

1. Rationale

- 1.1 The University of Prince Edward Island (UPEI) is accredited by the Canadian Council on Animal Care (CCAC) whose policies and guidelines are followed for all animal based research conducted on campus and/or by people representing the University. Without such accreditation, no federal funding for any field of research can be granted to an institution that uses animals in research, teaching, or testing.
- 1.2 The CCAC requires that animal use for research purposes must consequently be subject to two levels of review:
 - a) an independent, expert peer review of the scientific merit of the research protocol with category 'B', 'C', 'D' or 'E' procedures by independent, expert peers to determine whether the overall proposal has scientific value and is likely to contribute to the body of knowledge in the field;
 - b) a review by the ACC of whether the proposed animal use, as described within an animal use protocol, is acceptable, and whether the proposed animal-based methods are appropriate.
- 1.3 Both levels of review are equally important, and it is also important that:
 - a) the ACC respect the findings of the expert, independent peer review with regard to the scientific merit of the research and refer any questions on scientific merit to the research administration of the institution;
 - b) the researcher whose protocol is being examined by the ACC understands that the ACC will review the protocol with regard to animal-based methods, and collaborates with the ACC to determine the most appropriate methods to be used.
- 1.4 Where funding sources for research projects have competitive peer review processes with appropriate independence and expertise (e.g. federal granting agencies and others), the institution and the UPEI ACC can choose to accept these as providing evidence of scientific merit.
- 1.5 The Chairperson of the UPEI ACC has the option to request additional peer review on any submitted protocol, regardless of the agency funding and the status of peer review. This option is only used if there is a serious concern by the majority of the members of the ACC regarding the particulars of the animal model or experimental design not related directly to the merit of the general scientific content.
- 1.6 The CCAC requires all accredited institutions to have a mechanism to provide scientific merit review for all animal use protocols that have not already gone through a merit review via granting agencies or otherwise.

- 1.7 A Scientific Merit Review (SMR) process is in place at UPEI to ensure appropriate scientific merit review is provided for the ACC Animal Use Protocols (AUPs).

2. Scientific Merit Review Process

- 2.1 The ACC is responsible for initially determining if a protocol already has appropriate scientific merit.
- 2.2 The Chairperson of the SMR Committee is selected by the UPEI Vice President Academic and Research for a three year term and may serve for a maximum of eight consecutive years.
- 2.3 The Chairperson of the SMR Committee will receive AUPs for scientific merit review and will compile the responses received from the reviewers and principal investigator(s).
- 2.4 The Chairperson is responsible for initial review of the AUP to ensure it does not qualify for an appropriate exemption (*see section 4*).
- 2.5 The Chairperson will select at least two potential candidates to perform the required scientific merit review for each AUP. The candidates will remain anonymous to the ACC and the principal investigator(s).
- 2.6 The potential candidates for performing the review:
 - 2.6.1 Will have appropriate experience and/or knowledge in the relevant field, discipline or sub-discipline to adequately review protocol content.
 - 2.6.2 Must be free of real or perceived conflict of interest to the proposed research or investigators involved in the proposed research.
 - 2.6.3 May be the Chairperson, however, the latter will only review Animal Use Protocols if no other reviewer can be engaged to perform the review.
 - 2.6.4 May be from outside the University.
 - 2.6.5 Must agree to maintain confidentiality.
 - 2.6.6 Should not have published with the lead investigator or have any other potential conflict of interest (e.g. personal, financial).
- 2.7 The Chairperson will send a letter of invitation to the candidates to perform the review. Included in the letter will be an explanation of the scientific merit peer review process at UPEI, the reason for selecting the particular candidate and an explanation of conduct required (maintaining confidentiality, destroying materials, etc.).

- 2.8 With a notification from the candidate accepting the terms of the invitation, the AUP will be sent to the invited candidate exactly as presented to the ACC. Accompanying the AUP will be the SMR form (**Appendix 1**) to be completed by the candidate. A requested deadline will also be provided in this communication.
- 2.11 The response from the reviewers will confirm either:
- a) the criteria for scientific merit are met,
 - b) the criteria for scientific merit are met with suggestions/comments but approval not contingent on these,
 - c) the criteria for scientific merit are met with revisions required,
 - d) the criteria for scientific merit are not met.
- 2.12 If the responses unanimously indicate that the protocol meets criteria for scientific merit, the AUP will be deemed to fulfill this requirement and the result will be forwarded to the ACC.
- 2.13 If there is disagreement between the responses where only one review indicates the protocol meets the criteria for scientific merit, a third reviewer will be sought. The result of the three reviews will be forwarded to the ACC.
- 2.14 If the criteria for scientific merit are suggestions/comments:
- a) The reviews which should address any suggestions or comments on the AUP will be provided to the principal investigator. While not a requirement the principal investigator will be informed that the reviewer suggests that the principal investigator consider incorporating the suggested changes. If the principal investigator agrees they should submit an amendment to the UPEI Animal Care Committee indicating the modifications to the protocol.
- 2.15 If the criteria for scientific merit are revisions required:
- a) The reviews which should address any questions or concerns on the AUP will be provided to the principal investigator. The principal investigator will be asked to provide a response to each question. This will be forwarded by the Chairperson to the reviewer(s) who will be asked to acknowledge that the conditions have been addressed.
 - b) The conditions agreed upon by the reviewer and principal investigator will be forwarded to the ACC for attachment to the AUP.
- 2.16 If the responses unanimously indicate that the protocol does not meet the criteria for scientific merit, the protocol will not be deemed to fulfill this requirement and the result will be forwarded to the ACC.

3. Scientific Merit Review Committee Structure

- 3.1 The primary goal of the SMR process is to access reviewers who have the appropriate expertise and the necessary breadth and diversity of knowledge. The process involves the use of an electronic review platform to permit the engagement of reviewers from the scientific community.
- 3.2 The procedure for scientific merit is based on the scholarly peer review process by which experts in the same field of study evaluate the ACC AUPs with the objective of attesting to the probable scientific value of the research. The expectation of the reviews is that they provide an accurate and thorough assessment of the scientific merit of the protocol.
- 3.3 This process allows the committee structure to be comprised of experts from various institutions from around the world
- 3.4 Decisions are normally by consensus; more than 2 reviews will be sought in situations where there is disagreement between the reviews. The majority opinion will prevail, but all communication will be retained and will indicate the minority position. The Chairperson may have the deciding vote in the event of a tie.

4. Exemptions

The following criteria may allow for an exemption from undergoing scientific merit review process.

- 4.1 The AUP involves only animals used in teaching or diagnostic purposes.
- 4.2 For pilot studies, where the rationale for animal use is sound but appropriate scientific design cannot be achieved due to a lack of initial data, the requirement for assessment of scientific merit shall be determined either by the ACC or the SMR Chairperson.
- 4.3 A proposed project is deemed to be an extension of, or supplementary to, a peer reviewed project. In these cases, the AUP must be reviewed prior to the expiry of reviewed grant funding.
- 4.4 Projects described in the AUP have been peer reviewed through a granting agency and determined to have scientific merit, but have not been approved for funding. In these cases the investigator or the University must provide suitable documentation to the SMR Chairperson.
- 4.5 The project carries another form of peer review for scientific merit that is deemed acceptable by the Vice President Academic and Research.

4.6 Authority over exemptions.

4.6.1 Typically the ACC will be responsible for determining if an exemption is warranted, and in such cases will not submit the protocol to the SMR Chairperson.

4.6.2 The SMR Chairperson reserves the authority to determine if an exemption is warranted after the protocol has been submitted for their review. If an exemption from further peer review for scientific merit is applied to an AUP, an explanation from the SMR Chairperson will be forwarded to the Chairperson of the ACC.

5. Research Involving Proprietary Information

5.1 The view of UPEI and the CCAC is that private organizations must be able to demonstrate that their proposed animal-based research has been peer-reviewed for scientific merit.

5.2 The processes described in this document will be applied as necessary to AUPs involving private organizations or proprietary information with particular allowances as follows:

5.2.1 One candidate performing scientific merit review may be from within the research organization providing:

a) The candidate works independently from the particular research group proposing the research.

b) The candidate is not a direct subordinate of anyone listed on the AUP.

5.2.2 Any AUPs involving the use, in animals, of compounds that are not named for proprietary reasons will be reviewed by a Subcommittee of the Scientific Merit. Subcommittee members shall agree to sign confidentiality agreements with the Proprietor involved in the study. The investigator shall provide to the Subcommittee such documents and other information as would allow them to properly judge the scientific merit of the study. The Subcommittee shall consist of the ACC Chair, the University Veterinarian, Biosafety Officer and the Scientific Merit Chair. The Subcommittee has the ability to consult with individuals with expertise in the field of study relating to the AUP when necessary.



Scientific Merit Review Evaluation

Revised Form - July 2017

Canadian Council on Animal Care requires that all animal use protocols be subjected to peer review of scientific merit prior to their approval by the UPEI Animal Care Committee.

Please remember the information in this protocol is strictly confidential and must be treated as such at all times.

Protocol #: _____ File #: _____

Principal Investigator: _____

Protocol Title: _____

Place an "X" in a box and elaborate in space provided.

Question 1 – Specific Aims and Objectives

A) Is there a reasonable, clearly stated hypothesis or set of hypotheses (if applicable)?	Yes	No	N/A
B) Are the experiment(s) outlined able to test the hypothesis(es) stated?	Yes	No	N/A

Comments on hypothesis(es), if any.

C) Is the work outlined feasible?	Yes	No

Question 2 - Rationale

A) Is the rationale for conducting the study clear and scientifically sound?	Yes	No

If no, please comment on how the rationale section could be improved.

Question 3 – Significance of Research

A) Is the study likely to yield results that have scientific merit? (i.e. publication(s), regulatory approval, technical reports, patent, etc.)	Yes	No

If no, please elaborate.

Question 4 – Experimental Design

A) Does the proposed design justify animal numbers?

Yes

No

B) Is the research methodology clearly and adequately described?

Yes

No

If no, to any of the above, please elaborate below.

C) Is the proposed animal model appropriate?

Yes

No

If no, please elaborate below.

D) Has significant justification been provided for the use of animals in this research?

Yes

No

Overall Recommendation

A) Do you approve this protocol for scientific merit?

B) Comments/Suggestions but approval not contingent on these.

C) Are there any conditions upon which this approval is contingent?

Peer Reviewer

This information remains confidential to the Scientific Merit Review Committee.

Name: _____ Work #: (+area code) _____

Name of Institution: _____ Dept. _____

E-mail: _____

Reviewer Signature: _____ Date: _____