



Animal Care and Use Post Approval Monitoring Procedures			
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1. Overview

1.1 Purpose

The primary goal of the Post Approval Monitoring (PAM) program is to ensure animal well-being and to maintain regulatory compliance while working collaboratively with Principal Investigators (PI) and research personnel. Associated with this, the process will facilitate the science by serving as a resource to the researchers. The PAM process is positioned to convey IACUC policies of animal care and use, identify opportunities for improvement and make recommendations on how to achieve improvement. Ultimately, the PAM process will confirm that animal procedures are performed and conducted under an approved protocol is consistent with what the IACUC approved.

Continuing IACUC oversight of animal activities is required by federal laws, regulations, policies, and guidelines. PAM is a continuation of Institutional Animal Care and Use Committee (IACUC) oversight of animal activities, providing an assurance to regulatory agencies and to the research institution, that animal activities supporting research and teaching are monitored for compliance with approved IACUC protocols. The PAM Team validates compliance with approved protocols, regulations, and Drexel's animal care and use program policy, working collaboratively to build an educational partnership with researchers to fulfill this federal requirement. In addition to the PAM Program, other methods of continuing IACUC oversight include semiannual inspections and program reviews conducted every six months, daily monitoring of the animals by animal caretakers (at least twice per day for large animal species) and veterinary staff observations of the care and use of animals during weekly rounds, clinical case monitoring, during follow-up checks, laboratory visits, and when assisting the investigators in their research.

PAM serves to promote both animal welfare and regulatory compliance as well as to facilitate communication between laboratory personnel, the IACUC, University Laboratory Animal Resources (ULAR) and the Office of Research and Innovation (ORI). According to the Guide for the Care and Use of Laboratory Animals, PAM includes "continuing protocol review; laboratory inspections (conducted either during regular facility inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary and IACUC staff and members; and external regulatory inspections and assessments." PAM should encourage best practices in animal care management and welfare, as well as to promote a culture of compliance institution wide. When scientific research involves animals, reliable and meaningful results depend on proper and consistent animal care and use. Compliance with these principles is mandatory. Some benefits that may be gained from a PAM review, but are not limited to, are:

- Increased understanding of the regulations that guide our research projects.
- Increased communication concerning Federal regulations and University policies.
- Access to an individual to clarify the Federal regulations and University policies.

2. Definitions

Post Approval Monitoring (PAM) - a thorough review of key elements of an approved animal use protocol (laboratory, animal procedures, animal health monitoring records, training, use and handling of test articles, safety). The reviews are conducted to ensure animal subjects are cared for and used in compliance with the approved protocol, federal regulations, and university policies.



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Significant Finding – A finding, consistent with the PHS Policy, is directly pertaining to the health and safety of animals. Significant findings require prompt or immediate correction to ensure the safety of the animals. Examples, including but not limited to: the use of expired items on/with live animals, animals not receiving anesthetics and/or analgesics appropriately, improper aseptic surgical technique, conducting of animal-related activities without appropriate IACUC review and approval, failure to maintain appropriate records, etc.

Minor Finding – A finding where the solution need not be immediate and does not directly affect animal welfare. Examples, including but not limited to: minor administrative/documentation errors, cleanliness of space, peeling paint, etc. Ongoing inattention to a minor deficiency may result in a chronic problem indicative of a programmatic failure and may constitute a significant deficiency.

Repeat Finding – Any finding, significant or minor, that has been reported multiple times with an inattention to being remedied appropriately.

