Name:	**Policy on Post Approval Monitoring (PAM)**
Approving Authority:	Vice President Academic and Research
Approved:	28-APR-2023
Responsible Office:	Faculty of Graduate Studies and Research, Animal Care Committee
Responsibility:	Associate Vice President Research
Revision Date(s):	3-NOV-2023
Supersedes:	NA
Next Required Review:	2026

1. Preamble

1.1 As a certified institution of the Canadian Council on Animal Care (CCAC), Saint Mary's University (SMU) is required to have a Post Approval Monitoring (PAM) Program for all animal-based research and teaching activities to ensure each protocol is applied in practice as approved in principle and meets Animal Care Committee (ACC) and CCAC requirements, as outlined in the CCAC Policy: Certification of Animal Ethics and Care Programs and CCAC Policy: Terms of Reference for Animal Care Committees.

1.2 The PAM Program and associated feedback permits opportunities for improvement and refinement of animal use, animal care, animal facilities, record keeping, communications, and training.

1.3 The Policy on Post Approval Monitoring is ultimately the responsibility of the Vice President Academic and Research (VPAR). The VPAR has designated day-to-day responsibility for the Policy to the Associate Vice President Research (AVPR). The AVPR has authorized the SMU Animal Care Committee (ACC), and, in particular, the ACC Chair and ACC Coordinator, to manage the post approval monitoring program, to review it annually, and make recommendations on any changes to the AVPR.

2. Purpose

2.1 The purpose of this policy is to describe the Post Approval Monitoring Program.

3. Jurisdiction/Scope

3.1 This policy applies to all Principal Investigators (PI) who hold Animal Use Protocols (AUP) approved by the SMU ACC.

4. Definitions

ANIMAL CARE COMMITTEE (ACC)	The local representative of the CCAC responsible for ensuring that all animals used in teaching, research or testing at SMU are treated ethically and in accordance with the Canadian Council on Animal Care's (CCAC) policies and guidelines.
PRINCIPAL INVESTIGATOR (PI)	The faculty member who holds an approved Animal Use Protocol (AUP) and associated funding.
ANIMAL USER	Any faculty, staff, or student who use animals for research or teaching covered under CCAC mandate (for more information, see CCAC Requirement for submitting an animal protocol).
ANIMAL FACILITY MANAGER	Designated personnel who oversee animal facility activities and operations. SMU has an Animal Facility Manager (0.6FTE) who is responsible for the SMU Aquatic Research Facility. In some cases, a PI holds this role.
ANIMAL USE PROTOCOL (AUP)	A protocol outlining use of animals in research or teaching that has been submitted by a PI and reviewed and approved by the ACC.
NOTICE OF AWARD (NOA)	The document sent to the PI indicating approval of an AUP, which includes the PAM requirement for the protocol.
NON-COMPLIANCE	Occurs when an animal user, PI, or Animal Facility Manager is found in breach of an approved AUP, ACC policy, CCAC policy or guideline, or other regulatory requirement.

5. Policy

5.1 All ACC approved AUPs and associated animal facilities are subject to the Post Approval Monitoring Program as part of the regulatory requirements of the CCAC certification process and maintenance of the University's CCAC Certificate of GAP – Good Animal Practice®.

5.2 Continued protocol approval and/or renewal of all protocols held by a PI are subject to full cooperation with the PAM Program.

5.3 The ACC must review all PAM documentation, including PAM submissions for each approved AUP, ACC site visit reports, ACC Veterinarian site visit reports, and information on animal welfare assessments on an annual basis.

5.4 The ACC must work with PIs to ensure compliance with the procedures described in an approved AUP (e.g., through the implementation of the PAM Program). Issues and/or recommendations identified through the PAM Program must be communicated to the PI and resolved through collaboration between the PI and ACC. Breaches of compliance that cannot be corrected by the ACC in collaboration with the PI must be referred to the AVPR and VPAR.

5.5 The ACC must work with PIs and/or Animal Facility Managers to ensure the animal facility's compliance with relevant CCAC guidelines. Breaches of compliance that cannot be corrected by the ACC in collaboration with the PI and/or Animal Facility Manager must be referred to the AVPR and VPAR.

5.6 Authority of the ACC Chair and ACC Consulting Veterinarian

5.6.1 The authority of the ACC assigns the ACC Chair and the Consulting Veterinarian the right to observe unhindered any procedure involving animal-based research or teaching. In addition, the ACC Veterinarian has the authority to stop any procedure involving animals if the procedure deviates from what is described in the associated approved AUP.

5.6.2 The ACC delegates to the Consulting Veterinarian the authority to treat, remove from an AUP, or euthanize, if necessary, an animal according to the Veterinarian's professional judgement. The Consulting Veterinarian will attempt to contact the PI before beginning any treatment that has not previously been agreed upon. However, the Consulting Veterinarian has the authority to proceed with any necessary emergency measures, whether or not the PI and ACC Chair are available. A written report should be sent by the Consulting Veterinarian to the ACC Chair and PI following any such event, and any relevant procedures for reporting animal welfare incidents followed.

