

ANIMAL CARE COMMITTEE REVIEW PROCESS

PROTOCOL AUTHORS

All new principle investigators planning to start work with animals at Saint Mary's University should contact the Animal Care Coordinator animalcare@smu.ca to first determine if their work falls under the mandate of the SMU ACC committee. If SMU ACC ethical review is needed prior to beginning work, the Animal Care Coordinator will work with the author 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. PIs will be made aware of the public schedule for that year to plan for ACC meeting submission deadlines. No CCAC regulated animal-based work can begin until approved by the SMU ACC.

SUBMISSION OF FORMS

All Animal Care Committee submission forms are provided on the SMU ACC public website with most fields form-fillable. All submissions are electronic. PIs enter their protocol information into the appropriate **FIELDWORK** or **LABWORK** animal use protocol form and indicate if the work is **TEACHING** or **RESEARCH**. For research protocols requiring scientific merit review, the protocol author should include a supplemental form providing the additional information needed to conduct review. For teaching protocols, an additional **Teaching Appendix** form is submitted to include information required for pedagogical merit review. Any permits and training records must also be submitted, as per the instructions on the forms.

REVIEW

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

For teaching protocols, the Coordinator, in consultation with the senior administrator responsible for scientific and pedagogical merit review, arranges for a pedagogical merit review according to the **Pedagogical Merit Review Process**. For research protocols, the Coordinator verifies with the Research Grants Officer that a scientific merit review has taken place. In the case it has not, the Coordinator arranges for one according to the **Scientific Merit Review Process**. 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

The SMU ACC reviews all animal use protocols, including associated SOPs, with particular attention to 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. 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. The submission is added to the agenda of the next scheduled meeting of the ACC where it is reviewed and, if the Committee is ready to decide, a motion to approve it is voted upon.

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

At meetings, the SMU ACC reviews:

- NEW Submissions
- MAJOR AMENDMENT: Review of a major amendment to an approved protocol requires the full Committee.
- RENEWAL WITH AMENDMENT
- CLOSURE REPORTS: Closure Reports can be submitted to the Coordinator at any time and are disclosed to the Committee at the next meeting of the full ACC.
- Post-Approval Monitoring (PAM) REPORTS, videos, pictures to meet PAM requirements noted in the Notice of Approval (NOA): PAM Reports can be submitted to the Coordinator at any time and are disclosed to the Committee at the next meeting of the full ACC.
- RENEWALS: Renewal of an approved protocol requires the full Committee. Procols may be renewed up to two times.
- INTERIM APPROVALS: Under demonstrated extraordinary or emergency circumstances beyond the control of the PI or Committee, a NEW submission, or a MAJOR AMENDMENT may be considered by a sub-committee (composed of the Consulting Vet, a Community Member, the Coordinator, and the (scientific member) Chair) for interim approval until a full-committee review is possible. This option is not normally used.

Where further supportive information or clarification is needed directly from the PI, the committee will ask the PI to be available for questions (e.g., by phone contact) during the ACC meeting at which their submission is being reviewed. However, protocol authors and members of their teams are always recused from the review discussions and decision making of the Committee 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 Committee on those protocols.

REVIEW DECISIONS and POST-REVIEW DECISION and COMMUNICATIONS

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* (including approval of category of invasiveness and a defined PAM requirement) or (ii) *not to approve* the proposed work. Protocols are not approved upon conditions being met; there are no conditional approvals. Where the Committee has reviewed a submission and has decided more time and/or more information is needed to make a decision, this outcome be communicated to the PI. The decision or outcome is communicated to the PI in a **Post-Review Decision (PRD) MEMO** from the Chair, within one week of the meeting.

In the case of (i) above, the PI is asked to make any approved changes where applicable to the submission and to resubmit the revised AUPF. The PRD MEMO also informs the PI that, upon receipt of the revised AUPF 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 post-approval monitoring (PAM) requirement. The date of issue of that NOA is included and 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 revisions).

In the case of (ii) above the committee will outline the reasons the protocol was not approved for ethical merit. The protocol author may wish to make revisions to address these points and re-submit an updated protocol. In this case, the committee may conduct the re-review electronically and then vote to approve/not approve the updated protocol.

AMENDMENTS of ACTIVE PROTOCOLS

Changes to active protocols, are considered *amendments*. Protocol authors should first contact the Coordinator with their intention to amend a protocol to clarify requirements and effect change efficiently and compliantly. Communication between the 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 separately, below, in this document. To amend an approved protocol, the protocol author completes the **Amendment & Renewal form** and completes all applicable sections for an amendment, according to the instructions on the form, and submits to the ACC 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 it lists examples of different amendments under the minor and major categories, along with the necessary approval parties for each.**

	Reviewed by:				
	Full Committee	AC Coordinator	Chair	Consulting Veterinarian	Community Member(s)
MINOR Amendments – protocol number modified with {A, A2, A3, ...}					
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		●	●		
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		●	●	●	●
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	●				
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 a full Committee review (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 Chair, Coordinator, and Consulting Veterinarian.

Major amendments require a full Committee review 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 Chair, in consultation with the Consulting Veterinarian and Community Member, may decide to conduct the review electronically, under the same quorum and approval constraints as the 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 new number. The newly amended protocol number is generated by appending the appropriate suffix to the original number, from the series {A, 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 change, and communicate with the Facility Manager/Animal Care Technician or 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 part of the protocol at the time of the renewal. Renewal requests must be submitted

at a reasonable date 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** is submitted for the expired protocol immediately at the date of closure.

Guidelines for review of projects involving research collaborators between two or more institutions.

This section follows the CCAC policy paper on *Animal-Based Projects Involving Two or More Institutions (2003)* and the *May 2020 FAQ on this topic*. 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: A - an investigator carrying out animal-based work in a host institution; B - Animal-based projects undertaken in two or more institutions; and C – Investigators from different institutions doing field studies.

A - 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 focussing 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)

B. 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)

C. 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)