Institutional Animal Care and Use Committee (IACUC)
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Stables
(812) 535-5002

SAINT MARY-OF-THE-WOODS COLLEGE

Animal Use Protocol

Protocol Title:

Please Leave Blank
Proposal #:
Approval Date:
Expiration Date:

PRINCIPAL INVESTIGATOR CERTIFICATION

A. I certify that I have attended the institutionally required investigator training course.
B. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
C. I certify that all individuals working on this proposal who are at risk are participating in the institution's Occupational Health and Safety Program.
D. I certify that all individuals listed in Section A are authorized to conduct procedures involving animals under this proposal, have attended the institutional 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 the reporting animal welfare concerns.
E. 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 I.3 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.
F. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
G. I certify that I will notify the IACUC regarding any expected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
H. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

Principal Investigator

Name: Signature: Date:

DEPARTMENTAL ASSURANCE

My signature as Department Chairman certifies that the proposed research has been reviewed for the proper use of animal subjects. This review encompassed experimental design, scientific merit, and suitability of facilities to accommodate the proposed research.

Department Head

Name: Signature: Date:

VETERINARY ASSURANCE

1. **Required for USDA Categories D & E:** Medical care for animals will be available and provided as indicated by a qualified veterinarian. By accepting this responsibility, the veterinarian is providing assurance that any personal interest he/she might have in the project will not conflict with his/her responsibility for the provision of adequate veterinary care for the animals. Furthermore, the veterinarian provides assurance of review and consultation on the proper use of anesthetics and pain relieving medications for any painful procedures.

Attending Veterinarian Name | Attending Veterinarian Signature | Date

A. ADMINISTRATIVE DATA

Department:

Principal Investigator:

Mailing Address:

Phone: Email:

Position/Title:

Submission Type: Third Year R

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), co-funded investigator(s)], providing their department, telephone, and e-mail:

Personnel	Position	Department	Telephone	Email

B.ANIMAL REQUIREMENTS

Genus: Species:

Strain, Subspecies, or Breed: Common Name:

Approximate age, weight, or size:

Sex:

Bacteriological status:

[e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free conventional]

Viral status:

[e.g., simian immunodeficiency virus, simian retrovirus]

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 provide building and room number.]

Location(s) where manipulation will be conducted:

C. TRANSPORTATION

1. 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 and elevator(s) that will be used.

D. STUDY OBJECTIVES

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. Please comment on whether the study unnecessarily duplicates other studies.

E. RATIONALE FOR ANIMAL USE

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

2. Justify the appropriateness of the species selected. [The species selected should be the lowest possible on the *phylogenetic scale.*]

3. Justify 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

Include the following specific information in F.1, 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].
- **Radiation** [dosage and schedule].
- **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. [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.
- **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].
- **Surgical procedures** [provide details of survival and non-survival surgical procedures in Section G].

1. 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. A flowchart may be an effective presentation of the planned procedure.

2. A best practice is to provide an acceptable range of alternative items (e.g. alternative techniques, equipment, collection schedules, etc.) to avoid non-compliance due to off protocol work.

G. Surgery

If surgery is proposed, complete the following:

1. 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.

2. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.

3. Identify the location where surgery will be performed [building(s) and room(s)].

4. If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsibly 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, and holidays.

5. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.

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

7. 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.

8. Will more than one survival surgery be performed on an animal while on this study? If yes please justify.

H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

1. Pain or distress classification from USDA covered species. See Appendix 1 for classification definitions and examples.
2. Attachment 1

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	
					0
					0
					0
					0
					0
					0
				Total number of animals	0

I. CONSIDERATION OF ALTERNATIVES

1. Is the proposed use of animals duplicative

If yes, list the reference(s) and justify the need for duplication.

2. Describe your consideration of alternatives and your determination that alternatives are not available. Alternatives include the 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. List the sources or database searched of other sources concluded:

   ii. List the date(s) you conducted the search:

   iii. List the time periods covered by the search:

   iv. List the methods or key terms and (or) search strategy used:

If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system. Note that you must certify: That no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not.

J. ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS

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).

K. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route(s) of administration. If the method(s) of euthanasia include those **not** recommended by the AVMA Guidelines on Euthanasia [e.g., decapitation or cervical dislocation without anesthesia], provide scientific justification as to why such methods must be used. Indicate the method of carcass disposal if not described in Section L, below.

L. HAZARDOUS AGENTS

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

Hazardous Agent	Yes	No	Agent	Date of Biosafety Approval	Tracking #
Radionuclides					
Biological Agents					
Hazardous Chemicals or Drugs					
Recombinant DNA					
Controlled Substance					

Study Conducted at Animal Biosafety Level:
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 or radioactive waste and, if applicable, the monitoring of radioactivity.

M. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS
[e.g., cell lines, antiserum, etc.]

1. Specific Material:

2. Source:

3. Material Sterile or Attenuated:

4. Has the material been tested for pathogens? [e.g., MAP – Mouse Antibody Production; RAP- Rat Antibody Production; HAP- Hamster Antibody Production, PCR test]

5. I certify that the tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____ **Initials of Principal Investigator**

N. GENETICALLY ENGINEERED ANIMALS
Describe any anticipated phenotypic consequences of the genetic manipulations of the animals. Describe any special care or monitoring that the animals will require.

O. EXEMPTIONS FROM ENVIRONMENTAL ENRICHMENT FOR NUNHUMAN PRIMATES OR EXERCISE FOR DOGS

1. For nonhuman primates, are you seeking an exemption for scientific reasons from the institution's plan for environment enrichment?

If yes, provide the basis of this request.

2. For dogs, are you seeking an exemption for scientific reasons from the institution's plan to provide dogs with the opportunity for exercise?

If yes, provide the basis of this request.

P. FIELD STUDIES

If animals in the wild will be used, describe how they will be observed, any interaction with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if federal, state, and/or local permits are required and attach a copy of the permits that will be used.

Q. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

List any special housing, equipment, animal care or any departures from the Guides [e.g., special caging, water, feed, waste disposal, environmental enrichment, etc.].

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 purpose.

Examples:

- Breeding colonies of any animal species (USDA does not require lists 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 training personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implications 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 be 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 or postsurgical sequella from invasions of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Chairing of nonhuman primates not conditioned to the procedure for the time period used.

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.]

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:

Signature of Investigator Date

Signature of IACUC Chairperson Date