



Policy 374

Post Approval Monitoring (PAM) Program

Responsible Official:	Research Administration
Administering Division/Department:	Research Compliance and Regulatory Affairs / IACUC
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374.1 Purpose

The Emory Institutional Animal Care and Use Committee (IACUC) is under federal mandate to monitor all research activities related to animal use. Pursuant to the eighth edition of "*The Guide for The Care and Use of Laboratory Animals (Guide)*," this includes continuing IACUC oversight of approved animal activities related to ongoing protocol assessment and regulatory compliance (p. 33-34). This continued oversight is referred to as Post Approval Monitoring, or PAM. According to the Guide, PAM activities may include the following: continuing protocol review, laboratory and facility inspections, veterinary or IACUC observation of selected procedures, daily observation of animals, and external regulatory inspections. There is no regulatory guidance as to specific activities that must be performed. This document outlines the process for PAM at Emory University including the participants, the nature and periodicity of the monitoring activities, and the reporting mechanisms to document these activities.

374.2 Objectives

The primary goal of the PAM program is to monitor congruence between laboratory practice and the approved IACUC protocol, to ensure compliance. In addition, the PAM program may be utilized as one method to monitor the overall animal program and provide input to the IACUC regarding processes, identifiable risks, and to foster a positive research culture. The PAM program should also keep investigators aware of new policies, regulations, and guidelines that may affect protocol compliance and laboratory "best practices". Finally, the program should establish a collaborative partnership with investigators to promote animal welfare, a culture of compliance, and to provide open lines of communication between investigators, the IACUC, and the staff of the respective animal programs.

374.3 Participants

According to the eighth edition of "*The Guide*," PAM activity can be carried out by various individuals including IACUC Office staff, IACUC members, veterinary staff, animal care technicians, and others. The participation and responsibilities of the following groups are defined here.

374.3.1 IACUC members: IACUC voting members participate in PAM activities via the protocol review and approval process, semiannual site inspections, semiannual program review, and service on subcommittees, such as the Subcommittee on Animal Activities in Laboratories (SAAL), and the Noncompliance Investigations Subcommittee.

374.3.2 Animal Care Staff: This includes a number of people at various levels of responsibility including the Attending Veterinarians (AV), veterinary staff, training coordinators, and animal husbandry staff at both Emory University main campus and the Emory National Primate Research Center (ENPRC/EPC). These individuals carry out a large number of duties related to animal care and are thus active participants in the PAM program. Specific activities include but are not limited to: engagement in surgical training and proficiency assessments of research personnel, routine animal care and observation of animals on active studies, performance or oversight of surgeries including monitoring of anesthesia and analgesia, endpoint monitoring, and providing training for routine laboratory animal practices.



374.3.3 IACUC Office Staff: The IACUC office staff participate in several activities under the PAM program such as semiannual site inspection and program reviews, protocol reviews and approval, and validation of appropriate training and continuing education of staff. In addition, the IACUC office fosters collaborative relationships with research staff as a part of the PAM program through activities such as readiness rounds (visits to labs prior to inspections), dissemination of educational materials and policies/guidance, and training and guidance in protocol preparation and submission. Finally, the IACUC office staff perform formal PAM processes as described in more detail below

374.4 PAM Processes

PAM activities are detailed below. Several of these are performed on a continual basis and help to fulfill the overall oversight responsibility of the IACUC. Others are more directed and are documented as part of the formal PAM program. These are designed to be performed either periodically, or on an “as needed” basis, following an assessment of the risk for the occurrence of animal welfare issues or protocol non-compliance. All active animal care and use protocols are subject to PAM. The frequency of PAM activities directed at a specific protocol will be ranked in the following (descending) order: 1) protocols with a history of serious previous animal welfare issues, 2) protocols carried out in “high risk” laboratories, identified as such by the IACUC out of a combination of concerns for species used, activity, performance location, past poor performance, and other factors, 3) protocols that include “high risk” procedures, such as multiple survival surgeries, animals listed in class E, the use of death as an endpoint, and protocols involving prolonged restraint, 4) protocols with moderate risk non-terminal procedures performed in the laboratory, 5) “low-risk” protocols, with first priority to those containing species whose use is regulated through the Animal Welfare Act, 6) facilities and areas not used directly for animal experimentation.

374.4.1 Ongoing protocol review: Approved protocols are subject to review during the semi-annual inspection process and three-year renewal. Protocols may also be reviewed as part of a noncompliance or whistleblower investigation, due to specific questions raised by IACUC members or the animal care team, or as part of a formal PAM investigation.

374.4.2 Semiannual site inspections: These are performed by IACUC members with the assistance of the IACUC Office and animal care staff. Although aimed mainly at facilities, these inspections also aid protocol compliance review in the following manner: a) the inspection is a mechanism to monitor compliance with facility-related issues, b) inspectors examine drug storage and usage, c) inspectors examine surgical and procedure logs, d) inspections include (informal) assessments of the laboratory personnel knowledge of the content of the protocols they are working with, e) inspectors determine whether animal health or welfare is at risk, and f) inspectors disseminate information regarding new policies and the reinforcement of “best practices.” The IACUC office staff provides information to the site inspectors regarding approved protocols within investigator maintained procedural spaces to aid in this process and provides materials for dissemination to lab staff regarding relevant new or revised policies or standard operating procedures.

