



IACUC POLICY # 27
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 principle method by which institutions assure that investigators and others involved in conducting and supporting animal research do not digress from the written document and includes other relevant documents as well (i.e., surgery records, animal orders, number of animals used, drugs used, etc.). The goal of PAM is to improve communications between the IACUC and investigators and their staff to confirm accurate and consistent protocol description of animal use.

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 groups that have had past compliance issues and need regular oversight
5. Involve groups that the IACUC or the Attending Veterinarian designate for review

Active Processes

When a protocol is approved that requires PAM for surgical procedures, the approval letter will contain a statement requesting that the laboratory contact the Compliance Liaison (CL) to arrange a visit to their laboratory to observe the procedures described in the protocol. The CL will review the protocol and any related documents, then visit the laboratory and complete the attached checklist. The CL 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 are not listed in the approved protocol
2. Procedures 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.

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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)

Passive Processes

PAM will also occur as part of the overall quality assurance program already in place in the Animal Resource Facilities. Weekly rounds are made by a Quality Assurance Officer (QAO) through all ARF areas. This individual tracks much of the administrative details such as:

1. Ensuring that investigators do not acquire more animals than they are approved for
2. Ensuring that investigators have correct and in date AUP numbers
3. Ensuring that only animals listed in the approved protocol are ordered

In addition, all animals are checked every day by the ARF staff. These observations will often detect instances of noncompliance that result from tumors being allowed to grow to 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 the CL and /or the Attending Veterinarian. 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 Animal Resource Facility technical 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.

Information Sharing and Reporting

If possible, the CL will discuss the results of the inspection with the investigator or other lab personnel before leaving the laboratory. Animal welfare concerns will be reported to the IACUC and to the Attending Veterinarian. The checklist and comments prepared by the CL will be placed in the appropriate protocol file.

Follow-up

The CL, or other IACUC personnel, will follow up on any issues raised during a laboratory inspection. In most cases, issues raised will be addressed by:

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

