Animal Care Committee

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Responsibility for Revision	MSVU Research Ethics Coordinator
Responsibility for Implementation	Associate Vice-President (Research)

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 Animal Care Committee; the word 'must' indicates a mandatory requirement.

1) Background

Mount Saint Vincent University (MSVU) has a formal animal care agreement with Saint Mary's University (SMU), which specifies that SMU's Animal Care Committee (ACC) and two representatives (one regular member and one alternate) from MSVU will provide oversight of MSVU's animal ethics and care program. Oversight of MSVU animal-based research and teaching is provided by the ACC. The ACC reports to the MSVU Associate Vice President (Research), a direct report to the Vice-President Academic and Provost. MSVU has an internal committee, the Committee for Animal Use and Welfare (CAUW) which is responsible for the development and implementation of animal use policies and procedures at the University which adhere to Canadian Council on Animal Care (CCAC) guidelines and requirements.

2) Purpose

The purpose of the ACC is to ensure that all animals used in teaching, research or testing at MSVU are treated ethically and in accordance with the CCAC policies and guidelines as well as the following Terms of Reference (ToR), which follow current CCAC *Terms of Reference for Animal Care Committees*. The general expectations of the ACC do not deviate from those specifically listed in the CCAC Terms, which are summarized here:

a) the regular review (at least every three years) of
   i) the terms of reference
   ii) the security of the animals and research facilities
   iii) standard operating procedures (SOPs)
   iv) 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

b) maintaining a liaison with the CCAC Secretariat to convey pertinent information

c) submission of a CCAC animal use data form by the CCAC yearly deadline.

d) development and implementation of a crisis management plan for the animal facilities with the necessary details

e) conduct of educational seminars or workshops on related topics of animal care, when possible.

f) maintaining 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.
g) develop and maintain communication with animal welfare organizations.

3) Authority

The SMU Vice President Academic and Research (VPAR) is ultimately responsible for the animal care and use program at SMU and the MSVU Vice-President Academic and Provost (VPAP) is responsible for all animal care and use at MSVU, an organization for which the ACC oversees animal care through a Memorandum of Understanding.

Under the authority granted by the MSVU VPAP, the Associate Vice-President (Research) and Dean of Arts & Science at MSVU are granted oversight responsibility for the animal care and use program at the University.

a) The ACC and the consulting veterinarian have been granted authority by MSVU to:
   i) stop any procedure if it considers that unnecessary distress or pain is being experienced by an animal.
   ii) stop immediately any use of animals which deviates from the approved use, any non-approved procedure, or any procedure causing unforeseen pain or distress to animals.
   iii) have an animal euthanized humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.
   iv) order the withholding of research funds and/or animal ordering privileges for projects in noncompliance with the applicable requirements.
b) The ACC Chair and veterinarian shall always have access to any MSVU locations where animals are housed or used, this may include locations that may be proposed for use.
c) The ACC may delegate the authority to treat, to remove from a study, or to euthanize animals according to the veterinarian's professional judgement. The veterinarian may delegate this responsibility.
d) MSVU shall ensure that the MSVU Release of Funds form is submitted prior to release of any research funds (grants or contracts) that involve animal participants and certify that ACC approval is in place before funds are released;

4) ACC Membership

a) Members

The Animal Care Committee will have the following membership:

- Committee Chair (full-time faculty member, nominated by the SMU 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 Technician (*ex officio*);
- Animal Care Coordinator (*ex officio*);
- Research Grants Officer (*ex officio, non-voting*);
- 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 Saint Mary's University graduate student;
- At least one (up to two) community member(s) that do not have an affiliation with Saint Mary's and have not conducted research, teaching or testing involving 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, appointed by the MSVU Associate Vice-President Research;

*MSVU will wherever possible, appoint one alternate MSVU faculty member who has experience working with animals and who is appointed by the MSVU Associate Vice-President (Research).

b) Term of Appointment

Any MSVU ACC Committee member(s) shall be appointed for a three (3) year term and are normally renewable to a maximum of six (6) consecutive years.

c) Confidentiality

Committee members must respect the confidentiality of 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 proceedings that relate to MSVU use of animals should be provided by the ACC Chair or Coordinator, on behalf of the Committee, to the MSVU Research Office via the Research Ethics Coordinator.

i) All proceedings of the Committee are subject to the University's policies including Responsible Conduct of Research, Grants and Research Policies, and Conflict of Interest Policy.

ii) 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.

d) New Member Training

i) Newly appointed members should meet with the Coordinator and the Chair for basic training before preparing for their first meeting, to ensure they have access to the SMU ACC TOR, key policies, and an example of the most recent meeting minutes (and what confidentiality implies for members).

ii) Newly appointed community and student members also receive the Manual for Community Representatives (CCAC) and a link to the CCAC's Three R's microsite. Using the CCAC syllabus as a guide to ongoing training opportunities for existing members is required and documented and should be included as a standing agenda item at ACC meetings.

e) Support

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. The Research Ethics Coordinator at MSVU shall work closely with the SMU ACC Coordinator to ensure timely exchange of information and documentation required to fulfill its role in Animal Care at MSVU.

5) Meetings, Quorum and Reporting

a) The ACC shall establish a schedule of meetings and publish deadlines for submission of protocols.

b) There shall be at least five (5) meetings per year, or more as necessary to fulfill requirements as set out in the terms of reference and to ensure that all animal use at MSVU is in compliance with University, municipal, provincial, and federal guidelines as well as Canadian Council on Animal Care (CCAC) standards.

i) One of these scheduled meetings shall be the Annual General Meeting (AGM) normally scheduled in October or November.

ii) Additional meetings may be held as necessary.

iii) MSVU will host at least one ACC meeting per academic year.

c) 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.

d) Quorum shall be determined with 50% of the ACC membership plus one member.

i) Quorum must include the consulting veterinarian, a community member, the ACC Chair and the ACC coordinator.

e) Recordkeeping:
   i) The ACC reports to the MSVU Research Ethics Coordinator, a direct report to the MSVU Associate Vice-President (Research), who is in turn a direct report to the Vice-President Academic and Provost.
   ii) It is the responsibility of the ACC Coordinator to produce minutes documenting ACC discussions, decisions and modifications to MSVU protocols and forward them to the MSVU Compliance Officer/Research Ethics Coordinator. The MSVU Compliance Officer shall ensure that the Associate Vice-President (Research) is informed of all MSVU protocols and their status.

6) ACC Responsibilities

The ACC has a responsibility to 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. The ACC shall 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 within the institution, such as commercial or recreational activities, and should work with the persons responsible for these activities to ensure that animal care and use is undertaken according to appropriate procedures.

The ACC shall:

a) establish and implement policies and procedures that provide a system of animal care which complies with legal and ethical requirements and recommends on implementation of and modifications to policy;
b) at least every three (3) years review:
   i) its terms of reference to ensure compliance with the most recent CCAC guidelines or policies and changing needs within the institution, the scientific community, the animal welfare community and society as a whole,
   ii) the security of the animals and research facilities,
   iii) standard operating procedures and institutional animal care and use policies;
   iv) policies and procedures for monitoring animal care and experimental procedures within the institution.
c) inform potential investigators of their responsibility to bring to the attention of the ACC, any research or teaching protocol which involves the use of live animals before any work with animals commences or animals are brought on campus;
d) require that all animal users submit appropriate animal use protocol forms to the ACC Coordinator for forwarding to the ACC for review and approval; animal use protocol forms have been established by the ACC and shall be in compliance with CCAC policies and guidelines;
e) require animal users to use and refer to the appropriate Standard Operating Procedures (SOPs) as much as possible;
f) 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;
- 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;
- 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;

- 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 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);
- standards of husbandry, facilities and equipment;
- 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));
- procedures for euthanasia;

g) 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 (2004), 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:
      - unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters;
      - 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;
      - appropriate post-operative care is provided;
      - all due consideration is given to animal welfare, including environmental enrichment;

h) ensure that animal care users provide the following information for each protocol application:

- 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;
- 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;
- departmental affiliation;
- 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);
- for research or testing projects, funding source(s) and status of funding approval;
- for research projects, an indication of whether the project has received peer review for scientific merit;
- for teaching programs, a course number and an indication of whether the course has been bn 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);
- 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;
- lay summary;
- 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;
- 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;
- information with regard to the Three Rs (replacement, reduction and refinement alternatives) of animal use, to include:
    - 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;
    - 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;
    - a description of all of the refinements to be employed to protect and enhance animal health and welfare, which may include:
    - 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;
    - other medical treatments as appropriate, as indicated through veterinary consultations;
    - housing and husbandry methods, and environmental enrichment as a means to refine animal care; any limitations on environmental enrichment from that normally offered to animals in the institution, based on CCAC guidance, must be justified to the ACC;
    - refinements to the procedures to be employed on the animals;
    - refinements to the length of time that animals will be held/used;

- any other possible refinements;

- 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;
- 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;
- 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);
- 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;
- 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;
- 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;

i) ensure that each research project has been found to have scientific (or pedagogical) merit through independent peer review before approving the project; if the review is not carried out by an external, peer review agency, the ACC 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. The ACC 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 **ACC.POL.003 and ACC.POL.004**).

j) 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. Where necessary, the ACC may 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.

   i) 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.

   ii) 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.

iii) The 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.

iv) The ACC has defined its protocol review process: the Animal Care Committee Review Process document (ACC.POL.005);

k) 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.

i) 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.

ii) For any major changes to a protocol, require that a new application be submitted.

iii) The ACC has defined criteria as to what 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 ACC.POL.005);

l) 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;

m) 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.

n) ensure that:

- all procedures comply with CCAC guidelines and policy statements, and, if at variance with those guidelines and policy statements, require justification for the variance on scientific grounds.
- ensure that the pedagogical merit of teaching animal welfare protocols is evaluated;
- 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 to the ACC on the outcome (positive or negative) of any pilot studies;
- conduct Post-Approval Monitoring (PAM) - also see Section 100 below - which should monitor an appropriate amount of active protocols per year as deemed appropriate and based on risk. PAM can be via site visits and/or formal presentations to the ACC to ensure compliance by the investigators and to be proactive in anticipating concerns received from members of the community at large. In addition to PAM site visits, monitoring shall also include any combination of the following:
  (1) copies of approved protocols and certifications sent from ACC to MSVU Research Ethics Coordinator Officer for MSVU records;
  (2) periodic review of laboratory logbooks;
  (3) monthly MSVU laboratory inspections by an externally contracted aquatic biologist, MSVU Safety Officer, researcher;
  (4) at least one annual MSVU laboratory site visit by the ACC;

(5) periodic inspection by ACC Chair and/or veterinarian;
(6) creation of photos and/or videos of research conducted in the laboratories, including care, breeding, experiments;
(7) incident reports, veterinarian reports as well as site inspection reports to be filed with MSVU Compliance Officer and ACC;
(8) copies of publications filed with MSVU Compliance Officer and ACC;
(9) ensure that all MSVU laboratory personnel and other impacted MSVU community members are aware of the *Safe Disclosure of Employee Wrongdoing Policies and Procedures;*
(10) annual meeting with MSVU Safety Officer, Director of Facilities Management, Compliance Officer, Researcher, Dean of Arts & Science and Lab Safety members to discuss animal research on campus, assess and rectify any deficits in SOPs, policies, etc.;

o) maintain liaison with the CCAC Secretariat and with the provincial authorities, where applicable, and submit complete and accurate animal use information to the CCAC annually;
p) liaise with the CCAC Secretariat and with the provincial authorities, where applicable, and submit complete and accurate animal use information to the CCAC annually;
q) maintain a crisis management program for the animal laboratories and for the animal care and use program, in conjunction with any general institutional crisis management plan(s); and
r) sponsor, from time to time, seminars or workshops on the use of animals in science and the ethics of animal experimentation; this should include a formal orientation session to introduce new ACC members to the animal care and use program and its members, policies and procedures, as well as to the animal facilities and to CCAC guidelines and policies.
s) document all ACC discussions and decisions in the committee minutes and on attachments to the protocol forms;
t) 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
u) 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 3l)."
v) SMU and MSVU also have a responsibility to:
   i) work with the ACC to ensure that all Committee members and animal users have the opportunity to become familiar with the Canadian Council on Animal Care guidelines and policies statements, federal, provincial or municipal statutes that may apply, as well as institutional requirements;
   ii) support the work of the ACC by appointing a SMU ACC coordinator who will ensure that animal use protocols are well managed, that committee minutes and reports are produced and distributed promptly, that all exchanges between the ACC and animal users are well documented and filed in a timely manner, that ACC members and animal users are provided with necessary information; and that relevant communication with MSVU is undertaken in a thorough and timely manner. The Compliance Officer/Research Ethics Coordinator will be the point of contact for MSVU applications and administrative support.
   iii) 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;
   iv) ensure that ACC members are provided with the necessary initial training and ongoing learning opportunities to better understand their work and role; and
   v) value and recognize the work performed by the ACC.

7) Protocol Review

The process of an animal use protocol review is detailed in the MSVU Animal Protocol Review (**ACC.POL.005),** and summarized in 8.a-8.l below. This document includes the requirements and procedures for scientific and pedagogical merit review, instructions for protocol authors on how to submit an animal use protocol form (AUPF), the process by which the SMU ACC conducts ethical reviews of AUPs, the criteria for major and minor amendments to approved AUPs, and how the ACC handles collaborations with other institutions.

a) The ACC will review and assess all animal use protocols, with particular emphasis on the CCAC's Guide to the Care and Use of Experimental Animals, the Ethics of Animal Investigation policy statement and the guidelines on: animal use protocol review as well as on all other relevant CCAC guidelines and policy statements.
b) Where necessary, the ACC can require further supportive information from the investigator/instructor or meet with the investigator/instructor to ensure that all members of the committee understand the procedures to be used on the animal.
c) Protocols will be reviewed regarding the ethical treatment of animals in all aspects of the procedures including housing, maintenance and techniques.
d) Protocols submitted to the ACC should include sufficient information written in non-technical language, where possible, to describe and justify the experiments and methods to be used.
e) Normally protocols deemed to be CCAC Category of Invasiveness "E" will not be considered for approval.
f) The ACC shall discuss each protocol and detailed recommendations shall be recorded.
g) The ACC shall discuss protocols and make decisions on them during full committee meetings (except as otherwise provided) and shall attempt to reach decisions by consensus.
h) The protocol will either be approved, approved pending revision, or the Principal Investigator (PI) will be asked to re-submit.
i) The PI will be advised of the Committee's decision by email, asked to respond to any recommendations by email.
j) Each approved protocol shall be assigned a protocol number, which should be used to monitor the number of animals used.
k) Research and teaching protocols may be approved for an additional one year upon receipt and approval of an annual report and request for renewal prior to expiry.
l) Responsibility for interim review of protocols requesting immediate approval will be delegated to a protocol review subcommittee consisting of the ACC Chair, a veterinarian, a community representative, and the ACC Coordinator. If agreement cannot be reached on an interim review by the protocol review subcommittee, then the protocol should be submitted to the ACC for review. If approval is granted by the protocol review sub-committee, such interim approval will be subject to discussion and final approval at a full meeting of the ACC.

8) Appeals of ACC Decisions

Appeals to negative decisions by the ACC involving MSVU researchers shall include, wherever possible, the MSVU AVPR and/or the MSVU Dean of Arts & Science.

a) Because ethics review and the observance of research ethics at the University is premised on collegial relations between the ACC and researchers, a request for appeal must be a last resort.
b) An appeal may only be made on the grounds that there has been a miscarriage of justice, such as an error in process, procedural irregularity, lack of due process, and exceptions to the precepts of natural justice such as bias.
c) Any MSVU researcher's appeal of the ACC's decisions shall be made in writing to the SMU VPAR and copied to the MSVU AVPR who will jointly review the MSVU appeal and determine action.
d) Written appeals must be received within 10 working days of an ACC negative decision.
e) The mandate of those reviewing the appeal shall be to approve or reject the protocol as submitted.
f) If an appeal is upheld, the ACC will immediately review the animal use protocol in question. Decisions on appeals are final.

9) Post-Approval Monitoring Program (PAM)

A combination of onsite and remote PAM practices, veterinarian 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 MSVU ACC Post Approval Monitoring Program policy document (**ACC.POL.006**) for full details.

a) ACC Site Visits

i) 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.

ii) 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 (as well as the MSVU Research Ethics Coordinator for MSVU-related reports) in a timely manner.

iii) 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.

b) Consulting Veterinarian Site Visits

i) At least one site visit of the animal facilities at SMU and MSVU is conducted annually by the Consulting Veterinarian. These visits can be scheduled or non-scheduled visits.

ii) The Veterinarian writes a report for submission to the VPAR and Facility Manager (as well as the MSVU Research Ethics Coordinator for MSVU-related reports) 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.

c) Breaches of Compliance

i) The ACC is the body responsible for determining and working to correct breaches of compliance with approved animal use protocols and SOPs. The ACC 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).

ii) The Consulting Veterinarian and Animal Care Technician work in a collegial manner with animal users and attempt to correct deficiencies collaboratively.

iii) Where there are persistent breaches of compliance or threats to the health and safety of personnel or animals at MSVU, these must be reported to the AVPR.

iv) MSVU and the ACC Chair and ACC must promptly address these issues, through communications with the animal user(s), meetings and site visits, and further communications with the senior administrator, as necessary and in keeping with requirements of the *Tri-Agency Framework: Responsible Conduct of Research*.

10) References

The following documents have been used extensively in the formulation of this policy.

- Canadian Association for Laboratory Animal Medicine (CALAM) – https://www.calam-acmal.org/resources/Documents/CALAM-ACMAL%20STANDARDS%20OF%20VETERINARY%20CARE.pdf (Retrieved August 2020)
- Canadian Council on Animal Care - *Categories of Invasiveness in Animal Experiments* - https://www.ccac.ca/Documents/Standards/Policies/Categories_of_invasiveness.pdf (Retrieved December 2019)

- Canadian Council on Animal Care – *Crisis Management Plan* - https://www.ccac.ca/Documents/Assessment/Crisis-Management-Program.pdf (Retrieved September 2019)
- Canadian Council on Animal Care - *Guidelines on: Procurement of Animals Used in Science* - https://www.ccac.ca/Documents/Standards/Guidelines/Procurement.pdf (Retrieved December 2019)
- Canadian Council on Animal Care - *Terms of Reference for Animal Care Committee* - *https://www.ccac.ca/en/standards/guideline-development/terms-of-reference-for-guidelines-subcommittees.html* (Retrieved - September 2017)
- Saint Mary's University *Animal Care Committee Terms of Reference* (Retrieved October 2020)
- Three R's - http://3rs.ccac.ca/en/about/ (Retrieved September 2020)