CHAPMAN UNIVERSITY | INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

IACUC PROTOCOL APPLICATION

INSTRUCTIONS:
This form must be completed prior to submission to the IACUC. All fields are required. Please follow all instructions.

Information must be consistent with information presented in the Protocol Narrative.

Following completion of this application, submit Protocol Narrative, and application, and any supporting documents (if applicable) to iacuc@chapman.edu.

SECTION 1: PROTOCOL INFORMATION

Protocol Title			
Principal Investigator			
PI Phone		PI E-mail	
PI Department/Unit			
Funding Agency/ Sponsor		Award Number	

SECTION 2: RESEARCH PERSONNEL

List the Principle Investigator and all personnel with live animal contact. Only individuals listed below will be authorized to handle animals when IACUC approval is granted. Please attach an additional sheet if more spaces are needed.

All members of the study team (except the Administrative Contact) must complete the required CITI Training prior to being listed.

The Principal Investigator must meet the eligibility criteria as defined in the Chapman University Principal Investigator Eligibility Policy, and is responsible for all research activities. Administrative Contacts may or may not be engaged in research activities, but will receive all IACUC related communication.

Principle Investigator	
Co-Researcher Name:	

Study Team Member	CITI Training Complete	LAOHP Current
	◯ Yes ◯ No	◯ Yes ◯ No
	◯ Yes ◯ No	◯ Yes ◯ No
	◯ Yes ◯ No	◯ Yes ◯ No

Administrative Contact (AC):

AC E-mail: AC Phone:

Alternative Emergency Contact Person:
Emergency contact must be someone other than the Lead Researcher with the authority to make decisions about animal care. Contact listed here will be CC'ed on all email correspondence with the Principal Investigator.

Emergency Contact (EC) Name:

EC E-mail: EC Phone:

SECTION 3: STUDY FUNDING AND SCIENTIFIC MERIT REVIEW

Check the boxes that apply to indicate how the study costs will be supported. This includes any pending funding sources. For pending funding sources, list “Pending” in the Award/Proposal # field.

☐ Grant/ Sub Award
☐ Contract/ Sub-contract
☐ Department or campus funds
☐ Non-cash support from manufacturer/sponsor

List specific details below for each checked source of funding

Agency/ Sponsor Award/ Proposal #

Agency/ Sponsor Award/ Proposal #

Have the experiments described in this protocol application undergone peer review by the funding agency/ sponsor?

☐ Yes ☐ No

SECTION 4: ANIMAL NUMBERS

Based on the experimental design in this study, provide the following information about the animals in this project:

Genus-Species or Common Name: List the genus-species or common name of all vertebrate animals involved in the experimental design.
Condition Code: PREG: Animals purchased while pregnant
DWL: Dams with a litter
N/A: Not Applicable: This includes all other animals, regardless of age, under this code
Total # Required: Indicate the total number of animals involved in the project for the duration of the project or 3 years, whichever is less.
USDA Pain Categories:
B - Animals held only for breeding and not used for any research purpose. This includes founder/current breeder animals, replacement breeders, and animals produced but not used.
C - Momentary or no pain, distress or discomfort (e.g., needle stick).
D - Procedures reasonably considered painful or likely to cause discomfort or distress, but alleviated with analgesics, anesthesia or timely euthanasia.
E - Unrelieved pain, distress or discomfort (requires strong scientific justification)

- Each animal should be counted only once in this table. The most invasive or potentially painful procedure determines the USDA pain category.
- DO NOT list Individual strains or subspecies here. Please include complete information about strains, genetically modified animals, etc., in Section 3 of the Protocol Narrative.

Species	Condition Code	Total # Required (for 3 years)	USDA Pain Category

Animals in Category E:
Unrelieved pain, distress or discomfort requires strong scientific justification with particular attention to the significance, necessity, and potential benefits of the research.
Investigators must perform euthanasia on all moribund experimental animals unless there is scientific justification that euthanasia would invalidate experimental data collection.
If euthanizing a moribund animal would seriously harm the study, the scientific justification for using death as an endpoint must be provided below.

SECTION 5: PROCEDURES TO BE PERFORMED ON LIVE ANIMALS

- [ ] Administration of experimental agents
- [ ] Antibody production/collection (monoclonal & polyclonal)
- [ ] Breeding
- [ ] Blood/tissue collection in live animals
- [ ] Behavioral Tests
- [ ] Cardiac perfusion (terminal procedure involving replacement of blood with fixative while animal's heart is still beating)
- [ ] Euthanasia followed by tissue harvest
- [ ] Invasive field study (study of animals in their natural habitat involving an invasive procedure or one that harms or materially alters the animals' normal behavior)
- [ ] Any variations in standard housing or husbandry
- [ ] Use of Human Adult Stem Cells (including iPS cells)
- [ ] Minor survival surgery
- [ ] Major survival surgery (surgical procedures which either penetrate a body cavity or result in permanent impairment of normal functions)
- [ ] Multiple major survival surgeries
- [ ] Use of neuromuscular blocking
- [ ] Use of prolonged restraint
- [ ] Other

SECTION 6: HAZARDOUS AGENTS

Indicate which categories of hazards will be used in the study.

- ☐ A. Anasethetic Gases (e.g. isoflurance, urethane)
- ☐ B. Chemical and Biohazardous Agents (carcinogens, toxins, nanomaterials, investigational new drugs, infectious agents, human or primate materials, recombinant DNA, or select agents/toxins as defined by the CDC Select Agent Rule)
- ☐ C. Radioactive Hazardous Agents (iodinated proteins, irradiator, X-rays, lasers, etc)
- ☐ D. Other Hazardous Agents
- ☐ Other

Specify each checked hazard, including agent, method of administration, method used to capture waste gases, and Institutional Biosafety Committee review number if review was required.

SECTION 7: CONTROLLED SUBSTANCES

Refer to the U.S. Drug Enforcement Agency's list of Controlled Substances

Please check the boxes that apply to indicate which controlled substances will be used in the study.

- ☐ Ketamine
- ☐ Telazol
- ☐ Sodium Pentobarbital (including any prepared solutions that contain it)
- ☐ Buprenorphine
- ☐ Butorphanol
- ☐ Other

SECTION 8: ANIMAL HOUSING AND PROCEDURE LOCATIONS

A. Will any non-Chapman site(s) and offsite locations be used?

- ☐ Yes
- ☐ No

B. Building and Room Information

1. Laboratory Areas

For areas outside of the vivarium where live animals will be used, list the specific building and provide the room number.

Building: Room #:

Location will be used for:

☐ Animal Housing ☐ Non-Surgical Procedures ☐ Surgery

Building: Room #:

Location will be used for:

☐ Animal Housing ☐ Non-Surgical Procedures ☐ Surgery

Building: Room #:

Location will be used for:

☐ Animal Housing ☐ Non-Surgical Procedures ☐ Surgery

C. Indicate husbandry and housing responsibilities:

Check the boxes that apply.

☐ Animals housed in vivarium space with routine animal care and husbandry provided by Vivarium staff

☐ Animals held outside of vivarium housing room for more than 12 hours (e.g., in lab or procedures space)

☐ Laboratory staff to provide routine animal husbandry and care in vivarium or other location (e.g., lab space, PI maintained animals)

Provide justification for housing/holding outside of vivarium space:

SECTION 9: DISCLOSURE OF INVESTIGATOR'S FINANCIAL INTERESTS

The Principal Investigator of the protocol must ask the following question of ALL study team members:

"Do you, your spouse, and dependent children together have any disclosable financial interests (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research?"

Disclosable financial interests are:
- Ownership interest, stock, stock options, or other financial interest related to the research.
- Compensation related to the research, including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research, regardless of compensation.

A member of the study team who answers in the affirmative must be listed in the box below. An e-mail will be sent to the study team members listed below to obtain additional information regarding the specific financial interest(s). IACUC approval cannot be granted until all disclosures are reviewed.

Investigators with disclosable financial interests:

PRINCIPAL INVESTIGATOR CERTIFICATION:
I certify that all members of the study team have answered the financial interest question and only the individual(s) listed in the box above have a disclosable financial interest.

Principal Investigator Signature: _____ Date: _____

SECTION 10: INVESTIGATOR'S ASSURANCE

As Principal Investigator, I have ultimate responsibility of the performance of this study, the ethical and humane care and use of the animals, and strict adherence by all study team members to IACUC requirements, all federal, state and local laws, and regulations and policies of Chapman University governing the use of animals in research, teaching and testing. I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. I have performed the required alternatives searches and to the best of my knowledge, the experiments and procedures described in this protocol do not unnecessarily duplicate previous experiments, unnecessarily use animals, or unjustifiably expose animals to potentially painful, uncomfortable or distressful procedures.
3. All experiments and procedures involving animals will be performed under my supervision or that of another qualified professional listed on this protocol.
4. I will ensure that all study team members are qualified and authorized to conduct procedures involving animals under this protocol. This includes ensuring that all study team members, including myself have:

- Been (or will be) trained in handling and care of the involved species and approved procedures in this protocol, including the proper use of anesthetics, analgesics and experimental agents, and euthanasia.
- Read and understand the procedures outlined in the approved protocol.
- Completed the CITI Training on animal care and use and other required Vivarium training courses (as applicable).

5. Personnel will be allowed adequate time to obtain necessary training for this project and will not begin any procedures with live animals until they have been successfully trained.
6. All animal acquisition will be coordinated through the Vivarium and all animals will be housed in Vivarium, unless otherwise approved by the IACUC.
7. Emergency veterinary care is permitted for animals showing evidence of pain or illness not addressed specifically in the approved protocol, in addition to routine veterinary care as prescribed for individual species.
8. All study team members with direct animal contact are registered in the CU Lab Animal Occupational Health Program. All study team members are aware of the potential hazards associated with the use of live animals and animal tissues. In addition, I understand I am responsible for notifying EH&S if an individual's level of animal contact changes, due to changes in the protocol or job description.
9. I understand that, should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to assure that the description of animal use in the funding proposal(s) is identical in principle to that contained in this application. I will submit modifications and/or changes to the IACUC as necessary to assure these are identical.
10. I and all of the co-investigators and research personnel agree to comply with all applicable requirements for the use of animal in research, testing and teaching including, but not limited to, the following:

- Making no changes to the approved protocol without first having submitted those changes for review and approval by the Institutional Animal Care and Use Committee; and
- Promptly providing the IACUC with any information requested relative to the project; and promptly and completely complying with an IACUC decision to suspend or withdraw its approval for the project; and
- Obtaining continuing review prior to the date approval for this study expires (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and study activity must cease until IACUC current approval is obtained); and filing a final report with CU IACUC at the conclusion of this project.

Principal Investigator Signature: _____ Date: _____

Department Chair Signature: _____ Date: _____

Department Chair Printed Name: _____

DEPARTMENTAL APPROVAL

Chapman University
Institutional Animal Care and Use Committee

The Department Dean's signature is required if the study will be performed under the auspices of a Department (includes campus centers and school-based research units).

If the Department Dean is a member of the research team on this application (including Faculty Sponsor), approval must be obtained from the next highest level of administrative authority.

Department Assurance Statement:

By signing below, I hereby confirm that I have read the IACUC Application and Protocol Narrative and I certify that:

- The research is appropriate in design.

(i.e., the research uses procedures consistent with sound research design, the study design can be reasonable expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known)

- The Principal Investigator and Faculty Sponsor (if applicable) are competent to perform or supervise the study.

- There are adequate resources and funds available to support performance of this research, including costs associated with animal husbandry and care.

Printed Name of CU Department Dean: _____

Signature of CU Department Dean: _____

Date: _____