

IACUC SOP Number: 004	Version Number: 1.0
Effective Date: July 7, 2016	
Title: IACUC Post-Approval Monitoring (PAM) Program	

Purpose

The Post-Approval Monitoring (PAM) program outlines a methodology whereby an institution demonstrates to a regulatory body and/or external agency that they have a program of ongoing review for research procedures even after the protocol has received approval from the Institutional Animal Care and Use Committee (IACUC). PAM complements existing requirements for program review and inspection mandated in the regulations, policies and guidelines by performing a thorough review of those areas that have historically posed regulatory challenges for Princeton University. PAM bridges IACUC oversight and animal care related research activities. PAM provides the following benefits:

- Protects Princeton’s funding, assurances and reputation by pre-emptive identification of potential compliance deficiencies
- Provides guidance to the Principal Investigator (PI) and/or representative researcher to correct potential areas of non-compliance; therefore decreasing the likelihood that outside regulatory bodies and organizations (USDA/OLAW/AAALAC International) identify issues during a visit
- Ensures animal welfare and regulatory compliance by observing adequate care and use of laboratory animals in research and assuring that the work occurring is approved by the IACUC
- Provides a collegial resource to the research community by presenting an opportunity for education and exchange of information between individuals conducting research involving animals and the IACUC
- Facilitates an open dialogue to share current IACUC policies and guidelines with PIs, animal researchers, LAR, and IACUC members
- Identifies and provides training opportunities for researchers and staff
- Provides additional guidance and mentoring for student-initiated research protocols

Regulatory Background

The IACUC is responsible for conducting a continuing review of approved protocols in accordance with Public Health Service Policy (IV.C.5.) and Animal Welfare Regulations (Sec 2.31(d)). The University’s Institutional Official must sign an Animal Welfare Assurance Statement for OLAW, promising that Princeton University will conduct animal research in accordance with federal policy, the Guide for the Care and Use of Laboratory Animals, and other applicable regulations.

According to the Animal Welfare Regulations (Sec 2.31(d)):

“The IACUC shall conduct continuing reviews of activities [involving research animals] at appropriate intervals as determined by the IACUC, but not less than annually.” §2.31(d) (5)

The *Guide*, upon which the University’s accreditation with AAALAC International rests, states:

“[PAM] is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC’s initial protocol approval.... Methods [of PAM] include continuing protocol review; laboratory inspections (conducted either during regular facilities inspection 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.”(Guide p. 33)

The Princeton PAM program uses the following as standards, references and guidance:

- Animal Welfare Act
- Animal Welfare Regulations
- USDA Animal Care Policy Manual
- Animal Welfare Inspection Guide
- Guide for the Care and Use of Laboratory Animals
- Guide for the Care and Use of Agricultural Animals in Research and Teaching
- PHS Policy on Humane Care and Use of Laboratory Animals
- Guidance from OLAW
- AVMA Guidelines for the Euthanasia of Animals
- Princeton University’s Animal Welfare Assurance
- Princeton University’s AAALAC International program description
- Princeton IACUC Policies, Guidelines and SOPs
- Laboratory Animal Resources (LAR) Policies, Guidelines and SOPs
- EHS recommendation
- Occupational Health clearance

Scope

This policy applies to PIs and all individuals performing animal-related work conducted on an approved application for animal use at Princeton University.

Responsibilities

RIA: The PAM program falls under the authority of Research Integrity & Assurance.

IACUC: Oversees the animal care and use program including continuing review of approved/ongoing animal activities. The committee is responsible for program evaluations, review of protocols and amendments, reporting noncompliance, ensuring that individuals who work with animals are appropriately trained and qualified, and addressing animal welfare concerns involving the care and use of animals in research at the institution.

Research Compliance Specialist (RCS): Monitors procedures and practices associated with approved animal use protocols, identifies deficiencies related to research activity, provides suggestions for remediation, follow-up and training. The RCS is responsible for overseeing research-related activities and animal care as it relates to research activity.

Principal Investigator: Ensures that all aspects of the approved protocol are being followed by laboratory members and that all personnel working with animals in research and teaching are

adequately trained to perform approved procedures. The PI will be responsible for ensuring all identified deficiencies are rectified in a timely manner.

Procedure

The RCS will visit laboratories involved in animal-based research and teaching at Princeton University to observe the procedures performed on animals to determine if they are in accordance with those described in the approved protocol. For visits involving the use of USDA regulated species, a review of medical records will be conducted in advance of the visit to provide guidance in the proper preparation of these documents.

I. Activities:

The RCS reviews approved protocols and their procedures, personnel, lab study areas, and any other activity relating to the protocol. Once familiar with all aspects of the protocol(s) the RCS will schedule a visit to observe the protocol activities.

II. Protocol Risk Assessment:

Visits are based on a risk assessment of procedures performed, species used, or by recommendations by regulatory agencies. Protocol categories for risk consideration are:

- i. USDA category E
- ii. USDA category D
- iii. Non-USDA category E
- iv. Non-USDA category D
- v. Other Protocols or areas where deficiencies or concerns have been identified
- vi. Protocols that require additional oversight as requested by the IACUC

III. Methods of Review:

- a. 'Routine Review' is an observation session scheduled by the RCS with the PI or delegated laboratory representative.
- b. The RCS performs 'Follow-up' reviews to confirm resolution of any changes or deficiencies, if required or requested. In addition to RCS observations, deficiencies noted during Semi-Annual Inspections may also be assessed by a follow-up RCS visit or the Semi-annual Inspection may also be used to confirm correction of previously identified deficiencies.
- c. The RSC will visit labs on behalf of the IACUC to investigate a specific cause for concern.

