

**UNIVERSITY OF PRINCE EDWARD ISLAND
ANIMAL CARE COMMITTEE
TERMS OF REFERENCE**

ARTICLE I: MISSION STATEMENT

- 1.1** The University Animal Care Committee (the ACC) has general responsibility for ensuring that the use of animals in research, teaching, testing and service at the University conforms to the most rigorous ethical standards that are compatible with the goals of science. The basic ethical principles which it acts to maintain are that no physical or psychological discomfort may be caused to an animal except where there is a clear scientific justification for doing so, and that where such justification exists the level of discomfort caused will be no higher than what is absolutely necessitated by the scientific or educational purposes of the procedure in question. The ACC shall fulfill this responsibility in two ways:
- (a) by reviewing all individual research, teaching, testing and service project proposals involving the use of animals, so as to ensure that the above principles are respected in each case; and
 - (b) by formulating and recommending to the University administration such policies as would aim to preclude wilful or inadvertent violations of the above principles by those working for or affiliated with the University.

ARTICLE II: PREAMBLE

- 2.1** The ACC is a University committee, reporting to the Vice President Academic and Research pursuant to Board of Governors regulations governing the activities of all faculties engaged directly or indirectly in animal research.
- 2.2** The ACC's establishment is in accordance with the requirements of the regulations made under The Animal Health and Protection Act R.S.P.E.I. 1988, Cap. A-11.1. Section 5 of the regulations says:
- 5. With respect to the use of animals for the purposes of medical or scientific research, the standards of care should be those contained in the Guide to the Care and Use of Experimental Animals, Volumes I and II, published by the Canadian Council on Animal Care, 1993 (CCAC Guide). Volume I of the CCAC Guide requires that institutions carrying out animal research have an animal care committee reporting to the appropriate administrative officer at the institution.*
- 2.3** The ethical principles guiding the ACC are in accord with the recommendations of the CCAC, and shall be reviewed whenever new recommendations on ethics are forthcoming from that body or from relevant statutory agencies such as the Canadian Institutes of Health Research or the Natural Science and Engineering Research Council.
- 2.4** The procedural responsibilities of the ACC are in accord with the recommendations of the CCAC, and shall be reviewed whenever new recommendations on procedures are forthcoming from that body or from other relevant statutory agencies.

- 2.5** The ACC's domain of responsibility includes all research, teaching, testing and service, collection procedures. This includes the use of animals both at UPEI and its affiliated institutions, and those obtained from or studied in the field by University and affiliated personnel. It also includes activities involving animals conducted in or at University facilities by organizations or individuals from outside the University.
- 2.6** In order to ensure that animals are utilized only in necessary and valid research projects, any research proposal which would utilize animals must undergo peer review for scientific merit. The ACC may recognize a review conducted by the granting agency if such granting agency commonly conducts a peer review based on its own established procedures (e.g., Canadian Institutes for Health Research). Where funding is obtained internally or from a granting agency without approved peer review procedures, the ACC may establish procedures for review. These procedures should be conducted according to the most recent CCAC policy statement on: scientific merit and ethical review of animal-based research.

ARTICLE III: COMMITTEE MEMBERSHIP AND MEETINGS

3.1 The Committee shall be comprised of UPEI faculty members experienced in animal care and use as noted below:

- the Director of Animal Resources
- the University Veterinarian
- the Biosafety Officer
- at least one representative from each department that uses animals
- at least one representative from a department(s) that does not use animals
- at least one person who represents the community's interest and concerns and who has no other affiliation with the institution
- technical staff representation
- student representation, and
- a chair, who must not be directly involved in the management of the institutional animal facilities, nor be the laboratory animal veterinarian, nor be involved in the preparation of a significant number of the protocols under review by the Animal Care Committee

3.2 The University Vice President Academic and Research and ACC Chair will be responsible for maintaining diverse representation on these committees.

3.2.1 The ACC will make recommendations to the Vice President Academic and Research for appropriate members based on gaps in expertise and the Vice President Academic and Research will make the invitations to the potential members and will inform department chairs. Members would include: departmental (animal users and non-animal users), chair, community, and technical staff. The NRC-Charlottetown representative will be chosen by the institute. DVM students will apply and the ACC will choose the representative. The graduate student representative will be chosen by their peers. The ACC will forward the NRC-Charlottetown, DVM and graduate student names to the Vice President Academic and Research.

3.3 All duly appointed members shall be entitled to vote on resolutions of the ACC.

- 3.4** Members, other than students, shall be appointed for 3 year terms and may serve on the ACC for a maximum of 8 consecutive years. Students shall be appointed for one year terms and they shall be eligible for re-appointment.
- 3.5** Meetings shall be held on a monthly basis except for the month of December. Additional meetings may be held at the call of the Chair.
- 3.6** A quorum shall be 50% + 1 of the members of the ACC and must include the Community Representative and the University Veterinarian or designate.
- 3.7** 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.
- 3.8** Appeals of negative decisions of the ACC may be made according to the procedure outlined in Article VIII: Appeal Mechanism.
- 3.9** All deliberations, discussions and decisions of the ACC are subject to the University Board of Governors rules and guidelines on ethics, conflict of interest, disclosure and confidentiality. All members of the ACC accept as a condition of their appointment to the ACC that deliberations of the ACC are confidential and subject to these rules and guidelines.

ARTICLE IV: AUTHORITY

- 4.1** The ACC has the authority to:
- stop any objectionable procedure if it believes that unnecessary distress or pain is being experienced by an animal.
 - immediately stop any use of animals which deviates from the approved use, any non-approved procedure, or any procedure causing unforeseen pain or distress to animals.
 - have an animal euthanized if pain or distress caused to the animal cannot be alleviated.
- 4.2** The University Veterinarian, acting on behalf of the ACC, may at any time initiate any of the actions outlined in Section 4.1 without prior consultation with the ACC. Such actions will be reported to the ACC at its next scheduled meeting.

ARTICLE V: RESPONSIBILITIES OF THE ACC

- 5.1** The ACC has the following responsibilities:
- 5.1.1 To develop and promote standards, guidelines and procedures relating to the use of animals in research, teaching, testing and service at or for the University, which follow the CCAC Guidelines;
- 5.1.2 To assist the university community in obtaining information on and encouraging the use of alternatives to animals in research, teaching, testing, or service programs;
- 5.1.3 To inspect and undertake site visits of the University facilities as often as the ACC considers necessary, but at least annually, and monitor animal care procedures to ascertain that the facilities are kept to a standard that ensures continuous compliance

with CCAC guidelines; to ensure that written recommendations or commendations are sent to the person(s) responsible for the facilities and those responsible for the animal facilities respond to any ACC recommendations in writing; to ensure that site visit reports are always followed up on jointly by the Senior Administration and the ACC;

- 5.1.4 To establish procedures and be responsible for reviewing and approving Animal Utilization Protocols (AUPs); to co-ordinate and review procedures for the prevention of unnecessary suffering and the use of anaesthetics and analgesics;
- 5.1.5 To ensure that all AUPs have been properly evaluated by independent review and judged to have scientific and/or pedagogical merit;
- 5.1.6 To ensure that no research, teaching, testing or service involving animals be commenced without prior ACC approval of a protocol; further to this, that no animals be acquired or used before such approval.
- 5.1.7 To ensure that no animals be held for display or breeding purposes, or for eventual use in research, teaching, testing or service projects, without prior ACC approval of a written AUP;
- 5.1.8 To require adherence to CCAC guidelines and any guidelines issued by the ACC for the use of animals in teaching, particularly with respect to the multiple use of teaching animals. For teaching programs, a course number and an indication of instructional merit shall be included in the AUP.
- 5.1.9 To review and assess all AUPs through discussion at full committee meetings, with particular emphasis on the care and welfare of animals used in research, teaching, testing or service projects and, where necessary, require further supportive information from the investigator or meet with the investigator, to assure that all members of the ACC understand the procedures to be used on the animal.
- 5.1.10 To assure that all animal users have the opportunity to become familiar with the CCAC Guide including the "Ethics of Animal Experimentation", and any other statutes that may apply, and University requirements;
- 5.1.11 To ensure that animal users update their AUPs with any intended modifications, and inform the ACC of any unanticipated problems or complications encountered;
- 5.1.12 To ensure adequate care of animals in all stages of their life and veterinary assistance in case of sickness, injury and elective procedures. AUPs shall include a description of end point(s) of the experimentation, selected according to the most recent CCAC guidelines on: "Choosing an appropriate end point in experiments using animals for research, teaching, and testing."
- 5.1.13 To encourage pilot studies using a minimal number of animals when new approaches, methods, or products are being tried, before approving new, larger scale protocols. An indication of whether the study is acute or chronic is required. Pilot studies are valid only for one year, they cannot be renewed.