3. Post Approval Monitoring Program

3.1 PAM Priority Criteria

1. Highest priority
 - a. Category E procedures (scientifically justified unalleviated pain or distress)
 - b. Protocols with multiple and single major survival surgery, prolonged restraint, food/fluid restriction
 - c. USDA covered species
 - d. New protocol or new procedure on an approved protocol
 - e. Protocols with special requirements or exceptions
 - f. Protocols or procedures with past compliance issues
 - g. IACUC/Veterinarian designated protocols
2. Second Priority
 - a. Category D procedures with conditions not met above (e.g. single minor surgery, non-survival surgery)
 - b. Protocols with tumor models
 - c. Protocols with aged animals
 - d. Breeding protocols
3. Lowest Priority
 - a. Category C protocols (e.g. euthanize and harvest tissue)
 - b. Training protocols
 - c. Sentinel protocols

3.2 Post Approval Monitoring Protocol Selection

1. All lab animal activity at Drexel, including field studies, are monitored as a service to support and protect research staff in keeping their protocols and animal activities compliant with the latest federal and institutional standards.
2. Protocols are selected routinely, for cause, or as requested by the IACUC, veterinary staff, animal care staff, or lab personnel (self-monitoring).
 - a. Principal Investigators and lab personnel can request a PAM visit by completing the PAM Request Form located on the Drexel IACUC Post Approval Monitoring webpage. [PAM Request Form](#)
3. Protocols with higher pain categories, USDA-covered species, or complex procedures will take priority as identified in Section 2.1 and may be selected with more frequency.



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4. The PAM Team can conduct monitoring activities at any time and/or at random with no prior notice, especially involving ‘for cause’ monitoring.

3.3 Post Approval Monitoring Visit Expectations

1. PAM Team personnel can visit the laboratory and the facility where the animals are housed at any time, without notice. However, routine laboratory visits and surgical observations are generally scheduled. Both PI and research personnel should be present for the PAM visit.
2. The PAM Team shall use a “PAM Checklist” during visits and observations. This checklist shall be provided to the PI ahead of the visit to allow the PI and laboratory personnel to prepare. *Checklists can be found in Section 5. Resources.*
3. If documentation is complete and organized, the PAM checklist review will take approximately an hour. However, depending on the complexity of the protocol procedures, subsequent appointments may be required to observe procedures to complete a comprehensive assessment of the level of protocol compliance.
4. The PAM Team shall tour laboratory, clinical space, surgery areas, and procedure sites.
5. The PAM Team shall observe and compare procedures conducted in the laboratory with those listed in the approved protocol(s). Documented discrepancies and observed drift between procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI.
6. All records associated with the protocol can and will be reviewed (surgery records, use of controlled substances, training records, etc.). Records should be made available upon request of the PAM Team. Failure to produce records will be noted.
7. Animal misuse, mistreatment, neglect (welfare issues), and discrepancies which result in animal welfare concerns (i.e., deliberate animal misuse, mistreatment, or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC in accordance with the Public Health Service Policy. The IACUC Office, in conjunction with the IACUC Chair, will gather information to present to the IACUC for review and, if necessary, further investigation. Please refer to Drexel University’s IACUC Policy for Investigating Animal Welfare Concerns and Non-compliance activities.
8. If an issue that falls outside of the scope of the animal use and care post-approval monitoring visit is identified (e.g., research integrity, misconduct, biosafety concerns), the PAM Team will notify and collaborate with the applicable offices.

3.4 Post Approval Monitoring Exit Briefing

1. The PAM Team performs an exit briefing, discussing monitoring results with the Principal Investigator and/or other research personnel before leaving the laboratory.
2. Significant deficiencies that pose an immediate threat to animal welfare shall be referred to the Attending Veterinarian and IACUC for immediate resolution.
3. The PAM Team shall assist the Principal Investigator with resolving minor deficiencies found immediately before leaving the laboratory.
4. The Principal Investigators are given the opportunity to make corrections by modifying techniques or by submitting an amendment to their protocol(s) as a part of the corrective action plan discussed during the exit briefing. Assistance is also provided to navigate best practices for the most efficient and humanely productive science possible.



