

POST APPROVAL MONITORING PROGRAM

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The Vice President Academic and Research (VPAR) is ultimately responsible for the animal care and use program at SMU and the Vice-President Academic and Provost of Mount Saint Vincent University for all animal care and use at MSVU, an organization for which the SMU ACC oversees animal care through a Memorandum of Understanding. **The Canadian Council on Animal Care (CCAC) Guidelines state that the ACC is responsible for having a post-approval monitoring (PAM) program in place for all ACC-approved animal-based teaching and research activities.**

To that end, the ACC carefully considers the proposed animal use and agrees on a defined PAM Requirement for each approved protocol as part of the motion for its approval and this is communicated clearly on the Notice of Approval (NOA) to the PI. The PAM involves members' real-time visits to observe the approved practice at a mutually convenient time as coordinated by the ACC Coordinator. For remote PAMs the Committee asks for PIs to provide photos and videoclips to demonstrate approved field practices as described in AUPFs and SOPs. A combination of onsite and remote PAM monitoring practices, Vet Site Visit and feedback, and scheduled Site-Visits and feedback on animal facilities with full Committee participation, collectively constitutes a post-monitoring approval program. Feedback permits opportunities for real improvement and refinement of animal use, animal care, record-keeping, communications, training, and in the Committee's ability to fulfil its responsibility to determining and working to correct breaches of compliance most effectively by the Committee.

Post Approval Monitoring Requirements

PAM Requirements refer to a scheduled confirmation visit or 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 performed according to the approved Category of Invasiveness and to what has been described in the approved animal use protocol and associated SOPs.

A PAM visit or a PAM requirement assigned communicated on the NOA to the PI, involves the live or recorded observation in-place of those approved procedures that have the potential to or are expected to cause unnecessary pain and distress unless carried out as described and the application of endpoints optimized as detailed in the AUPF.

- Deciding a PAM Requirement

As part of the ACC review and approval of a protocol, the Committee agrees on a specific PAM requirement for the particular protocol. The PAM requirement is communicated to the PI on the Notice of Approval (NOA) MEMO. All protocols are reviewed annually along with their PAM Reports. Thus all protocols will receive one live PAM visit or have one PAM recording-requirement request per year. More details of the PAM and its scheduling (including assembling a group) are done by the Coordinator. All scheduling must be confirmed with the PI in writing (email accepted) with the Coordinator. In the case where the PI is required to provide a photo or video recording of a specific fieldwork activity, no scheduling of a live-visit with the PI is necessary. In the case of fieldwork performed on campus grounds, a live PAM visit may be feasible and therefore may be requested.

- Conducting PAM Visits/Requirements

The assembled PAM group is comprised of at least two members of the ACC. If the Coordinator is not present, one of the PAM group members agrees to be the recorder of observations. Members should arrive to conduct the PAM visit completely prepared for the task and for the space, with any personal protective clothing already acquired. PAM group members should have already prepared by quickly reviewing the protocol, the specific PAM requirement as communicated to the PI on the NOA, and any pertinent procedures or SOPs. The PI or any listed authorized and trained personnel can perform the task to be monitored. PAM observers should not obstruct the work of the handlers with the animals. Observations should be recorded, including information for any required logs, or other documentation. PAM observers should keep their questions to a minimum as this is a monitoring exercise and they are not an audience to an instructional demonstration.

In the case of a remote PAM exercise in a field location, there are no PAM group members on site. The PI and authorized personnel conduct the described procedure while filming a short video clip and/or collecting photos of the process, as the PAM requirement stipulates from the protocol review. The Coordinator can subsequently assemble a PAM group to observe the recording, together, at an agreed upon time, prepared with the appropriate protocol for comparison.

During each PAM visit or during the observation of the pre-recorded remote PAM, the team will compare the procedures being performed with those that are documented in the approved AUPF. A checklist will be constructed from the particular PAM requirement and checked against the observations during the visit. All findings will be documented in a PAM Review Report.

- Post-PAM Visit/Requirement

The PAM report is disclosed at the next meeting of the full ACC and formally recorded in the minutes. Any flagged issues are noted and added to the report. Training records on file for the authorized personnel may be reviewed at the meeting, as provided by the Coordinator. A copy of the PAM report and any recommendations (e.g. training, refinement of endpoint, etc.) or communications back to the PI from the Committee are included. All documentation generated during the PAM process, including email correspondence with respective labs, will be kept on file with the protocol.

