

**Animal Care and Use Committee (IACUC)**

**Animal Use Protocol Application**

*The 3Rs applied to animal research: reduce, refine, replace*

Cal Poly Pomona (CPP) is committed to promoting excellence in both teaching and research, as well as to the welfare of animals used for these purposes. The University has designated an institutional animal care and use committee, IACUC, to review proposals for research and teaching involving vertebrate animals. This application, when submitted to the IACUC, will be evaluated in terms of its compliance with all regulations (USDA, NIH, and campus policies), standards (bio- and chemical safety, training, welfare, etc.), and grant funding expectations regarding the use of animals. In all cases, ANIMAL USE MAY NOT PROCEED AT ANY LOCATION – ON OR OFF CAMPUS – until authorized by the IACUC.

**IACUC Protocol Version, January 2020**

* This protocol application is to be used for research, testing, teaching, and breeding activities with any vertebrate animals at Cal Poly Pomona. That includes both terrestrial and aquatic species, which were given greater emphasis in the 2011 version of the NRC *Guide for the Care and Use of Laboratory Animals*, which should be consulted in preparing the protocol.
* Complete the most current version of the protocol application for the proposed use of animals.
* Other guidelines that could be useful in the preparation of a protocol include:
* USDA/APHIS information and Animal Welfare Act Regulations <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/ct_awa_program_information>
* USDA’s policy 12 regarding “Consideration of Alternatives to Painful/Distressful Procedures”

Under Review as of January 29, 2019

* American Society of Mammalogists IACUC, Guidelines for the capture, handling and care of mammals as approved by the American Society of Mammalogists

<http://www.mammalsociety.org/articles/guidelines-american-society-mammalogists-use-wild-mammals-research-0>

* + Guidelines to the Use of Wild Birds in Research

 <https://birdnet.org/wp-content/uploads/2017/07/guidelines_august2010.pdf>

* + Use of Fishes in Research Committee, American Fisheries Society, Guidelines for the Use of Fishes in Research

<http://fisheries.org/docs/wp/Guidelines-for-Use-of-Fishes.pdf>

* The Canadian Council on Animal Care, guidelines on the care and use of fish in research, teaching, and testing <http://www.ccac.ca/Documents/Standards/Guidelines/Fish.pdf>
* Herpetological IIACUC of the American Society of Ichthyologists and Herpetologists, Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research

<http://www.asih.org/sites/default/files/documents/resources/guidelinesherpsresearch2004.pdf>

* + The Ag Guide, or the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, <https://www.aaalac.org/about/Ag_Guide_3rd_ed.pdf>
* The NIH Office of Laboratory Animal Welfare (OLAW) sites and brochures:
	+ Public Health Service (PHS) Grants Policy, <http://grants.nih.gov/grants/policy> <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>
	+ PHS Policy on Humane Care and Use of Laboratory Animals, <http://grants.nih.gov/grants/olaw/references/phspol.htm>
	+ What Investigators Need to Know About the Use of Animals, <http://grants.nih.gov/grants/olaw/investigatorsneed2know.pdf>

o The AVMA Guidelines for the Euthanasia of Animals (2013 edition) <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

* Please complete this MS Word protocol form by providing responses to all sections relevant to your proposed animal use procedures. Sections I through VIII must be completed for all studies. If relevant to the proposed procedures, subsections of Section IX must also be completed. **Please limit your entries only to regions with yellow background color, which will expand to accommodate larger entries.** If you copy text from another document and paste in this file, it will be helpful to the IACUC to change the background color of the pasted text to yellow or light yellow (to do so, select the region of interest, and choose “Borders and Shading…” under the “Format” menu item. You may also use the Highlight speed button if it is present on your tool bar). **Please do not delete any section.** **Sections not relevant to your study should be noted as NA for not applicable.**
* Items in blue are active links to resources, information, and assistance.
* The website (called the ePS for electronic protocol system) allows for uploading MS Word and PDF documents as attachments. These can be tables, figures, training records, sections of grant proposals, SOPs, etc.
* Rename the electronic MS Word file with your last name and a shorten tittle for the protocol application file. Fill and when completed upload the electronic signature page to the electronic protocol system (link available through ePS). **Approval of the protocol is contingent upon receipt of all signatures, training documentation, and occupational health documentation.**
* Submit your completed application (as a MS-Word file) to the IACUC to begin the review process through the on-line e-protocol system at <https://academic.cpp.edu/animalcare/>
* A minimum of ten days is required for a thorough protocol review by the IACUC, assuming the protocol is complete when submitted. **The typical time period is about three to four weeks, if all materials (training, RASQ, signatures, etc.) and items (e.g., responses to reviewer comments) are satisfied.** Reviews are conducted by designated member(s) and full committee methods. Both the usage (a justification for the use of animals is needed) and the welfare (pain and distress) of animals are evaluated. Some call this an ethical review. Protocols are approved for a maximum of three years per federal regulations. Thereafter, a new protocol will need to be submitted to the IACUC for review and approval **before** the current protocol expires. Annual reviews (progress reports) will also be required for review by the IACUC.
* Training in the use of animals and the hazards associated with animals are critical for successful and safe research and teaching. This is protective for both the PI(s) and the animal(s) involved. Animal users must demonstrate their knowledge and awareness through the completion of appropriate coursework. Training at [www.citiprogram.org](http://www.citiprogram.org) is required for all PIs named in this protocol to secure approval of animal use. More information is available on the IACUC website, from the Compliance Associates, and from Cindy Tessler MS RVT RLATG, the Animal Care Facility Coordinator, at 909.869.4955. **Additional training may be required before starting studies in the different animal facilities on campus.** Please, fully describe your experience and training in Section VIII. Attachments may be included through the ePS.
* Using animals in research and teaching endeavors has risks associated with it, including biological, chemical, and physical hazards. A personal assessment of your risk is required by federal regulations, and campus IACUC policies. Documentation of completing a RASQ (risk assessment safety questionnaire) is required on this protocol application. Information about safety and the RASQ process is available at the joint EH&S and IACUC website.
* Information about the IACUC at Cal Poly Pomona is available at <https://www.cpp.edu/research/research-compliance/index.shtml> For general assistance, you may email iacuc-office@cpp.edu or contact the Compliance Associate/IACUC administrator within the Office of Research, Maya Monges-Hernandez (909.869.4215; mayah@cpp.edu), or the IACUC Chair, Dr. Joanne Sohn DVM, MPH (909.869.2401; jsohn@cpp.edu).
	+ For information regarding the animal facilities and the available services, as well as for assistance with training in animal procedures and ordering animals, contact Cindy Tessler, the Animal Care Facility Coordinator, at 909.869.4955 or catessler@cpp.edu
	+ To obtain veterinary consultation regarding planning and implementation of the proposed animal use procedures - particularly surgery, analgesia, and anesthesia - contact the campus Attending Veterinarian: Dr. Melody Wallace at 909.869.6334 or mlwallace@cpp.edu.
* Persons may report (anonymously if desired) any apparent misuse of animals to the IACUC administrator, Associate Vice President for Research, any member of the IACUC, or a College Dean. There is notice of the “whistleblower” policy and procedure at the IACUC website. The whistleblower policy document is posted in animal environments across campus.

**California State Polytechnic University, Pomona**

**Animal Care and Use Committee (IACUC)**

**Animal Use Protocol Application**

*The 3Rs applied to animal research: reduce, refine, replace*

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| --- | --- |
| **Submission date:** |   |

**RESPONSIBLE INVESTIGATOR (must be a faculty member)**

|  |  |
| --- | --- |
| **Name:** |  |
| **Affiliation (college/dept.):** |  |
| **Campus phone number:** |  | **Emergency contact number:** |  |
| **E-mail (CPP, not Gmail or other):** |  |

**ANIMAL USE PROTOCOL**

|  |  |
| --- | --- |
| **Title of protocol:** |  |
| **Type of protocol:** | \_\_\_ research \_\_\_ teaching \_\_\_\_\_\_\_ research and teaching |
| **Type of application:** | \_\_\_ new \_\_\_ renewal of protocol #: \_\_\_\_current protocol #:\_\_\_ amendment to protocol #: \_\_\_\_\_\_\_ (use the MSWord track changes function to the approved protocol when submitting) |
| **Responsible technician(s) (name and phone number):** |  |
| **Grant information (title and #, funding source and dates):**  |  |

**ASSURANCE DECLARATION BY THE RESPONSIBLE INVESTIGATOR (faculty member):** I affirm that, to the best of my knowledge, the information provided in this Animal Use Protocol Application is complete and accurate, and no unnecessary duplication of previous work or experiment is being conducted. No significant changes (which would require an amendment) will be made without prior approval from the Cal Poly Pomona IACUC. I will address issues of training, safety, grant funding, and compliance with other applicable regulations.

