**Full Use Biomedical Protocol Application**

This form is for the use of live vertebrate animal subjects with contact including research, teaching, testing, or experimentation that involves a) any contact with any living vertebrate animal by any personnel, or b) any alteration of animal environment(s) during observational work for biomed investigators. The IACUC encourages anyone working with cephalopods to also fill out the form or include in a form. **Please fill out this form completely—enter NA where not applicable—and send** **as a Word document to** **iacuc@ucsc.edu****.** To select a checkbox, double click on the checkbox and set the default value to “Checked.” Questions and feedback regarding this form should be directed to iacuc@ucsc.edu.

**A. ADMINISTRATIVE DATA**

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| Submission date:MM/DD/YYYY |
| Protocol title: Enter protocol title here |
| Principal investigator: Enter name here |
| Department: Enter department here |
| Phone: (XXX) XXX-XXXX | Email: Enter email here | Mail stop: Enter mail stop here |
| Co-respondent(s) on protocol communications: Enter name(s), email address(es) here |

1. Provide the course name and number if this is a class activity.

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1. If this animal use protocol is externally funded, specify the funding source and Cayuse proposal number assigned by the Office of Sponsored Projects. 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](https://officeofresearch.ucsc.edu/compliance/services/iacuc-19-faqs.html#grant-protocol-congruency). Note that in general, grant proposal descriptions will be broad and IACUC protocols more specific. Add or delete rows as needed.

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| Funding Source | Cayuse proposal number(not the project number) | Comment |
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| Funding source | Cayuse proposal number |  |
| Funding source | Cayuse proposal number |  |
| Funding source | Cayuse proposal number |  |

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1. 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 or delete rows as needed. Named individuals must complete the “Group B: Biomedical Course for Vivarium Users” [CITI IACUC online training courses](https://officeofresearch.ucsc.edu/compliance/services/iacuc-19-faqs.html#training) and be enrolled in [Occupational Health Surveillance System (OHSS)](http://ehs.ucsc.edu/programs/research-safety/animal-contact/OHSS.html) at UCSC or equivalent at the individual’s home institution. Once your protocol is approved, any additional key personnel must be added by amendment (see [UCSC IACUC Forms webpage](https://officeofresearch.ucsc.edu/compliance/services/iacuc-18-forms.html) for the updated Protocol Amendment Form) **prior** to direct participation in the proposed activities.

For proposals with surgical procedures, named individuals performing the surgeries are also required to complete the “Aseptic surgery” module of “Group B: Biomedical Course for Vivarium Users,” “Post Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress,” and “Working with Mice in Research Settings” and/or “Working with Rats in Research Settings.”

Given the potential for other animal types, specific evidence of training, depending upon the animal model and study design, can be requested of the research staff by the IACUC, for example with zebrafish, birds, and marine mammals, which are not extensively covered in the CITI curriculum.

| Name | Institutional Affiliation | Protocol Study Role | Email address | Phone | completed?*enter date below* | Non-affiliated personnel affirmation\*  |
| --- | --- | --- | --- | --- | --- | --- |
| CITItraining | OHSS(safety) |
| Name | UCSC or specify | Role | Email address | ###-###-#### | [ ] date | [ ] date | [ ]  |
| Name | UCSC or specify | Role | Email address | ###-###-#### | [ ] date | [ ] date | [ ]  |
| Name | UCSC or specify | Role | Email address | ###-###-#### | [ ] date | [ ] date | [ ]  |

\*PI affirms by checking this box that non-affiliated individuals have completed animal care and use training and occupational health and safety assessment at the individual’s home institution.

1. In the event of an animal emergency, please provide the emergency contact information for how the PI and co-respondent(s) can be reached:

Enter text here

1. Briefly describe the qualifications of the PI and co-respondent(s) (if applicable) for conducting the specific procedures involving animal contact in this protocol.

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1. Briefly explain how the PI will ensure that personnel are properly trained (e.g., initial training, frequency re-training, method of keeping records on training activities) and supervised for participation in specific research activities. If there are restrictions on the participation of certain personnel, briefly describe the responsibilities of each role.

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| Enter text here |

**B. STUDY** **OBJECTIVES AND INTERPRETATION**

1. What is the purpose of this activity? (You may select more than one. To select a checkbox, double click on the checkbox and set the default value to “Checked.”)

