**IACUC Use Only:**

Proposal #: Click or tap here to enter text.

Approval Date: Click or tap here to enter text.

Expiration Date: Click or tap here to enter text.

**University of Wisconsin-Green Bay**

**Institutional Animal Care and Use Committee**

Animal Study Proposal Form

# Date: Click or tap here to enter text.

**A. ADMINISTRATIVE DATA**

Campus/Department: Click or tap here to enter text.

Principal Investigator/Instructor: Click or tap here to enter text.

Mailing address: Click or tap here to enter text.

Phone: Click or tap here to enter text.

email: Click or tap here to enter text.

Project title: Click or tap here to enter text.

Initial submission: [ ]  Renewal: [ ]  Modification: [ ]

Proposed begin and end date of project: Click or tap here to enter text.

(note: project cannot begin before IACUC approval)

Funding Source: Click or tap here to enter text.

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel [e.g., co-investigator(s)], providing their institution, department, and e-mail:

1. Click or tap here to enter text.

2. Click or tap here to enter text.

3. Click or tap here to enter text.

4. Click or tap here to enter text.

5. Click or tap here to enter text.

# ANIMAL REQUIREMENTS

Taxonomic Information: Click or tap here to enter text. [e.g., *Mus musculus*]

Strain, subspecies, or breed: Click or tap here to enter text. [e.g., C57BL/6]

Common name: Click or tap here to enter text. [e.g., Black6]

Approximate age, weight or size: Click or tap here to enter text.

Sex: Click or tap here to enter text.

Bacteriological status: [e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free (SPF), conventional, unknown]

Click or tap here to enter text.

Viral status: [e.g., simian immunodeficency virus, simian retrovirus, unknown]

Click or tap here to enter text.

Source(s): [e.g., name of vendor or breeder, or bred in-house]

Click or tap here to enter text.

Primary housing location(s): [If animals will be housed in lab or anywhere else outside central facility for more than 12 hours, provide building and room number.]

Click or tap here to enter text.

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.

1. **TRANSPORTATION**

Transportation of animals:

[Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe methods you will use to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route that will be used.]

Click or tap here to enter text.

1. **STUDY OBJECTIVES**

Aim of study:

[Briefly explain 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 in language that a layperson can understand.]

Click or tap here to enter text.

1. **RATIONALE FOR ANIMAL USE**
2. Rationale for animal use: [The rationale should include reasons why it is necessary to use animal models.]

Click or tap here to enter text.

1. Appropriateness of the species selected: [The species selected should be the lowest possible on the phylogenetic scale.]

Click or tap here to enter text.

1. Justification of the number of animals to be used: [The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible.]

Click or tap here to enter text.

# DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

Experimental design and procedures:

*[Briefly explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. 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. We suggest including the following specific information, if applicable:*

* ***Animal identification methods*** *e.g., ear tags, tattoos, collar, cage card, implant, etc.*
* ***Methods of restraint*** *e.g., restraint chairs, collars, vests, harnesses, slings, etc. Describe how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be used.*
* ***Experimental injections or inoculations*** *substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedule.*
* ***Blood withdrawals*** *volume, frequency, withdrawal site, and methodology.*
* ***Food or fluid restriction*** *If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. Amount earned during testing and amount freely given must be recorded and assessed to assure proper nutrition. If you are seeking a departure from the recommendations of the Guide, provide a scientific justification.*
* ***Pharmaceutical-grade and Non-pharmaceutical-grade Compounds*** *Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.*
* ***Other procedures*** *e.g., survival studies, tail biopsies.*
* ***Resultant effects****, if any, that the animals are expected to experience e.g., pain or distress, ascites production, etc.*
* ***Other potential stressors*** *e.g., noxious stimuli, environmental stress* ***and procedures to monitor and minimize distress****. If a study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.*
* ***Experimental endpoint criteria*** *e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.*
* ***Veterinary care*** *Indicate the plan of action in case of animal illness e.g., initiate treatment, call investigator prior to initiating treatment, euthanize.*

Please record your response below:

Click or tap here to enter text.

# SURGERY (if proposed)

If surgery is proposed, complete the following:

* 1. Surgical procedure(s): [*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 used. If your surgical procedure may cause momentary or slight stress, a* ***veterinarian consultation*** *and* ***letter of support*** *is required. Please contact the* *IACUC Chair for more information.*]

Click or tap here to enter text.

* 1. Individual(s) performing surgery: [*Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.*]

Click or tap here to enter text.

* 1. Location: [*Identify the location where surgery will be performed, building(s) and room(s)*]

Click or tap here to enter text.

* 1. Postoperative care: [*If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided, building(s) and room(s). Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.*

Click or tap here to enter text.

* 1. Euthanasia: [*If non-survival surgery, describe how euthanasia will be provided and how death will be determined.*]

Click or tap here to enter text.

* 1. Paralytic agents: [If paralytic agents are used during surgery, please describe how ventilation will be maintained and how pain will be assessed.]

Click or tap here to enter text.