I approve of the manner in which animal subjects will be used and will exert every effort to ensure that students and associates involved in the project are properly trained and will use the animals in a manner that is compliant with the procedure(s) described in this application. I have addressed any concerns of safety and occupational health associated with this protocol. I agree to submit the required IACUC Annual Renewals in a timely manner.

|  |  |  |
| --- | --- | --- |
| **Responsible investigator (faculty)** | **Signature (original required)** | **Date** |
|  |  |  |

**ADDITIONAL PERSONNEL:** Other personnel (research associates, students, teaching assistants, volunteers, etc.) involved in this study must sign here to affirm that they have read and understood the proposed animal use procedures. They further affirm that they will use the animals in a manner that is compliant with the procedures described in this application. Indicate that their training with the care and use of animals has been documented within this protocol and the date when the Risk Assessment Safety Questionnaire (RASQ) was submitted. **This is all required for protocol approval and animal usage.**

* <https://academic.cpp.edu/acuc_ehs/>
* <https://academic.cpp.edu/animalcare/>

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| --- | --- | --- | --- | --- |
| **Name** | **IACUC training documented (as applicable)** | **Date of eRASQ submission** | **E-mail address****(CPP only)** | **Signature**  |
|  | **CITI** | **Bldg. 92** | **other** |  |  | Proceed with DocuSign |
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**I. PROPOSED SPECIES, NUMBERS OF ANIMALS TO BE USED, SEX, AND HOUSING LOCATION.** Complete the table below. Additional species may be added to the justification narrative below.

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| --- | --- | --- | --- | --- |
| **Species and strain** | **Number per year** | **Overall amount for 3 years** | **Sex** | **Housing location** |
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Justify both the choice of species and the quantity (numbers) ‘planned’ to be used.

- For research, in each planned experiment, be sure to explicitly account for each experimental and control group and, where appropriate, statistical analyses. If animals are in short supply (e.g., an endangered species), provide a rationale (here and see Section IX, part 16) for their selection and their numbers. If any requirements exist for age and/or weight of animals, please provide justification for these specifications.

**II. RATIONALE FOR THE PROPOSED USE OF ANIMALS.** State briefly the broad objectives and specific aims of this animal use application intended either for teaching or research purposes. Explain succinctly, in lay terms, why these animals will be used in teaching, what knowledge will be gained by their use, or their relevance in improving human and/or animal health in a research project. Write it as if it were to be published in a community newspaper. Convince the public why animals are needed, why they must be used instead of an alternative.

**III. DESCRIPTION OF THE PROPOSED USE OF ANIMALS.** Provide a concise description of this teaching or research protocol with sufficient detail to allow its evaluation by the IACUC. Emphasize the animal aspects; include lab (bench) methods only as pertinent to understanding the animal usage and welfare. *From the ILAR Guide: “a clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the committee.”*

 A. For all proposals, be sure to include the laboratory and/or classroom location where the animal work will be performed. Will animals – live or dead – be taken away from the designated animal facility? Include, as attachments, reference materials (SOPs, lab procedures, descriptions of animal use, etc.) as part of this application. That is, do not refer to another document -- this application package must be complete and stand alone. Literature should be cited in section IX, part 19.). Include any special requests of animal facility personnel, e.g., the need for transportation of animals.

 B. Summarize the husbandry requirements (caging, feed, bedding, temperature, humidity, water for drinking and for aquatics, provisions for enrichment, lighting, etc.). Note any special care or veterinary concerns. Per the *ILAR Guide*, single housing of social species should be the exception; to not provide for social housing must be justified and approved by the IACUC.

 C. For teaching protocols, include information about the course and who will teach it. Describe the training – specific to the animals, procedures, and techniques in other sections (e.g., under euthanasia in V.D and generally in VIII).

 D, For research protocols, include, as appropriate, the research design, outline of the experimental procedures (e.g., breeding, surgery, manipulation, what tissues or other samples will be collected, the kinds of observations in behavioral or field studies), description of other methods to be used, data analysis, and literature references.

**IV. PROCEDURES TO LIMIT DISCOMFORT, PAIN, OR DISTRESS.** Complete the table below.

For "Pain Classification," indicate one of the following:

"A" for procedures which involve no pain or minimal distress to the animals studied (e.g., demonstrations, most nutrition studies, injections, venipuncture, tail biopsy at less than 30 days of age).

"B" for procedures where pain or distress will be controlled by the use of anesthetics, analgesics, or tranquilizers (e.g., surgical techniques, blood sampling under tranquilizer, tail biopsy at more than 30 days of age). ***Complete Section IX, subsection 6.***

"C" for studies where pain relieving drugs cannot be used to control pain (e.g., pain studies, or experiments where drug use would negate the design). ***Complete Section IX, subsections 3, 4, and 5, as relevant.***

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| **Species and strain** | **Number per year** | **Total number for 3 years** | **Sex** | **Pain classification****A, B, or C** |
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**V. METHOD OF EUTHANASIA.** All applications must include this section, even if euthanasia is not the intended means of disposal of animals when ending the protocol, as it may become necessary in an emergency or as the result of an irreversible decline in the health of an animal. *Note*: death must be assured before discarding the carcass.

