



INDIANA UNIVERSITY
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
Office of Research Compliance

Institutional Animal Care and Use Committee (IACUC)

Office of Research Compliance (ORC)

Post-Approval Monitoring (PAM) Program

Program Statement	Effective: <i>January 4, 2016</i>
Background	Last Updated: --
Procedures	
Contact	Responsible University Officer:
	Fred H. Cate
	<i>Vice President for Research</i>
ADDITIONAL DETAILS	
Web Address	Policy Owner:
	<i>Bloomington Institutional Animal Care and Use Committee</i>
	Policy Contact:
	<i>IACUC Administrator</i>

Program Statement

The Post-Approval Monitoring (PAM) program aims to create a liaison capacity between the IACUC and the research community at IUB. A successful PAM program enhances the IACUC's oversight of the Animal Care Program, and it provides insight to the Animal Research Community supported by the Program. While PAM is not a new regulation, it is critical to the long-term protection and integrity our of IUB's Program. PAM benefits the PI community in the following ways:

- *Compliance*: PAM ensures humane use of healthy animals (as approved by the IACUC). Coupled with protocol submission and inspections, PAM helps PIs meet their obligations to federal agencies and to IUB.
- *Communication and Education*: PAM improves communications between BIACUC, PIs, and lab staff and enhances development of accurate and consistent protocols for animal research. It also helps PIs maintain current understanding of the newest federal regulations and BIACUC policies.
- *Proactivity*: If compliance challenges are encountered during visits, PAM catalyzes internal solutions to smaller problems, reducing the likelihood that federal inspectors will note them as they grow larger. PAM strives to decrease the number of incidents that IUB must report to federal regulators and/or granting agencies.
- *Preparation*: Furthermore, PAM visits help PIs to prepare for upcoming inspections from external agencies (USDA, OLAW, AAALAC) and the BIACUC in a constantly evolving regulatory environment.
- *Feedback*: Finally, PAM also invites feedback from PIs about the BIACUC program. This two-way communication enables BIACUC to improve itself.

Thus, PAM enhances the University's Animal Use and Care Program by enhancing compliance, communication and education, proactivity, preparation, and feedback. It complements the protocol approval and inspection processes.

Background

Per the 8th edition of the *Guide* (p. 33-34):

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. Post-approval monitoring (PAM) is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC's initial protocol approval. PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures. The IACUC, veterinary, animal care, and compliance staff may all conduct PAM, which may also serve as an educational tool.

Most major research institutions use PAM as part of their Animal Care and Use Programs. Universities face increased regulatory oversight from federal and state authorities and steepened consequences for non-compliance (including loss of funding to investigators or to the University and/or substantial fines). Thus, PAM provides a purposefully overlapping vehicle for oversight, education, and communication as part of a three pronged programmatic approach, including:

(1) *Protocol submission (follow up with amendments)*: The first stage of the Animal Care and Use Program requires submission of a protocol. These federally-mandated submissions contain complete descriptions of proposed experiments/manipulations involving animal subjects. They are reviewed and approved by the BIACUC. Most approved protocols are amended, with varying frequency, to accommodate the changing nature of the research. BIACUC's role at this stage ensures compliance of the PIs changing research program with the regulations and policies enacted by external agencies and the Committee.

BLOOMINGTON INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Bloomington, IN 47408

(812) 855-5138

(2) *Inspections (semi-annually or annually)*: BIACUC inspection teams visit laboratories at semi-annual or annual intervals (depending on research conducted in the lab and the regulations that apply). These brief visits predominately focus on facilities. While fulfilling some of BIACUC's regulatory obligations to federal agencies, inspections do not focus on practices, education, communication, proactivity, feedback, etc., as PAM does.

(3) *Post-Approval Monitoring (once or more per 3 years)*: Through education, training, and outreach, PAM provides a complementary but more proactive method for ensuring Institutional regulatory compliance, for facilitating research activities with healthy animals, and for opening BIACUC-PI dialogue regarding changes or revisions to ongoing projects, including future research needs. This two-way dialogue focuses on practices, personnel, education, and communication.

