IACUC Protocol Post-Approval Monitoring Policy

**Introduction**

Post-Approval Monitoring (PAM) processes are an important part of the Purdue University Institutional Animal Care and Use Committee (IACUC) program for the care and use of animals in research, teaching, or testing. This process involves meaningful monitoring of the protocols that have been approved by the IACUC.

The PAM process may involve laboratory/site visits to observe animal procedures being performed, evaluation of record keeping, confirmation of proper personnel training, and discussions related to approved activities. The process is meant to facilitate dialogue and education between the IACUC and researchers.

These policies and procedures apply to all Purdue University IACUC protocols approved or otherwise overseen by the Purdue University IACUC.

**Definitions**

*For Cause Monitoring* – Method of monitoring conducted in response to reported complaints or potential anomalies related to an IACUC protocol.

*Monitor* - An Office of Research and Partnerships Post-Approval Monitor or a team consisting of IACUC Members or IACUC staff, or Laboratory Animal Program (LAP) Veterinarians selected to conduct monitoring activities.

*Random Selection Procedure* - Manner of selection based on review type without Investigator identifiers.

**Responsibilities**

A Monitor is responsible for conducting monitoring activities including, but not limited to, Random Selection Procedures, notification, scheduling, and conducting a monitoring visit. A Monitor will also draft timely reports summarizing the observations and adherence to the IACUC protocol.

The Purdue IACUC is responsible for reviewing Post-Approval Monitoring reports, maintaining documentation within the approved file, and making determinations associated with any findings or corrective actions related to the final report from the Monitor.

Principal Investigators and research personnel are responsible for upholding the requirements of the approved protocol, completing Post-Approval Monitoring documents, and completing the required PAM process.
**Selection Criteria**

The Monitor will select approved protocols based on the following criteria:

1. Active protocols with a USDA animal use category of D or E. These protocols may be subject to more frequent monitoring or at the request of the IACUC or LAV.

2. Any active protocol may be selected for post approval monitoring using a Random Selection Procedure. IACUC protocols do not need to have active animal use for the PAM process to occur.

3. For Cause Monitoring may be conducted at any time, with or without notice to the PI, if requested by the IACUC or LAV.

**Protocol Post-Approval Monitoring Process**

1. When a protocol is identified for PAM, the Monitor will send an initial notice to the Principal Investigator of the IACUC protocol. This message will notify the Principal Investigator of the PAM selection and explain preparations for the visit.

2. Prior to the visit, a pre-visit questionnaire will be sent to the PI via email and should be completed and returned to the Monitor within five business days. If the pre-visit questionnaire is not completed, the visit will still occur, but the Monitor will need to gather additional information from the PI during the monitoring visit.

3. The visit will be scheduled for a mutually agreeable time for the PI and the Monitor. The PI may ask for additional laboratory/teaching staff to assist with the visit, but during the visit, the PI will discuss the activities of the protocol. Whenever feasible, the Monitor will observe animals from the protocol and research/teaching activities.

4. The Monitor will complete the Protocol Post-Approval Monitoring Form during the visit. Problems or deficiencies noted on these visits will be corrected at the time the deficiency is noticed and further training/education provided, if needed. General observations will be discussed with the PI/personnel at the conclusion of the visit.

5. A summary of PAM visits, will be reported to the IACUC Administrator by the Monitor. The Monitor may attend any IACUC meetings in non-voting status to clarify any matters from the report. The final report will become part of the IACUC protocol record.
Purdue Animal Care and Use Committee (PACUC)

Protocol Post-Approval Monitoring Form

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Principal Investigator:____________________ Protocol #:____________________

Protocol Title:______________________________________________________________

Species:__________________ Site Visited:___________________________

Personnel Present:___________________________________________________________

Monitoring Team:___________________________________________________________

Monitoring Date:____________________ Monitoring Time:_______________________

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PROTOCOL AND PERSONNEL SECTION

Example

__ 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.

NOTES:__________________________________________

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Example

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.

NOTES:__________________________________________

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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.

NOTES:__________________________

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**Example**

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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.

NOTES:__________________________

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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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Example

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).

NOTES: __________________________________________
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Example