
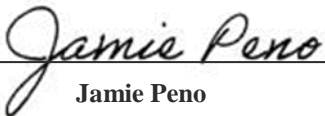


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|  <div> <div>DIVISION OF RESEARCH & INNOVATION</div> <div>Research Integrity & Compliance</div> </div> | | Institutional Animal Care and Use Committee Standard Operating Procedures | |
| <p align="center">Title: Post Approval Monitoring Methods</p> | | | |
| Effective Date: | December 22, 2020 | Document Number: | IACUC-SOP-01-15.00 |
| 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 | |
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PURPOSE

It is the responsibility of the UNT IACUC to assure that all animal use activity meets federal regulations, policies, procedures, and recommendations. This includes reviewing and approving all research proposals as well as ensuring that ongoing procedures and research activities have been reviewed and approved by the IACUC. In order to do this, post approval monitoring (PAM) procedures are essential to actively help researchers maintain their protocols within the most current procedures and guidelines.

SCOPE

Post Approval Monitoring methods are conducted by the IACUC and its' administrative staff in Research Integrity and Compliance.

It is the responsibility of the Principle Investigator to comply with PAM procedures and to follow approved protocols and procedures as written and to submit revisions for approval as needed throughout their experiments prior to making those changes.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton

IACUC- Institutional Animal Care and Use Committee

SOP/SOP's- Standard Operating Procedure(s)

PAM- Post Approval Monitoring

PI- Principal Investigator

PROCEDURES

I. Post Approval Monitoring Methods at UNT

A. Annual Reviews (see IACUC Procedure 01.10 Annual Reviews of Approved Protocols)

1. All protocols at UNT should submit an Annual Review Form to the committee. This annual update includes a summary of the progress that has been made in the last year as well as documents the animal usage numbers up to that point.
2. Annual Reviews give the PI an opportunity to evaluate and reflect on the progress of their study and is a good time to submit any amendments or modifications while the committee is already reviewing their project.

B. Facility Inspections (see IACUC Procedure 01.14 Facility Inspections and Program Reviews)

1. The IACUC performs facility inspections at least twice per calendar year.
2. Each lab approved for use for housing or procedures of any species is inspected at this time.
3. Inspectors may ask any personnel in the lab at the time of inspection, questions pertaining to their approved protocols and procedures and may ask to see lab procedure documents, animal husbandry logs, study data records, expiration dates on items for animal use, controlled substance storage and logs, storage areas of any items for animal use, personal protective equipment, required signage, caging, feed, bedding, etc.

C. Post Approval Monitoring Audits

1. PAM audits may be performed on active protocols anytime during regular UNT business hours.
 - a) Audits may be scheduled by the IACUC Chair or Administrator
 - b) Audit teams should consist of the IACUC Administrator and at least one IACUC member
 - c) Attempts should be made to schedule a time with the PI so that they themselves or a lab representative may be available within a two month period of the initial request.
 - i. The PI or their representative should be able to provide access to all documents, lab spaces, and supplies that are related to the protocol under audit.
 - ii. If the PI does not comply or respond to scheduling attempts within a timely manner they should be notified that ongoing experiments should stop and that the animals on the protocol will be transferred to the UNT holding protocol until an audit can be performed.
 - d) PAM audits will cover areas associated with the following as applicable:
 - i. Protocol and approved list of personnel
 - ii. Animal housing
 - iii. Lab areas
 - iv. Anesthesia and related drugs, supplies, equipment, and spaces
 - v. Surgical procedures and related drugs, supplies, equipment, and spaces
 - vi. Post-operative care and related drugs, supplies, equipment, and spaces
 - vii. Euthanasia methods and drugs, supplies, and equipment
 - viii. Hazardous Materials
 - e) To aid in preparation for an audit, PI's should refer to the IACUC Form 07-Animal Protocol Audit Checklist.
 - f) Auditors will bring a copy of the Checklist to complete as well as the approved study protocol and its associated amendments and documents to reference for comparison.
2. Any discrepancies or issues noted during the audit will be brought to the attention of

the PI or their representative at that time and will be documented.

- a) A copy of the audit report will be sent to the PI via email within 3 business days.
- b) The PI will be given a deadline with an appropriate amount of time to correct any items of note.
- c) Any discrepancies that concern animal welfare or compliance will be immediately reported to the Attending Veterinarian and IACUC Chair, further investigation or corrective action may be needed.
- d) The PI should follow up with the IACUC Administrator when items have been corrected by their deadline.
- e) All documents and correspondence will be filed in the IACUC office by the Administrator.
- f) Audit discrepancies will be reported on at the next Full Committee IACUC meeting and may be discussed as needed.
- g) Re-inspection may be needed to confirm discrepancies have been corrected.

REFERENCES

- 1. IACUC Form 07- Animal Protocol Audit Checklist
- 2. UNT IACUC Procedure 01.14 Program Reviews and Facility Inspections
- 3. UNT IACUC Procedure 01.10 Annual Reviews of Approved Protocols

APENDICES

IACUC Standard Operating Procedures