

Procedure: IACUC-10
Date: July 11, 2024
Enabled by: AWR, PHS
Supersedes: June 9, 2022

**UC Davis
Institutional Animal Care and Use Committee (IACUC)**

Title: Post-Approval Monitoring Program

I. Purpose:

The purpose of the Post-Approval Monitoring (PAM) Program is to ensure research and teaching activities involving live, vertebrate animals are conducted in accordance with all applicable federal and state laws, accrediting body regulations, University policies, and are consistent with the Principal Investigator's (PI) Institutional Animal Care and Use Committee (IACUC) approved protocols and amendments.

In addition to providing continuing IACUC regulatory oversight of animal activities, PAM activities should serve as a valuable educational and training tool with a focus on collaborative process improvement. This is achieved by confirming protocol compliance; identifying and ensuring correction of non-compliance; identifying and correcting protocol drift in advance of non-compliance; and providing opportunities for collaborative action between the PI, the veterinary staff, and the IACUC through education, training, redirection and increased oversight, as needed, to achieve and maintain a culture of compliance.

II. Policy:

Any approved Animal Care and Use Protocol may be subjected to PAM review, as follows:

- A. Approved projects may be selected and reviewed by the IACUC Staff under the authority of the IACUC, at the request of a member of the IACUC, at the recommendation of the Attending Veterinarian (AV) or AV delegate, or as a result of a USDA or other regulatory or accrediting body review.
- B. Under the delegated authority of the IACUC, PAM reviews may be conducted by IACUC Office Staff, Campus Veterinary Services (CVS) Staff, and/or a member of the IACUC accompanied by staff from the IACUC Office or CVS.

- C. All protocols are subject to a basic PAM procedure during routine annual-renewal review. More in-depth PAM may occur during scheduled laboratory and facility inspections, CVS visits, and/or through opportunistic observation. Protocols may be selected “for cause”. Additionally, protocols may be selected by a risk-based assessment to ensure adequate oversight of complex protocols (e.g., projects including novel techniques, surgical procedures, fluid regulation, category E protocols, field studies or USDA-covered species).

III. Procedure:

- A. For PAM reviews not related to protocol annual review, the IACUC Office will typically coordinate with the PI, the PI’s designee, and/or other appropriate individuals (e.g., facility or laboratory manager, veterinarian or veterinarian designee, surgeon) to conduct the review.
- B. PAM will generally include an in-person, online, or phone meeting with the PI or PI staff to discuss the status of the project and/or review project related records. PAM may also involve inspecting unique housing environments and/or specialized equipment, observing and monitoring procedures in progress, observing animals post procedure, or other activities deemed necessary by the IACUC.
- C. Any deficiencies or deviations from the approved protocol or amendments will be noted and corrective actions and timelines will be established at the time of the review. In all cases an educational and collaborative partnership with the PI and their staff is expected.
- D. In some cases, the outcome of the PAM will result in a written report where the PI may be required to respond by identifying corrective action they have taken or will take. This report is then submitted to the IACUC for review, discussion, and approval during a convened IACUC meeting.
- E. If a noted deficiency or deviation is considered significant, is not corrected within the allotted timeframe, or if there are repeat deficiencies or deviations, the IACUC will determine further corrective action. Funding agencies, AAALAC, OLAW, and/or USDA will be notified as appropriate, based on corrective action taken and per agency requirements.
- F. For PAM conducted through IACUC protocol annual renewal or during record auditing for the USDA Annual Report, an IACUC Office Research Compliance Specialist will review the approved protocol and amendments for consistency with current policies and regulations. The number of animals used, and the assigned pain/distress category will be assessed for continued congruency and accuracy.

- G. If discrepancies or questions are noted, the PI and/or veterinary staff are contacted for clarification. Any issues identified are brought to the attention of the IACUC and discussed at a convened meeting. A protocol amendment may be requested or the IACUC may authorize the IACUC Staff member to make corrections or modifications. This may include retroactively adjusting the pain category based on new information. PAM conducted by way of annual review will typically not generate a separate report. In these cases, items brought to the IACUC for discussion at a convened meeting will be noted in the IACUC meeting minutes.
- H. Per the Memorandum of Understanding (MOU) between the VA Northern California Health Care System and UC Davis, at least 5% or no fewer than five VA funded animal studies will be reviewed per semi-annual review period.
- I. All PAM review activities should be viewed as training opportunities geared to promoting animal welfare and supporting the University's research and teaching missions through building and fostering a culture of compliance. Some PAM reports will be created for the purpose of documenting PI's and/or their staff demonstrating quality animal care and ongoing compliance to reinforce activities that support the overall campus mission.

V. Resources:

- 1. Animal Welfare Act and Regulations
<https://www.nal.usda.gov/awic/animal-welfare-act>
- 2. PHS Policy
<https://olaw.nih.gov/policies-laws/phs-policy.htm>