1. Planned number of animals to be euthanized – zero is acceptable:
2. Describe the procedure to be employed, including the name, dosage, and route of administration if a chemical agent is to be used.
3. How will death be assured? (one method is to open the thoracic cavity of each animal and cut into the heart)
4. Who will perform the euthanasia task? Name the individual(s) and describe their qualifications (specific experience and training). (It is not acceptable to say, for example, the vet tech will do it.)
5. Does the procedure comply with guidelines appropriate to the animal (link to the [American Veterinary Medical Association Guidelines on Euthanasia](https://www.avma.org/KB/Policies/Documents/euthanasia.pdf) for typical species; consult other guidelines for non-traditional species)? Yes or No: .

If not, please justify:

**VI. ALTERNATIVES TO THE USE OF LIVE ANIMALS.** According to federal law, alternatives to the use of live animals must be considered by the PI. Alternatives – the 3 Rs - have been broadly defined to include: procedures that *reduce* the number of animals used (e.g., special statistical designs, sharing animals/specimens with several projects, etc.); *refinements* that decrease the pain or distress experienced by the animal; and methods that *replace* animals with non-animal alternatives or employ the use of animals with a lower taxonomic status. In some cases the 3Rs may actually entail using more animals to obtain significance and reduce the amount of pain and distress suffered by a single animal.

1. If your protocol includes any procedures to *reduce* or *refine*, please describe briefly.
2. If any alternatives (*reducing*, *refining*, or *replacing*) are available, and they are not being used, you must explain what they are and why they are not being used. This may be the case with some teaching protocols, where hands-on activity is required, or federally-mandated animal testing. Further, in the case of painful and/or distressful procedures, this must be justified per USDA’s policy 12.
3. If no alternatives (*reducing*, *refining*, or *replacing*) are available, please explain why.
4. For pain class 'B' and 'C' proposals, if no alternatives are available (as indicated in Section VI. C), then you must fully explain the basis for this assertion. If an electronic literature search constitutes part of the basis for this assertion, please provide:
5. The approximate date(s) you conducted the search:
6. What source(s) were searched:
7. What key words were used in the search:
8. The date range (time period, e.g., 2010 thru 2020) of the search:

**VII. UNNECESSARY DUPLICATION.** Federal regulations prohibit the unnecessary duplication of animal uses. The IACUC at Cal Poly Pomona recognizes that, sometimes, duplication may be necessary (e.g., pilot projects, teaching laboratory exercises, and student research projects that are intended to provide hands-on experience with techniques or equipment or to stimulate the students' intellect).

1. Does the proposed use of animals duplicate previous experimentation on the same species by anyone?
2. If the protocol does duplicate previous experimentation on this species, why is the duplication necessary?
3. If the protocol does not duplicate previous work, what is the basis for this assertion? (That is, are you familiar with the research in the field by virtue of your acknowledged expertise, as the result of your review of the literature, etc.? If your review of the literature involved a computerized search of one or more literature databases, please provide details of the databases, dates covered, and topics or keywords searched.)

**VIII. TRAINING IN PROCEDURES WITH LABORATORY ANIMALS.** Complete the appropriate section here, describing the training and *hands-on* experience of all persons involved with this protocol. Competence is a measure of knowledge, skills, and aptitudes (KSAs). Be specific to the techniques, manipulations, and animals which are to be used in this protocol. Include your (and others’) CITI training transcript number and date of completion. Write as if explaining everyone’s abilities to an auditor or inspector. Describe the roles and responsibilities of persons specifically named as additional personnel on the signature page of this application. *The protocol and amendments which add personnel to approved protocols cannot be approved until training is completed and documented.*

1. Research projects: For all participating individuals (principal investigator/faculty member, graduate students, undergraduate students, McNair scholars, collaborators, etc.), summarize the training pertinent to this investigation. Include on-line courses (e.g., [AALAS learning library](http://www.aalaslearninglibrary.org/), [CITI program](http://www.citiprogram.org)), certifications, experience, classroom training, continuing education, workshops, etc. Personal training records must be kept for review, which should include who was trained, who did the training, what type of training was done, and when. In summary form, describe that here. And indicate here who is responsible for maintaining these training records in the lab or environment where the animal usage will occur.
2. Teaching/laboratory projects: As the instructor (which includes teaching assistants), summarize your specific experience with the animals to be used and the associated procedures. In addition, describe the training to be given to the students relative to laboratory animals, which is not covered in the animal use sections II and III. Attach pertinent documents such as syllabi to the on-line ePS. Because students are being taught, they do not need CITI training, though some instructors assign parts of the curriculum.

