IUP IACUC Post Approval Monitoring Statement and Procedure

Introduction

Post-Approval Monitoring (PAM) of animal use protocols (AUPs) is a comparison of the actual activities occurring under an approved protocol against the written AUP itself. PAM is a principal method by which institutions assure that investigators and others involved in conducting and supporting animal research do not deviate from approved protocols and that other relevant documents (permits, logs, training certificates) are maintained in a compliant fashion. The goal of PAM is to improve communications among the IACUC, investigators, and research personnel to confirm accurate and consistent description and practice of animal use, and to maintain compliance with all appropriate regulations and best-practice guidelines.

Protocol selection for PAM

From a regulatory perspective, all protocols are subject to PAM. In practice, the primary focus will be on projects that:

1. Are classified as USDA Pain Category E (of primary concern) or D (of secondary concern), or
2. Involve surgical procedures, or
3. Utilize USDA-protected species, or
4. Involve investigators that have had past compliance issues, or
5. Involve investigators that the IACUC or the Attending Veterinarian designate for review.

PAM frequency

All protocols which match categories 1-3 (above) should receive PAM at a minimum of once during each 3-yr protocol approval period. New protocols in these categories will be slated for PAM during their first year of approval. Protocols meeting categories 4-5 (above) will receive PAM at the discretion of the IACUC. Protocols meeting none of the above categories will be grouped into a pool, from which a random sample (10-20%) would be selected for PAM in any given year.

PAM Procedure

When a protocol is identified for PAM, the IACUC PAM team (a rotating subset of IACUC members) will contact the investigator to arrange (at a mutually-agreed upon time) a visit to their laboratory or study site to observe the procedures described in their approved AUP. Prior to the site visit, the PAM team will review the AUP and any related documents. During the site visit, the PAM team will compare the procedures conducted to those approved in the AUP, and will document their inspection via the PAM checklist. Discrepancies between the procedures performed and those in the approved AUP will be brought to the attention of the investigator, as will any details related to animal numbers/sources, supplementary licenses/permits, experimental conditions, or other facets of the activities which have the potential to impact animal welfare or intended uses.

Examples of deviations include, but are not limited to, the following:

- Personnel performing procedures not listed in the approved protocol
- Procedures being performed that are not in the approved protocol
- Anesthetics, analgesics, tranquilizers, antibiotics, fluids, or other medications used that are not noted, of insufficient grade, or are different from those described in the AUP

- Failure to perform AUP procedures to promote animal welfare
- Lack of aseptic conditions/technique for survival surgery
- Euthanasia procedures that differ from those in the AUP
- Personnel that appear to lack the necessary training or supervision to appropriately perform AUP procedures
- Supporting documentation for animal use or care that is incomplete or unavailable
- Equipment and/or conditions that are not safe for humans and/or animals

Discrepancies which involve animal misuse, mistreatment, neglect or willful disregard for appropriate animal care will be reported to the IACUC Institutional Official (IO) and the Attending Veterinarian immediately. Discrepancies which do not immediately influence animal welfare will be summarized and reported to the IO only after discussion at an IACUC meeting and/or potential resolution with the investigator involved (described below).

Information Sharing/Reporting and Remediation of Discrepancies

PAM personnel will discuss the results of a visit with the investigator (and other personnel present) before leaving the visitation site. A completed checklist and follow-up summary report will be generated by the PAM team within 14 days of each visit. Copies of these documents will be

- placed into the IACUC files, and
- sent/given to the investigator, and
- presented to the IACUC chair as an agenda item for a convened meeting

Investigators will be invited to attend IACUC meeting discussion of their PAM visit and findings. Investigators in disagreement with any of the findings of the PAM will be given opportunity to consult directly with the IACUC IO and/or Attending Veterinarian, as required. The IACUC chair will generate a summary report for the IO for any PAM inspection that results in significant and/or unmitigated discrepancies.

Investigator Responsibilities

Investigators are expected to comply with PAM visitation requests, and to facilitate the scheduling of a mutually agreed-upon visitation time and place. Protocol senior personnel (e.g., faculty/staff) are expected to be present during a PAM visitation, and to facilitate the actions of the PAM team during the visit. Protocol supervisors should prepare for a PAM visit by ensuring the availability of the requisite AUP and associated documents. Investigators are asked to not alter their normal activities during a PAM visit, but rather to conduct their projects in their routine fashion. Following a PAM visit, investigators and protocol supervisors should maintain open communication with the IACUC, the Attending Veterinarian, and the Institutional Official, in order to remedy any procedural discrepancies that may have been noted during PAM.

Follow-up Activities

At the conclusion of any PAM visit and inspection, the IACUC will ask investigators for their regulatory needs with regard to PAM, and will offer its assistance with personnel training, record-keeping, or protocol revisions, as may be required.

IUP IACUC Post-Approval Monitoring Checklist

PAM visitation date:_____ PAM visitation site: _____

IACUC protocol(s) under review (#'s):_____

Investigator:_____ If student, faculty supervisor:_____

Protocol personnel present: _____

PAM team members present:_____

		Yes	No	Not observed	Not applicable	Notes:
Personnel	IACUC approved protocol available for reference	☐	☐	☐	☐	_____
	IACUC / veterinarian / IO contact information available	☐	☐	☐	☐	_____
	Personnel training documented	☐	☐	☐	☐	_____
	All personnel involved are listed in the protocol	☐	☐	☐	☐	_____
	Appropriate personal protective devices used	☐	☐	☐	☐	_____
	Environmental conditions safe/appropriate	☐	☐	☐	☐	_____
Animal uses	Animal species and number as approved	☐	☐	☐	☐	_____
	Drugs/medications/anesthetics as approved	☐	☐	☐	☐	_____
	Storage/documented use of controlled substances	☐	☐	☐	☐	_____
	Non-surgical animal manipulations as approved	☐	☐	☐	☐	_____
Surgical	Surgical techniques consistent with protocol	☐	☐	☐	☐	_____
	Aseptic technique used	☐	☐	☐	☐	_____
	Post-surgical analgesia appropriate	☐	☐	☐	☐	_____
	Post-surgical monitoring performed/documented	☐	☐	☐	☐	_____
	Surgical materials sterilized	☐	☐	☐	☐	_____
	Surgical materials not expired	☐	☐	☐	☐	_____
Euthanasia	Adverse consequences documented	☐	☐	☐	☐	_____
	Euthanasia performed per protocol	☐	☐	☐	☐	_____
	Secondary euthanasia method employed	☐	☐	☐	☐	_____
	Carcass disposition appropriate	☐	☐	☐	☐	_____
Colony	Experimental diet(s) used	☐	☐	☐	☐	_____
	Special housing used	☐	☐	☐	☐	_____
	Cleanliness / sanitation / density acceptable	☐	☐	☐	☐	_____
	Other environmental conditions acceptable	☐	☐	☐	☐	_____

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At the conclusion of a PAM visit, a signature from the IACUC protocol supervisor and one of the IACUC PAM team members is required:

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IACUC protocol supervisor signature Please print name CLEARLY

_____

IACUC PAM team member signature Please print name CLEARLY