Institutional Animal Care Program (IACP)		**UTSA**
Title: **Protocol and Amendment Review and Approval**		
Policy#: **IACP 011**	Date in Effect: 06/13/08	
Rev #: **04**	Rev Date: 0**5/13/16**	
Rev #: **05**	Rev Date: **02/03/23**	
In Effect ☒ Rescinded ☐	Date Rescinded:	

A) **GENERAL**

Any use of animals (defined as 'live or dead vertebrate animals') for teaching,

research, testing, experimentation or exhibition under the auspices of the

University of Texas at San Antonio (UTSA), regardless of funding source,

must be reviewed and approved by the UTSA Institutional Animal Care and Use

Committee (IACUC) prior to bringing the animals in to UTSA. The complete

description and justification for the use of animals must be submitted by the principal

investigator (PI) to the IACP (Institutional Animal Care Program) office

(iacuc@utsa.edu or 458-7733) using the Application for Animal Use form.

The PI must have a faculty appointment at UTSA or be employed as a UTSA

veterinarian; however, with the appointment of a UTSA veterinarian or faculty

member as a Co-PI, visiting scholars, post-doctoral students, or graduate students

may be allowed by the IACUC to serve as a PI.

The UTSA IACUC generally meets once a month. Applications for review by

the IACUC must be received no later than the published receipt deadline in

order to be placed on the agenda for that month's meeting. Meeting dates and

submission deadlines are published in the IACP webpage.
https://research.utsa.edu/compliance/iacuc.html

B) PROTOCOL APPROVAL (START OF STUDY)

1) NO WORK may begin with animals (including ordering animals) until all of the following have occurred:

   a) Enrollment, of all personnel listed on the protocol, in the Occupational Health Program (OHP) or the Student Medical Surveillance Initiative (SMSI).

   b) Completion of IACUC-required training by all personnel listed on the protocol; and

   c) Approval of the protocol application by the IACUC.

C) IMPLEMENTATION PROCESS

1) All investigators, research technicians, students, and other personnel involved in handling, treatment and use of animals are required to enroll in the OHP/SMSI. Enrollment is mandatory; participation is optional but highly encouraged.

   a) The PI is responsible for monitoring all individuals who work with live animals on his/her research, and ensuring that they either participate in the Program or sign a formal declination of participation.

   b) Enrollment in the OHP/SMSI must be completed prior to signing up for the LARC hands-on training.

2) All investigators, research technicians, students, and other personnel involved in handling, treatment and use of animals are required to complete all IACUC required training. (iacuc@utsa.edu or 458-7733)

a) Students rotating through laboratories with an approved animal protocol(s) must complete the training program and be approved by the IACUC prior to being added onto the approved protocol to work with animals.

b) The PI is responsible for ensuring that all individuals who work with live animals on his/her research have been listed on the applicable IACUC protocol, receive the appropriate IACUC-required training, ensures proficiency in surgery/special procedures, and are approved by the IACUC (except as noted in C.4. below).

3) Unaccompanied access to UTSA animal housing facilities (vivaria) will be given only to those who are listed on an approved protocol, have completed IACUC-required training and are enrolled in the OHP/SMSI.

4) Persons who are not listed on an approved IACUC protocol may not handle animals. The only exception is people participating in training under an IACUC-approved Training Protocol.

D) ONGOING REVIEW OF APPROVED PROTOCOLS

1) Annually, for protocols involving USDA-covered species, prior to the anniversary month of the most recent approval of the protocol, the PI must submit an *ANNUAL PROGRESS REPORT (APR)* for review and approval by the IACUC. The PI is responsible for submitting the completed APR form according to the published submission deadlines, Institutional Animal Care Program (IACUC) (utsa.edu) . The IACUC office will attempt to send courtesy electronic reminders prior to the due date. However, it remains the PI's responsibility to comply with this requirement.

2) Failure to submit completed forms in sufficient time to be placed on the IACUC agenda for consideration of approval before the study anniversary date will result in study being placed in an inactive status.

3) Protocols are approved for no more than three years. Every third year, prior to the anniversary month, the PI must submit a ***PROTOCOL RENEWAL*** IACUC-New-or-3-Year-Renewal-Application-updated-11-3-17.docx (live.com) for review and approval by the IACUC.

   a) The renewal protocol must be submitted on the current version of the protocol application form and completed in its entirety electronically.

   b) Although the renewal is the PI's responsibility, the IACUC office will notify the PI electronically when an active protocol is approaching expiration.

E) AMENDMENTS

1) Major protocol changes: Once a protocol has been approved, all major changes must be submitted to the IACUC office as a ***PROTOCOL AMENDMENT*** Institutional Animal Care Program (IACUC) (utsa.edu). The proposed changes must be approved by the IACUC or designee prior to implementation by the PI. The ***PROTOCOL AMENDMENT*** Institutional Animal Care Program (IACUC) (utsa.edu) is filled out electronically and submitted to the IACUC office in time to be included on the Agenda for the IACUC meeting at which the PI wishes the application reviewed.

   a) Examples of changes considered to be major include, but are not limited to:

   - Change in the objectives of a study.
   - Change from non survival to survival surgery, addition of survival surgery or multiple major survival surgeries.
   - Changes resulting in greater discomfort for the animals or in a greater

degree of invasiveness (e.g. withholding of analgesics; use of adjuvants; food or water restriction; prolonged physical restraint).

- Cervical dislocation or decapitation without anesthesia.
- Change of the species to be used.
- An addition of more than 20% of the originally approved number of animals, OR when the total number of animals requested in all amendments exceeds 20% of the originally approved number of animals in the protocol.
- Change in Principal Investigator.
- Changes in anesthetic or analgesic agent(s).
- Change in the method of euthanasia.
- Increase in the duration, frequency, or number of procedures performed on an animal.
- Unanticipated marked increase in clinical signs or in proportion of animal deaths.
- Increase in duration and/or severity of pain or distress to the animals.

- Addition of a strain that carries increased animal welfare concerns

2) Minor protocol changes: Once a protocol has been approved, minor changes may be administratively approved.

   a) Examples of changes considered to be minor include, but are not limited to:

   - Addition / deletion of a telephone number, room number, location or building name.
   - Misspellings &/or typographical errors.
   - Addition of new personnel other than the PI.
   - Changes in funding source.
   - An addition of up to 20% of the originally approved number of animals.
   - Addition of minor surgery (e.g. implantation of osmotic mini-pump).
   - Minor modifications in surgical techniques that lead to no increase in clinical consequences to the animal.
   - Addition of non-invasive sampling.
   - Reduced blood sampling volumes or frequency.

F) DESIGNATED MEMBER REVIEWS (DMR)

A PI can request review by the Designated Member Review process of any applications but such request must be justified and meet the criteria of Expedited Review Policy (IACP 006).