TEXAS A&M UNIVERSITY
SAN ANTONIO

| IACUC SOP | Protocol Review | |
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| SOP#116.00 | IACUC Approval: 5/10/2024 | IO Approval: 6/13/2024 |

**Purpose:**
To provide guidance regarding the protocol review process followed by IACUC.

**Statement:**
The use of all live vertebrate animals subject to oversight by Texas A&M University-San Antonio, whether for research, teaching, testing purposes must be submitted for evaluation by the IACUC. For active live animal use in clubs, demonstration or display an IACUC request for demonstration/display of live vertebrate animals form must be submitted prior to the event.

**Responsibilities:**
1. The Principal Investigator (PI) is responsible for submitting complete documents outlining the proposed activities related to the care and use of animals.

2. The Office of Research Compliance is responsible for processing submitted documents and notifying the PI of IACUC decisions.

3. IACUC is responsible for the review and approval of all live vertebrate animal use.

**Protocol Review Criteria**
In its review of protocols involving animals, the IACUC will consider whether the protocol is in accordance with PHS Policy and recommendations in the *Guide*. The IACUC will weigh the ethical consideration with the potential benefit to humans or animals by using the following criteria:
1. Procedures involving animals are described completely.
2. The layman summary should be understood by the public.
3. Procedures, numbers and species selection are scientifically justified.
4. Demonstration of the "three Rs."
    a. Replacement of the animal model with a non-animal model or a species phylogenetically lower justification of the species used.
    b. Refinement of procedures to enhance animal well-being and minimize/eliminate pain and distress.
    c. Reduction in number of animals used justification of animal numbers and group sizes
    d. Provide assurance that activities do not unnecessarily duplicate previous efforts.
5. Literature Review should follow the OLAW guidelines. The search for alternatives should encompass:
    a. search for alternatives to the procedure
    b. search for duplication of the study
    c. present the gaps the study fills.
6. Procedures that may cause pain or distress will be performed using the appropriate sedation, anesthesia, or analgesia, unless withholding such agents is justified for scientific reasons, in writing, and approved by IACUC.
7. Surgical procedures are performed aseptically, and personnel are appropriately trained in surgical technique and anesthesia monitoring.

8. Methods of euthanasia used are consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia unless a deviation is justified for scientific reasons in writing by the PI.
9. The living conditions of animals will be appropriate for the species and contribute to their health and comfort. Exceptions to the *Guide* recommendations for housing must be justified in writing.
10. Personnel conducting procedures on animals are or will be appropriately qualified or trained in those procedures.

**Definition of USDA Pain Categories**

| Category | Explanation | Example |
|---|---|---|
| **B** | Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes | • Animals on breeding protocols with no research or experimental component<br>• Animals acquired by the facility but held in quarantine or acclimation period prior to use<br>• Euthanizing animals on a holding protocol following current professional standards<br>• Observing animal behavior in their home enclosures without manipulation |
| **C** | Animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs | • Observing animal behavior in the lab<br>• Positive reward training or research<br>• Food restriction that reduces the animal's weight by no more than 15 percent of normal age-matched controls<br>• Manipulative procedures such as weighing, injections, palpations, skin scrapings, and radiography<br>• Administering an anesthetic, analgesic or tranquilizing drug to an animal for restraint purposes to perform a procedure that involves no pain or distress such as imaging procedures<br>• Exposure to mild alteration in environmental conditions with appropriate acclimation |
| **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 | • Surgical manipulations (survival or terminal) in which the animals received appropriate pre-, intra-, and post-operative anesthetics and analgesics<br>• Using Freund's complete adjuvant if alleviation of pain/distress occurs<br>• Tumor induction or implantation if alleviation of pain/distress occurs<br>• Induced infections or antibody production in which animals experience pain alleviated by analgesics<br>• Exsanguination under anesthesia |
| **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 | • Paralysis or immobilization of a conscious animal<br>• Any Category D procedure for which needed analgesics, tranquilizers, sedatives, or anesthetics are withheld for justifiable study purposes<br>• Toxicological, microbiological, or infectious disease research that requires continuation after clinical signs are evident without medical care or that requires death as an endpoint<br>• Food or water restriction which reduces the animal's weight by more than 15 percent of normal age-matched controls<br>• Certain types of forced exercise protocols that could reasonably be expected to cause distress or exhaustion<br>• Applying noxious stimuli that the animal cannot avoid/escape<br>• Exposure to extreme environmental conditions<br>• Long-term restraint (days to weeks) |

**Special Considerations**

The following items are identified in the *Guide* as areas requiring special consideration by the IACUC. The IACUC will review these areas as described below:

