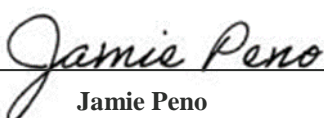
 <div> <div>DIVISION OF RESEARCH & INNOVATION</div> <div>Research Integrity & Compliance</div> </div>		Institutional Animal Care and Use Committee Standard Operating Procedures	
<p align="center">Title: Animal Use Protocol Approval Methods</p>			
Effective Date:	December 22, 2020	Document Number:	IACUC-SOP-01-07.00
Approval/Date: <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <hr style="width: 100%;"/> <p>Jamie Peno Director, Research Integrity and Compliance</p> </div> <div style="text-align: center;"> <p>12/22/2020</p> <hr style="width: 100%;"/> <p>Date</p> </div> </div>			
REVISION HISTORY			
Date	Section	Author	

PURPOSE

It is the responsibility of the UNT IACUC to assure 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 Review (DR) or a Full Committee Review (FCR) process.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton

IACUC- Institutional Animal Care and Use Committee

SOP/SOP's- 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 Pain Scale Classification of Procedures

PROCEDURES

I. Initial Administrative Review

- A. The most up to date forms will be posted on the UNT IACUC webpage through Research Integrity and Compliance. Forms and required attachments should be completed in their entirety and submitted for committee review to UNTIACUC@UNT.EDU.
- B. IACUC Administrators will review 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 review, the protocol will be sent to the Chair of the committee.
 - 1. The chair will either recommend the protocol go through the Full Committee Review process at a convened meeting or will send the protocol to all IACUC members and request the option for Designated Review.
 - a) The chair and any committee member may request that protocols go to FCR for any reason.
 - b) USDA Category E (see Procedure 01.06 Animal Use Protocol Submissions) protocols and those that request to deviate from regulations or institutional policies and procedures in respect to the care and use of the animals will automatically be required to go through the FCR process.

II. Designated Review Process

- A. Once the protocol has been circulated by the chair with a deadline for processing requests, committee members are given the opportunity to request that the protocol go through FCR at a convened meeting or approve the DR request. If a member does not respond by the given deadline it is assumed that they approve of the protocol being routed through DR.
- B. For protocols that are deemed to go through the DR Process, the chair will assign the Attending Veterinarian and one or two members that they feel would have the best knowledge and understanding of the proposed study.
- C. If a reviewer feels at any time during their review that the protocol should require further review they may request that it go through FCR.

III. Full Committee Review

- A. Protocols that will require review by FCR will be sent out to the entire committee via email, allowing adequate time for review prior to the next convened meeting.
- B. Investigators may be notified that their protocol will be reviewed at a full committee meeting and are invited to attend in order to answer any questions members may have prior to voting on approval.
- C. At the convened meeting, consisting of a quorum of voting members, members may have discussions on the proposal and may request clarifications and/ or modifications be made before a decision to approve can be made.

IV. Determinations

- A. The IACUC designated reviewers or committee can make the following determinations on submissions:
 - 1. Approval: an approval is to approve the protocol in its current form.
 - 2. Withhold Approval: this means the protocol is not approved, reasons for withholding approval will be given to PI's. Should they wish to address the concerns and make changes, they may withdraw the proposal and submit a new protocol.
 - 3. Modifications Requested for Approval: the PI may be asked to make modifications or clarifications to the submission and resubmit in order 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 DR assigned by original reviewers or the committee
- c) through FCR as requested by the committee

V. Notifications

- A.** PIs should be notified in writing via email through the IACUC Chair or administrators of the decisions made by the committee.
 - 1. Justifications and instruction will be provided for submissions that are not receiving approval.
 - 2. Approved submissions will receive an Approval Memo signed by the Committee Chair or designee (Co-Chair) along with a copy of the final approved version of any related documents. This Approval memo will include the study approval and expiration dates as well as due dates for annual review submissions (see Procedure 10 Annual Reviews of Approved Protocols) 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. PubMed Literature Search Engine
- 8. MedLine Literature Search Engine
- 9. UNT IACUC Policies and Procedures
- 10. UNT IACUC Procedure 01.09- Amendments to Approved Animal Use Protocols
- 11. UNT IACUC Form 01-Animal Use Protocol Form
- 12. UNT IACUC Procedure 01.08- Protocol and Grant Congruence Verifications

APENDICES

IACUC Standard Operating Procedures

UNT IACUC Form 01-Animal Use Protocol Form