**IX. SECTIONS TO BE SUBMITTED.** From the following list indicate which topics, as appropriate, are to be included in this proposed protocol by placing a check (or **X**) in front of the subsection number. Do not mark subsections that are not relevant to your protocol. Complete and submit ALL PARTS of the subsections you have checked.

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| --- | --- | --- |
|  | 1. | TEACHING LABORATORY EXERCISE |
|  | 2. | RESEARCH PROJECT (FACULTY OR STUDENT) |
|  | 3. | PAIN CLASSIFICATION "C" (see definition above) |
|  | 4. | ALTERNATIVES TO DEATH AS AN END POINT |
|  | 5. | PROLONGED RESTRAINT |
|  | 6. | PROCEDURES INVOLVING SURGERY, GENERAL ANESTHESIA, SEDATION, TRANQUILIZATION (must also include subsection 5 of Section IX) |
|  | 7. | SURGERY FOLLOWED BY RECOVERY (must also include subsections 5 and 6 of Section IX) |
|  | 8. | REPEATED SURGERY ON THE SAME ANIMAL (must also include subsections 5, 6, and 7 of Section IX) |
|  | 9. | COLLECTION OF ANIMAL TISSUES OR FLUIDS (from live animals) |
|  | 10. | MAINTENANCE OUTSIDE OF DESIGNATED ANIMAL HOUSING FACILITIES (> 12 consecutive hours) |
|  | 11. | AQUATIC SPECIES (fish, amphibia, and aquatic reptiles) |
|  | 12. | USE OF HAZARDOUS MATERIALS |
|  | 13. | USE OF BIOHAZARDS |
|  | 14. | USE OF TEST SUBSTANCES |
|  | 15. | USE OF CONTROLLED SUBSTANCES |
|  | 16. | MEANS OF DISPOSAL OR FURTHER USE FOR ANIMALS NOT EUTHANIZED |
|  | 17. | RESEARCH OR TEACHING UTILIZING WILD ANIMALS |
|  | 18. | WORK TO BE CONDUCTED OFF-CAMPUS (INCLUDING FIELD RESEARCH AND TEACHING) |
|  | 19. | COLLABORATORS OR EXPERTS CONTRIBUTING TO THE PROJECT |
|  | 20. | LITERATURE CITED FOR RESEARCH PROJECT (FACULTY OR STUDENT) |
|  | 21. | INVESTIGATOR PUBLICATIONS RESULTING FROM PREVIOUS USE OF ANIMALS IN RESEARCH |

**1. TEACHING LABORATORY EXERCISE.** If this protocol is to be used in a laboratory exercise in a regularly scheduled class, please complete this subsection. In the table below, please note the course(s) in which the proposed animal procedures will be carried out, the academic years during which the course will be taught, and the academic periods in which the course will be taught. Please also indicate the number of students who take the course and the number of animals that will be used per academic year.

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| --- | --- | --- | --- | --- |
| **Course prefix,****number and title** | **Academic years in which the course will be taught****(maximum of 3)** | **Semesters taught****(Fall, Winter, Spring, Summer)** | **Number of animals per year** | **Number of students per year** |
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1. Describe the rationale for the number of animals to be used. Include the number of students per animal or per animal encounter. [For example, a team of two or three students will practice blood withdrawal from one cow up to ten times, for a maximum total of 30 needle pricks per animal.]
2. Is a copy of the laboratory exercise attached for the IACUC to review? Yes or No: . What course objectives are satisfied by the use of animals? Provide the full citation of the source from which the exercise was taken.
3. Non-animal alternatives: If any laboratory exercise(s) in this course utilizes non-animal alternatives (e.g., videos, computer lessons, veterinary mannequins, mechanical teaching devices, or other simulations) or live tissue alternatives, briefly describe the exercise(s). If no laboratory exercises in this course utilize non-animal alternatives, please justify.
4. Occupational health and safety: All class participants must review the CPP “Risk Assessment Screening Questionnaire” to allow them to self-assess their risk to exposure with animals. It may be completed electronically at <https://academic.cpp.edu/ACUC_ehs/> to obtain a paper copy please contact the IACUC office iacuc-office@cpp.edu. Faculty are obligated to ensure that students have been made aware of it. Please indicate your understanding of this requirement by entering your initials here: .
5. Privately-owned animals: For situations where privately-owned animals will be used in the above named courses, there are two applicable policies as follows. 1) Memorandum of Understanding - Permission to have an Animal in a University Activity at <https://www.cpp.edu/~research/acuc/documents-and-links.shtml> and 2) the IACUC policy on “Privately-owned animals on campus, including use in classroom studies” available at the IACUC website. Please indicate your understanding of these policies by entering your initials here: .
6. How will the animals, both campus- and privately–owned, be identified and tracked for usage in teaching protocols? Who will be responsible for maintaining the records?

**2. RESEARCH PROJECT (FACULTY OR STUDENT).** Complete the relevant parts of this subsection if this protocol is for a faculty, graduate student, or undergraduate student research project (including term projects in regularly scheduled courses) which take place either on campus or off campus.

1. If this is a student project, please report the following information for all students involved.

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| --- | --- | --- | --- | --- |
| **Name** | **Bronco ID** | **Major** | **Status****(Undergraduate/Graduate)** | **Phone number** |
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1. If this is a student research project which is associated with a course, please indicate the course information (i.e., catalog number, McNair Scholar, Honors College, etc.). If this is a master's thesis research, simply indicate "thesis".
2. Project period (provide month and year): from  through .
3. If this proposal has been submitted for funding, provide the title of the submitted proposal (if different from title given above). **Provide relevant sections of the grant proposal (e.g., for PHS grants, section 12 on Vertebrate Animals, 1. Proposed use of animals and the section “other project information”) as uploaded .docs or PDFs:**

Source(s) of requested funding and date(s) submitted:

1. Occupational health and safety: All participants involved in research projects must review the CPP “Risk Assessment Screening Questionnaire” for self-assessment of one’s risk from exposure to animals and then possibly complete the "Confidential Health History Questionnaire for Students, Faculty, Staff and All Others Exposed to Laboratory Animals" as administered by CPP’s Environmental Health and Safety Office (links below). Faculty are obligated to ensure the submission of these documents.

 Please indicate your understanding of these requirements by entering your initials here: .

These documents may be obtained via the following links:

<https://www.cpp.edu/~research/acuc/documents-and-links.shtml>

e-version at <https://academic.cpp.edu/ACUC_ehs/>

**3. PAIN CLASSIFICATION "C".** Please answer the following questions for any section of the proposed animal study where there will be significant unavoidable pain or distress which cannot be relieved by the use of drugs:

1. What is the scientific justification for the procedure(s)? Explain why pain cannot be alleviated, document consideration of alternatives, and, if there are procedures involving less pain, explain why these procedures are not being used.
2. Has the IACUC Veterinarian been consulted in planning these procedures? Yes or No: .

If not, please explain:

**4. ALTERNATIVES TO DEATH AS AN END POINT.** The IACUC is concerned about humane endpoints as in LD50 or tumor studies. If the proposed use of animals is one in which painful or stressful outcomes are anticipated (pain class “C”), then it is necessary to include criteria to be used in identifying animals that are about to die (are moribund). Include your process for timely intervention to remove them from the study for treatment, or to euthanize them. You may attach recordkeeping forms to the ePS – please note that here.

1. If it is necessary to continue this experiment until any of the animals die as a result of the experiment, then fully justify the requirement.
2. Criteria – provide a list of observable criteria (e.g., weight loss, tumor size, physiological responses) to assess morbidity to use in identifying animals to be removed from the study.
3. Frequency of observation – what is the period of time during each experiment when morbidity is most likely to occur and, during this time, what will be the frequency of observation and assessment of the animals? Importantly, who will make these observations?
4. Process – what procedures are to be followed when it has been determined that an animal is to be removed from the study? Be sure to specify what individuals have the authority to make this determination and what other individuals, if any, must be contacted before animals are removed. What is to be done with animals removed from the study?
5. **PROLONGED RESTRAINT.** If animals will be subjected to prolonged (more than momentary) restraint; prolonged restraint is defined as physical restraint for periods longer than 15 minutes. Physical restraint for periods longer than this time must be described in detail and justified for approval by the IACUC

. Examples include having pigs in a sling and rodents in a tube for multiple blood samples for hours-long periods.

1. Type/Method of restraint (e.g., rabbit plastic restrainer, tethering, chairs, stanchion).
2. Time duration of restraint (e.g., 1 to 2 hours, overnight) and frequency.
3. Scientific justification for the restraint.

