INDIANA UNIVERSITY

Office of Research Compliance (ORC)
Institutional Animal Care and Use Committee (IACUC)

Post-Approval Monitoring (PAM)

FULL POLICY CONTENTS

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Office of Research Compliance, IACUC

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Policy Statement

The IACUC's accept responsibility for the care and use of animals involved in activities approved by the institution. The goal of the Post-Approval Monitoring (PAM) program is to create a liaison capacity between the IACUC and the research community, which improves communications, enhances accurate and consistent animal research protocol development, and ensures that animals are being used humanely, as approved by the IACUC. PAM is a conduit for communication and education between the investigative staff, the IACUC Committee, and the Laboratory Animal Centers (LAR/LARC)

Background

Federal and State regulations and University policies govern the use of animals in research and require investigators to submit complete descriptions of the proposed experiments involving animal subjects for Institutional Animal Care and Use Committee (IACUC) review and approval. The IACUC 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 Institutional regulatory compliance, facilitating research activities, and providing Principal Investigators (PIs) and their staff with an opportunity to discuss changes or revisions to ongoing projects 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 Use Category E (death as an endpoint).

2. Protocols associated with previous compliance incidents.
3. Protocols involving surgically invasive procedures (multiple survival surgery).
4. Protocols involving pilot studies.
5. Protocols using USDA-covered species.
6. Protocols that the IACUC or Veterinarians designate for review.
7. Protocols that require the use of satellite facilities.

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

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 researchers 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 project activities. The PAM liaison 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 liaison and the PI. The discussion will compare research procedures and activities being practiced in the lab 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 liaison will provide an informal, verbal assessment of any concerns to the PI. When applicable, the liaison will provide assistance with submitting an amendment and/or arranging for additional training.

Note: Animal misuse, mistreatment, neglect or willful disregard for appropriate animal care will be immediately reported to the IACUC Chair and the Attending Veterinarian.

PAM Records Review

For record-keeping purposes, the PAM liaison will compile and maintain appropriate records and report results to the IACUC as deemed necessary.