

Institutional Animal Care And Use Committee (IACUC)
University of California, San Francisco, Box 0962, 415-476-2197

IACUC FULL COMMITTEE APPLICATION TO USE VERTEBRATE ANIMALS IN RESEARCH OR INSTRUCTION

IMPORTANT:

SAVE THIS FORM IMMEDIATELY - BEFORE FILLING IT OUT. After saving it, start Word (or other word-processing program) and open the form from within that program (i.e., do NOT open it from your desktop).

INSTRUCTIONS are highlighted in yellow or another color in this form. If you do not see them on your screen, press the **Hide/Show button** on the Standard toolbar. This button looks like a backward P (paragraph sign). For assistance, call the IACUC office at 476-2197.

PART 1: ADMINISTRATIVE REQUIREMENTS

PRINCIPAL INVESTIGATOR: Name and Degree	University Title	Department
Campus Mailing Address	Phone/Fax /	E-mail
ALTERNATE RESPONSIBLE INDIVIDUAL (Required - Must match Emergency Contact Information form and Section A): Send correspondence? Yes [] No []		
Name and Degree	University Title	Department
Campus Mailing Address	Phone/Fax /	E-mail
CORRESPONDENCE TO: (other than Principal Investigator) (optional): Name and Degree		
	University Title	Department
Campus Mailing Address	Phone/Fax /	E-mail

Contacts & Personnel

PROJECT TITLE

APPLICATION PURPOSE: [] Research [] Instruction [] Other: _____ (e.g. LARC)

APPLICATION TYPE [] New [] Renewal* [] Major Modification*
*Current IACUC # _____ Expiration date _____

Title

PROJECT FUNDING SOURCES TYPE: [] Federal Gov* [] State or Other Gov. [] Other Private [] Industry [] Campus/UC-Wide Program [] Dept. Funds	NAME & NUMBER: Funding Agency Name: Grant or Contract #:
*Note: For new IACUC applications - If the research is (or will be) federally supported, submit through "preview" 1 copy of the "Vertebrate Animals" section from the appropriately matched grant application(s).	CHANGES: If this is a renewal application, are there any funding changes from last year? [] Yes [] No

Funding

SCIENTIFIC MERIT REVIEW

- Has this study been reviewed by the Departmental Review Committee (DRC)? (Attach DRC document) [] Yes [] No
- Has this study been reviewed or will it be reviewed by the NIH? (Attach NIH documentation, when available) [] Yes [] No
- Has this study been reviewed by a funding agency (other than NIH) on the "IACUC List of Funding Agencies That Conduct Acceptable Scientific Merit Review"? (Attach funding agency documentation, if available) [] Yes [] No

Funding

VETERINARY CONSULTATION Name of LARC Veterinarian Consulted	Date of Consult
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REGULATED MATERIALS:

[] Radioactive Materials [] Biological Materials [] Controlled Substances [] Human Tissue

Approval Number: _____

Expiration Date: _____

Will data from this study be used to apply for **Federal Drug Administration (FDA) approval** of a drug or device? Yes [] No []

If yes, contact LARC to ensure that the study is conducted according to FDA **Good Laboratory Practice (GLP)** (G)

Regulated Materials

USE OF HUMAN EMBRYONIC STEM CELLS: The CHR website has more information about the [regulation of human embryonic stem cells](#).

- Will human embryonic stem cells be used under this protocol? Yes [] No []
- If yes, are the human embryonic stem cells on the NIH Human Embryonic Stem Cell Registry? Yes [] No []
NIH Registry Provider Code: _____
- Does this protocol involve the transfer of a human somatic cell nucleus into an animal egg? Yes [] No []
- Does this protocol involve the combination of human embryonic stem cells with an animal embryo? Yes [] No []

CERTIFICATION OF PRINCIPAL INVESTIGATOR

I am thoroughly familiar with this protocol and certify its accuracy. I have read and included one (1) signed copy of the [Principal Investigator's Certification](#) with this application.

Signature

Date

PART 2: BASIC REGULATORY REQUIREMENTS

A. PERSONNEL

=Personnel Information	Species Used in This Project	Years of Experience (for <u>each</u> species listed)	Functional role(s) in this project for <u>each</u> species listed (Check all that apply)							Dates of IACUC Approved Training Courses.	
			SUPERVISION	CARE AND HANDLING	ANESTHESIA	SURGERY	POST-SURGICAL CARE	MONITORING	EUTHANASIA	BRER (No one may be grandfathered for BRER – see instructions.)	Species-Specific (for <i>each</i> species listed) (Enter "grandfathered," if this training is not required - see instructions)
Principal Investigator: Name: Degree & Title: Campus phone: Email:										Date	Date
Alternate Responsible Individual: Name: Degree & Title: Campus phone: Email:											
Name: Degree & Title: Campus phone: Email:											
Name: Degree & Title: Campus phone: Email:											
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Name: Degree & Title: Campus phone: Email:											
Continuation page attached? Yes <input type="checkbox"/> No <input type="checkbox"/>											

Enter in Contacts & Personnel: Functional Roles

Will any of the above listed personnel be responsible for training of personnel?
If yes, identify the trainer(s) by name and the specifics of the training.

Yes No

Contacts & Personnel:
Functional Roles

Trainer Name(s):
Specifics of training provided:

Include with your application one (1) copy of a completed [Emergency Contact Information](#)

Contacts & Personnel

Note: The IACUC must approve any new personnel **prior** to their undertaking any hands-on animal work. For new personnel to an approved study during the year, submit a [Request to Add Study Personnel](#) form to the IACUC office, Box 3002.

B. OBJECTIVES OF PROPOSED RESEARCH OR INSTRUCTION

In clear, concise, non-technical, lay language (i.e., the type of language used in a newspaper article) summarize the background, general hypothesis, experimental plan, and potential relevance of the findings or instruction to human or animal health and/or to the advancement of scientific knowledge. **Note:** Do not include a grant application, journal article or abstract.

Objectives

C. RATIONALE AND ALTERNATIVES TO THE USE OF ANIMALS

Federal regulations require that all investigators provide a narrative describing the rationale for using animals, the appropriateness of the species and the methods and specific sources used to determine that alternatives (e.g. replacement, reduction, refinement) to the use of animals and to the procedures have been considered.

Your narrative must address the following:

1. Explain **why animals are required** for your studies, and why replacements, such as cell culture, are not available to fully replace animals.
2. Explain **why the proposed species** are the most appropriate.
3. The United States Department of Agriculture (USDA) requires that you specify by name at least two sources or databases that you have used to determine:
 - That your proposed research is not unnecessarily or unintentionally duplicative;
 - That alternatives to animal research have been considered, and are not appropriate;
 - That alternatives to procedures that may cause more than momentary or slight pain or distress (as addressed in Section C.5) are not appropriate or available (for Category B and C studies).

Justifications & Alternatives (cont'd)

Identify At Least Two Sources Used:			
Search Site	Date of Most Recent Search	Years Covered	Keywords
1.			
2.			

Justifications & Alternatives

Other Resources (e.g., attendance at meetings, consultation with colleagues)	Date	Topics

Describe the steps you have taken to **reduce the number of animals** in your study (e.g., replacement of animals with *in vitro* procedures, refinement of experimental design, refinement of procedural techniques). Please be specific.

4. Do you anticipate the animals will experience more than momentary, or slight, pain, discomfort or distress as a result of your procedures? **Yes**, but pain, discomfort or distress **will** be relieved. (**Category B studies**), **Please** **Yes**, and pain discomfort or distress **will not** be relieved (**Category C studies**), **Please** **No**
- a) If pain, discomfort or distress **will** be relieved, *briefly* describe the measures you will use (e.g., earliest possible endpoints, anesthetics, analgesics, supportive care).
- b) If pain, discomfort, or distress **will not** be relieved, justify the need for Category C procedures and explain why pain-relieving drugs cannot be used. Your response will be incorporated, verbatim, into an annual report to the USDA and will be available for public release.

Justifications & Alternatives (cont'd)

D. JUSTIFICATION OF ANIMAL USE AND NUMBER OF ANIMALS REQUESTED

Note: Animal use must be kept to the minimum consistent with a sound scientific outcome.

1. For the upcoming year, identify each species and list all of the **experimental groups**.

Species and Experimental Groups	Number of Animals					
	ACQUIRED			BRED		
Species 1 (specify):	Category			Category		
Experimental Groups (list):	A	B	C	A	B	C
Totals for species 1:						
Species 2 (specify):	ACQUIRED			BRED		
Experimental Groups (list):	A	B	C	A	B	C
Totals for species 2:						
Continuation page attached? Yes <input type="checkbox"/> No <input type="checkbox"/>						

Animals

2. As required by federal regulations, describe **the statistical tests** (e.g., power analyses) **and/or other rationales** (e.g., tissue collection needs, breeding efficiency) that you used **to determine the number of animals required**. Please be specific.
Note: The IACUC may require consultation with a statistician from the UCSF [Division of Biostatistics](#) (476-9844).

3. a) Will you be using any animals **transferred** from another PI or protocol? Yes No

b) If yes, have the animals undergone **prior experimental procedures**? Yes No

c) If yes, **describe** the prior experimental procedures, **justify** use of the animals for your research **and submit** a completed [LARC Animal Transfer Form](#) with your application. **Also**, if the animals to be transferred are USDA regulated species and have had prior major operative procedures, complete Appendix 2, question 1.

Animals

Note: Animals **must** be transferred through the LARC Business Office (476-2204), using the LARC Animal Transfer Form. The IACUC must give **advance** permission to transfer animals that have undergone prior experimental procedures.

4. If this is a renewal or modification application, provide a **brief status report**, describe any **unexpected adverse effects on animal welfare**, (including unexpected **phenotypic abnormalities**) and explain any proposed **change in the number of requested animals per year**.

E. LOCATION OF ANIMALS

Animal Housing:	LARC space	<input type="checkbox"/>			IACUC Approval Date (PI Lab Housing)
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	
Survival Surgery:					
Regulated species	LARC space	<input type="checkbox"/>			
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	
Non-regulated species*	LARC Space	<input type="checkbox"/>			
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	
Non-Survival Surgery:					
Regulated species	LARC space	<input type="checkbox"/>			
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	
Non-regulated species*	LARC Space	<input type="checkbox"/>			
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	
Non-Surgical Procedures:					
Regulated species	LARC space	<input type="checkbox"/>			
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	
Non-regulated species*	LARC Space	<input type="checkbox"/>			
	PI space	<input type="checkbox"/>	Bldg(s)	Room(s)	

*rats, mice, birds, fish, frogs, etc.

Note: The IACUC must give **advance** permission if research animals will be used and/or housed in individual laboratories (PI space) more than 12 hours. The IACUC will inspect such locations every 6 months. To request permission, submit the [Request Form to Use Laboratory Housing or Study Areas for Research Animals](#) to the IACUC office, Box 6362.

Locations

PART 3: STUDY PROCEDURES

F. IACUC/LARC STANDARD PROCEDURES

Complete this section if you plan to use any of the [IACUC/LARC Standard Procedures](#) listed below.

1. Standard Procedures (Check all that apply).

- Tissue collection from animals euthanized under this protocol only (must adhere to the [2000 AVMA Panel on Euthanasia, 6th edition](#))
- Vascular perfusion with fixatives for tissue collection
- Production of genetically modified (transgenic, knock-out, knock-in) mice
 - I will be producing genetically modified mice at UCSF and I will follow IACUC/LARC Standard Procedures
 - I will be outsourcing to: Facility: _____, Contact Name: _____, Phone: _____
- Collection of tissues for genotyping
- Rodent identification - Specify method(s):
 - Metal ear tags
 - Ear notch punch
 - Tail tattoo
 - Electronic transponders
- Gonadectomy in rats and mice
- Renal capsule grafting in rats and mice
- Production of subcutaneous tumors in rats and mice
- Antibody production
 - I will be producing antibodies at UCSF and I will follow IACUC/LARC Standard Procedures
 - I will be outsourcing to: Facility: _____, Contact Name: _____, Phone: _____
- Implantation of osmotic pumps
- Retro-orbital bleeding of rodents
- Collection of Xenopus oocytes

NOTE: **ONLY** those techniques listed above are IACUC/LARC Standard Procedures. You **must** follow the procedures, as **specified**, or you will be out of compliance. Any variation must be described and justified in Section F.2, below, and **approved by the IACUC**.

2. Describe and justify any **proposed variations** of the IACUC/LARC Standard Procedures for the current application.

IACUC/LARC
Standard Procedures

G. PROCEDURES INVOLVING LIVING ANIMALS

- For each experimental group defined in Section D.1, describe all procedures to be carried out on living animals through euthanasia. Specify the duration of each procedure and how long the animals will survive. A table involving live animals is usually the clearest and most efficient format.
- If you are using ONLY IACUC/LARC Standard Procedures (see Section F, above), or are using them in addition to experimental procedures, do not describe the IACUC/LARC Standard Procedures in detail, but indicate which experimental groups (in Section D.1) are involved and when.

Procedures

H. ADMINISTRATION OF ANESTHETIC, THERAPEUTIC AND EXPERIMENTAL AGENTS

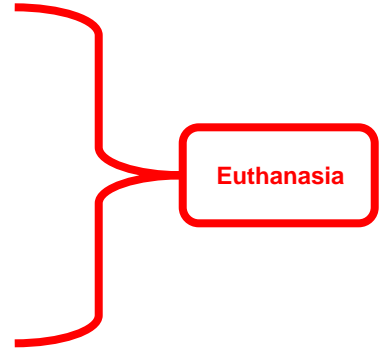
- List all anesthetic, therapeutic drugs and experimental/study agents administered to live animals. Express dosages as a range and as mg/kg, wherever possible.

Animal Species	Agent	Dose Range (mg/kg)	Route	Frequency & Total Duration
	Pre-anesthetics (if applicable):			
	Anesthetics:			
	Therapeutic Agents (analgesics, antibiotics, etc.)			
	Experimental Agents:			
Continuation page attached? Yes <input type="checkbox"/> No <input type="checkbox"/>				

Agents: Pre-Anesthetics and Anesthetics, Neuromuscular Blocking Drugs, Therapeutics, Analgesics, Experimental Agents

K. EUTHANASIA

1. Will you be following [IACUC/LARC Guidelines](#)?
Check all that apply:
 - Standard Euthanasia Guidelines for Large Animal (Non-Rodent) Species
 - Standard Euthanasia Guidelines for Rodents
2. Describe the methods of euthanasia for each species.



PART 4: APPENDICES

COMPLETE AND SUBMIT APPENDIX 1, 2, 3 AND/OR 4 ONLY IF APPLICABLE

APPENDIX 1. PHYSICAL RESTRAINT OF CONSCIOUS ANIMALS

Complete this section if animals will be restrained, **except** when the restraint is for a **brief examination, sample collection, or injection**.

1. Species and number of animals that will be restrained:
2. Duration and frequency of the restraint:
3. Describe the type of restraint that will be used.
4. Justify your need to restrain unanesthetized, unsedated, or untrained animals.
5. Describe how, and how frequently, the animals will be monitored during the period of restraint.
6. Specify what will be monitored.

Physical Restraint

APPENDIX 2. REPORTABLE EXCEPTIONS

If any of the listed procedures or situations pertain to **any** of the animals in your study, justify its use in the applicable section.

Note: For USDA-regulated species, your answer will be used, verbatim, in an annual report to the USDA.

1. Use of an animal in more than one protocol involving a major operative procedure from which it is allowed to recover
2. Restriction of food or water (e.g. inadequate nutrition and/or making feed available less than once a day and/or making water available less than twice a day for an hour each time).
3. Maintaining animals at temperatures and/or humidities outside the standard specified ranges
4. Not cleaning and/or sanitizing at required frequencies
5. Not providing diurnal lighting as required
6. Not meeting space requirements (including innovative enclosures)
7. Exceptions from the exercise plan for dogs or exceptions from the psychological well-being plan for primates

Reportable
Exceptions

APPENDIX 3. TISSUE SHARING

The IACUC encourages tissue sharing as a means of minimizing the use of living animals.

1. Complete the table if you are willing to make animal tissues available to other investigators.

Species		Species	
Strain		Strain	
Sex		Sex	
Age		Age	
Weight		Weight	
Tissues not available		Tissues not available	
Form of euthanasia		Form of euthanasia	
Describe tissue alterations due to your study.			
Species		Species	
Strain		Strain	
Sex		Sex	
Age		Age	
Weight		Weight	
Tissues not available		Tissues not available	
Form of euthanasia		Form of euthanasia	

Tissue Sharing / Live
Animal Disposition

2. Provide name and telephone number of contact person to discuss tissue-sharing arrangements:

APPENDIX 4. LIVE ANIMAL DISPOSITION

The IACUC encourages finding alternatives to euthanasia or "warehousing" of healthy animals no longer participating your study (e.g., transfer to other protocols or investigators, make available for adoption, transfer to primate colony).

Describe your plan, if you are willing to make live animals available after your study.