# Saint Mary's University Animal Care Committee Review Process

Updated: February 2025

This document outlines the submission and review process for proposed research and teaching activities involving animals. See the flowcharts for submitting a new research or teaching protocol for a summary of this process.

## PROTOCOL AUTHORS

All Principal Investigators (PIs) planning to start work with animals at Saint Mary's University should contact the Animal Care Committee Coordinator (animalcare@smu.ca) to first determine if their work falls under the mandate of the SMU Animal Care Committee (ACC). If SMU ACC ethical review is required prior to beginning work, the ACC Coordinator will work with the PI to develop a timeline for preparation and submission of all needed forms. This should be done at least 2 months in advance of any planned work. An annual schedule, including ACC meeting dates and submission deadlines for PIs, is posted to the SMU ACC website each December for the following year. No CCAC regulated animal-based work can begin until approved by the SMU ACC.

## SUBMISSION OF FORMS

All forms are provided on the SMU ACC website, and are submitted electronically to the ACC Coordinator via animalcare@smu.ca. PIs must complete an Animal Use Protocol (AUP) form using either the Fieldwork AUP or Laboratory AUP form and indicate if the work is for teaching or research purposes. Relevant supporting documents (i.e., Standard Operating Procedures, permits, training records, etc.) are submitted with the AUP. For research protocols requiring scientific merit review, the protocol author should include a supplemental document providing additional information needed to conduct review. For teaching protocols, a Teaching Appendix form is submitted and includes information required for pedagogical merit review.

## REVIEW

### 1. Prior to ethical review, all protocols must be found to have scientific or pedagogical merit.

For teaching protocols, the ACC Coordinator, in consultation with the senior administrator responsible for scientific and pedagogical merit review, arranges for a pedagogical merit review according to the Policy on Pedagogical Merit Review of Animal Use Protocols for Teaching and Training. For research protocols, the Coordinator verifies with the Research Grants Officer that a scientific merit review has taken place. If scientific merit review is required, ACC Coordinator, in consultation with the senior administration, arranges for a scientific merit review according to the Policy on Scientific Merit Review of Animal Use Protocols for Research, Testing, and Monitoring. Only protocols which have been reviewed and found to have merit are reviewed for ethics by the ACC.

## 2. Ethical review by the SMU ACC

Protocol submissions are added to the agenda of the next scheduled meeting of the ACC where they are reviewed and, if the Committee is ready to decide, a motion to approve the protocol is voted upon. The SMU ACC reviews all Animal Use Protocols (AUPs) and supporting documents (i.e., Standard Operating Procedures, permits, training records, etc.), with particular attention to the CCAC policy: Ethics of Animal Investigation, CCAC guidelines on: Animal Use Protocol Review, and all other relevant CCAC guidelines and policies. The Committee ensures that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, requires justification for the variance on scientific grounds.

Every effort is made by the ACC to carry out decisions on all review business at regularly scheduled in-person meetings. All protocols must be reviewed annually by the ACC; protocols are approved for a maximum period of 12 months and can be renewed twice.

At meetings, the SMU ACC reviews:

- NEW SUBMISSIONS: New protocols require review by the full ACC.
- RENEWALS: Renewal of an approved protocol requires review by the full ACC. Protocols are approved for a maximum period of 12 months and require renewal before expiration. Protocols may be renewed up to two times.
- AMENDMENTS: Review of a major amendment to an approved protocol requires the full ACC.
- RENEWALS WITH AMENDMENTS
- CLOSURE REPORTS: Closure Reports can be submitted to the ACC Coordinator at any time, and expired protocols require submission of a Study Closure report within two weeks after the expiry date. Study Closure Reports are disclosed to the Committee at the next meeting of the full ACC.
- INTERIM APPROVALS: Under demonstrated extraordinary or emergency circumstances beyond the control of the PI or ACC, a new submission or major amendment may be considered by an ACC sub-committee (composed of the Consulting Vet, a Community Member, the Coordinator, and the Chair) for interim approval until a full-committee review is possible. This option is not normally used.
- Post-Approval Monitoring (PAM) DOCUMENTS: This includes reports, videos, and/or pictures to meet PAM requirements outlined in the Notice of Approval (NOA). PAM Reports can be submitted to the ACC Coordinator at any time within the protocol approval period and are reviewed at the next meeting of the full ACC.
- ANIMAL WELFARE ASSESSMENT INFORMATION: This information is reviewed via PAM Reports, Consulting Veterinarian Site Visit Reports, ACC Site Visit Reports, protocol amendments and/or renewals (Progress Report section), Study Closures, Incident Reports, and any other communications regarding animal welfare.

