

Institutional Animal Care and Use Committee		UNTHSC
Title: Protocol Submission Process		
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Approved by IACUC Date:		

#### **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. PPROCEDURES**

##### **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. PIs will download the most recent version of the Animal Use Protocol Application from the IACUC website. If using more than one species, the Additional Species Form must also be completed. If requesting to breed animals, a Breeding Attachment for Animal Use Protocol must also be completed. Other forms may be necessary, please see the IACUC website or contact the IACUC Administrator for assistance.
- iii. Protocols shall be submitted to the IACUC Administrator, via email and a signed hard copy sent via inter-office mail.
- iv. The Administrator does a pre-review to assure that all regulations are followed and that all necessary information is included. The review comments are sent to the Principle Investigator (PI) for revisions.
- v. After revisions are received, a hard copy is sent to the Vet for vet review. If any comments are noted by the Vet, these are forwarded to the PI for any revisions to the protocol.
- vi. All corrections to a protocol must be submitted to the Administrator at least one week before the meeting date 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.**
- vii. The protocol will be reviewed by the full committee. The outcomes of the meeting will be one of the following:

1. Modifications required for approval by designated review: This is final approval by designated reviewers after modifications received by the PI.
  2. Modifications required for approval by full committee review: This is review after modifications at the next month's convened meeting.
  3. Approval in current form: Meets all standards approved in current form by full committee. The PI will be notified of the approval.
  4. Disapproval: The reasons for disapproval are given to the PI who may submit a revised protocol for review at a subsequent meeting.
- viii. If modifications are needed for approval, the Administrator will send the committee comments to the PI.
  - ix. After revisions from the PI are received by the Administrator, the PI's responses to the committee's comments as well as the revised protocol are submitted to the designated reviewers (if the outcome was review by designated review). The reviewers have 5 business days to approve or request additional corrections. After approval, the protocol is sent to the Chair for signature. The PI will be notified of the approval.
  - x. If modifications are needed for full committee review, after revision are received from the PI, they revised protocol will be presented at the next committee meeting.

**b. THREE YEAR RENEWALS**

- i. Renewal notices are sent to the PI via email at least four months before the current protocol will expire (this is the 90 day notice) and again at 60 days and 30 days. The 30 day notice is sent at least 30 days before the submission deadline for the month that the protocol should be reviewed at. This will avoid any disruption of any studies. Example: If a protocol expires on June 22<sup>nd</sup> (submission deadline is June 4<sup>th</sup> and the meeting date is June 25<sup>th</sup>), the 90 day notice is sent on February 1<sup>st</sup>, the 60 day notice sent on March 1<sup>st</sup> and the 30 day notice is sent on April 1<sup>st</sup>. This protocol would need to be reviewed at the May meeting to give enough time for approval before the expiration of the old protocol.
- ii. PIs are responsible for submitting their renewals in a timely manner if they wish to continue the project. The Administrator may send out additional reminder emails as a courtesy.
- 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 animals on the protocol will be transferred to the DLAM Holding Protocol. No procedures may be done on the animals until PI protocol approval (see "Holding Protocol Procedures").
- v. If a renewal protocol is not received or needed, the protocol will be allowed to expire. If any animals are on the protocol, they must be reassigned or euthanized before the expiration date.

c. EXPEDITED REVIEW

- i. Expedited 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 “Expedited Protocol Procedures.”