Prolonged restraint is defined as physical restraint for periods longer than 15 minutes. Physical restraint for periods longer than this time must be described in detail and justified for approval by the IACUC

**6. PROCEDURES INVOLVING SURGERY, GENERAL ANESTHESIA, SEDATION, TRANQUILIZATION.** (also complete subsection 5 of Section IX):

1. Number of animals to be operated on and/or anesthetized/sedated/tranquilized.
2. Describe the anesthetic, sedative, and tranquilizing agent(s) to be employed (state name, dosages/weight and route of administration).
3. Describe monitoring and supportive care (EKG, IV solutions, etc.) to be provided during surgery.
4. Provide a description of the surgical procedure. An SOP may also be attached to the ePS.
5. What are the training and experiences of individual(s) who will perform the surgery and/or anesthesia, sedation, and tranquilization? Be detailed in the response.
6. Are paralytic drugs (e.g., curare or pancuronium) to be used? If so, name the drug including dosage and route of administration and describe how the absence of pain will be assessed (use of paralytics without anesthesia is prohibited).

**7. SURGERY FOLLOWED BY RECOVERY.** If the animals are expected to regain consciousness following the surgical procedure, please answer the following (also complete subsections 5 and 6 of Section IX):

1. How will asepsis be maintained during the surgical procedure?
2. Describe the supportive care (fluids, warm environment, etc.) to be provided during recovery.
3. Describe analgesics and/or anti-inflammatory agents to be administered after surgery (state dosages, frequency, duration of medication administration, and route of administration).
4. Describe antibiotics to be administered after surgery (state dosages, frequency, duration of medication administration, and route of administration).
5. Who will provide postoperative care (including management of postoperative complications) which may be necessary during normal working hours as well as weekend and holiday care?

F. Describe the potential complications that could occur as a result of the procedure/surgery.

**8. REPEATED SURGERY ON THE SAME ANIMAL.** (also complete subsections 5, 6, and 7 of Section IX) If more than one major surgical procedure is to be performed on a single animal, please describe and justify. Know that the IACUC will especially review this subsection.

**9. COLLECTION OF ANIMAL TISSUES OR FLUIDS, WHETHER OR NOT INVASIVE.** This subsection is intended for live animals. If the procedures include harvesting during necropsy, please note that.

1. Describe what tissue(s), body fluid(s), or other samples are to be collected:
2. Amount to be collected and at what frequency:
3. Describe the method(s) of collection:
4. Will an anesthetic, sedative, or tranquilizer be administered prior to collection? Yes or No: .

(If yes, complete subsections 5 and 6 of Section IX).

**10. MAINTENANCE OUTSIDE OF DESIGNATED ANIMAL HOUSING FACILITIES.** If animals will be maintained in a laboratory or other area not designated for housing of laboratory animals at California State Polytechnic University, Pomona, for more than twelve consecutive hours, then answer the following:

1. Location and describe the facilities that will be used to house the animals:
2. Justification:
3. Who will provide the husbandry and veterinary care in this area? What is the experience and training of the individual(s)?

**11. AQUATIC SPECIES (fish, amphibia, and aquatic reptiles).** When aquatic species are to be used, there are specific animal care and use requirements to address. Some responses may overlap with field studies involving aquatics.

1. Provide details of tank(s) or enclosures and the cleaning schedule.
2. Describe maintenance of water quality (e.g., filtered, frequency of change, temperature, pH, nitrates, chlorine, etc.).
3. Describe routine animal care procedures (e.g., feeding schedule, checking for health of animals).
4. Describe any hazards (biological, chemical, or physical) associated with the maintenance and care of aquatic species and emergency procedures pertinent to the safety of aquatic species and personnel who care for them.

**12. USE OF HAZARDOUS MATERIALS.** If hazardous materials including radioisotopes and toxic substances are to be used, answer the following. Attach approval from the CPP Radiation Safety Committee and/or the Office of Environmental Health and Safety, as appropriate.

1. Radioisotope(s):
2. Other hazardous material(s) or toxin(s):
3. Amount to be used:
4. Role of material in study:
5. Degree and nature of risk to personnel:
6. Safety precautions for personnel directly and indirectly involved:
7. Means of storage of hazardous material:
8. Means of disposal of hazardous material including contaminated animal carcasses, bedding, and wastes:

**13. USE OF BIOHAZARDS.** If infectious agents, tumor cells, recombinant DNA, mammalian tissues, transgenic animals, genetically modified whole plants or other hazardous biological materials (see info at [link to list at EH&S](http://www.cpp.edu/~ehs/portals/biosafety/agents/index.shtml)) are to be used in the proposed study, it may be necessary to complete paperwork and obtain approval with the Institutional Biosafety Committee (IBC, <http://www.cpp.edu/~ehs/portals/biosafety/ibc.shtml>) in the Office of Environmental Health and Safety (EH&S). The IBC has a biosafety survey, instructions, and submission forms to help guide the process. Approvals from the IACUC and IBC can be done in parallel.

