

<b>Procedure Title:</b>	Scientific Merit Review of Animal Use Protocols (AUPs)
<b>Procedure ID:</b>	#OP 9-902C
<b>Manual Classification:</b>	Section 9 – Applied Research
<b>Linked to Policy:</b>	#9-902 Animal Care and Welfare
<b>Approved by Senior Management Team:</b>	January 10, 2022
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<b>Effective Date:</b>	February 1, 2022
<b>Next Review Date:</b>	January 2025
<b>Contacts for Procedure Interpretation:</b>	Vice President Applied Research and Innovation

## 1.0 – Purpose

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The purpose of this procedure (the “**Procedure**”) is to ensure that all research projects involving animals are subjected to an independent review by expert peers and outline the process for scientific merit review.

Terms not defined in this Procedure have the same meaning found in Policy #9-902 Animal Care and Welfare.

## 2.0 – Procedure

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### 2.1 - Overview

The Canadian Council on Animal Care states that “*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*” (CCAC policy statement on: scientific merit and ethical review of animal-based research.). It is Fleming College's responsibility to ensure that the appropriate mechanisms are in place to evaluate the scientific merit of proposed animal use for research.

### 2.2 – Procedural Guidelines for the Scientific Merit Review

- a) Applied research projects involving live animals must be subject to two levels of review before receiving final approval to proceed:
  - An expert peer review of the project's scientific merit
  - An ethical review by the Fleming College's ACC, as per the Animal Care and Welfare Policy (#9-902), of whether the proposed animal use is acceptable, and whether the proposed animal-based methods are appropriate
- b) According to CCAC requirements, Scientific Merit Reviewers must
  - Possess the expertise to adequately review the scientific proposal

- Be independent from the research under review (e.g., external to the research team and laboratory in which the research will be undertaken and must not be directly involved in research design and implementation).
  - Should not have been involved in any research activities with the PI within the past five years, either as co-worker, supervisor or reportee
  - Should not be in any potential conflict of interest (e.g. financial, personal)
  - Be external to the ACC
  - Selected by the Merit Review Committee (MRC)
  - The PI may submit recommendations for appropriate reviewers to the MRC
- c) The scientific merit review must be undertaken by a minimum of two expert peers and must be completed for all new Animal Use Protocols (AUPs) and for every subsequent renewal of AUPs that underwent changes.
  - d) The PI must submit the Scientific Merit Assessment Form to the ACC Coordinator at least four weeks in advance of scheduled ACC meetings.
  - e) The ACC Coordinator will inform the MRC and provide the MRC with the AUP and Scientific Merit Assessment form.
  - f) The MRC will assign to each PI Scientific Merit Reviewers and provide reviewers with required documentation/forms at least three weeks prior to the scheduled ACC meetings.
  - g) The Scientific Merit Reviewers will perform the review within two week of receiving the Scientific Merit Assessment form and send completed Scientific Merit Review forms to the ACC Coordinator at least one week prior to scheduled ACC meetings.
  - h) Any concerns and questions received from the Scientific Merit Reviewers must be addressed by the PI prior to AUP review by the ACC.

### **2.3 – Animal Care Committee Involvement**

- a) The Scientific Merit Review process must be completed in advance of the final AUP review by the ACC.
- b) The ACC must receive confirmation about the scientific merit of the proposed AUP before granting final approval. The ACC must respect the feedback from the scientific merit reviewers and any concerns must be forwarded to the MRC for consideration.

### **2.4 – Pilot Projects**

- a) Pilot projects used to explore new research direction are subjected to the same approval process if the new methodology is not covered within an existing merit reviewed AUP.

### **2.5 – Collaborative Projects**

- a) Each organization associated with an applied research project involving live-animals must undergo the scientific merit review process as outlined in this procedure, regardless of where the research is undertaken.

### **2.6 – Roles and Responsibilities**

- a) The Vice President Applied Research and Innovation is responsible to:
  - Ensure that a mechanism for scientific merit review is in place in alignment with this procedure
- b) The Merit Review Committee (MRC) is responsible to:

- Determine and assign to each PI scientific merit reviewers that are independent and subject matter experts
  - Provide the Scientific Merit Review form and completed Scientific Merit Assessment form to the Scientific Merit Reviewers at least three weeks prior to scheduled ACC meetings requesting completion and submission within two weeks' time
  - If outstanding questions or concerns have been identified, act as a liaison between the PI, the Scientific Merit Reviewers, and the ACC
- c) Principal Investigator (PI) is responsible to:
- Provide the ACC Coordinator with the appropriate AUP and completed Scientific Merit Form at least four weeks prior to ACC meetings
  - Address Scientific Merit Reviewers questions in a timely manner
  - Forward concerns with feedback or the review process to the MRC for consideration
- d) Scientific Merit Reviewers are responsible to:
- Perform the scientific merit review within two weeks of receiving the Scientific Merit form from the MRC.
  - Notify the MRC immediately if the timeline cannot be met
  - If applicable, identify themselves as not being 'experts' or 'independent' (as defined in this procedure) immediately upon receiving the Scientific Merit Review form.
  - Communicate with the MRC if outstanding questions or concerns have been identified
  - Submit the Scientific Merit Reviewer form to the ACC Coordinator upon completion, at least one week prior to scheduled ACC meetings
- e) The Animal Care Committee Coordinator is responsible to:
- Provide the Scientific Merit Assessment form to the PI
  - Forward Scientific Merit Assessment form to the MRC once received from PI
  - Provide the Scientific Merit Review form to the MRC
  - Liaise with the MRC and confirm the status of reviews
  - Identify outstanding scientific merit reviews of AUPs
  - Forward review results to the ACC
  - Provide the PI with written scientific merit reviewer feedback
  - If applicable, forward outstanding questions from the ACC to the MRC and act as a liaison until all outstanding concerns are resolved
  - Maintain a record of all scientific merit reviews undertaken by the MRC
- f) The Animal Care Committee is responsible to:
- Consider the scientific merit review outcome in approval of AUPs involving animals in research

### **3.0 – Related Documents**

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- Animals for Research Act, R.S.O. 1990, c. A.22

- Canadian Council on Animal Care: Ethics of Animal Investigation
- Canadian Council on Animal Care: Policy statement on: Scientific merit and ethical review of animal-based research.
- Policy #9-902 Animal Care and Welfare
- Operating Procedure #9-902A: Animal Care Committee Terms of Reference
- Operating Procedure #9-902B: Animal Use Protocols
- Operating Procedure #9-902D: Pedagogical Merit Review of Animal Use Protocols (AUPs)
- Operating Procedure #9-902E: Post Approval Monitoring (PAM)
- Operating Procedure #9-902F: Animal User Training Program
- Operating Procedure #9-902G: Reporting of Concerns
- Operating Procedure #9-902H: Animal Husbandry
- Scientific Merit Assessment Form
- Scientific Merit Review Form

#### **4.0 – History of Amendments & Reviews**

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Original approved by SMT September 25, 2019

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