REQUEST FOR APPROVAL OF ANIMAL CARE AND USE

California State University Fullerton

*(last revised 1/8/2018)* Protocol #\_\_\_\_\_\_\_\_\_

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| Principal Investigator: |  | Date: |  |

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| --- | --- | --- | --- | --- | --- |
| Department: |  | College: |  | Phone #: |  |

|  |  |
| --- | --- |
| Other Investigator(s)/Student(s): |  |

|  |  |
| --- | --- |
| Title or Topic of Project or Course Number and Title: |  |

Contact the IACUC Coordinator (657-278-7719; iacuc@fullerton.edu) or Chair (657-278-2849; pstapp@fullerton.edu) *before* you submit an application or if you have questions. Complete all relevant sections, then sign and return the form to the Coordinator as an email attachment. If your application is approved, you will be asked to send one signed, original and three photocopies to the IACUC Office (ASC Building, 1121 N. State College Blvd., Suite 231, Fullerton, CA 92834). You must also send one signed, digital copy via email attachment to the Coordinator.

Federal regulations require that the Institutional Animal Care and Use Committee (IACUC) review each project that uses vertebrate animals in research. Projects must be reviewed and approved annually. This protocol may be subject to publication under the Freedom of Information Act.

An Amendment to this protocol must be submitted to the IACUC if any changes are made in the protocol, including personnel changes, and the changes must be reviewed and approved prior to implementation.
**IACUC review and approval normally takes about 4-6 weeks.**

*Information on preferred methods for the care and use of animals may be obtained from the Director of Animal Care. You should also consult the National Agricultural Library (301-344-3212).*

*For emergencies, please call* ***John Chappell, the Director of Animal Care****, on campus at 657-278-5388.
You may also try* ***Dr. Scott Weldy, Campus Veterinarian****, at 949-855-9744.*

*The following questions are derived primarily from federal regulations: Parts 1, 2, and 3 of Title 9 of the Code of Federal Regulations (USDA) and NIH Guide for the Care and Use of Laboratory Animals.*

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| --- | --- | --- | --- | --- |
| New Application |  |  | Renewal Application (Give Previous Protocol No.) |  |

[If the procedures are identical to those in a prior project that has already been approved, please specify the Protocol Number of Previous Project: \_\_\_\_\_\_\_\_\_\_\_. In answering the questions below, please note any differences between this project and the one previously approved.]

|  |  |
| --- | --- |
| Funding Sponsor, if any:  |  |
| Overall Project Period: |  |  |  to |  |  |

Protocols can be approved for a maximum of 3 years; annual review and continuation is required.

**NATURE OF THE PROTOCOL/STUDY (Check all applicable items)**

\_\_\_\_\_ Observation \_\_\_\_\_ Inducement of a Disease State \_\_\_\_\_ Antibody Production

\_\_\_\_\_ Survival Study \_\_\_\_\_ Behavioral Study \_\_\_\_\_ Prolonged Restraint

\_\_\_\_\_ Terminal Study \_\_\_\_\_ Withholding of Food or Water \_\_\_\_\_ Multiple Survival Surgery

\_\_\_\_\_ Blood/Tissue Collection \_\_\_\_\_ Field Study \_\_\_\_\_ Other (provide details)

|  |  |
| --- | --- |
| Species/Strain (and common name) to be used:  |  |
| *[If more than one species is involved, provide this information for each species in a table.]* |
| Sex |  | Age  |  | Weight |  | Max. Number/yr  |  | Is this an Endangered Species? |
| Sex |  | Age |  | Weight |  | Max. Number/yr  |  | Yes |  | No |  |

***[NOTE:*** *Users of animals may be charged per animal per day for use of the campus animal facilities. Consult with the Director of Animal Care to determine the current per diem rates.]*

1. Current federal policy dictates that “the number of experimental animals should be the minimum number necessary to produce valid results. When possible and appropriate, a non-animal substitute should be used, or a species of lower phylogenetic order substituted if available.” (from NIH Publication 92-3415). With this in mind, please answer the following questions:

1.a. **for Research Projects:** Why is the project scientifically important? What are its scientific objectives? Why are these animals (species, number, etc.) appropriate?

Italicized text inside brackets provides information that is meant to be helpful to the PI in filling out the questions. **Please delete these sections before submitting the protocol application.**

*[The main point of this section is to justify the use of animals in a scientific study and to justify the number of animals to be used. Federal animal welfare legislation requires that the number of animals used be scientifically justified. Statements such as “We will need 150 rats to study the x system” or “We use 2 rabbits a week and therefore will need 100 rabbits per year” are not adequate for federal inspectors. Investigators must explain why the estimated number of animals to be used is necessary to achieve their specific scientific goals. This requires a brief description of the experimental design together with the number and species/strain of animals per group/subgroup in each experiment procedure. The total number of experiments/ procedures needed to complete the project should also be given and justified. It may be helpful to use a table to illustrate the distribution of animals among experimental and control groups and the number of animals in each group. Often, statistical power is an important consideration in the justification.]*

1.b. **for Research Projects:** If this protocol represents a renewal of a previously approved 3-year project, explain the relationship to that project.

1.c. **for Instructional Protocols:** Why is the project educationally important? What are its educational objectives? Why are these animals (species, number, etc.) appropriate?

2. From what sources will the animals be purchased or obtained?

3. What provisions are being made for the housing and care of the animals?

*[Please note that animals may not be held for more than 12 hours outside the animal facility unless it has been inspected by the IACUC (Director of Animal Care/Veterinarian/IACUC Chair) and meets all required standards for animal housing.]*

4. **Experimental procedures:**

4.a. What experimental procedures will be performed on the animals? Give details of any surgery, injections, use of radioactive materials, restraint, environmental modifications, stressful stimuli, etc.

4.b. What steps will be taken to minimize discomfort, distress, or pain for the animals?

5. **Surgery:**

5.a. If surgery is to be performed, what anesthetics will be used? Why are these the most appropriate for the circumstances? Who will administer the anesthesia? Give specific type, dose, and route of anesthesia administration (you may request information from the Veterinarian or Director of Animal Care). **NOTE**: Surgery performed on non-rodent species must be performed in a dedicated surgical facility.

5.b. Will any animals be subjected to more than one survival surgery? If so, please explain the scientific necessity for such a procedure.

5.c. If surgery is to be performed, what provisions have been made for pre-operative and post-operative care?

6. **Euthanasia:** If the animals are to be sacrificed, what method(s) of euthanasia will be used? Who will administer the euthanasia? Give specific type, dose, and route of anesthesia administration (you may request information from the Veterinarian or Director of Animal Care).

7. What procedures will be used if unexpected developments place the animal in danger or distress?

*[For example, contact the Veterinarian or the Director of Animal Care, contact the nearest veterinarian if off-campus, euthanize the animal if it is beyond help; if the latter is included, you must provide type, route, dosage, and who will administer the euthanizing agent – this information can be provided by the Veterinarian.]*

8. **Personnel training:** Who will carry out the experimental procedures? What training in the procedures have these persons had? Who provided the training?

*[USDA/ PHS require that investigators must assure/demonstrate the qualifications of all persons who work with animals, and must document the training of all such individuals. The Director of Animal Care can assist with training and documentation.]*

*[****NOTE:*** *All listed investigators and students must complete the CITI online training course “Using Animal Subjects in Research” and provide evidence of completion to the IACUC when submitting a protocol or continuation. Instructions can be found on the CSUF IACUC webpage* [*http://www.fullerton.edu/research/compliance/*](http://www.fullerton.edu/research/compliance/) *.]*

9. **Human health and safety:** Are there any specific, animal-use related risks to the health or safety of technicians, researchers, or students involved in the proposed project? If ‘YES’, please list them. If there are no specific animal-use related risks to personnel, answer ‘NO’.

 *[****NOTE:*** *Only list biological (e.g., infectious agents, toxins, recombinant materials, tissue cultures), chemical, physical, or radiation hazards that are* ***directly related to your use of animals****. Please
do not list here widely accepted risks or hazards generally associated with conducting research in a field or laboratory setting. ]*

10. **Permits:** Do all personnel involved in the project have valid permit(s) from outside agencies that are necessary for the project? **NOTE:** You must include a copy of all permits in each copy of the protocol submitted for review.

11. **Alternatives:**  Are alternatives to this use of animals feasible or useful? The Animal Welfare Act regulations require a statement by the investigator that alternatives were sought. For procedures that may cause more than momentary or slight pain or distress, investigators must also provide a written narrative of the sources consulted to determine whether or not alternatives to the procedure exist.

 Provide specific information on:

11.a. What alternatives have been considered, and why are they not suitable (based on scientific considerations)?

11.b. What literature search or source justifies the conclusion that there is no suitable alternative? If the proposed procedures may cause more than momentary or slight pain or distress, the USDA requires that the PI must do a search for alternatives to the procedure and state what sources were consulted, the search strategy or key works used, the date the search was done, and the years covered by the search. **Reduction, replacement, and refinement** must be addressed (not just animal replacement).

 *[****NOTE:*** *If you do an electronic database search, the USDA requires that you provide database(s) searched, key words used, the date the search was done, and dates covered by the search.*  *Two web sites with good information on alternatives are* [*http://altweb.jhsph.edu/*](http://altweb.jhsph.edu/) *and* [*https://www.nal.usda.gov/awic/about-awic*](https://www.nal.usda.gov/awic/about-awic)*.]*

12. **Duplication:** Does this work duplicate research that has been done on animals by other
 researchers? **OR** Does this work involve duplication to meet instructional goals?

 Provide specific information on:

12.a. What literature search or source has been consulted to provide assurance that there is no duplication?

*[If you do an electronic database search, the USDA requires that you provide database(s) searched, key words used, the date the search was done, and dates covered by the search.]*

12.b. If there is duplication, why is the duplication necessary?

I certify that:

1. This Protocol provides a complete and accurate description of all proposed uses of live vertebrate animals in this research or teaching activity. Any proposed revisions to animal care and use procedures will be promptly forwarded in writing to the IACUC for review.
2. I will comply with all regulations governing the importation, collection and/or maintenance of wild species, including obtaining permits from all applicable regulatory agencies prior to the acquisition of animals.
3. I have received and reviewed a copy of the CSUF Institutional Animal Care and Use Handbook and agree to abide by all applicable laws, policies and regulations, including the Animal Welfare Act, NIH Guide for the Care and Use of Laboratory Animals, and all CSUF policies and procedures regulating the humane use of vertebrate animals in instruction and research. I will ensure that students under my supervision have access to and are familiar with the Animal Care and Use Handbook.

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Principal Investigator: Type or print name Signature

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date

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Co-PI or student: Type or print name Signature

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 Date

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Co-PI or student: Type or print name Signature

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 Date

Approved**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Date: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 IACUC Chair