San Jose State University

­­­­­­­­­­­­­­­­­­­­­­­­­­­­­ *FOR IACUC USE*

Institutional Animal Care and Use Committee

**Protocol for Animal Care and Use**

***This Form Must Be Typed***

**A. Date Submitted**        [ ]  **New** [ ]  **Renewal of #**      [ ]  **Modification of #**

**Section 1: Project Information**

**B. *Project Title:***

**C. *Principal Investigator:***       **Department:**

**Mailing Address & Phone Number:**

**Fax Number:**       **Email:**

**D.**         **Affiliation:**

**Phone Number:**       **Fax Number:**        **Email:**

**E. *IACUC Approval Start Date (mm/dd/yy):***       ***IACUC Approval End Date:***

**F.1 *Type of Study:*** (*Check all that apply)*

[ ]  **Classroom or Instructional; include course numbers**       [ ]  **Breeding only**

  [ ]  **Research project** [ ]  **Field study (Instructional or Research)** [ ]  **Grant proposal**

**F.2**  **Funding:**  **Source(s):**

**F.3** **Will there be outside collaboration to handle animals, supply tissue or provide data for this work?** [ ]  **Yes** [ ]  **No**

If yes, provide details in Section 8 narrative.

**Section 2: Animal Specifications and Ethical Information**

**G. *Common Name Genus/Species Gender Weight Range Total Number Pain Category \*\****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

 **\*\* PROJECT PAIN AND DISTRESS CATEGORY DEFINITIONS ARE AVAILABLE ON THE** [**IACUC RESOURCES WEBPAGE**](http://www.sjsu.edu/research/iacuc/iacuc-forms/index.html)

[ ]  Attached is requested information on additional animal species that could not be included on this page.

**H.1 *Are the animal numbers listed in this proposal the minimum number necessary for this study?***

[ ]   **Yes**[ ]   **No,** If no, provide justification and/or explanation in section 8 narrative.

**H.2 *Will animals be removed from their natural habitat or maintained outside the ACF for >12 hours?*** [ ]  **Yes** [ ]  **No**

 **If yes, what location?** **[ ]  SJSU:**       **[ ]  MLML:**      **[ ]  Other:**

**I.REQUIRED FOR PAIN & DISTRESS CATEGORY III, IV and V STUDIES: Not Applicable** **[ ]  Investigators must consult**

**a qualified veterinarian to ensure that methods of analgesia, anesthesia, tranquilization, euthanasia and pre/post procedural care are current veterinary practice and employed where appropriate to minimize pain/distress to study animals:**

 **VETERINARIAN NAME AFFILIATION DATE CONSULTED**

**Section 3: Permits**

**J. *Are permits required to access, acquire and/or handle the animals used for this project?*** [ ]  **Yes** [ ]  **No**

If yes, fill in table below for all applicable permits.

 **Agency Permit Holder Permit Reference # Period Valid**

|  |  |  |  |
| --- | --- | --- | --- |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

[ ]  Attached is requested information on required permits that could not be included on this page.

**K. *Are any animals associated with the study a species of concern, threatened, or endangered?*** [ ]  **Yes** [ ]  **No**

If yes, provide details in the Section 8 narrative.

**Section 4: Personnel Working with Animals and Training**

 **L.1 *Name & Affiliation Role in Project Project Involvement & Relevant Veterinary Experience and Training***

|  |  |  |
| --- | --- | --- |
|       |  |       |
|       |  |       |
|       |  |       |
|       |  |       |

[ ]  Attached is requested information on additional personnel and/or relevant training that could not be included on this page.

**Role Definitions: *Lead Trainer*** is someone identified in a core; lead position assigned to train or supervise others in animal care and use.

 ***Unsupervised Support*** areindividuals who shall work independently in animal care and use.

 ***Supervised Support*** are individuals whose participation is strictly guided or assisted in duties related to animal care and use.

 ***Student Learners*** are individuals participating as students in course learning or training in animal care and use.

 **L.2 *CITI training course requirements for personnel working with animals by role in the project:***

The Principal Investigator (PI) must provide proof of successful completion of online training in animal welfare policy (either a or b below) available online through the Collaborative Institute Training Initiative (CITI). With input from the IACUC, the PI shall indicate what CITI training is required for personnel working with animals based on their role in the project:

 PI co-PI Lead Unsupervised Supervised Student Learner

1. **Basic Course - Working with the IACUC** [ ]  [ ]  [ ]  [ ]  [ ]  [ ]
2. **Wildlife Research Course** (a or b acceptable) [ ]  [ ]  [ ]  [ ]  [ ]  [ ]
3. **Working with**  **in research** [ ]  [ ]  [ ]  [ ]  [ ]  [ ]
4. **Reducing Pain and Distress in Rodents** [ ]  [ ]  [ ]  [ ]  [ ]  [ ]
5. [ ]  [ ]  [ ]  [ ]  [ ]  [ ]
6. [ ]  [ ]  [ ]  [ ]  [ ]  [ ]

**Section 5: Procedures and Manipulations Involving Animals**

**M.1  *Do you require guidance or assistance from the University Animal Care staff for this project?*** [ ]  **Yes** [ ]  **No**

 If yes, provide details in Section 8 narrative where UAC services are requested.

**M.2 *Will photographic or video images be taken of animals or activities described in the protocol?*** [ ]  **Yes** [ ]  **No**

If yes, provide details in Section 8 narrative of how such recordings will be made and used or disseminated.

**M.3 *Will non-pharmaceutical grade or experimental grade compounds be used in live animals?*** [ ]  **Yes** [ ]  **No**

If yes, describe and provide justification in Section 8 narrative how each product will be prepared and used.

**N. *Non-Surgical Procedural Overview:*** [ ]  ***Not Applicable***

 **1. Method of identification/marking:**

**2. Sampling:**       **Route:**

**Quantity:**        **Frequency:**

**Method of restraint:**        **Performed by:**

**3. Dosing:**       **Route:**

**Dose & Volume:**        **Drug concentration:**

**Frequency:**        **Method of restraint:**

**[ ]** Detailed in the narrative is requested information on additional procedures that could not be included on this page.

**O. *Field Study Manipulations:*** [ ]  ***Not Applicable***

 **1. Method(s) of Collection:**

 **Method(s) of Collection:**

 **Method(s) of Collection:**

**2. Sampling:**       **Route:**

**Quantity:**        **Frequency:**

**Method of restraint:**        **Performed by:**

**3. Device Application:**

**Device weight:**        **Percent weight to body mass:**

**Method of restraint:**   **Removal:**  [ ]  **No** [ ]  **Yes**

**4. Average to maximum holding time:**

**[ ]** Detailed in the narrative is requested information on additional procedures that could not be included on this page.

**P. *Surgical Procedure Overview:*** [ ]  ***Not Applicable***

1. **Surgical procedure**        **Invasive surgery?** **[ ]  Yes** **[ ]  No**
2. **Survival surgery?** [ ]  **Yes** [ ]  **No Multiple surgeries per animal?** [ ]  **Yes** [ ]  **No**
3. **Endotracheal intubation?** [ ]  **Yes** [ ]  **No Oxygen supplementation?** [ ]  **Yes** [ ]  **No**

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1. **Surgery to be performed at [ ]  SJSU:**       **[ ]  Other:**

**5. Pre-medication:**       **Route:**

**Dose & Volume:**        **Drug Concentration:**

**Administered by:**        **Method of Restraint:**

**6. Anesthetic:**       **Route:**

**Dose & Volume:**        **Drug Concentration:**

**Administered by:**        **Method of Restraint:**

**[ ]** Check if intraoperative records will be maintained and made available to the IACUC

**Q. *Post-Operative Care for Anesthetic Procedures:*** [ ]  ***Not Applicable***

 **1. Post-operative observations and care provided by:**

1. **Observation frequency**       **Location:**

 **3. Analgesic:**       **Route:**

**Dose & Volume:**        **Drug Concentration:**

**Administered by:**        **Frequency:**

**4. Treatment:**       **Route:**

**Dose & Volume:**        **Drug Concentration:**

**Administered by:**        **Frequency:**

**[ ]** Check it post-operative observation and care records will be maintained and made available to the IACUC

**Section 6: Use of Hazardous Materials or Infectious Agents**

Contact the campus [Environmental Health & Safety](https://www.sjsu.edu/fdo/departments/ehs/) group for assistance completing this section if needed. A campus [Biological Use Authorization](https://www.sjsu.edu/research/ibc/ibc-bua/index.html) may be required independent of the IACUC protocol application.

