Revised: 9/2007

FORM A

Office Use Only
Date Received: _____ IACUC Number: _____ Use Level: _____

IACUC
PROTOCOL REVIEW FORM

All protocols must be typed. Submit the original and 12 copies to the Office of Research Services, Room 27, 150, City Avenue (610-660-1205). Protocols must be approved by the IACUC prior to the initiation of any investigation or teaching activity involving vertebrate animals. Protocol titles should not exceed two lines of 50 characters each. This protocol form is divided into five sections. Every protocol must contain all sections. **Protocols should be submitted to the Office of Research Services by the 1st workday of the month for IACUC review on the 2nd Thursday of the month.**

Protocol Title: _____

_____

Estimated dates of protocol: From_____ To_____ (Not to exceed 3yrs.)

Funding Source: _____ **Grant #:** _____

Is this protocol part of a funded or non-funded Research, Training, Center, or Program grant? Yes____ No_

If yes, Title: _____ **P.I.:**_____

Principal Investigator: _____ **Dept.:** _____

Campus Mailing Address: _____

Telephone Numbers: Work ( ) _____-_____ Emergency (not work) ( ) _____-_____

E-mail Address: _____@_____

Co-investigator: _____ **Dept.:** _____

Telephone Numbers: Work ( ) _____-_____ Emergency (not work) ( ) _____-_____

E-mail Address: _____@_____

Day to Day Contact Person: _____ **Dept.:** _____

Telephone Numbers: Work ( ) _____-_____ Emergency (not work) ( ) _____-_____

E-mail Address: _____@_____

The signature of each participating department's chairperson is required. If the principal investigator is a department chairperson, the Dean's signature must be obtained. A faculty sponsor must sign for all projects conducted by students and other individuals who have not attained the rank of Assistant Professor.

Department chairperson_____Department_____Date _____

Department chairperson_____Department_____ Date _____

Faculty Sponsor_____Department _____Date_____
***Please note that in the case of an undergraduate/graduate student PI, the faculty sponsor assumes full responsibility for the research**

GENERAL INFORMATION

1. Please assign this protocol a **pain/distress category** using the PHS guidelines. See **Appendix I** for a more complete description. **(NOTE: PROTOCOLS IN CLASSES 3 AND 4 MUST HAVE THE ATTENDING VETERINARIAN'S SIGNATURE.)**

Class 1	Procedures involving little or no animal pain and distress.
Class 2*	Procedures involving mild stress to animals due to procedure or subsequent reactions.
Class 3**	Procedures requiring potentially stressful or painful conditions during the course of the study. You **MUST** provide a scientific justification below as to why you cannot use sedatives or analgesics.
Class 4**	Procedures requiring animals to endure stress or pain during the course of study. If Class 3 or 4, provide justification here.

2. If this protocol is categorized in pain/distress class 3 or 4 above, by law you must consider alternatives. These include less stressful procedures, replacing the species selected with one lower on the phylogenetic scale, and reducing the number of animals you are requesting. Please indicate the source(s) you examined for the alternatives and answer the following questions.
Note: If this is a class 3 or 4 protocol, you must answer question 29 or 36 as appropriate.

Animal Welfare Information Center (AWIC)	Index Medicus
Current Research Information Center (CRIC)	Literature Search
Biological Abstracts	Other (Please specify)

The NIH requires the following information: Date of Literature Search:_____

Years covered in the literature search: From_____ To_____

Key words used in literature search:

3. Clearly explain the **purpose, scope and significance** of the experiment or study. Include all anticipated benefits. Use terms that can be understood by a LAY PERSON without any scientific background. Scientific jargon should be held to a minimum.

4. Provide a BRIEF **description of the proposed research.** Describe in general terms what will be done to the animals; exhaustive detail is not required. The following items should be identifiable: **where the animals will be housed**; **the experimental design (including treatment groups and appropriate controls**); **the endpoint of the experiment**; and **any unusual procedures not covered in any of the GUIDES**.

5. Species and total number of animals needed for this research protocol which will be either procured from outside this protocol (whether from outside the University, i.e., vendors, or transferred from another protocol), or produced within this protocol (breeding). Total animals requested may not exceed the period of 3 years.

