Claremont McKenna College and Harvey Mudd College

Institutional Animal Care and Use Committee
PROTOCOL APPLICATION

Overview: This document is the IACUC protocol application for vertebrate animal use in the Kravis Department of Integrated Sciences at Claremont McKenna College and at Harvey Mudd College. Up to date participation in the college medical monitoring program and completion of all training requirements must also be documented for all personnel on the protocol.

Instructions for Applicants:

1. Note that only CMC or HMC faculty members can be the Principal Investigator on a protocol.
2. Respond to all questions. For any that do not apply, please answer "N/A". Include additional documents as an appendix if needed (e.g., flowcharts or illustrations, standard operating procedures, table of substances to be administered, hazardous compound or BSL-2 forms, etc).
3. Submit this application and any appendices to the IACUC Chair via iacuc.chair@cmc.edu
4. Protocols may be approved for up to 3 years. If you wish to continue the protocol at that point, it must undergo a triennial renewal process. If you expect to have animals continuously, be sure to initiate the renewal process well in advance of the end date so that you maintain an active approved protocol at all times.

IACUC USE ONLY

Protocol number: Click or tap here to enter text.

Filing Date: Click or tap here to enter text.

Method of review: Click or tap here to enter text.

Date of Approval: Click or tap here to enter text.

PROTOCOL APPLICATION

A. ADMINISTRATIVE INFORMATION

Project Title: Click or tap here to enter text.

Principal Investigator (PI): Click or tap here to enter text. **College:** Click or tap here to enter text.

PI email address: Click or tap here to enter text. **PI phone number:** Click or tap here to enter text.

1. External Funding Sources

If this animal use protocol is externally funded, specify the funding source and proposal number assigned by the Office of Sponsored Research. For PHS and NSF projects specifically, please ensure before submitting this IACUC application that the scope of work, species, numbers, agents and methods for them, procedures, and euthanasia methods are congruent between the grant and application – this is the PI's responsibility. Note that in general, grant proposal descriptions will be broad and IACUC protocols more specific. Add or delete rows as needed.

Funding Source	Proposal number	Comment
Funding source	Proposal number	
Funding source	Proposal number	
Funding source	Proposal number	

2. Authorized Personnel

List the names of all individuals authorized to conduct procedures involving animal contact under this proposal and provide their institutional affiliation, role, email, and phone number. Add rows as needed. Named individuals must complete CITI training modules, institutional lab safety training, and enroll in the Medical Monitoring Program for Vertebrate Animal Exposure prior to any participation in the proposed activities. Additional training of laboratory members by the PI may be required depending on the activities in the protocol (e.g., handling of the specific species; aseptic surgery technique). When applicable, this training must be documented before that individual engages in the activity. The ECHO and IACUC chair will confirm which trainings are required with the PI.

Name	Institutional Affiliation	Protocol Study Role	Email address	Phone	completed? *enter date below*	
					CITI training	Lab safety
Name	college	Role	Email address	###-###-####	☐ date	☐ date
Name	college	Role	Email address	###-###-####	☐ date	☐ date
Name	college	Role	Email address	###-###-####	☐ date	☐ date

3. Emergency Contact Information

Provide emergency contact information for the PI and if applicable, a laboratory member, who can be reached in the event of an animal emergency:

Click or tap here to enter text.

B. PROPOSAL OBJECTIVES

Briefly explain the aims of the study or activity, and, if appropriate, why the study is important to human or animal health, the advancement of knowledge, or the good of society. Use language and words which a layperson (non-medical, non-scientific) would understand.

Click or tap here to enter text.

C. ANIMALS REQUIRED

1. Provide information on the target animals to be studied for the duration of the protocol (up to 3 years). Add rows as needed.

Scientific Name	Common Name	Maximum number for 3 years
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

2. Identify the source of the animals to be studied (e.g., specify the vendor) or indicate here if you will have a production colony.
3. Click or tap here to enter text.

4. Identify any sites (e.g., RDSC Vivarium) where animal holding or manipulations will occur. With the exception of field sites, locations of animal use must be inspected and approved by the IACUC in advance of use, and will subsequently be part of semi-annual inspections.

   Click or tap here to enter text.

D. RATIONALE FOR ANIMAL USE

1. Provide a justification for animal use and the selection of species. Explain why it is necessary to use these animal models.

   Click or tap here to enter text.

