

Institutional Animal Care & Use Program - UTEP	
Title: Protocol and Amendment Review and Approval	
Policy#: 011	Date in Effect: 27 March 2015
Version #: A	Rev Date:
In Effect <input checked="" type="checkbox"/> Rescinded <input type="checkbox"/>	Date Rescinded:

A) RESPONSIBILITIES

It is the responsibility of all personnel using animals at UTEP to abide by this policy. Exceptions to these policies must be approved by the IACUC before implementation.

B) APPLICATION

This policy applies to all faculty animal users engaged in research and teaching at UTEP.

C) GENERAL

- 1) All submissions to the IACUC are electronic via IRBNet at www.irbnet.org. Necessary forms can be found within the IRBNet Library or the [IACUC Website](#). For any submission questions, the IACUC Office can be reached by e-mail at iacuc@UTEP.edu or by phone at 915-747-7913. Expiration deadlines are ultimately the PI's responsibility, however the IACUC office, through IRBNet will automatically send out courtesy 90 day, 60 day and 30 day expiration reminders prior to the protocol's actual expiration date.
- 2) Using the Application for Animal Use form, a complete description and justification (protocol or amendment) for the use of animals must be submitted by the principal investigator (PI) via IRBNet to the IACUC office. The PI must have a faculty appointment at UTEP or be the Attending Veterinarian unless otherwise approved by the UTEP Institutional Official. The UTEP 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 on the [IACUC webpage](#).

D) PROTOCOL APPROVAL (START OF STUDY)

- 1) NO WORK may begin with animals (including ordering animals) until all of the following have taken place:
 - a) Approval of the protocol application by the IACUC;
 - b) Completion of IACUC-required training by all personnel listed on the protocol; and
 - c) Enrollment of all personnel listed on the protocol in the Occupational Health Program. Enrollment is mandatory; participation is optional but highly encouraged.

E) IMPLEMENTATION PROCESS

- 1) All investigators, research technicians, students, and other personnel involved in handling, treatment and use of animals are required to complete all [IACUC required training](#). For more information on training requirements, please refer to the [IACUC website](#) or contact the IACUC office at 915-747-7913, iacuc@UTEP.edu.
 - a) Students rotating through laboratories with an approved animal protocol(s) must complete the training program prior to working with animals.
 - b) The PI is responsible to ensure that all individuals who work with live animals on his/her research have been listed in the applicable IACUC protocol, receive the appropriate IACUC-required training, are enrolled in the OHP, and are approved by the IACUC (except as noted in E) 3) below).
- 2) Unaccompanied access to UTEP animal housing facilities (vivaria) will be given to emergency response personnel and to those who are listed on an approved protocol, have completed IACUC-required training and are enrolled in the Occupational Health Program.
- 3) Persons who are not listed in an approved IACUC protocol may not handle animals. The only exceptions are people participating in training under an IACUC-approved Training Protocol or as approved for such training in the approved protocol. However, these individuals will be briefed on the occupational hazards to which they will be exposed and will sign a [liability form](#), which must be approved by the Attending Veterinarian or Veterinary Services Manager.

F) ONGOING REVIEW OF APPROVED PROTOCOLS ONLY FOR USDA COVERED SPECIES

- 1) Annually, prior to the anniversary month of the most recent approval of the protocol, the PI must submit an **ANNUAL PROGRESS REPORT** for review and approval by the IACUC. The PI is responsible for submitting the completed form according to the published submission deadlines. The IACUC office, through IRBNet will automatically send out a 90 day, 60 day and 30 day expiration reminders prior to the expiration 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 becoming expired. No research or teaching activities may continue in animals under an expired protocol. Continuation of research or teaching activities on an expired protocol will be reported to the appropriate funding and regulatory agencies. Animals already in the experimental queue should remain in the study until protocol procedures for their use have been completed. Furthermore, for other animals, no procedures other than routine husbandry care can be carried out until the protocol is reapproved.
- 3) Protocols are approved for no more than three years. Every third year, prior to the anniversary month, the PI must adhere to one of the following:
 - a) If the PI wishes to continue the study, an updated and completed **Request for Use of Animals Form** must be electronically submitted via IRBNet.
 - b) If the PI wishes to close the study and not continue any animal activity on the protocol, a Closing Report must be electronically submitted via IRBNet.
 - (1) If a Closing Report is not submitted within 60 days after the expiration date, PI will be notified by the IACUC office alerting them the protocol will be administratively closed.
 - c) Although the renewal and/or closure is the PI's responsibility, the IAUC office, via IRBNet will notify the PI electronically at 90 days, 60 days and 30 days when an active protocol is approaching expiration.

G) AMENDMENTS

- 1) Major protocol changes: Once a protocol has been approved, all major changes must be submitted electronically via IRBNet to the IACUC office as a [Protocol Amendment](#). The proposed changes must be approved by the IACUC prior to implementation by the PI and submitted 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).
 - Physical method of euthanasia without anesthesia or sedation (e.g., cervical dislocation or decapitation without anesthesia).
 - Change of the species to be used.
 - An addition of more than 10% of the originally approved number of animals, OR when the total number of animals requested in all amendments exceeds 10% 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.
- 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 10% of the originally approved number of animals.
- Adding or replacing a strain if the new strain has no increased health consequences as a result of the approved manipulation.
- Change in gender.
- Addition of non-invasive sampling.
- Reduced blood sampling volumes or frequency.

H) DESIGNATED MEMBER REVIEW (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 [*IACUC Policy 006 - Designated Member Review*](#).