SPECIES	NUMBER PROCURED	NUMBER PRODUCED

6. Why must you use the species you have selected? A separate justification must be provided below for each species.

7a. Animal Numbers: What is the scientific justification for the number of animals to be used? In addition, include information such as the number of control and experimental groups, number of animals per group or other reasoning. A table or flow chart describing experimental groups would be helpful. *NOTE: To ensure that the number of experimental animals is "the minimum necessary to produce valid results," OLAW recommends that "a biostatistician review protocols before submission to the IACUC or as part of the IACUC review." When the animals are to be used in any study for which there is no preliminary or pre-existing data (e.g., pilot study, etc.), numbers may also be justified by **(1)** previous experience in publications and other documentation; or **(2)** consultation with experts in the field by name, place, date, qualification, etc.*

7b. Have the animals in this study been used in other protocols? **___Yes ____No**

If Yes, Last date used _____; Protocol #_____

8. Will the animals will be taken out of the animal facility? **___Yes ____No**

If the animals will be outside of the facility for more than 12 hours, the location must be inspected by the IACUC and approved PRIOR to relocating the animals.

a.) Location (Room Number and Building): _____
b.) Will the animals remain alive out of the facility for more than 12 hours? ___Yes ____No
c.) Will the animals be returned to the facility? ___Yes ____No

9. Is an alternative method (tissue culture, computer models, bacterial cultures etc.) which does not require the use of living animals available for this proposed work? **___Yes ____No**

If there is, why must you use animals?

10. Does this research duplicate previous work? **___Yes ____No**

If yes, why is this duplication necessary?

11. Have all personnel involved directly with the animal program participated in the federally mandated training program conducted on the SJU Campus? **___Yes ____No**

List the names of those who have not attended and the date they will attend. (Call the Office of Research Services (610) 660-1271 for information about the training program.)

12. Personnel Qualifications: List the names of the persons performing the animal procedures and their qualifications with these procedures: (surgery, obtaining blood, giving injections, euthanasia etc.). **NOTE: If any of your staff have not received training, contact the Animal Facilities Manager at (610) 660-1271. Students should be identified as such.**

13. At the end of the experiment the animal(s) will be: *(Check the appropriate response(s) and provide the requested information.)*

a.) ___**Returned** to Animal Care Facility via an Animal Turn-In Form (available from the animal facility supervisor).

b.) ___**Transferred** to another protocol via an Animal Transfer Form (available from the animal facility supervisor).

c.) ___**Euthanized** as follows (provide the agent, route of administration, dose and describe how you will assure death has occurred). If the AVMA Guidelines for Euthanasia are not being followed, you must provide a scientific justification. A copy of the guidelines is available from ORS.

d.) ___**Disposal of Remains.** If animal is euthanized, how will animal disposal be handled?

PROTOCOLS INVOLVING POTENTIALLY HAZARDOUS CONDITIONS

* Check all the questions which apply to this protocol.

14. **YES** ___Radioisotopes will be administered to the animal.

ISOTOPE(S)	LICENSE NUMBER	NAME OF LICENSE HOLDER

15. Check all that apply to this protocol:

___Infectious Agents ___Hazardous Chemicals

___Transgenic Animal Development ___Carcinogens

___Human Source Material ___Zoonotic Microbes

All protocols using any of the above materials must include **FORM D** and receive written approval from the OSHA Safety Officer prior to final approval of this protocol by IACUC.

Scientists and their staffs involved in the type of protocols mentioned above and those using sheep and non-human primates are urged to participate in the University's Occupational Health program for animal handlers. Those with immune deficiencies and allergies are also encouraged to enter this program.

16. Will Cells, plasma or other **TISSUES OF ANIMAL ORIGIN** be injected into the animals? ___**Yes** ____**No**

To prevent possible zoonotic disease as well as the spread of rodent disease, all such material FROM A SOURCE OTHER THAN THE COLONY HOUSING THE RECIPIENT ANIMAL must be tested for the presence of infectious agents prior to use. Please provide the results of these tests.

a.) Which procedure (PCR, MAP testing etc.) was done to evaluate this tissue for contamination with infectious agent(s) and which lab did the testing?

ORIGIN OF THE MATERIAL	TEST PROCEDURE(S) PERFORMED	TESTING LABORATORY

b.) Did the results indicated that the material is free of infectious agent. ___**Yes** ____**No**

If NO, what agent is present? (NOTE: This material may still be used but it must be used in a containment suite.)

AGENT:_____

PROTOCOLS INVOLVING SPECIAL CONCERNS

* Check all the questions below which apply to this protocol.

17. Pharmaceutical or better grade medications will be used whenever they are attainable. **___Yes ____No**

18. A PARALYTIC agent is used. **___Yes ____No**

If yes, please provide additional information:

PARALYTIC AGENT	DOSAGE	ROUTE

a.) Give reason why it must be used and precautions you will take to insure the animal does not suffer pain or distress:

19. Does the protocol include the use of PROLONGED RESTRAINT (see **Appendix II** for definition of prolonged restraint)? **___Yes ____No**

If yes, describe the restraint, including duration, and explain here why it must be used.

20. Does the protocol involve the production and harvest of MONOCLONAL or POLYCLONAL ANTIBODIES. **___Yes ____No**

a) ___Yes ____No

I will follow **Appendix III**, "IACUC Policy for Monoclonal Antibody Production" **Appendix IV** "IACUC Policy for Polyclonal Antibody Production in Rabbits" and **Appendix V**, "IACUC Guidelines for the Use of Complete Freund's Adjuvant in Laboratory Animals" as appropriate. If NO, describe here the process you will follow.

b) ___Yes ____No

Will monoclonal antibodies be produced using the mouse ascites method? If yes, you must scientifically justify your use of the ascites method and explain why alternatives that avoid or minimize discomfort, distress and pain (e.g. in vitro methods) are unsuitable. Explain here.

21. Does the protocol involve injection of an agent into the FOOTPAD of animals. **___Yes ____No**

Provide a scientific justification and describe the steps you will take to reduce pain/distress in the animals.

22. Will Complete Freunds Adjuvant be administered? **___Yes ____No**

Scientific justification for use of Complete Freunds Adjuvant:

23. Does the protocol involve BLOOD COLLECTION as a non-terminal procedure. **___Yes ____No**

If yes, See **Appendix VI**. Retroorbital bleeds need prior anesthesia or sedation.

List frequency, route and volume (ml/Kg) of blood to be collected:

24. Will FOOD &/OR WATER DEPRIVATION be used? **___Yes ____No**

If so,

I will follow **Appendix VII**, "IACUC Policy for Food/Water Restriction." **____Yes ____No**

If **NO**, describe here the techniques you will use. Take care to respond to all concerns listed in Appendix VII.

25. Will SPECIAL HUSBANDRY procedures (such as reduced cage sizes, overcrowding, immunocompromised or single-housed animals) be needed? **___Yes ____No**

If yes, provide a complete description and justification.

26. Does the protocol involve the use or development of transgenic animals. **___Yes ____No**

If yes, contact the Office of Research Services (610)660-1271 for additional requirements and submissions.

27. Are there other, non-surgical procedures or treatments in this protocol which have the potential for causing the animal mild pain or distress? **___Yes ____No**

If yes, these procedures must be fully described here. Describe below the process you will follow to minimize that pain/distress. Include the frequency of observation and the endpoint of the experiment.

a) Describe procedures and clinical signs associated with pain/distress:

b) How frequently will you observe the animals and document these observations: (Example twice daily for three weeks)

c) Treatment(s) to provide relief:

DRUG	DOSE	ROUTE OF ADMINISTRATION	FREQUENCY

PROTOCOLS INVOLVING SURGERY

28. Check all of the choices below which apply to this protocol:

    a) ___The animals will recover from anesthesia (SURVIVAL SURGERY).

    b)___The animals will never recover from the anesthesia but surgery is initiated while they are still alive (NONSURVIVAL SURGERY).

    c) ___At least one of the animals will undergo more than one survival surgery (MULTIPLE SURVIVAL SURGERY).

    d)___ The animals are euthanized prior to surgery (TISSUE HARVEST).

29. Species and location where the surgery will be performed:

    SPECIES BUILDING ROOM NUMBER

30. All SURVIVAL SURGERIES must be done in a manner which will maintain a sterile surgical field. **Appendix IX**, "IACUC Guidelines for Rodent Survival Surgery" describes the techniques which must be followed in rodents. All other survival surgeries must be done in IACUC approved facilities using aseptic technique.

    I will follow the appropriate guidelines. ___**Yes** ____**No**

    If NO, explain below how you will prevent infection and justify the deviation(s) from the IACUC Guidelines.

31. List the pre-anesthetic and anesthetic agents, dosages, and routes of administration. (**Appendix XII** provides recommended anesthetics and analgesics for rodents and rabbits.)

    DRUG DOSE ROUTE OF ADMINISTRATION

    Describe below how you will determine depth of anesthesia and how you will provide additional agent(s) as needed.

32. If this protocol involves SURVIVAL OR NONSURGICAL SURGERY, provide a description of the surgical procedure. Include description of the surgical approach, suture materials used and suture patterns for larger animals (rabbits or larger). You may add one additional page if needed.

33. I/we will adhere to **Appendix X**, "IACUC Policy for Postoperative Surgical Care." **___Yes ____No**

If NO, you must explain below how and where you will maintain records which will document adherence to postoperative observation and treatments as stated in the protocol.

34. Please check the appropriate response below and provide the requested details.
Please note that "no analgesia needed" is not an acceptable response:

a) __I will routinely provide postoperative analgesia and other support as described below:

DRUG	DOSE (mg/kg)/FREQUENCY	ROUTE OF ADMINISTRATION

b)__I do not anticipate the need for postoperative support but will observe the animal as described below and provide such support as necessary.

DRUG	DOSE (mg/kg)/FREQUENCY	ROUTE OF ADMINISTRATION

c)___ If signs of pain/distress occur as described in 34d, the animal will be euthanized.

d)__ Characteristics observed and frequency of observation:

1. Signs indicative of pain/distress:

2. Frequency of observation (example-twice daily for 3 days post op):

e) Summary of controlled substances used in this protocol.

DRUG	DOSE (mg/kg)/FREQUENCY	ROUTE OF ADMINISTRATION

CERTIFICATION

I CERTIFY THAT I HAVE PROVIDED AN ACCURATE DESCRIPTION OF THE ANIMAL CARE AND USE TO BE FOLLOWED IN THE PROPOSED RESEARCH/TEACHING ACTIVITY. FAILURE TO REPORT TO THE IACUC CHANGES IN THE PROTOCOL MAY PLACE ME AND THE UNIVERSITY IN VIOLATION OF FEDERAL REGULATIONS. I ASSUME FULL RESPONSIBILITY FOR COMPLIANCE WITH SUCH REGULATIONS AND UNIVERSITY POLICIES BY ALL PERSONNEL INVOLVED WITH THIS PROTOCOL. I ASSURE THAT ALL PERSONS ASSOCIATED WITH THIS PROTOCOL HAVE BEEN APPROPRIATELY TRAINED AND ARE FULLY QUALIFIED TO PERFORM THE PROCEDURES THEY WILL CONDUCT ON THE ANIMALS.

Signature of Principal Investigator

Date

****

REVIEW OF PROTOCOL by the Attending Veterinarian is required for pain/distress PHS Class 3 and 4 protocols and any surgical protocol.

Signature Attending Veterinarian

Date

IACUC No._____

FORM B

OFFICE OF RESEARCH SERVICES
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
REQUEST FOR REAPPROVAL OF RESEARCH INVOLVING LABORATORY ANIMALS

PRINCIPAL INVESTIGATOR:_____ **DATE:**_____
GRANT #:_____ **SPONSORING AGENCY:**_____
TITLE:_____

Please provide the following information for studies conducted since your last approval date_____.

****

1. Is the research identified above still ongoing? **___Yes ____No**
   Please explain status, i.e.: project terminated ____ (termination date_____); not funded ____; withdrawn ____; still in proposal stage ____.

   If required, please explain:_____

2. Are only animal by products used in this research? **___Yes ____No** If yes, sign and date the form below.

3. Have you performed any research involving vertebrate animals during this period? **___Yes ____No**

4. How many animals were studied? Number:_____ Sex:_____
   Species/Strain:_____

5. How many animals were studied in which the research <u>did not</u> cause pain or distress?_____

6. How many animals were studied in which the research <u>did</u> cause pain or distress, but in which analgesics, anesthetics or tranquilizers <u>were</u> administered?___

7. How many animals were studied in which the research <u>did</u> cause pain or distress but which analgesics, anesthetics and tranquilizers <u>were not</u> administered because they would adversely affect the procedures, results or interpretation of the research?_____

8. Has the project changed in any way from the original submission to the IACUC originally and/or since last approval? **___Yes ___No**
   If yes, furnish the complete information of changes on a separate sheet. Any deviation from previously approved numbers, species, procedures, investigators, etc. must be submitted to the IACUC for approval.

