

UPEI Scientific Merit Review Subcommittee

Processes and Procedures

1. Rationale

- 1.1 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 any research project or program involving the use of animals undergo scientific merit review 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.
- 1.3 Evidence of scientific merit review is normally provided through granting agencies' application and funding processes.
- 1.4 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.
- 1.5 Working in co-operation with the UPEI Animal Care Committee (ACC), UPEI has in place a Scientific Merit Review Subcommittee (SMRS) whose role is to ensure appropriate scientific merit review is provided to ACC Animal Use Protocols (AUPs).

2. Processes and Procedures

- 2.1 Scientific Merit Review Subcommittee Composition.
 - 2.1.1 Chairperson
 - 2.1.1.1 The Chairperson is selected by the Vice-President, Office of Research & Development (ORD) for a term of no less than one year and no more than three years.
 - 2.1.1.2 The Chairperson is responsible for accepting Animal Use Protocols submitted by the ACC for Scientific Merit Review conducted by the Subcommittee.
 - 2.1.1.3 The Chairperson is responsible for initial review of the AUP to ensure it does not qualify for an appropriate exemption (*see section 4.2*).
 - 2.1.1.4 The Chairperson is responsible for sending invitations to potential reviewers to review protocols and the AUP protocols themselves.
 - 2.1.1.5 The Chairperson is responsible for accepting the completed reviews from the reviewers and forwarding the results to the Chairperson of the ACC.
 - 2.1.1.6 The Chairperson is responsible for calling meetings of the Subcommittee, maintaining the agenda, and compiling the minutes from the meetings.
 - 2.1.2 General Membership
 - 2.1.2.1 Appointed to the Subcommittee shall be one member from each UPEI Department that typically uses animals in research including: Biology, Psychology, Pathology and Microbiology, Health Management, Companion Animals, and Biomedical Sciences.
 - 2.1.2.2 Each member appointment will be made by the Chairperson of the SMRS upon recommendations from the representative Department Chairs, for terms of no less than one year and no more than three years.

2.1.2.3 Adjunct faculty will be accepted to sit on the subcommittee where appropriate.

2.2 Meetings.

2.2.1 Meetings are normally held at least biannually.

2.2.2 The primary purpose of the general meetings is to ensure the Scientific Merit Review Subcommittee is fulfilling its purpose to the ACC and the University with minimal disruption or unnecessary inconvenience to the researchers submitting AUPs.

2.2.3 A meeting may be called to resolve discrepancies or make final decisions on protocol review where the reviewer decisions are unclear or divided. These meetings may be performed over e-mail.

2.2.4 Quorum shall be 50% +1 of the membership.

2.2.5 Decisions are normally by consensus. Where a situation requires a vote, the majority opinion prevails, but minutes must indicate the minority position. The Chairperson has the deciding vote in the event of a tie.

2.2.6 All members of the SMRS accept as a condition of their appointment that deliberations of the SMRS are confidential.

3. Process of Scientific Merit Review

3.1 Animal use protocols are submitted to the ACC as per their published procedures. The ACC is responsible for initially determining if a protocol already has appropriate scientific merit.

3.2 As per Section 7 of the AUP, or by decision of the ACC, a request is forwarded to the Chairperson of the SMRS by either the coordinator or the Chairperson of the ACC to provide scientific merit review.

3.3 In cases where the necessity for scientific merit is questionable, the Chairperson of the SMRS may call for a vote of the SMRS to make the final decision (*see also section 4.2*)

3.4 The Chairperson of the SMRS will alone, or in consultation with the AUP investigator or other members of the SMRS, select at least two potential candidates to perform the required scientific merit review of the AUP.

3.5 The potential candidates for performing the review:

3.5.1 Will have appropriate familiarity in the field of proposed research.

3.5.2 Must be free of real or perceived conflict of interest to the proposed research or investigators involved in the proposed research.

3.5.3 May be a member of the SMRS including the Chairperson.

3.5.4 May be a member of the ACC providing only one such sitting member is selected for review.

3.5.5 May be from outside the University.

3.5.6 Must agree to maintain confidentiality.

- 3.6 Where possible, the Chairperson will utilize lists of potential reviewers as provided by the Vice President, ORD for internal candidates or by other agencies (ex. APICS).
- 3.7 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.).
- 3.8 With a notification from the candidate to accept performing the review under 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 SMRS review form (**Appendix 1**) to be completed and signed by the candidate. A requested deadline will also be provided in this communication.
- 3.9 The Chairperson will receive the reviews and compile the responses.
- 3.10 The responses will confirm:
 - a) the criteria for scientific merit are met,
 - b) the criteria for scientific merit are conditionally met, or
 - c) the criteria for scientific merit are not met.
- 3.11 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.
- 3.12 If there is only one review that indicates the protocol does not meet the criteria for scientific merit the AUP will be distributed to the membership for a vote either electronically or at a meeting (see *section 2.2*). The result of this decision will stand and will be forwarded to the ACC.
- 3.13 If the criteria for scientific merit are conditionally met:
 - 3.13.1 A designation by the reviewer will indicate that an AUP holds scientific merit. However, it would benefit significantly from modifications to the experimental design.
 - 3.13.2 The conditions suggested by the reviewers may be requested of the investigator, with agreement from the SMRS, prior to deeming the protocol as fulfilling the scientific merit requirement.
 - 3.13.3 Comments provided will be forwarded to the ACC.
- 3.14 If the responses unanimously indicate that the protocol does not meet the criteria for scientific merit, the protocol will be deemed not to fulfill this requirement and the result will be forwarded to the ACC.

4. Exemptions

- 4.1 The following criteria may allow for an exemption from undergoing the scientific merit review process.
 - 4.1.1 The AUP involves only animals used in teaching or diagnostic purposes.
 - 4.1.2 Pilot studies where the rationale for animal use is sound, but appropriate scientific design cannot be achieved due to a lack of initial data, soundness of the rationale for pilot studies shall be determined either by the ACC or the SMRS.

- 4.1.3 A proposed project is deemed to be an extension of, or supplementary to, a peer reviewed project.
 - 4.1.3.1 In these cases, the AUP must be reviewed prior to the expiry of reviewed grant funding.
- 4.1.4 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 SMRS.
- 4.1.5 The project carries another form of peer review for scientific merit that is deemed acceptable by the Vice President, ORD.

4.2 Authority over exemptions

- 4.2.1 Typically the ACC will be responsible for determining if an exemption is warranted, and in such cases will not submit the protocol to the SMRS.
- 4.2.2 The SMRS reserves the authority to determine if an exemption is warranted after the protocol has been submitted for their review.
- 4.2.3 If an exemption from further peer review for scientific merit is applied to a protocol by the SMRS, an explanation from the SMRS Chairperson will be forwarded to the Chairperson of the ACC.

5. Research Funded by Private Organizations or Projects 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:
 - 5.2.1.1 The candidate works independently from the particular research group proposing the research.
 - 5.2.1.2 The candidate is not a direct subordinate of anyone listed on the AUP.
 - 5.2.2 Proprietary information may be removed from the AUP prior to submission to reviewers providing the remaining information can still be judged for scientific merit.

APPENDIX 1



Animal Care Committee
 Scientific Merit Review Subcommittee
 Animal Utilization Protocol
 Scientific Peer Review Evaluation

Revised Form – August 2011

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 hypotheses, 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

Question 5 - Concerns or Questions

A) Do you have concerns or questions about this project?

Yes	No

If yes, please describe below.

Overall Recommendation

A) Does this work have scientific merit?

Yes	Yes - Conditionally	No

If "Yes Conditionally", or "No", please outline your concerns below.

Peer Reviewer

This information remains confidential to the Merit Review Committee.

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

Name of Institution: _____ Dept. _____

E-mail: _____

Review Signature: _____ Date: _____