Together, protocol submission, inspection, and PAM are designed to create a comprehensive, adaptable Animal Care and Use Program that enables PIs and Indiana University-Bloomington to best meet its compliance obligations to external regulators while ensuring animal welfare. PAM is a crucial part of our Program.

Procedures

Laboratory Selection

The PAM review will be performed a minimum of once every three years. If a laboratory experiences a violation, then the review may occur more frequently. The review may be initiated by the IACUC, veterinary staff or research staff.

The PAM visit will be conducted most often by the IACUC Administrator to ensure consistency and offer regulatory expertise. Occasionally, members of the IACUC or Veterinary staff may accompany the Administrator or conduct an independent visit. (The visitor is referred to as the 'PAM liaison.'

Note: *It is anticipated that all active laboratories will be visited at least once within the 3-year protocol approval period.*

Principal Investigator Notification

The Principal Investigator will be contacted at least two to four weeks in advance to schedule a PAM review. (Follow-up visits will likely occur with less advance notice). If applicable, the PI will receive a copy of the PAM checklist. This advance notification provides an opportunity for researchers to gather any relevant information and review protocol details. The PAM liaison will examine the selected protocol(s) prior to meeting with the PI. When appropriate, the review will include a meeting with the PI and other protocol associates.

PAM Review

The PAM liaison will compare research procedures and activities with those listed in the approved protocol to facilitate a discussion with the PI and lab group. PAM visits focus on:

- (1) *Review of IACUC approved protocols*: This protocol review ensures that lab practices are consistent with current federal regulations and IUB-based guidelines and policies. It also checks for completeness and uniformity of information provided. Additionally, discussions during a PAM visit may include a review of pilot studies, training mechanisms, terminal studies, new directions of a study and the application of animal (pain) use categories. Such protocol review enables timely communication and serves to enhance protocol development.
- (2) *Discussions with laboratory staff*: This communication ensures that protocols and approved procedures are being followed and that research personnel performing the procedures have been appropriately trained and approved in protocols. These discussions often proactively prompt timely submission of amendments (for procedures and personnel), thereby keeping PIs compliant with University and federal regulations.
- (3) *Review of records and other documentation*: Interpersonal dialogue about record-keeping (training, anesthesia regime, post-operative care, drug inventory and controlled substance logs, husbandry, etc.) helps to keep protocols compliant with effective oversight. Dialogue about record-keeping also creates opportunities to partner with the PI to create solutions for record collection and maintenance.
- (4) *Reports of non-compliance or animal welfare concerns*: When compliance or animal welfare concerns arise, PAM visits enable in-depth dialogue with PIs and staff involved. Thus, dialogue can then focus on accurate identification of the issues and subsequent steps to solve the problem encountered.

PAM-mediated discussions between PIs and PAM liaisons are not purposefully intended to uncover non-compliance. IACUC hopes that PAM visits will report evidence of good performance rather than noncompliance. However, if a noncompliant event is uncovered (involving (1) - (4) above and/or review of laboratories and facilities), the PAM liaison will immediately discuss the issue with the PI and review the best course of action. This action may include discussion with the IACUC Chair or Attending Veterinarian. Again, PAM aims to proactively address compliance issues before they become large and reportable.

At the conclusion of the PAM review, the PAM liaison will provide an informal, verbal assessment to the PI, highlighting strengths observed and potential room for improvements. A written summary will be sent to the PI as well. When applicable, the liaison will provide assistance with submitting an amendment and/or arranging for additional training.

PAM Records Review

In accordance with record-keeping guidelines mandated by federal regulations, the PAM liaison will compile and maintain appropriate records and report results to the BIACUC.

Contact

<i>Subject</i>	<i>Contact</i>	<i>Phone</i>	<i>Email</i>
PAM Procedure	IACUC Administrator	855-5138	Biacuc@indiana.edu

Web Address for this Policy

<https://research.iu.edu/policies/bloomington-animal-care-and-use.html>