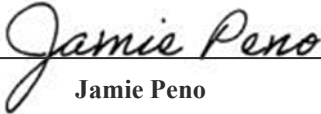


 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Animal Care and Use Committee Standard Operating Procedures	
Title: Animal Use Protocol (Submission) Approval Methods			
Effective Date:	December 22, 2020	Document Number:	IACUC-SOP-01-07.01
Approval/Date:  _____ Jamie Peno Director, Research Integrity and Compliance 12/22/2020 _____ Date			
REVISION HISTORY			
Date	Description	Author	
21-September-2026	Clarification of wording and timelines and elimination of repetition	J. Kissling	

PURPOSE

It is the responsibility of the UNT IACUC to ensure that all animal use activity meets federal regulations, policies, and recommendations. The UNT IACUC must therefore review and approve all proposals for animal use and provide guiding documents for documentation and evaluation of each Animal Use Protocol (AUP) submission.

SCOPE

This SOP will delineate the process in which submissions are reviewed. administratively and then must go through either a Designated Member Review (DMR) or a Full Committee Review (FCR) process.

DEFINITIONS AND ABBREVIATIONS

UNT - University of North Texas, Denton

IACUC - Institutional Animal Care and Use Committee

SOP/SOPs - Standard Operating Procedure(s)

AUP - Animal Use Protocol

PI - Principal Investigator

DR - Designated Member Review

FCR - Full Committee Review

USDA Categories - United States Department of Agriculture categories for procedures that may cause pain/distress

IACUC Submission – AUP or Amendment

PROCEDURES

I. Initial Administrative Review

- A. Current versions of IACUC forms and templates are posted on the UNT Research Integrity and Compliance IACUC webpage. Forms and required attachments should be completed in their entirety and submitted for review to untiacuc@unt.edu.
- B. IACUC Administrators will perform a pre-review of all submissions for completeness and compliance with regulations and grant or funding documents (see Procedure 01.08 Protocol and Grant Congruence Verifications). If any revision is necessary upon this pre-review, comments and requests will be sent to the PI. Once requested changes are completed, they should be returned to the IACUC email account to undergo pre-review once more.
- C. Following Administrative pre-review, the submission will be sent to the IACUC for consideration of DMR.
 - 1. The IACUC will be given a timeline to respond (typically 3-5 business days). If a member does not respond by the given deadline, it is assumed that they approve of the submission being routed through DMR.
 - 2. All submissions are eligible for DMR. However, submissions involving factors that may warrant enhanced IACUC oversight, including but not limited to Category E procedures, USDA-regulated species, researchers who are new to the institution, novel procedures, or other unique or potentially complex circumstances, will be highlighted for the IACUC to determine whether FCR is more appropriate.
 - 3. Any committee member may request FCR for a submission for any reason.

Additional Guidance: Category E procedures do not require Full Committee Review (FCR) under PHS Policy, the Animal Welfare Act Regulations, or institutional policy. However, Category E procedures may be identified for IACUC consideration regarding whether FCR is warranted based on the nature of the procedure, personnel experience, animal welfare considerations, or other factors

II. Designated Member Review Process

- A. If no request for FCR is made, the Chair will assign one or more Designated Reviewers (DRs) for the submission. Reviewers are given a review timeline (typically 3-5 business days).
- B. DRs may request FCR at any time for any reason during their review.

III. Full Committee Review

- A. Submissions for which FCR has been requested will be sent out to the entire committee, allowing adequate time for review prior to the next convened meeting.
- B. Investigators will be notified that their submission will be reviewed at a fully convened IACUC meeting and are invited to attend to answer any questions members may have prior to voting.
- C. At a convened meeting, consisting of a quorum of voting members, members will discuss the submission and may request clarifications and/or modifications before a determination is made.

IV. Determinations

- A. The IACUC DRs or committee can make the following determinations on submissions:
 - 1. Approve: approval of the submission in its current form.

2. Modifications Requested for Approval: the PI may be asked to make modifications or clarifications to the submission and resubmit to obtain an approval. The revised version of the submission may then be approved:
 - a) administratively for clerical changes and other minor requested modifications
 - b) through DMR assigned to original DRs or other members of the IACUC
 - c) through FCR as requested by any member of the committee
 3. Withhold Approval: submission is not approved, reasons for withholding approval will be documented and communicated to the PI. The PI may then withdraw the submission and resubmit with suggested changes.
- V. Notifications - PIs will be notified in writing by the IACUC Chair or Administrators of the decisions made by the committee.
- A. Justifications and instructions will be provided for submissions that require modification.
 - B. Approved submissions will receive an Approval Letter signed by the IACUC Chair, or designee, along with a copy of the final approved version of any related documents. This Approval Letter will include the study approval and expiration dates and any special stipulations or requirements made by the committee. These documents should be retained by the PI and readily available to laboratory staff/ participants.

REFERENCES

1. The Guide for the Care and Use of Laboratory Animals
2. Institutional Animal Care and Use Committee Guidebook
3. Animal Welfare Act
4. PHS Policy on Humane Care and Use of Laboratory Animals
5. AVMA Guidelines for Euthanasia
6. The Animal Welfare Information Center (AWIC)
7. UNT IACUC Policies and Procedures
8. UNT IACUC Procedure 01.09 - Amendments to Approved Animal Use Protocols
9. UNT IACUC Form 01.01 - Animal Use Protocol Form
10. UNT IACUC Procedure 01.08 - Protocol and Grant Congruence Verifications

APPENDICES

IACUC Standard Operating Procedures

UNT IACUC Form 01-Animal Use Protocol Form