RADFORD UNIVERSITY

Institutional Animal Care and Use Committee

Post-Approval Monitoring (PAM) Program

TITLE: Post-Approval Monitoring (PAM) Program	**Effective Date:** 22-May-2023
IACUC POLICY: 011 **REVISION: 0**	**Last Revised:**
SCOPE: This policy applies to all approved IACUC protocols	**Review Date:**
PURPOSE: To define an accepted method of post-approval monitoring of animal activities.	
KEYWORDS: Protocol review, Post-Approval Monitoring, PAM, IACUC PAM Liaison (IPL)	
Policy Owner: Research Compliance Office Radford University **Policy Contact:** Anna Marie Lee, Research Compliance Manager, alee16@radford.edu or irb-iacuc@radford.edu	

1. Background and Purpose

According to the current Guide for the Care and Use of Laboratory Animals, "continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies," and post-approval monitoring (PAM) "helps ensure the well-being of animals and may also provide opportunities to refine research procedures" (p. 33).

The Guide also states that PAM methods can include processes such as "continued protocol reviews, laboratory inspections, observations of selected procedures, and direct observations by qualified staff and IACUC members, as well as evaluations and inspections by external regulatory agencies" (p. 34)

The PAM policies discussed in this document are required by federal law to ensure continuing compliance after an animal activity has been approved by the Institutional Animal Care and Use Committee (IACUC). The overall goal of this PAM policy is to ensure that the procedures carried out in the laboratory, field, or classroom match those described in the approved protocol. These policies have also been established to educate Radford University's animal researchers and support its culture of compliance.

2. Policy

IACUC Protocols and PAM Policy

As a best practice in Radford's Animal Program, Principal Investigators (PIs) are strongly encouraged to meet with their staff and students before initiating an animal study to review the protocol in detail, so they are aware of their commitments made to the IACUC when the protocol was submitted.

The submission of a protocol by the PI represents a contract between the PI, Radford University, and the federal government (for projects receiving federal funds). The PI is solely responsible for maintaining compliance with their active protocols.

Triggers for PAM Review

Approved IACUC protocols may be selected randomly for PAM review or as a result of receiving complaints or concerns about noncompliance or animal welfare. Criteria that may increase the frequency of PAM protocol review include animal use in pain categories D or E, use of biohazards or carcinogens, physical restraint, and food or water restrictions, and/or past non-compliance.

Most PIs will receive an announcement to prepare for an upcoming PAM review visit. However, the AV has the authority to make unannounced PAM visits in certain situations where the AV, IACUC Chair or Vice-Chair feel there is an imminent threat to animal welfare, or a PI is not adhering to IACUC policies.

Possible areas addressed during the PAM Review

PAM reviews will be implemented by the Research Compliance Office (RCO), under the supervision of the IACUC, and performed by the AV or a qualified designated IACUC PAM Liaison (IPL). PAM visits can also include an EHS representative and an additional IACUC member. The PI for the study must attend these meetings. However, it is also a best practice for any co-PIs and students on the protocol to participate if possible.

The PAM review **may** evaluate the following areas, if applicable:

- Whether an IACUC animal use form is available on site
- A discussion of personnel training for specific animal procedures
- Whether personnel involved in animal work are listed on the animal use form
- The whistleblower poster is visible
- Gas anesthetics scavenged
- Expiration dates (drugs, other exogenous substances administered to animals) are accessible upon request
- Drugs listed are consistent with usage
- Species consistent with those listed in animal use form
- The use of animals is consistent with the information provided in the animal use form
- Aseptic technique used
- Post-surgical analgesia is appropriately administered
- Availability of animal health records
- Whether euthanasia performed is consistent with animal use form
- Adverse consequences are clearly documented
- Special diets used/storage
- There are no unapproved photo or video recording devices in the animal use area

3. PAM Review Process

Notification and Preparation

1. In most circumstances, the RCO will notify a PI through email that their protocol has been selected for PAM review at least one month before the inspection. At this time, the PI should review the *Possible areas addressed during the PAM Review (see above)* and use them as a guide for preparing for the review meeting.
2. In most circumstances, the PAM Review Inspection will be scheduled at the convenience of the PI and any co-PIs and research staff members available to attend the meeting. At a minimum, the PI for the selected protocol must be present during the PAM review to facilitate the review meeting.
3. When scheduling the PAM appointment, the PI will be instructed to make the approved protocol available in or near the workplace or lab to be referenced and all animal use data available during the inspection, including APRs, health records, and surgical records (if applicable). The RCO and EHS will assist the PI in obtaining the documentation required for the PAM Review Meeting.

PAM Review Meeting

4. During the review, the IPL will ask the PI to provide an oral report of their animal procedures. The PI's oral report will be assessed by comparing it against the approved procedures in the reviewed protocol, with specific attention paid to any drugs being administered, procedures being performed, and all surgeries (survival and non-survival), if applicable.
5. If any inconsistencies between what is stated in the PI's oral report and the procedures approved in the IACUC protocol are identified, the IPL will ask the PI to address them by either discontinuing the procedure or submitting an amendment to the protocol to the RCO.
6. The PI should use the meeting to ask the IPL questions and seek clarification of any issues that may have been raised during the PAM review.
7. Any issues identified during the PAM Review Meeting that pose a significant threat to animal welfare will be immediately referred to the AV (if they/them is not serving as the IPL or did not attend the PAM Review Meeting) for resolution and to the IACUC for further investigation.

PAM Review Meeting Follow-Up

8. The RCO, with assistance from the IPL, will be responsible for drafting a written report that is sent to the PI **within seven (7) business days** after the initial PAM Review Meeting. This report will summarize the IPL's findings, suggested corrective actions for any minor and significant deficiencies, and any additional recommendations for improvement.
9. Depending on the nature and severity of the deficiencies identified during the PAM Review Meeting, the PI will have between **three** (**3) and twenty-eight (28) business days *** from receipt of the initial PAM review report to correct any deficiencies and implement recommended corrective actions. Acknowledgment of receipt of the report within three (3) business days.

10. However, if a PI disagrees with the PAM review results, recommendations, or corrective actions, they must submit an appeal to the RCO within **three (3) business days *** of receiving the final PAM Review Meeting Report.
11. The IPL or AV will review and approve the proof of the PI's corrective actions for the deficiencies identified during the PAM Review Meeting and sent to RCO. If unacceptable, they will clarify what needs to be done to meet their expectations for corrective actions through an official letter from the RCO, and the PI will have **three (3) business days *** to make those corrections or justification.
12. Once the corrective actions have been made and approved, the PI will present a summary of the PAM review results and their corrective actions to the IACUC at the next monthly meeting, followed by a detailed discussion with IACUC members. PIs not on the IACUC will be invited to the IACUC monthly meeting. The point of this discussion will be to meet the Guide's requirements of determining if the PAM findings identified areas that should be addressed by new or refined IACUC policies, training, or procedures.

***If the PI does not meet the timelines outlined above, the IACUC will view this as an issue of noncompliance and initiate its noncompliance policy procedures.**

Resources

Guide for the Care and Use of Laboratory Animals: Eighth Edition. Washington, DC: The National Academies Press. https://doi.org/10.17226/12910.

REVISION HISTORY:

Revision	Summary of Revisions	Revision Date