

POLICY 7.15 – Post Approval Monitoring (PAM) Program

Policy Category: Research

Subject: Post approval monitoring program for all Animal Care Committee (ACC) approved animal-based science at Western

Approving Authority: Board of Governors

Responsible Officer: Vice-President (Research)

Responsible Office: Office of the Vice-President (Research)

Related Procedures:

Related University Policies: [MAPP 7.12](#) - Policy and Procedures for the Use of Animals in Research and Teaching

[MAPP 7.10](#) – Policy and Procedures for Standardized Training in Animal Care and “Use

[ACVS internal policies](#)

Effective Date: November 26, 2015

Supersedes: N/A

I. PURPOSE & SCOPE

This policy provides a framework for the establishment and maintenance of a post approval monitoring (PAM) program for all animal-based science at Western.

It applies to all animal-based science associated with the Western community under the oversight of Western’s Animal Care Committee (ACC). All approved Animal Use Protocols (AUPs) are subject to post approval monitoring by the ACC. PAM encompasses regular assessment of core AUP elements including but not limited to animal procurement, animal housing and husbandry, animal procedures, animal monitoring, sick animal response, animal health/procedural records, and related documentation.

POLICY 7.15 – Post Approval Monitoring (PAM) Program

II. DEFINITIONS

A Glossary of Terms used in this policy is listed in [Appendix 1](#).

III. POLICY

1. The Vice-President (Research), the Animal Care Committee (ACC), the ACVS Veterinarians, the Animal Care (AC) staff, and Principal Investigators (PIs) must have safeguards in place to ensure that difficulties experienced with any aspect of animal care or use can be effectively identified and addressed.
2. The ACC must actively work with PIs, ACVS Veterinarians and Animal Care (AC) Facility Supervisors, and their designates, to identify and correct all variances from approved AUPs, institutional policies and ACC-approved standard operating procedures (SOPs) and/or current veterinary standards.
3. The ACC must work with the members of ACVS veterinary and Animal Care staffs to ensure compliance with its decisions and with the conditions set out in approved Animal Use Protocols (AUPs).
4. All stakeholders must work collaboratively in a collegial manner in attempting to correct variances from the approved AUP and institutional policies and procedures.
5. The ACC and its designates must prioritize post approval monitoring (PAM) activities for AUPs by sensitive species, categories of invasiveness, and projects associated with previous incidents and non-compliance.
6. Persistent breaches of compliance or threats to the health and safety of personnel or animals must be reported promptly to the ACC Chair.
7. The ACC and ACC Chair must promptly address persistent breaches of compliance or threats to the health and safety of personnel or animals through communications with PIs and their staffs, related meetings and site visits, and communications with the Senior Administrator, as necessary.
8. Breaches of compliance that cannot be corrected by the ACC working with the concerned animal-based scientists, Veterinarians and Animal Care staffs must be referred to Senior Administration.
9. The Senior Administrator, or designate, must inform all members of the animal-based science program about sanctions to be taken in the event of serious breaches of non-compliance.
10. Animal procurement must be undertaken in accordance with the Animal Procurement Policy.
11. Sick animal response must be undertaken in accordance with the Sick Animal Response Policy.
12. Animal-based science record-keeping must be undertaken in accordance with the Animal Care and Use Records Policy.
13. Invasive animal procedures must be undertaken in accordance with the Inclusion of Veterinary Technicians in Invasive Procedures Policy.

POLICY 7.15 – Post Approval Monitoring (PAM) Program

14. Continuing Care visits and facilitation by the ACC and its designates must be undertaken in accordance with the Continuing Care Visits & Facilitation Policy.
15. Certifications of non-arms-length-managed sites must be undertaken in accordance with the Non-Arms-Length-Managed (NALM) Sites Policy.
16. The ACC must follow-up on concerns regarding animal-based science activities in accordance with the Concerns Identification, Project Refinements and Corrective Response Policy and related procedures.
17. ACC Leaders and ACVS Veterinarians must have unrestricted access to all areas where animals are held or used at all times.

IV. ROLES AND RESPONSIBILITIES

All stakeholders are expected to demonstrate collaborative, collegial communications and commitment to act in good faith.

