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Purpose

Lehigh University recognizes that ensuring and documenting compliance with approved animal care and use protocols is an important aspect of the animal care and use program. The purpose of post-approval monitoring (PAM) is to work constructively with investigators to facilitate their animal research and ensure accurate and consistent compliance with IACUC-approved protocols, funding agency requirements, state and federal regulations, institutional policies, and best practices. PAM is a service-oriented function of the IACUC and was established to help investigators stay in compliance and to be proactive in identifying potential problems with compliance. PAM reviews emphasize education, consultation, and training. PAM is also designed to help investigators, their teams, and the University prepare for external audits and inspections by funding, regulatory, and accreditation agencies.

Background

Federal regulations require that the institution and the IACUC provide program oversight and ensure that research activities are conducted as approved by the IACUC. General post-approval monitoring of approved protocols is achieved through several mechanisms, including protocol renewals, the IACUC's semi-annual animal facility inspections, and external regulatory inspections. PAM provides the sustained observation of approved protocols necessary to assess overall protocol, facility, and program performance. PAM assists the IACUC with its obligation and facilitates successful program oversight as required by federal guidelines. PAM enhances the IACUC's ability to monitor approved procedural activities, provide information about programmatic risks and associated issues, identify trends, and convey practical corrective plans for the identification and management of risks.

Roles/Responsibilities

- Principal Investigators (PIs) and their staff will respond to PAM requests in a timely manner, be present during PAM visits, verbally verify protocol-specific procedures, and support verification by providing access to study records. The PI may assign a designee to be present during the PAM visit. The PI and their staff will participate in the development and implementation of corrective actions when necessary.
- The Manager of Research Integrity will provide oversight and management of PAM. The Manager of Research Integrity will schedule and conduct PAM review sessions, discuss protocol-specific research activities with investigators during PAM review sessions, prepare accurate reports of PAM activity, provide recommendations for maintaining compliance, assist in the development and implementation of corrective and preventative actions, and provide training, consultation, and support to investigators and the IACUC as necessary to ensure compliance.
- The Central Animal Facility (CAF) staff will participate in PAM review sessions that occur in the facility, and will provide verbal verification of facility operations, policies, and procedures, and support verification by providing access to facility-related records.
- PAM is an extension of the oversight and educational function of the IACUC. The IACUC will receive and evaluate reports of PAM activity, identify corrective actions, and determine outcomes. As necessary, the IACUC will evaluate PAM reports to determine instances of noncompliance and make the appropriate corrective action and reporting recommendations to the Institutional Official.
- The Institutional Official (IO) will receive and evaluate reports of PAM activity. In consideration of the IACUC's determinations, the IO will provide guidance, resources, and support for systemic and policy changes, updates, and improvements to address issues identified through PAM activity.

Scope

PAM reviews are conducted both routinely and on a "for-cause" basis. All active protocols will receive at least one routine PAM review during the course of the first three years of approval by the IACUC. Unannounced for-cause reviews are conducted when a report of noncompliance is received or if the IACUC identifies a concern that requires further investigation. For-cause PAM reviews do not generally

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involve the breadth of a routine PAM review, and are conducted to either provide verification that corrective actions were implemented in response to earlier instances of noncompliance, or to gather information to confirm or disqualify a report of noncompliance.

PIs may also request PAM review in an effort to maintain compliance with federal and institutional policies, or to prepare for an external audit by a sponsor or federal agency. PAM review requests are encouraged, as the goal of PAM is to proactively assist investigators in conducting compliant research.

Procedures

Note: All animal laboratory visitors and protocol personnel involved in PAM review will wear the Personal Protective Equipment (PPE) prescribed for the activity of the laboratory.

- I. Selection of Protocols for Review
 - a. All active IACUC-approved protocols are subject to PAM review. Each active protocol is reviewed at least once during its three-year approval period. Only protocols that have been active for at least six months will be selected for routine PAM review.
 - b. Active IACUC-approved protocols involving the use of animals in the USDA Category D or E may be subject to more frequent review, or at the discretion of the IACUC.
 - c. Active IACUC-approved protocols involving less invasive procedures will be reviewed at the discretion of the IACUC.
- II. PAM Review Sessions
 - a. The Manager of Research Integrity is the primary IACUC representative responsible for conducting PAM review sessions.
 - b. In general, the Manager of Research Integrity, or a designee, will schedule PAM review with the PI or other research personnel in advance.
 - c. For-cause PAM review may be conducted at any time, with or without advanced notice to the PI or research personnel.
 - d. The Manager of Research Integrity is always accompanied by a second individual during the PAM review session. When reviews are conducted in the CAF, the second individual is the CAF Manager. When reviews are conducted in laboratories outside of the CAF, the second individual is the IACUC Chair. The PI or a designee will also be present during the PAM review session.
 - e. Prior to the PAM session, the PAM representatives will review the IACUC protocol file and familiarize themselves with the approved procedures, staff, training and qualification forms, animal numbers, and highlight any specific areas of interest. The Manager of Research Integrity will prepare the PAM Review Checklist, and send a separate checklist to the PI to help them gather information that they may need during the visit.
 - f. The PAM review session is centered on a dialogue between the investigators and the PAM representatives. During the session, the PAM representatives will ask the PI and other laboratory staff present to verbally describe their animal procedures. Using the PAM Review Checklist, the PAM representatives will discuss aspects of the research with the PI and other staff.
 - g. As a foremost goal of PAM review is to share information and answer questions, the PAM representatives will inform the PI and other personnel of any new or revised policies issued by the IACUC or the CAF.
 - h. There will be a review of the housing/breeding rooms and the laboratory areas used for experiments. Using the PAM Review Checklist to record observations, the PAM representatives will compare procedures conducted in the laboratory with those described in the approved protocol. Documented discrepancies between procedures performed in the laboratory and those listed in the protocol will be brought to the attention of the PI. Items that will be reviewed are listed on the attached PAM Review Checklist, and include the following sections:

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- i. Protocol and study procedures
 - ii. Personnel
 - iii. Anesthesia and analgesia
 - iv. Surgery
 - v. Post-Surgical Care
 - vi. Euthanasia
 - vii. Record Keeping
 - viii. Study animals
 - ix. Exceptions from Standards of Care / Exceptions to the Guide
- i. Animal misuse, mistreatment, or neglect, and discrepancies that result in animal welfare concerns (deliberate animal misuse, mistreatment, or neglect, or those that involve willful disregard of appropriate animal care) will be immediately reported to the IACUC in accordance with institutional policy and the PHS Policy. The Manager of Research Integrity will gather information to present to the IACUC for review, and if necessary, further investigation.
- III. PAM Review Information Sharing
 - a. At the conclusion of the PAM review session and before leaving the laboratory, the PAM representatives will discuss the results with the PI and other research personnel. If identified issues can be resolved during the review session, the PAM representatives will address them before leaving the laboratory so that the investigator may remain in compliance. The PI and the PAM representatives will sign a copy of the checklist with documented discrepancies. The checklist will be filed with the protocol in the IACUC records. The PI will be given an appropriate amount of time to correct identified discrepancies, and if necessary, a follow-up meeting will be scheduled.
 - b. The Manager of Research Integrity will send a written draft report of the review session to the PI. The investigators will have the opportunity to respond to the draft report before the final report is prepared. The response and all correspondence thereafter will be filed with the final report.
 - c. The Manager of Research Integrity will send a final written report of the PAM review results to the PI. The PI will be asked to verify the accuracy of the information provided in the final report.
 - d. The Manager of Research Integrity will present a semi-annual summary report of PAM review results to the IACUC and the IO.
- IV. PAM Review Follow Up
 - a. The Manager of Research Integrity will follow up on any issues that require protocol modifications or training. The Manager of Research Integrity will support any corrective action required by the laboratory by facilitating training and/or providing assistance with submitting modifications for review by the IACUC.
 - b. When necessary, additional PAM review sessions may be a part of the follow-up to facilitate corrective actions.

Recordkeeping

- I. A copy of the final PAM review report will be kept in the protocol file and provided to the PI. The report will consist of a written summary of topics discussed, any controverted issues relating to what had been discussed either during the PAM review visit or in response to the draft report, and confirmation of general areas of compliance.
- II. Information regarding noncompliance will be entered into a database maintained by the Manager of Research Integrity, for use in identifying institutional trends.