The Canadian Council on Animal Care (CCAC) requires that institutions conducting animal based research, teaching or testing establish an animal care committee (ACC), and that it be functionally active. Each committee’s operation must be governed by formal Terms of Reference that include the following Terms, but need not be limited to them. The ACC’s Terms of Reference must be tailored to reflect and refer to the institution’s animal care and use program, including the members of the program and the institution’s policies, practices and procedures.

Most institutions have a single ACC. A few large institutions choose to have more than one ACC: this is acceptable, as long as the ACC system is well structured to avoid potential conflicts of interest, and has an institutional ACC that oversees the work of the ACCs for the various units and establishes policies and procedures to ensure sound general standards in order to meet CCAC guidelines throughout the institution. The elements covered in this policy statement may be divided out between the various ACCs of an institution, as long as all elements are covered in an appropriate and structured fashion and are defined in suitable terms of reference for each committee.

ACCs may also choose to form subcommittees to work on specific areas such as protocol review or development of standard operating procedures (SOPs). Protocol review subcommittees should include at least one scientist, one veterinarian, one community representative, one institutional member who does not use animals, one technical staff representative and the ACC coordinator.

Institutional ACCs should be responsible directly to the senior administrator responsible for animal care and use for the institution (president, vice president, rector, CEO, etc.), and this link should be specified in writing. ACCs for faculties or other divisions of the institution should have representation on the institutional committee and report directly to it, in addition to the reporting line(s) to any other senior administrators. The CCAC policy statement on: senior administrators of animal care and use programs (in preparation) should be consulted for details on the roles and responsibilities of the institution and its senior administrators.

* May also be referred to as:
  - institutional animal care and use committees (IACUC)
  - animal research ethics boards (AREB)
  - Ethics Committees

and by other names, as long as their function is clear and they operate according to Terms of Reference based on this document.
The institution must work with the ACC to ensure that all animal users and caregivers are informed of and comply with institutional animal care and use policies and procedures.

The institution must be supportive of the committee's work. This includes appointing an ACC coordinator, who may work part-time for the ACC in the case of smaller institutions, whereas larger institutions will need one or more employee(s) to accomplish this work. The ACC coordinator must support the ACC by ensuring that animal use protocols are well managed, that committee minutes and reports are promptly produced and distributed, that all exchanges between the ACC and animal users are well documented and filed in a timely manner, and that animal users and ACC members are provided with necessary information.

The institution must also ensure that ACC members are provided with training opportunities to understand their work and role: these must include at least a formal orientation session, to introduce new ACC members to the institution's animal care and use program and its members, policies and procedures, as well as to the animal facilities and to CCAC guidelines and policies. Material on the CCAC website (and other relevant websites), such as the Modules on the Core Topics of the Laboratory Animal/Teaching Stream of the CCAC Recommended Syllabus, can be introduced as possible resources. Ongoing opportunities to better understand animal care and use in science should also be provided, such as time spent with animal care givers and users, access to relevant journals and materials, and meetings/workshops related to animal care and use, including the CCAC National Workshop.

The institution and its senior administrators must also ensure that the ACC is well respected within the institution, and that all ACC members and the ACC Chair are valued and recognized.

1. Membership

ACC members should be appointed for terms of no less than two years and no more than four years, renewable only up to a maximum of eight consecutive years of service. This maximum should not be exceeded, except in the case of very small institutions (i.e. those that have 3 or fewer animal users). This does not apply to ACC members who must be part of the ACC because of their role within the institution (ex officio members): the ACC Coordinator, the veterinarian(s) and the animal facility manager. The complement of the committees will vary and should be determined by the needs of each institution, but should include:

a) scientists and/or teachers experienced in animal care and use, who may or may not be actively using animals during their term on the ACC; there should be a minimum of two such members, and representation of all the major animal-using divisions of the institution must be ensured;

b) a veterinarian, normally experienced in experimental animal care and use;

c) an institutional member whose normal activities, past or present, do not depend on or involve animal use for research, teaching or testing;

d) at least one, and preferably two or more, person(s) representing community interests and concerns, who has (have) had no affiliation with the institution, and who has (have) not been
involved in animal use for research, teaching or testing; community representation must be ensured for all ACC activities throughout the year;

e) technical staff representation (either an animal care, an animal facility or an animal research technician) if there is (are) (a) technical staff member(s) actively involved in animal care and/or use within the institution;

f) student representation (graduate and/or undergraduate), in the case of institutions that have programs where students use animals; and

g) the ACC coordinator (the institutional employee who provides support to the ACC).

The senior administrator to whom the committee reports must not be a member of the ACC, but there can be a representative of the senior administration on the committee.

The person with overall responsibility for the animal facilities, whether a veterinarian, a scientist or a technical staff member, must be included on the ACC. In large institutions with several facilities, consideration can be given to having individual facility managers included on the ACC on a rotating basis.

ACCs benefit from having occupational health and safety and biosafety representatives (if this is not the case, other ways must be found of ensuring close links), and ACCs can also benefit from the presence of biostatisticians, ethicists and those responsible for public relations.

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, in order to avoid potential conflicts of interest. Provision should be made to co-opt other persons to the ACC as the need arises. A reasonable quorum, such as a majority of the members, should be established for ACC meetings, and the quorum should include community and veterinary representation. Meetings should be scheduled at times that are convenient for all members, including community representatives.

2. Authority

The ACC must have the authority, on behalf of the senior administrator responsible for animal care and use for the institution, to:

a) Stop any objectionable procedure if it considers that unnecessary distress or pain is being experienced by an animal;

b) Stop immediately any use of animals which deviates from the approved use, any non approved procedure, or any procedure causing unforeseen pain or distress to animals; and

c) Have an animal killed humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.

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.

Each institution must establish procedures for post-approval monitoring of animal use protocols, and must define the roles and responsibilities of the members of the ani-
mal care and use program in the monitoring process. The institutional ACC is the body responsible for determining and working to correct breaches of compliance with approved animal use protocols and SOPs. Breaches of compliance that cannot be corrected by the ACC working with the concerned animal users and veterinary/animal care staff must be referred to the senior administration, which must inform all members of the animal care and use program about sanctions that will be taken by the administration in the event of serious breaches of compliance.

As the ACC is generally not present when animal use protocols are being undertaken, the committee must work with the members of the veterinary and animal care staff to ensure compliance with its decisions and with the conditions set out in approved protocols. The veterinary and animal care staff must work in a collegial manner with animal users and attempt to correct deficiencies collaboratively. Where there are persistent breaches of compliance or threats to the health and safety of personnel or animals, these must be reported back to the Chair of the ACC, and the Chair and ACC must promptly address these issues, through communications with the animal user(s), meetings and site visits, and eventually communications with the senior administrator, as necessary.

The ACC must also delegate to the veterinarian(s) the authority to treat, remove from a study or euthanize, if necessary, an animal according to the veterinarian’s professional judgment. The veterinarian must attempt to contact the animal user whose animal is in poor condition before beginning any treatment that has not previously been agreed upon, and must also attempt to contact the ACC Chair, but the veterinarian must have the authority to proceed with any necessary emergency measures, whether or not the animal user and ACC Chair are available. A written report should be sent by the veterinarian to the animal user and to the ACC following any such event.

The veterinarian and ACC may also choose to delegate certain responsibilities to one or more senior animal care staff member(s).

3. Responsibility

It is the responsibility of the ACC to:

a) Ensure that no research or testing project or teaching program (including field studies) involving animals be commenced without prior ACC approval of a written use protocol; further to this, that no animals be acquired or used before such approval. This includes internally funded projects;

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 animal use protocol, except where current CCAC guidelines provide for exemptions. The ACC should also be aware of other animal-based activities, such as commercial or recreational activities, within the institution, and should work with the persons responsible for these activities to ensure that animal care and use is undertaken according to appropriate procedures;

c) Require all animal users to complete an animal use protocol form and ensure that the information therein includes the following points, clearly presented in a form that all members of the ACC can readily understand (supplemental information can be found in the CCAC
To facilitate the work of both protocol authors and ACC members, appropriate SOPs should be referred to as much as possible. Approved protocols and SOPs should be readily available in the areas where animal-based work is taking place.