2. Justify the number of animals to be used, which should be the minimum number required to obtain statistically valid results. Indicate how you arrived at your calculations and include justification for group size through a power analysis when possible. In this calculation, you should consider the number of animals produced in a production colony to achieve the necessary number of genetically appropriate individuals, if applicable. Note that all individuals from a production colony are counted against the total number of animals utilized.

   Click or tap here to enter text.

E. DESCRIPTION OF STUDY DESIGN AND ANIMAL PROCEDURES

Briefly explain the study design and specify all animal procedures. All research procedures involving animal contact must be described with sufficient detail. This description should allow

the IACUC to understand how an animal is handled from its entry into the study to the endpoint of the study. For complex study designs, flowcharts may be helpful and can be included as an appendix.

Provide an acceptable range of the specific items described below to allow flexibility in the use of professional judgment and avoid non-compliance with the protocol. Details of daily animal care should be provided in Section F. Surgical procedures should be discussed separately in Section G. Details of anesthetic, analgesic, or sedative drug use to alleviate pain or distress should be provided in Section H. Any departure from the *Guide for the Care and Use of Laboratory Animals* should be identified and justified.

Be sure to include the following specific information, as applicable:

- Individual animal identification methods such as ear tags, tattoos, collars, cage cards, and implants
- Methods and durations of restraint (other than manual restraint for sample draws or routine husbandry tasks)
- Administrations of substances by injection, gavage, or any other route**. If applicable, include a Table of Substances Administered as an appendix**, and note route of administration and schedule here.
- Sample collection including sample type, volume, frequency, withdrawal site, and methods
- Explanation and justification of any food or fluid restriction to be used.
- Use of non-standard food.
- Other procedures (e.g., survival studies, tail biopsies, conditioning/training).
- Potential stressors such as noxious stimuli and procedures to monitor and minimize distress
- Experimental endpoint criteria (e.g., tumor size, percentage body weight gain or loss, signs of toxicity)
- Surgical procedures (identify here and list details in Section G)

Click or tap here to enter text.

F. ANIMAL CARE

1. List any special considerations for housing, equipment, animal care or any departures from the *Guide for the Care and Use of Laboratory Animals*. The table below indicates important parameters of animal care and housing; indicate whether the study adheres to the vivarium standards (indicate “No special considerations”) or whether exemptions are requested from the IACUC. If exemptions are requested, explain and justify the request.

☐ If this protocol is for field work that will not involve animal husbandry, check this box and move to the next question.

Parameter	Note “no special considerations” or explain and justify any exemption
Housing	Enter text here
Social housing	Enter text here
Feed	Enter text here
Water	Enter text here
Lighting	Enter text here

Enrichment	Enter text here
Environment	Enter text here
Breeding/weaning	Enter text here
Other	Enter text here

2. Indicate the plan of action in case of unexpected illness, morbidity, or mortality for any study animal (e.g., initiate treatment, call investigator prior to initiating treatment, contact campus veterinarian, euthanize). Note that the IACUC veterinarian and the IACUC must be notified immediately in the event of the unanticipated death of a study animal during research activities.

   Click or tap here to enter text.

G. SURGERY

☐ **If no surgery will be performed, check this box and move to the next section.**

1. Identify and describe any surgical procedure(s) to be performed. Include pre-operative procedures and monitoring and supportive care during surgery. Include the aseptic methods to be used.

   Click or tap here to enter text.

2. Identify the facility or location where surgery will be performed.

   Click or tap here to enter text.

3. If survival surgery, describe post-operative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided. Include detection and management of post-operative complications during work hours, after hours, weekends and holidays.

   Click or tap here to enter text.

4. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.

   Click or tap here to enter text.

5. Will more than one survival surgery be performed on an animal during this study? If yes, explain and justify.

   Click or tap here to enter text.

H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

All procedures that involve more than momentary or slight pain and discomfort to animals require the appropriate use of analgesics, unless withholding of such agents is scientifically justified in writing and approved by the IACUC. This section must be filled out if you are working with any vertebrate animal.

- **Category B: No pain or distress.** E.g., breeding or holding colony animals.
- **Category C: No more than momentary pain or distress and no use of pain relieving drugs, or no pain and distress.** E.g., injections of non-painful substances, small-volume blood collection, positive reward training, routine euthanasia.

- **Category D: Pain/distress with alleviation**: E.g., surgery, exsanguination, etc. with appropriate anesthesia and analgesia as necessary.
- **Category E: Pain or distress, or potential pain or distress, that is not relieved with anesthetics, analgesics, or tranquilizer drugs or other methods for relieving pain or distress.** E.g., application of noxious stimuli such as electrical shock if the animal cannot avoid or escape and it is severe enough to cause injury or more than momentary pain or distress; infliction or burns or trauma, prolonged restraint, exposure to extreme environmental conditions.

