

Version No: 1.1 Effective Date: 4/1/2022	POST-APPROVAL MONITORING (PAM) POLICY	Supersedes Document Dated: 7/1/2020
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I. 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) Animal Care and Use Committee (ACUC)-approved AUP. Accordingly, PAM serves to promote both animal welfare and regulatory compliance as well as to facilitate communication between researchers, the ACUC, Office for Laboratory Animal Care (OLAC), and Office for Animal Care and Use (OACU). According to the current 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.” PAM should encourage best practices in animal care management as well as promote a culture of compliance institution wide.

II. Policy

ACUC oversight of animal research and teaching activities is required by federal laws, regulations, and policies. PAM is one of a variety of methods that is used by UC Berkeley to ensure ongoing protocol monitoring, regulatory compliance, and animal welfare.

III. Definitions

- A. Post-approval monitoring (PAM): Oversight methods to assure regulatory compliance within research facilities, approved protocols, and the well-being and protection of animals used in research.
- B. Investigator Care: Protocols approved by the ACUC authorizing PIs to perform daily, routine and/or non-standard husbandry techniques.
- C. Non-compliance: a deviation from protocol or programmatic performance standards not approved by the ACUC.

IV. Responsibilities

- A. ACUC – reviews protocols, approves policies and procedures related to ensuring compliance, and conducts semi-annual inspections and programmatic reviews as per delegate authority to OACU in cooperation with OLAC veterinarians as needed to conduct PAM.

B. OACU

- a. OACU staff as delegated by the ACUC, identifies, plans, and conducts PAM activities (in a variety of formats) with the PI and/or lab staff according to the criteria mentioned below in Section V. Selection of Protocols.
- b. Staff may conduct unannounced PAMs during facility walk-throughs, post-inspection follow-up, or as deemed necessary by the ACUC (for labs that are high risk and/or identified with repeated non-compliance issues).

C. OLAC

- a. Veterinarians – observes, trains and certifies lab personnel in conducting approved surgical and/or specialized procedures.
- b. Participates as needed with PAM depending on the nature of the visit and/or activities to be observed.

V. Selection of Protocols

In general, selection of protocols for PAM will 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. Protocols involving PI Care.
- D. New protocols or protocols involving procedures which are new to a particular lab.
- E. PIs new to campus.
- F. Studies or lab groups that have had protocol non-compliance or animal welfare issues.
- G. Studies or lab groups that the ACUC or veterinarians identify for follow-up monitoring.
- H. Protocols consisting of pilot studies.
- I. New lab personnel recently trained and/or certified on approved protocol procedures.
- J. Protocols with approved departures from the Guide and/or Animal Welfare Act.

However, the ACUC/OACU have the authority (and right) to conduct PAM activities at any time and/or at random with no prior notice.

VI. Assessment

PAM activities may include one or more of the following criteria:

- A. Preparedness of personnel and/or skills to perform animal research. This includes understanding the AUP, awareness of ACUC policies and guidelines applicable to the approved procedures, demonstrable knowledge

of Standard Operating Procedures 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 maintenance, calibration, biohazard disposal, and proper use of space).
- C. Pilot studies follow-up (i.e. progress, adverse events, unexpected mortality, etc.)

VII. Documentation and Follow-up

- A. PAM visits will be documented by the OACU staff.
- B. Observations made during a PAM visit that require follow-up will be provided by email to the Director of Research Subjects Protection, the ACUC Chair, the PI, and lab manager. The OACU analyst conducting the PAM will work with the PI and their lab as necessary to correct findings or deficiencies and to ensure that any necessary protocol modifications are submitted promptly as amendments.
- C. OACU will work with other units (e.g. OLAC, EH&S, Occupational Health) 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 their designee) will be notified immediately.
- E. PIs may appeal any PAM finding, report and/or recommendation by submitting an email outlining their concerns to 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.

References:

- [*Guide for the Care and Use of Laboratory Animals 8th 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.