Instructions

Updated: April 2001

Instructions **Seton Hall University**

Institutional Animal Care and Use Committee

ANIMAL COMPONENT OF RESEARCH PROTOCOL

Name of Principal Investigator: **Self Explanatory**

Proposal Title: **Self Explanatory**

Protocol No. (Set BY IACUC): **leave blank**

Submission Date: **Self Explanatory**

Animal Species: **Self Explanatory**

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

Protocols are approved for a maximum period of three years. Unless there is a specific reason (e.g., a five year funding grant) provide only a 3 year projection.

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.

The Appendix A-1 attachment is to be the abstract of the complete research protocol. This is to be a discussion regarding the animal procedures of the Research Protocol (animal groups, etc; anesthetics not doses)

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

Provide specifics regarding the species/strains anatomy, physiology, etc with references listed.

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

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II ANIMAL SUBJECT DESCRIPTION

Species: **Self Explanatory**
Sex: **Self Explanatory**
Strain/Breed: **Self Explanatory**
Age/Size:

Weights (e.g., 5 to 75 grams, 350 to 375 grams) generally replace age; if multiple groups are to be used list the weights of each group. Note: It is best to be aware of your expected vendor's catalog groupings and use them to avoid PO confusion by the purchasing department.

Source:

Use an approved vendor only and include the exact facility from which you want to receive animals.

Microbial Status (e.g., VAF, SPF, Conventional):

Check your specific vendor regarding its disease control status. Conventional means that the vendor has no disease control programs in effect. Such vendors would never be approved as an animal source.

Number of animals to be used per year: **Self Explanatory**

2000	2001	2002	2003

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

Research Protocols - Generally, a research protocol requires a statistical grouping of animals that is appropriate for the study. There needs to be some description of study groups, test group sizes, and statistical analysis, a statistician should be utilized or the statistical standard for the type of study performed should be referenced.

Teaching Protocols - Teaching protocols require only a statement regarding the number of animals needed for the class (e.g., 1 animal for every two students)

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 ____

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

B. Where are the animals to be housed?

State the room in which the animals are to be held when not undergoing research techniques.

C. What is the current IACUC program accreditation status?

Approved

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

YES _____ NO ____

If yes, state the animal care and use program:

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

2. Other, describe: **(e.g., self-inspected, full approval)**

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

YES _____ NO ____

If no, explain:

NO is not an acceptable selection

IV. EXPERIMENTAL PROCEDURES

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

State the room in which the animal procedures are to be 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 ____

Self Explanatory

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):

   Self Explanatory **(DO NOT give the Anesthetics here)**

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

   If yes, list and classify the hazardous material(s):

   Select one of the listed categories

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

   YES ____ NO ____

   Exclude the fact that the test animals may be anesthetized or given an analgesic for this consideration.

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

State here the anesthetic or analgesics to be used, if so stated in the above procedures description.

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

YES ____ NO _____

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

I.e., is the only procedure performed on the living animal, other than husbandry care, euthanasia for the purpose of tissue collection?

C. Specimen Collection

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

YES _____ NO ____

If yes, proceed to item F. Euthanasia.

This does not relate to surgical procedures, only to tissue/fluid collection.

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

YES ____ NO ____

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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):

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

Self Explanatory

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:

Self Explanatory

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

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

YES ____ NO ____

If no, proceed to Item E.

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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 ____

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

YES ____ NO ____

Self Explanatory

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?

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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?

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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.

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F. Euthanasia

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

YES ____ NO ____ NA _____

Animals used in the study that were not euthanized or did not die during the conduct of the study, what is to be done with these animals? This does not include animals purchased but not used in the study.

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:

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b. Who will perform euthanasia and what is the training and experience with the procedure?

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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.

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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 _____

The key word is "experienced". Above a procedure was considered painful if it would cause discomfort in the absence of measures such as anesthesia, which of course is the reason for giving anesthesia, etc. Pain is considered discomfort

greater than that experienced during routine medical procedures such as usual injections (e.g., not intrathecal, intracardiac, intraocular).

If yes, complete 1. through 3:

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

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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:

This requires a statement regarding the need for conscious, living, sentient animal for your study. Indicating that this procedure is conventional for the protocol performed is good support for your contention that the protocol is necessary. A literature reference IS EXPECTED, listing the database searched and key words used.

Example databases include:

PubMed National Library of Medicine
www.ncbi.nlm.nih.gov/entrez/query.fcgi

PubScience
Pubsci.osti.gov

ScienceDirect
www.sciencedirect.com

PsycInfo (Vale)
www.valenj.org

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:

NO is not an acceptable response

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

YES ____ NO _____

If yes, describe and justify:

Self Explanatory

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:

A locked, secure storage compartment is necessary, as is some method of logging the use of the drug (e.g., a signed Drug inventory book, a signed study log book).

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

YES ____ NO ____

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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:

Yes is not a satisfactory answer for this question.

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