

**IACUC Use Only – Leave Blank**

Protocol #:

Approval Date:

Expiration Date:

Species:

Category:

**ANIMAL STUDY PROPOSAL**

**Instructions:** Click on highlighted boxes to enter text. 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**

[ ]  **Initial Submission** [ ]  **Modification** [ ]  **Initial Pilot Submission**

|  |  |
| --- | --- |
| Principal Investigator Name: |          |
| Project Title |          |
| PI Role: |          |
| College/School: |          |
| Department: |          |
| Mailing Address: |          |
| City: |          |
| State: |          |
| Phone: |          |
| Email: |          |

**Personnel**

|  |  |
| --- | --- |
| Name and Degrees/Certifications: |          |
| Office Phone: |          |
| Mobile Phone: |          |
| Email: |          |
| Study Role(s) | [ ]  Principal Investigator[ ]  Key Personnel[ ]  Collaborator[ ]  Student Researcher |
| Type of involvement in the study | [ ]  This person will not be working directly with animals[ ]  Anesthesia[ ]  Surgical Procedures[ ]  Euthanasia[ ]  Non-Surgical Procedures[ ]  Animal Handling/RestraintDescription: (indicate 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)           |
| Completed CITI training according to Montclair policy? | [ ]  Yes[ ]  No |
| Is this personnel a student? | [ ]  Yes[ ]  No |
| Date of University Health Services Clearance (MM/DD/YY): |           |

|  |  |
| --- | --- |
| Name and Degrees/Certifications: |          |
| Office Phone: |          |
| Mobile Phone: |          |
| Email: |          |
| Study Role(s) | [ ]  Principal Investigator[ ]  Key Personnel[ ]  Collaborator[ ]  Student Researcher |
| Type of involvement in the study | [ ]  This person will not be working directly with animals[ ]  Anesthesia[ ]  Surgical Procedures[ ]  Euthanasia[ ]  Non-Surgical Procedures[ ]  Animal Handling/RestraintDescription: (indicate 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)          |
| Completed CITI training according to Montclair policy? | [ ]  Yes[ ]  No |
| Is this personnel a student? | [ ]  Yes[ ]  No |
| Date of University Health Services Clearance (MM/DD/YY): |          |

|  |  |
| --- | --- |
| Name and Degrees/Certifications: |          |
| Office Phone: |          |
| Mobile Phone: |          |
| Email: |           |
| Study Role(s) | [ ]  Principal Investigator[ ]  Key Personnel[ ]  Collaborator[ ]  Student Researcher |
| Type of involvement in the study | [ ]  This person will not be working directly with animals[ ]  Anesthesia[ ]  Surgical Procedures[ ] Euthanasia[ ] Non-Surgical Procedures[ ]  Animal Handling/RestraintDescription: (indicate 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)           |
| Completed CITI training according to Montclair policy? | [ ]  Yes[ ]  No |
| Is this personnel a student? | [ ]  Yes[ ]  No |
| Date of University Health Services Clearance (MM/DD/YY): |           |

**Are you adding additional personnel?** [ ]  **Yes** [ ]  **No**

**If yes, please add them in Appendix A: Multiple Personnel.**

**B. FUNDING**

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

**If yes, please attach funding narrative associated with this research and complete the table below.**

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |  |
| --- | --- | --- |
| **Proposal Award Title** | **Funding Agency** | **Award/Contract/Grant Number** |
|            |            |            |
|            |            |            |
|            |            |            |

**C. STUDY OBJECTIVES and RISK/BENEFIT ANALYSIS FOR LAYPERSON**

In **lay language for a non-scientist**, briefly summarize the overall intent/objectives of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society.

**Risk/Benefit Analysis**: In 2-3 sentences and using **lay language for a non-scientist**, describe the potential risk to research animals, as well as the potential benefits of the research for humans, animals and/or the advancement of science.

**Risk:**

**Benefit:**

Do you have a recent protocol approved within the last five years which is similar to this application, or which this application will replace?