1. The Vice-President (Research) is responsible to:
 - a) provide adequate resources to establish and maintain an effective post-approval monitoring program for animal-based projects having approved AUPs
 - b) ensure clear roles and responsibilities for individuals and groups involved in the PAM process
 - c) provide direct support to the ACC, as requested
 - d) meet regularly with the ACC Chair and ACVS Director to discuss concerns and ways of addressing them
2. UCAC is responsible to:
 - a) provide direct support to the ACC and its leadership, as requested
 - b) via its designates, annually review CCAC policy and guidelines to ensure Western remains current with changes to regulatory requirements
 - c) annually review and approve all institutional policies associated with Western's PAM program
3. ACVS Director is responsible to:
 - a) provide leadership support to the ACC Chair in PAM undertakings
 - b) meet regularly with the ACC Chair and Vice-President (Research) to discuss concerns and ways of addressing them
 - c) provide ACVS Veterinarians with sufficient resources to fulfill PAM obligations
4. ACVS Veterinarian(s) responsible for the PAM program is (are) responsible to:
 - a) provide day-to-day assistance and information with respect to animal care and use to animal-based scientists and Animal Care staffs in remaining compliant with approved AUPs and institutional and CCAC standards by ensuring,
 - (i) individual animal users are comfortable handling animals and carrying out procedures successfully, and that they are able to do so in appropriate conditions, and
 - (ii) endpoints are applied as approved by the ACC to avoid unnecessary distress to animals
 - b) act as a designate of the ACC as outlined by other PAM policies and procedures
 - c) advise the ACC of current veterinary standards

POLICY 7.15 – Post Approval Monitoring (PAM) Program

- d) act as a designate of the ACC, when requested, to ensure new procedures and those more likely to result in animal pain or distress are closely monitored
 - e) inform the ACC of any animal health and welfare concerns that are not readily resolved through work directly with PIs and their staffs
5. ACC is responsible to:
- a) align its PAM practice with all UCAC-approved PAM policies and procedures
 - b) educate animal-based scientists regarding all institutional and regulatory policies and procedures associated with the PAM program
 - c) work with Principal Investigators, ACVS Veterinarians and Animal Care staffs to fully understand and, as needed, to give direction on modifying an animal-based project that diverges from the approved AUP, and/or institutional, regulatory and/or veterinary standards by
 - d) performing regular site visits, and
 - e) promptly addressing concerns with animal-based science brought to its attention through effective communication
 - f) ensure new animal procedures and those more likely to result in animal pain or distress are closely monitored
 - g) provide assistance to an animal-based scientist in amending his/her AUP when it cannot be successfully continued in practice as originally approved for technical or logistical reasons
 - h) promptly address persistent breaches of compliance or threats to the health and safety of personnel or animals
 - i) apprise the Vice-President (Research) of all non-compliance instances
6. ACC Chair is responsible to:
- a) ensure the ACC is educated on and aligns its practice with all UCAC-approved PAM policies and procedures
 - b) lead in undertaking timely, effective, collegial and collaborative communications with all persons and groups involved in the PAM program
 - c) meet regularly with the ACVS Director and Vice-President (Research) to discuss concerns and ways of addressing them
 - d) take the lead in promptly addressing persistent breaches of compliance or threats to the health and safety of personnel or animals through effective communications with the animal users, meetings and site visits, and communications with the Vice-President (Research) and ACVS Director
7. ACC Coordinator is responsible to:
- a) assist animal-based scientists with their AUP paperwork to ensure it is up-to-date and complete
 - b) facilitate the process of amending an AUP when it cannot be successfully continued in practice as originally approved for technical or logistical reasons
 - c) support the ACC, ACC Chair, Facility Managers, ACVS Veterinarians, ACVS Operations Manager and ACVS Director, or designates, in their efforts to deliver this policy effectively
8. Animal Care Facility Supervisors are responsible to:
- a) provide day-to-day assistance and information with respect to animal care and use to animal-based scientists and Animal Care staff in remaining compliant with approved AUPs and institutional and CCAC standards by ensuring that:
 - i. animal scientists and their staffs are comfortable handling animals and carrying out procedures successfully, and that they are able to do so in appropriate conditions, and