5.7 Roles and Responsibilities

5.7.1 Principal Investigator (PI)

It is the responsibility of the PI to:

- work collaboratively with the ACC, and in particular the ACC Coordinator, to ensure that prescribed in-person PAM requirements are scheduled at a time that coincides with the work, and such requirements are completed within the protocol approval period and as listed on the NOA.
- ensure that PAM requirements involving videos and/or photos are completed and submitted to the ACC for review within the protocol approval period and as listed on the NOA.
- respond to requests by the ACC Coordinator for scheduling and document

requests within a reasonable timeframe (e.g., 14 days).

- ensure that all trained and authorized animal users listed on an AUP are aware of, and comply with, the approved AUP.
- ensure that daily animal welfare assessments are performed in animal facilities according to species specific scoring systems (Appendix A). The oversight of animal welfare assessments can also be the responsibility of the Animal Facility Manager if applicable.

5.7.2 Animal Care Committee

It is the responsibility of the ACC to:

- ensure each protocol is applied in practice as approved in principle and that facilities meet Animal Care Committee (ACC) and CCAC requirements through the PAM Program components as outlined in Section 6.1.
- review all PAM documentation on a continual basis, make recommendations to PIs and/or Animal Facility Managers as needed, and work with PIs and/or Animal Facility Managers to ensure recommendations are addressed.
- report non-compliance to the VPAR and/or AVPR if resolution cannot be reached.

5.7.3 VPAR and/or AVPR: it is the responsibility of the VPAR and/or AVPR to consult with the ACC if resolution of non-compliance cannot be reached.

5.8 Compliance

5.8.1 Non-compliance as defined in Section 4 is a serious breach of Saint Mary's University Policy on Integrity in Research and Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct, and may be investigated according to the *Procedures for Reporting and Investigating Scholarly Misconduct* and, if found not to be in compliance, the PI will face outcomes as described in the Policy.

6. Related Policies, Procedures & Documents

6.1 Components of the Post Approval Monitoring Program and associated procedures

6.1.1 An individual PAM requirement for each approved AUP indicated of the Notice of Approval (NOA), which must be completed during the approval period

A PAM requirement refers to a prescribed assignment, made to demonstrate that:

- The activities of animal-based research and teaching are those which have been approved.
- The approved invasive procedures are to be performed according to the approved Category of Invasiveness and to what has been described in the

approved Animal Use Protocol (AUP) and associated Standard Operating Procedures (SOP).

During AUP review, the ACC carefully considers the proposed animal use and agrees on a defined PAM requirement for each protocol as part of the motion for its approval. The PAM requirement assigned and communicated to the PI on the NOA involves either live or recorded observation of approved procedures, including those that have the potential to, or are expected to cause, unnecessary pain and distress unless carried out as described in the approved AUP, and the application of endpoints as described in the approved AUP.

All PAM documents (i.e., PAM Reports, videos and/or photos, communications, etc.) are reviewed by the ACC at the next ACC meeting, formally recorded in the meeting minutes, and kept on file with the associated AUP. The completion date of the PAM requirement is recorded in the ACC Protocol Tracker. If feedback from PAM results in recommendations from the ACC Committee, the ACC communicates this to the PI and facilitates these recommendations where appropriate.

In-Person PAM Requirements

An in-person PAM requirement includes the completion of a PAM checklist by each attending ACC member, which are then consolidated into one document to become the PAM Report. At least two ACC members should attend in-person PAM; however if this is not possible, the ACC Coordinator can perform the PAM requirement and document the visit via video and/or photo to accompany the PAM Report. ACC members must prepare for an in-person PAM by wearing proper clothing and personal protective equipment if necessary, and reviewing all relevant documents (i.e., AUP, SOP, NOA which indicates the PAM requirement, etc.). ACC members should not obstruct the work of animal users during the visit, and keep their questions to a minimum as this is a monitoring exercise as opposed to an instructional demonstration.

Video and/or Photo PAM Requirements

For PAM that require videos and/or photos, these along with any other relevant documents are submitted to the ACC Coordinator using animalcare@smu.ca. Narration of the video (if possible) and/or a short written description to accompany videos and/or photos is recommended.

6.1.2 ACC Site Visits

Scheduled site visits of the animal facilities at both SMU and Mount Saint Vincent University (MSVU) are conducted once per year. These visits include the entire ACC membership and are required per CCAC Policy: Terms of reference for animal care committees. Completion of an ACC Site Visit Checklist by each ACC member captures observations, recommendations, and commendations. Following the site visit, a single copy of the consolidated checklists becomes the ACC Site Visit Report, and the report is provided to the Animal Facility Manager. If feedback from a site visit results in recommendations, the ACC and Animal Facility Manager work together to address the

recommendations in a timely manner.

6.1.3 Consulting Veterinarian Site Visits

The Consulting Veterinarian performs site visits of each animal facility at least twice per year. These site visits can be scheduled or non-scheduled visits. The Consulting Veterinarian may exercise their authority to access all locations to which they are entitled, and the Animal Welfare Assessment Checklist is used to guide the visit. The Consulting Veterinarian prepares a report for submission to the VPAR and Animal Facility Manager, and a copy of it is provided to the ACC Chair for ACC records. The report may include recommendations, and the ACC must ensure that any recommendations and/or action items resulting from the site visit report be addressed in a timely and efficient manner.

