Animal Care Committee

Policy Name	**Post Approval Monitoring Program (PAM)**
Policy Number	ACC.POL.006
Origin	Committee on Animal Use and Welfare (CAUW)
Authority	Associate Vice-President Research
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Responsibility for Revision	Research Ethics Coordinator
Responsibility for Implementation	Associate Vice-President Research

The Saint Mary's University (SMU) 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 (VPAP) of Mount Saint Vincent University (MSVU) for all animal care and use at MSVU, an organization for which the ACC oversees animal care through a Memorandum of Understanding. The Canadian Council on Animal Care (CCAC) Guidelines state that the Animal Care Committee (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.

1) **Post Approval Monitoring (PAM) Requirements**

    a) 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.

b) **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.

c) **Conducting PAM Visits/Requirements**
   i) 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.
   ii) 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.
   iii) 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.

d) **Post-PAM Visit/Requirement**
   i) 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.
   ii) 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.
   iii) 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.

2) **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.

3) **Consulting Veterinarian Site-Visits**
At least one site visit of the animal facilities at SMU is 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. There is no prescribed checklist to be used. 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.

4) **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 SMU VPAR (senior administration) and the MSVU AVPR for any MSVU-related breach, 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.

5) **Animal Welfare**
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 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 and will also attempt to contact the ACC Chair. 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.

6) Resources
This Document has been informed by the following 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)

7) Acknowledgements
MSVU would like to acknowledge that this policy has been adapted from the SMU ACC PAM Policy (2020) at Saint Mary's University