

| Name: | Policy on Scientific Merit Review of Animal Use Protocols for Research, Testing, and Monitoring |
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| Policy Number: | 8-1023 |
| Approving Authority: | Vice President Academic and Research |
| Approved: | 18-NOV-2020 |
| Responsible Office: | Faculty of Graduate Studies and Research, Animal Care Committee |
| Responsibility: | Associate Vice President Research |
| Revision Date(s): | 3-NOV-2023 |
| Supersedes: | NA |
| Next Required Review: | 2026 |

1. Preamble

- 1.1 As a certified institution of the Canadian Council on Animal Care (CCAC), Saint Mary's University (SMU) is required to have a policy to ensure scientific merit review of proposed animal use in research as outlined in the <u>CCAC policy statement on: scientific merit and ethical review of animal-based research</u>.
- 1.2 The Policy on Scientific Merit Review of Animal Use Protocols for Research, Testing, and Monitoring is ultimately the responsibility of the Vice President Academic and Research (VPAR). The VPAR has designated day-to-day responsibility for the Policy to the Associate Vice President Research (AVPR). The ACC Coordinator can assist in an administrative role only to facilitate the scientific merit review process.

2. Purpose

2.1 The purpose of this policy is to describe scientific merit review requirements and processes for research involving animals.

3. Jurisdiction/Scope

3.1 This policy applies to all proposed research activities which require approval of an Animal Use Protocol by the SMU Animal Care Committee (for more information, see <u>CCAC Requirement for</u> submitting an animal protocol).

4. **Definitions**

| ANIMAL CARE COMMITTEE (ACC) | The local representative of the CCAC responsible for ensuring that all animals used in teaching, research or testing at SMU are treated ethically and in accordance with the Canadian Council on Animal Care's (CCAC) policies and guidelines. |
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| PRINCIPAL INVESTIGATOR (PI) | The faculty member who has submitted an Animal Use Protocol (AUP) and holds associated funding. |
| ANIMAL USE PROTOCOL (AUP) | A protocol outlining use of animals in research or teaching that has been submitted by a PI and reviewed and approved by the ACC. |
| EXTERNALLY FUNDED RESEARCH | Funding from federal, provincial, or private organizations or foundations. |
| INTERNALLY FUNDED RESEARCH | Funding from internal Saint Mary's University sources. |
| INDEPENDENTLY FUNDED RESEARCH | Research that is not fully supported by funding from external or internal sources. This includes research activities which use personal funds, or research activities that do not require funding. |

5. Policy

- 5.1 Per <u>CCAC policy statement on: scientific merit and ethical review of animal-based research</u>, Saint Mary's University research administration is responsible for ensuring that basic and applied research involving animal use be independently reviewed for scientific merit through a formal process by expert peers and found to have scientific merit before an associated Animal Use Protocol (AUP) undergoes ethical review by the ACC. The AVPR has been delegated the authority and responsibility to administer the Policy on Scientific Merit Review of Animal Use Protocols for Research, Testing, and Monitoring.
- 5.2 Scientific merit review applies to:
 - a) 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.
 - b) research that is undertaken with start-up funds, except where it is associated with a previous project that has undergone scientific peer review.
 - c) collaborative animal-based projects (e.g., where a protocol of a lead PI at another institution includes collaborative work by a SMU PI; where a protocol of a lead PI at SMU includes collaborative work by a PI at another institution).
- 5.3 Scientific merit review does not apply to regulatory testing or to teaching/training, except where students are being trained as partners in research projects including honours, undergraduate, and graduate level research.

- 5.4 Where there are questions about whether proposed research requires scientific merit review, the research administration is responsible for working with the PI to determine if the work is covered within an existing peer-reviewed program. The research administration must then communicate their conclusions to the ACC.
- 5.5 Through the Research Grants Officer (RGO), the ACC receives solicited confirmation (via the ACC Coordinator) that each submitted AUP to the ACC has been found to have scientific merit according to the formal process detailed in Section 6.1 before it is subjected to ethical review by the ACC.
- 5.6 Through the RGO, the research office receives confirmation of AUP approval from the ACC before releasing funds for the associated research activities involving animals. If ACC approval has not yet been received, a partial release of funds can be requested by the PI via the research office and must include an outline of the use of funds to ensure that the funds will not be used for activities that require ACC approval. For more information, contact the RGO.
- 5.7 Scientific merit reviewer requirements

Two independent scientific merit reviews by external, expert peer-reviewers must be conducted before an associated AUP can undergo ethical review by the ACC. Scientific merit review involves review of the proposed AUP and supporting documents (e.g., standard operating procedures, etc.) and completion of the Scientific Merit Peer Review Form. Reviewers must not be directly involved in the AUP design or implementation, and they should have relevant experience and/or knowledge to adequately review the AUP and supporting documents.

Peer-reviewers must comply with the <u>SMU Policy on Conflict of Interest in Research</u> 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 or have plans to collaborate with the PI in the immediate future;
- be an employee of a non-academic organization with which the University Member has had collaboration with in the past six years;
- have any other potential conflict of interest (e.g., personal, financial) with the applicant (PI).

