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The purpose of the Saint Mary's University Animal Care Committee (SMU ACC) is to ensure that all animal 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. The SMU ACC is governed by the following Terms of Reference (ToR), which follow The Canadian Council on Animal Care (CCAC) current CCAC Policy: Terms of Reference for Animal Care Committees.

NOTE: Use of the words 'should' and 'must' in this document is consistent with their defined use in the CCAC Guidelines: the word 'should' indicates an obligation for which any exception is justified to and approved by the SMU ACC; the word 'must' indicates a mandatory requirement.

1. MEMBERSHIP

SMU ACC membership is reviewed and appointed by the Vice President Academic and Research. Terms of office for non *ex officio* Committee members are three years, with the possibility for renewal, and should not exceed eight years of consecutive service.

The Committee includes:

- Committee Chair (full-time faculty member, nominated by the Dean of Science and/or the
 Associate Vice President Research and appointed by the VPAR). The Chair should not be directly
 involved in the management of SMU's Animal Facilities, be a clinical veterinarian for SMU, be an
 employee responsible for ensuring CCAC guideline compliance, or be involved in a significant
 number of animal use protocols submitted to the committee.
- Consulting Veterinarian (ex officio);
- Animal Care Facility Manager (ex officio);
- Animal Care Coordinator (ex officio);
- Two faculty members experienced in animal-based research;
- One faculty member whose teaching, testing and research activities do not involve or depend on the use of animals,
- One faculty member from Mount Saint Vincent University whose animal care program oversight is described in a Memorandum of Understanding with Saint Mary's University;
- One Saint Mary's University graduate student;
- At least one (up to three) community member(s) that do not have an affiliation with Saint Mary's and have not conducted research, teaching or testing involving animals.

NOTE: Committee members must respect the confidentiality of SMU ACC matters and the privacy and/or intellectual property of those who submit material for review. Committee members must not distribute or share any ACC material. All deliberations, discussions, and decisions of the Committee are confidential. Communication of any recommendations, decisions or proceeding should be made by the ACC Chair or Coordinator, on behalf of the Committee. All proceedings of the Committee are subject to the University's policies including Grants and Research Policies, and Conflict of Interest Policies Policy. Newly appointed members should meet with the Coordinator and the Chair for basic training before



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preparing for their first meeting as outlined in the Policy on Animal Care and Ethics Training for Animal Care Committee Members at Saint Mary's University, and discuss what confidentiality implies for members. Newly appointed community and student members also receive the Manual for Community Representatives (CCAC). Ongoing training for ACC members is required as outlined in the Policy on Animal Care and Ethics Training for Animal Care Committee Members at Saint Mary's University should be included as a standing agenda item at ACC meetings. Training records of ACC members are updated and maintained by the ACC Coordinator.

The ACC coordinator supports the ACC by ensuring that animal use protocols are well managed, that committee minutes and reports are promptly produced and distributed, that all exchanges between the ACC and animal users are well documented and filed in a timely manner, and that animal users and ACC members are provided with necessary information.

2. AUTHORITY

The SMU Vice President Academic and Research (VPAR) is ultimately responsible for the animal care and use program at SMU and to 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 SMU ACC has the authority, on behalf of the VPAR, to:

- a) Stop any procedure if it considers that unnecessary distress or pain is being experienced by an animal.
- b) Stop immediately any use of animals which deviates from the approved use, any nonapproved procedure, or any procedure causing unforeseen pain or distress to animals.
- c) Have an animal euthanized humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.
- d) Order the withholding of research funds and/or animal ordering privileges for projects in noncompliance with the applicable requirements.

The ACC Chair and the Consulting Veterinarian must have access at all times to all areas where animals are or may be held or used.

2.1 Post Approval Monitoring (PAM) Program

A combination of onsite and remote PAM practices, Vet Site Visit and feedback, and scheduled Site-Visits and feedback on animal facilities with full Committee participation, collectively constitutes a post-approval monitoring 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. See the SMU ACC Post Approval Monitoring Program Document for more details.



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2.2 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.
- 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 in a timely manner.
- Where feedback from the site visit results in recommendations the ACC communicates this to the Facility Manager, who responds to the recommendations with dates of completion to be sent to the Coordinator.

2.3 Consulting Veterinarian Site-Visits

- Per the Standards of Veterinary Care (2020) of the Canadian Association for Laboratory Animal Medicine, at least two site visits of the animal facilities at SMU and MSVU is conducted annually by the Consulting Vet. These visits can be scheduled or non-scheduled visits.
- 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 manner.

2.4 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. 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 Facility Manager 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 to the AVPR. Non-compliance is a serious breach of <u>Saint Mary's</u> <u>University Policy on Integrity in Research and Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct</u>, and may be investigated according to the *Procedures for Reporting and Investigating Scholarly Misconduct* and, if found not to be in compliance, will face outcomes as described in the Policy.



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3. RESPONSIBILITY

3.1 It is the responsibility of the SMU ACC to adhere to the responsibilities described in the CCAC
Terms of Reference for Animal Care Committees policy, quoted below:

- a) "Ensure that no research or testing project or teaching program (including field studies)
 involving animals be commenced without prior ACC approval of a written use protocol; further
 to this, that no animals be acquired or used before such approval. This includes internally
 funded projects;
- b) Ensure that no animals be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior ACC approval of a written animal use protocol, except where current CCAC guidelines provide for exemptions. The ACC should also be aware of other animal-based activities, such as commercial or recreational activities, within the institution, and should work with the persons responsible for these activities to ensure that animal care and use is undertaken according to appropriate procedures;
- c) Require all animal users to complete an animal use protocol form and ensure that the information therein includes the following points, clearly presented in a form that all members of the ACC can readily understand (supplemental information can be found in the CCAC guidelines on: animal use protocol review, 1997). To facilitate the work of both protocol authors and ACC members, appropriate SOPs should be referred to as much as possible. Approved protocols and SOPs should be readily available in the areas where animal-based work is taking place.
 - i. project title and descriptive procedural keywords or brief description of the procedures to be conducted on animals, as defined in the CCAC Animal Use Data Form;
 - ii. per the Saint Mary's University Policy on Animal Care and Ethics Training for Researchers, principal investigators/teachers, and all personnel (post-doctoral fellows, research staff, graduate and undergraduate students) who will handle animals, along with their training and qualifications with respect to animal handling (see point 3m) iii)); in the case of undergraduate students, who may have very little training, close supervision is required;
 - iii. departmental affiliation;
 - iv. proposed start date, proposed end date (if the study is to take place over more than one year, the work and numbers of animals for the first year only should be approved, and further work can then be approved in yearly protocol renewal(s) or new protocols see Section 3g) on protocol renewals);
 - v. for research or testing projects, funding source(s) and status of funding approval;
 - vi. for research projects, an indication of whether the project has received peer review for scientific merit;



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- vii. for teaching programs, a course number and an indication of whether the course has been reviewed with respect to the pedagogical merit of using live animals; institutional or departmental curriculum committees can be called upon to provide a review of pedagogical merit to the ACC; a specific appendix or separate protocol form can be used to better capture information relevant to the ethical review of teaching programs (see Section 12 of the CCAC guidelines on: animal use protocol review);
- viii. for testing projects, an indication that the testing has been planned according to the most current regulatory requirements, using guidelines acceptable to the regulatory agency(ies) and which meet the requirements of the CCAC policy statement on: ethics of animal investigation; that the planned animal use not exceed the requirements of the regulatory authorities if it does, justification for the additional animal use must be provided;
- ix. lay summary;
- x. an indication of the use of biohazardous, infectious, biological, chemical or radioactive agents in animal-based projects; and, if so, an indication of institutional approval of this use;
- xi. category(ies) of invasiveness in animal experiments and for wildlife studies as defined in the CCAC policy statement on: categories of invasiveness in animal experiments (1991), in Appendix D of CCAC guidelines one: the care and use of wildlife (2003), and Purpose of Animal Use (PAU) as defined in the CCAC Animal Use Data Form;
- xii. information with regard to the Three Rs (replacement, reduction and refinement alternatives) of animal use, to include:
 - xii.1 a description of why sentient animals must be used for the project, of how the applicant arrived at this conclusion (e.g., searches of databases on alternatives), and of possible replacement alternatives (non-animal methods, cell/tissue culture, computer simulations, audio-visual teaching methods, the replacement of sentient animals with animals of lower sentiency, etc.) and justification if these are not to be employed;
 - xii.2 justification of the species and numbers of animals to be used over the course of the year, to emphasize reduction of animal use within an appropriate experimental design, while ensuring that sufficient numbers of animals will be used to fulfill requirements for statistical significance/scientific validity in the case of research projects, or for acceptance of regulatory tests;
 - xii.3 a description of all of the refinements to be employed to protect and enhance animal health and welfare, which may include:
 - xii.3.1 anesthesia and analgesia, including dosages and methods of use, for all invasive protocols; strong scientific justification must be provided for not using anesthesia or analgesia in the case of invasive protocols;
 - xii.3.2 other medical treatments as appropriate, as indicated through veterinary consultations; xii.3.3 housing and husbandry methods, and environmental enrichment as a means to refine animal care; any limitations on



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- environmental enrichment from that normally offered to animals in the institution, based on CCAC guidance, must be justified to the ACC;
- xii.3.4 refinements to the procedures to be employed on the animals; xii.3.5 refinements to the length of time that animals will be held/used; xii.3.6 any other possible refinements;
- xiii. a clear description detailing the procedures that are carried out on the animals (referring to appropriate SOPs as much as possible); the use of graphic representations is encouraged;
- xiv. a description of the experimental and human endpoint(s) of the experimentation, selected according to the CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching and testing, 1998 (refer to institutional SOPs, if available and relevant); the person(s) responsible for monitoring the animals and applying endpoints should be identified, and the schedule for monitoring animals and any relevant checklists of signs and symptoms to be used when evaluating the animals should be included; all protocols, even non-invasive ones, must identify endpoints, to ensure that any animals requiring treatment are treated and that animals are not simply kept indefinitely; relevant information for identifying and applying endpoints must be readily available, preferably posted, in the area where the animal based work is taking place;
- xv. a description of capture, restraint, transportation and/or housing of animals used in field studies, as well as any other information pertinent to field studies, such as capture of non target species, ecological impacts and potential injuries or mortality during capture or transportation, if relevant; wildlife studies should be addressed in either a separate section or appendix of the protocol form, or can have their own protocol form, especially where a significant number of wildlife studies are undertaken (see the suggested wildlife protocol form in Appendix B of the 2003 CCAC guidelines on: the care and use of wildlife);
- xvi. the method of euthanasia, if used; justification for any physical euthanasia methods, or for any methods that deviate from those described in the most recent CCAC guidance on euthanasia;
- xvii. a description of the fate of the animals if they are not to be euthanized, including the length of time that they are to be held;
- xviii. any other information considered important or necessary and pertinent, including information or results derived from any relevant previous protocols; the description and use of previous relevant results is particularly important to ensure that methodologies are not simply re-used without learning from any animal welfare problems that were encountered in the past, that the protocol continues to have relevant goals and methodology, and that appropriate refinements to protect and enhance animal welfare are sought and implemented;



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- d) Ensure that each research project has been found to have scientific merit through independent peer review before approving the project; if the review is not carried out by an external, peer review agency, SMU requires that it be obtained according to the CCAC policy statement on: the importance of independent peer review of the scientific merit of animal-based research projects, 2000. SMU has implemented a mechanism through which non-peer-reviewed projects are reviewed for their scientific merit either by calling upon the expertise of individual independent peers or by making use of scientific committees or advisory boards (see Saint Mary's University Policy on Scientific Merit Review of Animal Use Protocols for Research, Testing, and Monitoring).
- e) Review and assess all animal use protocols, with particular emphasis on the CCAC policy statement on: ethics of animal investigation and CCAC guidelines on: animal use protocol review as well as on all other relevant CCAC guidelines and policy statements and, where necessary, require further supportive information from the investigator/teacher or meet with the investigator/teacher to ensure that all members of the committee understand the procedures to be used on the animal. Information exchanges and ACC discussions with protocol authors can be very useful, but protocol authors and members of their teams must always clearly remove themselves from ACC decision-making on their own protocols.