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| [ ]  Grant/Contract [ ]  Research [ ]  Pilot Study [ ]  Student Project [ ]  Teaching [ ]  Public Display[ ]  Other: Please Specify |

1. Briefly explain the aim 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.

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**C. ANIMAL REQUIREMENTS**

1. Provide information on the target animals to be studied for the duration of the protocol (up to 3 years). If animals of the same species are to be studied in different categories (e.g., by age, sex, or mass) please list them on different rows. Add or delete rows as needed. More information is available about [animal numbers on UCSC IACUC FAQs web page](https://officeofresearch.ucsc.edu/compliance/services/iacuc-19-faqs.html#animal-numbers) (Sections C and D).

| Common name(e.g., mouse) | Genus and species(e.g., *Mus musculus*) | Strain or subspecies | Age and Sex | Mass (weight)range | Number requested |
| --- | --- | --- | --- | --- | --- |
| Common name | Genus and species | Type | Class | Mass | Number |
| Common name | Genus and species | Type | Class | Mass | Number |
| Common name | Genus and species | Type | Class | Mass | Number |

1. Identify the source of the animals to be studied (e.g., specify the approved vendor) or indicate here if you will have a production colony to supply mice.

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1. Identify any sites (e.g., UCSC Vivarium) where animal holding or manipulations will occur. Note that animals may not be held outside of UCSC Vivarium-controlled sites for more than 12 hours.

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**D. RATIONALE FOR ANIMAL USE**

1. Provide a justification for animal use—explain why it is necessary to use animal models.

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1. Justify the appropriateness of the species selected, which should be the lowest possible on the phylogenetic scale.

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1. 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. For more information, see about [animal numbers on UCSC IACUC FAQs web page](https://officeofresearch.ucsc.edu/compliance/services/iacuc-19-faqs.html#animal-numbers).

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**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. A best practice is to 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. The use of each procedure should be clearly related to the study objectives. Details of daily animal care should be provided in Section F. Surgical procedures should be separated under Section G. Details of anesthetic, analgesic, or tranquilizer 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*](http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-use-of-Laboratory-animals.pdf) 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)
* Experimental injections or inoculations including substances such as infectious agents, adjuvants, etc., and doses, sites, volume, route, and schedule
* Other substances administered to animals including any drugs, biologics, or reagents to be used, and dosage, route, schedule
* Sample collection including sample type, volume, frequency, withdrawal site, and methods
* Radiation including dosage and schedule
* Explanation and justification of any food or fluid restriction to be used
* Other procedures (e.g., survival studies, tail biopsies, conditioning/training)
* Potential stressors such as noxious stimuliand 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)

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**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*](http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-use-of-Laboratory-animals.pdf) (e.g., special caging, water, feed, waste disposal, environmental enrichment, etc.). Identify and justify any special requests, such as late weaning, trio breeding and inbred strains where more than 14 pups might be expected, delayed cage changing following parturition, etc. Standard enrichment is provided (reference [UCSC IACUC Policy Vivarium Animal Housing and Enrichment](https://officeofresearch.ucsc.edu/compliance/services/iacuc-01-policies.html)) — note and justify special enrichment/why enrichment cannot be offered.

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1. 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 campus veterinarian and the IACUC must be notified immediately in the event of the unanticipated death of a study animal during research activities.

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1. Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported outside of the primary holding facility, describe the methods and containers you will use to comply with [USDA regulations](https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf).

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1. Indicate the plan of action to assure continuity of your research in the case of catastrophic events, such as earthquake or disease resulting in the loss of your colony animals from the Vivarium. For example, consider whether appropriate mice are commercially available, if other institutions maintain colonies of your mouse strains, or if you will have frozen sperm or embryos.

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**G. SURGERY**

 A discussion with the campus veterinarian may be required prior to conducting any surgeries.

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.

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1. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.

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

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1. 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.

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

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

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**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 or cephalopod, regardless of USDA status.**

Refer to the [Pain and Distress Classifications](https://officeofresearch.ucsc.edu/compliance/files-iacuc/pain-and-distress-classifications.pdf), adding or deleting rows as needed. All subjects requested in section C of this protocol must be assigned a classification. If you are proposing Class E procedures, contact the campus (attending) veterinarian at vet@ucsc.edu and download and complete a [Class E justification form (in addition to this current form) from the UCSC IACUC website](https://officeofresearch.ucsc.edu/compliance/services/iacuc-18-forms.html).

| Species (common name) | Pain/Distress Classification(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) | Class | Number | Number | Number | Number |
| Species (Common name) | Class | Number | Number | Number | Number |
| Species (Common name) | Class | Number | Number | Number | Number |
| Total number of animals | Number |

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

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1. For animals assigned to Classification D or E, 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 described painful procedure, as well as during the procedure. If no anesthesia and/or analgesia utilized, provide a justification why. If no post-procedure analgesia will be used, explain why post-procedure pain relief is not necessary. Note that if pain-relieving measures are warranted but do not meet the requirements of the study, then a Class E Justification Form should be submitted in addition to the current form. For questions, contact the campus veterinarian or contact EH&S at ehs@ucsc.edu.

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1. 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.

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**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.

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1. Indicate whether standard CO2 euthanasia will be used at the Vivarium, or else specify the method and the individual(s) responsible for performing euthanasia techniques. 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](https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals) (current is 2020) require written approval from the IACUC and campus veterinarian.

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**J. COLLECTION OF VERTEBRATE SAMPLES**

1. List any samples to be collected for the study, including common and scientific names of species and sample types. Diagnostic samples obtained for veterinary use only need not be included here. If permit(s) are required, please provide details in Section K.

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1. Describe why the samples or specimens are needed, how these materials are to be collected, or indicate whether and how they will be received from others for use in this activity.

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1. Researchers working on unfixed tissues of primates and wild animals may be exposed to pathogens such as Hantavirus, hepatitis-B, and herpesvirus Simiae. Please indicate below whether your work involves specimens that may carry pathogens, or if you are working with specimens with little or no medical history. If so, contact biosafety@ucsc.edu.

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| [ ]  N/A [ ]  Handling of potentially hazardous biological material [ ]  Contacted biosafety@ucsc.edu |

**K. 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 the IACUC.

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1. 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

1. Did you contract with a company that is not AAALAC-accredited to produce antibodies or transgenic animals for this activity?

[ ]  Yes [ ]  No

**L. HEALTH AND SAFETY CONSIDERATIONS**

1. The use of hazardous substances, equipment, or procedures may require special approval from UCSC Environmental Health & Safety, Institutional Biosafety Committee, and/or the Radiation Safety Committee. Indicate whether you are using any of the following substances in your research. If so, identify the substance(s) and provide status of your usage permissions. Relevant links are provided in the table below.

| Substance | Contact | Agent(s) | Authorization Status |
| --- | --- | --- | --- |
| [ ]  None | -- | -- | -- |
| [ ]  Biological Agents | [IBC](http://ehs.ucsc.edu/programs/research-safety/biosafety/index.html) | Agent(s) | None, Pending, or Approved |
| [ ]  Recombinant DNA | [IBC](http://ehs.ucsc.edu/programs/research-safety/biosafety/index.html) | Agent(s) | None, Pending, or Approved |
| [ ]  Hazardous Chemicals | EH&S | Agent(s) | None, Pending, or Approved |
| [ ]  Controlled Drugs | [EH&S](http://ehs.ucsc.edu/programs/research-safety/controlled-substances/index.html) | Agent(s) | None, Pending, or Approved |
| [ ]  Radionucleotides | [RSC](http://ehs.ucsc.edu/programs/research-safety/radiation/index.html) | Agent(s) | None, Pending, or Approved |

This study will be conducted at [Animal Biosafety Level](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_sect_V.pdf): [ ]  1 [ ]  2 [ ]  3 [ ]  4

1. Describe the practices and procedures required for the safe handling and disposal of animal tissues and material associated with this study, unless covered by an existing IBC authorization.

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1. Specify any biological material and/or animal products for use in animals (e.g., cell lines, antiserum, etc.). Indicate the source of the material, whether it is sterile or attenuated, and whether it has been tested for pathogens. Confirm that the materials to be used have not been passed through rodent species outside of the UCSC Vivarium.

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**M. 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 campus (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 course](https://officeofresearch.ucsc.edu/compliance/services/iacuc-19-faqs.html%22%20%5Cl%20%22training) required by the IACUC.

[ ]  I certify that I am aware that all individuals working on this protocol who are at risk are required to participate in an institution's [occupational health and safety program](https://ehs.ucsc.edu/programs/research-safety/animal-contact/OHSS.html).

[ ]  I certify that I am aware that all individuals working on this protocol are required to attend the [CITI IACUC online training course](https://officeofresearch.ucsc.edu/compliance/services/iacuc-19-faqs.html%22%20%5Cl%20%22training) or an equivalent animal care and use training, and have received 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 significant changes in this study.

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

**PROTOCOL SUBMITTED BY THE PRINCIPAL INVESTIGATOR**

Signature of principal investigator: Signature Date: MM/DD/YYYY

**IACUC FINAL APPROVAL**

Certification of review and approval by the UC Santa Cruz Institutional Animal Care and Use Committee:

Approval signature: Date: