



Name:	Scientific Merit Review of Animal Use Protocols for Research, Testing, and Monitoring
Policy Number:	8-1023
Origin:	SMU Animal Care Committee
Approved:	2020-NOV-18
Issuing Authority:	Vice President Academic and Research
Responsibility:	Associate Vice President Research
Effective Date:	2020-NOV-18

Scope and Purpose:

According to the Canadian Council on Animal Care (CCAC) the University's research administration is responsible for ensuring that basic and applied research by Saint Mary's University researchers in which animals will be used must be independently reviewed for scientific merit through a formal process by expert peers and found to have scientific merit before subsequently being subjected to an ethics review by the University's Animal Care Committee (ACC). Scientific merit review does not apply to regulatory testing or to teaching/training (except where students are being taught/trained as partners in research projects – including honours projects, undergraduate and graduate level research). Scientific merit review does apply to pilot study research (*except where the purpose of the pilot study is to develop or evaluate a new method within the context of a peer-reviewed research program). Scientific merit review also applies to research that is undertaken with start-up funds (*except where it is associated with a previous project that has undergone scientific peer review). Scientific merit review applies to collaborative animal-based projects (e.g. where a protocol of a lead PI at another institution includes collaborative work by a listed SMU researcher; where a protocol of a lead PI at SMU includes collaborative work by a non-SMU research collaborator).

*Where there are questions about whether proposed research falls within the exemption descriptions above, the research office is responsible for working with the principal investigator to determine whether or not the study is covered within an existing, peer-reviewed program, and for presenting its conclusions to the animal care committee.

The purpose of the Policy is to have a formal, established mechanism for ensuring that all proposed research involving animals is reviewed for scientific merit by external expert peers independent of the Saint Mary's Animal Care Committee (ACC) and satisfy such requirement of the University by the national accrediting body of the CCAC. The VPAR's Office is ultimately responsible for this mechanism. The ACC Coordinator can assist in an administrative role only, to facilitate the process.

The relevant CCAC policy documents that inform this SMU Policy are:

- *CCAC Policy Statement for Senior Administrators Responsible for Animal Care and Use Programs* and specifically APPENDIX II of this policy statement. (CCAC, 2008)
- *CCAC Policy Statement on Scientific Merit and Ethical Review of Animal-Based Research* (CCAC, 2013)
- *CCAC FAQ on Scientific Merit and Ethical Review of Animal-Based Research* (CCAC, 2019)

Policy:

In accordance with the CCAC Guidelines and the Saint Mary's University Animal Care and Use Program, animal use in research must only be undertaken if expert, independent opinion has attested to the probable scientific value of the research within its field. Proposed animal use for research must be independently peer-reviewed for its scientific merit before it can undergo ethics review by the ACC. Animal-based work can then proceed only if the ACC finds the use of animals acceptable ethically and in practice (i.e. the proposed animal-based methods should be appropriate for the work and meet institutional and CCAC Guidelines and standards). The Research Grants Officer (RGO) works out of the research office and is an ex-officio non-voting member of the ACC, attending all animal ethics review meetings of the ACC. Through the RGO, the ACC receives solicited confirmation that each animal-based research protocol has been found to have scientific merit according to the formal process detailed below, before it is subjected to ethics review by the ACC and; through the RGO, the research office receives confirmation of protocol approval from the ACC before releasing funds for animal-based work for the corresponding project.

Externally funded proposals of research involving animals are submitted to the ACC by the principal investigator (PI) using the animal-use protocol form which includes a section for the funding source and grant number required information as well as a checkbox for confirmation of peer review. In the case of externally funded proposals that do not appear to use a peer review mechanism with appropriate independence and expertise, the funding source may be able to demonstrate, to the research administration's satisfaction, that the project has been peer-reviewed by independent experts, and should be able to describe the process in writing. The ACC must receive confirmation from the PI and the research office that the work described in the research animal use protocol is part of a research project or program that has been found to have scientific merit through independent, expert review. Indication of NSERC funding is normally taken by the ACC as evidence of scientific merit for the entire funding period and the proposal is subsequently subjected to ethics review by the ACC. Otherwise, through the RGO, the ACC asks for confirmation from the research office on whether the listed funding source is sufficient evidence of scientific merit.

- If the RGO on behalf of the research office communicates to the ACC Chair confirmation that scientific merit has already been demonstrated through the competitive peer-review process for the proposed work, the proposal is subsequently subjected to the ethics review process as described in the ACC Terms of Reference, to determine whether the proposed animal use and proposed animal-based methods as described within the animal use protocol are acceptable according the CCAC Guidelines. Confirmation of scientific merit from these sources remains valid for the entire funding period.
- If the RGO on behalf of the research office communicates to the ACC Chair that scientific merit has not yet been demonstrated, the submission is immediately subjected to the scientific merit review process described below.

Internally funded proposals of research involving animals are submitted to the ACC by the principle investigator (PI) using the animal-use protocol form which includes a section for the funding source and grant number (if applicable) as required information, as well as a checkbox for confirmation of peer review. The grant proposal is submitted upon request. The ACC must receive confirmation from the PI and the research office that the work described in the research animal use protocol is part of a research project or program that has already been found to have scientific merit through independent, expert review. Through the RGO, the ACC asks for confirmation from the research office on whether the listed funding source is sufficient evidence of scientific merit.

- If the RGO on behalf of the research office communicates to the ACC Chair that scientific merit has already been demonstrated for the proposed work through the funding process, the proposal is subsequently subjected to the ethics review process as described in the ACC Terms of Reference, to determine whether the proposed animal use and proposed animal-based methods as described within the animal use protocol, are acceptable according the CCAC Guidelines. The ACC can ask for the process by which scientific merit was assessed to be submitted to the ACC in writing, so a formal process is documented/demonstrated.
- If the RGO on behalf of the research office communicates to the ACC Chair that scientific merit has not yet been demonstrated, the submission is immediately subjected to the scientific merit review process described below.

Non-funded proposals of research involving animals are submitted to the ACC by the principle investigator (PI) using the animal-use protocol form which includes a checkbox for confirmation of peer review, and further scientific context is submitted to the ACC upon request. The ACC must receive confirmation from the principal investigator that the work described in a research animal use protocol is part of a research project or program that has been found to have scientific merit through independent, expert review, which should be confirmed by the research administration.

Through the RGO, the ACC asks for confirmation from the research office on whether the listed funding source is sufficient evidence of scientific merit.

- If the RGO on behalf of the research office communicates to the ACC Chair that scientific merit has already been demonstrated for the proposed work, the proposal is subsequently subjected to the ethics review process as described in the ACC Terms of Reference, to determine whether the proposed animal use and proposed animal-based methods as described within the animal use protocol, are acceptable according the CCAC Guidelines. The ACC can ask for the process by which scientific merit was assessed to be detailed and submitted to the ACC in writing, so a formal process is documented/demonstrated.
- If the RGO on behalf of the research office communicates to the ACC Chair that scientific merit has not yet been demonstrated, the submission is immediately subjected to the scientific merit review process described below.

Scientific Merit Review Process

Two independent scientific merit reviews by external, expert peer-reviewers must be conducted *before* the protocol can be considered for subsequent ethics review by the ACC. Expert peer-reviewers must not be directly involved in the protocol design or implementation, and they should have appropriate experience and/or knowledge in the relevant field, discipline or sub-discipline to adequately review

protocol content. They must comply with the SMU Policy on Conflict of Interest on Research and therefore in relation to the PI they must not be:

- a personal friend or relative;
- be from the same University department/program;
- have been a research supervisor or graduate student of the University Member within the past six years;
- be providing letters of support;
- have collaborated with the University Member within the past six years or has plans to collaborate in the immediate future;
- is an employee of a non-academic organization with which the University Member has had collaboration within the past six years;

and they must not have any other potential conflict of interest (e.g., personal, financial).

The Associate Vice President Research (AVPR) has been delegated authority and responsibility to administer the Scientific Merit Review Process. In administering the Review Process, the AVPR will:

- Receive support from the ACC Coordinator through provision of all required documents to conduct the review;
- Receive support from the ACC Coordinator through provision of email contacts of the ACC Coordinators at select Canadian universities identified by the AVPR;
- Contact ACC Coordinators at two selected Canadian universities, providing them a request for names of potential appropriate merit reviewers, giving only the title of Protocol (along with an indication of a need for relatively quick turnaround time);
- Upon receiving names of potential reviews from these Coordinators, review online research profiles of the suggested reviewers to ensure appropriateness for the review;
- Contact the individuals and personally request their assistance in providing the review (again, providing at that time only the protocol name and the need for quick turnaround) and asking if they have any conflicts of interest in conducting the review;
- Once the reviewers have been identified, send the AUPF and any supporting documents (e.g. SOPs) to conduct the review to the reviewers with instructions that the reviewers are asked to:
 - rate the proposed research in terms of originality/potential contribution to scientific knowledge, research design/methodological approach, data analysis, objectives, and hypotheses;
 - elaborate on the ratings;
 - recommend to approve as is, revise, or reject the protocol;
 - return the reviews directly to the AVPR once they are completed;
- In the event of conflicting or inconsistent reviews from two reviewers, a third review will be solicited following the above process, to provide an arbitrating viewpoint;
- Report the result of the review to the ACC Chair, Coordinator and RGO;
- Send the complete reviews to the RGO to hold for record keeping purposes;
- Provide the PI Researcher the de-attributed comments from the reviewers, in case they may want to do adjustments to the protocols before review by the ACC.