

Post Approval Monitoring (PAM) Program

Performance Standard Statement: The goal of the post-approval monitoring (PAM) Team is to work with and support research faculty, staff, and students, ensure accurate and consistent protocol performance in an educational, collegial, and caring manner focused on ensuring animal welfare and consistent research practices.

Background: Self-regulation, by continued oversight of approved animal study protocols (ASP) is required by federal laws, regulations, and guidelines, although the specific structure of the institutional program may vary.¹ The PAM team is a unit in the IACUC Office that provides oversight of animal activities on behalf of and under the purview of the Institutional Animal Care and Use Committee (IACUC). The Northwestern PAM team works in collaboration with research personnel to confirm consistency with approved protocols to satisfy federal requirements.

Definitions:

- **Adverse Event:** An unexpected outcome of an approved procedure that leads to animal harm or mortalities.
- **Animal Welfare:** In the context of this document, assuring the health and safety of animals that are undergoing approved procedures.
- **Deviations:** Inconsistencies within an ASP such as between procedures, sequence and timing, or between procedure sections.
- **IACUC:** Provides regulatory required oversight and ensures self-regulation as described in the *PHS Policy, Animal Welfare Act, and Guide for the Care and Use of Laboratory Animals*.
- **Minor Noncompliance:** A deviation from approved procedures, regulations or guidelines that do not pose significant potential harm to the health or safety of an animal or to personnel working with animals.
- **Mock Procedure:** A review of procedure set up, equipment, substances, and relevant policies and guidelines without the use of live animals.
- **PAM Finding:** Observations reported to the IACUC ranging from recommendations for procedure flexibility, process improvements, minor, and serious noncompliance.
- **Requested Observation:** PAM initiated due to an IACUC, CCM, or laboratory concern about one or more procedures, documentation, etc.
- **Rounds:** Visiting animal use spaces to provide oversight on the wellbeing of animals as well as completion of cages side and room level documentation.
- **Self-Regulation:** regular monitoring of the program for animal care and use by an IACUC.
- **Self-Reporting:** The process of submitting a summary of an adverse event or noncompliance including a plan to prevent future incidents.
- **Serious Noncompliance:** Deviation from approved procedures, regulations or guidelines

that poses significant potential for causing harm to the health or safety of an animal or to personnel working with the animal.

Roles:

- **Principal Investigators (PI):** Work in conjunction with the PAM Team to facilitate PAM activities. The PI may delegate coordination to a designee.
- **PAM Team:** Provides educational opportunities, observe experimental activities, prepare accurate reports, and if necessary, facilitate training and provide recommendations for maintaining compliance. The PAM Team also maintains related records and corresponds with the IACUC.
- **IACUC:** Provides operational oversight of the PAM Team and the PAM program, assuring that the IACUC receives reports or updates on items of concern and provides training support as required to assure compliance.

Required Protective Measures:

The PAM Team, as well as other visitors, will wear the Personal Protective Equipment (PPE) deemed appropriate for the specific activity/procedure of the laboratory.

The laboratory must notify and provide the PAM Team of any PPE required for procedure observations.

PAM Program:

- I. Process of Selecting Laboratories for PAM:
 - A. All laboratories with approved ASPs are subject to PAM periodically (typically once every three years). We prioritize projects involving USDA species and USDA Pain Category E. New species additions or changes to procedures may be subject to additional monitoring.
 - B. Laboratories may request PAM Visits, education, and outreach.
 - C. In general, the PAM Team or designee will contact the laboratory in advance to schedule monitoring sessions of planned experimental procedures.
 - D. The PAM team conducts rounds of animal use areas to assess animal wellbeing and room level documentation. The PAM team may reach out to the PI with any concerns, provide additional training, educational outreach, or initiate PAM visits.
- II. Process of Monitoring:
 - A. The PAM Team initiates a PAM with a laboratory with an introductory discussion which includes information about the PAM Program, reviewing in-lab training record requirements, options for procedure observations and/or audits of ASPs, expectations, and resources based on laboratory needs.

- B. During the PAM process, the laboratory has the opportunity to discuss their research and review procedures prior to an observation to identify drift to prevent noncompliance.
 - This step may happen during the PAM initial discussion, at any time during the PAM process, or at the laboratories request.
 - C. The PAM Team makes an appointment for procedure observations of one or more planned experimental procedures; an audit of one or more ASPs. In either case, follow-up appointments may be scheduled to ensure any concerns have been addressed.
 - Mock procedure observations may be conducted in advance of a scheduled procedure.
 - The PAM Team compares the procedure conducted to the approved ASP, offering recommendations on workflow improvements and flexibility where applicable.
 - Recommendations based on discrepancies noted between procedures performed in the lab and those listed in the ASP will be brought to the attention of the PI.
 - D. The PAM Team utilizes the “PAM PI Summary Report” as a reference for the procedure observation or protocol audit.
 - E. Laboratory personnel (in-lab) training documents and animal health records may be requested during the PAM process.
- III. PAM Liaison:
- A. The PAM Team will act as a liaison between laboratories and the IACUC.
 - B. Incidents of minor noncompliance may be managed by the PAM Team. Repeated incidents of minor noncompliance will be brought to the IACUC Chairs for evaluation.
 - C. The PAM Team may be assigned to assist in preventing and correcting minor and/or serious noncompliance at the request of the IACUC, veterinary team, and anonymous reports.
 - Animal welfare concerns, misuse, mistreatment, neglect or willful disregard for appropriate animal care will be immediately reported to the IACUC. The IACUC Office, in conjunction with the IACUC Chair, will gather information to present to the IACUC for review and investigate, if necessary.
 - Self-Reporting of serious noncompliance will be requested by the PAM team or designee if animal welfare issues or concerns are observed during PAM activities.
 - The PAM Team will act as an advocate for the lab upon submission of the self-report of noncompliance or a reported concern to the IACUC.
 - In collaboration with the veterinarians, research procedure(s) being observed may be placed on hold if human or animal welfare issues are observed.

- Issues that pose an immediate threat to animal welfare will be referred to the Attending Veterinarian or their designee for immediate resolution.

IV. Process of Sharing PAM Findings:

- A. The PAM Team discusses monitoring results with the PI and/or other research personnel before leaving the laboratory.
- B. The PAM Team will provide a summary of each observation to the PI and other research personnel as applicable outlining what went well and any requirements or recommendations to the procedure and/or process.
- C. The PAM Team sends a written draft of the PI Summary Report with the monitoring results to the PI and other research personnel as applicable. The PI will have an opportunity to respond to the draft report prior to its finalization. If no concerns are noted, the report is finalized.
- D. The PAM Team presents a monthly report to the IACUC regarding any PAM findings, including resolved minor noncompliance issues for their review.

V. Follow-Up Process:

- A. The PAM Team 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).
- B. Additional monitoring sessions may be included to ensure IACUC requirements are implemented.

VI. Record Keeping:

- A. PAM findings will be utilized by the PAM Team for analysis of institutional trends, training, or revisions to IACUC documents.
- B. Digital copies of the final PI Summary reports and monthly reports will be kept by the IACUC Office for at least three years.²

References:

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>