

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
Policy #13
PROTOCOL APPROVAL, IMPLEMENTATION, REVIEW and AMENDMENT PROCESSES

In concurrence with
TTUHSC El Paso Assurance #D19-01056 and
Federal Regulations and Guidelines

I. Purpose

Any use of live vertebrate animals (including teaching, research, testing, experimentation and exhibition) that occurs under the auspices of TTUHSC El Paso (regardless of funding source) must first be reviewed and approved by the IACUC.

The TTUHSC El Paso IACUC meets on the second Friday of each month. Items for consideration by the IACUC must be received by the published deadline in order to be placed on the agenda for that month's meeting. Submission deadlines are published at the [IACUC website](#).

II. General requirements for Animal Use at TTUHSC El Paso

Before bringing live animals into TTUHSC El Paso,

- A. The PI must have a faculty appointment at TTUHSC El Paso (as defined by **TTUHSCEP Operating Procedure 73.08**, unless otherwise approved by the TTUHSC El Paso Institutional Official.
- B. The PI must have either:
 - 1) an animal protocol approved by the TTUHSC El Paso IACUC, or
 - 2) written approval of the Institutional Veterinarian (IVet) to transfer animals onto the Laboratory Animal Resource Center (LARC) holding protocol.
- C. The LARC **must** be notified and an import form must be submitted for approval.
- D. Please be aware that an Material Transfer Agreement (MTA) may be required to import animals from another institution (guidance can be obtained from TTUHSC El Paso Research Contracts and Agreements).

III. Training Requirements

- A. IACUC-required CITI training must be completed by all personnel listed on the protocol. Educational requirements are available on the IACUC website, under the 'Help' section of iRIS, and through the
Reviewed and Approved by the TTUHSCEP IACUC: 06/14/2024
Page 1 of 4

IACUC Staff (Contact information available on the IACUC webpage). Training must be completed every 3 years. Renewal training is identical to the initial CITI course.

- B. All personnel listed on the protocol must be enrolled in the Occupational Health and Safety Program (OHS) and must visit the OHS Nurse for evaluation of the completed Health Questionnaire, before working with animals. The questionnaire is available as a fillable form from the IACUC website, under the 'Help' section in iRIS, and through the IACUC Staff (Contact information available on the IACUC webpage). An updated questionnaire must be evaluated by OHS every 3 years.
- C. All personnel must also contact Safety Services for appropriate PPE fitting as needed for different Animal Biosafety Levels (ABSL) in the LARC (e.g. N95 respirator or CAPR in ABSL-3).
- D. All personnel must comply with LARC training programs before accessing the LARC facility.
- E. Sanctions may be imposed for people whose training or OHS clearance has lapsed including temporary suspension from animal use until these items have been updated.

IV. Submission of Initial Protocol (Start of Study)

- A. The PI must complete an online IACUC Initial Application Form in [iRIS](#) for review by the TTUHSC El Paso IACUC. Specific information regarding this process can be found at IACUC Webpage.
- B. IACUC recommends that the applicant consult with iVet before submitting the application for review by the TTUHSC El Paso IACUC to reduce the number of resubmissions.
- C. The protocol must be reviewed and approved by the TTUHSC El Paso IACUC before animal use may begin.

V. General requirements for animal use

- A. Students or temporary personnel working in laboratories must participate in the IACUC training programs before working with animals.
- B. The PI must ensure that individuals who work with live animals on his/her research are listed on the IACUC protocol, receive the appropriate IACUC-required training, and are approved by the IACUC (except as noted in section V.D below).
- C. Access to TTUHSC El Paso facilities housing animals will be given only to those who are listed on an approved protocol, have completed IACUC-required training and are enrolled in the Occupational Health and Safety Program. Please be aware that the personnel will need to complete an access form and packet before LARC access is granted.
- D. Animals may **only** be handled by the people specifically listed on the IACUC protocol, the Institutional Veterinarian and the LARC animal care staff. The only exception is for people who are receiving

training under the IACUC-approved LARC Training Protocol.

VI. Ongoing Review of Approved Protocols

- A. **Annual Status Reports (ASR):** The PI must submit an ASR for review and approval by the IACUC before the 1-year and 2-year anniversary of the approval date of the protocol. The PI will receive electronic notification before the anniversary month and must update the last approved version of his/her study application. The PI must submit all required forms before the study anniversary date. Otherwise, the study will be placed "on hold" until the ASR is submitted. Although submission of the ASR is the PI's responsibility, automatic notices are sent through the iRIS system when an active protocol is approaching its expiration date.

All research personnel listed on the protocol must have current training (section III) in order to avoid delays in approval.

- B. **Three-year renewals:** Every third year, the PI must renew their existing animal use protocol (i.e., initiate a 3-year renewal) for review and approval by the IACUC before the anniversary month. A revised version of the study application must be attached to the submission. This will count as the ASR for that year. Although submission of the renewal is the PI's responsibility, automatic notices are sent through the iRIS system when an active protocol is approaching its expiration date. If the PI fails to submit all required forms with sufficient time to be placed on the IACUC agenda for consideration of approval before the study anniversary date, then the study will expire and must be resubmitted as a new protocol for reinstatement. Please keep in mind that the 3-year renewal is akin to the initial approval process. Renewal requires a Full Committee Review and all aspects of the protocol are reviewed. Thus, please prepare the submission appropriately in advance of the deadline.

All research personnel listed on the protocol must have current training (section III) in order to avoid delays in approval.

C. **Post-committee review process:**

After submitted protocols and amendments are presented and discussed at a convened meeting of the IACUC, the committee members present will vote to either a) approve, b) require modifications to secure approval, or c) withhold approval. When the IACUC requires modifications of a protocol in order to secure approval, the members will vote to follow one of the procedures described below:

- 1) A second Full Committee Review (FCR), following the procedures delineated above.
- 2) A designated member review (DMR), if approved unanimously by all members at the meeting, following the procedures described in Policy #7 Designated Reviews. However, if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR.
- 3) Minor modifications may be confirmed by IACUC administrative personnel, if approved by the designated members (if DMR) or unanimously by all members at the meeting when the protocol was presented (if FCR).

VII. Amendments

- A. Once a protocol has been approved, any and all changes must be submitted to the IACUC as a protocol amendment. The amendment must be submitted electronically through iRIS, as a revision of the approved protocol. All proposed changes must be approved by the IACUC before implementation by the PI.
- B. Certain additions, deletions, and/or changes to a protocol (for example, a change in personnel) may occur via the Administrative Approval process as outlined in Policy #20 ([Administrative Approval of Amendments](#)).
- C. Certain changes to the protocol (for example, changes in the anesthesia regimen, or the use of a different AVMA-approved euthanasia method) may occur through Veterinary Administrative Approval, provided that they do not impact animal welfare, as outlined in [Policy #27 Policy #27 \(Veterinary Administrative Approval for Significant Protocol Changes \(VVC\)\)](#).

Related policies

Investigators must comply with all other institutional policies at TTUHSC El Paso and Federal Guidelines. This list includes, but is not limited to, the following:

IACUC Policy 0: Introduction to IACUC policies and procedures

IACUC Policy 7: Designated Reviews

IACUC Policy 12: Procurement, Housing and Accountability for the use of Live Vertebrate Animals

IACUC Policy 20: Administrative Approval of Amendments

IACUC Policy 22: Review of Grant Content with IACUC Protocol

IACUC Policy 27: Veterinary Administrative Approval for Significant Protocol Changes (VVC)

IACUC Policy 28: Standard Extension During Emergencies

LARC Policy: Importation of Animals to the TTUHSC El Paso LARC