**R. *Will Chemically Hazardous Substances be used in this Study?* [ ]  No [ ]  Yes** If yes, complete section R.

1. **Compound/Agent**
2. **Hazard classification:**       (Attach copy of SDS)
3. **Adverse health effects:**
4. **Personnel to have contact with this agent:**

**5. Personal protective equipment used:**

Provide details on precautions taken with chemical storage, handling, decontamination & disposal in Section 8 narrative.

**[ ]** Attached is requested information on additional agents that could not be included on this page.

**S. *Will Biologically Infectious Agents be used in this study?* [ ]  No [ ]  Yes** If yes, complete section S.

**1. Organism/ Agent**

**2. Classification:**        **Biosafety Level:**

1. **Adverse health effects:**
2. **Personnel to have contact with this agent:**

**5. Personal protective equipment used:**

 Provide details on precautions taken with agent storage, handling, decontamination & disposal in the Section 8 narrative.

 **T. *Are Personnel Handling Wildlife or Working in the Field?* [ ]  No [ ]  Yes** If yes, complete section T.

**1. Zoonosis potential**

**2. Adverse health effects:**

**3. Identify health safety precautions to be taken (such as prophylaxis, bite kit, medical surveillance etc.):**

**[ ]** Attached is requested information on additional agents that could not be included on this page.

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**Section 7: Euthanasia of Animals**

**U. *Will animals be euthanized as part of this study?* [ ]  Yes [ ]  No**

 1. If not, can animals be transferred to another SJSU approved protocol at the end of the study? **[ ]  Yes [ ]  No**

 2.Will moribund or mortally injured animals be euthanized with input from a qualified veterinarian? [ ]  **Yes** [ ]  **No**

**V.**  ***Method of Euthanasia*** *(Experimental or as a Contingency):*

**1. Physical Means:** [ ]  ***Not Applicable***

**i. Method used:**

**ii. Method of restraint:**

**iii. Will pre-sedation be used prior to physical means? [ ]  Yes [ ]  No** If not, justify in Section 8 narrative.

**iv. For instructionals, will students be expected or allowed to perform this procedure? [ ]  Yes [ ]  No [ ]  NA**

**2. Chemical Injection:** [ ]  ***Not Applicable***

**Agent:**       **Route:**

**Dose & Volume:**        **Drug Concentration:**

**Administered by:**        **Method of Restraint:**

 **3. Inhalational Method:** [ ]  ***Not Applicable***

1. **Agent:**
2. **Means of administration**

**W. *Do all euthanasia methods conform to the*** [**AVMA Guidelines on Euthanasia**](https://www.avma.org/sites/default/files/2020-01/2020-Euthanasia-Final-1-17-20.pdf)**? [ ]  Yes [ ]  No,** explain:

**X. *Final* *Disposition of Animal Carcasses and Tissue:***

**1. How will carcasses or tissues be disposed of?** [ ]  **In biohazard bags and placed in cooler located in DH-437**

[ ]  **Other:**

**Section 8 Narrative Addendum: Project Description and Justification**

**Y. *Non-technical Description and Justification of Project.*** (To be typewritten and attached to the completed application)

**1. Name of Primary Investigator(s) and Title of Study;**

**2. Where appropriate, insert any tables and additional information where indicated in Sections 2, 3 & 4 of the application form;**

**3. Project Purpose** *and* **Research Objective;**

**4. Hypothesis being tested** *and* **Anticipated Results;**

**5. Methods and Procedures**

1. Provide a detailed lay description of all aspects of animal care and use from animal acquisition to completion of the study;
2. Where appropriate, insert images, tables and additional information where indicated in Sections 5 & 6 of the application form;
3. For student instructionals, include a detailed plan for student preparation in the care and use of live animals.

 **6. Project justification, including, where appropriate, literature search for sections b & c \*\***

**a. REDUCTION: provide written justification/calculations as to the number of animals required for the study.**

[**Power and sample size calculator**](http://www.3rs-reduction.co.uk/html/6__power_and_sample_size.html)

**b. REPLACEMENT: justify the rationale for using animals, appropriateness of species to be used, and examine alternatives to the live animal model where appropriate.**

[**Johns Hopkins Center for Alternatives to Animal Testing**](https://caat.jhsph.edu/resources/index.html)

**c. REFINEMENT: investigators must explore alternatives to all procedures that cause more than momentary or slight pain, discomfort or distress in live animals as defined by pain and distress category III, IV and V (USDA D & E).**

[**USDA Animal Welfare Information Center on alternatives**](https://www.nal.usda.gov/awic/alternatives-literature-searching)

1. **Conclude with a general harm-benefit analysis statement based on the highest pain and distress level assignment associated with live animal activities and the project goals.**

 **\*\* The literature search should be presented in narrative format to include: 1) date the search was conducted, 2) search engines used or sources referenced, 3) key words used in the search, 4) years covered by the search, 5) citing articles in support of the search objective, and 6) conclusion in summary as to the results of the literature search.**

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**Section 9: Investigator Assurances and Department Endorsement**

**Z. *Animal Welfare Assurance Statements and Principal Investigator Signature:***

 *Acknowledge each statement by checking the box for each line item and signing below*

[ ]  The IACUC protocol and activities involving animals described herein are complete and accurate.

[ ]  Activities herein do not unnecessarily duplicate previous experiments involving animals.

[ ]  I will obtain written approval from the IACUC before initiating any changes to the animal care and use protocol.

[ ]  The care and use of the animals will comply with all IACUC policies, including SJSU Policy on the Humane Care and Use of Animals (Policy S14-6 and subsequent revisions thereof), which I have read and understand.

[ ]  Proper consideration has been given to selection of the animal model and numbers, including statistical or rational group size determination, and careful experimental design to maximize the use and minimize the loss of animals.

[ ]  All animal manipulations have been refined to that which will minimize or avoid discomfort to the greatest extent possible given the study objective. Where required, I have consulted a qualified veterinarian and explored the pertinent scientific literature, and the sources and/or databases cited and have found no valid alternative to procedures described herein that may cause greater than momentary or slight pain or distress to the animal, including supportive care relief.

[ ]  The IACUC and/or Campus Veterinarian will be promptly notified of any unexpected study results that adversely affects animal welfare, including unanticipated pain, distress, morbidity or mortality.

[ ]  All personnel working with animals shall be: identified in the IACUC protocol; review and have access to the IACUC approved protocol in the laboratory; properly trained, guided, supervised and assisted in humane and scientifically acceptable standards in veterinary monitoring, animal manipulation and record keeping, including administration of anesthetics, analgesics, and euthanasia where indicated. My designee or I shall train and verify individual proficiency of personnel directly responsible for animal care, manipulation or surgery and document that such training has occurred.

[ ]  Where applicable, all animal work shall be conducted in accordance with a valid scientific collection and/or access permit, public and private, and will not commence until all necessary permits are approved by the permitting agency.

[ ]  My designee or I shall discuss with all personnel project hazards and safety procedures, including the respective Health Risk Category information provided by IACUC. All personnel are entitled to health consultation with a physician and treatment under the University’s Laboratory Animal Occupational Health Program. Contact the University Animal Care office to enroll.

 Principal Investigator NamePrincipal Investigator SignatureDate

**AA. *Acknowledgement by Department Chair:*** *Required only for instructional activities involving animals*

Having read the project description, I hereby endorse the animal-related activity on behalf of the department or college.

 Department Head or Faculty SponsorDepartment Head or Faculty Sponsor SignatureDate

**Section 10: Institutional Animal Care and Use Committee Approval**

**BB. *IACUC Review of Protocol # Health Risk Category: RC-1\_\_\_ RC-2\_\_\_ RC-3 \_\_\_\_***

**Approved as Presented** [ ]  **Approved with Modification** [ ]  **Approval Denied** [ ]



 SJSU IACUC Chairperson NameSJSU IACUC Chairperson SignatureDate

***IACUC Remarks, Required Modifications or Explanation of Approval Denial:***

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