The committee must also ensure that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, require justification for the variance on scientific grounds. ACCs should both discuss protocols and make decisions on them during full committee meetings, rather than through individual reviews, and should attempt to reach decisions by consensus. Electronic tools are widely used for protocol management purposes and to facilitate and expedite the submission and review of protocols. This is encouraged as long as ACCs or protocol review subcommittees continue to meet in person for protocol discussions and final approvals.

An ACC may delegate the responsibility of interim approvals to an interim approval subcommittee, which must include at least one scientific member, one veterinarian and one community representative, one of which should preferably be the chair of the ACC. However, such interim approvals should only be used infrequently, and the interim review process, including exchanges between the ACC and protocol authors, must be documented and must then be subject to discussion and final approval at a full meeting of the committee. The ACC has defined its protocol review process: the SMU Animal Care Committee Review Process document;

f) Ensure that animal users update their protocols with any modifications they intend to make, and approve any modifications to a protocol before they are implemented. Minor modifications (e.g., 1 or 2 animal users added or removed, a small number of animals added, etc.), as defined by the ACC, can be approved by the Chair of the ACC or a delegate. For any major changes to a protocol, require that a new one be submitted. The SMU ACC has defined criteria as to what



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constitutes a major change to a protocol (e.g., a considerable increase of the number of animals required vs. the number in the original protocol, a change of species, use of more invasive or more frequent procedures, use of entirely new procedures, or other criteria; see the SMU Animal Care Committee Review Process document).

Ensure that animal users report any unanticipated problems or complications, as well as on the steps they have taken to address the problem(s), to the ACC;

- g) Review all protocols annually, i.e., within a year of commencement of the project; annual renewals should be approved by at least a scientist, a veterinarian and a community representative and should be brought to the attention of the full ACC for its information. Institutions may choose to use a shorter protocol renewal form, but no matter what form is used, all protocol renewals must emphasize:
 - i. the number of animals used in the preceding year;
 - ii. the number of animals needed for the year to come, with a justification;
 - iii. a brief progress report, describing any complications encountered relative to animal use (unpredicted outcomes, and any animal pain, distress or mortality), any amendments to the original protocol, and any progress made with respect to the Three Rs of replacement, reduction and refinement of animal use;
 - iv. a brief report on the adequacy of the endpoints for the protocol, and on any complications encountered or refinements made relative to protecting animals from pain, distress or mortality; and
 - v. any other changes from the original protocol.

Require the submission of a new protocol after a maximum of three consecutive renewals;

- h) Document all ACC discussions and decisions in the committee minutes and on attachments to the protocol forms;
- i) Define an institutional appeal mechanism that can be used by the author of a protocol in the event that animal use is not approved by the ACC. This mechanism should include appropriate expertise and ensure a separate, fair and impartial process. The CCAC may be called upon for information purposes; however, appeals cannot be directed to the CCAC;
- Ensure that all ACC members and animal users have the opportunity to become familiar with the CCAC Guide and CCAC policy statement on: ethics of animal investigation and all other CCAC guidelines and policy statements, federal, provincial or municipal statutes that may apply, as well as institutional requirements;



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- k) Ensure appropriate care of animals in all stages of their life and in all experimental situations. Veterinary care must be available. Formal arrangements must be made to obtain the services of a veterinarian, at least on a consultative basis, if they are not readily available within the institution. These formal arrangements must be based on the elements contained in the CALAM/ ACMAL Standards of Veterinary Care of the Canadian Association for Laboratory Animal Medicine (2020), which define the roles and responsibilities of veterinarians involved in scientific animal care and use programs;
- I) Establish procedures, commensurate with current veterinary standards, to ensure that:
 - i. unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters;
 - ii. anesthesia and analgesia are properly and effectively used; the only exception to this may be when agents must be withheld as a scientifically justified requirement of the study, and that this has been approved by the ACC. Painful studies requiring exemption from the use of either anesthetics or analgesia must be subject to particular scrutiny, not only prior to approval, but also during the experiment;
 - iii. appropriate post-operative care is provided;
 - iv. all due consideration is given to animal welfare, including environmental enrichment;
- m) Ensure that policies to provide for a system of animal care that will meet the needs of the institution are established and implemented, and include:
 - the requirement that all animal care and animal experimentation are conducted according to CCAC guidelines and policies, and to any federal, provincial and institutional regulations that may be in effect;
 - ii. ensuring adequate animal care and management of the animal facilities, in particular by verifying that there is a person clearly designated to be in charge of animal care and management of the animal facilities, who should be a member of the ACC (see Section 1), and who should keep the other ACC members updated on the activities within the animal facilities;
 - iii. per the Saint Mary's University Policy on Animal Care and Ethics Training for Researchers and the Policy on Animal Care and Ethics Training for Animal Care Committee Members, the training and qualifications of animal users and animal care personnel; veterinarians and animal care staff must receive continuing education in their field, and animal users (scientists/study directors, post-doctoral fellows, graduate students and research technicians) must receive appropriate training according to the CCAC guidelines on: institutional animal user training, 1999, either within the institution or through the programs of other institutions;
 - iv. an occupational health and safety program for those involved in animal care and use, in collaboration with the institutional authorities on occupational health and safety, that



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- will appropriately protect all those who may be affected by animal-based work, according to CCAC guidelines (see Chapter VIII of Volume 1 (2nd Edn, 1993) of the CCAC Guide or the most recent CCAC guidance on occupational health and safety);
- v. standards of husbandry, facilities and equipment;
- vi. standard operating procedures for all activities and procedures that involve animals, including animal care and facility management SOPs (typically produced by the veterinary and animal care staff), and animal use SOPs (typically produced by animal users, in collaboration with veterinary/animal care staff as needed); the ACC should receive all SOPs and ensure that all necessary SOPs are produced and regularly reviewed (see also Section 5a)iii));
- vii. procedures for euthanasia;
- n) Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not; and
- o) In the case of projects involving proprietary or patentable research or testing, ensure that as much information as possible is provided to the ACC in terms of what effects to expect on animal health and welfare, and insist on close monitoring of animals in order to respect the elements outlined in 31)."

3.2 Review Process and Monitoring of Approved Protocols

The review process at SMU is outlined in the <u>Saint Mary's University Animal Care Committee Review Process</u> document. This document includes the process by which the SMU ACC conduct ethical reviews of AUPs, appeal processes, the criteria for major and minor amendments to approved AUPs, and how the SMU ACC handles collaborations with other institutions.

The Post Approval Monitoring process at SMU is outlined in the SMU ACC Policy on Post Approval Monitoring.

4. MEETINGS

There should be at least FIVE Committee meetings per year, one of which is an annual general meeting. Additional meetings may be called if necessary. A quorum includes 50% of the ACC Membership plus one member, and must include the Consulting Veterinarian, a Community Member, the Chair, and the Coordinator. The schedule of ACC meetings and associated submission deadlines for the entire calendar year should be made public in late December of the previous year. The annual general meeting is normally held in October or November.



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5. GENERAL

The general expectations of the ACC do not deviate from those specifically listed in the <u>CCAC Terms of Reference for Animal Care Committees policy</u>, which are summarized here:

- the regular review (at least every three years) of
 - o the terms of reference
 - the security of the animals and research facilities
 - standard operating procedures (SOPs)
 - policies and procedures for monitoring animal care, and experimental procedures within
 the institution including identification of the persons responsible for monitoring animal
 health and welfare and the procedures carried out by the ACC to conduct monitoring
- maintaining a liaison with the CCAC Secretariat to convey pertinent information
- submission of a CCAC animal use data form by the CCAC yearly deadline.
- development of a crisis management plan for the animal facilities with the necessary details (See Saint Mary's University Animal Care Crisis Management Program)
- hold educational seminars or workshops on related topics of animal care, when possible.
- maintain a high profile within the university and the community to demonstrate the university's efforts in promoting animal welfare and in the interest of transparency.
- develop and maintain communication with animal welfare organizations.



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Saint Mary's University Animal Care Organization Chart

