UNIVERSITY of WISCONSIN-GREEN BAY

IACUC Use Only:

Proposal #:
Approval Date:
Expiration Date:

University of Wisconsin-Green Bay
Institutional Animal Care and Use Committee

Animal Study Proposal Form

Date:

A. ADMINISTRATIVE DATA

Campus/Department:

Principal Investigator/Instructor:

Mailing address:

Phone: email:

Project title:

Initial submission: ☐ renewal: ☐ modification: ☐

Proposed begin and end date of project:

(note: project cannot begin before IACUC approval)

Funding Source:

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.

2.

3.

4.

5.

B. ANIMAL REQUIREMENTS

Taxonomic Information: [e.g., *Mus musculus*]

Strain, subspecies, or breed: [e.g., C57BL/6]

Common name: [e.g., Black6]

Approximate age, weight or size:

Sex:

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

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

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

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.]

Location(s) where manipulation will be conducted:

Number of Animals to be used:

Year 1:
Year 2:
Year 3:
Total:

C. 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.]

D. 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.]

E. RATIONALE FOR ANIMAL USE

1. Rationale for animal use: [The rationale should include reasons why it is necessary to use animal models.]

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

3. 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.]

F. 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 courseof 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 animalsare 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 trainingto 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 forassessing 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 therecommendations 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, ascitesproduction, 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 methodsthat will be used to minimize pain and distress.*
- ***Experimental endpoint criteria*** *e.g., tumor size, percentage body weight gain or loss, inability to eator drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity must be specified whenthe administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expectedto 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, callinvestigator prior to initiating treatment, euthanize.*

Please record your response below:

G. SURGERY (if proposed)

If surgery is proposed, complete the following:

a. 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 orslight stress, a* ***veterinarian consultation*** *and* ***letter of support*** *is required. Please contact the IACUC Chair for more information.*]

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

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

d. 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 complicationsduring work hours, after hours, weekends and holidays.*

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

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

g. 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). Ifyes, please explain.]*

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

H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

1. Pain or distress classification for USDA covered species. See Appendix 1 for classification definitions andexamples.

2. Attachment 1, Explanation for USDA Classification E, must be completed only for animals listed inClassification E.

Species (common name)	USDA Classification *B, C, D or E	Number of animals used eachyear			3 years total number of animals
		Year 1	Year 2	Year 3	
Total number of animals					

3. 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 alternativesare not available. Delineate the methods and sources used in the search. Database references must includedatabases 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.

I. 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 providean 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 thename of the agent(s), the dosage range, route(s) and schedule of administration. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).*]

J. 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.]

K. 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:

Protocol Number:

[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.]

L. PRINCIPAL INVESTIGATOR CERTIFICATIONS

By submitting this form:

I certify that personnel listed in section A have completed required CITI training courses.

Investigator Name	Course	Completion Date

- 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):

Date:

IACUC Chair Signature:

Date:

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 arehandled 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 applicableregulations.
- 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 involvingno 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 chairrestraint for an adapted nonhuman primate.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conductedinvolving 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 practicesuch 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 specieswithout a true orbital sinus *[e.g., guinea pigs]*.
- Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain ordistress 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 conductedinvolving 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, microbialvirulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry orother 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 mustbe 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 Internetvia 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:

Animal study proposal title:

Species and number of animals listed in Classification E for each year: Species:
Number of animals:
year 1 –

year 2 –

year 3 -

Total: -

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

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:

For Attachment 1 explicitly:

Signature of investigator (if USDA Classification E):

Date:

Signature of IACUC Chairperson:

Date: