CSULB IACUC PROTOCOL APPLICATION #_____

THE PROJECT

I. PROJECT DATA

A. DATE: Click here to enter a date.

B. NAME OF PRINCIPAL INVESTIGATOR (Section Instructions): Click here to enter text.

1. eMail: Click or tap here to enter text.

2. Phone Number: Click or tap here to enter text.
Please provide best contact number

C. PROJECT TITLE (Section Instructions): Click here to enter text.

D. EXPECTED PROJECT DATES (Cannot exceed 3 years) Section Instructions
From Click here to enter a date. To Click here to enter a date.

E. STATUS:

☐NEW ☐Renewal of IACUC #: Click here to enter text.

☐Protocol previously reviewed at another institution: Click here to enter text.

F. FUNDING SOURCE (if applicable, Section Instructions): Click here to enter text.

G. PROJECT TYPE (Section Instructions): Click to choose an item.

(If protocol is for observational purposes only, fill out Animal Observation Form instead.)

1. If Project Type is "Training" Describe training projects.

Click here to enter text.

2. How many trainees do you anticipate per year? Click here to enter text.

3. How many animals per trainee (or trainees/animal) will be needed? (Show calculations and reasoning.)

Click here to enter text.

II. PROJECT SUMMARY

A. RATIONALE AND SIGNIFICANCE Section Instructions

Enter Text Here

B. PROCEDURES INVOLVING ANIMAL SUBJECTS Section Instructions

Enter Text Here

C. DEFINITIONS OF TECHNICAL TERMS

Term	Definition

ANIMALS

III. USE OF ANIMALS

A. Description of Animals (Please complete an additional section for each species)
Section Instructions

1. Species: Click here to enter text.
2. Strain(s) or Breed(s): Click here to enter text.
3. Sex: Click here to enter text.
4. Age: Click here to enter text.
5. Weight: Click here to enter text.

B. Procurement Source (If unsure, consult Animal Facilities Coordinator at *562-985-5483*)

☐ External Vendor ☐ In-House Breeding

☐ Other (Specify): Click here to enter text.

C. Are special permits required for trapping, fishing, housing, or importing animals?

Click to choose an item.
(If yes, Please submit copies of the permits as part of your application package)

Scientific Collecting Permit (SCP) #:

Click here to enter text.

D. Animal Use Sites:

Building: Click here to enter text. Room: Click here to enter text.

Other: Click here to enter text.

E. State Special Needs (Housing, Lighting, Diet, Sanitation, Etc.) Section Instructions:

Click here to enter text.

IV. JUSTIFICATION FOR USE OF PROPOSED ANIMAL MODEL Section Instructions

A. The following information sources were used in an attempt to identify viable alternatives to the proposed animal model and avoid unnecessary duplication of the experiments (check all that apply): Section Instructions

☐MEDLINE ☐WEB OF SCIENCE ☐BIOLOGICAL ABSTRACTS ☐ RePORT

☐AGRICOLA (National Agricultural Library)

☐LITERATURE AWARENESS SERVICE (Specify databases): Click here to enter text.

☐PROFESSIONAL JOURNALS (Specify): Click here to enter text.

☐PROFESSIONAL MEETINGS (Specify): Click here to enter text.

☐PERSONAL COMMUNICATIONS WITH COLLEAGUES (Specify): Click here to enter text.

☐Other (Specify): Click here to enter text.

For literature searches, the following Keywords were used: Click here to enter text.

B. Alternatives:

1. Could the proposed work be accomplished in clinical studies or with human tissue in compliance with ethical and regulatory standards? Click here to choose an item.

2. Could the proposed work be accomplished through computer simulation? Click here to choose an item.

3. Could the proposed work be accomplished with established cell lines? Click here to choose an item.

4. Could the proposed work be accomplished using animal tissues or primary cell lines obtained from other CSU LONG BEACH researchers? If animal tissues could be used, consult Animal Facilities Coordinator (5-5483) Click here to choose an item.

5. Written, narrative assurance that alternatives were considered and found not suitable and that the activities do not unnecessarily duplicate previous experiments conducted by you or others. (Use sample narrative in Instructions, if appropriate.) Section Instructions
Click here to enter text.

V. JUSTIFICATION OF ANIMAL NUMBERS Section Instructions

A. List all animals being used by species. Give the sample size (number) of animals being used by species.

Species	Strain	Number
	TOTAL:	

B. Specify each group of animals and assigned n (number of animals) per group (Separate by Experiment if applicable).

Enter Text Here

C. What is the justification of your sample size? Section Instructions

☐Based on pilot study

☐Based on numbers of students expected. (Explain): Click here to enter text.

☐Based on prior protocols (provide statistical analysis).
Click here to enter text.

☐Based on statistical analysis (provide statistical analysis):
Click here to enter text.

☐Based on other methods (show calculations and reasoning).
Click here to enter text.

PROCEDURES
Section Instructions

VI. EXPERIMENTAL PROCEDURES **NOT** INVOLVING SURGERY AND/OR EUTHANASIA Section Instructions

☐Not applicable. Skip to next section.

A. Chronological Description of All Non-surgical Procedures

B. List substance(s) to be employed or evaluated. (Please complete an additional section for each e.g. Substance #2, #3, etc.)

Substance #Click to choose an item.
Substance Name: Click here to enter text.

1. When given? Click here to enter text.

2. Duration, Frequency & Route: Click here to enter text.

3. Dosage (Unit per Body Weight): Click here to enter text.

4. Expected Experimental Effect on Animal: Click here to enter text.

5. Expected Detrimental Effect on Animal: Click here to enter text.

6. Is the substance pharmaceutical grade. Click to choose an item.

   If No, please provide rationale for using non-pharmaceutical grade.

   Click here to enter text.

7. If the researcher is administering a control substance which requires a DEA permit, please indicate the expiration date of the current permit and the limitations it imposes on the person registered.

   DEA permit #: Click here to enter text.
   Expiration Date: Click here to enter a date.
   Restrictions on Registrant: Click here to enter text.

VII. DESCRIPTION OF SURGICAL PROCEDURES Section Instructions

☐Not applicable. Skip to next section.

A. Pre-Operative.

1. Give a brief description of pre-operative procedures in chronological order

Click here to enter text.

B. Surgery.

1. Give a brief description of planned surgery in chronological order

Click here to enter text.

2. Where will surgery take place? Section Instructions

Bldg: Click here to enter text. Room: Click here to enter text.

Other: Click here to enter text.

3. Is aseptic technique practiced? Section Instructions
Click here to choose an item.

4. What is the surgery outcome?
Click to choose an item.

C. List substance(s) [i.e. chemicals, agents, devices, medications, etc.] to be employed or evaluated. (Please complete an additional section for each e.g. Substance #2, #3, etc.) Section Instructions

Substance #Click to choose an item.
Substance Name: Click here to enter text.

1. When given? Click here to enter text.

2. Duration, Frequency & Route: Click here to enter text.

3. Dosage (Unit per Body Weight): Click here to enter text.

4. Expected Experimental Effect on Animal: Click here to enter text.

5. Expected Detrimental Effect on Animal: Click here to enter text.

6. Is the substance pharmaceutical grade. Click to choose an item.

   If No, please provide rationale for using non-pharmaceutical grade.

   Click here to enter text.

7. If the researcher is administering a control substance which requires a DEA permit, please indicate the expiration date of the current permit and the limitations it imposes on the person registered.

   DEA permit #: Click here to enter text.
   Expiration Date: Click here to enter a date.
   Restrictions on Registrant: Click here to enter text.

D. Post-Operative (if Survival)

1. Where will animals recover?

Bldg: Click here to enter text. Room: Click here to enter text.

Other: Click here to enter text.

2. Describe supportive care and identify by name who will administer this care. Section Instructions

Click here to enter text.

3. Will antibiotic or analgesic therapy be used? Section Instructions

Click to choose an item.

If yes, indicate agent, dosage, duration, frequency and route of administration.

Click here to enter text.

4. Is more than one survival surgical procedure to be performed on any animal? Section Instructions

Click here to choose an item.

If yes, indicate the time interval between surgeries and justify the need for multiple survival surgeries.

Click here to enter text.

VIII. ANIMAL EUTHANASIA

A. Are all animals being euthanized at the conclusion of the protocol?

1. ☐Yes.

Describe procedures and list agents, dosages and routes of administration.

Click here to enter text.

2. Are these procedures in compliance with the current recommendations for euthanasia? (see AVMA Guidelines for Euthanasia of Animals)
Click here to choose an item.

a. If NO provide justification for non-compliance
Click here to enter text.

Dead animals must be transported separately from live animals. Contact the Animal Facilities Coordinator 562-985-5483 for more information.

3. ☐ No, animals will be kept alive at the conclusion of the protocol.

a. Describe what will be happen to the animals at the conclusion of the protocol.

Click here to enter text.

B. Are any animals expected to die other than by euthanasia (e.g., lethal dose studies, intraoperative mortality, adverse response to medication, aging, etc.)?
Click here to choose an item.

1. If yes, give expected numbers (or % of total animals) and describe the circumstances under which they may die.

Click here to enter text.

C. Describe the steps to be taken if animals become sick, injured, or expire unexpectedly.

☐Veterinarian will be consulted.

☐Other (please explain): Click here to enter text.

IX. PAIN, DISTRESS, AND EMERGENCY CARE Section Instructions

A. Are procedures to be employed that are intended to study pain?

Click here to choose an item.

If yes, describe and justify Section Instructions:

Click here to enter text.

B. Will animals undergo prolonged (more than one hour) restraint?

Click here to choose an item.

If "yes," describe procedure, including the time period of restraint, and justify the necessity for the procedure:

Click here to enter text.

C. List Individual(s) to be contacted in case of animal health emergency:

Name: Click here to enter text.

Telephone Number(s): Click here to enter text.

X. BIOHAZARDOUS/RADIOACTIVE MATERIALS

☐Not applicable. Skip to next section.

A. Identity of Biohazard, Carcinogen, Radioisotope or Radiation Dose, if any
Section Instructions:

Click here to enter text.

B. Description of Use and Precautions (e.g., adverse effects, personal protective equipment, handling, decontamination, disposal) Section Instructions:

Click here to enter text.

C. Will affected animals be housed in the Vivarium after treatment?

Click here to choose an item.

D. Responsible Individual, if any: Section Instructions

Name: Click here to enter text.
Email: Click here to enter text.
Telephone: Click here to enter text.

If your project requires the use of biohazardous, carcinogenic, radioactive materials, or radiation-producing devices on campus premises, you must contact the College of Natural Sciences & Mathematics Safety Office at (562)985-5623. For research involving radioactive material, the IACUC will not proceed with the review process until Radiation Safety has approved the use of these substances. **Include approval in application package.**

XI. PI ASSURANCE

Principal Investigator Assurance:

- I agree to abide by the *Guide for the Care and Use of Laboratory Animals*, the USDA Animal Welfare Regulations (CFR 1985) and Public Health Service Policy on Humane Care and Use of Laboratory Animals (1996) and the University's policies governing the use of vertebrate animals for research, testing, teaching, or demonstration purposes.
- I also certify that the proposed studies do not represent unnecessary duplication of experiments. I will permit emergency veterinary care to animals showing evidence of pain or illness, if the desired effect(s) of the above-approved techniques are not achieved.
- The information provided above is accurate to the best of my knowledge. No deviation procedures (where proposed), will be attempted without prior written approval from IACUC.
- Appropriate space and funding will be assured prior to commencing work on this proposal.
- The use of non-animal alternatives has been considered and found unacceptable at this time.
- I declare that all procedures involving live vertebrate animals will be performed under my direct supervision or under that of another qualified scientist as listed on this protocol. Technicians or students who will be involved have been trained in proper procedures in animal handling and in any invasive procedures or euthanasia to be used in this project.
- The activities described in this application are consistent with those described in all related grants and contracts.

PI Signature: _____ Date: _____

If this form is submitted electronically through the PI's email account that is considered a valid electronic signature.

XII. PERSONNEL & QUALIFICATIONS

If more than one person will be working with animals, please copy and paste an additional section for each. All personnel must receive a copy of the protocol.

Last Name	First Name	eMail	Campus ID	Classification
				PI ☐ Co-PI ☐ Student ☐ Technician ☐ Volunteer ☐
Procedure/Training Description			Proficient (Y/N)	Trainer (if Not Proficient)*

Training Requirements

The Principal Investigator (PI) and all Key Personnel must complete:

- The "Working with the IACUC" online course offered by Collaborative Institutional Training Initiative (CITI)
- The Basic CITI course for the species being used on the protocol i.e. "Working with Rats in Research Settings," "Working with Mice…," "Working with Fish…," etc.
    - Field Protocols should complete the "Wildlife Research" course.
- The CNSM Safety Office Basic Lab Safety Training if the protocol is Vivarium or lab based
- The Vivarium Orientation if the protocol is Vivarium based.
- Additional Trainings may be required by IACUC depending on the protocol.
- Be advised that If the protocol is supported by a grant, the funding organization may also require additional trainings

For IACUC Office use only:

Type/round of submission	Version	Submission Received Date	Approval date
New protocol			

APPLICATION FORM INSTRUCTIONS

SUBMISSION OF THE APPLICATION

- The Attending Veterinarian of CSU Long Beach must be consulted in the design of your study

- In compliance with the USDA Animal Welfare Act regulations, Public Health Service Policies, and the Office of Laboratory Animal Welfare (NIH) the CSULB Institutional Animal Care and Use Committee (IACUC) is required to review and approve, require revisions in (to secure approval), or, if appropriate, withhold approval of proposed activities related to the care and use of animals at CSU Long Beach.

- Applications must be reviewed and approved by the IACUC before any animals can be ordered, procured, or used.

- In some cases, sponsoring agencies require documentation of approval before an award is made.

- The IACUC only approves activities involving the use of animals for one year at a time. When the entire project period exceeds one year, an annual review of the activities by the IACUC is accomplished through submission of an Annual Report Form. This form will be submitted by the Principal Investigator (PI) prior to the expiration date.

- All applications, annual reports, protocol modifications, and personnel forms must be submitted to the IACUC Coordinator. *Please contact the IACUC Coordinator (X5-5314) for further information.*

THE PROJECT

Section I: PROJECT DATA

I.B. NAME OF THE PRINCIPAL INVESTIGATOR: There can be only one Principal Investigator (PI) of record. The PI must be the person listed on the grant or contract that corresponds with this IACUC Application.

I.C. PROJECT TITLE: If there is a grant or contract that corresponds with this IACUC Application, the project title should be the same as that of the grant or contract. If this is a subproject of a larger grant, list the grant title and the subproject title.

I.D. PROJECT DATES: Indicate the date that you desire this approval to begin. The start date should be the same as the anticipated start dated of the corresponding grant and/or contract, and must be within one year of submitting this Application to the Research Office. Regarding the end date, the entire duration of the project cannot exceed three years.

I.G. FUNDING SOURCE: If funded, indicate funding source.

SECTION II: PROJECT SUMMARY

II.A. RATIONALE AND SIGNIFICANCE: Explain how the results of this project can be expected to add to the body of scientific knowledge and/or positively impact health care of humans and/or animals? If applicable, include in this section how many people suffer from the condition/illness that your research work is trying to address. "Lay" language should be used, and if technical terms are used, they should be defined in lay language in section II.C.

II.B. PROCEDURES INVOLVING ANIMAL SUBJECTS: Provide a step by step narrative description of the biomethodology.

ANIMALS

SECTION III: USE OF ANIMALS

III.A. If you have questions about how to complete this section, contact the Consulting Veterinarian 310-423-7684, fax 310-423-0290, john.young@cshs.org.

III.E. "Special" needs include such things as accessing animals during the customary quarantine period, unique diet or water requirements, unique photoperiods, individual housing of animals, breeding of animals, need for containment for hazardous agents, access to animals during off-hours, transport of animals outside of research facilities, etc.

SECTION IV: JUSTIFICATION FOR USE OF PROPOSED ANIMAL MODEL

Investigators are required by federal regulations to provide a description of the methods and sources of information used to determine that alternatives to the proposed animal model and procedures are not appropriate. The term "alternatives" refers to the 3 R's - Reduction, Refinement, and Replacement: Reduction of animals to be used to the minimum number necessary to reach meaningful results; Refinement of biomethodology to produce the least amount of stress and/or pain in the animals; Replacement of animals higher on the evolutionary (phylogenetic) scale with lower animals, and/or replacement of animals with such procedures as tissue cultures, computer simulations, etc.

IV.A. A database search is required. Check all sources or methods used.

IV.B.5. Sample Narrative

> *"I have performed a database search on (insert date), covering the years (insert years searched), using the above named sources and keywords. Based on (insert number) of years of experience in this field, in conjunction with attendance at meetings and personal communications with my colleagues, I believe that (1) the procedures I have chosen represent the best alternative to performing this work; (2) that the (insert species) animal model is the most appropriate for conducting my work; and (3) that the proposed studies do not unnecessarily duplicate the work of any other groups in my field."*

SECTION V: JUSTIFICATION OF ANIMAL NUMBERS

If multiple studies are included in this application, complete a separate Section V for each one.

V.B. What is the justification of your sample size?

- Pilot Study: A Pilot Study involves relatively few animals. A pilot is done if there are no results available from similar studies, and data is needed to plan or determine the feasibility of a larger study. Sample size represents the best estimate for results.

- Number of Students: The following will be required in the annual report for training protocols:
  - Names of people who were trained.
  - What were they trained to do?
  - Dates of training.
  - Names of faculty conducting training.
  - How many animals per trainee/procedure were used?

Therefore, keep documentation of each training as it occurs.

- Statistical Analysis: Differentiate among all experimental and control groups. A group refers to a set of animals with the identical protocol (i.e., drug dosage, time point, age/strain/sex of animals, etc.), applied to them. Provide sufficient detail to enable the IACUC to determine how the groups relate to the justification. If your data will be used for statistical tests, your sample size should be justified on the basis of statistical power. If you need statistical assistance, please call the IACUC Chair or the Office of Research & Sponsored Programs x55314. Please allow sufficient time (3 weeks) prior to submission deadlines for meetings and analyses. Attach the supporting sample size report or materials used in power or precision calculations.

If statistical power analysis is not applicable (i.e., tissue collection, antibody preparation, etc.), provide a clear description -- including calculations -- of how the number of animals was determined. Sufficient information must be provided for the IACUC to fully understand your reasoning and verify the numbers.

PROCEDURES

Outline all procedures to be performed on live animals in a brief, chronological step-by-step description. Do not include drug dosages, animal numbers, or other details provided elsewhere. "Lay" language should be used, and if technical terms are used, they should be defined in lay language in section II.B.

SECTION VI: EXPERIMENTAL PROCEDURES **NOT** INVOLVING SURGERY AND/OR EUTHANASIA

Examples: restraint techniques (manual, restraint device, chemical), anesthesia, body fluid collection (blood, urine), gavage, oral administration of liquids or solids (special diets, pharmaceuticals), non-standard housing (metabolic caging), etc.

If medications, chemicals, special diets, devices, anesthetics, sedatives, or tranquilizers are used in the non-surgical procedures, list them under Section VI.B. Reproduce this section for each substance/device to be used.

SECTION VII: DESCRIPTION OF SURGICAL PROCEDURES

For the purposes of this Application, "Surgery" is defined as any procedure that involves an incision. *Injections, blood collection, or euthanasia procedures alone are not surgery.*

In your chronological description of pre-surgical and surgical procedures include the following:

- fasting (duration)
- preoperative sedatives/tranquilizers (agent, dosage, and route)
- preoperative antibiotics (agent, dosage, and route)
- anesthetics (agent, dosage, and route)
- surgical site preparation
- site of incision
- Surgical manipulations, and method of wound closure.

If different surgical protocols are used for different groups of animals, specify the procedures for each group chronologically.

VII.B.2. All major survival surgical procedures in non-rodent species (FYI - rabbits are not rodents), must be performed in designated surgical facilities.

VII.B.3. Definition of aseptic technique - minimum criteria:

- *Rodent Species*
  - Clipping of hair from incision site and application of a betadyne preparation ("prep") to the skin.
  - Use of sterile instruments (for rodents, cold sterilization is acceptable. NOTE: isopropyl alcohol is not a cold sterilant.)
  - Use of examination gloves. Certain rodent surgical procedures (organ transplants, for example) require more strict aseptic techniques including wearing of surgical gloves, cap and mask, and/or draping of the surgical field.
- *Non-Rodent Mammals (e.g., rabbits)*
  - All of the above techniques apply, plus the following :
  - Use of sterile instruments (sterilized via autoclave).
  - Use of surgical (not exam) gloves, cap, mask, and gown.

VII.C. Chemicals, agents, devices, medications, etc., employed or evaluated during surgical procedures (NOTE: Non- experimental (routine) anesthetics, sedatives or tranquilizers should be listed under Section VI.E: pre-surgical and surgical procedures - and not here.)

VII.C.1.d. In answer to "Expected Experimental Effect on Animal": Answer what effect is intended with relation to the experiment. "Expected Detrimental Effect on Animal" refers to any adverse side-effect the substance may cause in the animal. Reproduce this section for each substance/device to be used.

VII.D.2. Supportive care always includes observation of the animal until recovery from anesthesia. Additionally, supportive care can include monitoring temperature, pulse, and respiration; providing supplemental heat and/or fluids; administration of analgesics and/or antibiotics; and observation of incisions.

VII.D.3. If good aseptic technique is employed, and the surgical site is not a source of contamination (i.e., the gastrointestinal tract), prophylactic antibiotics are not indicated.

The general guideline for administration of analgesics is if a human undergoing a similar surgical procedure would benefit from analgesic treatment, then you should assume that the animal would also. Many animals, such as rodents, will not show that they are in pain. Indications of stress and pain are species specific.

VII.D.3.b. **Multiple survival surgeries are strongly discouraged**. The IACUC can only approve multiple survival surgical procedures on the same animal, if justified on a scientific basis. *Economics or cost savings are not acceptable justifications.*

IX Pain, Distress and Emergency Care

IX.A.1. If yes is checked for IX.A, include a justification based on the scientific merit and potential benefits that would outweigh the induced discomfort and animal stress.

The IACUC can grant approval for non-AVMA (American Veterinary Medical Association) recommended euthanasia procedures, if they are clearly and scientifically justified (supported by literature references), and only after competency in the proposed method is verified by the Attending Veterinarian.

X Biohazardous/Radioactive Materials

X.A. If you plan to use biohazardous or carcinogenic materials in your project, you must contact the Science Safety Office at x55623. If you plan to use radioactive materials in your project, you must contact the Radiation Safety Office at x55623.

X.B. Indicate how the biohazard, carcinogen, radioisotope, or radiation dose is administered to live animals and what precautions are to be taken to ensure the safety of the Vivarium personnel and other animals.

X.D. Indicate by name the individual(s) responsible for ensuring the required measures described in X.B are followed.

OTHER FORMS AND DOCUMENTS

Request for Modification

During the conduct of an approved project it may become necessary to modify or deviate from the approved protocol. Such changes must be communicated to the IACUC for approval prior to the implementation of the change by use of the Request for Modification of an Approved Project form. The Request for Modification must be typed and submitted to the Attending Veterinarian by email and the Office of University Research. The Attending Veterinarian will either forward the Request for Modification to the IACUC Chair with recommendation for approval and comments or return it to the applicant for change. If approved, the Chair will send the approved Modification to the Office of University Research indicating approval. The IACUC Chair can approve minor modifications to an approved protocol. If approved, the modified activity may begin. The Modification will then be placed on the next IACUC agenda for notice to the full Committee. Requests for a major modification requires review and approval at a convened IACUC meeting.

Request for Modification

- Increase in animal numbers over 10% requires full IACUC review at a convened meeting.
- Significant modifications require full IACUC review and approval prior to implementation.
- A change in species requires submission of a new Animal Use Protocol Application.
- Modification to procedures of radiation exposure, radioactive materials, carcinogens, or biohazards (including Recombinant DNA) requires full IACUC review at a convened meeting

Changes to Personnel should be reported using the IACUC Personnel and Training form. Use this form to report when personnel are assigned or removed from a protocol, to record their training, or to note any changes in status.

Annual Report

Annually, the IACUC must review all animal use protocols. This is accomplished through the completion of an Annual Report form that will be sent to the Principal Investigator by the Research Office prior to the expiration of the current approval period. Field Exempt Protocols do not have to submit an annual report unless requested to do so by the IACUC.

Annual Report Form