UNIVERSITY OF NORTH CAROLINA
CHARLOTTE

**Animal Care and Use Program**

# Policy: Procedure on Post-Approval Monitoring

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| **Objective:** | To provide guidance on the procedure for conducting post-approval monitoring. |
| **Author:** | Attending Veterinarian, Laboratory Animal Resources |
| **Date:** | July 25, 2022 |

## Scope

This policy describes procedures for Post Approval Monitoring (PAM) of protocols. The purpose of PAM is to ensure that protocol activity remains compliant with appropriate regulations and to improve the quality of research by detecting errors and/or omissions to be corrected.

## Procedures

1. IACUC will select protocols for PAM based on the following criteria:
   - **a.** Random selection utilizing the IACUC protocol database during semi-annual program review (approximately 10% of the protocol population);
   - **b.** Protocols with history of noncompliance with federal regulations requests;
   - **c.** Protocols that have had numerous adverse incidents;
   - **d.** Protocols involving greater than minimal risk;
   - **e.** Protocols from new Principal Investigators (PIs).
2. When a study has been chosen for PAM, an email letter of notification will be sent 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 areas and records to be examined.
3. The IACUC Coordinator will assign IACUC members to conduct the PAM. The IACUC, AV, Animal Care and Research Protections Staff may all conduct PAM.
4. The PAM team will review the protocol file prior to the visit.
5. Areas examined during a PAM visit include but are not limited to:
   - **a.** Adherence to protocol;
   - **b.** IACUC documentation (e.g., approval letter, protocol, subject recruitment materials);
   - **c.** Subject study records and data;
   - **d.** Correspondence with the IACUC;
   - **e.** Unanticipated problems or adverse events documentation (if applicable);
   - **f.** Annual Progress Reports;
   - **g.** Data management/storage system (e.g. locked cabinet, data encryption);
   - **h.** Changes to the original protocol and applicable amendments.
6. At the conclusion of the PAM visit, the team will discuss findings directly with the PI and personnel who performed the work.
7. 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 period of time;
   - **d.** Education for the investigator or research staff;

**e.** Limitations on the research activities;
**f.** Suspension or termination of the research.

**8.** A report detailing the findings and the outcome of a PAM visit will be sent via email to the PI, the PI's chair or director, the full IACUC, and Institutional Official as appropriate.

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

**10.** Copies of PAM reports and all related correspondence will be kept within the protocol file.

## 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

Approved August 27, 2012
Re-approved May 18, 2015
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