

SOP: # 203 Effective Date: 03/23/2022	POST APPROVAL MONITORING	Supersedes Document Dated: 9/16/2020
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1. PURPOSE:

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.

This SOP applies to all Purdue University IACUC protocols approved or otherwise overseen by the Purdue University IACUC.

2. DEFINITIONS:

- 2.1 *Directed Monitoring* – Method of monitoring conducted at request of the IACUC or IACUC Administrator based on research aim, species, risk or pain category.
- 2.2 *For Cause Monitoring* – Method of monitoring conducted in response to reported complaints or potential anomalies related to an IACUC protocol. Expedited Review.
- 2.3 *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.
- 2.4 *Random Selection Procedure* - Manner of selection based on review type without investigator identifiers.

3. PROCEDURES

3.1 Selection Criteria

- 3.1.1 The Monitor will select approved protocols based on the following criteria:
 - (a) 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 a Laboratory Animal Veterinarian (LAV).
 - (b) Any active protocol may be selected for Directed monitoring based on record-keeping requirements (e.g. wildlife, client owned

animals, livestock) risk level, species, or funding source (e. g DoD, USDA). Though primary preference for monitoring will be given to those projects including active animal use within the past year, IACUC protocols do not need to have active animal use for the PAM process to occur.

- (c) Any active protocol may be selected for post approval monitoring using a Random Selection Procedure. Though primary preference for monitoring will be given to those projects including active animal use within the past year, IACUC protocols do not need to have active animal use for the PAM process to occur.
- (d) For Cause Monitoring may be conducted at any time, with or without notice to the PI, if requested by the IACUC or LAV.

3.2 Post Approval Monitoring Process

- 3.2.1 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.
- 3.2.2 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.
- 3.2.3 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.
- 3.2.4 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.
- 3.2.5 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.

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4. 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 requesting Directed or For Cause Monitoring, 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.

5. APPLICABLE REGULATIONS AND GUIDELINES

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition.