University of Missouri-St. Louis Application for Authorization to use Animals in Research or Teaching

The University of Missouri-St. Louis Institutional Animal Care and Use Committee (IACUC) is required by federal regulations to review all projects (research, teaching, or other) involving the use of live vertebrate animals. This includes new or competitive renewal research proposals as well as the use of live vertebrate animals in teaching demonstrations and/or student laboratory studies. This review is necessary for compliance with provisions of the Animal Welfare Act, for federal granting agencies, and for maintaining our accreditation by the American Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Instructions

Using the attached form, a Principal Investigator (PI) or course director must submit a protocol for any research or teaching activity involving live vertebrate animals. The protocol must be approved by the IACUC without restrictions before the proposed use of animals can commence. The IACUC welcomes inquiries during the planning stages about technical or humane aspects of the proposed research or instruction. Early consultation with the attending veterinarian regarding any facet of animal use can reduce the likelihood that protocol approval will be delayed due to questions arising during the protocol review. Please direct any questions regarding animal care to the Office of Research Administration (ORA) or the Chairperson of the IACUC.

The completed **typed** protocol review form (and attached narrative, if applicable), as well as 8 copies, should be submitted to John C. Hancock III at R223 Research Building, (314) 516-5928, or ORA at 341 Woods Hall, (314) 516-5894. All necessary signatures must be obtained before submission. A protocol must be received in the Office of Research Administration (ORA) at least two weeks before the monthly IACUC meeting at which it will be reviewed so that copies can be distributed to all members of the IACUC. The Committee may: 1) approve; 2) approve with conditions imposed; 3) request further information; or 4) disapprove. The investigator/instructor will be notified in writing of protocol disposition by the chairperson of the IACUC. Investigators and course directors are encouraged to submit their protocols for review well in advance of the start date of a proposed study to avoid possible delays in initiation of the study. The IACUC meets only once a month (Contact ORA for meeting dates), and protocols must be received at least two weeks before the IACUC meeting.

Complete all portions of the protocol form up to and including Section D. Complete a copy of Appendix 2 for each individual involved in the study. For sections E - J, complete and <u>submit only those sections</u> that are <u>applicable</u> to your proposed study.

Protocols will be valid for a maximum of three years from the date of protocol approval. Continuation of a project beyond the approved 3-year period will require submission of a new protocol.

Federal regulations require that protocols be updated annually. For this purpose, a two-page Annual Continuation Review form, which requests information about the status of the covered activity, will be sent to investigators approximately one month before the anniversary of the protocol's approval. Any anticipated change in procedures, number of animals to be used, or personnel should be submitted to the IACUC in the form of an amendment to the original protocol <u>before such changes are instituted</u>. The continuation form is also available online from the ORA website (www.umsl.edu/services/ora/IACUC/html).

Protocol Number -
ORA Use Only

University of Missouri - St. Louis Protocol for Review by Institutional Animal Care and Use Committee

Principal Investigator (PI) Name and Title (typed)	PI Department Address / Phone		
PI Signature / Date	PI Home Address / Phone / E-mail Address		
Faculty Sponsor/Department Head Signature / Date (Required for student projects)	Sponsor Name / Title (typed)		
Project Title			
Proposed Start Date (Month/Day/Year):	Proposed End Date (Month/Day/Year):		
Co-Investigator Name and Title (typed)	Co-Investigator Department Address / Phone		
Co-Investigator Signature / Date Co-Investigator Home Address / Phone			
Funding source (grant or contract, agency, departmental funds, or none)			
This application is: NewRenewalModification	If this is a renewal or modification, previous protocol number:		
Biomedical Index Category (see Appendix 1). Mark one, as appropriate:ABCD			
Obtain all necessary signatures before forwarding to the Office of Research Administration, 341 Woods Hall To be completed by the IACUC:			
Reviewed by IACUC:			
Date:			
Signature of Chair, IACUC			
() Approved () Approved pending modification () Disapproved Comments:			

University of Missouri-St. Louis Authorization to use Animals in Research or Teaching

cipal Investigator/Course Director	
of Project:	
licant's Certification	
I am familiar with and will comply with the legal established under federal and state laws and poli Animal Welfare Act, the principles in the U.S. In for the Utilization and Care of Vertebrate Anima Training," and the standards in the "Guide for the	cies, as well as university policies (e.g nteragency Document entitled "Princip Ils Used in Testing, Research, and
I certify that I am familiar with, experienced in, animal manipulations and procedures described the supervision and training of any person who phave made arrangements (documented herein) for knowledgeable and experienced people.	herein; that I assume responsibility for performs work on this project; or that I
I further certify that all the information provided accurate as of the date submitted. Any revisions protocol will be submitted immediately in the forwarded to the IACUC for review.	to animal care and use as outlined in t
Applicant has been trained in the general issues of training program provided by UM-St. Louis or a	
Institution	on Date
and in procedures relevant to this protocol, as do Documentation Log (Appendix 2).	
Signature	Date

	1.	Indicate the person respons	ible for daily supervision	of animal use and	d procedures.
	Nam	ne	Email		
	Lab	Office	Lab/Office	Phone	
	2.	List all additional personne in emergencies. Name	l involved in the project. Work Phone	Record in the ord Office	der to be called Lab
	3.	Complete the training form with handling the animals. approval, a training form (A submitted to ORA.	If new individuals are ac	ded to the protoco	ol after protocol
B. SUMMARY OF PROPOSED ANIMAL STUDY Using the outline below, provide a brief description of the proposed animals. Please use language easily understood by a non-scientist. be appropriate for release by the Office of University Communication general inquiries from outside sources about the study.			<u>-scientist</u> . The de	escription should	
	1.	Specific scientific questions	s addressed (or course fo	cus for a teaching	project):
	2.	General goals and experime	ental design:		
	3.	Significance of the study:			

Provide a brief outline of procedures involving animals:

Proposed start date and time frame for the project:

12/17/2002 page 4

4.

5.

C. ANIMAL USE

1. **Affirmation** that the proposed animal use is not unnecessarily duplicative.

In submitting this protocol, the PI or course director affirms that the proposed animal use does not unnecessarily duplicate previous experiments.

- 2. **Justification** of animal uses, species and numbers.
 - a. Justify the choice of species selected for the project.

- b. Justification of number of animals used.
 - For laboratory studies or field studies with a fixed experimental design, provide justification for the number of animals to be used. Include the definition of experimental groups and the number of animals needed per group. Provide the rationale for determining these numbers, including statistical considerations where appropriate.

2) For field studies involving animal surveys or capture and release, please indicate the optimal numbers of each species that will be surveyed and/or the upper limit on numbers of animals that will be captured. If the number that will be surveyed is contingent on local conditions, so state.

3. Alternatives to potentially painful procedures

The Animal Welfare Act requires that a principal investigator consider alternatives to proposed procedures that may cause <u>more than momentary pain or distress</u> to the animals and that the PI provide a description of methods or sources used to determine that alternatives are not available. Alternatives include refinement of procedure(s) to reduce the amount of pain and/or distress, reduction of the number of animals used, and replacement of animal use with non-animal systems.

		es that may cause more than momentary
		ases searched, literature sources, or other
	ces consulted to determine that no alte	
appr	ropriate to the proposed study exist. $\underline{\mathbf{I}}$	The UMSL-IACUC requires that a literature
sear	ch be performed for all protocols class	sified as a B, C or D Biomedical Index.
	_ Library Resources	MGI – Jackson Lab
	_ MEDLINE/Current Contents	CAAT – John Hopkins
	_ BIOSIS	CRIS
	_ Biological Abstracts	CRISP
	_ Biological & Agricultural Index	Primate Information Center
	_ NIH Grants Database	COS – NSF Grants Database
	_ AGRICOLA	COS – Expertise Database
		-
	Consultation with expert in the fie	ld (Provide details below.)
	both the start-date and end-date of the minimum of 10 years and end in the was searched, list each database and	present year). If more than one database
b.	For each database search indicated a database.	bove, list all keywords used to search the
c.	5	pout alternatives to potentially painful with knowledgeable experts, please identify of their expertise.

