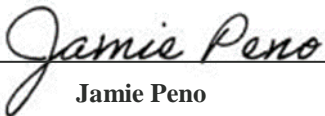
 <div> <div>DIVISION OF RESEARCH & INNOVATION</div> <div>Research Integrity & Compliance</div> </div>		Institutional Animal Care and Use Committee Standard Operating Procedures	
Title: Amendments to Approved Animal Use Protocols			
Effective Date:	December 22, 2020	Document Number:	IACUC-SOP-01-09.00
Approval/Date: <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  _____ Jamie Peno Director, Research Integrity and Compliance </div> <div style="text-align: center;"> 12/22/2020 _____ Date </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. It is the responsibility of the Principal Investigator (PI) to submit all proposals and modifications accurately and receive approval prior to conducting any animal work.

SCOPE

Modifications should be submitted in the same manner as an Animal Use Protocol (AUP) initial submission, using the UNT IACUC Form 02 AUP Amendment Form and should be approved in writing prior to any changes on a study taking place. (see SOP 01.07 Animal Use Protocol Approval Process)

- A. Modifications are reviewed administratively for completeness and compliance with regulations and then may go through a Designated Review, Full Committee Review, or Veterinary Verification and Consultation (VVC) process for approval. (see Procedure 07 Animal Use Protocol Approval Process)
- B. Documentation of all amendments will be retained and those approved administratively and via VVC will be reported on at the next convened IACUC meeting.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton

IACUC- Institutional Animal Care and Use Committee

OLAW- Office of Laboratory Animal Welfare

USDA- United States Department of Agriculture
AVMA- American Veterinary Medicine Association
SOP/SOP's- Standard Operating Procedure(s)
AUP- Animal Use Protocol
PI- Principal Investigator
Co-PI- Collaborating Principal Investigator
DR-Designated Member Review
FCR- Full Committee Review
VVC- Veterinary Verification and Consultations Review

PROCEDURES

- I. Amendment Requests**
 - A.** Modifications should not change the objectives, purpose, or aims of the original protocol (Changes of this nature should be considered a new study and submitted as a new AUP).
 - B.** Amendments should be used to correct problems or modify the study design to better achieve the goals of the approved study.
- II. Minor Modifications**
 - A.** Minor Modifications may be approved by the IACUC Chair and may include changes in:
 - a) Personnel (aside from PI) additions or deletions
 - b) animal sourcing
 - c) location changes within IACUC approved labs
 - d) Title changes
 - e) Funding changes
 - f) Additional procedures during terminal surgery or post euthanasia
- III. Major Modifications**
 - A.** Significant changes to an approved AUP will go through an administrative review and will then will be processed by DR, FCR, and in some cases VVC.
 - 1. Modifications that require DR or FCR include, but are not limited to, changes in:
 - a) PI or Co-PI
 - b) unaffiliated research personnel (see Procedure 12 Institution Collaborations and Unaffiliated Research Personnel)
 - c) animal numbers
 - d) animal species
 - e) classification under USDA pain and distress categories
 - f) methods of restraint
 - g) invasive procedures
 - h) tissue or blood collection
 - i) data collection methods or time-points
 - j) drug or treatment changes
 - k) methods of euthanasia
 - 2. Some significant modifications may be approved through VVC by the UNT Attending Veterinarian or appropriate designee.
 - a) The Attending Veterinarian, as subject matter expert, will determine if a requested change meets the criteria described by OLAW and this procedure for VVC approval and holds the discretion to approve the request or require the request go through DR or FCR at any time.
 - b) Significant changes that may **not** be approved via VVC at UNT include changes:
 - i. from a non-survival surgical procedure to a survival surgical procedure
 - ii. resulting in greater pain, distress or degree of invasiveness
 - iii. to add a new procedure type

- iv. in housing or use/procedural locations not currently approved by UNT IACUC
- v. in species
- vi. that may impact personnel safety
- c) Significant changes that may be approved via VVC, provided they do not violate the above constraints, include changes:
 - i. in dosing or agents administered for anesthesia, analgesia, sedation, or experimental substances.
 - ii. in the method of euthanasia to another AVMA approved method.
 - iii. in the duration, frequency, type, or number of experimental procedures provided they are to substitute equivalent or improved procedures that may result in improved animal well-being and/or data collected.
 - iv. requesting additional animals provided the increase is not more than 10% greater than the original approved number and the species is not one regulated by USDA.
 - v. in housing of animals not regulated by the USDA as long as the space meets minimum requirements as specified in the Guide for the Care and Use of Laboratory Animals.

REFERENCES

1. UNT IACUC Policies and Procedures
2. UNT IACUC Form 02- AUP Amendment Form
3. OLAW PHS Policies
4. The Guide for the Care and Use of Laboratory Animals
5. AVMA methods for euthanasia

APPENDICES

IACUC Standard Operating Procedures

UNT IACUC Form 02- AUP Amendment Form