1. Housing of social species
   a. Single housing of social animals must be justified (does not include single housing for veterinary/clinical concerns about animal well-being)
2. Experimental and Humane Endpoints
   a. The IACUC should assess the appropriateness of the endpoints based on the following:
      i. A precise definition of the humane endpoint (including assessment criteria).
      ii. The frequency of animal observation.
      iii. Training for personnel responsible for assessment and recognition of humane endpoints.
3. Unexpected Outcomes/Adverse Events
   a. The IACUC should review expected adverse events identified in the protocol and assess the appropriateness of the monitoring plan for such events.
4. Prolonged Physical Restraint
   a. Restraint devices should not be considered a normal method of housing and must be justified in the protocol. The protocol must address the following items:
      i. Description of the duration of confinement.
      ii. Acclimation and monitoring procedures.
      iii. Ensure that Pain and Distress classification is congruent to frequency, method and duration of physical restraint.
      iv. Criteria for removing animals that do not adapt or acclimate; and
      v. Provision for veterinary care for animals with adverse clinical consequences.
5. Multiple Survival Surgical Procedures (on a single animal)
   a. May be categorized as major or minor and will be evaluated to determine effects on the animal's well-being and be adequately justified by the PI.
   b. Multiple major survival surgery may be approved based on the following considerations:
      i. Surgeries are essential components of a single research protocol.
      ii. Scientifically justified by the PI. Cost savings alone is not an adequate justification.
      iii. Necessary for clinical reasons.
6. Food and Fluid Regulation
   a. The protocol should use the least restriction necessary to achieve goals while maintaining animal well-being. The PI should address monitoring methods in the protocol for the IACUC to review.
7. Use of Non-Pharmaceutical-Grade Agents
   a. The use of non-pharmaceutical-grade agents will be reviewed for justification.

**Review Types**

1. Full Committee Review (FCR) – A process of IACUC review where all IACUC members are provided with the proposed animal care document(s) and requires a convened meeting of a quorum (>50%) of the IACUC members to take actions on the proposed protocol.
2. Designated Member Review (DMR) – A process of IACUC review where all IACUC members are provided with the proposed animal care document(s) and, if no member requests that document receive a full committee review, at least one member will review the proposed

research document(s). The designated members(s) have authority to approve, require modifications, or request a full committee review.

3. Administrative review- A process where the IACUC office reviews document for minor changes and has the authority to approve or send to full committee. Administrative approval may occur:
   a. After FCR when administrative changes are requested (i.e. typos, miscalculations, waiting on approvals from other groups, etc.) upon a unanimous vote by the quorum present.
   b. Directly for changes in personnel, animal use site, grant funding, vendor.
   c. Tissue Use Protocols (SOP 106)
   d. Request or demonstration or display of live animals (SOP 113)

**IACUC Actions**

After review of a protocol, the IACUC may take one of several actions as defined below and specified in SOP 103:

1. **Approval** – The IACUC determines the review criterion was met and the PI may begin experiments or procedures as described in the protocol.
2. **Modifications required for approval** – The IACUC determines that the protocol is approvable contingent upon receipt of a very specific modification. This action results in the protocol being sent to DMR or administrative approval.
3. **Withhold approval** – The IACUC determines the review criterion was not met.

**De Novo Applications**

The PHS Policy requires a complete protocol submission/resubmission every three years. Annual updates and renewals will be reviewed annually. The PI is required to submit an updated protocol for continuing activities prior to the three-year expiration of their protocol if they wish to continue work. The IACUC will review the protocol based on the criteria defined in this policy.

**References:**

1. National Research Council. Institute for Laboratory Animal Research. 2011. Guide for the Care and Use of Laboratory Animals. Public Health Service, Bethesda, MD.
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals http://grants.nih.gov/grants/olaw/references/phspol.htm.
3. ARENA/OLAW Institutional Animal Care and Use Committee Guidebook. Second edition, 2002.
4. Animal and Plant Health Inspection Service, USDA. US Animal Welfare Act (AWA 1990) and Regulations (PL-89-544, as amended, 7USC Ch. 54) 2008. CFR Title 9, Subchapter A - Animal Welfare. U.S. Government Printing Office, Washington, D.C.

**History:**

Version 01 - Initial Approval: 2/10/2023

Version 02- Approved 5/10/2024

IO Approved: 3/29/2023; 6/13/2024

**Reviewer Checklist**

## I. All Protocols

☐Does the protocol meet basic standards for scientific merit?
☐Are the objectives of the proposed research clear?
☐Are the procedures clearly described?
☐Are experimental endpoints and duration of experiments clear?
☐Are the effects on the condition of the animals clearly stated?
☐Is the justification for the number of animals clear and logical?
☐Are alternatives to animal use and refinements of procedures documented?
☐Are the methods of euthanasia appropriate?

## II. As Required

☐If alternative housing and husbandry methods are proposed, are they acceptable and justified?
☐If pain relief would be withheld, is the scientific justification adequate?
☐If multiple survival surgery is proposed, is the scientific justification adequate?
☐If biohazardous material use is proposed, are appropriate measures described for handling?
☐If animals may become seriously ill or debilitated, are criteria for interventional euthanasia defined?

## III. Veterinary

☐Are the proposed anesthesia and analgesia appropriate?
☐Are there refinements to the procedures which you would like the Investigator to consider?
☐Do you anticipate complications to the procedures not considered by the Investigator?
☐Are post-procedural care and observation adequate?