Policy Statement

The Purdue Animal Care and Use Committee (PACUC) accepts responsibility for the care and use of vertebrate animals involved in activities approved by the institution. The goal of the Post-Approval Monitoring (PAM) program is to create a liaison between the PACUC and the academic/research community, which improves communications, enhances accurate and consistent vertebrate animal protocol development, and ensures that animals are being used humanely. PAM is a conduit for communication and education between the investigative staff, the PACUC, and the Laboratory Animal Program (LAP). Post-approval monitoring visits will be conducted by at least one of the laboratory animal veterinarians (LAV) and the PACUC Administrator. The PACUC chair and the Animal Exposure Occupational Health Program Specialist will attend whenever possible.

Background

Federal regulations and University policies govern the use of vertebrate animals and require investigators to submit complete descriptions of the proposed activities involving animals for Institutional Animal Care and Use Committee (IACUC), hereinafter referred to as PACUC, review and approval. The PACUC evaluates each protocol to ensure compliance with these regulations and policies. The PAM visit is an important component of a comprehensive animal care and use program, which provides a well-defined, complementary method for ensuring regulatory compliance, facilitating research, teaching, and testing activities, and providing Principal Investigators (PIs) and their staff with an opportunity to discuss changes or revisions to ongoing activities and the animal care program.

Procedures

Protocol Selection

The selection of protocols for a PAM review is performed with either a focused and/or random approach, with emphasis on the following:

1. Protocols classified as USDA Category E.
2. Protocols associated with previous compliance incidents.
6. Protocols that the PACUC or LAP veterinarians designate for review.
7. Protocols that require the use of satellite facilities.

Principal Investigator Notification

The Principal Investigator (PI) will typically be contacted at least 2 to 4 weeks in advance, to schedule a PAM visit. The PI will receive a copy of the PAM checklist. This advance notification provides an opportunity for PI’s to gather any relevant information and review protocol details. The PAM visit is intended to be an educational tool, ensuring that approved protocols accurately reflect the activities. The PAM review team will examine the selected protocol(s) prior to meeting with the PI. When appropriate, the visit will include a meeting with the PI and other protocol associates.

PAM Review
The PAM review is intended to be a discussion between the PAM review team and the PI. The discussion will compare procedures and activities being practiced with those listed in the approved protocol. Discrepancies observed will be discussed and could include, but are not limited to:

1. Unapproved personnel performing protocol procedures.
2. Procedures performed that are not listed in the approved protocol.
3. Anesthetics, analgesics, tranquilizers, antibiotics, or other medications used in the laboratory that are not noted in the protocol or are not used in accordance with the protocol.
4. Procedures listed in the protocol to promote animal welfare (e.g., post-op monitoring) that are not performed or are not documented.
5. Survival surgery is not performed aseptically.
6. Euthanasia procedures differing from those listed in the approved protocol and/or not using an approved secondary method.
7. Lab personnel appear to lack the necessary training to appropriately perform protocol procedures.
8. Documentation of animal care, post-op care or study-related procedures is unavailable or incomplete.
9. Conditions unsafe for humans and/or animals.
10. The use of expired materials (e.g., drugs, experimental agents, suture material, sterile supplies, etc.).

At the conclusion of the PAM visit, the PAM review team will provide an informal, verbal assessment of any concerns to the PI. When applicable, the team will provide assistance with submitting an amendment and/or arranging for additional training.

**PAM Records Review**

For record-keeping purposes, the PACUC Administrator will maintain the PAM records and report the results to the PACUC at its next regularly scheduled meeting.
Protocol Post-Approval Monitoring Form

Principal Investigator: ___________________________  Protocol #: _______________________

Protocol Title: _____________________________________________________________________________

Species: ___________________________  Site Visited: ___________________________

Personnel Present: __________________________________________________________________________

Monitoring Team: __________________________________________________________________________

Monitoring Date: ___________________________  Monitoring Time: __________________________

PROTOCOL AND PERSONNEL SECTION

___ Y ___ N 1. A current copy of the approved protocol (and subsequently approved amendments) is available in, or near, the site visited.

___ Y ___ N 2. All personnel involved in the project are listed on the protocol and have completed the PACUC orientation program and the occupational health program participation/declination form.

___ Y ___ N 3. The principal investigator and all project personnel have accurate knowledge of the procedures approved on the protocol and have received training relevant to the project.

___ Y ___ N 4. The principal investigator and other project personnel (working without direct supervision) have accurate qualifications documented in the PACUC office via Animal Care and Use Qualification Forms.

NOTES: ___________________________________________________________________________________

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STUDY PROCEDURES SECTION

__ Y __ N 5. The procedures being conducted are approved in the protocol or amendments.

__ Y __ N 6. The site visited has a dedicated workspace for the animal procedures being conducted.

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ANESTHESIA SECTION

__ Y __ N 7. The methods of anesthesia used are approved in the protocol.

__ Y __ N 8. The anesthetized animals are appropriately monitored according to the protocol.

__ Y __ N 9. The inhalant anesthetics are properly scavenged or exhausted.

__ Y __ N 10. The anesthesia dosages, frequency, and routes of administration are recorded.

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SURGERY SECTION
__ Y  __  N  11. The surgeries are appropriately recorded.

__ Y  __  N  12. The surgical procedures are performed in an approved area.

__ Y  __  N  13. The facilities are clean and organized.

__ Y  __  N  14. The use of sterile gloves and instruments are utilized when performing recovery surgery.

__ Y  __  N  15. The animals are aseptically prepped when performing recovery surgery.

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POST-SURGICAL/PROCEDURAL CARE SECTION

__ Y  __  N  16. The post-surgical/procedural monitoring and care being performed are as approved in the protocol.

__ Y  __  N  17. The analgesics used are as approved in the protocol and available.

__ Y  __  N  18. The analgesic dosages, frequency, and routes of administration are recorded.

__ Y  __  N  19. The post-surgical/procedural care is recorded.

__ Y  __  N  20. The recovery area is appropriate.

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EUTHANASIA SECTION

__ Y __ N 21. The methods of euthanasia are as approved in the protocol.

__ Y __ N 22. The euthanasia dose and route of administration are recorded, if applicable.

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GENERAL INFORMATION SECTION

__ Y __ N 24. The number of animals used is recorded and kept current.

__ Y __ N 25. The injections, blood collection, and fluid collection are as described in the protocol.

__ Y __ N 26. The drugs, fluids, sutures, etc., are within the expiration date.

__ Y __ N 27. The principal investigator has live animals outside of the approved housing facility for more than 12 hours.

__ Y __ N 28. Occupational health and safety issues are properly addressed, posted, and/or documented (e.g., hazard assessment posted to include appropriate PPE, emergency contact list posted, N-95 mask, gloves, eye protection, other PPE).

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