



Research Office IACUC	Post Approval Monitoring Program	Approved 8/14/2019
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Post Approval Monitoring Program

A. Policy

It is the policy of the Oregon State University Institutional Animal Care and Use Committee (IACUC) that monitoring of approved studies be routinely conducted by the Animal Program Office and members of the IACUC for quality control and improvement, investigator education, and enhanced protection of animal subjects used for research or teaching.

Post Approval Monitoring (PAM) is integrated into numerous regulatory functions including continuing protocol review, semiannual laboratory and facility inspections, daily observation of animals, reviews of adverse or unexpected experimental outcomes via Incident Reports, record reviews of procedures, usage of controlled agents, and a standardized Post Approval Review (PAR) process.

This policy focuses on the Post Approval Review (PAR) process which may include meetings with PI's and laboratory staff and/or observation of laboratory practices and procedures to compare performance with approved activities.

B. Purpose

PAM allows the OSU Animal Care and Use Program to regularly review animal care and user activities, confirm and document compliance with approved protocols and regulatory requirements, work with users to enhance animal well-being, identify and correct deficiencies, and importantly, prepare for external regulatory and accrediting site visits and reviews.

PAM Program goals include proactively maintaining compliance with the approved protocol while research projects evolve, and improving communication between animal researchers and the IACUC.

PAR is intended to be a collegial and mutually beneficial review of approved activities, and an opportunity for education and sharing program expectations. Outcomes of these discussions are beneficial to the researcher by either confirming that procedures are humane and compliant, or, identifying protocol 'drift' and helping to amend protocols to prevent future concerns.

C. Scope

The PAM Program applies to all IACUC-approved research and teaching activities and all approved IACUC protocols are subject to Post Approval Review (PAR).

D. Procedures and Guidelines

Once a protocol is approved, the IACUC has the responsibility to ensure that the procedures carried out in the laboratory, field, and/or procedure/housing areas are as described in the protocol. In order to promote continuing compliance, PAR sessions are scheduled by the Animal Program Office with IACUC-approved participants, including Principal Investigators.



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PARs facilitate examination of research study documents (protocols and associated records and SOP's) and review of related activities (procedures), generally involving meetings with participants associated with the project, and may include observations of approved procedures.

Approved projects and activities will be selected and reviewed by the Animal Program Office staff under the authority of the IACUC. Projects may be selected randomly or by risk-based assessment regarding the species involved and the level of procedure invasiveness to ensure adequate oversight of complex protocols.

Protocols prioritized for PAR will include those involving pain categories D and E using either USDA or non-USDA species, new investigator protocols, or to assess post-procedural monitoring and care or based upon the details of previous incidents. If a researcher has several active IACUC protocols, as many activities and procedures as possible will be reviewed during the PAM discussion.

A synopsis of the overall laboratory performance and any potential concerns will be openly discussed at the conclusion of the meeting to confirm the accuracy of the observations and/or review. Following the discussion, any issues and resolution plans will be summarized in a post-visit correspondence email. Collaboration to correct non-compliant items or any suggestions for improvement will be ongoing between the PI, their staff, the Animal Program Office, the Attending Veterinarian, and/or the IACUC to assist with implementing necessary changes.

The IACUC will be updated on a monthly basis of all activities. The committee will receive a summary of all visits performed, their outcome, and the status of any corrective action plans. Members may provide feedback and modifications to any corrective action plans, which will be communicated to the PI.

E. References

- a. *The Guide for the Care and Use of Laboratory Animals (Eighth Edition)*, Institute of Laboratory Animal Resources, National Academy Press, Washington D.C., 2011. , p.33.
- b. *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, Office of Laboratory Animal Welfare, National Institutes of Health, Public Health Service, 2002. V.D.5
- c. *Animal Welfare Regulations*, Code of Federal Regulations, Title 9, Ss2.31 (d)(5)
- d. AAALAC FAQ: C5
- e. OLAW NIH FAQ: G6