

# POST-APPROVAL MONITORING GUIDELINES

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## 1. Background

Post-approval monitoring (PAM) of approved Animal Use Protocols (AUPs) ensures that research and teaching activities involving live vertebrate animals are conducted in accordance with all applicable federal laws, regulations, and policies and guidelines, and that such activities are consistent with the Principal Investigator's (PI) ACUC-approved AUP. Accordingly, PAM serves to promote both animal welfare and regulatory compliance as well as to facilitate communication between researchers, the Animal Care and Use Committee (ACUC), Office for Laboratory Animal Care (OLAC), and Office for Animal Care and Use (OACU). According to the 8<sup>th</sup> edition of the Guide for the Care and Use of Laboratory Animals, PAM includes "continuing protocol review; laboratory inspections (conducted either during regular facility inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary and IACUC staff and members; and external regulatory inspections and assessments."

## 2. Selection of Protocols

Selection of protocols for PAM may be random or may be targeted to include a cross section of species and pain/distress categories (C, D, E) with an emphasis on the following criteria:

- a. Procedures classified as Pain/Distress Category E.
- b. Studies involving species regulated by the United States Department of Agriculture (USDA).
- c. New protocols or protocols involving procedures which are new to a particular lab.
- d. Studies or lab groups that have had non-compliance or animal welfare issues.
- e. Studies or lab groups that the ACUC or veterinarians identify for follow-up monitoring.

- f. Protocols involving PI Care
- g. Protocols consisting of pilot studies

### 3. Scheduling and Conducting PAMs

- a. Post-approval monitoring is a shared responsibility between the ACUC and OLAC.
- b. OACU staff schedule PAM visits in advance with the PI and/or lab manager and conduct PAM visits on behalf of the ACUC according to the criteria mentioned above.
- c. OLAC veterinarians may participate in PAM visits if observation of procedures at the start of a study is required or, when a new procedure is added to an approved AUP. OLAC veterinarians may also conduct post-approval monitoring on surgical procedures after personnel have been certified to perform the procedure independently.
- d. ACUC members may accompany OACU staff on PAM visits
- e. PAM monitoring may include visiting a PI's lab meeting.

### 4. Assessment

PAM monitoring will assess one or more of the following:

- a. Preparedness of personnel to perform approved procedures, including understanding of the AUP, demonstrable knowledge of SOPs relevant to the AUP, training/skill in assigned procedures, and knowledge of appropriate contacts for various potential problems.
- b. Suitability of procedure areas (facility or room location and documentation of equipment, calibration, biohazard disposal, and proper use of space).
- c. Appropriate performance of pilot studies and newly approved procedures in an AUP.
- d. Capacity for husbandry staff to report or raise concerns about animal care.

### 5. Documentation and Follow-up

- a. PAM visits will be documented and preliminary findings reported to the ACUC Executive Committee. The ACUC Executive Committee will determine when preliminary PAM findings will be forwarded to the ACUC for discussion or action.
- b. Findings, if any, will be provided by email to the PI and lab manager. The OACU analyst conducting the PAM will work with the PI and his/her lab as necessary to correct deficiencies and to ensure that any necessary protocol modifications are submitted promptly as amendments.
- c. The analyst will work with other units (e.g. EH&S, Occupational Health, OLAC) as necessary to facilitate and ensure compliance and lab safety.
- d. If noncompliant activity that threatens animal welfare is observed during a PAM visit, the AV (or his/her designee) will be notified immediately.

- e. PIs may appeal any PAM finding, report and/or recommendation by submitting an email outlining his/her concerns to [ACUC@berkeley.edu](mailto:ACUC@berkeley.edu). The ACUC Executive Committee will review the appeal and forward a recommendation to the ACUC to decide on an appropriate course of action.
- f. All training conducted following a PAM will be documented.

References:

- [Guide for the Care and Use of Laboratory Animals 8<sup>th</sup> Edition](#) pages 33-34.
- [PHS Policy](#) IV.B.4, 6-7; C.1-7; D.1-3.
- Animal Plant Health Inspection Service (APHIS). United States Department of Agriculture (USDA). [Code of Federal Regulations, Title 9 \(Animals and Animal Products\) Chapter 2, Subchapter A \(Animal Welfare\)](#), Subpart C – Research Facilities §2.31.c-e.