The ACC will ask PIs to be available for questions (e.g., by phone contact, virtually, or electronically) during the ACC meeting at which their submission is being reviewed if further supportive information or clarification is needed. However, PIs and members of their teams are always recused from the review

discussions and decision making of the ACC on their own protocols. Similarly, any ACC member who is also a PI or member of another PI's team is also excused from the review discussions and decision- making of the ACC on those protocol submissions.

**REVIEW DECISIONS, POST-REVIEW PROCESSES, AND APPEALS**

Decisions to approve submissions are based on consensus voting outcomes of positive motions (i.e., the motion is always to *approve* the request). The decision therefore is normally:

(i) *to approve*: this includes approval of category of invasiveness and a defined Post Approval Monitoring requirement.

(ii) *not to approve:* protocols are not approved upon conditions being met; there are no conditional approvals.

In the case of (i) above, the PI is asked to make any approved changes where applicable and to resubmit the revised AUP. A Post-Review Decision Memo (PRD) informs the PI that, upon receipt of the revised AUP, that an electronic official copy of their approved protocol will be returned to them along with a Notice of Approval (NOA) including: protocol number, name, start date and expiry date, any permit number, category of invasiveness, animals used, location of animals and experiment, names of authorized personnel and PI, and the PAM requirement (for more information, see the SMU ACC Policy on Post Approval Monitoring). The date of issue of that NOA is included, along with any NOA associated with that root protocol number (e.g., 18-02, 18-02A1, 18-02A2 etc., marking the date of original NOA and all subsequent dates of NOA issued for approved amendments).

In the case of (ii) above, where the ACC has reviewed a submission and has decided more time and/or more information is needed to make a decision, this outcome is communicated to the PI in a PRD Memo from the Chair within one week of the meeting, and will outline the reasons the protocol was not approved for ethical merit. The PI may wish to revise the protocol and supporting documents to address these points and re-submit to the ACC for re-review. The committee may conduct the re-review electronically if feasible, followed by a vote. If the re-review cannot be handled electronically, it will be added to the agenda for the next scheduled full meeting of the ACC.

If resolution cannot be reached through consultation between the ACC and the PI, the PI has the right to request, and the ACC has an obligation to provide, reconsideration of a negative decision by ACC through the following process:

1. The PI appeals the decision of the ACC in writing to the AVPR.

2. The AVPR will review the documents provided by the ACC and the PI. The AVPR will consult with others as required, including but not limited to, members of the ACC, the PI, external reviewers with relevant expertise, and the CCAC.
3. The AVPR will issue a decision in writing to the ACC and the PI. This decision will be final.

## AMENDMENTS OF ACTIVE PROTOCOLS

Changes to active protocols are considered *amendments*, and require review and approval by the ACC before work on the modified protocol can begin. PIs should first contact the ACC Coordinator with their intention to amend a protocol to clarify requirements and effect change efficiently and compliantly. Communication between the ACC Coordinator and the Consulting Veterinarian, ACC Chair, and animal care staff is essential to the provision and sharing of consistent and valid information and advice.

There are two kinds of amendments: *minor* and *major*, and these are described in the table below. To amend an active protocol, the PI must submit an Amendment & Renewal form to the ACC Coordinator via animalcare@smu.ca, ensuring that all applicable sections for an amendment are completed according to the instructions on the form.
Multiple changes to a single protocol can be requested by completing all applicable sections of a single amendment form. **Requested amendments will be determined to be minor or major upon receipt by the ACC Coordinator, Chair and Veterinarian. The table below is not exhaustive, but includes examples of different amendments under the minor and major categories, along with the necessary approval parties for each.**

| | Reviewed by: | | | | |
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| **MINOR Amendments – protocol number modified with {A1, A2, A3, …}** | **Full Committee** | **AC Coordinator** | **Chair** | **Consulting Veterinarian** | **Community Member(s)** |
| Administrative corrections or a relatively modest amount of specific information that corrects one or more deficiencies in the protocol which do not alter the invasiveness or goal of the original protocol | | ● | | | |
| Modification of the title of the protocol which does not alter original goal | | ● | ● | ● | |
| Adjustments to number of animals used, to correct for the impact of other approved changes on a related protocol | | ● | ● | | |
| Addition of SMU research personnel with demonstrated training records | | ● | ● | | |
| Removal of non-essential research personnel who have left the study | | ● | ● | | |

