UNIVERSITY OF NORTH CAROLINA
CHARLOTTE
ANIMAL CARE AND USE PROGRAM

POLICY: Procedure on Post-Approval Monitoring

Objective:	To provide guidance on the procedure for conducting post-approval monitoring.
Author:	Attending Veterinarian, Laboratory Animal Resources, ORPI
Date:	11/7/2023

Scope

This policy describes procedures for Post Approval Monitoring (PAM) of protocols. PAMs are implemented to ensure that protocol activity remains compliant with appropriate regulations and provide an opportunity for IACUC members to become more familiar with the work of PIs and staff. PAMs aim to improve the quality of research by detecting deviations, errors, and/or omissions and implementing appropriate corrections. PAMs also provide an opportunity to reflect and refine procedures with animals.

Procedures

1. IACUC Staff (with input from the ORPI & Attending Veterinarian (AV)) will select protocols for PAM based on the following criteria:

- **a.** Protocols from **new Principal Investigators (PIs)**
- **b.** Protocols with history of **noncompliance** with federal regulations
- **c.** Protocols that have had **numerous adverse incidents**
- **d.** Protocols involving moderate or uncontrolled pain (**USDA Pain Category D or E procedures**)
- **e.** Protocols with **multiple survival surgeries**
- **f.** Random selection utilizing the IACUC approved protocol database.

2. PAMs will occur throughout the year as can be scheduled to accommodate researchers, the AV, and ORPI staff. PAMs need not be performed at the same time as the semi-annual inspections and review.

3. PAMs will be a minimum of 4 per fiscal year.

4. When a protocol has been chosen for PAM, notification is sent via email to the PI with a request for a mutually agreeable date and time to meet with the PI and all available research personnel. The letter will also include physical areas, records, and hands-on techniques to be examined.

5. The IACUC Staff will assign IACUC members to conduct the PAM. All IACUC members, including the AV and *ex officio* members may conduct PAM. IACUC members will be sent a request for a mutually agreeable date and time to meet with the PI and their staff. This request letter will include a copy of the protocol, animal usage information, and locations where the research is performed for review prior to the PAM visit. Areas examined during a PAM visit include (but are not limited to):

- **a.** Adherence to the IACUC approved protocol and applicable laws, policies, and guidelines
- **b.** IACUC documentation (e.g., approval letter, protocol, related researcher documents)
- **c.** Subject study records and data (including anesthesia, surgery, and post-op monitoring

logs)
- **d.** Correspondence with the IACUC
- **e.** Unanticipated problems or adverse events documentation (if applicable)
- **f.** Annual Renewals / Progress Reports
- **g.** Data management / storage system (e.g., locked cabinet, data encryption)
- **h.** Changes to the original protocol and applicable amendments
- **i.** Review of personnel training and proficiency certification.

6. At the conclusion of the PAM visit, the team will verbally summarize the findings for the PI and personnel who performed the work.

7. A memo will be sent to the PI that includes discussions and findings during the PAM.

8. PAM results will be shared with the IACUC for further discussion and determination of any needed follow-up or corrective actions.

9. Actions after a PAM visit may include (but are not limited to) recommending:
- **a.** Acknowledgement/acceptance without further recommendation
- **b.** A request for modification of the research protocol or procedures
- **c.** Scheduling an additional PAM visit after a predetermined time period
- **d.** Education or retraining for the investigator or research staff
- **e.** Limitations on the research activities
- **f.** Suspension or termination of the research.

10. Depending on individual PAM findings, the PI may receive a follow-up report from the IACUC regarding any necessary corrective measures to be taken.

11. In cases of follow-up actions, the Institutional Official will receive a final report detailing the findings and action plan.

12. The PI's supervisor (Chair, Director, etc.) will be notified when appropriate.

13. PIs who disagree with the PAM report or IACUC decision(s) concerning the visit may appeal in writing to the IACUC through the Office of Research Protections and Integrity (ORPI).

14. PAMs are designed to be collaborative and collegial. Any event determined to be adverse shall be noted with a separate *Adverse Event Report* and evaluated by the IACUC for further action (per *SOP: Reporting Adverse Events, Abnormal Behaviors/Conditions, and Other Incidents*).

15. Each PAM and subsequent follow-up will be done on a case-by-case basis.

16. Copies of PAM reports and all related correspondence will be kept within the digital protocol file in the Office of Research Protections & Integrity (ORPI).

References

National Research Council. *Guide for the Care and Use of Laboratory Animals: Eighth Edition*. Washington, DC: The National Academies Press, 2011. Pp 33-34.

Silverman, Jerald, Suckow, Mark A., and Murthy, Sreekant, Eds. *The IACUC Handbook*: *Third Edition*. Boca Raton, FL: CRC Press, 2014. Chapter 30, pp 719-750.

Office of Laboratory Animal Welfare, Public Health Service. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Washington, D.C.: Department of Health and Human Services. Revised August 2015.

Revision History

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