The date of the PAM visit (in person or remote) should be recorded in the Protocol Tracker. Where feedback from the PAM visits/requirements results in recommendations (e.g., amendments to protocols and/or SOPs), the ACC communicates this to the PI and facilitates where appropriate. The PAM Report should be a part of the annual review of each protocol.

The ACC, together with the Consulting Veterinarian, may report to the Senior Administrator(s) via the Chair on ethical concerns observed in relation to any observation, where deemed appropriate, which could lead to imposed sanctions as per Saint Mary's University Policy on Integrity in Research and Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct.

ACC Site-Visits

Scheduled site visits of the animal facilities at both SMU and MSVU are conducted once per year. Site-visits include the entire ACC membership, allowing all members the chance to visit animal care and use sites once annually, adhering to CCAC Guidelines. The ACC Site-Visit Checklist is used to capture the observations of the group and, following the group debrief a single copy of the consolidated Checklist becomes the ACC Site-Visit report. The report is provided to the Facility Manager. Where feedback from the site visit results in recommendations the ACC

communicates this to the Facility Manager and facilitates where appropriate.

Consulting Veterinarian Site-Visits

At least two site visits of the animal facilities at SMU are conducted annually. Vet site visits can be scheduled visits or non-scheduled visits. The Vet may exercise his/her authority to access all locations to which they he/she is entitled. The Animal Welfare Assessment Checklist is used to guide the visit (see more information under: Animal Welfare). The Vet writes a report for submission to the VPAR and Facility Manager and a copy is provided to the ACC Chair for the ACC record. The report may include recommendations and the ACC must ensure that any recommendations and/or action items resulting from the vet site visit feedback/report be addressed in a timely and efficient manner.

Animal Welfare

Animal welfare assessment

Assessment of the welfare of animals used for scientific purposes is an important part of the overall PAM program. “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.” CCAC Guidelines on animal welfare assessment (2021)

The CCAC guidelines: Animal welfare assessment (AWA) state that “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 their research teams in the SMU Aquatic Facility and other animal housing labs following species specific scoring systems (Appendix A). Vet site visits follow the same scoring system to guide their visits as well as an animal welfare assessment checklist. PAM site visits can also be supported using the AWA checklist. As with the PAM checklist, any AWA recommendations will be given to the PIs with date of completion, and this will be disclosed to the Committee at the next ACC meeting with any follow-up actions.

Breaches of Compliance

The ACC is the body responsible for determining and working to correct breaches of compliance with approved animal use protocols and SOPs. Breaches of compliance that cannot be corrected by the ACC working with the concerned animal users and veterinary / animal care staff must be referred to the VPAR (senior administration), who must inform all members of the animal care and use program about any sanctions that will be taken by the senior administration in the event of serious breaches of compliance.

The Committee must work with animal users and handlers to ensure compliance with its decisions and with the conditions set out in approved protocols (e.g., through the implementation of its PAM program, and through regular site visits). The Consulting Veterinarian and Animal Care Technician work in a collegial manner with animal users and attempt to correct deficiencies collaboratively. Where there are persistent breaches of compliance or threats to the health and safety of personnel or animals, these must be reported back to the Chair of the ACC, and the Chair and ACC must promptly address these issues, through communications with the animal user(s), meetings and site visits, and eventually communications with the senior administrator, as necessary.

Authority of the ACC Chair and Consulting Veterinarian

The authority of the ACC assigns the Chair of the Animal Care Committee and/or the University Consulting Veterinarian the right to observe unhindered any procedure involving animal-based research or teaching. In addition, the University Consulting Veterinarian has the authority to stop any procedure involving animals if the procedure deviates from an AUP (See SMU ACC Terms of Reference).

The ACC delegates to the Consulting Veterinarian the authority to treat, remove from a study, or euthanize, if necessary, an animal according to the Veterinarian's professional judgment. The Consulting Veterinarian will attempt to contact the PI whose animal is in poor condition 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 Veterinarian to the animal user and to the ACC Chair following any such event, and procedures for incident reporting are followed.

This Document is informed by the relevant documents:

The CCAC Policy Statement on Terms of Reference for Animal Care Committees (2008)

The Addendum to CCAC Policy Statement on Terms of Reference for Animal Care Committees Requirement for Submitting an Animal Protocol (May 2018)

CCAC Post-Approval Monitoring: the CCAC Perspective (Workshop Slides June 14, 2014)

CCAC Guidelines on: Animal Welfare Assessment (2021)

Appendix A: Animal Welfare Assessment Descriptors and scoring

*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. Airstones submerged were 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 slightly out of acceptable range. See chart for action	Red: Water quality parameters are significantly outside acceptable range resulting in immediate threat to animal welfare	