- d. Did the search results or consultations indicate that there might be alternative procedures that would be potentially less painful or distressing?
 IF YES, please provide justification for why the alternative procedures are not appropriate for the proposed study.
 - **IF NO**, please acknowledge by typing the PI's initials and including the date of acknowledgement.
- e. Did any of the search results or consultations indicate that there may be appropriate non-animal model alternatives, such as *in vitro* systems, to the use of animals proposed in this protocol?

D. SPECIFIC PROPOSAL

Write a brief but complete description of the proposed use of each species, including procedures. What will be done with the animals? How will they be affected, changed, or altered?

E. NON-SURGICAL PROCEDURES (Include only if applicable.)

- 1. Describe all non-surgical manipulations to be performed on research animals in this study. List probable clinical responses to and potential complications of the experiments. Indicate how these complications will be managed.
- 2. List any anesthetics, analgesics or neuromuscular blocking agents which will be used during non-surgical procedures. **For each species,** list agents, dosage and route of administration. List probable clinical responses to and potential complications of the experiments.

F. SURGICAL PROCEDURES (Include only if applicable.)

1. For Survival Surgical Procedures

For each species, describe in detail the surgical procedures to be used, specifically: pre-surgical preparation, anesthetic regimen (drugs, dosage and route of administration), surgical technique, and postoperative care. If post-operative analgesics are necessary, include name of drug, dosage, route and frequency of administration. If analgesics will not be used, explain why. If analgesics must be withheld, provide scientific justification with references.

a. List probable clinical responses to and potential complications of the surgical procedures. Indicate how these complications will be managed. List who will be responsible for providing postoperative care.

b. If multiple major survival surgeries are planned, provide as an attachment an explicit description of and justification for the medical and/or scientific aspects of the investigation that require the performance of multiple major survival surgeries on particular animal subjects. A major surgical procedure is defined as a surgical intervention that penetrates and exposes a body cavity or one which produces a permanent impairment of the animal's physical or physiological functions.

2. For Non-survival Surgical Procedures (if applicable)

A non-survival surgical procedure is one in which animals <u>do not recover from anesthesia</u>.

For each species, describe concisely the surgical and experimental procedures, including anesthetic regimen to be employed. List agents, dose, and route of administration for each species. Describe how the animal(s) will be euthanized.

G. FIELD STUDIES (Include only if applicable.)

1.	List any permits required and indicate whether they have been obtained.	
2.	List	the study site(s).
3.		field study described will be: (Check all that apply.) Observation of free living animals Live capture and release Non-survival collection.
4.		d Study Techniques. nplete the following questions that are relevant to your project. Please give a short description of observation technique(s).
	b.	Describe method(s) of capture to be used, including devices to be used, frequency with which these devices will be checked, estimated maximum time animals will be restrained before release, and precautions which will be taken to reduce non-target captures.
	c.	If drugs are to be used, indicate which drug(s), reason for use, dosage, route, and frequency of administration, and who will administer drug(s).
	d.	If marking procedures are to be used, please describe.
	e.	If a telemetry package is to be used, describe the weight and size of the total package, type of antennae (including length), and how it will be attached or implanted. Also, describe the procedure for removal of the package from the animal at the end of the study.
	f.	If blood or other tissue samples are to be taken, describe procedure(s) to be used, including number, frequency, and weight/volume of sample(s) to be taken.

Н.	Wil	HAZARDOUS AGENTS (Include only if applicable.) Will any known or suspected hazardous agents be used? (If YES, Place an "X" in the specific categories below).		
		Infectious agents		
		Transplantable tumors		
		Carcinogens		
		Toxic chemicals		
		Radioisotopes*		
		*Please attach documentation of approval by Radiation Safety.		
	1.	List hazardous agents that will be used during the performance of the study. For EACH agent to be used on animals, provide concentration, dosage and route of administration.		
	2.	Describe specific safety procedures to be followed in protecting other animals and personnel from the hazardous agents. Include applicable information regarding approval for use of hazardous agents, e.g., Radiation safety checklist, Material Safety Data Sheets (MSDS) and personal protective equipment (PPE).		
I.		IMAL CARE (Include only if applicable.) Please describe any deviations from standard animal husbandry practices. Please list any specific instructions for the vivarium staff.		
	2.	Will animals be housed on wire-bottom caging for longer than eight months? If <u>ves</u> , please provide scientific justification for the need to house in wire bottom caging versus bedded polycarbonate caging.		

