

TITLE:	Post-Approval Monitoring (PAM)
Policy Number:	2016-055
Responsible Department:	Institutional Animal Care and Use Committee
Policy Contact: Designation: E-Mail:	Donald E. Walters, Ph.D. Chair, Institutional Animal Care and Use Committee dewalters@westernu.edu
Approval Date:	10/12/16
Reviewed:	11/8/17 (No changes); 7/8/2020
Revised:	1/31/17 (Added Exit Interview); 7/8/2020 (Added OLAW requirement for facility inspections and revised non-reportable issues)

PURPOSE OF POLICY: To ensure the well-being of vertebrate animals used in research at Western University of Health Sciences (WesternU) owned or operated facilities and that such research is conducted in compliance with all applicable federal regulations and guidelines and Institutional Animal Care and Use Committee (IACUC)-approved policies.

POLICY INFORMATION: Section 2.31 of the [Animal Welfare Act](#) charges the Institutional Animal Care and Use Committee (IACUC) with continuing oversight of all research activities involving the use of vertebrate animals. According to the National Research Council's [Guide for the Care and Use of Laboratory Animals \(Guide\)](#), continuing oversight may be accomplished through a variety of post-approval monitoring (PAM) mechanisms such as "...continuing protocol review; laboratory inspections; 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". Moreover, the Office of Laboratory Animal Welfare (OLAW) requires that the IACUC of institutions that receive federal research funds inspect on a semiannual basis all areas that house research animals in an institutionally owned or operated facility.

Protocol Selection Criteria: Protocols will be selected for PAM based on the following criteria:

- ❖ Principal Investigator (PI) history (e.g. past non-compliance issues)
- ❖ Multiple survival surgeries involved
- ❖ Food/water restriction involved
- ❖ Prolonged physical restraint involved
- ❖ Pain category D protocols (pain or distress; drug relieved)*
- ❖ Pain category E protocols (pain or distress; no relief provided)

- ❖ Protocols requiring housing of animals outside of a vivarium
- ❖ Recommendations from Animal Care Staff
- ❖ Reports from other personnel (e.g. faculty, students, laboratory technicians, etc.)

*Protocols in pain categories D and E will receive higher priority for review than protocols in pain category C, although all protocols are subject to review regardless of the pain category.

POLICY: The PI shall be notified at least one month in advance, either by the IACUC Secretary or the IACUC Chair, that one or more of their protocols will be reviewed. A meeting date and time will be selected when the PI and as many other research personnel as possible that are named in the protocol are available. The protocol review will be conducted in the PI's office, laboratory or other available space. **This does not, however, preclude spot inspections for cause.**

Prior to meeting with the PI, Monitors will familiarize themselves with the selected protocol(s) and any amendments or attachments. Using the Post-Approval Monitoring Checklist as a guide, Monitors will highlight areas of interest and formulate questions that they may have.

Exit Briefing: At the conclusion of the review, the Monitor shall discuss the observations with the PI and other available research personnel named in the protocol to confirm that the observations are accurate. The PI and research personnel may offer additional information at this time. However, **Monitors do not have the authority to approve or disapprove any changes in processes or procedures. They cannot negotiate an outcome. That authority belongs only to the IACUC.**

If corrective actions are needed, a timeline for their correction will be established with the PI at the time of the review. A report that includes the findings, recommendations for improvement, any action(s) to be taken and/or follow-up inspections, if needed, will be submitted to the IACUC for review during a convened meeting. The IACUC may, at its discretion, require changes in any corrective actions or timelines agreed upon at the time of the review. If so, the IACUC will notify the PI, in writing, of any such changes. The PI will receive a copy of the final report(s) which will be filed in the corresponding protocol folder(s).

Appeal Process: If the PI disagrees with the PAM results and/or suggestions stated in the report and/or corrective actions recommended by the IACUC, the PI may submit, in writing, an appeal **within 30 days** of receipt of the final report to the IACUC Chair. The Chair shall bring the appeal before a convened meeting of the IACUC for discussion and a final decision. At the discretion of the Chair, the PI may be invited to attend the meeting to present their case. Regardless, the decision of the IACUC shall be final.

All documentation pertaining to the PAM process will be kept in strict confidence and on file in the IACUC office.

Section IV.F.3 of [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#) states that "The IACUC, through the Institutional Official, shall promptly provide the Office of Laboratory Animal Welfare ([OLAW](#)) with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the Guide; or
- c) any suspension* of an activity by the IACUC."

*IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy and require a convened meeting of a quorum of the voting members of the IACUC and a vote of a majority of the quorum present. In consultation with the IACUC, the Institutional Official (IO) must review the reasons

for the suspension and take appropriate corrective action(s) and report the action(s) with full explanation to OLAW.

As stated in the Office of Laboratory Animal Welfare's (OLAW) notice [NOT-OD-05-034](#), a comprehensive list of definitive examples of reportable situations is impractical. However, situations for which OLAW expects to receive a report include, but are not limited to:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

Situations **not** normally required to be reported include, but may not be limited to:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- cage mishaps involving bedding and water flow which lead to actual or potential animal welfare issues.