**D. PAST HISTORY OF PROTOCOL**

[ ]  **Yes** [ ]  **Not applicable**

If yes, please answer the following:

Please highlight any significant changes in this application from what was previously approved in the prior protocol and, if applicable, provide prior protocol number:

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

**E. ANIMALS and HUSBANDRY**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Laboratory****Species**  | **Laboratory****Strain, subspecies or breed (e.g., C5&BL)** | **Wildlife****Animal group (e.g., lizards, frogs, etc.)** | **Sex and approximate age, weight or size** | **Total number of animals to be used/year** | **Source (e.g., name of vendor or breeder, bred in-house)** | **Primary housing location(s)** | **Location(s) of experiment or surgical suite** |
|                 |               |                 |                 | **Year 1:**              **Year 2:**                **Year 3:**                 |                 |                 |                 |
|                 |                 |                 |                 | **Year 1:**                **Year 2:**                **Year 3:**                 |                 |                |                 |
|                 |                 |                 |                 | **Year 1:**                **Year 2:**                 **Year 3:**                 |                 |                 |                 |

**Total number of animals to be used:**

**For studies conducted in the Vivarium:**
[ ]  Please select this box to confirm husbandry needs and space have been reviewed with LAR. (lar@montclair.edu).

**If your animals are housed *inside* the Vivarium, please check Yes or No if there will be any special husbandry needs:**

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

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

[ ]  **Yes, there are special husbandry requirements (ex. feeding, housing, bedding, caging, lighting, single-housed, enrichment, etc.). Please describe below:**

**If your animals are housed *outside* of the Vivarium, please include your husbandry plans and documentation methods below. \*Note – if attachments are submitted, please list the title of each attachment below.\***

**For wildlife animals, please include a list of species below:**

**F. FIELD STUDIES**

Is this a field study?

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

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:

If the environment will be disturbed, describe any significant impacts:

**G. WILDLIFE/SITE PERMITS**

Have appropriate permits (e.g. federal or state collecting, scientific handling, site permits or endangered/threatened species permits) been obtained? **Please provide a copy of your permit approval with this application.**

[ ]  **Yes** [ ]  **No** [ ]  **N/A**

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

**H. TRANSPORTATION**

Transportation of animals must conform to all institutional guidelines/policies and federal regulations.

[ ]  **Animals will be transported**

[ ]  **Not applicable**

Briefly describe the methods of transportation:

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 the USDA regulations:

**I. RATIONALE FOR ANIMAL USE**

1. The number of animals used in each project should be the minimum required to obtain statistically valid results. In the boxes below:
2. Explain your rationale for animal use. **The rationale should include reasons why non-animal models or non-vertebrate alternatives (tissue culture, invertebrate animal models, computer simulations, etc.) cannot be used:**
3. Explain the appropriateness of the animal model/species selected:

If applicable, describe the number of animals to be used for each experiment in the table below.

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |  |
| --- | --- | --- |
| **Experiment or Procedure** | **Animals/Group** | **Groups/Experiment** |
|           |            |            |
|           |            |            |
|            |            |            |

1. Explain how you arrived at these animal sample sizes. Provide a detailed scientific/statistical justification used to determine the animal numbers requested (e.g. power analysis):

If this is a pilot study, exploratory project, or teaching protocol then provide a brief narrative of how you determined sample size:

**J. 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 (SOP’s) or husbandry protocols as separate attachments, if applicable.**

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |
| --- |
| **Experimental Design:** |
|            |

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |
| --- | --- |
| **Animal Species (Group for wildlife)** | **Animal Procedures** |
|            |            |
|            |            |
|            |            |
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|            |            |

**Will you be collecting blood and tissue?** [ ]   **Yes** [ ]  **No**

**If yes, add details below:**

**Will there be animal identification?** [ ]  **Yes** [ ]  **No**

**If yes, add details below:**

**K. PAIN and 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.

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Animal Species (Group for wildlife)** | **Animal/****Experimental Group** | **USDA classification B, C, D or E** | **Year 1** | **Year 2** | **Year 3** | **3 year total number of animals** |
|            |       |            |            |            |            |            |
|            |       |            |            |            |            |            |
|            |       |            |            |            |            |            |
|            |       |            |            |            |            |            |
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**Total number of all species of animals over the 3 years (should equal total from Section E):**

**L. ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER MEDICAL TREATMENTS**

[ ]  **Yes, my study will involve anesthesia or analgesic** [ ]  **Not applicable**

**If you checked the “Yes” box above, has a veterinary consult been obtained?** [ ]  **Yes** [ ]  **No**

In the chart below, specify the drugs used to anesthetize, sedate, tranquilize, provide medical treatment (analgesics, antibiotics, NSAIDs, etc.) and/or to euthanize research animals. (Where anesthetic combinations are called for, list each drug separately):

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reason for use** | **Drug Name** | **Dose** | **Route** | **Frequency of administration** | **Total number of doses** |
|            |            |            |            |            |       |
|            |            |            |            |            |       |
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|            |            |            |            |            |       |

**List any appropriate citations here:**

**M. CONTROLLED DRUGS AND OTHER SUBSTANCES**

**Does this study involve the use of controlled drugs?** [ ]  **Yes** [ ]  **No**

**If yes, please describe the following:**

**Location and storage description (i.e., double-locked cabinet) of drugs as specified in DEA registration:**

**DEA Registration Number:**

**Describe use of inventory log for tracking controlled drugs (Drug Enforcement Agency requirement):**

**List drug name and schedule below.**

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |
| --- | --- |
| **Drug Name** | **Drug schedule (1-4)** |
|       |       |
|       |       |

**Controlled Drug Use: I have reviewed and understand the University Controlled & Dangerous Substances Policy:**[ ]  **Yes** [ ]  **No**

**N. SURGERY**

[ ]  **Surgery part of protocol** [ ]  **Not applicable (skip to Section O)**

If surgery is part of protocol, please complete the section below. If more space is needed, please attach a separate labeled Word document.

1. Describe preoperative procedures (e.g. fasting, analgesic loading):

1. Identify and describe surgical procedure(s) to be performed:

1. Describe monitoring and supportive care during surgery:

1. Aseptic methods to be utilized:

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

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

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

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

1. Are paralytic agents used during surgery? [ ]  **Yes** [ ]  **No**

If yes, please scientifically justify the use of paralytic agents:

If yes, please describe how ventilation will be maintained and how pain will be assessed:

1. Will more than one major survival surgery be performed on an animal while on this study?

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

If yes, please justify:

If yes, please describe timetable and conditions in the table below.

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |  |
| --- | --- | --- |
| **Surgery** | **Time between next surgery** | **Conditions for not proceeding to another surgery (Health assessment prior to surgery)**  |
|       |       |       |
|       |       |       |

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

**Methods of euthanasia described below should include those required as part of the protocol. A humane method of euthanasia must be provided for all protocols in the event of disease, injury, pain or severe distress in the next section (Section P).**

**Will animals be euthanized as part of the protocol?** [ ]  **Yes** [ ]  **No**

**If yes, please complete the questions below. If no, please skip to Section P.**

Indicate the proposed method of euthanasia and appropriate references; include any justification when appropriate:

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 Animals 2020 Edition, provide scientific justification why such methods must be used:

Indicate the method of carcass disposal:

Who will be responsible for carrying out the final disposition of the animals?

Where will the final disposition take place?

If animals **will not be** euthanized, indicate disposition:

[ ]  Return to colony, flock or herd

[ ]  Adoption

[ ]  Breeders and non-experimental animals may be transferred to another AUP

[ ]  Other (please describe):

**Unexpected illness, adverse health effects, or death of experimental animals must be reported immediately to the Attending Veterinarian.**

**P. HUMANE ENDPOINTS**

**EXPECTED** (Scientific endpoint): Where pain or distress is a necessary part of the study (as indicated in Section K as category D or E), a humane endpoint must be used and approved by the IACUC.

Briefly specify any **experimental effects on animal health that *may* occur**, and include the time points and methods for the humane endpoint to be used.

Please identify the humane endpoint for each species in the table below.

**Note: If additional rows are required in the table, please consolidate the text into the existing rows.**

|  |  |
| --- | --- |
| **Species** | **Humane Endpoint**  |
|            |            |
|            |            |
|            |            |

**UNEXPECTED** illness from natural causes or adverse health effects may occur where a humane endpoint or treatment intervention to relieve unnecessary pain or distress may be indicated. (Note: This is for all protocols, regardless of pain category indicated in Section K.)

If **unexpected illnesses or adverse health effects occur**, what is your intervention plan?

[ ] Humane Euthanasia

Specify humane euthanasia methods:

[ ] Treatment/intervention will be applied in order to prevent or relieve unnecessary pain or distress.

Consultation with the Attending Veterinarian or Laboratory Animal Research Director at the time of treatment/intervention is recommended.

If emergency treatment/intervention is occurring in the Vivarium, please note any treatments that should be avoided by LAR staff (e.g., antibiotics).

**Q. HAZARDOUS AGENTS/BIOLOGICAL MATERIAL\* and BIOSAFETY LEVEL**

\*Hazardous agents include biohazards, animal products, infectious agents, highly toxic chemicals, controlled drugs and radiation hazards.

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

[ ]  **Not applicable**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Hazardous Agent** | **Yes** | **Agents** | **Date of IBC Protocol Approval** *(if applicable)* | **Source** | **IBC Protocol #** | **Biosafety Level** **(Choose 1 or 2)**(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)). |
| Radionuclides | [ ]  |            |            |            |            | 1 [ ] 2 [ ]  |
| Biological Agents/Materials | [ ]  |            |            |            |            | 1 [ ] 2 [ ]  |
| Hazardous Chemicals or Drugs | [ ]  |            |            |            |            | 1 [ ] 2 [ ]  |
| Recombinant DNA or potential human pathogens | [ ]  |         |         |         |         | 1 [ ] 2 [ ]  |

Note: If you checked ‘Yes’above for ‘Recombinant DNA or potential human pathogens,’ attach documentation of Institutional Biosafety Office/Committee Approval.

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:

**R. LITERATURE SEARCH for UNECESSARY 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 and to ensure that proposed research does not unnecessarily duplicate previous experiments. Search for alternatives to specific, potentially painful and/or distressful procedures and search for alternatives to animal use.

* + 1. You must search at least two databases, including searching keywords **Reduce, Replace** and **Refine** (the 3 R’s) in part of your search. Please list the databases below:
1.

ii.

iii.

* + 1. Date of search:
		2. Years covered by search:
		3. Key words or search strategies **(In addition to your search, remember to include a search using the keywords Reduce, Replace and Refine)**:
		4. Results of search:

**S. PRINCIPAL INVESTIGATOR ASSURANCES**

1. I certify that I have completed the institutionally required investigator training course. For more information, [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.
4. I certify that the individuals currently listed in the Personnel section and those added in future modifications will have read the approved protocol and 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.
5. For all USDA Classification D and E proposals: I certify that I have reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternatives to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
7. 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.
8. I certify that I am familiar with and will comply with all pertinent institutional, state and federal rules and policies.
9. I certify that I will provide members of the IACUC access to all animals and any documentations/records upon request.

**Date:**

**PI Signature:**

**APPENDIX A: Multiple Personnel**

|  |  |
| --- | --- |
| Name and Degrees/Certifications: |            |
| Office Phone: |            |
| Mobile Phone: |            |
| Email: |            |
| Study Role(s) | [ ]  Principal Investigator[ ]  Key Associate[ ]  Collaborator[ ]  Student Researcher |
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| Is this personnel a student? | [ ]  Yes[ ]  No |
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