**ANIMAL STUDY PROPOSAL **

|  |  |
| --- | --- |
| Approval Date: approve date  | Expiration Date: expiration date  |
| Protocol #: protocol #  |  |

Leave Blank Institutional Animal Care and Use Committee

**Instructions:** Save this file to your computer. After completing and signing this form, send it as an email attachment to iacuc@montclair.edu.

1. **ADMINISTRATIVE DATA**

Today’s Date: today’s date

Principal Investigator Name: Click or tap here to enter text.

 PI Role: Click or tap here to enter text.

 College/School: Click or tap here to enter text.

 Department: Click or tap here to enter text.

 Mailing Address: Click or tap here to enter text.

 City: Click to enter text. State: state

 Zip: Click to enter text Phone: phone

 Email: Click or tap here to enter text.

Project Title: Click or tap here to enter text.

[ ] Modification [ ] Initial Submission [ ] Initial Pilot Study Submission

**Personnel**

Name and Degrees/

Certifications: Click or tap here to enter text.

Office Mobile Email:

Phone: Click to enter text. Phone: Click to enter text. Click or tap to enter text.

Study Role(s) [ ]  Principal Investigator [ ]  Key Associate [ ]  Collaborator [ ]  Student Researcher

Select the types of involvement this person will have in the study and then describe his/her experience in the box below. Indicate their length of experience with the species and procedures described in this study. If the individual has no prior experience, indicate what procedures the person will be trained in and who will provide the training.

[ ] This person will not be working directly with animals [ ] Anesthesia [ ] Surgical Procedures

[ ] Euthanasia [ ] Non-Surgical Procedures [ ] Animal Handling/Restraint

Description: Examples of experience: 1) Researcher has served as PI on multiple animal protocols and has been trained in surgical techniques described in this protocol. 2) Student employee has received PI delivered training on IP injection routes as well as training on husbandry.

Completed the appropriate CITI training according to MSU policy? [ ] Yes [ ]  No

Is this personnel member a student? [ ]  Yes [ ]  No

Date of University Health Services Clearance: MM/DD/YY

**Personnel**

Name and Degrees/

Certifications: Click or tap here to enter text.

Office Mobile Email:

Phone: Click to enter text. Phone: Click to enter text. Click or tap to enter text.

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Completed the appropriate CITI training according to MSU policy? [ ] Yes [ ]  No

Is this personnel member a student? [ ]  Yes [ ]  No

Date of University Health Services Clearance: MM/DD/YY

**\*NOTE: If you would like to include additional personnel, please add them in Appendix A: Multiple Personnel.**

1. **FUNDING**

Is this animal research funded or pending funding? [ ]  Yes [ ]  No

Proposal Award Title: Click or tap here to enter text.

Funding Agency: Click or tap here to enter text.

Award/Contract/Grant Number: Click or tap here to enter text.

1. **ANIMAL REQUIREMENTS**

|  |  |
| --- | --- |
| Species and strain: [list all e.g., musculus] | Click or tap here to enter text. |
| If a variety of species are expected please state a broad description here: | Click or tap here to enter text. |
| Strain, subspecies, or breed: [e.g., C5&BL] | Click or tap here to enter text. | Common Name: [e.g., black lab mouse] | Click or tap here to enter text. |
| Approximate age, weight or size: | Click or tap here to enter text. |
| Sex: | Click or tap here to enter text. |
| Source: [e.g., name of vendor or breeder, bred in-house] | Click or tap here to enter text. |
| Primary housing location(s): | If you plan to use the Vivarium facilities please reach out to the Vivarium Director and LAR (lar@montclair.edu) to confirm husbandry requirements and availability of space. |
| For studies conducted in Vivarium: | [ ] Please select this box to confirm husbandry needs and space have been reviewed with LAR (lar@montclair.edu). |
| Location(s) where manipulation will be conducted: | Click or tap here to enter text. |
| Number of Animals to be Used: |
| Year 1: | Click or tap here to enter text. |  |
| Year 2: | Click or tap here to enter text. |
| Year 3: | Click or tap here to enter text. |
| Total: | Click or tap here to enter text. |  |

Is approval requested for any special husbandry needs?

Note that special husbandry needs that are approved must be implemented through direct arrangements with Laboratory Animal Resources 9LAR). For example, providing medicated feeding or water. If you are reporting a new species, please provide the necessary husbandry SOPs.

[ ]  **No, there are no special husbandry requirements.**

[ ]  **Yes, there are special husbandry requirements.**

If yes, please describe below:

If you require source font formatting, you may submit this question as a separate labeled Word document.

1. **STUDY OBJECTIVES**

**Briefly explain in language understandable to a layperson the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society.**

**Note: If more space is needed, you may attach a separate labeled Word Document.**

If you require font formatting, you may submit this question as a separate labeled Word document.

Is this protocol intended as a Classroom/Teaching/Training research experience?

[ ]  **Yes** [ ]  **No**

Please describe your plans for training students in animal welfare and safety:

1. **RATIONALE FOR ANIMAL USE**
2. **Explain your rationale for animal use. *[The rationale should include reasons why non-animal models cannot be used.]***
3. **Justify the appropriateness of the species selected.**
4. **Justify the number of animals to be used. [The number of animals should be the minimum number required to obtain statistically valid results.]**

If you require font formatting, you may submit this question as a separate labeled Word document.

1. **Literature Search for Unnecessary Duplication: This search is required for all animal use protocols.**

Provide evidence of literature review and a database search to confirm no alternatives are possible including:

[search for alternatives to specific, potentially painful and/or distressful procedures, search for alternatives to animal use, and to ensure that proposed research does not unnecessarily duplicate previous experiments.]

You must search at least two databases and keywords must include reduce, replace, and refine.

Indicate Literature

Sources Searched:

Click or tap here to enter text.

Date of Search: Click or tap here to enter text.

Years covered by

Search:

 Click or tap here to enter text.

Search Strategy

and/or key words:

Reminder to use keywords reduce, replace, and refine in your search.

Results of Search: Click or tap here to enter text.

1. **DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES**

**Briefly explain the experimental design and specify all animal procedures. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Please include standard operating procedures or husbandry protocols as separate attachments if applicable. Specifically address the following where relevant.**

**Note: If more space is needed, you may attach a separate labeled Word Document.**

If you require font formatting, you may submit this question as a separate labeled Word document.

1. **TRANSPORTATION**

Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported on public roads or out of state, describe efforts to comply with USDA regulations. Briefly describe the methods of transportation.

[ ]  **Animals will be transported**

[ ]  **Not applicable**

If you require font formatting, you may submit this question as a separate labeled Word document.

1. **FIELD STUDIES**

Is this a field study?

[ ]  **Yes** [ ]  **No**

Have appropriate permits (e.g. federal or state collecting permits) been obtained?

[ ]  Yes [ ]  No

*Please provide a copy of your permit approval with this application.*

 Click or tap here to enter text.

Describe the permits required, when they were/will be obtained, and permit expiration dates:

Describe how the animals will be observed, any interactions with other animals, whether the animals will be disturbed or affected and any special procedures anticipated. If endangered or threatened species are encountered, please describe any special procedures.

Click or tap here to enter text.

1. **SURGERY**

[ ]  **Surgery part of protocol** [ ]  **Not applicable**

If surgery is part of protocol, please use Appendix B: Surgery Protocols to provide further details. If more space is needed, please attach a separate labeled Word document.

1. **PAIN OR DISTRESS CLASSIFICATION**

**Category B**

Animals being bred, acclimatized, or assigned to a holding protocol. This category may also include animals being used in observational studies or euthanasia on animals for which no procedures were performed.

**Category C**

Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress, and do not require the use of pain-relieving drugs. This category includes most injections, most blood collection techniques, tail snips on rodents less than 17 days of age and euthanasia on animals that only experienced momentary or slight pain as a result of experimental procedures.

**Category D**

Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics, and/or tranquilizing drugs. This category includes euthanasia as a means of providing humane relief for animals experiencing pain or distress as a result of experimental procedures.

**Category E**

Animals are subjected to potentially painful or stressful procedures that are NOT relieved with anesthetics, analgesics, tranquilizing drugs, and/or euthanasia. Withholding anesthesia/analgesia/euthanasia must be justified in writing and approved by the IACUC. This documentation may be submitted as a Word document to the IACUC.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Species (common name) | USDA classification\*B, C, D, or E | Year 1 | Year 2 | Year 3 | 3 year total number of animals |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
| Total number of animals (should equal from Section C): |   |   |   |   |

1. **ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS**

[ ]  **My study will involve anesthesia or analgesic**

*For animals indicated in Section J, Category D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration with any appropriate citations. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).*

Click or tap here to enter text.

[ ]  **Not applicable**

1. **METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY**

*Indicate the proposed method of euthanasia and appropriate references. If applicable, please provide a secondary method for confirming euthanasia. If a chemical agent is used, specify the dosage and route of administration. If the method(s) of euthanasia include those* ***not*** *recommended by the AVMA Guidelines for Euthanasia of Animal 2013 Edition, provide scientific justification why such methods must be used. Indicate the method of carcass disposal:*

Click or tap here to enter text.

What are the humane endpoints for animals on this study?

Click or tap here to enter text.

What are the plans for animals found sick or dead?

Click or tap here to enter text.

1. **HAZARDOUS AGENTS/BIOLOGICAL MATERIAL: (Hazardous agents include biohazards, animal products, infectious agents, highly toxic chemicals, controlled drugs and radiation hazards)**

[ ]  **Hazardous agents/biological material is involved in this research**

[ ]  **Not applicable**

Use of hazardous agents requires the approval of the Institutional Biosafety Office/Committee. Attach documentation of approval for use of recombinant DNA or potential human pathogens.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Hazardous Agent | Yes | No | Agents | Date of Biosafety Approval | Source | Tracking # |
| Radionuclides |[ ] [ ]    |   |   |   |
| Biological Agents/Materials |[ ] [ ]    |   |   |   |
| Hazardous Chemicals or Drugs |[ ] [ ]    |   |   |   |

Study Conducted at: (for CDC description of biosafety levels [click here](https://www.cdc.gov/labs/BMBL.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fbiosafety%2Fpublications%2Fbmbl5%2Findex.htm)

[ ]  Biosafety Level 1 [ ]  Biosafety Level 2

|  |
| --- |
| Enter text.  |
| Enter text.  |

IBC Protocol Registration #:

IBC Status:

*Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity:*

If you require font formatting, you may submit this question as a separate labeled Word document.

1. **PRINCIPAL INVESTIGATOR ASSURANCES**

|  |
| --- |
| Year |

1. I certify that I have completed the institutionally required investigator training course. For more info, [click here](https://www.montclair.edu/iacuc/research-training-and-certification/). Year of course completion:
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this proposal who are at risk are participating in the

Institution's Occupational Health and Safety Program.

1. I certify that the individuals listed in the Personnel section are authorized to conduct procedures involving animals under this proposal, have attended any institutionally required investigator training course, and received training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns.
2. For all USDA Classification D and E proposals (see section I.1.): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in Section I.1. and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
3. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
4. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
5. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.
6. I certify that I will provide members of the IACUC access to all animals and any documentation/records upon request.

Date Click or tap here to enter text.

PI Signature Click or tap here to enter text.

**APPENDIX A: MULTIPLE PERSONNEL**

**Personnel**

Name and Degrees/

Certifications: Click or tap here to enter text.

Office Mobile Email:

Phone: Click to enter text. Phone: Click to enter text. Click or tap to enter text.

Study Role(s) [ ]  Principal Investigator [ ]  Key Associate [ ]  Collaborator [ ]  Student Researcher

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Completed the appropriate CITI training according to MSU policy? [ ] Yes [ ]  No

Is this personnel member a student? [ ]  Yes [ ]  No

Date of University Health Services Clearance: MM/DD/YY

**APPENDIX B: SURGERY PROTOCOL ONLY**

Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures (e.g., fasting, analgesic loading), and monitoring and supportive care during surgery. Include the aseptic methods to be utilized.

Click or tap here to enter text.

Who will perform surgery and what are their qualifications and/or experience?

Click or tap here to enter text.

Where will surgery be performed and postoperative care provided (building and rooms)?

Click or tap here to enter text.

If survival surgery, describe postoperative care required, frequency of observation, and identify the responsible individual(s). Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.

Click or tap here to enter text.

If non-survival surgery, describe how humane euthanasia is enacted and how death is determined.

Click or tap here to enter text.

Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.

Click or tap here to enter text.

Will more than one major survival surgery be performed on an animal while on this study? If yes, please justify:

Click or tap here to enter text.