

BROCK UNIVERSITY ANIMAL CARE COMMITTEE: TERMS OF REFERENCE

Preamble:

The Brock University Animal Care Committee (herein termed ACC) is responsible for ensuring that research, teaching, or testing involving animals conducted at Brock University complies with the Animals for Research Act (Province of Ontario), the guidelines and policy statements of the Canadian Council on Animal Care (CCAC), and any other relevant municipal, provincial or federal laws or guidelines.

Research and teaching activities involving animals are critical to the mission of Brock University. The University works with the ACC to ensure that all the animal users and animal care staff are informed of and comply with, the Canadian Council on Animal Care (CCAC) policies, Ontario Ministry of Agriculture, Food and Rural Affairs Animals for Research Act, and the Canadian Association for Laboratory Animal Medicine (CALAM) Standards of Veterinary Care, along with all applicable legislation and institutional animal care and use policies. The ACC advises, reports to, and is supported in its work by the Vice-President, Research-and adheres to University policies as outlined in the Faculty Handbook, Section 3, Subsection C, Policy Statement 2.3: Animal Care and Use. The committee's functions are indicated by the following Terms of Reference.

1. Appointment Process

The Vice-President Research will be responsible for appointing members to the ACC. Recommendations may be based upon input provided by the current ACC.

2. Membership

- a) The ACC membership and representation consists of:
 - i. At least one representative from each department with one or more researchers active, or with a record of activity, in research involving animals, to be nominated by the Department Chair; with a mandate to solicit input from and communicate relevant non-confidential ACC information to departmental researchers;
 - ii. At least one representative from a department whose normal activities (past or present) do not depend on or involve animals in research, teaching or testing;
 - iii. At least one, and preferably two, community representatives not affiliated with the University who will represent community interests, concerns, and who have not in past or present engaged in research or teaching involving animals;



- iv. A veterinarian(s), experienced in laboratory animal medicine (appointed member, *ex officio*);
- v. Two student representatives preferably graduate and/or honors undergraduate, from either of the animal users' departments who have experience in research involving animals, nominated by Department Chairs in consultation with the Chair of the ACC;
- vi. The Manager, Animal Care Services (ACS) (*ex officio*,) who is designated by the Vice-President, Research, as the person in charge of animal care and management of the animal facilities, and who keeps the ACC updated on the activities within the animal facilities.
- vii. Animal Care Committee Coordinator
- viii. A representative from the Health, Safety and Wellness department (ex officio); and
- ix. Technical staff representation from Animal Care Services (ex officio).
- b) Members are normally appointed for a term of no less than two years and no more than four years, renewable at the VPR's discretion to a maximum of eight consecutive years. This does not apply to ACC members whose membership on the ACC is associated with job related duties at Brock (ex officio members: the ACS Manager, ACC Coordinator, Veterinarians and Health Safety, and Wellness).
 - Student representation should be appointed for a term of no less than one year. At no time will more than 50% of the committee change at one time. Members may resign their position by written letter to the Chair.
- c) The VPR in consultation with the membership, will appoint a Chair and Vice Chair of the ACC from among its members as defined above. The Chair of the ACC is appointed for a three-year term, and the Vice-Chair for a two-year term. ACC Chairs are limited to a maximum of three consecutive terms with the third term being limited to a two-year term.

The Chair will not be directly involved in the management of the institutional animal facilities, nor be a clinical veterinarian for the institution, nor be animal health or veterinary personnel charged with ensuring compliance with CCAC guidelines, nor is involved in the preparation of a major number of protocols to be reviewed by the committee, in order to avoid potential conflicts of interest.

The Vice-Chair ordinarily will not have formal duties beyond remaining apprised of current ACC and Chair business. When the Chair is absent; is unable to act in response to urgent ACC business; or is in, or under review for, a conflict of interest, the Vice-Chair will serve pro term as the Chair in all relevant matters.

d) Interim approval sub-committee which must include at least one scientific member, one veterinarian and one community representative, and the ACC Chair or designate.



Interim approvals will be used infrequently and only when absolutely necessary. The interim review process, including exchanges between the ACC and the protocol authors, will be documented and then subject for discussion and final approval at the full meeting of the committee.

3. Authority

The ACC has the authority, on behalf of the Vice-President Research, who is responsible for animal care and use for the institution, to:

- a) Stop any procedures if it considers that unnecessary distress or pain is being experienced by an animal;
- b) Immediately stop any use of animals which deviates from the approved use, or any non-approved procedure;
- c) Ensure that if pain or distress caused to an animal cannot be alleviated, the animal will be humanely euthanized;
- d) Ensure the University's consulting veterinarian(s) has the authority to treat, remove from a study or euthanize, if necessary, an animal according to their professional judgment. The consulting veterinarian(s), either directly or in consultation with the Manager ACS, must, whenever possible, attempt to contact the animal user who is responsible for the animal prior to beginning any treatment that has not previously been agreed upon and must also attempt to contact the ACC Chair. The veterinarian can however proceed with any necessary emergency measures whether or not the animal user and Chair are available. While decision-making rests with the veterinarian, if warranted, emergency actions can be delegated to the ACS Manager, but this would occur only in exceptional circumstances and only if the consulting veterinarian is not available. Attempts to contact the veterinarian, the animal user and the Chair must be documented. A written report should be sent by the veterinarian(s) or the ACS Manager, to the animal user and to the ACC following any such event;
- e) The Chair of the ACC and the veterinarian(s) must have access at all times to all areas where animals are or may be held or used.

4. Responsibility:

It is the responsibility of the ACC to:

 a) Ensure that no research, testing project or teaching program involving animals (including field studies) commences without ACC review and approval in the form of a written Animal Use Protocol (AUP), and that no animals are procured or used prior to such approval;



- b) Ensure that no animals be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior ACC approval of a written AUP;
- c) Ensure that appropriate care of animals in all stages of their life and in all experimental situations is provided via the support of consulting veterinary services. Responsibility for securing veterinary services, ensuring that the appropriate standards and qualifications are met, defining roles and responsibilities and all other aspects of the contractual arrangements rests with the VPR office. These formal arrangements are based on the elements contained in the CALAM Standards of Veterinary Care (2020) which defines the roles and responsibilities of veterinarians involved in scientific animal care programs;
- d) Develop procedures which are commensurate with current veterinary standards and ensure that:
 - i. Unnecessary animal stress and injuries leading to pain or distress are avoided:
 - ii. Anesthesia and analgesia are properly and effectively used; the only exception to this may be when agents must be withheld as a scientifically justified requirement of the study that has been approved by the ACC;
 - iii. Appropriate post-operative care is provided;
 - iv. Exceptional consideration is given to animal welfare, including environmental enrichment;
- e) Review and assess all AUPs, with emphasis on the CCAC's guide to the care and use of experimental animals (Section 5), CCAC policy statement on ethics of animal investigation, and CCAC and ACC policies, procedures, and guidelines, where necessary;
- f) Ensure that for both research and teaching protocols, a peer review for scientific and/or pedagogical merit is carried out. If peer review of research projects is not carried out by an external peer review agency, the ACC requires that a peer review be conducted according to the CCAC policy on scientific merit and ethical review of animal-based research, and the mechanism in place is conducted via the Office of Research Services as per standard operating procedure (SOP) AUPO2 Assessment of protocols in absence of peer review from a funding agency;
- g) Ensure that all personnel working with animals are trained and qualified in animal care and use. Prior to conducting activities related to research or teaching involving animals, all personnel must receive appropriate training in accordance with guideline requirements (CCAC guidelines on: training of personnel working with animals in science, 2015) and must be associated with an AUP. The Brock University Animal User Training Program is overseen by the ACS Manager who maintains a training database, and liaises with principal investigators (PIs), students and the ACC. Training that animal users receive either within the institution or via external institutions is



reported to, assessed by and recorded by the ACC;

- h) Encourage the use of pilot studies when new approaches, methods or products are being developed. Pilot studies can be developed as part of an AUP or requested by the ACC as part of the approval process for a new AUP. The ACC requires that animal users report back results from a pilot study to the ACC prior to moving forward with the main study;
- i) Review, revise and when appropriate approve SOPs that directly impact animal welfare. SOPs reviewed by the ACC will be reviewed at least once every 3 years;
- j) Oversee the post-approval monitoring (PAM) program. PAM activities are described in SOP COMP01 Post approval monitoring program. Any breaches of compliance found during the PAM audits that cannot be sufficiently resolved by the ACC must be referred to the Vice-President Research, who will mediate the discussion between the ACC and the PI;
- k) Document all ACC discussions and decisions in the committee minutes/notes and on attachments to the applications to use animals for research or teaching forms;
- Ensure all animal users have the opportunity to become familiar with the CCAC's guidelines and policy statements as well as all applicable federal, provincial, municipal, or institutional regulations that may apply;
- m) Ensure that animal users report to the ACC any unanticipated problems or complications, as well as the steps taken to address these issues;
- n) Develop procedures for investigating reports of non-compliance. All faculty members, staff, and students must adhere to all current ACC and CCAC policies, procedures, and guidelines. The PI named on the AUP is ultimately responsible for the care and welfare of the animals contained in the AUP;

To inspect and undertake site visits of the University animal facilities as often as the ACC considers necessary, but at least annually, to ensure that the facilities are kept to a standard that is in 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. Processes for Animal Use Protocols



- a) It is required that all animal users complete an AUP form and ensure that the information therein includes the following points, and that they are clearly presented in a form that all members of the ACC can readily understand:
 - i. project title, descriptive procedural keywords, and a brief description of the procedures to be conducted on animals;
 - ii. principal investigator/instructors, and all personnel (post-doctoral fellows, research staff, graduate, and undergraduate students) who will handle animals, along with their training/qualifications and department affiliation;
 - iii. all animal information including species, strains, and numbers for the 4-year life of the protocol should be included;
 - iv. for research or testing projects, funding source(s) and status of funding approval
 - v. for research projects, an indication of whether the project has received peer review for scientific merit;
 - vi. for teaching programs, a course name, number, and an indication of whether the course has been reviewed with respect to the pedagogical merit:
 - vii. for testing projects, an indication that the testing has been planned according to the most current regulatory requirements, using guidelines acceptable to the regulatory agency(ies) and which meet the requirements of the CCAC Policies; that the planned animal numbers used not exceed the requirements of the regulatory authorities if it does, justification for the additional animal use must be provided;
 - viii. lay summary;
 - ix. an indication of the use of biohazardous, hazardous chemical or radioactive agents in animal-based projects;
 - x. category(ies) of invasiveness and Purpose of Animal Use (PAU) as defined in the CCAC Guidelines;
 - xi. the Three Rs (**replacement**, **reduction and refinement** alternatives) of animal use, to include:
 - justification of why sentient animals must be used for the project, how the applicant arrived at this conclusion (e.g., searches of databases on alternatives). Consideration of putative replacement alternatives (e.g., non-animal methods, cell/tissue culture, computer simulations, audiovisual teaching methods, the replacement of sentient animals with animals of lower sentiency) and justification if these are not to be employed;
 - justification of the species and numbers of animals to be used over the
 course of the year, to emphasize reduction of animal use within an
 appropriate experimental design, while ensuring that sufficient numbers
 of animals will be used to fulfill requirements for statistical
 significance/scientific validity in the case of research projects, or for
 acceptance of regulatory tests;



- awareness of of the potential **refinements** to be employed to protect and enhance animal health and welfare, which may include:
 - additional anesthesia and analgesia, including dosages and methods of use;
 - other medical treatments as appropriate, as indicated through veterinary consultations;
 - housing and husbandry methods, which should include environmental enrichment as a means to refine animal care; any limitations on environmental enrichment from that standardly offered to animals in the institution, must be justified to the ACC;
 - refinements to the procedures to be employed on the animals;
 - refinements to the length of time that animals will be held/used;
 - any other possible refinements;
- xii. a description clearly detailing all of the procedures that are carried out on animals (referring to appropriate SOPs when applicable);
- xiii. a description of the endpoint(s) of the experimentation, selected according to the CCAC guidelines on: Identification of scientific endpoints, humane intervention points, and cumulative endpoints. The individuals(s) responsible for monitoring the animals and applying endpoints must be identified, and the schedule for monitoring animals and any relevant monitoring sheets should be included; all protocols, even non-invasive ones, must identify endpoints, to ensure that any animals requiring treatment are treated and that animals are not simply kept indefinitely; relevant information for identifying and applying endpoints must be readily available, preferably posted, in the area where the animal-based work is taking place;
- xiv. a description of capture, restraint, transportation and/or housing of animals used in field studies, as well as any other information pertinent to field studies, such as capture of non-target species, ecological impacts and potential injuries or mortality during capture or transportation, if relevant;
- xv. the method of euthanasia, if used; justification for any conditionally acceptable euthanasia methods, or for any methods that deviate from those described in the most recent CCAC guidance on euthanasia;
- xvi. a description of the fate of the animals if they are not to be euthanized, including the length of time that they are to be held;
- xvii. any other information considered important or necessary and pertinent.
- b) Review all protocols annually, within a year of commencement of the project; annual renewals may be approved via the entire ACC or subcommittee and should be tabled at the next scheduled ACC meeting.

Protocol renewals must include:

- i. the number of animals used in the preceding year;
- ii. the number of animals needed for the year to come (must be consistent with the AUP);



- iii. a brief progress report, describing any complications encountered relative to animal use (unpredicted outcomes, and any unanticipated negative welfare impact and mortality), any amendments to the original protocol, and any progress made with respect of the three Rs of replacement, reduction and refinement of animal use;
- iv. a brief report on the adequacy of the endpoints for the protocol, and on any complications encountered or refinements made;
- v. any other changes from the original protocol.

Require the submission of a full protocol after a maximum of three consecutive renewals.

- c) Ensure that animal users update their protocols with any modifications they intend to make, and approval is granted before they are implemented.
 - Minor amendments are normally those which reflect changes that do not significantly influence the welfare of animals. These changes require submission of amendment form which will be appended to the AUP by the ACC Coordinator and can include:
 - i. Changes to personnel associated with an AUP;
 - ii. Increases in animal numbers of up to 20% or the addition of new non-invasive procedures that are designed to better achieve the general objectives of the project as defined in the approved AUP.

Minor amendments of a protocol may be approved by the ACC Chair or subcommittee. Minor amendments will be provided for information to the full ACC at the subsequent ACC meeting.

Major amendments are defined as changes that may be considered invasive and may have an impact on animal welfare.

Major changes normally include:

- i. change in the lead researcher;
- ii. changes in animal numbers greater than 20%;
- iii. change of species;
- iv. significant change in or more invasive procedure.
- v. increase in the level of invasiveness.

The applicant submits the amendment request form to the ACC Coordinator who reviews for completeness, and if complete will distribute the application to the entire ACC for review at the next scheduled ACC meeting. Major amendments must be approved by the full ACC.



d) The ACC discusses protocols and amendments during full Committee meetings. The ACC arrives at decisions by consensus following discussion. The ACC will work with protocol authors as required until the content of the AUP has satisfied any conditions or clarifications requested by the ACC. All members of the ACC must be reasonably satisfied that the work has been refined as much as possible and that safeguards are in place for the animals.

The ACC decision categories for proposed AUPs are:

Approval:

• AUP activities can proceed, subject to annual review and renewal for a maximum of four (4) years.

Conditional Approval:

- Given for AUPs where the committee is satisfied with the rationale, compliance with CCAC and Brock policies but requires revisions of a minor nature in order for the proposed AUP to reach full approval.
- The revisions that are required will be specific, documented and communicated to the PI by the ACC Coordinator.
- The revisions can be approved by the sub-committee and Chair
- Under the conditional approval status, no animal related activities are permitted.

Interim Approval:

- Given under exceptional circumstances, and as judged by those delegated by the ACC (see Interim Approval 2d).
- This level of approval allows the activities described in the AUP to proceed but is subject to review by the full ACC at its next meeting where either conditional or full approval will be granted.
- In exceptional circumstances direct interim approval can be given by a subcommittee of the ACC. The subcommittee consists of the Chair, the Consulting Veterinarian(s), the Community Representative(s) and a faculty member. The exceptional circumstances (e.g., unforeseen circumstances that arise under a research or teaching protocol that require immediate consideration) must be documented at the next scheduled ACC meeting.

Decision Deferred:

- May be given for AUPs where the ACC finds that revisions of a substantial nature would be required in order to achieve approval.
- The nature of deficiencies in the proposed AUP will be communicated to its author by the ACC Coordinator.

Rejected:



- Given where the ACC finds that there are fundamental faults that preclude the proposed AUP from reaching compliance with the Animals for Research Act (Province of Ontario), the guidelines and policy statements of the CCAC, and/or any other relevant municipal, provincial or federal laws or guidelines.
- The nature of deficiencies in the proposed AUP will be communicated to its author by the ACC Chair or ACC Coordinator.

6. Appeal Process:

Researchers who have received a decision from the ACC regarding the approval or renewal of a protocol or have been requested to make significant modifications to a protocol may appeal the decision to the Vice-President, Research.

- i. The Vice-President, Research shall appoint an ad hoc ACC appeals committee and direct the appeal to this Committee for review and a recommendation to the VPR.
- ii. The ACC appeals committee is given the responsibility for adjudicating an appeal from the author of a research or teaching protocol where the use of animals is not approved by the ACC.
- iii. The ACC appeals committee shall consist of five individuals, at least three of whom are knowledgeable of the CCAC guidelines and policy statements, federal and provincial legislation and regulations in the use of animals in research and teaching, and do not currently sit on the ACC committee. Composition of the committee will include two faculty members from departments that historically use animals for teaching or research, and one faculty member from a department that does not use animals. A veterinarian and a community representative who are not part of the active ACC complete the committee, with consideration given for inviting these individuals from another institution or former members of the ACC.

The ACC appeals committee may recommend upholding or overturning the ACC decision. In the event that the ACC decision is overturned, the protocol will be returned to the ACC for reconsideration in light of factors adduced by the Appeals Committee.

Having received the appeals committee's recommendation, the Vice-President, Research or designate shall communicate their subsequent decision to the applicant and the ACC Chair.

The decision of the Vice-President, Research, is final and there are no further appeals.

7. Meetings

a) ACC Meetings



- i. The ACC shall meet at least 8 times per year and as often as necessary to fulfill their terms of reference and be satisfied that all animal use within their jurisdiction is in compliance with institutional, municipal, federal and provincial regulations and guidelines.
- ii. A quorum consists of 50% plus one member, and must include a veterinarian, chair (or chair's delegate), one community representative and one Brock faculty member active and/or experienced in research involving animals. Members who are not able to attend are encouraged to send in written comments before the meeting;
- iii. Minutes detailing ACC discussions and decisions must be produced for each meeting in a timely manner, and must be available to all ACC members, and the Vice-President Research.

b) Site Visits:

Site visits provide a better understanding to the work being conducted in the institution and allow the ACC members to meet those working in the spaces to discuss their needs, monitor animal-based work according to approved protocols and SOP's and to assess the physical makeup of the facilities.

- i. Each member will conduct a site visit of the animal facilities where animals are used at least once per year.
- ii. During the site visit each member or a group of members will be asked to fill out a site visit form, which they may choose to submit anonymously.
- iii. Site visit forms will be submitted to the ACC Coordinator;
- iv. Animal Care Coordinator will compile the site visit observation notes and forward the results/comments to the ACC Chair and committee as well as the Vice-President, Research;
- v. The observation notes from each site visit will be discussed at the subsequent ACC meeting and be included in the minutes. These reports will be provided to the Vice-President, Research;
- vi. The ACC should visit the Animal Care Facility and areas in which animals are used at least once per year and such visits, which typically occur as part of a regular meeting, should be documented in an Animal Facility Inspection Report. The ACS manager should respond to any ACC recommendations in writing, and issues raised in Inspection Reports should be resolved jointly by the senior administration and the ACC. More frequent ACC site visits may be performed in order to follow up on AUPs that have raised significant concern during the protocol review and/or the PAM process and/or via any animal welfare complaint. These site visits may be carried out by the Chair of the ACC or delegate, who may be accompanied by other members or animal care committee.

c) General



- a) The ACC must consider all protocols as privileged communications and members (including alternates) must maintain confidentiality;
- b) The ACS Manager ensures that any changes to the Brock University Animal Care and Use Program including changes in the senior administrator responsible for animal care and use (Vice-President, Research), the Chair of the ACC, Veterinarian, or the ACS Manager are communicated to the CCAC Secretariat and OMAFRA Inspector. While the ACC is not responsible for such communications it maintains a record of these communications;
- c) The ACC regularly reviews and if necessary, revises at least every 3 years:
 - i. its terms of reference and institutional animal care and use policies;
 - ii. security precautions and procedures for animals and research facilities;
 - iii. standard operating procedures (SOPs)
- d) Ensure that the Animal Use Data Form is completed and submitted to the CCAC by March 31 of each year and that the Animals Used in Research Teaching and Testing Form is completed and submitted to the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA) by March 1 of each year. Responsibility for completion and submission of these forms is delegated from the ACC to the ACS Manager and forms are brought to the ACC meeting following the deadlines;
- e) Ensure that a crisis management program is in place for the animal facilities and for the animal care and use program, in conjunction with any general institutional crisis management plan(s);
- May, from time to time, sponsor seminars or workshops on the use of animals in science and the ethics of animal research, and encourage as many animal users, ACS staff, students, ACC members and other interested parties to attend;
- g) Try to achieve and maintain a high ethical profile within the institution and in the community in order to demonstrate the institution's efforts in promoting animal welfare and transparency regarding animal experimentation.

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