for this / these change(s). Include appropriate references from the scientific literature for any changes in drug identities, doses, or administration regimens, as well as your statement for minimizing the number of animals used in the study:

Up to one additional page may be submitted with this request. If changes are deemed by the IACUC Chair to be too extensive, you may be requested to submit a ***Category 3 Review – Expedited Review*** *instead.*

I certify that the information provided on this form is complete and correct to the best of my knowledge.

Principle Investigator / Faculty Member's Signature

This page and the cover page are all that are required for ***Category 1B – Modification Review****. Please submit an original paper copy of this page and the cover page to the IACUC Chair.*

☐ Category 2 – Expedited Review

This review is appropriate if all of the following criteria are met:

1. This proposal is primarily for work of limited scope conducted by students as a component of their education. Examples include exercises, experiments or projects associated with the laboratory component of a course, or undergraduate research conducted as independent study or advanced course work or during a summer program.
2. At least one of the faculty members listed above is a member of Macalester's IACUC and, as such, approves of the protocol as written.
3. The IACUC member listed above will train and supervise the students' work involving animals
4. The pain/discomfort induced during or after the experiment does not exceed Category C.
5. The time frame of proposed activities will expire at the end of the term or summer in which it is submitted or after three months, which ever is longer.
6. All of the methods, drugs and dosages to be used in the work have been approved by the IACUC within the last three years.

☐ Category 3 – Standard Review

This review is appropriate if one or more of the criteria for Category 2 are <u>not</u> met. Examples include new studies or approaches, or more extensive studies driven primarily by faculty research plans where the protocol may be active for several months or years.

☐ ***Category 2 – Expedited Review*** *and* ***Category 3 –Standard Review****, require completion of the entire protocol form. Please submit an original paper copy of the entire form to the IACUC Chair.*

I. Animal Requests

List the animals requested for use, including the pain class for each, and the number that will be used over the three-year period in the column corresponding to the source of animals.

Animal Request Table

Species	**Pain Class**[1] (one per row)	Number of Animals to be Used over Three-year Period by Source					**Total Number**
		#Purchased (or received from other institution)	**# Transferred**		**# Bred In-house**	**# Other** (Specify: captured, wildlife, observation)	
			From IACUC study number	# of Animals			

[1]Pain or Distress Class

Please categorize the overall pain, distress and/or trauma that the animal(s) involved in this study will encounter. Categories adapted from the *Swedish Classification of Research Experiments*, and the Scientist's Center for Animal Welfare Bulletin, *Categories of biomedical experiments based on increasing ethical concerns for non-human species*.

☐ **A.** Experiment is completely non-invasive and non-traumatic. Animals will be observed without manipulation of their environment.

☐ **B.** Experiment is expected to produce little or no discomfort. Animals may be subjected to occasional simple invasive procedures such as blood sampling or injections; physical behavioral testing without significant restraint or noxious stimuli; experiments on completely anesthetized animals that do not regain consciousness; and standard methods of euthanasia that induce rapid painless unconsciousness, such as anesthetic overdose.

☐ **C.** Experiment is expected to produce some discomfort. Animal may experience minor discomfort, anxiety, illness, or pain of short duration. This includes behavioral experiments on awake animals involving restrain; food and/or water deprivation for short periods (≤24 hours); limited exposure to noxious stimuli from which escape is either possible or not possible; social isolation or crowding; repetitious minor invasive procedures, such as frequent blood sampling; surgical procedures under anesthesia from which the animal will recover consciousness; exposure of blood vessels and/or implantation of chronic catheters; and gonadectomy. Concern for Category C procedures will increase in proportion to the degree and duration of distress or discomfort.

☐ **D.** Experiment is expected to involve significant but unavoidable distress or pain. Animals will be subjected to the induction of behavioral stress to test the effect of that stress; major surgical procedures that will result in significant postoperative discomfort or functional deficit; repeated exposure to noxious stimuli from which escape is not possible; and prolonged periods (hours) of physical restraint. Experiments anticipated to produce Category D discomfort present an explicit responsibility to the Principle Investigator(s) to explore alternative designs so as to minimize unavoidable distress.