- 5.1.14 To ensure that testing projects have been planned according to the most current regulatory guidelines, and that the planned animal use does not exceed the requirements of the regulatory authorities; if it does, justification for the additional animal use must be provided.
- 5.1.15 To maintain liaison with: 1) the CCAC Secretariat, and inform the Secretariat of any changes to the program; 2) the senior administrator responsible for animal care and use; 3) the chairperson of the ACC, or the veterinary or senior animal care personnel.
- 5.1.16 To submit complete and accurate animal use information in the CCAC Animal Use Data Form (AUDF) format for all protocols annually (animal use information for each calendar year must be submitted by March 31 of the following year) and also in pre-assessment documentation.
- 5.1.17 To review and approve ACC related Standard Operating Procedures (SOP) and maintain an active SOP Databank that is available to all animal users.
- 5.1.18 To ensure the Post Approval Monitoring Program is administered.
- 5.1.19 To ensure that only competent individuals are permitted to handle animals.

ARTICLE VI: PROCEDURES OF THE ANIMAL CARE COMMITTEE

- 6.1** The ACC shall meet monthly except for the month of December. Additional meetings may be held at the call of the Chair.
- 6.2** The ACC shall require that all University personnel and University affiliated research teams who are planning to use animals for teaching, service or research, complete and submit to the ACC an animal utilization protocol (AUP), where the principal investigator normally would hold a faculty appointment or be emeritus or be a sessional faculty member. The deadline for submission of new, renewal or amended AUPs is the first Friday of the month. All submissions that meet the deadline will be considered at that month's meeting of the ACC. The ACC will maintain the AUP on file.
- 6.3** The ACC shall develop, review and approve ACC Standard Operating Procedures (SOPs). SOP review may be delegated to ACC members with the appropriate expertise, but SOPs should be accessible to all ACC members, and the full ACC should review all SOPs that involve procedures that may result in deleterious effects to animal health or welfare. ACC SOPs are to be reviewed at least every three years.
- 6.4** Minutes reporting all ACC discussions and decisions shall be produced for all ACC meetings, and a copy of those minutes shall be forwarded to the Vice President Academic and Research.
- 6.5** The ACC shall submit its terms of reference to the Vice President Academic and Research for approval. Amendments to these terms of reference may be considered and approved by majority vote of the members of the ACC and such amendments shall take effect upon the submission of the proposed amendments and approval by the Vice President Academic and Research.

ARTICLE VII: PROTOCOL REVIEW PROCESS

- 7.1 Principal investigators of AUPs that are about to expire are reminded 2 months in advance of the expiry date by the ACC Administrative Assistant of the need to file a renewal form.
- 7.2 The agenda and AUPs received prior to the monthly submission deadline shall be provided to all members on the Committee at least one week in advance of the meeting.
- 7.3 New submissions shall be reviewed by the full ACC, at the monthly meeting. Each protocol description shall be in the form approved by the ACC and shall be available from the Administrative Assistant to the ACC or from the Chair of the committee.
- 7.4 Annual renewals, submitted on the abbreviated form, shall be reviewed by the full ACC, at the monthly meeting.
- 7.5 New AUPs must be submitted after 3 annual renewals. These are reviewed by the full ACC, at the monthly meeting.
- 7.6 Amendments shall be submitted to the ACC on the appropriate form. Minor amendments can be submitted anytime but require up to a two week review period. Major amendments shall be reviewed by the full ACC, at the monthly meeting.
- 7.7 **“Minor” Amendments**
Minor amendments are unlimited. Minor amendments are defined as changes that are minimally invasive with no significant impact on animal welfare. Minor amendments are normally reviewed by the ACC Chair, University Veterinarian and Biosafety Officer and they have the discretion to recommend that minor amendments be reviewed by the full ACC when deemed necessary. Minor amendments submitted at the same time and for the same protocol as major amendments will be directed to a full ACC meeting. Approximately a two week period shall be given to review minor amendments. The ACC Chair will sign off on the approved minor amendments and will also send e-mail notifications to the investigator or instructor. Minor modifications will be documented in ACC meeting minutes.
- Minor Amendments include the following (this list is not exhaustive):
- 7.7.1 Addition or removal of principal instructor(s) or faculty on **teaching and service** animal use protocols (AUPs);
- 7.7.2 Changes in personnel **on all AUPs** carrying out procedures;
- 7.7.3 Reasonable additions to approved animal numbers with adequate justification (a total increase of 20% or less in animal numbers from the original protocol); an addition of a new strain of the same species;
- 7.7.4 Protocol extension up to and less than one month;
- 7.7.5 Change in funding (provided it does not impact scientific merit peer review);
- 7.7.6 Change in animal source/supplier (consultation with Facility Manager is required);
- 7.7.7 Change in animal use location (consultation with Facility Manager is required);