POLICY 7.15 – Post Approval Monitoring (PAM) Program

- ii. endpoints are applied as approved by the ACC to avoid unnecessary distress to animals
 - b) act as a designate of the ACC as outlined by other PAM policies and procedures
 - c) inform the ACC or its designates of any animal health and welfare concerns that are not readily resolved through direct work with PIs and their staffs
- 9. Principal Investigator (PI) is responsible to:
 - a) treat all animals with respect and dignity
 - b) assist the ACC in complying with institutional, CCAC, OMAFRA and Health Canada standards and requests
 - c) undertake his/her AUP in practice as approved in principle by the ACC
 - d) ensure his/her research staff who directly work with animals are apprised of, appropriately trained and competently undertake only those procedures in a manner outlined within the approved AUP
 - e) work with the ACC Coordinator to ensure his/her AUP is up-to-date and complete
 - f) work with research and animal care staff to ensure animal use records align with the Animal Care and Use Records Policy.
 - g) work with the ACC and/or its designate(s) to ensure new procedures and those more likely to result in animal pain or distress are appropriately classified (category or invasiveness) and associated monitoring procedures implemented
 - h) work with the ACC and its designates to promptly resolve any concerns brought to his/her attention

POLICY 7.15 – Post Approval Monitoring (PAM) Program

APPENDIX 1 - Glossary of Terms

Animal Based Science – Any and all use of animals including display, teaching, research, and testing

Animal Care Committee (ACC) - A subcommittee of the University Council on Animal Care, officially named the Animal Use Subcommittee, but hereto referred to as the ACC; the institutional animal care committee “responsible for overseeing all aspects of animal care and use and for working with animal users, animal care personnel and the institutional administration”; responsible to ensure animal ethics and care for animal-based science and animal displays directly associated with Western’s Research Community is in accordance with all regulatory and institutional policies and guidelines.

ACC Executive Team - A subset of the ACC tasked with performing preliminary assessments of concerns and related evidence brought forward to the ACC; developing recommendations for Project Refinements and Action Plans; and assigning a specific PI Rep to incidents as they arise. This subset must include at least one ACC and ACVS leader, an ACVS veterinarian, ACC Community Rep, and ACC Coordinator.

ACC Leaders – ACC Chair and Vice Chair(s)

Animal Use Protocol (AUP) – The ACC’s mandatory animal ethics form that contains details of a AUP holder’s intended live vertebrate animal care and use, which must be reviewed and approved by the ACC in advance of animal-based science or public viewing of displayed animals.

CCAC – The Canadian Council on Animal Care is a not-for-profit organization, created in 1968 to oversee the ethical use and care of animals in science (research, teaching and testing) throughout Canada.

Concerns – Anything raised to any member regarding animal health and/or welfare, human safety, and AUP-related issues. Concerns will be reviewed by an ACC Executive Team, as appropriate. Concerns will be communicated to the PI before they are classified as either Incidents or Non-Compliance.

Designate – An individual who is adequately trained and appropriately experienced with the animals under his/her care/oversight, and who is authorized to act on behalf of either the ACC, VP Research, ACVS Director, ACVS Veterinarian, a Principal Investigator, or a Facility Supervisor.

Animal Care (AC) Facility Supervisor – A trained, competent individual responsible for the oversight of an area or facility that houses research animals, and who is accountable to the ACVS Director for animal health and welfare-related matters.

NALM Certification – Annual, announced assessment of a NALM (non-arms-length managed) site using an ACC approved NALM checklist performed by designates of the ACC and involving related PIs and their staff.

Principal Investigator (PI) – A scientist responsible for undertaking animal-based science in alignment with an approved Animal Use Protocol and current veterinary standards of animal care.

Sanction – Immediate measures taken to stop Non-Compliance, e.g. AUP ‘on hold’

Senior Administration – University Council on Animal Care (UCAC) members, including the Vice-President (Research)

Senior Administrator – The Vice-President (Research), Chair of the UCAC.

University Council on Animal Care (UCAC) – Western’s Senate committee ultimately responsible for the Animal Ethics and Care program directly associated with Western’s Research Community.

Western’s Research Community – Institutions and their departments involving animal-based scientists having Animal Use Protocols under the jurisdiction of Western’s Animal Care Committee (ACC).