374.4.3 Training and continuing education: The IACUC Office provides educational opportunities via the AALAS Learning Library and various webinars. Face-to-face and hands-on formal training are primarily managed by the animal care programs of the Emory main campus and the Emory National Primate Research Center. Initial training and proficiency evaluations, as well as protocol-specific hands-on training and continuing education are required as detailed in IACUC Policy 354 ([Education and Training](#)).

374.4.4 Ongoing oversight by animal program: Animal-related activities that occur within the facilities under the purview of the Animal resources programs on the Emory main campus or those of the Emory National Primate Research Center are subject to routine monitoring and evaluation by the staff of these programs. These include, but are not limited to, a) observations of animal health and welfare, b) periodic observations of standard procedures, and c) monitoring of compliance with rules regarding signage, the use of personal protective equipment, and adherence to standard laboratory practices. In addition, members of the veterinary staff at both sites are heavily involved with the performance of certain procedures, most notably surgery and post-operative monitoring. Records documenting activities required by IACUC policies are maintained within the animal care programs and will be relayed to the IACUC upon request.



374.4.5 Standard periodic monitoring: This activity is performed by the IACUC Office staff and provides a mechanism for ongoing, periodic review of animal-related activities performed by a lab group. This review is performed on an individual protocol basis or based on a group of related protocols from the same PI or group. The extent of the review varies from case to case, ranging from an extensive review of the entire protocol(s) to a focused review of specific activities. The review may involve, alone or in combination, direct observation of procedures, a review of records, standard operating procedures, and/or training documents, or specific review of the protocol content.

374.4.6 “For cause” protocol monitoring: There are numerous reasons why more

frequent, or “off schedule” monitoring may be appropriate as indicated in the subsequent descriptions. These activities are generally performed by IACUC Office staff but may also be performed by other individuals as defined below.

374.4.6.1 Specific instances of noncompliance: PAM visits are frequently part of the IACUC’s responses to instances of non-compliance. The PAM visits are put into place to ensure completion of all corrective actions and continued compliance moving forward. This can be a one-time request or may include periodic PAM monitoring. Details of the PAM activity will vary based on the nature of the precipitating event. Training coordinators and veterinary staff at the Departments of Animal Resources on the Emory main campus or the Emory National Primate Center may be involved if retraining or competency assessment is needed. Additional monitoring sessions may be included as part of the follow-up to facilitate identified corrective actions.

374.4.6.2 Specific request (other than noncompliance): At times, the IACUC, veterinary staff, or others may raise concerns related to specific protocols not related to any noncompliance. It is critical that issues of this type be addressed in a timely manner so that more serious issues do not arise. These will be handled on a case-by-case basis.

374.5 Other PAM Activities

374.5.1 Exemptions to standard policies: In some cases, the IACUC grants exemptions to standard policies. Dependent upon the nature of such exemptions, periodic monitoring of the activity, or documentation of receipt and distribution of standard reports are required. These will be monitored on a case-by-case basis and will generally be the responsibility of the IACUC Office staff. In some cases, these issues are also monitored during semiannual site inspections.

374.5.2 Changes in policies: Periodically, the policies or regulations of the IACUC, the University, or those of outside agencies change such that action is required by laboratory staff to meet the new standards. The IACUC office will disseminate this information through email communication, by posting the new guidelines on the IACUC web site, and by personal communications with lab staff. If alterations to approved protocols are required, the IACUC office will assist in this process. Compliance with these new standards will be monitored primarily through semiannual site inspections (IACUC members) and standard monitoring (IACUC Office staff, animal care staff).

374.5.3 Data collection and distribution: In some instances, the IACUC requests periodic or end point reporting from laboratories as a requirement for protocol approval or maintenance. Common instances of this include pilot experiments, and ongoing reporting of animal welfare in cases of experiments in class E animals. The IACUC staff will bear primary responsibility for obtaining this data and making it available to the IACUC.

374.5.4 Random walk through (Readiness Rounds). One mechanism for developing a “culture of compliance” is to be available to investigators and to become familiar with their laboratories and facilities. To this end, IACUC staff will periodically visit laboratories and facilities to check in with investigators and their staff, to answer questions, or to disseminate information.

374.6 Data Collection and Reporting Mechanisms

374.6.1 Initial Report Generation: PAM activities conducted by the IACUC Office staff are documented by the IACUC office. Reports of findings are generated and reviewed with the IACUC Director. Protocol violations that affect



the health and welfare of the animals are immediately reported to the Attending Veterinarian and to the Noncompliance Investigations Subcommittee. Other minor infractions, such as mislabeled cage cards, will be resolved through continuing education and may not be reported as noncompliance. Inspection findings that represent an immediate danger to animal welfare will result in on-site action. In this case, both the attending veterinarian or his/her designee, and the IACUC Office will be notified to address the activity as appropriate.

374.6.2 Reports to Investigators: Once the PAM activity is complete, a letter indicating the findings will be forwarded to the PI. If no significant deviations from protocol are noted, the PI will be issued a letter of commendation. If there are findings of protocol deviation, or if there are other notes of concern based on observation, the PI will be notified along with guidance regarding appropriate action to resolve the concern(s).

374.6.3 Reporting to the IACUC: The PAM liaison will present a summary of PAM activity conducted by the IACUC Office staff before the full committee on a monthly basis. In addition, the PAM liaison will present the current status of the PAM program to the executive IACUC committee upon request.

Contact Information

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Revision History

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