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| Justified location change of experiment / of animal housing – on the university property | | ● | ● | | |
| Justified location change of experiment as per all required field permits | | ● | ● | | |
| Change in funding information resulting from new information or from a correction. Note: Chair will also consult with the SMU Research Grants Officer ACC Member on any request relating to funding information. | | ● | ● | | |
| A minor change to the procedures, where the effect on animals is equivalent or better, and does not require new skills of the personnel | | ● | ● | ● | ● |
| A refinement in drug or exposure time | | ● | ● | ● | ● |
| A refinement to increase the amount of animal monitoring | | ● | ● | ● | ● |
| A refinement to a less invasive, less distressful, or less painful procedure | | ● | ● | ● | ● |
| A change of euthanasia method (must also be CCAC–acceptable) | | ● | ● | ● | ● |
| A change in anesthetic agent used (CCAC-acceptable) | | ● | ● | ● | ● |
| Addition of a hybrid that precludes an increase in the category of invasiveness | | ● | ● | ● | ● |
| Transfer of animals between AUPs, affecting final disposition information and animal source information | | ● | ● | ● | ● |
| A change in animal source information | | ● | ● | ● | ● |
| Reasonable additions of already-approved animals (up to 10%; 20% for fish) with adequate justification (for COI A-C only) | | ● | ● | ● | ● |
| A protocol extension beyond expiry date, up to one month | | ● | ● | ● | ● |
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| **MAJOR Amendments – requires a new protocol number** | | | | | |
| A change in species with different husbandry and/or different handling needs | ● | | | | |
| A protocol extension of more than one month and up to one year (renewal) | ● | | | | |
| A change in the principal investigator (PI) | ● | | | | |
| An addition of a research collaborator outside of SMU | ● | | | | |
| A complex change to the procedures or introduction of a novel change/procedure | ● | | | | |
| A change to the procedures that increases the level of invasiveness | ● | | | | |
| A significant addition of already-approved animals (>10%; >20% for fish) in the original non-amended version of the protocol, with adequate justification | ● | | | | |
| Addition of a new capture technique | ● | | | | |

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| Addition of a new test, new exposure, or new experimental condition | ● | | | | |
| Substantial number of smaller modifications to a single protocol (may require submission of a NEW protocol) | ● | | | | |
| A change from survival to non-survival | ● | | | | |
| Change(s) to procedure than may induce increased pain or distress | ● | | | | |
| Modification(s) to listed experimental and/or humane endpoints | ● | | | | |
| A change in COI in the direction of a more negative impact on an animal's welfare | ● | | | | |

Minor amendments do not always require review by the full ACC (e.g., addition of a new animal user). However, the Committee reserves the right to subject a minor amendment to a full Committee review at the discretion of the ACC Chair and the Consulting Veterinarian, which will add further time to the review process. Otherwise, users can expect a quick turnaround time for minor amendments that only require the ACC Chair, Coordinator, and Consulting Veterinarian.

Major amendments require review by the full ACC and are considered at the next scheduled meeting of the ACC following amendment submission. In special circumstances where the PI has clearly demonstrated that this will negatively impact scientific/pedagogical merit, the ACC Chair, in consultation with the Consulting Veterinarian and Community Member, may decide to conduct the review electronically, under the same quorum and approval constraints for in-person ACC meetings. Major amendment requests must include full details of the changes along with necessary documentation. Any request to amend a protocol in conjunction with renewal requires the review of the full Committee.

In the case that the amendment request is approved, a Notice of Approval is issued to the PI, along with an official copy of the approved amended protocol with updated protocol number. The newly amended protocol number is generated by appending the appropriate suffix to the original number, from the series {A1, A2, A3, etc.} according to the number of times it has already been amended, the new protocol and number cancels its precursor protocol. It is the responsibility of the PI to display information, inform relevant personnel of any changes, and communicate with the Facility Manager and/or animal users, and any other necessary parties regarding the change.

**RENEWALS OF ACTIVE PROTOCOLS**

PIs may wish to renew their original protocol for up to an additional 12-month period up to a total approval time of 3 years (maximum of 2 renewals). Renewals are requested by completing the Renewal & Amendment form and completing all sections including a detailed progress report. The PI can also request to amend the protocol at the time of the renewal. Renewal requests must be submitted in advance of the expiry to be reviewed at a scheduled ACC meeting prior to the expiry date.

After two renewals, the request is submitted as a NEW protocol and a completely new submission is required. A Closure Report must be submitted for the expired protocol immediately at the date of closure.

**PILOT STUDIES**

PIs are encouraged to submit pilot studies when new approaches, methods, or products are being tested. Pilot studies are an effective tool for determining humane intervention points, to perfect technique, to demonstrate feasibility, to provide justification for proceeding with larger studies, or to estimate statistical variability. Typically, the number of animals requested is low as the purpose of the study is testing the methodology, not confirming a scientific hypothesis.

