

Post Approval Monitoring Program

Post Approval Monitoring (PAM) for IACUC¹ protocols is aimed at improving communication between animal researchers and the IACUC, prepare CSU Animal Care and Use Program (ACUP) for reviews/inspections performed by any of the following agencies:

- USDA APHIS² Animal Care unannounced inspections
- OLAW³
- AAALAC International⁴

The goal of PAM is to be educational and to help the Principal Investigator (PI) ensure their approved protocol accurately reflects animal activities performed. This program will help the IACUC to proactively solve problems and resolve issues before they adversely impact the important research conducted at CSU. PAM is a component of the IACUC's programmatic oversight which also includes observations of protocol procedures, semiannual inspections, investigation of concerns, and routine veterinary visits to facilities.

Protocol Selection: Protocols selected for PAM are tiered as follows:

- Protocols with current concerns brought to the IACUC
- Protocols that involve pain category D & E using USDA covered species
- Protocols that involve pain category D & E using other species
- Protocols that involve pain category C using USDA covered species
- Protocols with variances
- All other protocols.

The IACUC will review at least 10% of approved projects annually and should examine all protocols during the course of their three-year approval period.

Specific PAM Objectives:

- To compare approved procedures with animal activities performed and direct any discrepancies to the amendment process so the protocol complies with applicable regulations and CSU IACUC Policies.
- To communicate changes in PHS Policy, USDA regulations, and CSU IACUC policies to researchers.
- To communicate to the IACUC the status of animal husbandry, facility operations, and program personnel supporting research and teaching activities.

¹ IACUC: Institutional Animal Care and Use Committee

² USDA APHIS: United States Department of Agriculture, Animal and Plant Health Inspection Service

³ OLAW: Office of Laboratory Animal Welfare

⁴ AAALAC International: Formerly Association for Assessment and Accreditation of Laboratory Animal Care

Process for Conducting PAM:

1. PAM Personnel⁵ notify PIs of an upcoming PAM review. A mutually agreeable time for this review, preferably within 60 days of initial notification, is set. Protocols with past compliance issues or those reported to the IACUC may receive significantly less notice (24-48 hours) prior to review. The IACUC retains the right to monitor animal use without prior notice.
2. PAM Personnel use the PAM Checklist (See Appendix 1) during the review to ensure consistency. The PI is encouraged to invite all protocol personnel to participate in the PAM review. PAM Personnel gather information about protocol activities, including procedures performed, who performed them, and address PI questions about CSU ACUP.
3. PAM Personnel will read and review the protocols to familiarize themselves with the IACUC-approved activities prior to meeting PI/protocol personnel.
PAM Personnel inform the PI of the PAM review outcome and documents, including discrepancies between procedures performed and the IACUC-approved protocol. Such discrepancies may include:
 - Personnel performing procedures not listed in the approved protocol.
 - Procedures performed not listed in the approved protocol.
 - Anesthetics, analgesics, tranquilizers, antibiotics, or other medications used not listed in the protocol, or were not used in accordance with the protocol.
 - Procedures listed in the protocol to promote animal welfare (e.g. post-op monitoring procedures) not performed or documented, as stated in the approved protocol.
 - Survival surgery not performed aseptically.
 - Euthanasia procedures inconsistent with protocol.
 - Protocol personnel not trained or performed procedures inappropriately.
 - Supporting documentation for animal care, post-op care, or other study procedures were incomplete or unavailable.
 - Conditions not safe for humans and/or animals.
 - Outdated materials (drugs, experimental agents, suture, sterile supplies, etc.) used.
 - Equipment (e.g. anesthetic vaporizers) not calibrated.

Report animal misuse, mistreatment, neglect, or willful disregard for appropriate animal care will be immediately reported to the IACUC Chair and the Attending Veterinarian (AV). Corrective action will be determined by the IACUC.

Process of Sharing Information Concerning the Review:

1. PAM Personnel discuss the results with the PI/protocol personnel before leaving the laboratory.

⁵ PAM Personnel: AV/delegates, IACUC members, RICRO IACUC staff.

2. PAM Personnel prepare a written review (PAM Report) for the PI to address specific items. The IACUC may also review this information. The IACUC will be updated with this information by PAM Personnel at IACUC meetings, and this will be summarized in the meeting agenda. The IACUC determines whether:
 - a. No further action needed.
 - b. Protocol(s) need an amendment.
 - c. Notify relevant oversight agencies, e.g. AAALAC, OLAW, and/or USDA, based on corrective action plan and/or agency requirements.
3. IACUC meeting minutes will reflect the IACUC's decision:
 - a. Appropriate action taken; IACUC considers the matter closed.
 - b. Requests further action as outlined by PAM Personnel.
4. PAM Personnel notify PI of the IACUC's decision.

Process of Follow-up:

PAM personnel follow up with PI on any issues raised during a PAM review requiring protocol modifications, new personnel orientation, or additional training.

Process for PI Appeal:

PIs who disagree with PAM review findings and/or recommendations may appeal to the IACUC via email: CSU_IACUC@mail.colostate.edu. The information will be passed on to the IACUC and may result in one of the following:

1. Uphold PAM report as is.
2. Recommend modification of PAM report.
3. Request PI to meet with the IACUC in person to discuss further.

Recordkeeping:

IACUC administrators will retain copies of PAM Reports and associated communications on behalf of the IACUC. The PI will be notified by PAM Personnel that relevant protocol(s) went through Post Approval Monitoring, and the PAM review is:

1. closed out, and the protocol is in good standing
2. still ongoing
3. a reportable non-compliance has been discovered

Appendix 1: PAM Checklist

Protocol #, Title:	
Animals, numbers:	
PI:	
Date of Audit:	
Audit Personnel:	
Lab Personnel:	
Procedures	

COMMENTS:

Recommendations:

Virtual PAM			
Yes	No	N/A	
			1. All animal procedures are approved and consistent with the IACUC-protocol
			2. Animal Records reviewed, are up to date and complete, including Surgical/procedural and daily care checks
			3. Review variances
			4. All staff have access to and understand the protocol and can describe their duties and practices related to the project
			5. All staff are enrolled in the Occupational Health Program
			6. Staff listed on the protocol are up to date
			7. Animal facilities are listed correctly
			8. Rooms that have animal activities have been inspected in the last 6 months
			9. Adverse (unexpected) events promptly reported to the IACUC.

In Person PAM:

Animal Welfare			
Yes	No	N/A	
			1. All animal procedures are approved and consistent with the IACUC-protocol.
			2. Animals properly identified, appear healthy and well cared for.
			3. Review variances
			4. Reporting Animal Welfare Concerns flyer posted.
			5. Health care is overseen by veterinarian

			6. Euthanasia equipment is in good working order.
			7. Adverse (unexpected) events promptly reported to the IACUC.
			8. Surgical technique is adequate
			9. Monitoring of surgical animals is adequate, including post-op care
			10. Anesthesia machines serviced every 2 years. Waste anesthetic gases scavenged appropriately.

Facility			
			1. Animal Facilities are listed correctly on protocol, areas are clean and uncluttered.
			2. Rooms that have animal activities have been inspected in the last 6 months
			3. Drugs, materials, and feed are in date and properly stored. Gas tanks are secured appropriately.
			4. Biohazards identified, safety precautions and entry requirements followed.
			5. Pest control program in place.

Recordkeeping			
			1. SOPs, daily logs or checklists are maintained
			2. Animal health, procedure, and study records are current and adequate.

Personnel			
			1. All staff have access to and understand the protocol and can describe their duties and practices related to the project.
			2. All staff are enrolled in the Occupational Health Program
			3. Staff listed on the protocol are up to date
			4. Staff are adequately trained. Training records are current.

<i>IACUC Admin: Office Use Only</i>			
			<i>Count PAM Review as IACUC Semi-Annual inspection</i>
			<i>Biosafety personnel present at PAM Review</i>