☐ **E.** Experiment is expected to inflict severe pain on unanesthetized, conscious animals. Experiments in this category are generally considered inappropriate for research at Macalester College; IACUC approval for protocols expected to produce Category E pain is highly unlikely. Such experiments include the use of muscle relaxants or paralytic drugs for surgical restraint without the concomitant use of anesthetics to induce loss of consciousness; sever trauma inflicted on unanesthetized, conscious animals; recovery of consciousness after sever physical trauma has been inflicted under anesthesia; and any other traumatic procedures performed without the use of anesthetics, analgesics and/or tranquilizers, including toxicity testing and exposure to radiation.

II. Specific Animal Requirements

Species: _____ **Approximate Age or Weight:** _____

Sex: _____ **Source or Vendor:** _____

Location where animal manipulation or experimentation will occur:

Primary housing location: _____

Will animals be housed outside the animal facility longer then 12 hours? ☐ Yes ☐ No

a. **If 'Yes', where will they be housed? Provide justification for the location of housing*:***

a. Housing Concerns for Rodents:

Provide a detailed description, justification and the alternative plan for any unchecked items in the space provided below each item.

☐ **Conventional bacteriological and viral status.**

☐ **Conventional methods of transportation to and from the Facility and within the building.**

☐ **Housed in standard cages.**

☐ **Housed at standard number of animals per cage.**

☐ **Standard levels of behavioral management, including environmental enrichment and social grouping.**

☐ **Standard food and water *ad libitum*.**

☐ **Standard environmental conditions of lighting intensity and duration, ventilation, humidity, temperature and noise level / control.**

☐ **Housed only with members of the same species.**

☐ **Standard bedding changes and cage sanitation.**

☐ **Animals pose no special health hazards to personnel.**

☐ **Veterinary treatment or euthanasia is authorized for any animal in the study deemed by Animal Facility worker to be in need of such treatment or relief due to illness, injuries inflicted by cage mates, or injuries incident from protocols. Animal care workers will attempt to contact the Principle Investigator or a Student Investigator listed on this form prior to euthanizing the animal. However, suffering animals will be euthanized without approval if a qualified Investigator cannot be reached.**

b. Housing Concerns for Non-mammalian Vertebrates:

The Macalester College Animal Facility provides standard housing and care for rodents and zebrafish. Upon the introduction of other vertebrates, it is the responsibility of the Faculty Investigator to provide training and documentation to the Animal Facility Manager outlining the standard housing and care conditions for that species. Standard care will be provided to vertebrates not listed here by animal care workers as time allows. No special care, including special feeding, veterinary care, or environmental monitoring, will be provided unless arrangements are made directly with the Animal Facility Manager in advance. Invertebrate animals and their care are outside the purview the Macalester College IACUC and Animal Facility.

Provide a detailed description, justification and the alternative plan for any unchecked items in the space provided below each item.

☐ **I have provided documentation and/or training to the Animal Facility Manager regarding the conditions required for standard care of this species.**

☐ **I have made arrangements with the Animal Facility Manager for the provision of standard care to this species.**

☐ **This species requires no special care, or I have made arrangements for such care in consultation with the Animal Facility Manager.**

☐ **The animals pose no special health hazards to personnel.**

☐ **Veterinary treatment or euthanasia is authorized for any animal in the study deemed by an Animal Facility worker to be in need of such treatment or relief due to illness, injuries inflicted by cage mates, or injuries incident from protocols. Animal care workers will attempt to contact the Investigator(s) listed on this form prior to euthanizing the animal. However, suffering animals will be euthanized without approval if a qualified Investigator cannot be reached.**

III. Experimental Design and Animal Use

Purpose of the Study:
Briefly explain, in language understandable to a layperson, the aim of this study, and why the study is important to human or animal health, the advancement of knowledge, or the good of society, including the training of future scientists.