J. EUTHANASIA (Include only if applicable.)

State the technique used for performing euthanasia on each species. Be specific regarding euthanasia agent, dosage and route of administration. If proposed method of euthanasia is not consistent with the recommendations contained within the 2000 (or most recent) Report of the AVMA Panel on Euthanasia (see http://www.AVMA.org), please provide justification. What will be the final disposition of the animals at the end of the study? Provide the names of individuals performing euthanasia.

Appendix 1 BIOMEDICAL INDICES

A Procedures do not induce pain, discomfort or distress greater than that produced by routine injections or venipuncture.

Includes simple procedures such as parenteral injections; blood sampling; physical examinations; live animal evaluations; behavioral testing without significant restraint or noxious stimuli; holding of animals for experimental purposes; nutritional studies; breeding studies; or approved methods of euthanasia which result in rapid loss of consciousness.

B Procedures which may cause **minor** distress or pain of short duration.

Includes nonsurvival surgical procedures performed under general anesthesia; surgical procedures performed under anesthesia that may result in some post-operative discomfort, but no gross anatomical or functional deficits; behavioral experiments on awake animals that involve restraint (less than 4 hours); noxious stimuli from which escape is possible; social isolation or crowding; induction of infection or infestation which is expected to produce mild or no clinical disease; application of toxic agents that do not produce major functional deficits and will result in mild or no clinical disease or discomfort.

C Procedures which may induce **more than** minor distress or pain.

Surgical procedures performed under general anesthesia that may result in significant post-operative discomfort or functional deficit; prolonged periods (more than 4 hours) of physical restraint; noxious stimuli from which escape is not possible; experiments involving extremes in environmental conditions; prolonged restrictions of food or water intake; administration of Freund's Complete Adjuvant.

D Procedures which may induce **severe** distress or pain.

Infliction of severe trauma on unanesthetized animals; permitting recovery of consciousness after severe trauma has been caused under anesthesia; induction of infection which is expected to cause serious clinical disease or death; application of toxic agents that may cause major functional deficits or serious clinical disease; chronic maintenance of a disease/functional deficit where the endpoint is death of the animal; severe chemical or physical injury experiments.

APPENDIX 2 Training Documentation Log

Please complete one form for each individual involved in the project.

Complete only the areas that apply to the current protocol

Each individual listed on this protocol must be aware of responsibilities to the institution and the animals in his/her care. The principal investigator certifies that individuals involved in the project demonstrate competence with techniques described in the protocol including those to minimize animal pain and distress.

Training documentation for (name):

Title of Project:

Principal Investigator:

Procedure	Species *	Training Method**
Animal Welfare issues and the Animal		
Welfare Act		
Occupational Health Issues related to		
laboratory animal work		
Occupational Health Issues related to field		
studies, including rabies where appropriate		
Animal Handling/Restraint		
Identification of Individual Animals		
(as appropriate)		
Euthanasia		
Blood/Tissue Collection Techniques		
Injection Techniques		
Animal Husbandry		
Anesthesia		
Analgesia		
Aseptic Technique		
Surgical Techniques (general)		
Surgical Technique (specific)		
Intraop Care/Monitoring		
Postop Care/Monitoring		
Lab Animal Breeding		
Animal Trapping		
Other Procedures - Please list		

^{*} List all species included in protocol for which training on individual procedures was obtained.

- 1. Training by PI/Lab Staff
- 2. Training by IACUC (i.e. wet labs, videos, seminars)
- 3. Training by Animal Welfare Unit personnel or veterinarian
- 4. Other (please provide brief explanation)

^{**}Specify method(s) of training from the following list: