

LOMA LINDA UNIVERSITY HEALTH IACUC #

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) RADIATION SAFETY COMMITTEE (RSC) Application Form

RESEARCH PROTECTION PROGRAMS

Loma Linda University • 24887 Taylor St, Suite 202 • Loma Linda, CA 92350 (909) 558-4531 (voice) / (909) 558-0131 (fax)

IMPORTANT! PLEASE NOTE: After completing this application, email a draft to <u>*iacuc@llu.edu*</u> for the required administrative prescreening. Once the application is accepted for submission to IACUC, provide a signed application to the Research Protection Programs. Please use at least a 10-point font. Handwritten forms are not accepted.

1.0 Investigators

1.1 Principal Investigator (last name, first name, MI, degrees)	Dept./S	ection	Ext.	LLU-em	nail		Academic Rank
1.2 Co-Investigator, Co-PI, or technician	Ext.	LLU-email			FAX	Campus mai	ling address
familiar with day-to-day operations:							g
1.3 Individual completing this form on behalf of the PI:	Ext.	LLU-email			FAX	Campus mai	ling address
1.4 TITLE OF PROJECT						·	
1.5 Grant funding title if different from 1.4							
1.6 Project Type	Teach	nina 🗌 Studer	nt Project	Product	Testing [Field Study	Other

1.7 Project Roster: Personnel with animal contact. Provide the names of all the individuals working with live vertebrate animals on this project. Include all investigators, students, post-doctoral fellows, staff research associates, post-graduate researchers, and laboratory assistants who will actually work with the animals, including those from other institutions that may come here for collaboration. Do not include staff of the Animal Care Facility (ACF) unless they are active participants in the proposed research plan.

Note: The principal investigator is responsible for keeping this roster updated and amending the protocol when staff are added to or removed from this project. Change Requests must be submitted in writing to the IACUC and must be approved prior to implementation.

Training, experience, and role relevant to the procedures described in this protocol.				
t	his protocol.			

Last Name, First Name, MI, degrees	Status	Department/Institution (if not LLU)		
Phone number and e-mail address:				
Training, experience, and role relevant to the procedures described in this protocol.				

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Last Name, First Name, MI, degrees	Status	Department/Institution (if not LLU)		
Phone number and e-mail address:				
Training, experience, and role relevant to the procedures described in this protocol.				

1.8 Project Roster: Personnel with no live animal contact. Provide the names of all the individuals responsible for the design, conduct, or reporting of this project. For IBC purposes, include those who will be working with tissues or euthanized animals.

Note: The principal investigator is responsible for keeping this roster updated and amending the protocol when staff are added to or removed from this project. Change Requests must be submitted in writing to the IACUC and must be approved prior to implementation.

Last Name, First Name, MI, degrees	Status	Department/Institution (if not LLU)
Phone number and e-mail address:		
Role in the design, conduct, or reporting of the study.		

Last Name, First Name, MI, degrees	Status	Department/Institution (if not LLU)
Phone number and e-mail address:		
Role in the design, conduct, or reporting of the study.		

Last Name, First Name, MI, degrees	Status	Department/Institution (if not LLU)
Phone number and e-mail address:		
Role in the design, conduct, or reporting of the study.		

Last Name, First Name, MI, degrees	Status	Department/Institution (if not LLU)
Phone number and e-mail address:		
Role in the design, conduct, or reporting of the study.		

1.9 Training. [This application cannot be approved without completion of the Animal Care and Use Training (ACUT), Occupational Health program.]A. Animal Care Facility will provide

3 Revised: 07/21/15

- (1) LLU Animal Care and Use Training and Education program for all personnel participating in research involving animals before initiating animal research activities. Enrolling in the Occupational Health Program is one component of the training program.
- (2) Specific training related to procedures in the study, e.g., anesthesia, euthanasia, etc.

B. Office of Environmental Health and Safety will provide

- (1) Blood-borne Pathogens Training for personnel working with human tissue and/or blood products.
- (2) Compressed Gas Training for personnel working with compressed gases.
- (3) Shipping Dangerous Goods Training for personnel who will be shipping any dangerous goods, including, but not limited to, infectious or toxic substances, dry ice, and flammable materials.
- (4) Laboratory Safety Training for all personnel working in laboratories.

2.0 Certification Statements

2.1 Principal Investigator

I have read and agree to abide by the policies outlined in the LLU Manual for Those Who Use Animals. This project will be conducted in accordance with all applicable laws, policies, and regulations governing the use of animals including:

- 1. PHS Policy on Humane Care and Use of Laboratory Animals.
- 2. Animal Welfare Act (7 USC 2131 et Seq.) and Animal Welfare Regulations (9 CFR Parts 1,2, 3)
- 3. The Guide for the Care and Use of Laboratory Animals
- 4. LLU Animal Welfare Assurance of Compliance with PHS on Humane Care and Use of Laboratory Animals.

These proposed research activities will not unnecessarily duplicate previous experiments.

I will obtain approval from the IACUC before initiating any change in the study design, procedures, or personnel by submitting a written request to IACUC for approval.

I will ensure that all personnel are adequately trained in: (1) the handling and restraint of all species used, and (2) the experimental procedures used. I will ensure that my instructions are followed and that all personnel are thoroughly familiar with the contents of this protocol. I will also ensure that all staff, students, and collaborators working with animals in this protocol are enrolled in the LLU Animal Users Occupational Health Program.

U will notify the IACUC regarding any unexpected study results that negatively impact the welfare of the animals, including, but not limited to, those that require veterinary care or treatment not described in the approved protocol.

U will consult with the Attending Veterinarian when animal procedures are classified in pain category C, D, or E.

I will notify the Attending Veterinarian when unanticipated pain/distress, morbidity, or mortality occurs with animals approved for use under this protocol. I recognize that the veterinary staff will contact me as soon as possible using the emergency contact information that I provide in this application, but I understand that such contact may not always be possible prior to providing treatment or performing euthanasia.

I will instruct all personnel in my laboratory that they must inform me if they believe that the treatment of any research animal is inappropriate. If the situation is not resolved or they do not feel comfortable discussing it with his or her supervisor, the individual should consult with the Director of the Animal Care Facility (ext. 44316), the Chair of the IACUC c/o Research Protection Programs (ext. 44531), or the Director of Research Integrity (ext. 88166), or a complaint may be made anonymously through the Compliance Reporting Line, at 800-249-9953.

Principal Investigator Signature

Title

Date

2.2 Department Chair of Principal Investigator

This project has been reviewed for scientific merit and has the academic endorsement of this department.

Department Chair Signature

Printed Name

Date

3.0 Funding Source(s)

3.1 List sources of funding:

(a)

(b)	
The above are: For profit Non-profit Government Internal Funds	
Grant Number Banner Number	LLeRA Number

3.2 For non-governmental funding provide the following:

	Sponsor Name
	Address
Ī	Contact name, title, and phone number
A.	Does the sponsor expect you to provide an interim or final report of the research results? No. Yes.

B. Is the sponsor covering all of the expenses related to this study? Yes. No. If "No", identify the source of the remaining funds.

Source, contact name, and phone number:

C. Contract Information. Describe below.

3.3 Research Conflict of Interest. All personnel responsible for the designing, conducting, or reporting of research must complete training and submit a disclosure. Forms are located at http://www.llu.edu/assets/research-affairs/docs/research-coi-training-chart.pdf

Note: IACUC approval of protocol will be delayed when disclosures are not submitted. IACUC notification of approval will be coordinated with the review of potential conflicts by the Research Conflict of Interest Committee.

4.0 Project Summary

- 4.1 Abstract. (In 250 words or less, describe the purpose, the procedures, the number of animals and pain category, and what is expected to be accomplished).
- **4.2** Lay Summary. Using simple terms (non-technical, newspaper language, high school vocabulary), briefly summarize the purpose (objectives) and potential benefits (significance) of this project. *Details of scientific methods are not required here.*

5.0 Animal Care

5.1	Animal Husbandry Requirements. Please check one. 🗌 Standard care 🗌 Special husbandry requirements (Describe below, e.g., special
	food, water, temperature, humidity, light cycles, caging type, and bedding).

5.2 Animal Housing

Location:	Day use only (<12 hrs.):	
Animal Care Facility Space Allocation (Contact animal care) ¹	Approved Pend	ing 🗌 Not Applicable
Animals will be maintained by: ACF Investigator (at	<i>ttach husbandry SOP</i>) 🗌 Oth	er (<i>attach husbandry SOP</i>)

5.3 Environmental Enrichment. Animal Care Facility will provide environmental enrichment for all laboratory animals (e.g., social housing, tubes, hide boxes, foraging supplements) in accordance with Federal Regulations. If environmental enrichment is not suitable for your research protocol, justify below.

¹ Contact the Attending Veterinarian at the Animal Care Facility, ext. 44316, for current information about training and record keeping requirements.

5.4 Instructions for Animal Care staff (check applicable)	
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Sick An Call Investigator Veterinarian to tre Terminate Necropsy	Call Investigato	gator		Pest Control Call Investigator OK to use pesticides No pesticides in animal area
5.5 What veterinari	an or veterinary clinic will provide care f	for your	animal	ls?
Attending Veterin	arian Other Veterinarian, comple	te below	ľ	
*If you checked "othe	r veterinarian," provide the following:		r	r1
Veterinarian name		Ad	ldress	
Day phone			Fax	
Emergency phone			Email	
5.6 Personal Protect	tive Equipment (PPE) required for anima	al room		
Select appropriate ite	ms to be worn or used in the animal room:			
	Lab Coat/Coveralls		Shoe C	Covers/Booties
	Disposable or Utility Gloves		Head C	Cover
	NIOSH Certified Dust Mask		Disinfe	ectant footbath
	Eye/Face Protection			
	NIOSH Certified Fitted Respirator – type:			

Other; describe:

6.0 Research Animals

6.1 Species

Common name & strain	Sex	ex Number of animals to be used each year				
		Year 1	Year 2	Year 3	3 Yr. Total*	Source*
Total number of animals						

*Indicate if animals are from a breeding colony maintained by your lab or from time-pregnant mothers. If animals are from breeding colonies, indicate how animals will be selected and indicate what will happen to the animals not used in the study.

6.2 Study Groups and Numbers. The number of rows should correlate with the number of study groups in your Experimental Procedures. You may add as many rows as needed. The chart must fully account for the number of animals to be used in this protocol.

Study Group	Procedures & Drugs	No. of Animals	Pain and Distress Category (B-E)
	Total number of animals (this must equal the total from section 6.0)		

Note: If the pain level is Category C, D, or E, a veterinary consult is required prior to submission to IACUC.

Name of Veterinarian:

Date of Consult:

- 6.3 Species rationale. Provide the rationale for the species chosen, any considerations given to the use of non-mammalian or invertebrate species, or the use of non-animal systems (e.g., cell or tissue culture or computerized models). Cost should not be used as a justification, except as a means to choose among species that are equally well-suited for the proposed project. For a field study, explain how this work will benefit the particular species or population under study.
- 6.4 Animal numbers justification. Explain how you arrived at the number of animals required. If preliminary data is available, and if relevant, use a power analysis or other statistical method to determine the number of animals needed. For studies in which a statistical method such as a power analysis is not appropriate (e.g., pilot studies or tissue collection), briefly describe how the number of the requested animals was determined. Additionally, describe the consideration given to reducing the number of animals required for this study. This could include any *in vitro* studies performed prior to the proposed animal studies.
- 6.5 Transgenic/Knockout Animals. Will genetically modified animals be used? No. Yes. If yes, please identify the specific modifications below. Describe any phenotypic consequences of the genetic manipulations to the animals that may affect their clinical presentation or cause them to require special care.
- 6.6 Describe any precautions that must be taken to protect animals, ACF staff, or researchers.
- 6.7 Provide a complete description of the surgical procedure(s), including anesthesia, analgesia, and/or neuromuscular blocking agents. If the procedure(s) will be performed by ACF staff or veterinary staff with an established, IACUC-approved SOP, identify the SOP title.
- 6.8 Field Studies: If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any anticipated special procedures. You must also complete Section 12.

7.0 Project Details

- 7.1 Project Objectives and Significance. Provide a brief description of the objectives and significance of the study.
- 7.2 Experimental Procedures. Describe the use of animals in your project in detail. Use terminology that will be understood by individuals outside your field of expertise. Describe all animal procedures in a logical progression, beginning with the receipt of the animals and ending with euthanasia or the study endpoint.
- 7.3 List each study group and describe all the specific procedures that will be performed on each animal in each study group. Supply a flowchart or algorithm to help the committee understand your research study.

7.4 Is the protocol for NIH funded research? No. Yes. For an NIH funded grant, attach the relevant animal-related pages from your grant application. This will allow the IACUC to compare the protocols with the animal work that is proposed in your grant as is required by Public Health Services policy.

8.0 Surgery

- 8.1 Was surgery indicated in section 7.1 above? No. If no, skip sections 8.2- 8.4, and move on to section 8.5. Yes. If yes, complete the following:
- 8.2 Where will the surgery be conducted?

Building:	Room:	
Who will perform the surgery?		
8.3 Will you have multiple major su procedures.	irgical procedures? No. Y	es. If yes, provide scientific justification for multiple major surgical

8.4 Will you have anesthesia monitoring? No. Yes. If yes, describe physiologic parameters monitored during the procedure to assess adequacy of anesthesia and under what circumstances additional anesthesia will be administered.

8.5 Will you have post-surgical monitoring? No. Yes. If yes, complete the following:

List the physiologic parameters that will be monitored, at what interval(s), and for what duration.

When will analgesics be administered and at what interval(s)? *Note: Post-procedural analgesics should be given whenever there is possibility of pain or discomfort that is more than slight or momentary.*

If post-operative analgesics cannot be given, provide scientific justification.

8.6 Will you use drugs and experimental agents, including research agents, anesthetics, analgesics, tranquilizers, neuromuscular blocking agents, and antibiotics?

□ No. □ Yes. If yes, complete the following:

Species	Drug	Dose (mg/kg)	Route	When and how often will it be given?

8.7 Will neuromuscular blocking agents be used? Note: These can conceal inadequate anesthesia and therefore require special justification.

No. Yes. If yes, complete the following:

Why do you need to use a neuromuscular blocking agent?

What physiologic parameters will be monitored during the procedure to assess the adequacy of anesthesia?

Under what circumstances will incremental doses of anesthetics or analgesics be administered?

8.8 Adverse effects. Describe all significant adverse effects that may be encountered during the study, such as pain, weight loss, discomfort, reduced growth, fever, anemia, neurological deficits, behavioral abnormalities, or other clinical symptoms of acute or chronic distress or nutritional deficiency. If genetically-altered animals are used, describe any potential adverse effects that could be associated with the desired genotype, if known.

9.0 Monitoring

- 9.1 Describe criteria for monitoring the well-being of the animals in the study. Also, if adverse effects are observed, what criteria will be used to terminate/modify the procedure(s)?
- 9.2 How will the signs listed in section 8.8 be ameliorated or alleviated? Or provide scientific justification if these signs cannot be ameliorated or alleviated.

IMPORTANT! *Note:* If an unexpected, significant adverse, effect occurs (including the death of animals), a complete description of the event and the steps taken to alleviate the adverse effect must be reported to the IACUC as soon as possible.

10.0 Disposition of Animals

10.1 At what point in the study, if any, will the animals be euthanized?

- **10.2 Describe the method used to ensure the animal will not revive**. Some examples of appropriate methods are removal of the heart, induction of bilateral pneumothorax, or observation of rigor mortis.
- **10.3 Is death an endpoint**² in your experimental procedure? No. Yes. If yes, explain below why it is not possible to euthanize the animals at an earlier point in the study. If you can euthanize the animals at an earlier point, describe the clinical signs that will dictate euthanasia.
- **10.4 Methods of euthanasia** In the event of unanticipated injury or illness, describe the method(s) of euthanasia below. If anesthetic overdose is the method, specify the agent, dose, and route.

Species	Method	Drug	Dose (mg/kg)	Route

10.5 What will be done with any animals not used at the conclusion of the project?

- Euthanized by methods outlined in 10.4 above
- Euthanized by other methods (specify):

² "Death as an endpoint" refers to acute toxicity testing, assessment of virulence of pathogens, neutralization tests for toxins, and other studies in which animals are not euthanized, but die as a direct result of the experimental manipulation.

Returned to production/breeding unit (*Note: Current breeding protocol required.*)

Returned to wild (*Note: Permits required*)

Transferred to another approved protocol IACUC#

Other (specify):

11.0 Alternatives and Unnecessary Duplication

11.1 Literature Search. *Note:* Federal law explicitly requires the investigator to conduct a literature search to determine whether (1) there are any alternative methodologies by which to conduct this project, or (2) there are alternative methodologies, but these are not appropriate for your particular project. "Alternative methodologies" refers to reduction, replacement, and refinement (the three R's) of animal use, not just animal replacement.

Date on which you conducted this search (must have been within the last six months):



List the databases searched or other sources consulted (a minimum of two databases/sources). Include the years covered by the search.

Database/Source Name	Dates Covered	Keywords / Search Strategy

11.2 Result of search for alternatives. Comment on the application(s) of any identified alternatives, including how these alternatives may or may not be incorporated to modify a procedure to either lessen or eliminate potential pain and distress.

11.3 Has this study been conducted previously? No. Yes. If yes, explain why it is scientifically necessary to replicate the experiment.

12.0 Field Studies

- 12.1 Do you have a field location? No. If no, skip the rest of Section 12 and move on to Section 13. Yes. If yes, describe the location(s) of the field sites including the name of the country and the specific regions.
- 12.2 Will animals be held for periods of longer than 24 hours? No. Yes. If yes, describe the temporary holding facilities, how long the animals will be held, where they will be held, and who is responsible for their care.
- 12.3 Will animals be held for periods of less than 24 hours? No. Yes. If yes, specify below the duration, and describe the temporary holding facilities.

12.4 Permits and Authorizations. Are local, regional, or national permits or authorizations required for the observation, capture, transportation, data collection, or other proposed activity involving these animals? \square No. \square Yes. If yes, provide the following, and attach copies of approval:

Agency	Contact person	Phone number or email	Permit or Authorization number	Dates of approval

12.5 Will animals be transported from one location to another or from field to LLU? No. Yes. If yes, provide point of origin, final destination, method of animal transport, procedures used to protect animals, and the person responsible for transport.

12.6 Will animals be released? No. Yes. If yes, describe the location of release and indicate whether permits are required

Location of release	Are permits required?

13.0 Transfer of Materials

13.1 Will research material be transferred into or out of LLU for this project? No. Yes. If yes, a Material Transfer Agreement signed by an institution representative will be required, if it is not already included in another agreement. Complete either the incoming or outgoing MTA request available at: <u>http://www.llu.edu/research-affairs/transferring-research-data-and-materials.page</u>

13.2 Will any materials be brought in from a foreign country? 🗌 No. 🗌 Yes. If yes, describe the material, origination of the material

Note: Questions regarding Material/Animals Transfer Agreements (MTA) should be addressed to Research Affairs Financial Management, ext. 43947.

14.0 Human Stem Cells

14.1 Does this project involve the use of Human Stem Cells? 🗌 No. If no, skip the rest of Section 14 and move on to Section 15.0.

Yes. If yes, answer the following three questions:

1. Does this project involve the creation or use of human embryonic stem cells?
No. Yes.

2. Does this project use human induced pluripotent stem (iPS) cells derived from humans using genes or proteins? 🗌 No. 🗌 Yes.

3. Does this project involve transplantation of human neural stems cells into laboratory animals? No. Yes. If yes, indicate the number of cells, the route of injection or transplantation site, and the stage of development of the recipient.

If any questions in Section 14.0 are marked "yes", a review by the Embryonic Stem Cell Research Oversight Committee (ESCROC) may be required.

15.0 Radiation and Lasers

15.1 Provide the following information about the use of radiation and lasers.

Does this protocol involve the use of ionizing radiation (e.g., radioactive materials, diagnostic x-rays, radiation therapy dosages)?	Yes No
Does this protocol involve the use of non-ionizing radiation (e.g., electric fields, magnetic fields, RF, microwaves)?	Yes No
Does this protocol involve the use of lasers?	Yes No

If any questions in section 15.0 are marked "yes," complete Section 15.1. *Note:* A review by the Radiation Safety may be required. If not, skip and move on to Section 16.0.

Note: Contact Radiation Safety at ext. 44913 for assistance.

15.2 Radiation/Laser Use Details. Provide a brief description for the items listed below.

1. Description of use, including type of radiation (e.g., x-ray machine / isotopes / non-ionizing / lasers):
2. Location of use:
3. Dose to be delivered:
4. Description of irradiation procedures:
5. Any unusual hazards related to this procedure:
6. List the name(s) and qualifications of the person(s) performing irradiations:

16.0 **Biological and Hazardous Materials**

16.1 Will your work involve recombinant or synthetic nucleic acid molecules?

□ No. □ Yes. If yes, specify below.

What is/are the plasmids?

What is/are the host(s)?

What is/are the vector(s)?

What gene(s) have been or will be cloned?

What is/are the source(s) of the recombinant DNA or RNA?

What Animal Biosafety Level (ABSL) will be applied to your work in regards to the Section above?

16.2 Experimental Procedures using recombinant DNA or RNA. Provide all relevant details of your research design and methods pertaining to your work with recombinant DNA or RNA.

16.3 Will you work with any microbes, prions or toxins? No. Yes. If yes, specify below.

Microbe, Prion or Toxin	Biosafety Level ³	Contai Used⁴	inment E	quipme	ent	Most recent certification date for BSC or any type of hood:
		BSC	CFH	OB	Other:	
Example: <i>E. coli</i> K12	BSL 1					
1.	BSL					
2.	BSL					
3.	BSL					
4.	BSL					
5.	BSL					

16.4 Additional personal protective equipment. List the additional personal protective equipment (PPE) not mentioned in section 5.5 that will be used when working with the microbe and/or toxins.

16.5 Will you work with human blood, blood components, body fluids, organs, or tissues? 🗌 No. 🗌 Yes. If yes, specify below.

Material	Source
Will human material be handled in a biological safety cabinet	? No. Yes. If yes, specify the certification date of BSC : / /

No. Yes.

Will human material be handled on the open bench?

⁴ Abbreviations: BSC, Biological Safety Cabinet; CFH, Chemical Fume Hood; OB, Open Bench

³ See website http://www.cdc.gov/od/lhs/pdfiles/4th%20BMBL.pdf for description.

16.6 Indicate how you will apply Universal Precautions to your work with human materials.

16.7 Will you work with cell lines? No. Yes. If yes, specify the materials below.

Material	Source

16.8 Will animals be transported through public or patient hallways? No. Yes. If yes, describe specifics:

Note: Click here to download required protocols for animal use in patient areas: <u>Application for Use of Ionizing Radiation in Protocols Involving</u> <u>Animals</u> and <u>Protocol for Cleaning up after Animals at the Proton Treatment Center</u>.

Contact Environmental Health and Safety or Institutional Biosafety Committee (ext. 44999) for assistance.

17.0 Chemicals

17.1 Will you be using any anesthetic gases? No. Yes. If yes, describe.

17.2 Will you be using any other compressed gas(es)? No. Yes. If yes, describe.

17.3 Will you be using any cryogenics, such as dry ice or liquid nitrogen? No. Yes. If yes, describe.

17.4 Will you be using any physical agents, such as heat, high voltage, noise or vibration? 🗌 No. 🗌 Yes. If yes, describe.

17.5 Will you be shipping any biological materials? No. Yes. If yes, describe.

17.6 Will you be shipping any hazardous materials (for purposes of shipping, hazardous materials include explosives, gases, flammable liquids, flammable solids, spontaneously combustible substances, self-reactive substances, oxidizers and organic peroxides, toxic materials, infectious materials, radioactive materials, corrosives, and dry ice)? \Box No. \Box Yes. If yes, describe.

IMPORTANT! *Note:* Federal law⁵ requires each laboratory to maintain its own individual Chemical Hygiene Plan. A general Chemical Hygiene Plan for Loma Linda University and related entities can be found on the LLUAHSC Environmental Health and Safety Website. Ensure that you have Material Safety Data Sheets for all the chemicals that you will be using in this protocol.

⁵ See <u>www.osha.gov</u>, "Laws & Regulations"; "Standards"; Part 1910.1450