

Procedure Title:	Post Approval Monitoring (PAM)
Procedure ID:	#OP 9-902E
Manual Classification:	Section 9 – Applied Research
Linked to Policy:	#9-902 Animal Care and Welfare
Originally Approved:	September 2019
Approved by Senior Management Team (SMT):	March 2024
Effective Date:	March 2024
Next Review Date:	2027
Contact for Procedure Interpretation:	Executive Vice President, Applied Research

1.0 – Purpose

The purpose of this procedure (the “**Procedure**”) is to outline the procedures for post-approval monitoring of AUPs associated with educational and research activities involving live animals.

Terms not defined in this Procedure have the same meaning found in Policy #9-902 Animal Care and Welfare.

2.0 – Procedure

2.1 - Overview

- a) The Canadian Council for Animal Care (CCAC) requires institutions to establish procedures for post-approval monitoring (PAM) of Animal Use Protocols (AUPs) and to define the roles and responsibilities of the members of the animal care and use program in the monitoring process.
- b) Furthermore, PAM is required to meet the demands of the Natural Science and Engineering Research Council of Canada who outlines that institutions must have procedures in place to monitor ongoing work and to ensure conformity with federal and provincial guidelines, regulations, and laws covering the use of animals in research, teaching and testing.

2.2 – Procedural Guidelines for Post Approval Monitoring (PAM)

- a) Post-approval monitoring programs (PAMs) assure compliance with CCAC and Fleming College’s policies, guidelines and procedures. PAMs are a combination of policies, practices and procedure to ensure that animal use protocols and standard operating practices are applied in practice as approved in principle by the Animal Care Committee (ACC).
- b) Establishing a PAM is the responsibility of the ACC.

- c) PAM will be based on information from various sources, including
- Animal Users
 - Animal Use data
 - PAM reports
 - Photo/video documentation
 - Incident Reports
 - ACC site visits
 - Stakeholder concerns
 - Student feedback
 - Record of training
- d) PAM activities must be prioritized for sensitive species and activities associated with reported incidences and history of non-compliance.

2.3 – Roles and Responsibilities

- a) All stakeholders are expected to work collaboratively and collegially to ensure that variances from ACC-approved AUPs and SOPs are addressed and resolved in a timely manner.
- b) Animal Users must adhere to Fleming College's Animal Care and Welfare policies and procedures and practices outlined in approved AUPs and SOPs. PIs must submit a Post Approval Monitoring report annually. AUPs shall not be renewed if a PAM report was not forwarded to the ACC.
- c) The ACC is responsible to:
- Educate PIs regarding all institutional policies and procedures related to the PAMP
 - Establish and oversee the PAMP, receive and analyse reports, conduct site visits, inspect animal holding facilities, and suggest corrective actions on matters of concern.
 - Ensure new animal procedures are closely monitored
 - Work actively with PIs to determine variances from ACC-approved AUPs and SOPs.
 - Promptly address serious or repeated instances of non-compliance through consultation with the PI and Animal Users, site visits and communication with administration. Processes and any attendant consequences will be communicated in writing to the PI by the ACC Coordinator.
- d) The ACC Veterinarian is responsible to:
- Receive and analyse reports, conduct site visits, inspect animal holding facilities, and suggest corrective actions on matters of concern.
 - Ensure new animal procedures are closely monitored
 - Promptly address serious or repeated instances of non-compliance through consultation with the PI and Animal Users, site visits and communication with administration.

- e) The ACC Coordinator is responsible to:
 - Assist PIs with their PAM paperwork and required documentation to ensure it is up-to-date and complete
 - Facilitate the process of amending an AUP
- f) The ACC Chair is responsible to:
 - Take the lead in addressing breaches of compliance or reports of concerns and/or complaints through effective communication with the PI
 - Ensure that ACC practices align with PAM policies and procedures
 - Lead the scheduling of PAM site visits
- g) The PI is responsible to:
 - Submit a Post Approval Monitoring report including supporting documentation
 - Undertake their AUP in practice as approved by the ACC
 - Ensure that all animal users are appropriately trained and competently undertake activities as outlined in the approved AUP
 - Work in a collegially with the ACC to address any concerns brought to their attention in a timely manner
 - Ensure their AUP is up-to-date and complete and inform the ACC Coordinator promptly if changes to the AUP are required
 - Keep accurate and detailed animal use records

2.4 – Immediate Termination of Animal Use

- a) Any member of the ACC can initiate immediate termination of animal use as a result of a site visit, an incident report, or reported concerns and complaints.
- b) The required steps are as follows:
 - Consultation with the PI to discuss corrective measures and seek resolution
 - Where resolution cannot be achieved, the ACC Chair will consult with ACC members to reach a decision whether the animal use will be terminated. As many ACC members as possible shall be include in the process.
 - The ACC Chair will inform the PI immediately if a decision to terminate animal use was reached. This will be followed up by written documentation detailing the nature of the concern and rationale for the decision. The document shall be dated and signed by the ACC Chair and forwarded to the PI, their manager, and the Executive Vice President, Applied Research.
 - The PI shall comply immediately with the decision

2.5 – Incident Reporting

- a) It is the responsibility of the PI or Animal Care Facility staff to report unexpected animal related mortalities or incidences:
 - The PI shall submit an Incident Report form promptly after the event to the ACC Coordinator.
 - The ACC Coordinator will inform the ACC Committee of the incident
 - The ACC Chair and Veterinarian will communicate with the PI and determine in consultation with ACC members the next steps

- The PI will be informed of the outcome of the investigation
- The ACC has the authority to revoke AUP approval
- Incident has to be incorporated into PAM for review by ACC Committee

3.0 – Related Documents

- Animals for Research Act, R.S.O. 1990, c. A.22
- Tri-Agency Framework: Responsible Conduct of Research (2016)
- Canadian Council on Animal Care: Ethics of Animal Investigation
- Canadian Council on Animal Care: Terms of Reference for Animal Care Committees
- Policy #9-902 Animal Care and Welfare
- Operating Procedure #9-902A: Animal Care Committee Terms of Reference
- Operating Procedure #9-902B: Animal Use Protocols
- Operating Procedure #9-902C: Scientific Merit Review of Animal Use Protocols (AUPs)
- Operating Procedure #9-902D: Pedagogical Merit Review of Animal Use Protocols (AUPs)
- Operating Procedure #9-902F: Animal User Training Program
- Operating Procedure #9-902G: Reporting of Concerns
- Operating Procedure #9-902H: Animal Husbandry
- Animal Use Post Approval Assessment Form
- Post Approval Monitoring Form
- Incident Report Form

4.0 – History of Amendments & Reviews

Date	Action
September 2019	Original Approved
January 2022	Reviewed, revised and approved
March 2024	Reviewed, revised and approved