Institutional Animal Care and Use Committee		UNT Health
Title: Post-Approval Monitoring		
Document #: 026	**Version #:** 05	
Approved by IACUC Date: August 22, 2025		

A. BACKGROUND INFORMATION

a. University of North Texas Health at Fort Worth (UNT Health) has established a post-approval monitoring program to meet federal requirements of continuing reviews of activities involving research animals after the IACUC's initial protocol approval.

b. The post-approval monitoring program is an essential component of a comprehensive Animal Care and Use program that gives an opportunity for:

   i. The investigator to discuss concerns and/or changes needed in active protocols.

   ii. The IACUC to meet with the personnel actively involved in animal research by giving a personalized review of relevant policies.

   iii. The IACUC to ensure all animal research is being done in-line with federal regulations and institutional policies/procedures.

B. RESPONSIBILITIES

a. It is the responsibility of the IACUC Administrator to schedule audits and to follow procedures.

b. It is the responsibility of the IACUC members to volunteer, when their time allows, to facilitate the post-approval monitoring audits. IACUC Members should be aware that their expertise may be called upon to serve on a particular audit.

c. It is the responsibility of the Principal Investigator (PI) or their designee to respond to the IACUC Administrator in a timely manner to post-approval monitoring audit requests, to be present at the audit and to answer truthfully all questions.

C. PROCEDURES

a. Post-approval monitoring is met in various ways at UNT Health; however, to fulfill this requirement within this program, this SOP will cover the following topics:

   i. Scheduling an Audit.

   ii. Preparing for an Audit

   iii. Conducting an Audit

   iv. Post Audit Correspondence

   v. Resolution Process and IACUC Review

b. Scheduling and Conducting an Audit:

i. Each month, a few protocols will be chosen for an audit based on their activity level and the date of the PI's last audit.
    1. Active protocols may be audited more than once during their three-year approval period, unless there is cause for a more frequent schedule.
    2. These audits are <u>in addition</u> to the regular semi-annual inspections the IACUC performs.

ii. Types of Audits:
    1. Document Review Audit: An audit of the documentation associated with the protocol. This will include all protocol documents, protocol status sheets (animal numbers), training records, and animal records (i.e., health records, monitoring records, surgical logs, breeding logs, guillotine logs, drug logs, etc…). The IACUC Office staff will perform this audit.
    2. Laboratory Audit: A traditional audit in the animal use laboratory with a discussion of various aspects of the research project with the PI and lab members. An IACUC Administrator and a volunteer from the IACUC will perform this audit. An IACUC member may be selected based on their expertise.
    3. Procedure Observation Audit: The Audit Team will observe procedures associated with the protocol. The IACUC Administrator and a volunteer from the IACUC will perform this audit. An IACUC member may be selected based on their expertise.

iii. Conducting an Audit:
    1. Document Review Audit: The PI will be notified via email that their protocol was selected for a Document Review. The email may ask the PI to provide certain records needed to perform the audit. A checklist will be used to review the records. At the conclusion of the review, the IACUC administrator may set a meeting with the PI or designee to discuss the records, seek clarifications, and discuss any findings. If there are no questions or findings, there may not be a need for the meeting.
    2. Laboratory Audit: The PI will be notified via email at the beginning of the month that their protocol was selected for a laboratory audit and to find a time for which the PI or designee is available for an audit that month. A request will be sent to the IACUC members, requesting a volunteer for this audit. If no member volunteers for the audit, the IACUC staff will assign a member to the audit team. Once the audit team is established, the IACUC office will send a meeting invite to the PI and audit team. At the conclusion of the audit, the

audit team will discuss any findings with the PI. The PI will also be provided an opportunity to ask any questions.

3. Procedure Observation Audit: The PI will be notified via email at the beginning of the month that their protocol was selected for this type of audit. The Audit team will coordinate with the researcher a time to observe procedures associated with the protocol. The audit team will don proper PPE as they observe the procedure. After the procedure, a time will be reserved for the audit team to discuss any findings from the observation of procedure(s) with the Principal Investigator. Discrepancies between the procedures performed in the lab and those listed in the protocol will be documented on the checklist used to conduct the audit. Any findings, concerns, or recommendations will be brought to the attention of the Principal Investigator during the meeting.
4. Note: If a PI does not respond to the IACUC Administrator after two attempts (2 months) to set a time for an audit, the IACUC Administrator will schedule a date(s) and time(s) for the following month. If the PI (or designee) does not or cannot attend, the animals on the protocol will be placed on the Holding Protocol until the PI complies. For Procedure Observation Audits, if the PI fails to respond after two attempts, the animals on the protocol will be placed on the Holding Protocol
5. For each audit type, there is an assigned checklist that will be used to complete the audit. The checklist will be provided to the PI, designee (if applicable), and the audit team prior to the audit. Audits will be conducted in accordance with the audit type, described above.
6. Following the audit, the PI and the auditors will sign a copy of the checklist with documented discrepancies. The PI will be given an appropriate time period to correct these discrepancies and if necessary, a follow up meeting will be scheduled. An Audit Memo, signed by the IACUC Chair, along with the audit checklist will be sent to the PI to close the Audit.

c. Post Audit Correspondence:
   i. At the monthly meeting, the IACUC will receive a report of all protocols audited and any discrepancies that were found. At any time, members of the IACUC may request to see the completed protocol audits.
   ii. Any discrepancies found during a Post Approval Audit which results in animal welfare concerns or non-compliance will be immediately reported to the IACUC and the Director of DLAM.

d. Resolution Process and IACUC Review:
    i. Representatives of the IACUC will review any discrepancies found during a Post Approval Audit and conduct further investigation if necessary and report their findings to the IACUC committee at the next meeting.
    ii. Once the findings of the investigation have been discussed a corrective action plan will be determined by the IACUC.
    iii. If a significant non-compliance is identified, a letter will be sent from the IACUC Chair explaining the basis of the non-compliance finding and any required corrective actions required.
    iv. IACUC decisions can be appealed in writing. However, the sanctions listed in the corrective action plan will remain in place until the IACUC committee can review further.
    v. If the non-compliance requires reporting to federal agencies (OLAW and/or USDA) or other funding sources, a report detailing the circumstances and corrective action plan will be made and signed by the Institutional Official.

D. Attachments:

a. Post Approval Monitoring Audit Checklist – Document Review
b. Post Approval Monitoring Audit Checklist – Laboratory Audit
c. Post Approval Monitoring Audit Checklist – Procedure Observation

E. References:

a. The Guide for the Care and Use of Laboratory Animals (2011), National Academies Press, Washington, D.C.
b. Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.
c. PHS Policy on Humane Care and Use of Laboratory Animals, NIH, Office of the Director, Revised 2015.