

IACUC Policy on Post Approval Monitoring

Introduction

Post-Approval Monitoring (PAM) of animal use protocols (AUPs) is a comparison of the actual activities occurring under an approved protocol against the written animal use protocol. PAM is a principal method by which institutions assure that investigators and others involved in conducting and supporting animal research do not deviate from the written document and that other relevant documents are maintained in a compliant fashion (i.e., surgery records, animal orders, number of animals used, drugs used, etc.). The goal of PAM is to improve communications among the IACUC, investigators, and research staff to confirm accurate and consistent description and practice of animal use.

All protocols are subject to PAM; ideally, all protocols would be actively monitored for compliance. However, the primary focus of PAM will be on projects that:

1. Involve surgical procedures;
2. Are classified as Pain Category E;
3. Utilize USDA covered species;
4. Involve PIs or groups that have had past compliance issues;
5. Involve PIs or groups that the IACUC or the Attending Veterinarian designate for review.

Active Processes

I. Part A: Verification of Surgical Proficiency

When a protocol is approved that requires PAM for surgical procedures, the approval letter will contain a statement requesting that the laboratory contact the Department of Laboratory Animal Resources (DLAR) Veterinary Staff to arrange a visit to their laboratory to observe the procedures described in the protocol. Specific observations may also be requested by the IACUC. DLAR Veterinary Staff will review the protocol and any related documents, then visit the laboratory to perform the observation. DLAR Veterinary Staff will compare procedures conducted in the laboratory with those listed in the approved protocol. Documented discrepancies between the procedures performed in the lab and those listed in the protocol will be brought to the attention of the investigator. Examples of deviations include, but are not limited to, the following:

1. Personnel performing procedures not listed in the approved protocol;
2. Procedures being performed that are not in the approved protocol;
3. Anesthetics, analgesics, tranquilizers, antibiotics, fluids, or other medications used in the lab are not noted in the protocol, are different from those listed in the protocol, or are not used in accordance with the protocol;
4. Anesthetics, analgesics, tranquilizers, antibiotics, fluids, or other medications used in the lab are not pharmaceutical grade;
5. Procedures listed in the protocol to promote animal welfare are not being performed, or documented, as approved in the protocol;
6. Survival surgery is not performed aseptically;

7. Euthanasia procedures that differ from those listed in the protocol;
8. Personnel appear to lack the necessary training to appropriately perform procedures described in the protocol;
9. Supporting documentation for animal care, post-operative care, or other study procedures is incomplete or unavailable;
10. Conditions are not safe for humans and/or animals;
11. Outdated materials are in use;
12. Equipment not calibrated (i.e., anesthetic vaporizers).

II. Part B: Protocol Review - Practices and Procedures

Protocols will be selected for review based on the criteria outlined in the Introduction. The Principal Investigator (PI) will receive a notice of intent from the IACUC office that includes a copy of the PAM checklist. There will be a follow-up phone call or email about one week after the initial notification to schedule the a visit and answer any questions the PI may have. Protocol audits will be conducted by the IACUC Administrator.

Before meeting with the PI and staff, the IACUC Administrator will review the animal use protocol and note specific items of interest for inspection, review, and/or discussion.

The IACUC Administrator may compare procedures conducted in the laboratory with those listed in the approved protocol. Discrepancies noted between the procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI. Such discrepancies may include:

- a. Personnel performing procedures are not listed in the approved protocol.
- b. Procedures performed in the lab are not listed in the approved protocol.
- c. Anesthetics, analgesics, tranquilizers, antibiotics, or other medications used in the lab are not noted in the protocol, are different from those listed in the protocol, or are not used in accordance with the protocol.
- d. Procedures listed in the protocol to promote animal welfare (e.g. post---op monitoring procedures) are not being performed, or documented, as approved in the protocol.
- e. e. Survival surgery is not performed aseptically.
- f. Euthanasia procedures that differ from those listed in the protocol and/or a method for ensuring death (e.g. after CO₂ exposure) are not employed.
- g. Lab personnel appear to lack the necessary training to appropriately perform procedures listed in the protocol.
- h. Supporting documentation for animal care, post-op care, or other study procedures is incomplete or unavailable.
- i. Conditions are not safe for humans and/or animals.
- j. Outdated materials (drugs, experimental agents, suture, sterile supplies, etc.) are used.

Animal misuse, mistreatment, neglect or willful disregard for appropriate animal care will be reported to the IACUC Chair and the Attending Veterinarian immediately.

Passive Processes

PAM will also occur as part of the overall quality assurance program already in place in the Department of Laboratory Animal Resources. Monthly rounds are made by a Quality Assurance/Quality Control Officer (QA/QC) through all DLAR areas. Any research regulatory noncompliance will be reported to the IACUC Administrator.

In addition, all animals are checked every day by the DLAR staff. These observations will often detect instances of noncompliance that result from tumors being allowed to grow too large, poor surgical technique, or exceeding reasonable humane endpoints. When the technicians have concerns about sick animals they complete a sick animal form and the animal is seen by DLAR Veterinary Staff. Because the number of faculty members that use animals in their research is not currently large, technicians are often familiar with the research being performed and are able to recognize and report things that are out of the ordinary.

Monitoring of protocols where animals fall under USDA pain category E is largely carried out by the DLAR animal care staff as they provide daily care for the animals. All sick animals, regardless of pain category, are reported in writing to the Animal Health Technologist (AHT). The AHT sees the animal and decides upon appropriate treatment in consultation with the Attending Veterinarian. The Attending Veterinarian determines whether or not the level of pain is congruent with what is described in the protocol and reports discrepancies to the IACUC.

The IACUC office, through receipt of documentation from PI labs, verifies completion of training. For surgical procedures, the documentation will trigger verification of proficiency via the Part A form. If Part A has not been completed, the CM and CL work in conjunction with the PI to complete it as soon as possible.

Information Sharing and Reporting

If possible, compliance personnel will discuss the results of a visit with the investigator and/or lab personnel before leaving the laboratory. A follow-up report will be sent to the PI and presented to the IACUC as an agenda item at a convened meeting. PIs in disagreement with audit findings and/or recommendations may appeal to the IACUC by contacting the IACUC Program Manager, who will include the contested items in the monthly report for discussion and disposition by the IACUC. Animal welfare concerns will be reported to the IACUC and to the Attending Veterinarian. Compliance monitoring documents will be maintained in the IACUC office.

Follow-up for PAM activities

DLAR or IACUC office personnel will follow up on any issues raised during any active or passive PAM activity. In most cases, issues raised will be addressed by:

1. Appropriate training;
2. Reverting to the procedures that were described in the approved protocol;
3. Amending the existing protocol;

On occasion, additional monitoring sessions may be required as part of corrective action by the IACUC. These may or may not be scheduled, as appropriate for the situation. Any animal welfare concerns raised may be referred to the IACUC Chair, the Attending Veterinarian, and/or the IACUC Administrator for resolution.