DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance	**Institutional Animal Care and Use Committee** **Standard Operating Procedures**

Title: Amendments to Approved Animal Use Protocols

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Approval/Date:

Jamie Peno — 12/22/2020

Jamie Peno — **Date**

Director, Research Integrity and Compliance

REVISION HISTORY		
Date	**Description**	**Author**
19-October-2026	Added responsibilities, clarified purpose and scope	J. Kissling

PURPOSE

To establish procedures for the submission, review, and approval of amendments to approved Animal Use Protocols (AUPs), ensuring appropriate IACUC oversight of proposed changes prior to implementation and compliance with applicable regulations, institutional policies, and animal welfare requirements.

SCOPE

This SOP applies to modifications of approved Animal Use Protocols (AUPs) that do not substantially change the objectives, purpose, or specific aims of the approved study. Changes that fundamentally alter the scope or intent of the study require submission of a new AUP.

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/SOPs - Standard Operating Procedure(s)
AUP - Animal Use Protocol
PI - Principal Investigator
Co-PI - Collaborating Principal Investigator

DMR - Designated Member Review
FCR - Full Committee Review
VVC - Veterinary Verification and Consultation

RESPONSIBILITIES

I. The IACUC is responsible for reviewing and approving animal use activities and proposed amendments to approved AUPs to ensure compliance with applicable regulations, institutional policies, and animal welfare requirements.

II. The PI is responsible for submitting accurate and complete amendment requests and obtaining IACUC approval prior to implementing changes to an approved AUP or conducting associated animal activities.

PROCEDURES

I. Amendment Requests

Modifications should be submitted using the UNT IACUC Form 02 AUP Amendment Form emailed to untiacuc@unt.edu.

A. Modifications are reviewed administratively for completeness and compliance with regulations and then may go through a Designated Member Review, Full Committee Review, Veterinary Verification and Consultation (VVC) process, or Administrative Approval process. (see Procedure 07 Animal Use Protocol Approval Process)

II. Minor Modifications – Administrative Approval

A. Minor Modifications may be approved administratively 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 non-invasive procedures during terminal surgery or procedures post-euthanasia

III. Major Modifications

A. Significant changes to an approved AUP will go through an administrative review and will then be processed by DMR, FCR, and in some cases VVC.

1. Modifications that require DMR 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 DMR 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.

DOCUMENTATION AND RECORDKEEPING

Documentation of all amendments will be retained and those approved administratively and via VVC will be reported at the next convened IACUC meeting.

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