Purpose:
The oversight and evaluation of animal care and use, including the review of proposals that involve animals to ensure that the criteria established in the PHS Policy, “Guide for the Care and Use of Laboratory Animals”, is followed. In its review of proposals, the IACUC’s primary goal is to facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

Scope:
The use of all live vertebrate animals subject to oversight by Texas A&M University Commerce, whether for research, education, testing, production (breeding), or health surveillance purposes must be submitted for evaluation by the IACUC. The use of tissues, organs, or other parts of dead animals, if received as such, is exempt from IACUC review.

Responsibilities:
The IACUC is responsible for the review and approval of all animal care and use activities. Each IACUC member is responsible for recusing themselves during the deliberation and decision in which they have a conflict or perceived conflict of interest.

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

The IACUC office is responsible for processing submitted documents and notifying the PI of IACUC decisions.

I. Protocol Review Criteria
In its review of protocols involving animals, the IACUC will consider whether the protocol is in accordance with PHS and USDA Policy and recommendations in the “Guide” and “Ag 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 and should be understood by all members of the committee.
2. Demonstration of consideration 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. Must provide assurance that activities do not unnecessarily duplicate previous efforts.
3. 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, by the PI.
4. Surgical procedures are performed aseptically, and personnel are appropriately trained in surgical technique and anesthesia monitoring.
5. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
6. 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.
7. The living conditions of animals will be appropriate for the species and contribute to their health and comfort. Exceptions to the “Guide” and “Ag Guide” recommendations for housing must be justified in writing.
8. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
9. Personnel conducting procedures on animals are or will be appropriately qualified or trained in those procedures.
10. If applicable, all hazards used on animals are approved by the appropriate Safety Officer/Committee.

II. 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; and/or
      iv. The response required upon reaching the humane endpoint.
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. Criteria for removing animals that do not adapt or acclimate; and
      iv. 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;
      iii. Cost savings alone is not an adequate justification.
      iv. 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.
III. Review Types

1. **Full Committee Review (FCR)** – A process of IACUC review where all IACUC members are provided with the proposed research document(s) and requires a convened meeting of a quorum (>50%) of the IACUC members to take actions on the proposed research document(s).

2. **Designated Member Review (DMR)** – A process of IACUC review where all IACUC members are provided with the proposed research 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.

IV. IACUC Actions

After review of a protocol, the IACUC may take one of several actions as defined below:

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.

V. De Novo Applications

The PHS Policy requires a complete review of protocols at least every three years. 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.

VI. Amendments

All changes to an approved protocol require IACUC approval and must be submitted through an amendment form to the IACUC prior to implementing the change. For example, the protocol may need to be presented for consideration:

- When experimental data suggests a better way to address a research question
- When unanticipated findings change the course of an experiment
- When clinical complications arise during the course of an experiment
- When the number of animals, location or personnel is going to be changed

The IACUC committee reviews the suggested change of protocol, decides according to IV. via FCR or DMR, or suggests a De Novo Application to the PI.

V. Annual Review of Protocols

PHS Policy (IV, C, 5) requires that a complete IACUC review of PHS supported protocols be conducted at least once every three years. This constitutes a de novo review three years after approval of the protocol. AWAR (§2,31,d,5) requires annual reviews of protocols. TAMUC research compliance provides a 30 day notice to the PI and requires that reapproval is sought prior to expiration of the protocol.

References:
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals

History:
Version 01 – Petra Collyer, Austin Templer, Marsha Keenan