



Post-Approval Monitoring Program

Standard Operating Procedure

University Research Compliance

Performance Standard:

The goal of post-approval monitoring (PAM) is to work with, and in support of, academic and research personnel and to confirm accurate and consistent Animal Care and Use Protocol performance in a collegial and unobtrusive manner.

Background:

Post-approval monitoring of active Institutional Animal Care and Use Committee (IACUC) Animal Care and Use Protocols (ACUPs) is performed to provide assurance to regulatory agencies and Oklahoma State University that research and academic programs using live animals is monitored for compliance with approved IACUC protocols. PAM confirms consistency with approved protocols and accuracy of practices. The PAM Specialist will confirm compliant performance by observation and document review assuring the animal care or use activity is being performed in accordance with federal regulations, approved IACUC ACUPs and Standard Operating Procedures (SOPs) at OSU sites and facilities.

ROLES:

- **Primary Investigators and personnel:** Will work with the PAM Specialist as he or she observes and confirms described monitoring procedures pertaining to their ACUP.
- **PAM Specialist:** Will work with the Primary Investigator and personnel to observe activities and review records and documents as described in the ACUP, prepare accurate reports of his or her observations to the PI and the IACUC and provide recommendations for maintaining compliance.
- **IACUC Manager:** Shall provide operational oversight and management of the PAM Specialist and the compliance monitoring program, assure the IACUC receives reports or updates on items of concern and provide regulatory guidance and support as required to assure compliance and corrective action when necessary.

Program Expectations:

The specific obligations of the PAM program are to:

- Ensure there are no issues or activities that might threaten animal welfare
- Ensure that teaching activities and research procedures are performed as described in the ACUP
- Keep the IACUC informed about program status and process
- Protect the reputation of animal use in teaching activities and research at Oklahoma State University
- Serve as a resource to the research and academic community
- Support the advancement of strong science and education
- Facilitate regulatory compliance

I. Selection of Animal Care and Use Protocols for Review:

- A. All active ACUPs at OSU are included in the selection process and may be subject to a PAM visit.
- B. The selection process utilizes a Random Number Generator to determine which ACUP sites will be visited (Appendix I).

PROTECTION PROCEDURES REQUIRED:

The PAM Specialist (and other visitors) shall wear the PPE prescribed for the specific activity at the site specified.

II. Process of Monitoring:

- A. After ACUPS are selected, the PAM Specialist will contact the Primary Investigator, via an email letter, informing them of a pending PAM visit and schedule an appointment convenient to them and their personnel or when specific procedures described in their ACUP are being performed (Appendix II). A request will be made to have all pertinent records and documentation available for review at the time of the scheduled visit.
- B. During each monitoring visit, the PAM Specialist will compare procedures conducted with those listed in the ACUP. The PAM specialist will use a checklist as a guide to review items such as personnel, procedures, animal husbandry, records, etc. (Appendix III).
- C. An "Exit Briefing" with the PI and/or study personnel will take place after the monitoring visit at which time documented discrepancies, if any, will be brought to their attention.
- D. Observations of animal misuse, mistreatment or neglect (welfare issues) or discrepancies which result in animal welfare concerns, will be immediately reported to the attending veterinarian or his designee and the IACUC Chair for immediate resolution. These reports will be made available to the IACUC upon request.
- E. The PAM Specialist shall send a written report of the monitoring results to the Principal Investigator describing any deficiencies observed. When no concerns are noted during the site visit, a letter will be sent to the PI and study personnel commending them for their continued full compliance with the IACUC.
- F. A follow-up visit, if deemed necessary, may be requested by the IACUC Chair
- G. All documents pertaining to the site visits will be stored electronically on a secure server and hard copies stored in the PAM Specialist's office.
- H. A summary report of visits and findings will be presented to the IACUC at the monthly meetings.