1. Has the proposed use been reviewed and approved by the IBC? Enter, as appropriate: yes, no, unsure, in process.
2. Please explain the current status of the IBC application and provide appropriate documentation, e.g. biosafety survey submission ID number and approval memo.
3. What animal Bio-Safety Level (ABSL) is recommended for these biohazards by the appropriate regulatory agencies? Please consult the current edition of “Biosafety in Microbiological and Biomedical Laboratories” (CDC/NIH) for guidance and the documentation of procedures. Additionally, per the NIH Office of Biotechnology Activities, “The maintenance of a transgenic rodent colony (i.e., breeding within a particular transgenic strain) at BL1 is an activity that is exempt from the NIH Guidelines and, as such, does not require IBC registration and approval. The maintenance of a transgenic rodent colony at BL2 or higher falls under Section III-D-4-b and requires IBC approval”.
4. What are the genus, species, and serotype of pathogenic organisms included in this study?
5. Describe the pathogenicity of the organism(s) or agent(s) being used. What PPE (personal protective equipment) is needed for personnel?

**14. USE OF TEST SUBSTANCES.** If a test substance (e.g., a dietary additive) other than the hazardous materials described above is to be administered, answer the following:

1. Test substance(s), dosages, and route(s) of administration:
2. Number of animals to receive the test substances:
3. What are the expected outcomes of administration? How will the animal(s) react? Will there be any toxic metabolites in blood, urine, feces, bedding, etc., as personnel safety concerns?

**15. USE OF CONTROLLED SUBSTANCES.** If controlled substances (e.g., narcotics or barbiturates) are to be used, describe security arrangements and who (name(s) and DEA license number) will be responsible for the record keeping (details at <http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm>) and use of these drugs. To determine whether a substance used in your proposed experiments is a controlled substance, review the information provided by the [U.S. Department of Justice Drug Enforcement Administration](http://www.deadiversion.usdoj.gov/schedules/). Controlled substance records are subject to inspection by the IACUC at any time while this protocol is in effect.

**16. MEANS OF DISPOSAL OR FURTHER USE OF ANIMALS NOT EUTHANIZED.** Please describe as applicable. Per federal guidelines on recombinant or synthetic nucleic acid molecules, genetically-modified organisms are not permitted to be used as food for other animals. For example, transgenic mice cannot be fed to the reptiles, but wild types can be.

**17. RESEARCH OR TEACHING UTILIZING WILD ANIMALS**

1. If animals will be obtained from a commercial supplier, give the supplier's name:
2. If you will be responsible for capturing animals from wild populations, attach a copy of the appropriate wildlife agency approval(s), and answer the following questions:
	1. Describe the method of capture. Describe safety and protective measures for personnel involved.
	2. Describe procedures to ensure the well-being of the animals after capture and during transportation to and from the research site. See the IACUC policy on transport of animals while conducting studies in the field.
3. Do you have written and available SOPs (standard operating procedures)? Yes or No: . Please attach and describe:

D. Are any of the animals being used classified as endangered species or at risk of endangerment? Are special permits required (CITES – the Convention on International Trade in Endangered Species of Wild Fauna and Flora, California Department of Fish and Wildlife, etc.)?

**18. WORK TO BE CONDUCTED OFF-CAMPUS (INCLUDING FIELD RESEARCH AND TEACHING)**

* 1. If the research or teaching involves the use of some Cal Poly Pomona facilities (e.g., the housing of animals) but will occur primarily at another institution which is taking responsibility for approval of the protocol, provide a copy of the IIACUC approval from that host institution. If this is the case, you need only complete the sections of this protocol form which relate to the use of Cal Poly Pomona facilities. Please provide a clear explanation of how the Cal Poly Pomona facilities will be involved under Section III "Description of the proposed use of animals."
	2. Field research or teaching: Complete all relevant sections of this protocol application. Explain the location of the study site and, where appropriate, provide evidence of permission (permit, license; see 17.D.) to use the site. See also the IACUC policy on transport of animals while conducting studies in the field regarding animal care and personnel safety.

**19. COLLABORATORS OR EXPERTS CONTRIBUTING TO THE PROJECT.** List all collaborators or other experts who will contribute substantially to this project, and explain their participation and qualifications for the intended contributions.

**20. LITERATURE CITED FOR THE RESEARCH PROJECT (FACULTY OR STUDENT).** Provide a complete list of the literature cited. This could be relevant to the animal model, housing, methods, or other.

**21. PRINCIPAL INVESTIGATOR (PI) PUBLICATIONS RESULTING FROM PREVIOUS USE OF ANIMALS IN RESEARCH.** Provide a complete list of PI publications that have resulted from the use of animals in research.