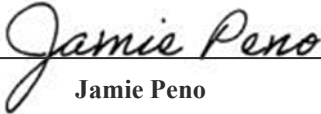


 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Animal Care and Use Committee Standard Operating Procedures	
Title: Annual Review of Approved Protocols			
Effective Date:	December 22, 2020	Document Number:	IACUC-SOP-01-10.01
Approval/Date:  _____ Jamie Peno Director, Research Integrity and Compliance 12/22/2020 _____ Date			
REVISION HISTORY			
Date	Description	Author	
21-September-2026	Updated to reflect requirement for USDA-covered species only	J. Kissling	

PURPOSE

It is the responsibility of the UNT IACUC to ensure 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 to update the IACUC on progress made toward goals and objectives.

SCOPE

This SOP describes the process for completing and submitting an Annual Report. It is the responsibility of the PI to submit Annual Reports for IACUC approved work at UNT when requested. For protocols involving the use of USDA-covered species, it is the responsibility of the PI to submit Annual Reports for protocols in a timely manner and ensure that approval of the annual report is obtained without lapse to the protocol. Any lapse or closure of protocol may require reporting to funding agencies by the IACUC.

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

DMR - Designated Member Review

FCR - Full Committee Review

USDA - United States Department of Agriculture

PROCEDURES

- A.** Annual Reports 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 Report Form.
 - 1. Annual Reports 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 sufficient time for review and processing.
 - 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 report 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 for Approved Protocols).
- C.** Prior to study expiration on year 3, either a Final Report (see IACUC Procedure 01.11 Final Reporting for Approved Protocols) is due, or a full protocol renewal by submission of a new AUP is required for projects extending past 3 years.
- D.** Annual Reports are reviewed administratively for completeness and compliance with current regulations and the previously approved submissions for that protocol. Annual Reports are then distributed to the IACUC for review.
- E.** Questions from the IACUC are communicated to the PI by the IACUC Administrator.
- F.** Additional follow-up may be required including, but not limited to, submission of an amendment and completion of training.
- G.** Annual Reports for protocols involving the use of USDA-covered species will go through a Designated Member Review (DMR) or Full Committee Review (FCR) process for approval. (see IACUC Procedure 01.07 Animal Use Protocol Submission Approval Process)
 - 1. These reports must receive approval in writing from the IACUC, signed by the IACUC Chair or designee, prior to their annual review date or the study will be closed and any remaining animals will be transferred to a holding protocol.
 - 2. Studies that are closed will require full renewal by submission of a new AUP.
 - 3. Animals cannot be manipulated or handled by the investigator or other lab staff while the animals are on a holding protocol.
 - 4. Studies that experience a lapse or closure may require reporting to funding agencies.
- H.** Documentation of all Annual Reports will be retained and reported at the next convened IACUC meeting.
- I.** Annual Report Content
 - 1. The annual report should include 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 including publications, presentations, and conferences
 - 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 requested modifications 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 01.07 Animal Use Protocol Submission Approval Process
5. UNT IACUC Form 02 - AUP Amendment Form
6. UNT IACUC Form 03 - AUP Annual Report Form
7. OLAW Public Health Service (PHS) Policy
8. The Guide for the Care and Use of Laboratory Animals

APPENDICES

IACUC Standard Operating Procedures

UNT IACUC Form 03 - AUP Annual Report Form