Refer to the above pain and distress categories and consult with the veterinarian or the IACUC Chair if uncertain. Add or delete rows as needed. All subjects requested in section C of this protocol must be assigned a classification. If you are proposing Class E procedures, be sure to explain and justify these below.

Species (common name)	Category (B, C, D or E)	Number of animals used each year			3 years total number of animals
		Year 1	Year 2	Year 3	
Species (Common name)	Category	Number	Number	Number	Number
Species (Common name)	Category	Number	Number	Number	Number
Species (Common name)	Category	Number	Number	Number	Number
				Total number of animals	0

1. Specify any procedures that meet the criteria for Classification D or E.

   Click or tap here to enter text.

2. For animals assigned to Category D, specify the anesthetics, analgesics, sedatives or tranquilizers that will be used. Include the name of the agent(s), the dosage range, route(s) and schedule of administration. Describe tracking and security of controlled drugs. Be sure to describe the proposed anesthesia/analgesia that will be used following the painful procedure, as well as during the procedure.

   Click or tap here to enter text.

3. For animals assigned to Category E, provide a full explanation justifying the use of the procedure(s) and the rationale for withholding drugs or alternative methods to relieve pain and/or distress. For example, provide scientific justification that such drugs would adversely affect the test/study results, or cite all regulation(s) and/or Federal Agency policies that prohibit the use of these drugs or alternative methods.

   Click or tap here to enter text.

4. Consideration of Alternatives: If any procedures fall into Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate the methods and sources used in the search. Database references must include databases searched, the date of the search, and the keywords used. Alternatives include methods that (1) refine existing tests by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole-animal use with *in vitro* or other tests. If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system.

   Click or tap here to enter text.

I. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

1. Indicate if euthanasia is planned in the design of the study or whether it would only be considered in case an animal becomes moribund unintentionally during the course of the study. If euthanasia is not planned, describe what will be done with the remaining animals at the endpoint of the study.

   Click or tap here to enter text.

2. Specify the method of euthanasia proposed. If a chemical agent is proposed, specify the dosage range and route(s) of administration. Any proposed methods that deviate from the AVMA Guidelines for the Euthanasia of Animals (current is 2020) require written approval from the IACUC and attending veterinarian.

   Click or tap here to enter text.

J. RESEARCH AUTHORIZATIONS/CONTRACTS

1. Is another IACUC involved in this activity? If so, provide an explanation, approved protocol number, date of approval, and contact information for that IACUC.

   Click or tap here to enter text.

2. Indicate if federal, state, and/or local permits are required and whether they have been obtained or applied for. Provide the agency, number, and expiration date for each authorization. Be advised that while IACUC approval may be granted prior to permit acquisition, no animal use activities can occur without both IACUC and required agency authorizations. The IACUC may request copies of these authorizations at any time. Add additional rows if needed.

Agency	Permit number or ID	Expiration	Application status/comment
Agency	Permit Number	Date	Status
Agency	Permit Number	Date	Status

If the permit period does not cover the entire protocol period, confirm that research will not continue without renewal of necessary authorizations.

Confirm or state N/A

K. PRINCIPAL INVESTIGATOR CERTIFICATIONS

☐ I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity, or mortality will be reported to the attending veterinarian and the IACUC.

☐ I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

☐ I certify that I have completed the CITI IACUC online training courses required by the IACUC.

☐ I certify that I am aware that all individuals working on this protocol are required to participate in the institution's Medical Monitoring Program for Vertebrate Animal Users.

☐ I certify that I am aware that all individuals working on this protocol are required to attend the CITI IACUC online training courses, and before starting work on this protocol, they will receive training appropriate to their role, such as in: the biology, handling, and care of this species; aseptic surgical methods and techniques; the concept, availability, and use of research or testing methods that limit

the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers; and procedures for reporting animal welfare concerns.

☐ I certify that either no procedures will be performed which may cause more than momentary pain or distress OR that I have reviewed the pertinent scientific literature and/or databases and have found no valid alternative to any Classification D and/or E procedures described herein.

☐ I certify that I will obtain approval from the IACUC before initiating any changes in this study.

☐ I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

☐ **I certify that submission of this form electronically via email to the IACUC Chair will be taken as my signature on this document.**