

ANIMAL COMPONENT OF RESEARCH PROTOCOL

Double-click in boxes to enter information or checkmarks. Text boxes will expand to any length.

Name of Principal Investigator:

Proposal Title:

Protocol No.(Research Administration Office):

Date:

Animal Species:

USE A SEPARATE FORM FOR EACH SPECIES

Anticipated beginning date ; ending date

OVERVIEW

1. Briefly describe the purpose of the study, experimental procedures and manipulations of the animals, and the expected outcome in lay terms. Describe the sequence of the manipulations and procedures. [Summarize in narrative form the procedures and manipulations to be performed using animals and explain why they are performed.] DO NOT DESCRIBE DETAILS OF SURGICAL PROCEDURES HERE.

2. 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.]

3. Personnel & Qualifications. Give the name(s) of all individual(s) who will work with the animals in this study. Describe their education, training and relevant experience with experimental animals. [This must enable reviewers to determine that manipulations of animal subjects are performed by individuals who are qualified to accomplish the procedures skillfully and humanely. See #21 on page 5 for training documentation requirement.] A LISTING OF ACADEMIC DEGREES ALONE IS NOT RESPONSIVE TO THIS QUESTION.

NAME	HIGHEST DEGREE	YEARS AND TYPES OF RELEVANT EXPERIENCE

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

ANIMAL SUBJECT DESCRIPTION

4. Animal Characteristics:

Strain/Stock/Mutant/Breed:

Sex:

Age/Size:

Source:

Microbial Status (Check one): SPF

Conventional

Axenic

Feral

Other (Describe)

Approximate number of animals to be used per year:

Year 1

Year 2

Year 3

Year 4

Year 5

5. Describe how the number of animals needed for the study was determined.

[For your convenience, a tool for power calculation is provided at: <http://calculators.stat.ucla.edu/powercalc/>

If using a different method, the specific statistical methods or a clear rationale used to determine the numbers of animals needed MUST be provided.]

ANIMAL HUSBANDRY AND CARE

6. 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 7. 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 I by the WSU Institutional Animal Care and Use Committee [IACUC] for scientific reasons.]

7. Animal housing location:

Room Number:

Name of institution, if not WSU:

8. The current AAALAC accreditation status of the facility where animals will be housed: ACCREDITED NON-ACCREDITED . If Non-Accredited, attach a copy of the OPRR Assurance Statement, and a copy of the latest USDA site visit report for the Non-Accredited facility.

9. Give the name of the veterinarian, or the institutional resource, that is responsible for providing adequate veterinary care to the animals:

[Adequate veterinary medical care must be provided as described in Federal regulations.] When a Veterinary Medical Consultant is used to provide care, regulations require that a written program of veterinary care be available.

EXPERIMENTAL PROCEDURES

10. Location where experimental procedures will be performed:

Building name and room number

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

NO PROCEED TO ITEM 12. YES ATTACH APPENDIX 2, TEST SUBSTANCES.

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

NO PROCEED TO ITEM 13. YES ATTACH APPENDIX 3, SPECIMEN COLLECTION.

13. Will SURGERY be performed as part of the experimental protocol? NO

PROCEED TO ITEM 14. YES ATTACH APPENDIX 4, SURGERY, THEN PROCEED TO ITEM 14.

14. Is death an endpoint in this study? NO PROCEED TO ITEM 15. YES Explain why an earlier endpoint is not acceptable. EUTHANASIA IS NOT A DEATH ENDPOINT.

OTHER EXPERIMENTAL PROCEDURES

15. Will animals be subject to experimental procedures that are not noted elsewhere in ITEMS 11-13? NO PROCEED TO ITEM 16. YES Check the following applicable procedures and answer questions 15a-f.

Physical restraint

Noxious stimuli

Forced exercise

Behavioral manipulations

Other(Describe)

15a. Describe each procedure and the expected outcome. Include the chemical, physical, or behavior modifying characteristics of the stimulus or material administered or withdrawn.

15b. Who will perform the procedure?

15c. Describe the length of time each procedure will last.

15d. Will the procedure cause more than momentary pain or discomfort? NO PROCEED TO ITEM 15e. YES Describe the procedures or methods that will be used to minimize pain and discomfort, THEN PROCEED TO ITEM 15e.

15e. Describe the methods for monitoring the condition of the animal during the length of the procedure and during the post-procedure period.

15f. 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

EUTHANASIA OR OTHER DISPOSITION OF ANIMALS

16. Are animals euthanized for tissue collection or at the completion of this study? NO PROCEED TO ITEM 17. YES ANSWER QUESTIONS 16a-e. [For guidance on acceptable methods of euthanasia, reference should be made to the 1993 Report of the AVMA Panel on Euthanasia, JAVMA, Vol 202:229-249, 1993.]

16a. Name of the chemical agent(s) that will be used:

Dose: Route:

16b. Physical method that will be used:

If a combination of chemical and physical methods will be employed, name both.

16c. Justify any method of euthanasia that is NOT recommended by the AVMA Panel on Euthanasia.

16d. Give the name(s) of the person(s) who will perform the euthanasia:

16e. Are these persons experienced with this method of euthanasia? YES PROCEED TO ITEM 18. NO Name the experienced person who will train them.

17. Describe method of disposition of experimental animals, other than euthanasia, after completion of the study:

MANDATORY CONSIDERATIONS

18. You are required by Federal law to declare if the procedure to be employed has the potential to cause more than momentary or slight pain or distress? [The United States Department of Agriculture has determined that surgery conducted under anesthesia is a potentially painful procedure.] If it will not, PROCEED DIRECTLY TO ITEM 19. If it will, YOU MUST ANSWER QUESTIONS 18a-b.

18a. Provide a narrative description of the methods and sources used to determine that suitable alternatives such as less sentient animal models, computer models, and tissue culture were not available or applicable to this study. 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:

1. the name of the database(s) searched;
2. the date the search was performed;
3. the period covered by the search, and
4. the key word and/or the search strategy used.

18b. Provide the name of the veterinarian who has been involved in planning this experiment:

MISCELLANEOUS FEDERAL REQUIREMENTS

19. 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.

20. Will a flammable anesthetic agent be used in *ANY PORTION OF* these animal studies? NO PROCEED TO ITEM 21. 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

21. Certification by Principal Investigator. [PI's signature is mandatory.]

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.

Signature	Date
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22. 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. COMMENTS AND DISSENTING VIEWS MUST BE GIVEN IN ITEM 23.

Typed Name	Signature	Date
Veterinary Medical Officer or VM Consultant		
Chairperson, IACUC		

23. Comments:

24. APPENDICES ATTACHED: None Special Husbandry Surgery
Test Substances Specimen Collection

SPECIAL HUSBANDRY PRACTICES
(Complete only if applicable)

1. Description of 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. If different from ITEM 3, 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

TEST SUBSTANCES
(Complete only if applicable)

1. Class of the test substances or other material:

- | | | |
|--|---|--|
| <input type="checkbox"/> A. Radioisotope | <input type="checkbox"/> E. Tissues/Cells | <input type="checkbox"/> I. Biomaterial |
| <input type="checkbox"/> B. Infectious Agent | <input type="checkbox"/> F. Pharmacological Agent | <input type="checkbox"/> J. Excreta or Body Fluids |
| <input type="checkbox"/> C. Carcinogen | <input type="checkbox"/> G. Adjuvants | <input type="checkbox"/> K. Other (Describe) |
| <input type="checkbox"/> D. Toxic Chemical | <input type="checkbox"/> H. Antigenic substance | |

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

<i>SUBSTANCE NAME</i>	<i>CLASS</i>	<i>DOSE</i>	<i>FREQUENCY</i>	<i>ROUTE</i>	<i>DURATION</i>
1.					
2.					
3.					
4.					
5.					

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 THE NAMES OF PERSONNEL WHO WILL WORK WITH HAZARDOUS MATERIAL then proceed to ITEM 5:

5. SAFETY PRECAUTIONS. SIGNATURE REQUIRED. [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 Veterinary Medical Officer, 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.]

Director, Environmental Health & Safety _____
(signature)

SPECIMEN COLLECTION PRIOR TO EUTHANASIA
(Complete only if applicable)

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. . [Any procedure that penetrates a body orifice, the integument, or a hollow visceral organ is invasive.]

TISSUE OR FLUID COLLECTED METHOD OF COLLECTION

<i>TISSUE OR FLUID COLLECTED</i>	<i>METHOD OF COLLECTION</i>	<i>AMOUNT</i>	<i>FREQUENCY</i>

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.*

<i>AGENT</i>	<i>DOSE</i>	<i>FREQUENCY</i>	<i>ROUTE</i>

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.

SURGERY
(Complete only if applicable)

1. Procedures. 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. Preoperative procedures:

<input type="checkbox"/> Fasting (Length _____)	<input type="checkbox"/> Clip Hair	<input type="checkbox"/> Disinfect Site
<input type="checkbox"/> Withhold Water (Length _____)	<input type="checkbox"/> Scrub Site	<input type="checkbox"/> Place Catheter
<input type="checkbox"/> Other:		

4. Preoperative medications. INCLUDE SEDATIVES/TRANQUILIZERS/OTHER PRE-ANESTHETIC MEDICATIONS HERE.

DRUG	DOSE	ROUTE

5. Intraoperative medications and support. INCLUDE ANESTHETIC AGENTS/ PARALYZING AGENTS/FLUIDS/PHARMACEUTICALS ESSENTIAL TO SUPPORT THE SURGICAL PROCEDURE.

DRUG	DOSE	ROUTE

6. PARALYZING AGENTS. Federal regulations prohibit the use of these agents without general anesthesia. If you use these agents, you must check here . Why is it necessary to use these agents?

7. Intraoperative monitoring of the animal's condition. 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 THE FOLLOWING QUESTIONS:

8a. How long will the animal survive?

8b. 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:

8c. Which of the following aseptic techniques will be used?

<input type="checkbox"/> None (Explain:)	<input type="checkbox"/> Sterile instruments	<input type="checkbox"/> Face mask	<input type="checkbox"/> Gloves
<input type="checkbox"/> Surgeon scrub	<input type="checkbox"/> Gown	<input type="checkbox"/> Other (Describe:)	

8d. Will only one major survival surgical procedure be performed on a single animal? YES NO . IF NO, EXPLAIN WHAT WILL BE DONE, AND GIVE A SCIENTIFIC JUSTIFICATION FOR MORE THAN ONE PROCEDURE ON A SINGLE ANIMAL.

8e. Describe the post operative care, including drugs, fluids, and physical support methods, that will be given to the animals:

<i>DRUG OR FLUID</i>	<i>DOSE</i>	<i>FREQUENCY</i>	<i>ROUTE</i>	<i>DURATION</i>

PHYSICAL SUPPORT METHODS:

8f. Who will be responsible for post operative care?

Their after work contact phone number must be provided to the WSU staff. Check here to indicate that it has been provided .