6. **Related Policies, Procedures & Documents**

- 6.1 Scientific Merit Review Process
 - a) The AVPR receives support from the ACC Coordinator through provision of all required documents to conduct the review.
 - b) The AVPR receives support from the ACC Coordinator through provision of email contacts to the ACC Coordinators at select Canadian institutions identified by the AVPR.

- c) The ACC Coordinator contacts coordinators or equivalent at two selected Canadian universities with a request for names of potential appropriate reviewers, providing only the protocol title and indication of a need for relatively quick turnaround time (four week maximum).
- d) Upon receiving names of potential reviewers, the AVPR surveys associated online research profiles to ensure suitability for the review of the proposed animal work.
- e) The ACC Coordinator contacts the potential reviewers and requests their assistance in providing a scientific merit review while providing only the protocol title, indicating the need for a relatively quick turnaround time (four week maximum), and requesting confirmation that they have no conflict of interest in conducting the review.
- f) The ACC Coordinator sends to each confirmed reviewer the AUP and supporting documents to conduct the scientific merit review, along with the Scientific Merit Reviewer Comment Form to complete.
- g) In the event of conflicting or inconsistent reviews from the two selected reviewers, a third reviewer will be solicited following the same process outlined in Sections 6.1 a-f to provide an arbitrating viewpoint.
- h) The ACC Coordinator reports the results of the scientific merit review to the AVPR, ACC Chair, and Research Grants Officer (RGO). The RGO retains a copy of the Scientific Merit Reviewer Comment Form and any associated documents or communications for their records.
- i) The ACC Coordinator provides the PI with the de-attributed Scientific Merit Reviewer Comment Forms and the PI can adjust the AUP and supporting documents if desired before either: i) ethical review by the ACC if the research activities were found to have scientific merit, or ii) resubmission of the AUP and supporting documents to reviewers (via the ACC Coordinator) if the research activities were not found to have scientific merit.

6.2 Externally funded research

Externally funded proposals of research involving animals are submitted to the ACC by the PI using the AUP form which requires the funding source and grant number information, and confirmation of scientific merit 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 must 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 (via the ACC Coordinator) must receive confirmation from the PI and

the research office that the work described in the AUP 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 confirmation to the ACC Coordinator that scientific merit has already been demonstrated through competitive peer review during the funding process for the proposed work, the AUP is subsequently subjected to ethical review by the ACC as described in the <u>Saint Mary's University Animal Care Committee Terms of Reference</u>. Confirmation of scientific merit review from the source remains valid for the entire funding period.

If the RGO, on behalf of the research office, communicates to the ACC Coordinator that scientific merit has not yet been demonstrated, the AUP and supporting documents are immediately subject to the Scientific Merit Review Process described in Section 6.1.

6.3 Internally funded research

Internally funded proposals of research involving animals are submitted to the ACC by the PI using the AUP form which requires the funding source and grant number information, and confirmation of scientific merit review. The grant proposal is submitted upon request of the ACC. The ACC (via the ACC Coordinator) must receive confirmation from the PI and the research office that the work described in the AUP is part of a research project or program that has been found to have scientific merit through independent, expert review. The ACC Coordinator requests confirmation from the RGO that the funded source listed on the AUP is sufficient evidence of scientific merit review.

If the RGO, on behalf of the research office, communicates confirmation to the ACC Coordinator that scientific merit has already been demonstrated through competitive peer review during the funding process for the proposed work, the AUP is subsequently subjected to ethical review by the ACC as described in the <u>Saint Mary's University Animal Care Committee Terms of Reference</u>. The ACC can request that the process by which scientific merit was assessed be submitted to the ACC to ensure that a formal process is demonstrated and documented.

If the RGO, on behalf of the research office, communicated to the ACC Coordinator that scientific merit has not yet been demonstrated, the AUP and supporting documents are immediately subject to the Scientific Merit Review Process described in Section 6.1.

6.4 Independently funded research

Independently funded proposals of research involving animals are submitted to the ACC by the PI using the AUP form which requires funding source information (if applicable) and confirmation of scientific merit review. Further scientific context is to be submitted to the ACC

upon request. The ACC (via the ACC Coordinator) must receive confirmation from the PI and the research office that the work described in the AUP is part of a research project or program that has 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 confirmation to the ACC Coordinator that scientific merit has already been demonstrated for the proposed work, the AUP is subsequently subjected to ethical review by the ACC as described in the <u>Saint Mary's University</u> <u>Animal Care Committee Terms of Reference</u>. The ACC can request that the process by which scientific merit was assessed be submitted to the ACC to ensure that a formal process is demonstrated and documented.

If the RGO, on behalf of the research office, communicated to the ACC Coordinator that scientific merit has not yet been demonstrated, the AUP and supporting documents are immediately subject to the Scientific Merit Review Process described in Section 6.1.

Related Policies:

CCAC policy statement on: scientific merit and ethical review of animal-based research

CCAC policy: Requirement for submitting an animal protocol

Saint Mary's University Policy on Conflict of Interest in Research

Saint Mary's University Animal Care Committee Terms of Reference