WICHITA STATE UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
ANIMAL PROTOCOL FORM

Date:

Principal Investigator:

Title of Project:

Protocol #: Animal Species:

Funding source: RTT grant/proposal #:

You must submit a copy of the project summary and the animal section submitted with your proposal.

OVERVIEW

1. Briefly describe the purpose of the study, experimental procedures and manipulations of the animals, and the expected outcome in lay terms. Include a justification of what you want to do and how it contributes to your work. If this is a DeNovo submission, please provide a justification or rationale for continuing this protocol and explain any changes from the previous iteration of the study. (If there were any adverse events or unanticipated problems, please see appendix 5).

2. Describe the sequence and rationale of the manipulations and procedures. DO NOT DESCRIBE DETAILS OF SURGICAL PROCEDURES HERE. Step-by-step bullet points are helpful.

3. PROPOSED ANIMAL USAGE:

SPECIES	Total # Requested For Protocol	Total # Anticipated For Year 1	Total # Anticipated For Year 2	Total # Anticipated For Year 3

4. NATURE OF THE PROTOCOL/STUDY:

- ☐ Survival (Chronic) Study
- ☐ Terminal (Acute) Study
- ☐ Multiple Surgeries
- ☐ Multiple Procedures
- ☐ Other:
- ☐ Prolonged Restraint
- ☐ Neuromuscular Blockers
- ☐ Antibody Production
- ☐ Blood/Tissue Collection
- ☐ Inducement of a Disease State
- ☐ Inducement of Behavioral Stress
- ☐ Administration of Test Substances
- ☐ Transgenic Breeding

5. (USDA) PROJECT (Pain) CATEGORY: ☐ B ☐ C ☐ D ☐ E

Category B: Breeding or Holding Colony Protocols

Category C: Involves *procedures that cause no pain or no more than momentary or slight pain* and no pain-relieving drugs are used.

Category D: Involves *procedures that may cause more than momentary or slight pain or distress* for which appropriate sedatives, analgesics, or anesthetics will be administered.

Category E: Involves *procedures that may cause more than momentary or slight pain or distress for* which sedatives, analgesics, or anesthetics cannot/will not be administered due to scientific considerations/ requirements.

6. Describe the characteristics of the animal selected that justify its use in the proposed study. [Consider such characteristics as body size, species, strain, breed, data from previous studies or unique anatomic or physiologic features.]

7. Give the names of all individuals who will work with the animals in this study. **All personnel are required to complete CITI training every 3 years.** *If additional space is needed, submit a separate word document*.

Name and highest degree	**Department**	**Email Address**	**Faculty, student, etc**	**Years & Relevant Experience**	**Role/Responsibility for this project**

7a. If personnel do not have experience, how will they be trained?

7b. Have all Wichita State University faculty and unclassified staff listed as personnel completed a disclosure of conflict of interest and time commitment for WSU within the last 12 months?

☐ Yes ☐ No - contact Compliance at compliance@wichita.edu. ☐ N/A

7c. Do any of the personnel (including students or their immediate family members and those unaffiliated with WSU) on the project have financial arrangements with the sponsoring company or the products or services being evaluated which may include consulting agreements, management responsibilities or equity holdings in the sponsoring company?

☐ Yes - contact Compliance at compliance@wichita.edu ☐ No ☐ N/A

ANIMAL SUBJECT DESCRIPTION

8. Strain/Stock/Mutant/Breed: Sex: Age/Size:

9. Source:

Microbial Status (Check one): ☐ SPF ☐ Conventional ☐ Axenic ☐ Feral

☐ Other**:**

10. Describe how the number of animals needed for the study was determined. [The specific statistical methods or a clear rationale used to determine the numbers of animals needed MUST be provided.]

ANIMAL HUSBANDRY AND CARE

11. Are animal husbandry and routine handling practices and procedures for this study, including animal health monitoring, diet, cage, environmental control, exercise (where required), environmental enrichment (where required), and means of identification, described in the Wichita State University (WSU) standard operating procedures manual?

☐ YES - PROCEED TO ITEM 12.

☐ NO - ATTACH APPENDIX 1, SPECIAL HUSBANDRY PRACTICES. [All husbandry and care practices must meet standards described in the Animal Welfare Regulations and the Guide for the Care and Use of Laboratory Animals unless they have been specifically excepted in Appendix 1 by the WSU IACUC for scientific reasons.

12. Animal housing location:

Name of institution, if not WSU:

13. The current AAALAC accreditation status of the facility where animals will be housed:

☐ ACCREDITED

☐ NON-ACCREDITED - If Non-Accredited, attach a copy of the OLAW Assurance Statement, and a copy of the latest USDA site visit report for the Non-Accredited facility.

EXPERIMENTAL PROCEDURES

14. Location where experimental procedures will be performed including building name:

15. Will test substances be administered? [Radioisotopes, toxic, antigenic, pharmacologic, infectious, carcinogenic, or other types of substances, biomaterials or cells administered to live animals are considered to be test substances.]

☐ NO, PROCEED TO ITEM 16. ☐ YES, ATTACH APPENDIX 2 - TEST SUBSTANCES.

16. Will specimens be collected prior to euthanasia? [All body fluids and tissues are considered specimens.]

☐ NO, PROCEED TO ITEM 17. ☐ YES, ATTACH APPENDIX 3 - SPECIMEN COLLECTION.

17. Will SURGERY be performed as part of the experimental protocol?

☐ NO, PROCEED TO ITEM 18. ☐ YES, ATTACH APPENDIX 4 - SURGERY

18. Is death an endpoint in this study?

☐ NO, PROCEED TO ITEM 19. ☐ YES, Explain why an earlier endpoint is not acceptable:

19. Will animals be subject to experimental procedures that are not noted elsewhere in ITEMS 15-18?

☐ NO - PROCEED TO ITEM 27.

☐ YES - Check the following applicable procedures and answer questions 20-26.

☐ Physical restraint ☐ Noxious stimuli ☐ Forced exercise ☐ Behavioral manipulations
☐ Other:

20. Describe each procedure and the expected outcome. Include the chemical, physical, or behavior modifying characteristics of the stimulus or material administered or withdrawn.

21. Who will perform the procedure?

22. Describe the length of time each procedure will last.

23. Will the procedure cause more than momentary pain or discomfort?

☐ NO - PROCEED TO ITEM 24.

☐ YES - Describe the procedures or methods that will be used to minimize pain and discomfort:

24. Describe the methods for monitoring the condition of the animal during the length of the procedure and during the post-procedure period:

25. Provide the name(s) of the person(s) responsible for monitoring the condition of the animals:

26. You must provide to the WSU Staff the phone numbers where they can be reached during and after work hours. Check here to indicate this has been done. ☐

EUTHANASIA OR OTHER DISPOSITION OF ANIMALS

27. Are animals euthanized for tissue collection or at the completion of this study?

☐ NO - PROCEED TO ITEM 33.

☐ YES - ANSWER QUESTIONS 28-32. [For guidance on acceptable methods of euthanasia, reference should be made to the 2020 AVMA Guidelines on Euthanasia located at: https://www.avma.org/KB/Policies/Documents/euthanasia.pdf

28. Two methods of euthanasia must be used - a chemical method and a physical method are recommended.

A. Name of the chemical agent(s) that will be used:

Dose: Route:

B. Name the physical method that will be used:

29. Justify any method of euthanasia that is NOT recommended by the AVMA Guidelines on Euthanasia or state N/A.

30. Give the name(s) of the person(s) who will perform the euthanasia:

31. Are these persons experienced with this method of euthanasia?

☐ NO - Name the experienced person who will train them:

☐ YES - PROCEED TO ITEM 32.

32. Describe the fate of experimental animals, other than euthanasia, after completion of the study:

MANDATORY CONSIDERATIONS

33. Do the procedures to be employed have the potential to cause more than momentary or slight pain or distress (Category D or E)? [The United States Department of Agriculture has determined that surgery conducted under anesthesia is a potentially painful procedure.]

☐ NO - PROCEED DIRECTLY TO ITEM 36.

☐ YES - ANSWER QUESTIONS 34-35.

34. Provide a narrative description of the methods and sources used to determine that suitable alternatives were not available or applicable to this study such as less sentient animal models, computer models, and tissue culture. The following are examples of relevant methods that may be supportive of your effort: AGRICOLA database, MEDLINE database, CAB Abstracts database, AWIC TOXLINE database, BIOSIS database, scientific journals, scientific meetings, and/or scientific discussions.

When a database search is the primary means of meeting this requirement, the narrative must, at a minimum, include:

a. the name of the database(s) searched:

b. the date the search was performed:

c. the period covered by the search:

d. the key word and/or the search strategy used:

MISCELLANEOUS FEDERAL REQUIREMENTS

All drugs classified by the DEA as controlled substances that will be used in this study must be stored in a locked cabinet and accessible only to authorized persons in accordance with DEA regulations.

35. Will a flammable anesthetic agent be used in *ANY PORTION OF* these animal studies?

☐ NO - PROCEED TO ITEM 36.

☐ YES - A COPY OF AN APPROVED "REQUEST TO USE EXPLOSIVE ANESTHETICS" must be on file with the Environmental Health and Safety Fire Safety Chief.

SIGNATURES

36. Certification by Principal Investigator.

I certify that these studies do not unnecessarily duplicate previous experiments. I further affirm that, to the best of my knowledge, information provided in this Animal Component of Research Protocol is complete and accurate and that no significant changes will be made without advance approval of the IACUC. I agree to provide records of personnel training when requested by USDA inspectors.

Principal Investigator Signature Date

37. Approval Signatures

The undersigned have evaluated the care and use of animals described in this protocol in accordance with provisions of the Animal Welfare Act, the PHS *Guide for the Care and Use of Laboratory Animals*, and find that the procedures described are appropriate and acceptable.

Attending Veterinarian Signature Date

IACUC Chair Signature Date

38. APPENDICES ATTACHED:

☐ None ☐ Special Husbandry (Appendix 1) ☐ Test Substances (Appendix 2)

☐ Specimen Collection (Appendix 3) ☐ Live Surgery (Appendix 4)

☐ Unanticipated Problems (Appendix 5)

APPENDIX 1

SPECIAL HUSBANDRY PRACTICES

(Complete only if applicable or mark N/A here ☐)

1. Describe non-standard practices or procedures: [Examples include: close confinement, temperature extremes, food or water deprivation, dietary manipulations, special housing, modified light cycle, restricted observation, restricted enrichment, etc.]

2. Justification:

3. Who will perform the procedure?

4. Describe the length of time each procedure will last:

5. Will the procedure cause more than momentary pain or discomfort?

☐ NO - PROCEED TO ITEM 6.

☐ YES - Describe the procedures or methods that will be used to minimize pain and discomfort.

6. Describe the methods for monitoring the condition of the animal during the length of the procedure and during the post-procedure period:

7. Provide the name(s) of the person(s) responsible for monitoring the condition of the animals:

You must provide to the WSU Staff the phone numbers where they can be reached during and after work hours. Check here to indicate this has been done. ☐

APPENDIX 2

TEST SUBSTANCES

(Complete only if applicable or mark N/A here ☐)

1. Class of the test substances or other material:

☐ A. Radioisotope
☐ B. Infectious Agent
☐ C. Carcinogen
☐ D. Toxic Chemical
☐ E. Tissues/Cells
☐ F. Adjuvants
☐ G. Antigenic substance
☐ H. Biomaterial
☐ I. Excreta or Body Fluids
☐ J. Pharmacological Agent
☐ K. Non-Pharmaceutical-grade substance (see below)

When Non-Pharmaceutical-grade substances are used, ensure that toxic or unwanted side effects are not introduced. Explain if the pharmaceutical grade is not available and provide justification on a separate document following the chart guidance located at: https://oacu.oir.nih.gov/system/files/media/file/2021-06/b14_pharmaceutical_compounds.pdf (**Include** the pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered)

2. Identify the test substances or other material that will be administered to the animals:

SUBSTANCE NAME	*CLASS*	*DOSE*	*FREQUENCY*	*ROUTE*	*DURATION*

3. Will the test substance(s) cause pain or distress to the animal?

☐ NO - PROCEED TO ITEM 4.
☐ YES - Describe the measures that will be taken to alleviate or minimize these effects.

4. Is the test substance considered to be a hazardous material?

☐ NO - *STOP HERE.*

☐ YES - Give names of personnel who will work with hazardous material then proceed to ITEM 5:

5. If you are using any radio-isotope, or hazardous material of any type, you must have authorization to work with these materials by the Director of Environmental Health and Safety. The Director's signature indicates that he has consulted with the Attending Veterinarian, and that adequate precautions, containment facilities, protective devices, carcass and waste disposal, cleanup procedures, and other necessary safety procedures are in place to protect personnel and prevent accidental animal exposure to the hazardous material. Please provide a letter documenting the safety precautions that will be used.

Director, Environmental Health & Safety Date

APPENDIX 3

SPECIMEN COLLECTION PRIOR TO EUTHANASIA

(Complete only if applicable or mark N/A here ☐)

1. Will invasive procedures be employed to collect tissue or body fluids from live animals during this experimentation?

   ☐ NO - PROCEED TO ITEM 2.

   ☐ YES - Characterize the procedure in the box below. [Any procedure that penetrates a body orifice, the integument, or a hollow visceral organ is invasive.]

Tissue Or Fluid Collected	Method Of Collection	Amount	Frequency

2. Will the procedure cause more than momentary pain or distress?

   ☐ NO - PROCEED TO ITEMS 4 & 5.

   ☐ YES - Give the anesthetic agent, sedative, or tranquilizing agent that will be used. *IF NONE IS TO BE USED, PROCEED TO ITEM 3.*

Agent	Dose	Frequency	Route

APPENDIX 3 (continued)

3. Justification for omission of pain relieving agents:

4. Describe the method of restraint used to execute this task for all procedures where surgical plans of general anesthesia are not detailed in number 2 above:

5. Briefly describe the non-invasive procedure and how the specimens will be collected:

APPENDIX 4

LIVE SURGERY

(Complete only if applicable or mark N/A here ☐)

1. Describe the surgical procedures in enough detail so that reviewers will be able to determine what is actually being done to the animal.

2. Who will do the surgery?

3. Pre-operative procedures:

	Fasting - Length:	☐ **Clip Hair**	☐ **Disinfect Site**
	Withhold Water - Length:	☐ **Scrub Site**	☐ **Place Catheter**
	Other:		

4. Preoperative medications: *Include sedatives/tranquilizers/other pre-anesthetic medications here.*

Drug	Dose	Route

APPENDIX 4 (continued)

5. Intraoperative medications and support: *Include anesthetic agents/paralyzing agents/fluids/ pharmaceuticals essential to support the surgical procedure*.

Drug	Dose	Route

6. Federal regulations prohibit the use of paralyzing agents without general anesthesia. Will you use paralyzing agents?

☐ NO – PROCEED TO ITEM 7

☐ YES - Why is it necessary to use these agents?

7. Describe the methods used to monitor the state of anesthesia and general well-being:

8. Will the animal subjects regain consciousness following surgery?

☐ NO - STOP HERE

☐ YES - ANSWER ITEM 9-15

9. How long will the animal survive?

10. Will the surgery be performed in a room or area suitable for aseptic surgery?

☐ YES - Identify the location where surgery will be performed:

☐ NO - Explain:

APPENDIX 4 (continued)

11. Which of the following aseptic techniques will be used?

☐ Sterile Instruments ☐ Gloves ☐ Gown ☐ Surgeon Scrub ☐ Face Mask

☐ None:

☐ Other:

12. Will multiple survival surgical procedures be performed on a single animal?

☐ YES - PROCEED TO 13.

☐ NO - PROCEED TO 14.

13. Will the multiple survival surgeries be MAJOR? (As a general guideline, major survival surgery [e.g., laparotomy, thoracotomy, joint replacement, and limb amputation] penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection (Brown et al. 1993). Minor survival surgery does not expose a body cavity and causes little or no physical impairment; this category includes wound suturing, peripheral vessel cannulation, percutaneous biopsy, etc.

☐ YES - Explain:

☐ NO - PROCEED TO 14.

14. Describe the post-operative care, including drugs, fluids, and physical support methods, that will be given to the animals:

Drug or fluid	Dose	Frequency	Route	Duration

14a. Physical support methods:

15. Who will be responsible for post operative care?

An emergency contact phone number must be provided to the WSU staff. Check here to indicate that it has been provided. ☐

APPENDIX 5

Unanticipated Problems or Adverse Events
(Complete only if applicable or mark N/A here ☐)

PROBLEMS/ADVERSE EVENTS

Describe any unanticipated adverse events in the past 3 years and include morbidity or mortality, the cause(s), if known, and how these problems were resolved. If NONE, this should be indicated.