Methods to be used:
Attach a document detailing the apparatus and all procedures to be performed on the animals, up to and including euthanasia, in the execution of this study.

Experimental Design:
Provide an overview of the experimental design; including experimental groups, number of animals per group, treatments, and methods of data acquisition and interpretation. Provide citations of the studies on which this work will be based.

Rationale for the use of animals in this study:
Include reasons why non-animal models cannot be used.

Justify the appropriateness of the species used:
Species selected should be the least sentient of all realistic options.

Justify the number of animals to be used:
Numbers should be the minimum number required to give statistically significant results.

Justify any pain and suffering inherent to the study, and the pain control methods to be used:
Animal suffering should be minimized to the least realistic level necessary for the study.

a. Experimental Design and Animal Use: Procedures and Methods Checklist

Indicate which of the following procedures/methods are included in this study. For each checked procedure, please provide the requested information.

☐ **Animal identification methods:**

Method: _____ Marking Frequency: _____
Sedation / Anesthesia: _____ Method of restraint: _____

☐ **Experimental injections or inoculations:**
Drugs administered to reduce or eliminate pain are described in a later section.

Substance: _____ Volume per dose: _____

Dose: _____ Site / route of administration _____

Schedule of injections, frequency: _____ Schedule of injections, duration: _____

Sedation / Anesthesia: _____ Method of restraint: _____

Relevant literature citations:

Multiple Injections: ☐ Yes – Methods must address ☐ No

☐ **Blood withdrawal:**

Volume: _____ Site of withdrawal: _____

Frequency: _____ Method: _____

Sedation / Anesthesia: _____ Method of restraint: _____

☐ **Radiation:**

Dose: _____ Schedule: _____

Relevant literature citations:

☐ **Prolonged Restraint:**
Fill this out if restraint will be longer than required to complete routine procedures.

Method: _____ Duration: _____

Acclimation Schedule: _____ Sedation / Anesthesia: _____
Relevant literature citations:

☐ **Other potential stressors:**
Include water or food deprivation, noxious stimuli, environmental stress, etc.

Type of stress:

Methods used to monitor, evaluate, and minimize animal distress:

☐ **Experimental protocols using morbidity or mortality endpoint criteria:**
Weight loss or gain; tumor size; inability to eat, drink, or perform other functions; behavioral abnormalities; clinical markers or symptoms; signs of toxicity; death, etc.

List criteria to be used to determine when euthanasia is to be performed; death as an endpoint must be scientifically justified:

Relevant literature citations:

☐ **Special need for veterinary care:**

Veterinary care required:

Who will provide such care? How will the caregiver be trained?

IV. Survival Surgery

If the study intends to utilize survival surgery, attach a detailed description addressing each item in the list below.

☐ **Yes** ☐ **No** **This study will utilize survival surgery.**

- If **No**, continue onto section IV. Pain or Distress Classification

- **Describe preoperative procedures (fasting, analgesic loading)**
- **Describe surgical procedure, including aseptic technique (include detailed protocol)**
- **Describe method used to monitor and adjust anesthesia during surgery**
- **Describe methods for preventing and/or managing post-operative infections**
- **Describe support provided during recovery from anesthesia**
- **Indicate who will perform the surgery. Describe their qualifications and training.**

- **Where will the surgery be performed, and where will post-operative care be provided?**
- **Describe the postoperative care required: including frequency of observation, who will provide postoperative care, and a description of efforts for monitoring and managing postoperative complications during work hours, after hours, and on weekends and holidays. Involvement of Animal Facility personnel in the performance of these duties must be determined in consultation with the Animal Facility Manager prior to submitting this protocol. A written statement from the Animal Facility Manager to that effect must accompany this protocol.**
- **If paralytic agents will be used during surgery, describe how ventilation will be maintained, and how pain will be assessed and managed.**
- **If major survival surgery will have been performed on any animal prior to that animal being placed in this study, explain and justify. Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions, and includes laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation.**
- **Will more than one survival surgery be performed on an animal while in this study? If yes, please explain and justify.**

V. Controlled Substances

Complete the information below if this study will utilize anesthesia, analgesia, tranquilizing, or other agents considered controlled substances.

Agent: _____ **Dosage:** _____

DEA Schedule: _____ **DEA License #:** _____

DEA License Holder _____

Route of Administration: _____ **Schedule of Administration:** _____

Storage Procedures: _____ **Use Log Location:** _____

Relevant literature citations:

VI. Method of Euthanasia and / or Disposition of Animals at End of Study

Indicate the disposition of animals at the end of this study.

Method for animals that are to be euthanized:

Chemical Agent: _____ **Dose – *If relevant:*** _____
Method of Administration: _____

Is method recommended by the AVMA Panel Report on Euthanasia?
Unanesthetized cervical dislocation and decapitation are not among the recommended methods. For further information, see: http://www.AVMA.org/resources/euthanasia.pdf.

Yes ☐ **No** ☐

If method is not AVMA recommended, justify its use:

VII. Dual Use of Research Agents of Concern

Use of dual use of research agents of concern (DURC) requires additional oversight from the Institutional Review Entity. Protocol review for DURC will take additional time. Applicants should plan accordingly:

Agents and Toxins	Yes	No	Date of Approval
Avian influenza virus (highly pathogenic)	☐	☐	
Bacillus anthracis	☐	☐	
Botulinum neurotoxin	☐	☐	
Burkholderia mallei	☐	☐	
Burkholderia pseudomallie	☐	☐	
Ebola virus	☐	☐	

Foot-and-mouth disease virus	☐	☐	
Francisella tularensis	☐	☐	
Marburg virus	☐	☐	
Reconstructed 1918 influenza virus	☐	☐	
Rinderpest virus	☐	☐	
Toxin-producing strains of *Clostridium botulinum*	☐	☐	
Variola major virus	☐	☐	
Variola minor virus	☐	☐	
Versinia pestis	☐	☐	

VIII. Hazardous Agents - Other

Use of hazardous agents requires the approval of the faculty or staff director charged with the oversight of that agent:

Hazardous Agent	Yes	No	Agent	Date of Approval	Initials of Director
Radiochemicals	☐	☐			Heather McCollor
Biological Agents (not listed above)	☐	☐			Steve Sundby
Hazardous Chemicals	☐	☐			Tom Varberg
Recombinant DNA	☐	☐			N / A

This study is being conducted at Animal Biosafety Level: ☐ **1** ☐ **2** ☐ **3** ☐ **4**

- No hazardous agents = Level 1

Describe the practices and procedures required for safe handling and disposal of contaminated animals and material associated with this study.

If applicable, describe the methods for removal of radioactive waste and the monitoring of radioactive materials.

IX. Signatures

We the undersigned declare the following:

☐ **1. That the information given in this protocol is accurate to the best of our knowledge.**

☐ **2. That I have applied for all necessary card and key access to the Macalester College Animal Facility.**

☐ **3. That I have filed a *Macalester College Animal Facility Health and Safety Form* and a *Macalester College Animal Facility New Researcher Checklist* with the Animal Facility Manager.**

☐ **4. That I have received or will receive training in all experimental procedures involving animals, and that I will be supervised in the procedure until I gain adequate proficiency to work independently.**

Primary Faculty Investigator: _____
Signature Date

Secondary Faculty Investigator: _____
Signature Date

DEA Licensee: _____
Signature Date

Student Investigator: _____
Signature Date

Student Investigator: _____
Signature Date

Student Investigator: _____
Signature Date

Student Investigator: _____
Signature Date

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Signature Date