IACUC Guideline 012: Post-Approval Monitoring Program

> **Purpose: Federal laws and regulations mandate IACUC oversight of approved animal activities. Post-Approval Monitoring (PAM) for animal use protocols aims to enhance communication between researchers and the IACUC, preparing our animal program for USDA and PHS inspections. The PAM process is designed to be educational, assisting Principal Investigators (PIs) in ensuring their approved protocols accurately reflect the project's activities.**

Background

The PAM program is a component of the IACUC's programmatic oversight which also includes:

- scheduled observations of protocol-related procedures
- IACUC semi-annual inspections
- investigation of concerns
- routine veterinary visits to facilities

The specific objective of UW-PAM involves:

- To cooperatively compare the approved procedures and the day-to-day work and to ensure that UW's animal research complies with university & federal policies and regulations.
- To communicate to the researchers any changes in the federal policies and guidelines, as well as the University standards that must evolve to keep our program in compliance.
- To communicate to the IACUC any questions and/or concerns with animal husbandry, facility operations, and program personnel related to the work that is approved in the protocol

Guideline

PAM Reviews: PAM Reviews can be performed by PAM Coordinator, Attending Veterinarian (AV) and/or their delegates, additional IACUC members, and additional REDD personnel.

Protocol Selection:

Protocols selected for the PAM process are prioritized as follows:

- High risk protocols
    - Complicated surgical procedures
    - Large number of animals
    - USDA-covered species
    - USDA (Pain) Category E protocols
    - High risk infectious agents in animals

o   Protocols that pose added risk to human researchers

- Protocols with previous noncompliance
- New techniques for UW
- New species to UW
- New PIs to UW
- Discretion of IACUC

PAM Frequency:

All active protocols involving the Category E designation, and all USDA-covered species will be monitored at least once every three years, or more frequently, at the discretion of IACUC or Attending Veterinarian.

Process for Conducting PAM Review:

1. PAM personnel will contact the PI in advance to schedule monitoring sessions of planned experimental procedures. To prepare for PAM, please access the UW-PAM checklist.

2. Prior to the meeting with the research staff, PAM personnel will read and review the protocols to gain a better understanding of animal use as approved by the IACUC. During this review PAM personnel can formulate specific questions for the research team.

3. The PAM process involves a brief meeting with the PI. The PI is encouraged to invite all personnel affiliated with the protocol to participate in the meeting as research associates and students are often involved in conducting animal work. During the meeting, PAM personnel will gather information about the work related to the protocol, including the types of procedures performed and who performs them, and address questions or concerns about UW's Animal Care and Use Program that the PI might have.

4. PAM personnel and PI set up a mutually agreeable time for the PAM observational review within a reasonable time frame and during which the procedure(s) of interest will be carried out. In some cases, multiple observations may be required.

    Please note that protocols with past compliance issues or those reported to the IACUC may receive significantly less (24-48 hours) notice prior to monitoring. The IACUC retains the right to monitor animal use without prior notice.

During each monitoring session, PAM personnel will compare procedures conducted in the research setting 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 PI.

Process of Sharing PAM Findings:

1. PAM personnel will discuss the results with the PI and other lab personnel before leaving the laboratory.
2. PAM personnel will prepare a written review (PAM Report) and send it to the PI to address any concerns.
   - PAM personnel may advise the PI directly if a protocol amendment is needed.
   - After the PI responds, the PAM Report and checklist will be presented to the IACUC for awareness. The IACUC will then review this document, as well as the **UW-PAM checklist** in the meeting agenda and determine if relevant regulatory agencies need to be notified. The meeting minutes will reflect the IACUC's decision.
3. The PI is notified of the IACUC's decision.

Process of Follow-up:

1. The PAM personnel will follow up on any issues that require protocol modifications, orientation of new personnel, additional education, or training. The PAM Team will support the laboratory with IACUC requirements and PAM recommendations by facilitating the required training and/or submission preparation (e.g. addendum, de novo).
2. Additional monitoring sessions may be included to ensure IACUC requirements are implemented.

Recordkeeping:

A copy of the final PAM Report with the record of all corrective actions, will be kept on file by the UW IACUC. PAM results will be recorded by the UW for use on institutional trends or follow-up.

Resources

1. Guide for the Care and use of Laboratory Animals (eighth edition):
https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf.

2. Policy on Humane Care and Use of Laboratory Animals (Policy):
https://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf.