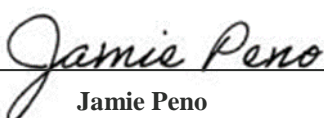
 <div> <div>DIVISION OF RESEARCH & INNOVATION</div> <div>Research Integrity & Compliance</div> </div>		Institutional Animal Care and Use Committee Standard Operating Procedures	
<p align="center">Title: Annual Reviews of Approved Protocols</p>			
Effective Date:	December 22, 2020	Document Number:	IACUC-SOP-01-10.00
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. It is the responsibility of the Principal Investigator (PI) to submit annual reviews for their protocols in a timely manner in order to update the IACUC on their progress and request the continuation of their previously approved work.

SCOPE

This SOP delineates the process for completing and submitting an annual review.

It is the responsibility of the Principal Investigator to submit Annual Reviews for all IACUC approved work at UNT, regardless of USDA species use or pain categorizations.

It is the responsibility of the Principal Investigator to submit Annual Reviews of their protocols in a timely manner and ensure that approval of the annual review is obtained without lapse to their protocol. Any lapse in approvals may be required to be reported to funding agencies by the IACUC and will result in halting of access to funds.

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

PROCEDURES

- I.** Annual Review of an approved UNT Animal Use Protocol
 - A.** Annual Reviews should be submitted for the first 2 anniversaries of the 3 years of an approved study in the same manner as an Animal Use Protocol (AUP) initial submission, using the UNT IACUC 03 AUP Annual Review Form.
 - 1. Annual reviews will be accepted as early as 60 days prior to their due date and should be submitted no later than 14 days prior to ensure the appropriate amount of time for review and processing is given.
 - 2. Review dates each year are based on the initial date of approval for the study.
 - B.** At the time of annual review, if a protocol is no longer needed or the work has been completed, the annual review form may be completed and should indicate that the study may be closed. Alternatively, a Final Report Form may be submitted at any time to close out a protocol (see IACUC Procedure 01.11 Final Reporting of Approved Protocols).
 - C.** Prior to study expiration on year 3, either a Final Report (see IACUC Procedure 01.11 Final Reporting of Approved Protocols) is due or a full protocol renewal is required for projects extending past 3 years.
 - D.** Annual reviews are reviewed administratively for completeness and compliance with current regulations and the previously approved submissions for that protocol. Annual reviews then may go through a Designated Review (DR) or Full Committee Review (FCR) process for approval. (see IACUC Procedure 01.07 Animal Use Protocol Submission Approval Process)
 - 1. Protocols involving USDA covered species (see IACUC Procedure 01.06 Animal Use Protocol Submissions) and those funded through PHS agencies or the US Department of Defense (DOD) must be reviewed by DR or FCR.
 - a) These protocols must receive approval in writing from the IACUC prior to lapse in their annual review date or the study may be closed and any remaining animals will be transferred to the University Holding Protocol.
 - b) Studies that are closed will require full renewal by submission of a new AUP.
 - c) Animals cannot be manipulated or handled by the investigator or other lab staff while the animals are on the holding protocol.
 - d) Studies that experience a lapse/ or closure may need to be reported to funding agencies and will result in the halting of access to funds.
 - E.** Documentation of all annual reviews will be retained and those approved administratively and or by Designated Review will be reported on at the next convened IACUC meeting.
 - F.** Annual Review Content
 - 1. The annual review should be a status update and an abridged version of the protocol application including any amendments that have been approved and should include:
 - a) a description of progress made over the previous year.
 - b) the number of animals used over the previous year (for each species).
 - c) the number of animals used to-date (for each species).
 - d) assurance of personnel training and other related requirements for the year.
 - 2. Any changes that may be desired at this time of review should be submitted separately as an amendment (see IACUC Procedure 01.09 Amendments to Approved Protocols).

REFERENCES

1. UNT IACUC Policies and Procedures
2. UNT IACUC Procedure 01.11 Final Reporting of Approved Protocols
3. UNT IACUC Procedure 01.09 Amendments to Approved Protocols
4. UNT IACUC Procedure 01.06 Animal Use Protocol Submissions
5. UNT IACUC Procedure 01.07 Animal Use Protocol Submission Approval Process
6. UNT IACUC Form 02- AUP Amendment Form
7. UNT IACUC Form 03- AUP Annual Review Form
8. OLAW PHS Policies
9. The Guide for the Care and Use of Laboratory Animals

APENDICES

IACUC Standard Operating Procedures

UNT IACUC Form 03- AUP Annual Review Form