Seton Hall University

Institutional Animal Care and Use Committee

ANIMAL COMPONENT OF RESEARCH PROTOCOL

Name of Principal Investigator:

Proposal Title:

Protocol No. (Set BY IACUC):

Submission Date:

Animal Species:

Anticipated beginning and ending dates of animal studies described in this protocol: From to

I. OVERVIEW (attach an abstract or copy of the project description as Appendix A-1)

A. Describe experimental procedures and manipulations of the animals and their intended purpose. Be brief and specific.

B. Describe the characteristics of the animal that justify its use in the proposed study.

C. Qualifications (State the name(s) and describe qualifications (education and training and relevant experience with experimental animals) of individuals conducting the study).

II ANIMAL SUBJECT DESCRIPTION

Species: Strain/Breed:
Sex: Age/Size:
Source:
Microbial Status (e.g., VAF, SPF, Conventional):

Number of animals to be used per year:

2011	2012	2013	

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

III. ANIMAL HUSBANDRY AND CARE

A. Are all animal husbandry and other handling practices and procedures, including animal health monitoring, diet, primary enclosures, environmental control, and means of identification as described in the local standard operating procedures manual?

YES ____ NO ____

If no, attach a description of deviations from standard procedures and practices as Appendix A-2.

B. Where are the animals to be housed?

C. What is the current IACUC program accreditation status?

Self Inspection

D. Are animals to be housed in non-SHU facilities?

YES _____ NO ____

If yes, state the animal care and use program:

1. AAALAC - full, deferred continued, probationary, provisional.

2. Other, describe:

E. Is medical care for animals available and provided as necessary by a qualified veterinarian?

YES _____ NO ____

If no, explain:

IV. EXPERIMENTAL PROCEDURES

A. Location (building and room number) at which experimental procedures are performed:

B. Test Substance, Cells or Hazardous Materials

Will toxic, antigenic, pharmacological, infectious, carcinogenic or other types of test substances or cells be administered to live animals as part of the experimental protocol? (Use of radioisotopes in animals is not permitted)

YES ____ NO ____

If no, proceed to item C,

1. List the test substance(s), amount to be used, frequency and route of administration, and expected effects of the substance(s):

2. Hazardous Materials
   a. Toxic _____
   b. Antigenic _____
   c. Pharmacological _____
   d. Infectious _____
   e. Carcinogenic _____
   f. Other (non radioisotope)
      (Describe: _____)

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

YES ____ NO

If yes, describe and state what measures will be taken to alleviate or minimize these adverse effects.

4. Is death used as an end point in this study?

YES ____ NO

If yes, explain why an earlier end point is not acceptable.

C. Specimen Collection

1. Is animal use limited to euthanasia followed by tissue harvesting?

YES _____ NO ____

If yes, proceed to item F. Euthanasia.

2. Are invasive procedures to be employed for collection of tissue or body fluids from live animals during experimentation?

YES ____ NO ____

If yes, complete items a. through d.:

a. Tissue or body fluid(s) to be collected:

b. Method of specimen collection:

c. Amount and frequency of collection:

d. Anesthetic, sedative or tranquilizing agent and dosage administered for specimen collection:

D. Surgery

1. Are surgical procedures to be performed as part of the experimental protocol?

YES ____ NO ____

If no, proceed to Item E.

If Yes describe the surgical procedure(s):

2. What preoperative procedures(e.g., fasting) and medication, including anesthetics and analgesics, will be employed prior to surgery?

3. Are paralytic agents used in conjunction with surgical manipulations?

YES ____ NO ____

If yes, describe the method to assess the absence of perceived pain by the animal subject:

4. Describe the monitoring and supportive care provided during surgery:

5. Are animal subjects expected to regain consciousness following major surgical manipulation?

YES ____ NO ____

If no, proceed to Item E.

If yes, complete Items a. through d.:

a. Is aseptic technique followed including use of sterile surgical gloves and instruments, and aseptic preparation of the surgical field?

YES ____ NO ____

b. Is more than one major survival surgical procedure to be performed on a single animal?

YES ____ NO ____

c. What care will be provided during the postoperative period (including drug dosages) and what criteria will be used to assess the need for analgesics?

d. What arrangements will be made for providing routine postoperative care and detection and managing postoperative complications during the normal work day, weekends, holidays and after normal duty hours?

E. Other Experimental Procedures

Will animals be subject to any experimental procedures not noted elsewhere on Section IV (e.g., prolonged physical restraint, food or water deprivation, noxious stimuli, environmental stress)?

YES ____ NO ____

If yes, describe the procedure(s) and methods that will be employed to monitor animals and minimize discomfort.

F. Euthanasia

1. Are animals surviving an experiment euthanatized at completion of the study?

YES ____ NO ____ NA _____

If yes, complete questions a. through c.:

a. What procedure will be employed for euthanasia? If a chemical agent is to be used, list dosage and route of administration:
b. Who will perform euthanasia and what is the training and experience with the procedure?
c. Does the method of euthanasia meet current recommendations of the AVMA Panel on Euthanasia?

YES ____ NO ____

If not, provide justification for deviating from the recommendations.

V. SPECIAL CONSIDERATIONS

A. Are procedures employed that are likely to cause more than momentary or slight pain or distress to the animals?

YES ____ NO

If yes, complete 1. through 3:

1. Describe the procedures and the pain to be experienced:

2. Have alternatives, such as a less sentient animal model, computer models or tissue culture been considered?

YES ____ NO ____

If yes, describe methods and sources used to determine that suitable alternatives were not available:

3. Has a Doctor of Veterinary Medicine been consulted in planning the procedure as stipulated in the Animal Welfare Act?

YES ____ NO ____

If no, explain:

B. Are procedures employed that are intended to study pain?

YES ____ NO

If yes, describe and justify:

C. Are drugs classified by the DEA as controlled substance used?

YES ____ NO

If yes, list the substances to be used and give precautions to be taken to avoid unauthorized access to these substances:

D. Is a class room to be used for animals studies?

YES ____ NO

If yes, attach details:

E. Is ether or any other explosive anesthetic agent to be used?

YES ____ NO

If yes, attach description and give the safety considerations taken:

VI. SIGNATURES

A. Certification by Principal Investigator

I affirm that to the best of my knowledge, information provided in this Animal Component Research Protocol is complete and accurate and that no changes will be made without advance approval of the IACUC. I further certify that these studies do no unnecessarily duplicate previous experiments.

Signature Date

B. Approval Signatures

The undersigned have evaluated the care and use of animals described in this protocol in accordance with provisions of the USDA Animal Welfare Act, the PHS Guide for the Care and Use of Laboratory Animals and the U.S. Interagency Research Animal Committee Principles for the Utilization and Care of Research Animals and find the procedures described appropriate and acceptable. (Comments and dissenting views may be noted below the approval signatures.)

Typed Name Signature Date

_____
Attending Veterinarian

_____
Chairperson IACUC

_____
Committee Member

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Committee Member

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Committee Member

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Committee Member

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Committee Member