* 1. Previous surgery: [*Has major or minor survival surgery been performed on any animal prior to being placed on this study? Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)*. *If yes, please explain.]*

Click or tap here to enter text.

* 1. Repetitive survival surgery: [*Will more than one survival surgery be performed on an animal while on this study? If yes, please justify.*]

Click or tap here to enter text.

# PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

1. Pain or distress classification for USDA covered species. See Appendix 1 for classification definitions and examples.
2. Attachment 1, Explanation for USDA Classification E, must be completed only for animals listed in Classification E.

|  |  |  |  |
| --- | --- | --- | --- |
| **Species (common name)** | **USDA****Classification**\* **B, C, D or E** | **Number of animals used each year** | **3 years total number of animals** |
| **Year 1** | **Year 2** | **Year 3** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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| **Total number of animals** | Click or tap here to enter text. |

1. Consideration of Alternatives

If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate the methods and sources used in the search. Database references must include databases searched, the date of the search, period covered, and the keywords used. Alternatives include methods that:

* refine existing tests by minimizing animal distress,
* reduce the number of animals necessary for an experiment, or
* replace whole-animal use with *in vitro* or other tests.

Click or tap here to enter text.

# ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS (If Used)

Anesthetics, analgesics, sedatives, tranquilizers: [*For animals indicated in Section H.1. Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that will be used. A best practice is to provide an acceptable range of the specific items to allow flexibility in the use of professional judgment and avoid* *non-compliance due to work conducted off protocol as a result of overly restricted parameters. Include the name of the agent(s), the dosage range, route(s) and schedule of administration. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).*]

Click or tap here to enter text.

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

Euthanasia and disposal: [Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is not consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used. Indicate the method of carcass disposal if not described in Section K. below.]

Click or tap here to enter text.

1. **HAZARDOUS AGENTS, BIOLOGICAL MATERIAL, AND GENETICALLY ENGINEERED ANIMALS**

(If your work involves hazardous agents, please contact Scott Piontek, Environmental Health Specialist, pionteks@uwgb.edu (920) 465-2273)

**IBC Approval: (if required)**

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

Approval Date: Click or tap here to enter text.

Protocol Number: Click or tap here to enter text.

[Principle investigators/instructors planning to work with Recombinant DNA, Biological toxins, Microorganisms and viruses, Prions, Animal tissues, cell lines, or blood products, Plant pathogens, Nanotechnology, Dual use research of concern. Must also gain approval from the UW-Green Bay Institutional Biosafety Committee (IBC). Questions regarding the role of the IBC and its relevance to your proposal should be directed to ibc@uwgb.edu.]

1. **PRINCIPAL INVESTIGATOR CERTIFICATIONS**

By submitting this form:

I certify that personnel listed in section A have completed [required CITI training courses.](https://about.citiprogram.org/en/series/animal-care-and-use-acu/)

|  |  |  |
| --- | --- | --- |
| Investigator Name | Course | Completion Date |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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* I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
* For individuals working with the animals who are not listed in section A. I certify that they have been trained by the principal investigator.
* *For all USDA Classification D and E proposals (see section H.1*.) I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in Section H.2. 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.
* I certify that I will obtain approval from the IACUC before initiating any significant changes in this study including changes in personnel.
* 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.
* I certify that, to the best of my knowledge, I will comply with all pertinent institutional, state, and federal rules and policies.

PI Signature (type name): Click or tap here to enter text.

Date: Click or tap here to enter text.

IACUC Chair Signature: Click or tap here to enter text.

Date: Click or tap here to enter text.

**Appendix 1 - USDA Classifications and Examples**

**Classification B:** Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

## Examples:

* + Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are handled in accordance with IACUC approval, the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
	+ Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations.
	+ Animals held under proper captive conditions or wild animals that are being observed.

**Classification C:** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

## Examples:

* + Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice [dog cephalic, cat jugular] or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
	+ Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

**Classification D:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

## Examples:

* + Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, and laparotomy or laparoscopy.
	+ Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus *[e.g., guinea pigs]*.
	+ Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics, anesthetics, tranquilizers, or supportive care.

**Classification E:** Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

## Examples:

* + Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
	+ Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
	+ Negative conditioning via electric shocks that would cause pain in humans.
	+ Chairing of nonhuman primates not conditioned to the procedure for the time period use.

**NOTE REGARDING CLASSIFICATION E:** An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act (FOIA), and may be publicly available through the Internet via USDA’s website

# Attachment 1 - Explanation for USDA Classification E

[This report is required to accompany USDA Form 7023 to support any USDA Classification E listings. If no animals in USDA Classification E, leave blank]

This document must be typed.

Name of investigator: Click or tap here to enter text.

Animal study proposal title: Click or tap here to enter text.

Species and number of animals listed in Classification E for each year: Species:

Number of animals:

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.

Description of project including reason(s) for species selection:

Click or tap here to enter text.

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

Click or tap here to enter text.

**For Attachment 1 explicitly:**

Signature of investigator (if USDA Classification E): Click or tap here to enter text.

Date: Click or tap here to enter text.

Signature of IACUC Chairperson: Click or tap here to enter text.

Date: Click or tap here to enter text.