IACUC Policy #13: Protocol Review and Approval Procedures

1. Background

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

The TTUHSC IACUC meets on the second Friday of each month. Items for IACUC consideration must be received by the submission deadline available on the IACUC website to be placed on the next month’s meeting agenda.

2. General Requirements for Animal Use at TTUHSC

Before utilizing live animals at TTUHSC,

A. The Principal Investigator (PI) I must have a faculty appointment at TTUHSC (as defined by TTUHSC Operating Procedure 73.08), or Texas Tech University (as described in IACUC Policy #14 and the Memo of Understanding between TTU and TTUHSC) unless otherwise approved by the TTUHSC Institutional Official.

B. The PI must have either:

   1) an animal protocol approved by the TTUHSC IACUC\[10\]; or,

   2) written approval of the Institutional Veterinarian (IVet) to transfer animals into the Laboratory Animal Resources Center (LARC) Holding Protocol. In this case, the PI must have a protocol already approved by another agency/institution’s IACUC, and provide the approved protocol to the TTUHSC IACUC. Animals on the LARC Holding Protocol may not be utilized until the TTUHSC IACUC approves the protocol.

C. All ordering or import of animals must be processed through the LARC, and is subject to IVet approval.

3. Submission of the Initial Review Submission Form (Start of Study)

A. The PI must submit a completed Initial Review Submission Form in iRIS for IACUC consideration and review. This e-form includes the attached IACUC Application describing the protocol information.

B. After submission of an Initial Review Submission Form, the following items must be completed before animal use may begin:

   1) The protocol must be approved by the IACUC.

   2) IACUC-required CITI training must be completed by all personnel listed on the protocol[6]. Contact the IACUC staff for details.

   3) All personnel listed on the protocol must be enrolled in the Occupational Health and Safety Program (OHSP). The PI is responsible for ensuring that this requirement is met.

   4) A protocol for research involving hazardous chemicals and biological materials and recombinant or synthetic nucleic acid molecules must be approved by the TTUHSC Institutional Biosafety Committee (IBC) or TTU IBC (for School of Veterinary Medicine IACUC protocols).
5) In order to access TTUHSC Vivaria, all personnel on the protocol must complete a LARC Orientation with the facility supervisor.

4. General Requirements for Animal Use

A. Students or temporary personnel working in laboratories must participate in the training program before working with animals.

B. The PI must ensure individuals listed on protocol(s) receive the appropriate IACUC training[^10], are qualified and competent in the animal procedures or are closely supervised by qualified and experienced personnel[^8], and are approved to handle animals by the IACUC (except as noted in section 4.D below).

C. Access to TTUHSC Vivaria will be given only to persons
   1) listed on an IACUC-approved protocol;
   2) with completed IACUC-required training;
   3) enrolled in the Occupational Health and Safety Program; and,
   4) after completion of the LARC Orientation by the facility supervisor.

D. Persons not listed on an IACUC-approved protocol may not handle the animals. The only exception is those persons who are participating in training under an IACUC-approved Training Protocol.

5. Continuing Review of Approved Protocols

The IACUC’s review responsibilities do not end with initial approval of the protocol. The IACUC is obligated by both AWAR and the PHS Policy to conduct ongoing reviews of protocols[^7] which serve to ratify the decisions of the IACUC on the current status of the protocol.

A. Annual Status Reports (ASR)

The PI will submit an ASR e-form in iRIS for review[^4] and approval by the IACUC every year before the anniversary month of the latest approval date of the protocol. The PI will receive an iRIS e-notification before the anniversary month. The ASR may be without changes requested to the IACUC Application, or the ASR may be with changes requested to the IACUC Application.

An ASR without changes does not require the approved IACUC Application be revised. An ASR with changes must be accompanied by an Amendment e-form submission describing the changes being requested. The Amendment e-form submission must include a revised IACUC Application version be attached. The PI must submit all required forms with sufficient time to be placed on the IACUC agenda for consideration of approval before the study anniversary date.

B. Three-Year Renewals

Every third year, the PI must submit the IACUC 3-Year Renewal e-form in iRIS with a revised IACUC Application attached for review and approval by the IACUC before the anniversary month. This will count as the ASR for that year. Renewals must be submitted as an update of the last approved version of the IACUC Application. The PI will receive an iRIS e-notification before the anniversary month, and must update the last approved version of the IACUC Application.
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 the protocol must be resubmitted as an Initial Review Submission Form for reinstatement.

**Non-Use Administrative Termination of Protocol**
The 21st Century Cures Act, Section 2034 (d) mandates federal efforts to reduce administrative burden for researchers while maintaining the integrity and credibility of research findings and protection of research animals. Therefore, if animals have not been ordered or used during the previous 36 months since the Initial Review Submission or Three-Year Renewal was approved, the study will be administratively terminated. If administrative termination of a “non-use” protocol occurs, Investigators may submit an *Initial Review Submission Form* and the IACUC will consider the judicious use of animals in research and will assess the scientific importance of the study.

**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[^1]

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. 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 staff, if approved by the designated members (if DMR) or unanimously by all members at the meeting when the protocol was presented (if FCR).

**D. Procedures related to animal care and use, housing and management should be continuously evaluated, and when indicated, should be refined or replaced[^2].** During the continual review of protocol procedures, investigators may be asked to make changes in their protocol due to regulatory changes and advances in veterinary standards of care.[^8]

**E. Research described in an NIH grant application[^10] must be congruent with any corresponding TTUHSC IACUC-approved protocol.**[^9]

**6. Amendments**

**A.** Once a protocol has been approved, any and all changes requested must be submitted as an IACUC Amendment in iRIS. The Amendment must include an attached revised IACUC Application. All proposed changes must be approved by the IACUC or designee before implementation by the PI[^10].

**B.** Certain additions, deletions, and/or changes to an approved protocol may occur via the Administrative Approval process as outlined in Policy #20.

**C.** Significant changes to an approved protocol may occur via the Veterinary Verification and Consultation[^3] process as outlined in Policy #20.
References

1. Animal Welfare Act and Animal Welfare Regulations § 2.31
2. AVMA Animal Welfare Principles
3. Guidance on Significant Changes to Animal Activities NOT-OD-14-126
4. Guide for the Care and Use of Laboratory Animals
5. Institutional Animal Care and Use Committee Guidebook
6. Standards and certification process for humane handling, care, treatment, and transportation of animals. 7 U.S.C. § 2143
8. US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
10. What Investigators Need to Know About the Use of Animals. NIH Publication No. 16-6009