

University of Cincinnati Animal Care and Use Program

Post Approval Monitoring

Overview and Goal

An important part of University of Cincinnati's Animal Care and Use Program (ACUP) is Post Approval Monitoring (PAM). Post approval monitoring is performed by the IACUC office and applicable ACUP personnel, with oversight and support from the Institutional Animal Care and Use Committee (IACUC). PAM consists of monitoring the animal program as a whole, as well as all animal use post IACUC approval. PAM's purpose is to routinely evaluate that ACUP processes are efficient, animal use/housing areas are appropriate, and animal use is in alignment with the IACUC protocol. PAM methods include but are not limited to protocol and program review, lab visits, procedural observations, semi-annual inspections, evaluation of record keeping, and investigating non-compliance. An emphasis is placed on the program being collegial, educational, and supportive of the animal research being conducted at the University.

Regulatory Mandate

1. The IACUC is currently responsible for conducting a continuing review of approved protocols in accordance with Public Health Service Policy (IV.C.5.) and Animal Welfare Regulations (Sec 2.31(d)).
2. The 8th edition of the "Guide" (p 33) describes the elements of continuing review and offers the IACUC guidance on the effective implementation of post approval monitoring (PAM).

Types of PAM Activities

Semiannual Inspections and ACUP Program Review

1. Facility inspections and program evaluation are conducted at least once every six months. At least one IACUC member (two for USDA areas) will inspect each housing, surgery, or procedure location. In areas where no USDA regulated species are housed, the IACUC may elect to use ad hoc consultants in place of the two IACUC members. However, the committee remains responsible for the evaluation and the report. **Non-surgical or non-housing satellite areas may be inspected annually.**
2. All IACUC members are offered the opportunity to participate in the inspections. IACUC members utilize checklists and have access to an online training for IACUC inspections.
3. A summary of findings (acceptable, minor deficiency, or significant deficiency) is provided to the committee and any required corrections are addressed with the Principal Investigator (PI) when warranted. The PI is expected to correct deficiencies in a reasonable timeframe.
4. Follow-up visits may be conducted in areas where issues are identified.
5. The report of semiannual inspection and program review is submitted to the Institutional Official (IO) on behalf of the IACUC, along with inspection documents identifying minor and major deficiencies and corrective actions taken.
6. If at any time a programmatic issue or concern is identified, an investigation/evaluation for improvement will occur (i.e., ACUP training, ACUP processes, LAMS processes).

Protocol Monitoring and Visits

1. Selection of Protocols for Review
 - a. All active protocols involving the use of animals may be subject to a PAM visit.
 - b. Protocols are selected using an internal risk assessment taking in account protocol activity (i.e., multiple surgeries, withholding analgesia, USDA covered species, significant changes, historical non-compliance, upcoming triennial review). Protocols may also be

selected “for cause” which would indicate that non-compliance may have been reported or observed.

- c. PAM personnel are responsible for protocol selection and review. During protocol review and in conjunction with PI or designee, animal activities will be selected for observation.
- d. In the event no animal activity is being conducted, the protocol review and visit will be placed on hold with request for PI to send notification once animal activities resume.

2. Process of Monitoring

- a. PAM visits and observations will be conducted by the Compliance Liaison or appropriate ACUP personnel.
- b. Visits are typically scheduled to accommodate the researcher. “For cause” visits may be conducted at any time, with or without advance notice to the PI or research personnel.
- c. For scheduled visits, the PI or designee should be responsive in scheduling the visit and present to facilitate the visit. In the event the PI or lab personnel are not willing to participate, the IACUC may be notified for discussion and devising course of action.
- d. The visit may include two parts: meeting with the PI or designee and observation of animal activity. Observation may include surgery, husbandry care, colony management, technical skill/procedure(s), record keeping practices, or other activities as described in the animal use protocol.
- e. During each monitoring session, the Compliance Liaison or designated ACUP personnel will compare procedures conducted in the laboratory with those listed in the approved protocol. Discrepancies will be brought to the attention of the PI/research personnel.
- f. At the visit’s end, the Compliance Liaison may discuss monitoring results with the PI and other research personnel before leaving the laboratory.
- g. If an animal welfare issue is observed, it shall be referred to the LAMS Veterinarian or designee for immediate resolution. The LAMS Veterinarian or designee, in discussion with the IACUC office may ask the PI to place research procedures on hold until the IACUC can review the issue.

3. Follow-Up Process

- a. Post-visit, the PAM personnel will provide the IACUC a summary of positive findings and/or suggestions for improvement during a scheduled monthly committee meeting.
- b. PI will receive a final letter and report on behalf of the IACUC that may include positive findings, suggestions for improvement, protocol modification recommendations, and/or personnel training deemed appropriate.
- c. PI and research staff are expected to correct/address any deficiencies or items of concern in a reasonable timeframe.

4. Recordkeeping

- a. The visit information may be used for trending or follow-up, and determination of general training or information needs.

Non-Compliance Monitoring

1. The Compliance Liaison or applicable ACUP personnel will follow up on any reported non-compliance as described in the [106 Reporting Concerns policy](#).
2. Animal Users that have committed unintentional non-compliance are obligated to self-report to IACUC@uc.edu or 513-558-5103.
3. Animal Users that have observed or have concerns about inappropriate care and use of live animals are obligated to report:
 - Anonymous Compliance Hotline: 1-800-889-1547 or www.uc.edu/report
 - Animal Regulatory Compliance Office: 513-558-5103, IACUC@uc.edu
 - Attending Veterinarian: 513-558-5518