- 7.7.8 Change in protocol title or course number and name (which does not change the intent of the protocol);
- 7.7.9 Implementations to procedural refinements in drugs (where the effects on the animals are commonly thought to be equivalent or better), housing, handling, substance administration or sample collection.
- 7.8 “Major” Amendments**
Up to three major amendments can be requested over the duration of the protocol, any further major amendments will require a new protocol. Major amendments are defined as all amendments that do not qualify as minor amendments and will be directed to a full ACC meeting
- 7.9 Proposed Amendments that Constitute a New Protocol Submissions include:**
- 7.9.1 A change in the main objective of the study/course/service or a change in the direction of the research (hypotheses and objectives) from those described in the grant request and/or in the existing animal use protocol;
- 7.9.2 Change of principal investigator(s) on research AUPs.
- 7.9.3 Multiple major amendments to the original approved parent protocol;
- 7.9.4 Addition of a level “E” category of invasiveness procedure. (This will generally require the submission of a pilot protocol).
- 7.10** Peer review for scientific merit shall be sought for all research protocols with category “B”, “C”, “D” or “E” procedures if not funded by agencies that conduct thorough independent peer review of all research proposals. In addition, regardless of the funding source, peer review for scientific merit may be sought for any AUP where, in the judgment of the ACC, the specifics of animal use have not been adequately justified or explained. Peer review for scientific merit where warranted will be the responsibility of the Scientific Merit Review Committee (SMR).
- 7.11** The ACC is responsible for initially determining if a protocol already has appropriate scientific merit. The Chairperson of the SMR Committee will receive all AUPs requiring scientific merit review evaluation. The Chairperson is responsible for initial review of the AUP to ensure it does not qualify for an appropriate exemption. 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).
- 7.12** The potential candidates for performing the review:
- 7.12.1 Will have appropriate experience and/or knowledge in the relevant field, discipline or sub-discipline to adequately review protocol content.
- 7.12.2 Must be free of real or perceived conflict of interest to the proposed research or investigators involved in the proposed research.
- 7.12.3 May be the Chairperson, however, the latter will only review Animal User Protocols if no other reviewer can be engaged to perform the review.
- 7.12.4 May be from outside the University.

- 7.12.5 Must agree to maintain confidentiality.
- 7.12.6 Should not have published with the lead investigator or have any other potential conflict of interest (e.g. personal, financial).
- 7.13** The Chairperson of the SMR 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.).
- 7.14** Upon 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 to be completed by the candidate. A requested deadline will also be provided in this communication.
- 7.15** The Chairperson of the SMR will receive the reviews and compile the responses.
- 7.16** The responses will confirm:
- 7.16.1 the criteria for scientific merit are met,
- 7.16.2 the criteria for scientific merit are met with suggestions/comments but approval not contingent on these,
- 7.16.3 the criteria for scientific merit are met with revisions required,
- 7.16.4 the criteria for scientific merit are not met.
- 7.17** 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.
- 7.18** 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.
- 7.19** If the criteria for scientific merit are suggestions/comments:
- 7.19.1 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.
- 7.20** If the criteria for scientific merit are revisions required:
- 7.20.1 The reviews which should address any questions or concerns with 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.

- 7.20.2 The conditions agreed upon by the reviewer and principal investigator will be forwarded to the ACC for attachment to the AUP.
- 7.21** 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.
- 7.22** All teaching AUPs involving the use of live animals require pedagogical merit. Pedagogical Merit Review (PMR) must be assessed by Departments prior to submitting a new Animal Utilization Protocol (AUP) Teaching Form to the ACC.
- 7.20.1 The PMR Form and AUP Teaching Form and any other pertinent information (i.e., course material, lab manual or other relevant material) are submitted to the Department Chair.
- 7.20.2 After the PMR Form has been approved it is attached to the hard copy of the AUP Teaching Form and submitted to the ACC.
- 7.23** An AUP must be reviewed and approved by the ACC prior to the use of live animals in courses offered by the University of Prince Edward Island.
- 7.24** To view post-approval monitoring (PAM) process refer to <http://www.upei.ca/research-services/research-certifications/animal-care>.
- 7.25** To view ACC-CP-12 Codes of Practice - Animal Based Projects Involving Two or more Institutions refer to <http://www.upei.ca/research-services/research-certifications/animal-care>.
- 7.26** Any AUPs involving the use, in animals, of compounds that are not named for proprietary reasons will be reviewed by a Subcommittee of the ACC. 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 potential hazards to animals. The Subcommittee shall consist of the ACC Chair, the University Veterinarian, Biosafety Officer, and 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. The Subcommittee also has the ability to invite other members of the ACC to participate when necessary.
- 7.27** The ACC shall give AUPs either approved, conditionally approved, deferred, withdrawn or rejected status. Approval shall be for a maximum of one year less one day. The ACC Chair informs the principal investigators of the decisions taken by the ACC normally within 2 days after the monthly meeting.
- 7.27.1 Conditional approval is given to protocols in which some detail is missing. Conditional approval may be changed to an approved status once the additional information requested from the principal investigator by the ACC has been received by the Chair.
- 7.27.2 Deferred status is given to protocols that require major revisions.
- 7.27.3 If revisions are requested they should be submitted to the ACC Administrative Assistant as soon as possible. Minor revisions will be reviewed and responded to by the ACC Chair, where major revisions will be considered at the next monthly ACC meeting.

7.27.4 If revisions are not received within 3 months, the application will be closed and a new application will be required.

7.27.5 Purchase / use of animals can only begin once the investigator has received a Certificate of Approval from the ACC Chair by email.

7.28 It is the responsibility of the investigators and staff named on the AUP to report concerns of animal welfare, animal health, deviations in approved animal use or any other factors affecting animal care to the University Veterinarian, in a timely manner.

ARTICLE VIII: APPEAL MECHANISM

8.1 Researchers or course coordinators may appeal negative decisions of the Animal Care Committee.

8.2 Appeals shall be made in writing to the Vice President Academic and Research within 2 weeks of notification of the decision. The Vice President Academic and Research shall proceed to strike an ad hoc Appeals Committee whose composition shall reflect that of the ACC (i.e., to include, at minimum, a scientist, a veterinarian, and a community representative.)

8.3 The mandate of the Appeals Committee shall be to approve or reject the protocol, as submitted.

8.4 The Appeals Committee shall have access to all documentation related to the protocol in question, and may interview members of the ACC or the appellant, as necessary.

8.5 Normally, the Appeals Committee shall render its majority decision to the President of the University (or designate) within one month.

8.6 This decision is final.

ARTICLE IX: CHAIRPERSON

9.1 The Chairperson of the ACC is selected in accordance with the rules governing University committees upon the recommendation of the Vice President Academic and Research for a term of three years, with the possibility of renewal.

9.2 In the event of his or her absence the Chairperson may designate another member of the ACC to serve temporarily as Chairperson. In the event of the incapacity of the Chairperson, the Administrative Assistant of the ACC shall hold a poll of the committee members for the designation of an interim Chairperson who shall be responsible to call a meeting within 6 weeks of the interim appointment. The first item on the agenda of that meeting shall be the election by majority vote of the replacement Chairperson of the ACC. Every ACC must have a chair who should not be directly involved in the management of the institutional animal facilities, nor be a clinical veterinarian for the institution, nor be an animal health or veterinary personnel member charged with ensuring compliance with CCAC guidelines, nor be involved in the preparation of a significant number of the protocols to be reviewed by the Committee.

- 9.3 The ACC Administrative Assistant in consultation with the Chairperson is responsible for preparing minutes and agendas for the meetings of the ACC.
- 9.4 Administrative policy with respect to the relationship between the ACC and those applying for ACC approval of AUPs is the responsibility of the Chairperson.
- 9.5 Where issues of ACC policy are concerned, the Chairperson will be the public spokesperson of the ACC.
- 9.6 The Chairperson advises the applicants to the ACC and the appropriate Deans, where necessary, of ACC decisions concerning AUPs, and signs all approvals, renewals and denials of protocols and amendments to protocols.
- 9.7 The Chairperson shall ensure that the ACC maintains records of its decisions regarding AUPs in a manner satisfactory to the CCAC.
- 9.8 The Chairperson shall ensure that renewal/continuance forms for on-going AUPs are reviewed by the committee.
- 9.9 The Chairperson shall act as advisor to the Vice President Academic and Research in matters of animal care and as liaison with the CCAC.

ARTICLE X: ANIMAL CARE CRISIS MANAGEMENT PROGRAM & PLAN

- 10.1 The Canadian Council on Animal Care requires that all institutions which use experimental animals have in place a crisis management program for their animal facilities and for their animal care and user program. The crisis management plan is meant to offer supplemental instructions on the care of animals owned by the University in the event if a serious crisis and is meant to be implemented in conjunction with the general institutional crisis management plan which is in the UPEI Emergency Response Plan.