i) project title and descriptive procedural keywords or brief description of the procedures to be conducted on animals, as defined in the CCAC Animal Use Data Form;

ii) principal investigators/teachers, and all personnel (post-doctoral fellows, research staff, graduate and undergraduate students) who will handle animals, along with their training and qualifications with respect to animal handling (see point 3m iii)); in the case of undergraduate students, who may have very little training, close supervision is required;

iii) departmental affiliation;

iv) proposed start date, proposed end date (if the study is to take place over more than one year, the work and numbers of animals for the first year only should be approved, and further work can then be approved in yearly protocol renewal(s) or new protocols - see Section 3g) on protocol renewals);

v) for research or testing projects, funding source(s) and status of funding approval;

vi) for research projects, an indication of whether the project has received peer review for scientific merit;

vii) for teaching programs, a course number and an indication of whether the course has been reviewed with respect to the pedagogical merit of using live animals; institutional or departmental curriculum committees can be called upon to provide a review of pedagogical merit to the ACC; a specific appendix or separate protocol form can be used to better capture information relevant to the ethical review of teaching programs (see Section 12 of the CCAC guidelines on: animal use protocol review);

viii) 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 policy statement on: ethics of animal investigation; that the planned animal use not exceed the requirements of the regulatory authorities - if it does, justification for the additional animal use must be provided;

ix) lay summary;

x) an indication of the use of biohazardous, infectious, biological, chemical or radioactive agents in animal-based projects; and, if so, an indication of institutional approval of this use;

xi) category(ies) of invasiveness as defined in the CCAC policy statement on: categories of invasiveness in animal experiments, and Purpose of Animal Use (PAU) as defined in the CCAC Animal Use Data Form;

xii) information with regard to the
Three Rs (replacement, reduction and refinement alternatives) of animal use, to include:

xii.1 a description of why sentient animals must be used for the project, of how the applicant arrived at this conclusion (e.g., searches of databases on alternatives), and of possible replacement alternatives (non-animal methods, cell/tissue culture, computer simulations, audio-visual teaching methods, the replacement of sentient animals with animals of lower sentiency, etc.) and justification if these are not to be employed;

xii.2 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;

xii.3 a description of all of the refinements to be employed to protect and enhance animal health and welfare, which may include:

  xii.3.1 anesthesia and analgesia, including dosages and methods of use, for all invasive protocols; strong scientific justification must be provided for not using anesthesia or analgesia in the case of invasive protocols;

  xii.3.2 other medical treatments as appropriate, as indicated through veterinary consultations;

  xii.3.3 housing and husbandry methods, and environmental enrichment as a means to refine animal care; any limitations on environmental enrichment from that normally offered to animals in the institution, based on CCAC guidance, must be justified to the ACC;

  xii.3.4 refinements to the procedures to be employed on the animals;

  xii.3.5 refinements to the length of time that animals will be held/used;

  xii.3.6 any other possible refinements;

xiii) a clear description detailing the procedures that are carried out on the animals (referring to appropriate SOPs as much as possible); the use of graphic representations is encouraged;

xiv) a description of the endpoint(s) of the experimentation, selected according to the CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching and testing, 1998 (refer to institutional SOPs, if available and relevant); the per-
son(s) responsible for monitoring the animals and applying endpoints should be identified, and the schedule for monitoring animals and any relevant checklists of signs and symptoms to be used when evaluating the animals 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;

xv) 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; wildlife studies should be addressed in either a separate section or appendix of the protocol form, or can have their own protocol form, especially where a significant number of wildlife studies are undertaken (see the suggested wildlife protocol form in Appendix B of the 2003 CCAC guidelines on: the care and use of wildlife);

xvi) the method of euthanasia, if used; justification for any physical euthanasia methods, or for any methods that deviate from those described in the most recent CCAC guidance on euthanasia;

xvii) 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;

xviii) any other information considered important or necessary and pertinent, including information or results derived from any relevant previous protocols; the description and use of previous relevant results is particularly important to ensure that methodologies are not simply re-used without learning from any animal welfare problems that were encountered in the past, that the protocol continues to have relevant goals and methodology, and that appropriate refinements to protect and enhance animal welfare are sought and implemented;

d) Ensure that each research project has been found to have scientific merit through independent peer review before approving the project; if the review is not carried out by an external, peer review agency, the institution should require that it be obtained according to the CCAC policy statement on: the importance of independent peer review of the scientific merit of animal based research projects, 2000. The institution must implement a mechanism through which non-peer-reviewed projects are reviewed for their scientific merit either by calling upon the expertise of individual independent peers or by making use of scientific committees or advisory boards;

e) Review and assess all animal use protocols, with particular emphasis on the CCAC policy statement on: ethics of animal investigation and CCAC guidelines on: animal use protocol review as well as on
all other relevant CCAC guidelines and policy statements and, where necessary, require further supportive information from the investigator/teacher or meet with the investigator/teacher to ensure that all members of the committee understand the procedures to be used on the animal. Information exchanges and ACC discussions with protocol authors can be very useful, but protocol authors and members of their teams must always clearly remove themselves from ACC decision-making on their own protocols.