IV. Process:

- a. Visit: After the RCS reviews the approved protocol and its approved amendments, a face-to-face visit is scheduled in advance with the PI or associated research personnel, if the protocol involves the use of USDA regulated species, the RCS will also review the medical records in advance of the visit. The RCS will compare procedures and records with those listed in the approved protocol. The RCS understands and respects that not all procedures may be observed due to their delicacy and experimental requirements. In cases where direct monitoring is not appropriate, the RCS can review animal and procedure records to evaluate compliance with the approved protocol and provide recommendations or assistance as needed.

- b. Exit Briefing: At the completion of observations, the RCS will conduct an ‘Exit Briefing’ with the PI and/or designated laboratory representative. The goal of this dialogue is to facilitate the needs of the lab, answer lab member questions, and discuss any protocol deficiencies observed. The RCS will consider all information provided by the lab staff and, if deficiencies are identified, provide recommendations for implementing corrective actions, including consultation with the AV or IACUC, scheduling training, identifying resources and/or submitting amendments.
 - i. The RCS will work with the PI and/or laboratory staff to resolve most minor deficiencies immediately while in the lab. Occasionally it may be necessary to consult with members of the RIA office, the AV, or the IACUC Chair to determine how best to handle observed deficiencies. Examples of minor deficiencies and corrective action plans:

Minor Deficiency	Corrective Action Plan
Expired bottle of analgesic (Meloxicam/Buprenorphine)	Immediate & proper disposal of drug
Qualified and trained but unapproved lab member working on protocol	PI submission of Personnel Amendment
Overcrowded cages	Reassignment of animals to appropriate cages
Animal work in an unapproved room	PI submits amendment to add animal room, IACUC inspects the room for approval
Inappropriate use of expired materials (e.g. suture, fluids)	Guidance on acceptable versus unacceptable uses of expired materials

- ii. According to the OLAW PHS Policy, “a significant deficiency... is or may be a threat to the health or safety of the animals.” (IV.B.3.) In the rare event that a significant deficiency is identified, these will be brought to the immediate attention of the AV, IACUC Chair, and RIA office so that these concerns can be addressed as soon as possible and under the direction of the AV. The significant deficiencies will be shared with the full IACUC to make them aware of the deficiency and to allow the opportunity for discussion. The following items are examples of significant deficiencies: failure to follow analgesic regiment/pain relief as described in the protocol resulting in animal pain or distress, use of an unapproved method of euthanasia, performance of an unapproved surgical procedure on live animals, or unapproved, untrained, and unqualified personnel performing a procedure on live animals.
- c. Post-Visit: The RCS documents the occurrence of the PAM visit. An email communication with PAM findings will be sent to the PI, including the recommendations and corrective actions shared with the research personnel at the time of the exit briefing. The IACUC

administrative staff shares the necessary information, e.g. copies of policies, links to forms, and processes to follow, for the PI to address any deficiencies. The PI or lab manager should remain in contact with the RCS throughout the implementation of the resolution process and send an email upon completion of resolution. The RCS will continue to be a resource for any further information. If required or requested, the RCS will re-visit the laboratory, post-incident resolution, to confirm the effectiveness of the corrective action. PIs who are in disagreement of the outcome of the visit are encouraged to address the concern to the IACUC at any time. The IACUC, IACUC Chair, AV, and if necessary the Institutional Official will review the appeals.

V. Recordkeeping: The RCS maintains a list of reviewed laboratories to demonstrate that Princeton University has a self-auditing process of approved IACUC protocols.

VI. The RCS will give verbal reports to the IACUC to inform the committee of any trends in non-compliance, areas in need of improvement, or areas of improvement.

References

ARENA [Applied Research Ethics National Association]. 2002. Institutional Animal Care and Use Committee Guidebook. Bethesda: Office for Laboratory Animal Welfare, National Institutes of Health.

AWA [Animal Welfare Act as amended] 2007. U.S.C. Title 7, § 2131-2159.

AWAR [Animal Welfare Act Regulations], 9 CFR Ch. 1; Animal Welfare, Part 1-4. Revised January 1, 2005. HREA [Health Research Extension Act of 1985]. Animals in Research, Sec. 495. Public Law 99-158. November 20, 1985.

IRAC [Interagency Research Animal Committee] U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. 1985. Office of Animal Care and Use [OACU] of the NIH.

NIH [National Institute of Health]. 2002. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Bethesda: NIH Office of Laboratory Animal Welfare (OLAW)

NRC [National Research Council]. 2011. Guide for the Care and Use of Laboratory Animals, 8th Ed. Washington: National Academy Press.

From OLAW website:

- [FAQ. Is post approval monitoring required?](#)
- *Contemporary Topics*. 1996; 35(5). Model for Performing Institutional Animal Care and Use Committee: Continuing Review of Animal Research.

Version History

Version Number	Revision Date	Revisions
1.0	July 7, 2016	Initiation