9. Are paralytic agents being utilized in this study? **___Yes ____No**

10. Is Complete Freund's Adjuvant used in this study? **___Yes ____No**
   Have you reviewed the IACUC Guide for the use of Freund's? **___Yes ____No**
   If no, explain:

11. Have unexpected animal deaths occurred in relation to this protocol? **___Yes ____No**
    If yes, Number of Deaths:_____, % of Total Number Used:_____%

12. Have you and all personnel, (scientists, students and technicians), working with animals in your laboratory completed the Animal Care Training Program? **___Yes ____No**
   If no, please explain on separate sheet giving specific names of those who have not participates and when they plan to attend.

<u>PLEASE RETURN TO</u>:
Office of Research Services
215MP

_____
Principal Investigator

APPROVED:_____
DATE:_____

_____
Date

IACUC No._____

FORM C

SAINT JOSEPH'S UNIVERSITY
OFFICE OF RESEARCH SERVICES
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

RESEARCH CONDUCTED AT COLLABORATING INSTITUTIONS OR FACILITIES

This face sheet must be typed and utilized by Saint Joseph's University investigators who plan to conduct research testing and testing activities involving vertebrate animals at non-Saint Joseph's University sites. Complete this form, submit one copy of the animal protocol approved by the IACUC at the site where the work will be performed, along with the IACUC approval letter. Protocol titles should not exceed two lines of 50 characters each, or in accordance with sponsor requirements.

Date:_____

Principal Investigator:_____

Protocol Title:_____

_____

Protocol # at site where the work will be performed:_____

Estimated dates of protocol: From:_____ To:_____

Location where animals will be used:_____

Are animals purchased with University funding sources: **___Yes ____No**

If YES, please complete the following information:

Sponsor:_____

Grant #:_____

SJU IACUC Prime # (if applicable):_____

Number of animals charged to this grant: (May not exceed a 3 year period)

Species/Strain	# of animals	Sex	Age	Weight

**If multiple funding sources are planned for this research, please attach to this page, a copy of the protocol and the IACUC approval letter(s) for each application.*

IACUC No._____

FORM D

BIOLOGICAL AND/OR CHEMICAL HAZARDS

You have indicated that your protocol may involve biologically and/or chemically hazardous materials and must be approved by the Institutional Safety Office or the Chemical Hygiene Officer. You must submit a completed copy of this form to Safety Officer or Chemical Hygiene Officer for approval PRIOR to receiving final IACUC approval. Please call 660-1791 if you have any questions or need a recombinant DNA registration document [see (a)5. below].

a) Infectious Agents (including rDNA and human source material) **___Yes ____No**

1. Give agent name(s) below:
   Name:_____
   Name:_____
   Name:_____
   Name:_____
2. Do you use human blood, tissue, cells, body fluids in your research? **___Yes ____No**, If yes, answer #3.
3. a. Have all lab personnel attended Bloodborne Pathogens training within the last year? **___Yes ____No**
   b. Were personnel offered free hepatitis B vaccination? **___Yes ____No**
   c. Is an Exposure Control Plan completed and current for the laboratory? **___Yes ____No**
4. Do you perform tissue culture? **___Yes ____No** If yes, give name(s), designation(s), species, etc. of cell line(s):__

5. Will you be using rDNA constructs that require Institutional Biosafety Committee approval to generate? **___Yes ____No**
   List relevant Registration Document #(s): _____

b) Hazardous Chemicals: **___Yes ____No**

1. Indicate hazard classes and names of chemicals used:
   a. acutely toxic: **___Yes ____No**, _____
   b. reactive: **___Yes ____No**, _____
   c. reproductive hazard**: ___Yes ____No**, _____
   d. carcinogen: **___Yes ____No**, _____
   e. formaldehyde**: ___Yes ____No**
2. Have all lab personnel attended Lab Safety training within the last year? **___Yes ____No**
3. Is the Chemical Hygiene Work Plan current and posted in each laboratory space? **___Yes ____No**

c) Do you infect the animals with or expose them to any agents identified in sections a) or b) above? **___Yes ____No**

d) Complete the table below:

Agent	Dose	Admin. Route	Metabolism	Excretion

1. Is special containment required for animal housing? **___Yes ____No**
   If yes, explain:_____

2. Are special disposal/handling procedures needed for waste, animal bedding or carcasses? **___Yes ____No**
   If yes, explain:_____

3. Do animal handlers require special personal protection or vaccination prior to experimentation? **___Yes ____No**
   If yes, explain:_____