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3.5 Post Visit

1. The PAM Team shall send a written draft report of the monitoring results and recommended action plans, where applicable, within 10 days to the Principal Investigator and participating research personnel following the monitoring event via email. The Principal Investigator will have an opportunity to respond to the draft report with a plan, timeline, and responsible roles to address improvement report within 10 days before the final report is prepared.
 - a. IACUC leadership will be notified of significant and/or repeat findings.
2. The PAM Team shall send a final written report of the monitoring results and improvement action plans to the Principal Investigator after improvements are completed or with a timeframe for completion.
 - a. Department Chairs will be included in the communication of final reports involving significant and/or repeat findings.
3. The PAM Team presents a monthly summary of PAM visits to the IACUC at each scheduled IACUC Meetings.

3.6 Post Approval Monitoring Follow-Up Process

The PAM Team will follow up on any non-compliance that requires protocol modifications or training. The PAM Team will support the laboratory with corrective action(s) by facilitating the required training, performing additional monitoring sessions, amendment submission preparation, and verification of completion of action plan. The PAM Team and the IACUC Office will continue to be a resource to the Principal Investigator and research personnel with any questions or request for further guidance.

3.7 Recordkeeping

The IACUC Office, as part of the Office for Research & Innovation, will maintain reports of all PAM visits. Metrics gathered from reports will be used to track trends to improve current training and/or develop new training or resource opportunities to better support the research community. Documents shall be retained for a minimum of three years after animal use activities documented in PAM reviews or active animal use protocols have ceased unless otherwise specified. Reference DU Office of the General Counsel Records Management Policy: [Record Retention Schedule RecordManagementProgramMasterSchedule102319.ashx \(drexel.edu\)](https://www.drexel.edu/recordmanagement/RecordRetentionSchedule102319.ashx)

4. Responsibilities

4.1 The Office of Research & Innovation Responsibilities

The Office of Research & Innovation (ORI) is committed to the health and safety of both personnel and animals. The PAM Team, as part of ORI, is responsible for maintaining this guidance document, applicable tools, training, and monitoring of the program. For inquiries regarding these procedures, please contact the Director of Animal Welfare, as part of ORI. The PAM Team is also responsible for the following:

1. The PAM Team corresponds, documents, maintains records, and consults with the IACUC such that the IACUC receives timely reports or updates on items of significance non-compliance.



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2. The PAM Team works in conjunction with investigators and research personnel to organize monitoring events, in addition to observing animal procedures and reviewing records to certify compliance with approved protocols.
3. The PAM Team works with, and in support of, investigators to ensure research is conducted within the limits of approved protocols and in compliance with Federal Regulations.
4. The PAM Team assists investigators in understanding regulatory compliance and assure good science through monitoring and training.

4.2 Principal Investigator Responsibilities

The Principal Investigator (PI) is responsible for ensuring that all aspects of the approved protocol are understood and followed by all personnel on the approved protocol. Furthermore, it is the PI's responsibility to ensure all personnel working with animals are adequately trained to perform approved procedures. The PI will be responsible for assisting the PAM Team in scheduling PAM visits, providing records as requested, and for ensuring all identified deficiencies are rectified in accordance with the corrective action plan timeline.

5. Resources

1. [QA/QI Post Approval Monitoring \(PAM\) Checklist](#)
2. [QA/QI Post Approval Monitoring \(PAM\) Animal Housing Checklist](#)
3. Public Health Service Policy on Humane Care and Use of Laboratory Animals | NIH-OLAW | 2015 [Public Health Service Policy on Humane Care and Use of Laboratory Animals Office \(nih.gov\)](#)
4. Guide for the Care and Use of Laboratory Animals (8th Edition) | 2011 | Pages 33-34 [Guide for the Care and Use of Laboratory Animals, 8th edition. National Academies Press \(nih.gov\)](#)
5. Animal Welfare Act and Animal Welfare Regulations | Animal and Plant Health Inspection Service, U. S. Department of Agriculture | 2022| [Animal Welfare Act and Animal Welfare Regulations \(usda.gov\)](#)
6. OLAW FAQ G.6. Is post approval monitoring required? <https://olaw.nih.gov/faqs#/guidance/faqs?anchor=50381>

6. Revisions

6.1 Revision

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