FORM A

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.

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>NUMBER PROCURED</th>
<th>NUMBER PRODUCED</th>
</tr>
</thead>
</table>

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.

<table>
<thead>
<tr>
<th>ISOTOPE(S)</th>
<th>LICENSE NUMBER</th>
<th>NAME OF LICENSE HOLDER</th>
</tr>
</thead>
</table>

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?

<table>
<thead>
<tr>
<th>ORIGIN OF THE MATERIAL</th>
<th>TEST PROCEDURE(S) PERFORMED</th>
<th>TESTING LABORATORY</th>
</tr>
</thead>
</table>

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:

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE</th>
<th>ROUTE OF ADMINISTRATION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE (mg/kg)/FREQUENCY</th>
<th>ROUTE OF ADMINISTRATION</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE (mg/kg)/FREQUENCY</th>
<th>ROUTE OF ADMINISTRATION</th>
</tr>
</thead>
</table>

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.

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE (mg/kg)/FREQUENCY</th>
<th>ROUTE OF ADMINISTRATION</th>
</tr>
</thead>
</table>
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 did not cause pain or distress?  _______

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

7. How many animals were studied in which the research did cause pain or distress but which analgesics, anesthetics and tranquilizers were not 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.

PLEASE RETURN TO:
Office of Research Services
215MP

APPROVED:__________________________

DATE:__________________________

Principal Investigator

Date
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)

<table>
<thead>
<tr>
<th>Species/Strain</th>
<th># of animals</th>
<th>Sex</th>
<th>Age</th>
<th>Weight</th>
</tr>
</thead>
</table>

*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:

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose</th>
<th>Admin. Route</th>
<th>Metabolism</th>
<th>Excretion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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: