

Post Approval Monitoring Guidance

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
- 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.

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

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

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

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 a checklist 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.
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: RICRO_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:

RICRO 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

PAM Checklist

A. Animal Welfare

1. All animal procedures including post-procedural monitoring and care are consistent with the IACUC-approved protocol.
2. Are animals identified properly, appear healthy and well cared?
 - a. Are species and animal numbers consistent with approved protocol?
 - b. Are food and water supplies appropriate and in date?
 - c. Are animals monitored daily, including weekends and holidays?
3. Is the Reporting Animal Welfare Concerns (Whistle Blower Policy) flyer posted?
4. Is veterinary care of animal is overseen by a veterinarian?
 - a. How often does the veterinarian interact with the animals?
 - b. Are sick animals reported to the veterinary staff
 - c. Study personnel, as well as animal care staff, report animal morbidity and mortality
5. Is euthanasia performed appropriately and consistent with protocol?
 - a. Is the equipment in good working order and directions posted as appropriate?
 - b. Are humane endpoints adhered to?
6. Are adverse (unexpected negative) events reported to IACUC and/or Attending Veterinarian?
 - a. Is what to report clear?
 - b. Are post-procedural problems reported to the veterinary staff?
 - c. Study personnel, as well as animal care staff, report animal morbidity and mortality
7. Is surgical technique is adequate and performed in an appropriate location?
 - a. Is asepsis observed in recovery surgery or when otherwise required?
 - b. Is a surgical scrub (hand wash) performed?
 - c. Do the surgeons wear sterile gloves and gown, mask, shoe covers, and cap if appropriate during surgery?
 - d. Is surgical field prep adequate?
 - e. Are sterile (steam or gas autoclave glass bead sterilizer) or adequately disinfected (e.g. bactericidal solution) instruments used?
 - f. Are implantable devices sterile before surgery?
 - g. Is anesthetic agent use consistent with protocol?
 - h. Is surgery location clean, uncluttered, and appropriate for the species and surgery type?
8. Monitoring of surgical animals is adequate, including post-op care
 - a. Is the monitoring adequate, consistent with protocol, and documented?
 - b. Are sutures or staples, removed by 14 days after surgery?
 - c. Are analgesics and rescue analgesic given?
9. Are anesthesia machines serviced every 2 years and waste anesthetic gases scavenged?

B. Facility

1. Are Animal Facilities correctly listed and inspected by the IACUC?
 - a. Facilities where animals are housed/used are clean, safe and uncluttered.
 - b. Is there adequate temperature control for indoor facilities?
 - c. Is there shelter for outdoor facilities?
 - d. Is there adequate space for all animals to feed?
2. Are drugs, materials and feed in date and properly stored?
 - a. Is secure storage used?
 - b. Are unopened bags stored off the floor?
 - c. Are compressed gas tanks secured adequately?
3. Are safety procedures are in place?
 - a. Are animal carcasses and other waste disposed of properly?
 - b. Any biohazard signage is properly posted
 - c. Are proper precautions including appropriate PPE and during entry/exit followed?
 - d. No human food/drink are allowed in or stored animal areas
4. Is a pest control program is in place?

C. Recordkeeping

1. SOPs, daily logs or checklists are maintained for husbandry
2. Staff are trained to perform their duties.
 - a. Training records, including biosafety, are up-to-date
3. Animal health, procedure, and study records are adequate and current.
 - a. Are medical/surgical/observational/treatment/disposition notes complete?
 - b. Is there an up-to-date inventory of the number of animals used in each pain category on the protocol?

D. Personnel

1. Do personnel have access to and read the current protocol
 - a. Were amendments submitted for any changes in the protocol?
 - b. Do the PI and personnel have accurate knowledge of the protocol?
 - c. Personnel can describe their duties and practices related to the project.
2. All staff are trained to perform their duties
 - a. Are training records complete and up-to-date, and available?
3. All staff are enrolled in the Occupational Health and Safety Program (OHSP).
4. All staff who have physical contact with the animals are on the protocol.