6.1.4 Animal Welfare Assessment

Assessment of the welfare of animals used in research and teaching is an important part of the PAM Program. Per the CCAC Guidelines: Animal Welfare Assessment: "Good welfare is characterized by maximizing animals' positive experiences while minimizing their negative ones. This approach to ensuring good welfare is already at the core of many existing practices, such as health monitoring, humane intervention point implementation, post-approval monitoring, and the assignment of categories of invasiveness. Formal welfare assessments are another tool to ensure that animals have the best possible welfare."

The CCAC Guidelines: Animal Welfare Assessment also state: "The animal care committee is responsible for overseeing the implementation of welfare assessments, but the assessments themselves should be completed by a team involving protocol authors and their delegates, veterinarians, and animal care personnel. Where possible, the assessments should draw on information gathered through research, veterinary, and husbandry activities."

Daily animal welfare checks must be performed by PIs and/or animal users in all animal facilities following species-specific scoring systems (Appendix A). The Consulting Veterinarian will use the same scoring system to guide their site visits, along with an animal welfare assessment checklist. In-person PAM requirements can also be supported using the animal welfare assessment checklist. Animal welfare assessment information is continuously reviewed by the ACC in the form of PAM Reports, Consulting Veterinarian Site Visit Reports, ACC Site Visit Reports, protocol amendments and/or renewals (Progress Report section), Study Closures, Incident Reports, and any other communications regarding animal welfare. If review of animal welfare information by the ACC results in recommendations, the recommendations will be communicated to the PI and/or Animal Facility Manager who will work with the ACC to ensure that the recommendations are addressed in a timely manner.

Related Policies:

CCAC policy: Certification of Animal Ethics and Care Programs

CCAC policy: Terms of Reference for Animal Care Committees

CCAC policy statement for: senior administrators responsible for animal care and use programs

CCAC policy: Requirement for submitting an animal protocol

Saint Mary's University Policy on Integrity in Research and Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct

Related Guidelines:

CCAC Guidelines: Animal Welfare Assessment

Appendix A: Animal Welfare Assessment Descriptors and Scoring for Fishes

*The Consulting Vet can provide further instructions and action as required

Scoring	A	B	C	D
Action*	None	Careful monitoring, Observation 1x per day, Inform Facility Manager	Observation 2-3x per day, inform Facility Manager, PI, and Vet if multiple fish/tanks, Humanely euthanize after consultation	Humanely euthanize immediately according to AUP. Inform Facility Manager, PI, and Vet if multiple fish/tanks.
Descriptors				
Appearance	Scales/plates normal (not protruding outwards), gill cover normal, fins/spines fully developed, no change in weight	Small injuries/lesions, 1 cyst, bent spine	Exophthalmos (pop-eye), gill cover reduced, large lesions, fins frayed, signs of weight loss, 2 or more parasitic cysts	Scales completely erected, clearly bloated abdomen, extensive injuries, rapid weight loss, loss of fins, formation of tumours, fungus, mortality
Behaviour	Normal feeding, breeding, schooling behaviour	Less activity compared to control, reduced food uptake	Hyperventilation, gasping, inactivity, hyperactivity, little or no feed uptake	Prolonged inactivity, gasping (>3 hrs). Convulsions, twitching (moribund)
Swim Position:	Normal position in water column, normal swimming movements	Position in water column clearly changed, or equilibrium slightly affected	Equilibrium clearly affected, fish lay sideways on bottom but normal respiration, fish stay at surface water for long periods, constant movement in circles	Swimming on back with uncoordinated movements for an extended period of time (>3hrs)

Note: If end point has been reached, inform Facility manager and vet immediately to determine if an incident report must be filled out. Investigate if Reportable Animal Welfare Incident (RAWI) Report needs to be initiated

*The Consulting Vet can provide further instructions and action as required

Scoring	A	B	C	D
Action*	None	Clean/replace problem areas, Inform PI/Facility Manager, Observation 1x per day	Clean/replace problem areas, Observation 2 - 3x per day, inform Facility Manager, PI	Remove fish from tank as needed. Humanely euthanize as needed. Clean/address problem areas. Inform Facility Manager, PI, and Vet if multiple fish/tanks.
Environment	Tanks and lids are clean/ideal conditions according to species, density of fish is adequate for tank size. Equipment in good working order. Air stones submerged where applicable.	Tanks are not ideal condition for species; higher than normal densities for fish but remain healthy. Tanks and Filters require cleaning/new media	Fish beginning to show signs of stress due to environmental conditions	Inadequate environmental/tank conditions for species
Action*	Green: See chart for ranges and action	Yellow: See chart for ranges and action	Red: See chart for ranges and action	
Water Quality	Green: Water quality parameters are within acceptable ranges	Yellow: Water quality parameters are sightly out of acceptable range. See chart for action	Red: Water quality parameters are significantly outside acceptable range resulting in immediate threat to animal welfare	