

Institutional Animal Care and Use Committee		UNTHSC
Title: Post-Approval Monitoring		
Document #: 026	Version #: 01	
Approved by IACUC Date: August 26, 2014		

A. BACKGROUND INFORMATION

- a. A continuing program to audit approved animal use protocols is an essential component of a comprehensive Animal Care and Use program. Such a program provides an excellent method of ensuring institutional regulatory compliance by allowing a more thorough inspection of individual labs and animal related procedures.
- b. Post approval monitoring gives the investigator the opportunity to discuss concerns and/or changes needed in active protocols.
- c. This program also allows the IACUC to meet with the personnel activity involved in animal research giving a personalized review of relevant policies.

B. RESPONSIBILITIES

- a. It is the responsibility of the IACUC Administrator to schedule audits and to follow this procedure.
- b. It is the responsibility of the IACUC members to volunteer, when their time allows, to facilitate the post-approval monitoring audits.
- c. It is the responsibility of the Principal Investigator (PI) 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 all necessary questions from an audit truthfully. The PI may also assign a designee to attend the audit.

C. PROCEDURES

- a. Each month, a few protocols will be chosen at random to be audited. The protocols chosen will be protocols that have been active in the last 6 months. Each active protocol will be audited at least once during its three-year approval period.
- b. Audits will be performed by two people, with at least one representative from the IACUC.
- c. The PI will be contacted before or around the first of the month to find a time or times that the PI is available for an audit for that month. The PI shall respond and the IACUC Administrator will find a volunteer(s) for the time chosen by the PI.
 - i. If a PI does not respond to the Administrator after two attempts (2 months) to set a time for an audit, the Administrator will schedule a date(s) and

time(s) for the third 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.

- d. An email will be sent to the PI, any lab staff that will attend, and the auditors with the protocol, other pertinent documents and a check list to help the investigators gather information that they may need.
- e. The auditors will review the animal use protocol and any amendments prior to the audit to familiarize themselves with approved procedures and the staff, to compare used animal numbers with approved animal numbers, and to highlight any areas of interest to be discussed at the audit.
- f. Using the Post Approval Monitoring Checklist, the auditors will discuss aspects of the research project with the Investigator and research staff. In addition, there will be a review of the housing/breeding rooms and the laboratory areas used for experiments. Documented discrepancies between the procedures performed in the lab and those listed in the protocol will be brought to the attention of the Principal Investigator.
- g. Following the audit, the PI and the auditors will sign a copy of the checklist with documented discrepancies which will be filed with the protocol in the IACUC office. The PI will be given an appropriate time period to correct these discrepancies and if necessary, a follow up meeting will be scheduled.
- h. 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.
- i. 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. Further investigation and corrective action will be determined by the IACUC.