

**California State University, Stanislaus  
Institutional Animal Care and Use Committee  
SOP: IACUC Protocol Review Requirements and Checklist**

**Purpose**

The IACUC must review and approve all proposed components of a protocol involving the care and use of vertebrate animals.

**Review Procedures**

- A quorum must be present for all deliberations and votes.
- Consultants may be invited to assist the IACUC in review of complex issues, however, they will not have voting privileges.
- The minutes, recorded by the IACUC Administrator, must include discussions about the protocol in sufficient detail so as to reflect the depth of the consideration by the committee.
- The following elements are considered in the IACUC review:
  - ♦ Hypothesis and specific aims
  - ♦ Species and number of animals required and justification of same
  - ♦ Justification of species and why work can't be done in a lower phylogenetic species
  - ♦ Where animals will be housed and unusual housing and husbandry requirements including restriction of food or water
  - ♦ Building and room numbers where experiments will be performed
  - ♦ Adequacy of training and experience of personnel in the procedures used
  - ♦ All manipulations and experimental procedures
  - ♦ Justification of food/water deprivation and/or prolonged or unusual restraint, if performed
  - ♦ Literature search for alternatives to pain/distress
  - ♦ Statement of how procedures have been refined to reduce pain/distress/morbidity and whether death is used as an endpoint
  - ♦ List of all chemical agents used for sedation, analgesia and anesthesia including doses and route of administration
  - ♦ Description of surgical procedures and post-surgical monitoring
  - ♦ Description of anesthesia and post-surgical monitoring
  - ♦ Description and justification of multiple major survival surgeries
  - ♦ Criteria and process for timely interventions, removal of animals from a study, or euthanasia if painful or stressful outcomes are encountered
  - ♦ Method of euthanasia or disposition of animal
  - ♦ Safety of working environment for personnel
  - ♦ Investigator/Instructor's assurance that the work does not involve unnecessary duplication of efforts

## IACUC PROTOCOL REVIEW CHECKLIST

**Protocol Number:**

**Project Title:**

**Investigator/Instructor:**

Based on your review of the above referenced protocol, complete the following sections as they relate to the corresponding sections of the protocol:

### Project Summary for Layperson

Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the study objectives written in language understandable to a lay person?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the rationale and purpose of the study clear?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is it clear why the study is important to human or animal health, the advancement of knowledge, or the good of society?

### Study Objectives

Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the project design clear and does it make it possible to track animals throughout the course of the study?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the procedures to be performed on the animals adequately described?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Do these procedures include monitoring after normal work hours, weekends, and holidays?

### Animals

Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the number of animals requested reasonable for the goals of the proposed studies?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the types of animals appropriately classified for each species listed?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Does the number of animals described in the text of the protocol match the number requested in the table?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Has the building and room number(s) where the research will be conducted been provided?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If animal identification methods are employed are they clearly described and appropriate?

### Justification for Animal Use

Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Have at least two independent databases been searched?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Will this study unnecessarily duplicate any previous work?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If yes, is the justification for proceeding with the proposed studies adequate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the justification for the choice of animal species adequate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the justification for the number of animals to be used adequate?

### Pain and Distress

Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If the study involves the restraint of animals, is it justified appropriately and are any sedation, acclimation, and/or training procedures adequately justified?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the resultant effects that the animals may be expected to experience (e.g., pain or distress, ascites production, etc.) clearly described and justified?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the description of the methods that were employed to <u>refine</u> existing tests or procedures in order to minimize animal distress adequate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For blood withdrawal, is the volume, frequency, withdrawal site(s) and methodology clearly described and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are other procedures such as tail biopsies or tail bleeding clearly described and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the plan of action that will be followed in case of animal illness clearly described?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the project endpoint criteria (tumor size/appearance, percentage body weight gain/loss, inability to eat or drink, behavior abnormalities, clinical symptomatology, or signs of toxicity) clearly stated and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the procedures to monitor pain and distress clearly indicated and adequate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are other potential stressors (e.g., food or water deprivation, noxious stimuli, environmental stress) clearly described and justified?
<b>Use of Anesthetic Agents/ Drug Enforcement Agency (DEA) Regulated Controlled Substances</b>			
<b>Yes</b>	<b>No</b>	<b>N/A</b>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Have all anesthetics, analgesics, sedatives, and tranquilizers been listed along with their dosages and routes of administration?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the dosages consistent with accepted veterinary practice?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If inhalation anesthetics are to be used, are proper scavenging procedures and safety precautions described?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If the project will involve controlled substances, has the location, security, and logging of use been adequately described?
<b>Euthanasia and Final Disposition of Animals</b>			
<b>Yes</b>	<b>No</b>	<b>N/A</b>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the criteria to be used to determine when euthanasia is to be performed clear and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the method of euthanasia for the animal species/age clearly described and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is this method approved by the AVMA Panel Report on Euthanasia?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Has a method been included to ensure the death of the animals?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the method of carcass disposal indicated and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If death is an endpoint, is it scientifically justified?
<b>Surgery (if applicable)</b>			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the type of surgical procedure (survival/non-survival) correctly identified?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Has the location where the surgery is to be performed specified and is this an approved site?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the <u>pre-operative</u> procedures (fasting, analgesic loading, etc.) clearly described and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is the description of the surgical procedure(s) complete and are appropriate aseptic procedures included for survival surgeries?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the monitoring and supportive care procedures to be used <u>during</u> surgery clearly described and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the individuals who will perform the surgery identified and are they qualified to perform the procedure(s)?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For <u>survival surgery</u> , is the post-operative care and the frequency of observation clearly described and appropriate?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For <u>survival surgery</u> , is a procedure described for the detection and management of post-operative complications during normal work hours, weekends, and holidays described and appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If this is non-survival surgery, is the method of euthanasia and the determination of death clearly described and adequate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If paralytic agents are to be used, is the description of how ventilation will be maintained and how pain will be assessed clearly described and adequate?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If major survival surgery has been performed on the animals prior to being placed on this study, is the prior surgical procedure described?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If more than one survival surgery will be performed, is the justification for the second survival surgery acceptable?

### Experience and Training

Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are all individuals who will participate in this study listed?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are all listed individuals, including Co-PI's and students, appropriately qualified and trained?

### Summary (Other Issues or Recommendations):

### Recommendation

<input type="checkbox"/> Approve	<input type="checkbox"/> Modifications Required to Secure Approval	<input type="checkbox"/> Withhold Approval
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<b>TYPED NAME – IACUC MEMBER</b>	
<b>SIGNATURE &amp; DATE</b>	