

## IACUC Post-Approval Monitoring - SOP

1. The IACUC provides oversight to the Post-Approval Monitoring (PAM) program to ensure compliance with Federal, state, local and institutional regulations and policies and also to fulfill the requirement of the [Guide](#). The program, herein referred to as PAM, is intended to achieve the following objectives:
  - a. Ensure animal well-being,
  - b. Keep the IACUC and Institutional Official informed about program status and processes,
  - c. Communicate IACUC positions on matters of animal care and use concern to researchers,
  - d. Provide on-the-spot education and training needs in the laboratory,
  - e. Protect the institution's reputation,
  - f. Serve as a resource to the research community,
  - g. Support advancement of strong science, and
  - h. Facilitate regulatory compliance.
2. Background - The [Guide](#) requires the IACUC to oversee and evaluate the institution's animal program, procedures, and facilities to ensure that they are consistent with recommendations as prescribed in the [Guide](#), the [Animal Welfare Act \(AWA\)](#), and the [Public Health Service \(PHS\) Policy](#).
  - a. Applicability - All laboratories, surgical suites, housing areas and satellite facilities that house animals or are utilized for animal procedures are subject to monitoring. Additionally, all active IACUC protocols are subject to monitoring.
  - b. Type and Method of Assessments
    - i. *Routine Review*: Routine audits will be performed at the discretion of the IACUC.
    - ii. *Select or 'For cause' Review*: "For cause" monitoring may be conducted at any time, with or without advance notice to the PI or research personnel. "For Cause" reviews may be performed when requested by federal agencies and/or the IACUC.
    - iii. *Follow-up Review*: These assessments will be performed for the purpose of confirming resolution of any concerns or deficiencies found during regular PAM or during the Semi-Annual Program Review and Facility Inspection Process. These monitoring visits may be unannounced.
    - iv. *Other*: The IACUC will also utilize continuing review/annual/triennial reviews, monitoring by Animal Care Facility (ACF) staff, and veterinarian-scheduled observations of procedures identified as necessary during protocol reviews to achieve its PAM objectives.
3. Post-Approval Monitoring Process - The IACUC will perform PAM of approved research protocols to ensure consistency between written procedures and actual laboratory procedures. Monitoring will be performed at the discretion of the IACUC and include review of items such as:

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- a. Protocol personnel and training;
  - b. Animal breeding;
  - c. Procedures for anesthesia, post-surgical care, and euthanasia;
  - d. Recordkeeping;
  - e. Surgical procedures and aseptic technique;
  - f. Transport of animals;
  - g. Hazardous materials;
  - h. Pharmaceutical Drugs and Chemicals.
4. The goal of PAM is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner. In this regard, for Routine Review, the PI and research personnel (where applicable and possible) must be present during the PAM process.
  - a. Documented discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the PI. Issues that pose an immediate threat to animal welfare shall be referred to the AV or designee and the IACUC for immediate resolution.
  - b. At the end of the review process, the PAM review team shall discuss the observations with the animal lab personnel and the PI.
5. Roles and responsibilities:
  - a. The PI and all protocol personnel must be familiar with IACUC policies and procedures, the USDA and [Guide](#) requirements and must be knowledgeable about changes in regulations and standards that may affect the way in which research is conducted.
  - b. The PI will facilitate IACUC observation of procedures during PAM to ensure appropriate documentation and that such procedures are performed in compliance with the approved protocol.
  - c. Office of Regulatory Services will coordinate visits, correspondence, documentation, maintain records, and correspond with the IACUC and PI.
  - d. The IACUC shall maintain oversight of the PAM program and review related procedures and effectiveness during its Semi-Annual Program Review.
  - e. Results of PAM reviews are reported to the IACUC. When appropriate, the IACUC shall recommend corrective actions on PAM reports that contain deviations to assure compliance.
6. The protocol is selected by the IACUC for post-approval monitoring.
7. Once the protocol is selected, the Specialist will create the PAM committee, normally consisting of the Chair or Vice-Chair, ACF Manager and at least one other voting member. The committee's availabilities are determined so that they can be coordinated with the PI.
8. The Specialist will notify the PI about the PAM.