Office of Research, Grants and Contracts
Standard Operating Procedures (SOP)

SOP Title	Post Approval Monitoring				
Date Last Revised	01/13/2019	Date Created	10/01/2018	Revision #	
SOP Number	7	Required by:	☐OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☐Researcher	☒Institutional		
Subgroup	☐ NKU Compliance	☐IRB	☒IACUC	☐IBC	

1.0 PURPOSE

To explain the process of Post Approval Monitoring (PAM) of active IACUC protocols at NKU.

2.0 GENERAL INFORMATION AND SCOPE

Post Approval Monitoring (PAM) of animal use protocols (AUPs) is a comparison of the actual activities occurring under an approved protocol against the written AUP itself. PAM is a principal method by which institutions assure that investigators and others involved in conducting and supporting animal research do not deviate from approved protocols and that other relevant documents (permits, logs, training certificates) are maintained in a compliant fashion. The goal of PAM is to improve communications among the IACUC, investigators, and research personnel to confirm accurate and consistent description and practice of animal use, and to maintain compliance with all appropriate regulations and best-practice guidelines.

2.1 PROTOCOL SELECTION

From a regulatory perspective, all protocols are subject to PAM. In practice, the primary focus will be on projects that:

1. Are classified as USDA pain categories of E (primary concern), D (secondary concern), or C (tertiary concern), or;
2. Involve surgical procedures, or;
3. Involve investigators that have had past compliance issues, or;
4. Involve investigators/protocols that the IACUC or Attending Veterinarian designate for review

2.2 PAM FREQUENCY

Protocols which match categories 1-3 (above) should receive PAM at a minimum of once during each 3-year protocol approval period. Protocols meeting one of the above categories will be grouped into a pool, from which a random sample will be selected for PAM in any given year.

The IACUC will attempt to conduct a PAM visit for all projects during their three year approval period unless the project ends prior to the three year expiration date.

2.3 INVESTIGATOR RESPONSIBILITIES

Investigators are expected to comply with PAM visitation requests, and to facilitate the scheduling of a mutually agreed-upon visitation time and place. Protocol senior personnel (e.g., faculty/staff) are

expected to be present during a PAM visitation, and to facilitate the actions of the PAM team during the visit. Protocol supervisors should prepare for a PAM visit by ensuring the availability of the requisite AUP and associated documents. Investigators are asked to not alter their normal activities during a PAM visit, but rather to conduct their projects in their routine fashion. Following a PAM visit, investigators and protocol supervisors should maintain open communication with the IACUC, the Attending Veterinarian, and the Institutional Official, in order to remedy any procedural discrepancies that may have been noted during PAM.

3.0 PROCEDURES

3.1 INITIAL PLAN AND COMMUNICATION

The Principal Investigator will be contacted by the IACUC Chair to schedule the PAM visit approximately one month in advance to select a mutually agreed upon date for the PAM visit. A rotating subset of IACUC members (with a goal of two) will be selected which may include any IACUC Member, the IACUC Chair, or the Attending Veterinarian. The IACUC Administrator may be present during the PAM visit to document findings. External consultants may be utilized. Prior to the site visit, the PAM team will review the AUP and any related documents.

3.2 CONDUCTING THE PAM VISIT AND FINDINGS

During the site visit, the PAM team will compare the procedure conducted to those approved in the AUP, and will document their inspection via the PAM checklist. Discrepancies between the procedures performed and those in the approved AUP will be brought to the attention of the investigator, as will any details related to animal numbers/sources, supplementary licenses/permits, experimental conditions, or other facets of the activities which have the potential to impact animal welfare or intended uses.

Examples of IACUC noncompliance/discrepancies include, but are not limited to, the following:

1. Procedures being performed by personnel not listed in the approved protocol
2. Procedures being performed that are not in the approved protocol
3. Anesthetics, analgesics, tranquilizers, antibiotics, fluids, or other medications used that are not noted, of insufficient grade, expired, or different from those described in the AUP
4. Lack of aseptic conditions/technique for survival surgery
5. Euthanasia procedures that differ from those in the AUP
6. Personnel that appear to lack the necessary training or supervision to appropriately perform AUP procedures
7. Supporting documentation for animal use or care that is incomplete or unavailable
8. Equipment and/or conditions that are not safe for humans and/or animals

See SOP #16 (IACUC) Procedure for Investigating Concerns Involving Animal Care and Use (Animal Research Non-Compliance) for findings that meet the definition of minor non-compliance or significant non-compliance.

3.3 FOLLOW UP FROM THE PAM VISIT

PAM personnel will discuss the results of the PAM visit with the investigator (and other personnel present) before leaving the visitation site. A completed PAM checklist and follow-up summary report will be generated by the PAM team within 15 business days of the site visit. Copies of these documents will be:

1. Placed into the IACUC files, and
2. Sent/given to the investigator, and
3. Presented to the IACUC Chair as an agenda items for the next convened meeting

Investigators may be invited to attend the next IACUC meeting discussion of their PAM visit and findings. Investigators in disagreement with any of the findings of the PAM will be given the opportunity to consult directly with the IACUC IO and/or Attending Veterinarian, as required. The IACUC Chair or IACUC Administrator will generate a summary report for the IO for any PAM inspections that result in significant and/or unmitigated discrepancies.

Also at the conclusion of any PAM visit and inspection, the IACUC will ask investigators for their regulatory needs with regard to PAM, and will offer its assistance with personnel training, record-keeping, or protocol revisions, as may be required.

4.0 REFERENCES

The Guide for the Care and Use of Laboratory Animals, Eight Edition

5.0 FORMS OR ATTACHMENTS

NKU Post Approval Monitoring Checklist
SOP #16 (IACUC) Procedure for Investigating Concerns Involving Animal Care and Use (Animal Research Non-Compliance) – under revision

6.0 DEFINITIONS

Noncompliance: the failure or refusal to comply with a federal or internal regulation or to deviate from protocol procedures approved by the IACUC.

Significant non-compliance: indicates a serious breach of laws, regulations, or university policy which compromises the function of the IACUC or puts researchers or animals at risk of undue harm.

Minor non-compliance: typically arises in instances where a policy or regulation has been violated, but the risk of harm to researchers or animals is minimal and the IACUC authority or function has not been compromised. Minor non-compliance can often be corrected at the institutional level.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	11/26/2019	☐
Chair	☒	11/26/2019	☐
Institutional Official	☒	11/26/2019	☐

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☐		☐	
IACUC Chair	☐		☐	
Institutional Official	☐		☐	