Q1 **California State University, Bakersfield

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

Q2
**IACUC Protocol Form**
 Today's Date [Original Submission Date]

Q3 **ALL PROTOCOLS MUST BE REVIEWED AND APPROVED BEFORE ANY ANIMALS CAN BE PROCURED OR ANY RESEARCH OR TEACHING ACTIVITIES CAN BEGIN.**  Submission and review of protocols is guided by the Policy and Procedures for the Protection of Animals in Research and Education:  California State University, Bakersfield (November, 1997). Provide all of the information requested.  Indicate N/A in any sections that are not applicable.

 Please work in the MS-Word version of this document and then copy and paste all of the information into this form.

 Faculty:  Please make your Department Chair aware of your Protocol submission.

Q4 For all new protocols not yet approved undergoing review:

 [Please choose from the options below and enter in the Protocol Number where applicable]

 ***[Instructions for Revisions:  Be sure to enter your changes in ALL CAPS so that we can find them easily.]***

* New Protocol (Proceed to Q#6)
* For Revisions, enter the Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* First Revision and Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Second Revision and Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Third Revision and Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Does not apply, see Question 5 below

Q5 For modifications to previously approved protocols:

 [Please choose from the options below and enter in the Protocol Number]

 ***[Instructions for Modification Requests:  Be sure to enter your changes in ALL CAPS so that we can find them easily.]***

* Protocol Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* First Modification and Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Second Modification and Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Third Modification and Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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* Does not apply

Q6 TITLE OF PROJECT

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Q7 RESPONSIBLE INVESTIGATOR NAME [Faculty research mentor, if student research.]

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Q8 RESPONSIBLE INVESTIGATOR E-MAIL

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Q9 RESPONSIBLE INVESTIGATOR CITI (Collaborative Institutional Training Initiative) ACU-Animal Care & Use (also known as HCUAS-Humane Care & Use of Animal Subjects) TRAINING COMPLETION REPORT

Q10 DEPARTMENT:

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Q11 Department Chair Name

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Q12 STUDENT INVESTIGATOR NAME(S) [Do not include student research assistants for faculty research.]

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Q13 STUDENT INVESTIGATOR E-MAIL ADDRESSES

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Q14 STUDENT INVESTIGATOR CITI- ACU-HCUAS TRAINING COMPLETION REPORT(S)

Q15 ADDITIONAL STUDENT INVESTIGATOR CITI-ACU-HCUAS TRAINING COMPLETION REPORT(S) Upload Here

Q16 Occupational Health & Safety in the Care and Use of Research Animals
 [Health and Safety Screening] (link to information on the website)

* I have read & I understand the CSUB -OHS Information
* I have given my students the information above and I confirm that they have read and understood the information
* I have uploaded any necessary Waiver forms, see below

Q17 Upload any waiver forms here:

Q18 Indicate the Occupational Health & Safety Information

|  |  |  |
| --- | --- | --- |
|  | No Known Medical Risk Factors | Medical Risk Factors Waiver Form Signed |
| Principal Investigator  |  |  |
| Student Investigator  |  |  |
| Research Assistant  |  |  |
| Click to write in  |  |  |
| Click to write in  |  |  |
| Click to write in  |  |  |
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Q19 Comments or additional information:

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Q20 For multiple students & adding additional students with a Request for Modification, you may use the Research Personnel List Form (*link to form*) and upload it here:

Q21 Indicate the Activities of Key Personnel

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Student Supervision | Data Collection | Animal Care | Anesthesia/Analgesia | Surgery | Euthanasia | Other |
| Principal Investigator  |  |  |  |  |  |  |  |
| Student Investigator  |  |  |  |  |  |  |  |
| Research Assistant  |  |  |  |  |  |  |  |
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Q22 Please explain if indicated "other" in question above

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Q23 RESEARCH ASSISTANT NAMES

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Q24 RESEARCH ASSISTANT E-MAIL ADDRESSES

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Q25 RESEARCH ASSISTANT CITI -ACU- HCUAS TRAINING COMPLETION REPORT (Upload here)

Q26 ADDITIONAL RESEARCH ASSISTANT CITI -ACU- HCUAS TRAINING COMPLETION REPORT

Q27 ADDITIONAL RESEARCH ASSISTANT CITI-ACU-HCUAS TRAINING COMPLETION REPORT

Q28 ATTACH AN ADDITIONAL DOCUMENT HERE [For example, permit, authorization from an agency, CITI Training completion report(s)]

Q29 ATTACH AN ADDITIONAL DOCUMENT HERE [For example, permit, authorization from an agency]

Q30 ATTACH AN ADDITIONAL DOCUMENT HERE [For example, permit, authorization from an agency]

Q31 ATTACH AN ADDITIONAL DOCUMENT HERE [ [For example, permit, authorization from an agency]

Q32 ATTACH AN ADDITIONAL DOCUMENT HERE [ [For example, permit, authorization from an agency]

Q33 **PROJECT ELEMENTS**

Q34 PROJECT EMPHASIS (select one):

* TEACHING
* RESEARCH

Q35 ANIMAL SPECIES:

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Q36 ESTIMATED NUMBER OF ANIMALS/YEAR:

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Q37 SOURCE OF ANIMALS:

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Q38 SOURCE OF PROJECT FUNDING:

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Q39 Additional Information:

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Q40 Rationale for Modifications (please enter the date of your proposed modification(s)):

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Q41 Upload any supporting documents here:

Q42 QUALIFICATIONS OF PERSONNEL

Q43 QUALIFICATIONS OF THE PRINCIPAL INVESTIGATOR:

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

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Q44 TRAINING AND SUPERVISION OF STUDENTS:

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Q45 Additional Information:

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Q46 OVERVIEW OF THE PROJECT

Q47 THE RATIONALE FOR THE RESEARCH OR EDUCATIONAL ACTIVITY:

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Q48 METHODOLOGY (use terminology understandable to non-specialist):

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Q49 POTENTIAL EDUCATIONAL, SCIENTIFIC, AND TECHNOLOGICAL BENEFITS:

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Q50 Additional Information:

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Q51 Rationale for any modifications (please add the date of your proposed modification):

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Q52 JUSTIFICATION FOR USE OF ANIMALS

Q53 JUSTIFICATION OF THE SPECIES SELECTED:

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Q54 CONSIDERATION OF ALTERNATIVES NOT USING ANIMALS:

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Q55 MINIMIZATION OF THE NUMBER OF ANIMALS:

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Q56 NO UNNECESSARY DUPLICATION OF PREVIOUS EFFORTS (for research protocols explain how you reviewed the literature):

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Q57 Add any additional information Here:

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Q58 Rationale for any modifications (please add the date of the proposed modification):

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Q59 SPECIFICS OF ANIMAL INVOLVEMENT

Q60 FOOD OR WATER RESTRICTIONS, BEHAVIORAL MODIFICATION OR AVERSIVE CONDITIONING, USE OF RESTRAINT, FLUID COLLECTION PROCEDURES, PROVISIONS FOR COMPLICATIONS:

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Q61 DESCRIBE ANY SURGICAL PROCEDURES IN DETAIL, INCLUDING: ALL DRUGS TO BE USED, PRE-OPERATIVE CARE, METHODS AND FREQUENCY OF MONITORING ANESTHESIA, AND POST-OPERATIVE CARE:

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Q62 DESCRIBE ANY PAIN OR DISCOMFORT TO BE EXPERIENCED BY THE ANIMALS AND THE PROCEDURES TO BE USED TO MINIMIZE THESE:

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Q63 IF THE STUDY REQUIRES NO ELIMINATION OF PAIN OR DISTRESS, EXPLAIN WHY:

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Q64 DESCRIBE ANY HAZARDOUS MATERIALS THE ANIMALS WILL BE EXPOSED TO AND INDICATE THE HAZARDS, INCLUDING TO HUMANS. INDICATE PRECAUTIONS FOR HEALTH AND SAFETY OF ALL INVOLVED:

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Q65 IF EUTHANASIA OF ANIMALS IS PART OF THE PROJECT, DESCRIBE THE METHOD AND PROCEDURE. IF NOT, WHAT WILL OCCUR TO THE ANIMALS AFTER COMPLETION OF THE PROJECT?

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Q66 Add any additional information here:

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Q67 Rationale for any modifications:

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Q68 CARE AND HOUSING OF ANIMALS

Q69 DESCRIBE THE PLANNED PROCUREMENT, TRANSPORTATION, AND STORAGE OF THE ANIMALS UNTIL THEY COME INTO THE CARE OF THE INVESTIGATOR(S):

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Q70 DESCRIBE THE HOUSING PROVISIONS FOR THE ANIMALS:

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Q71 WHO IS TO CARE FOR THE ANIMALS ON A DAILY BASIS?

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Q72 HOW IS MEDICAL CARE TO BE PROVIDED?

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Q73 ANIMAL DISPOSITION PROCEDURES FOLLOWING EUTHANASIA?

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Q74 PROVISIONS FOR NOTIFICATION IN CASE OF EMERGENCIES OR UNUSUAL OCCURRENCES?

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Q75 Add any additional information here:

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Q76 Rationale for any modifications (please add the date of your proposed modifications):

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Q77 HUMAN HEALTH AND SAFETY

Q78 DESCRIBE ALL HUMAN HEALTH AND SAFETY RISKS ASSOCIATED WITH THE USE OF ANIMALS IN THIS PROTOCOL.

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Q79 ANIMAL CONTACT HOURS, PER INDIVIDUAL HANDLER, PER WEEK:

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Q80 EXPLAIN THE STEPS THAT WILL BE TAKEN TO MINIMIZE THE ABOVE HEALTH AND SAFETY RISKS.

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Q81 •ANTICIPATED PAIN AND DISTRESS• (Section A)

Q82 ADAPTED FROM ORLANS (1990) & SHAPIRO & FIELD (1987): [REVISED 26 MARCH 2004]

Q83 SELECT ONE CATEGORY

* PROTOCOLS INVOLVING EITHER NO LIVING MATERIALS, LIVE ISOLATES, OR MOST INVERTEBRATE SPECIES. EXAMPLES: THE USE OF TISSUE CULTURE AND TISSUES OBTAINED AT NECROPSY OR FROM THE SLAUGHTERHOUSE; THE USE OF EGGS, PROTOZOA, OR OTHER SINGLE-CELLED ORGANISMS; USE OF INVERTEBRATE SPECIES WITH A SIMPLE NERVOUS SYSTEM.
* PROTOCOLS WITH VERTEBRATE SPECIES IN THEIR NATURAL SETTING. EXAMPLES: PASSIVE OBSERVATIONS OF VERTEBRATES IN THEIR NATURAL SETTING; MANIPULATIONS IN THE NATURAL SETTING INVOLVING NO FOOD OR WATER DEPRIVATION, NOXIOUS STIMULATION, OR RESTRAINT.
* PROTOCOLS WITH VERTEBRATE SPECIES IN STANDARD BEHAVIORAL LABORATORY STUDIES. EXAMPLES: PROTOCOLS WITH RODENTS IN OPEN FIELDS; STUDIES OF RODENTS IN LEARNING APPARATUS INVOLVING POSITIVE REINFORCEMENT, INCLUDING MILD FOOD OR WATER DEPRIVATION.
* PROTOCOLS THAT CAUSE LITTLE PAIN OR STRESS TO VERTEBRATE SPECIES. EXAMPLES: PROTOCOLS INVOLVING INVERTEBRATES WITH COMPLEX NERVOUS SYSTEMS; VERTEBRATE STUDIES INVOLVING THE SHORT-TERM AND SKILLFUL RESTRAINT OF ANIMALS FOR PURPOSE OF OBSERVATIONS OR PHYSICAL EXAMINATION; INJECTION OF NON-TOXIC MATERIAL BY THE FOLLOWING ROUTES: INTRAVENOUS, SUBCUTANEOUS, INTRAMUSCULAR, INTRAPERITONEAL, OR ORAL; ACUTE NON-SURVIVAL STUDIES IN WHICH THE ANIMALS ARE COMPLETELY ANAESTHETIZED AND DO NOT REGAIN CONSCIOUSNESS; APPROVED METHODS OF EUTHANASIA FOLLOWING RAPID UNCONSCIOUSNESS; SHORT PERIODS OF FOOD AND/OR WATER DEPRIVATION EQUIVALENT TO PERIODS OF ABSTINENCE IN NATURE.
* PROTOCOLS THAT CAUSE MODERATE PAIN OR STRESS TO VERTEBRATE SPECIES. EXAMPLES: VERTEBRATE STUDIES INVOLVING CANNULATION OR CATHETERIZATION OF BLOOD VESSELS OR BODY CAVITIES UNDER ANESTHESIA; MINOR SURGICAL PROCEDURES UNDER ANESTHESIA, SUCH AS BIOPSIES, PARATOSCOPY; SHORT PERIODS OF RESTRAINT BEYOND THAT FOR SIMPLE OBSERVATION OR EXAMINATION, BUT CONSISTENT WITH MINIMAL DISTRESS; SHORT PERIODS OF FOOD AND/OR WATER DEPRIVATION WHICH EXCEED PERIODS OF ABSTINENCE IN NATURE; BEHAVIORAL PROTOCOLS ON CONSCIOUS ANIMALS THAT INVOLVE SHORT-TERM, STRESSFUL RESTRAINT; USE OF NOXIOUS STIMULI FROM WHICH ESCAPE IS POSSIBLE.
* PROTOCOLS THAT CAUSE SIGNIFICANT STRESS OR PAIN TO VERTEBRATE ANIMAL SPECIES. EXAMPLES: VERTEBRATE STUDIES INVOLVING MAJOR SURGICAL PROCEDURES CONDUCTED UNDER GENERAL ANESTHESIA WITH SUBSEQUENT RECOVERY; INDUCTION OF ANATOMICAL OR PHYSIOLOGICAL ABNORMALITIES THAT WILL RESULT IN PAIN OR DISTRESS; APPLICATION OF NOXIOUS STIMULI FROM WHICH ESCAPE IS IMPOSSIBLE; PROLONGED (SEVERAL HOURS OR MORE) PERIODS OF PHYSICAL RESTRAINT; INDUCTION OF BEHAVIORAL STRESSES SUCH AS MATERNAL DEPRIVATION, AGGRESSION, PREDATOR-PREY INTERACTIONS; PROCEDURES WHICH CAUSE SEVERE, PERSISTENT, OR IRREVERSIBLE DISRUPTION OF SENSORIMOTOR ORGANIZATION.
* PROTOCOLS THAT CAUSE SEVERE PAIN NEAR, AT, OR ABOVE THE PAIN TOLERANCE THRESHOLD OF UNANAESTHETIZED CONSCIOUS ANIMALS. EXAMPLES: USE OF MUSCLE RELAXANTS OR PARALYTIC DRUGS FOR SURGICAL RESTRAINT WITHOUT THE USE OF ANESTHETICS; SEVERE BURN OR TRAUMA INFLICTION ON UNANAESTHETIZED ANIMALS; TOXICITY TESTING AND EXPERIMENTALLY-INDUCED INFECTIOUS DISEASE OR OTHER INDUCED CONDITIONS THAT HAVE DEATH AS THE ENDPOINT; ATTEMPTS TO INDUCE PSYCHOTIC-LIKE BEHAVIOR; KILLING METHODS NOT USDA APPROVED; INESCAPABLY SEVERE STRESS OR TERMINAL STRESS.

Q84 USDA PAIN/DISTRESS CLASSIFICATION (Section B)

* **USDA Category B**. Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.
* **USDA Category C**. Animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.
* **USDA Category D**. Animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used
* **USDA Category E**. Animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)

Q85 Additional USDA Category Explanations and Examples  http://oacu.od.nih.gov/ARAC/documents/USDA\_Reports.pdf

Q86 AFFIRMATION OF ACCURACY

Q87 When the information in this protocol is complete, checked, approved by the faculty mentor -- if a student project -- Proceed to the submission section

Q88 Required

* I affirm the accuracy and truth of the information in this document

Q89 Required

* I understand that submission is the first step in the IACUC review and authorization process. I will receive an E-mail submission confirmation after I submit this form.

Q90 Please enter a phone number where you can be reached, should we have questions:

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Link to Online IACUC Protocol Form in Qualtrics:

<https://csub.co1.qualtrics.com/jfe/form/SV_5zEAGKyOcJvyJq5>