1. **Background**

Post-approval monitoring (PAM) of approved Animal Use Protocols (AUPs) is done to ensure that research and teaching activities involving live vertebrate animals are conducted in accordance with all applicable federal law, regulations, policies, and are consistent with the Principal Investigator’s (PI) ACUC-approved AUP. This monitoring is necessary to ensure: 1) animal welfare; 2) institutional regulatory compliance; 3) compliance of animal procedures with approved ACUC protocols; 4) proactive self-regulation by researchers; and 5) transparency with improved communication between the ACUC, OLAC, OACU and researchers. It also provides an opportunity to meet with personnel actively engaged in animal research to discuss concerns and/or changes needed in active projects.

2. **Selection of Protocols**

Over the course of a fiscal year, selection of protocols may be random or may be targeted to include a cross section of species and pain categories (C, D, E) with an emphasis on the following characteristics:

a. All studies classified as Pain Category E.
b. Studies involving USDA-covered species.
c. New protocols or protocols involving procedures which are new to a particular lab.
d. Protocols that have been approved with specific requirements, to assure that the requirements have been met.
e. Studies or lab groups that have had past compliance issues.
f. Studies or lab groups the ACUC or veterinarians designate for review.

3. **Scheduling and Conducting PAMs**

a. Analysts from the Office for Animal Care and Use (OACU) 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.
b. OLAC veterinary staff 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, and/or during personnel training.
c. ACUC members may accompany OACU Analysts as part of an initial or follow-up PAM visit and/or as deemed necessary.
d. PAM monitoring may include visiting a PI’s lab meeting.

4. **Assessment**
a. PAM monitoring will assess the level of personnel preparedness, including understanding of AUP, training/skill in assigned procedures, and knowledge of appropriate contacts for various potential problems.
b. Additionally, if PI is approved for PI Care of Animals, evaluation of preparedness of animal care staff (understanding of SOPs, the Guide, the caretaker’s ability to identify sick animals and overcrowded cages and to demonstrate skill in assigned tasks) will be assessed.
c. New procedure areas (new facility or room location and documentation of equipment, calibration, biohazard disposal, and proper use of space).
d. Pilot studies and newly approved procedures in an AUP.
e. Husbandry staff being empowered to report or raise concerns about animal care.
f. PAM monitoring will ask standardized questions about the AUP and related topics.

5. **Documentation and Follow-up**
a. PAM visits will be documented using ACUC approved criteria and reported at the next full committee meeting. (See attached forms in Appendix).
b. Findings, if any, will be sent to the PI and key staff and the analyst conducting the PAM will work with the PI and his/her lab as necessary to correct deficiencies and ensure that any protocol modifications that may be needed 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 is observed during a PAM visit that represents an animal welfare concern, the AV (or his/her designee) will be notified immediately and a report of noncompliance will be made promptly to the Director of Research Subject Protection. Appropriate action as determined by the ACUC will ensue.
e. PIs may appeal any PAM finding, report and/or recommendation by submitting an email outlining his/her concerns to ACUC@berkeley.edu. The ACUC Executive Committee will then review said PAM report and appeal and decide on an appropriate course of action on a case-by-case basis.

**References:**
A. *Guide for the Care and Use of Laboratory Animals 8th edition* pages 33-34.
B. PHS Policy IV.B.4, 6-7; C.1-7; D.1-3.