Occasionally, the ACC will suggest a pilot study. A pilot study requires the submission of an Animal Use Protocol Form. The PI must report the results of the pilot study to the ACC, whether the study was successful or not. If the study will continue to a larger study, the PI must submit a new Animal Use Protocol Form.

**GUIDELINES FOR REVIEW OF PROJECTS INVOLVING RESEARCH COLLABORATORS BETWEEN TWO OR MORE INSTITUTIONS**

This section follows the CCAC policy: Animal-Based Projects Involving Two or More Institutions and the CCAC FAQ: Animal-Based Projects Involving Two or More Institutions, and serves the ACC in its deliberations in the cases where various parts of an animal-based project are carried out by more than one institution. Three cases are described below:

**1. An investigator carrying out animal-based work in a host institution**

"An institutional ACC is responsible for overseeing the work carried out by all members of the institution who use animals for research, teaching or testing. Therefore, a member of an institution who wishes to carry out animal-based work within a host institution's facilities must first submit a written animal use protocol describing the project to the ACC of his or her home institution. This ACC must review the project to ensure that it meets the committee's normal standards and does not contravene any institutional policies on animal care and use. The home institution's ACC can then approve the protocol in principle, conditional to the approval of the protocol by the host institution's ACC.

The host institution's ACC, having received the approval in principle of the protocol from the home institution's ACC, can then review the protocol focusing primarily on whether the animals can be housed, cared for and used appropriately according to CCAC guidelines and policies, given the host institution's facilities and resources. The host institution's ACC must approve the protocol before the protocol can begin, and normally before animals are acquired. It must also take responsibility, with the collaboration of the animal care and veterinary staff of the host institution, for oversight of the protocol and of the welfare of the animals to be used. The host institution's ACC must inform the home institution's ACC of its decision and of any relevant conditions or details accompanying the decision.

To facilitate this process for all of those involved, it is suggested that the use of a single protocol form be agreed upon by the ACCs and the investigator, and that the chairs of each ACC communicate directly with each other to discuss any questions that either committee may have. This will minimize delays in the review process while ensuring that each committee is clearly informed and that each can make the most appropriate decision in light of this information." (CCAC, "Animal-Based Projects Involving Two or More Institutions", 2003)

**2. Animal-based projects undertaken in two or more institutions**

"Investigators from two or more institutions may choose to undertake a collaborative project in which the animal-based work is to be divided between the animal facilities of the various institutions. For these projects, the ACC of each institution involved must receive a written animal use protocol detailing the animal-based work to be undertaken within the facilities for which it is responsible. This protocol must also provide a brief description of the overall joint Project as a whole. Any interactions between the institutions relative to the animal-based work (e.g., transfer of animals from one institution to another, special requirements to ensure the health and welfare of the transferred animals, etc.) must be understood and accepted by the ACCs of each of the institutions involved.

Once again, clear and direct communication between ACCs is strongly recommended to facilitate the process and to ensure that CCAC guidelines and policies are applied, and animal care and use is appropriately overseen throughout all phases of a collaborative project. The ACC of the home institution of the principal investigator should normally take the lead in providing an ethical review of the most comprehensive protocol and should coordinate and address questions and comments from the other ACCs involved." (CCAC, "Animal-Based Projects Involving Two or More Institutions", 2003).

**3. Field studies**

"Field studies often involve more than one institution or agency and, when this is the case, section B.3.1.2 of the CCAC guidelines on: the care and use of wildlife are the guidelines to be followed: "When multiple research partners are involved in a project, the ACC of the principal investigator should normally take the lead in providing an ethical review of the protocol. Co-operating investigators should be responsible for provision of the reviewed protocol to their home institution, indicating that approval has already been given by the lead ACC. Any questions concerning the reviewed procedures from the home ACCs of the co-operators should be directed to the lead ACC for resolution. Home institutions or agencies should be aware of all projects being conducted by their investigators and should ensure that the procedures to be used are ethically acceptable and comply with all legislative and other applicable standards. "Where more than one ACC is involved in the review of a protocol (e.g., when research is conducted outside of the jurisdiction of the home institution), a well defined arrangement between the ACC of the home institution and the host organization, for monitoring the proposed project and the welfare of the animals, should be agreed upon before the project begins. ACCs need to be aware of the protocols and progress of projects which are being carried out locally. The local ACC is often the point of contact for the public and should be able to answer questions concerning wildlife studies in their area." (CCAC, "Animal-Based Projects Involving Two or More Institutions", 2003)