

Institutional Animal Care and Use Committee		UNTHSC
Title: Protocol Submission Process		
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A. BACKGROUND INFORMATION

- a. The IACUC at the University of North Texas Health Science Center has the responsibility to assure that all animal use activity meets federal law mandates, Public Health Service policy, the Guide recommendations and all accreditation expectations.

B. RESPONSIBILITIES

- a. It is the responsibility of the Principal Investigator (PI) to submit protocol submissions in a timely manner to allow for proper review.

C. PROCEDURES

a. INITIAL PROTOCOL REVIEW

- i. For protocols to be considered for review at an IACUC meeting, they must be submitted by the submission deadline listed on the IACUC website (this is three weeks before the meeting date). Submission deadlines and meeting dates are posted on the IACUC website.
- ii. The link to the electronic protocol form is posted in the IACUC Forms section of the IACUC Website.
- iii. The assigned IACUC Administrator performs a pre-review to assure that all regulations are followed and that all necessary information is included. The review comments are sent to the (PI) for revisions, if necessary. All corrections to a protocol must be submitted to the Administrator by the date designated by the Administrator in the correspondence to the PI to be considered to be reviewed at the next meeting. If changes are not completed by this time, this may result in the protocol being delayed until the following month’s convened meeting.
- iv. The protocol is sent to the Veterinarian for the veterinary review, and the Environmental Health and Safety members for the safety reviews. Any comments noted during this review will be presented to the IACUC and included in the communication to the PI.
- v. The PI may request for the protocol to be reviewed via Designated Member Review. This request must be accepted by the IACUC Chair, before being processed in accordance with SOP 019.
- vi. Otherwise, the protocol will be reviewed by the full committee. The outcomes of the meeting will be one of the following:
 - 1. Full Approval in current form: Meets all standards approved in current form by full committee. The PI will be notified of the approval.

2. Modifications Required to Secure Approval, followed by Designated Member Review: Some minor changes are needed to the study before final approval can be provided (the necessary modifications are sent to the PI, following the meeting). The final approval is completed by designated reviewers, assigned at the meeting after modifications received by the PI. Generally, the members designated as reviewers may be the IACUC Administrator (for minor modifications needed), or the original reviewers assigned to the protocol.
 3. Modifications Required to Secure Approval by Full Committee Review: This is reviewed by the full committee at a convened meeting, after modifications are made by the PI.
 4. Withhold Approval: The reasons for approval to be withheld are given to the PI. The PI may choose to make changes to the protocol and submit it, but it will be treated as a new protocol.
- vii. If Modifications are Required to Secure Approval, the Administrator will send the committee comments in writing to the PI.
 - viii. If Modifications are Required to Secure Approval by designated review, the PIs response to the committee's comments, along with the revised protocol are submitted to the designated reviewers for review. Any correspondence leading up to the review, will be handled through the Administrator. The PI will be notified of the approval.
 - ix. If Modifications are Required to Secure Approval by Full Committee Review, the PIs response to the committee's comments, along with the revised protocol, will be presented at the next committee meeting.
 - x. If modifications are required to secure approval, and the PI is non-responsive to the Administrator for at least three months, the Administrator will contact the PI, indicating that if no response is received within two weeks, the study will be withdrawn from further IACUC consideration. At that time, if there is still no response, then the protocol will be withdrawn. If the PI wishes to pursue this study after it has been withdrawn, a new protocol application will need to be submitted for review.

b. THREE YEAR RENEWALS

- i. The PI will receive a renewal notification through the electronic system at three months, two months, and one month before the protocol submission deadline for the month before the protocol expires to avoid any disruption of any studies.
- ii. PIs are responsible for submitting their renewals in a timely manner if they wish to continue the project.
- iii. The review process for three-year renewals is the same as for initial protocol submissions, listed above.
- iv. In the case of a renewal not being approved before the protocol's expiration date, the PI will be notified in writing, and the animals on the protocol will be transferred to the DLAM Holding Protocol until the protocol is reviewed and approved. Animals cannot be manipulated or handled by the investigator or other laboratory staff while the animals are on the holding protocol.

- v. If a renewal protocol is not received or needed, the PI may close the protocol, or it will be allowed to expire. Any animals on the protocol must be reassigned or euthanized before the expiration date.
- c. SCIENTIFIC PEER REVIEW AND CHAIR REVIEW PROCESS
- i. All studies which have PHS funding (e.g., such as NIH funding) undergo a scientific peer review, as part of the grant submission and review process.
 - ii. For studies that will not undergo a formal peer review process through the funding agency (i.e., departmentally or privately funded projects) the IACUC will conduct the scientific peer review (to verify the scientific validity of the study). In the event the IACUC feels that external expertise or consultation is needed during the review of a project, the IACUC may bring in a peer reviewer or external consultant to ensure the scientific validity of the study. This will be done on an as-needed basis, at the discretion of the IACUC Chair and Committee.
 - iii. For departmentally/ internally funded studies, the Department Chair will conduct a Chair Review of the project (within the electronic submission system), to confirm the funding source and acknowledge that the project is being submitted for IACUC review.
- d. DESIGNATED MEMBER REVIEW
- i. Designated Member Review can be requested under certain circumstances. This is accelerated review where the application can be reviewed at a time other than at a full committee meeting. For procedural information, see SOP 019 “Expedited (DMR) Protocol Procedures.”
- e. CLOSING OF PROTOCOLS
- i. A PI at any time may close the protocol by logging into the electronic system and selecting “Request Closure” in the protocol form. Completing the Request Closure form will formally close the protocol.
 - ii. If the annual renewal for USDA covered species protocol is not received for review, and approved, before the expiration date, it will enter into a “Lapsed” state. This protocol will be considered inactive, and any animals housed on the protocol will be transferred to the holding protocol, in which no procedures may be done on the animals. If the PI wishes to continue this study, the PI will need to create the annual review and submit to the IACUC for review. It will not become active for animal use until this is approved.
 - iii. If the Triennial Review is not received and approved before the three-year expiration date (regardless of species) will enter into a “Lapsed” state. This protocol will be considered inactive, and any animals housed on the protocol will be transferred to the holding protocol, in which no procedures may be done on the animals. If the PI wishes to continue this study, the PI will need to create the

Triennial Review, and submit for the IACUC to review. It will not become active for animal use until this is approved.

- iv. The IACUC may reserve the right to administratively close out protocols in which the PI is no longer able to fulfill the role as PI, and there is no one available to take the PI's place.

D. REFERENCES

- a. [Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.](#)
- b. [USDA Animal Welfare Act Regulations and Standards, 9 CFR Parts 1, 2, 3 and 4.](#)
- c. [PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.](#)
- d. [Health Research Extension Act of 1985, Public Law 99-158, November 20, 1985, "Animals in Research." Available from OLAW, National Institutes of Health, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982.](#)
- e. [Guide for the Care and Use of Laboratory Animals, Eighth Edition. National Academy Press, Washington, D.C. 2011.](#)