The committee must also ensure that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, require justification for the variance on scientific grounds. ACCs should both discuss protocols and make decisions on them during full committee meetings, rather than through individual reviews, and should attempt to reach decisions by consensus. Electronic tools are widely used for protocol management purposes and to facilitate and expedite the submission and review of protocols. This is encouraged as long as ACCs or protocol review subcommittees continue to meet in person for protocol discussions and final approvals.

An ACC may delegate the responsibility of interim approvals to an interim approval subcommittee, which must include at least one scientific member, one veterinarian and one community representative, one of which should preferably be the chair of the ACC. However, such interim approvals should only be used infrequently, and the interim review process, including exchanges between the ACC and protocol authors, must be documented and must then be subject to discussion and final approval at a full meeting of the committee. The ACC should define its own protocol review process, with or without (a) protocol review subcommittee(s), in its Terms of Reference. This process should include or refer to clear instructions to protocol authors, to ensure that all animal users in the institution understand how the ACC works, when it meets, how to fill out and submit a protocol form and what to expect after submission of the form;

f) Ensure that animal users update their protocols with any modifications they intend to make, and approve any modifications to a protocol before they are implemented. Minor modifications (e.g., 1 or 2 animal users added or removed, a small number of animals added, etc.), as defined by the ACC, can be approved by the Chair of the ACC or a delegate.

For any major changes to a protocol, require that a new one be submitted. ACCs should define, in writing, their own criteria as to what constitutes a major change to a protocol (e.g., a considerable increase of the number of animals required vs. the number in the original protocol, a change of species, use of more invasive or more frequent procedures, use of entirely new procedures, or other criteria).

Ensure that animal users report any unanticipated problems or complications, as well as on the steps they have taken to address the problem(s), to the ACC;

g) Review all protocols annually, i.e., within a year of commencement of the project; annual renewals should be approved by at least a scientist, a veterinarian and a community representa-
tive and should be brought to the attention of the full ACC for its information. Institutions may choose to use a shorter protocol renewal form, but no matter what form is used, all protocol renewals must emphasize:

i) the number of animals used in the preceding year;

ii) the number of animals needed for the year to come, with a justification;

iii) a brief progress report, describing any complications encountered relative to animal use (unpredicted outcomes, and any animal pain, distress or mortality), any amendments to the original protocol, and any progress made with respect to 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 relative to protecting animals from pain, distress or mortality; and

v) any other changes from the original protocol.

Require the submission of a new protocol after a maximum of three consecutive renewals;

h) Document all ACC discussions and decisions in the committee minutes and on attachments to the protocol forms;

i) Define an institutional appeal mechanism that can be used by the author of a protocol in the event that animal use is not approved by the ACC. This mechanism should include appropriate expertise and ensure a separate, fair and impartial process. The CCAC may be called upon for information purposes; however, appeals cannot be directed to the CCAC;

j) Ensure that all ACC members and animal users have the opportunity to become familiar with the CCAC Guide and CCAC policy statement on: ethics of animal investigation and all other CCAC guidelines and policy statements, federal, provincial or municipal statutes that may apply, as well as institutional requirements;

k) Ensure appropriate care of animals in all stages of their life and in all experimental situations. Veterinary care must be available. Formal arrangements must be made to obtain the services of a veterinarian, at least on a consultative basis, if they are not readily available within the institution. These formal arrangements must be based on the elements contained in the CALAM/ACMAL Standards of Veterinary Care of the Canadian Association for Laboratory Animal Medicine (2004), which define the roles and responsibilities of veterinarians involved in scientific animal care and use programs;

l) Establish procedures, commensurate with current veterinary standards, to ensure that:

i) unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters;

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, and that this has been approved by the ACC.
Painful studies requiring exemption from the use of either anesthetics or analgesia must be subject to particular scrutiny, not only prior to approval, but also during the experiment;

iii) appropriate post-operative care is provided;

iv) all due consideration is given to animal welfare, including environmental enrichment;

m) Ensure that policies to provide for a system of animal care that will meet the needs of the institution are established and implemented, and include:

i) the requirement that all animal care and animal experimentation are conducted according to CCAC guidelines and policies, and to any federal, provincial and institutional regulations that may be in effect;

ii) ensuring adequate animal care and management of the animal facilities, in particular by verifying that there is a person clearly designated to be in charge of animal care and management of the animal facilities, who should be a member of the ACC (see Section 1), and who should keep the other ACC members updated on the activities within the animal facilities;

iii) the training and qualifications of animal users and animal care personnel; veterinarians and animal care staff must receive continuing education in their field, and animal users (scientists/study directors, post-doctoral fellows, graduate students and research technicians) must receive appropriate training according to the CCAC guidelines on: institutional animal user training, 1999, either within the institution or through the programs of other institutions;

iv) an occupational health and safety program for those involved in animal care and use, in collaboration with the institutional authorities on occupational health and safety, that will appropriately protect all those who may be affected by animal-based work, according to CCAC guidelines (see Chapter VIII of Volume 1 (2nd Edn, 1993) of the CCAC Guide or the most recent CCAC guidance on occupational health and safety);

v) standards of husbandry, facilities and equipment;

vi) standard operating procedures for all activities and procedures that involve animals, including animal care and facility management SOPs (typically produced by the veterinary and animal care staff), and animal use SOPs (typically produced by animal users, in collaboration with veterinary/animal care staff as needed); the ACC should receive all SOPs and ensure that all necessary SOPs are produced and regularly reviewed (see also Section 5a)iiii);

vii) procedures for euthanasia;

n) Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the
study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not; and

o) In the case of projects involving proprietary or patentable research or testing, ensure that as much information as possible is provided to the ACC in terms of what effects to expect on animal health and welfare, and insist on close monitoring of animals in order to respect the elements outlined in 3l).

4. Meetings

Animal care committees should meet **at least twice per year** (most institutions in Canada have programs which will require more frequent meetings) and as often as necessary to fulfil 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 CCAC guidelines. Minutes detailing ACC discussions, decisions and modifications to protocols must be produced for each meeting, and must be forwarded to the senior administrator responsible for animal care and use.

In addition, the ACC should regularly visit all animal care facilities and areas in which animals are used, in order to better understand the work being conducted within the institution, to meet with those working in the animal facilities and animal use areas and discuss their needs, to monitor animal-based work according to approved protocols and SOPs, to assess any weaknesses in the facilities (ageing facilities, overcrowding, insufficient staffing and any other concerns) and to forward any recommendations or commendations to the person(s) responsible for the facilities and for animal use.

Visits of the animal facilities should be conducted at least once a year, and should be documented through the ACC minutes or written reports. Those responsible for the animal facilities should respond to any ACC recommendations in writing, and site visit reports should always be followed up on jointly by the senior administration and the ACC. For small institutions, the full ACC may tour the facilities as a group; for larger institutions, visits to animal care facilities and areas in which animals are used may be divided between the various members of the committee. No matter what the process employed, each member of the ACC should participate in some of the facility visit(s) on an annual basis.

More frequent ACC site visits should be made as necessary to follow up on any protocols that have raised significant concern during the protocol review process, or where problems have been encountered with a protocol being carried out in practice or with other aspects of animal facility operations; these visits may be carried out by the Chair of the ACC or delegate, accompanied or not by other members or animal care staff.

5. General

The animal care committee:

a) Must regularly review (at least every three years):

   i) its Terms of Reference to meet new CCAC guidelines or policies and changing needs within the institution, the scientific community, the animal welfare community and society as a whole, and expand its Terms of Reference to meet the requirements of each institution;
ii) the security of the animals and research facilities;

iii) standard operating procedures and institutional animal care and use policies; 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; and

iv) policies and procedures for monitoring animal care and experimental procedures within the institution, including the identification of the persons responsible for monitoring animal health and welfare, and the procedures carried out by the ACC to conduct monitoring;

b) Must maintain liaison with the CCAC Secretariat, and inform the Secretariat of any changes to their program: to the senior administrator responsible for animal care and use, the chairperson of the ACC, or the veterinary or senior animal care personnel;

c) Must 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;

d) Must develop a crisis management program for the animal facilities and for the animal care and use program, in conjunction with any general institutional crisis management plan(s). This program must detail plans in the event of power outages (short and prolonged), work stoppages, fires, natural disasters, large chemical spills and other similar crises, and must include a communications plan for addressing public and media inquiries on concerns related to animal use;

e) Should, from time to time, sponsor seminars or workshops on the use of animals in science and the ethics of animal experimentation, and encourage as many animal users, animal caregivers, students, ACC members and other interested parties to attend as possible;

f) Should try to achieve and maintain a high profile within the institution and in the community in order to demonstrate the institution’s efforts in promoting animal welfare and to allay some of the public concerns regarding animal experimentation; and

g) Should be open to developing and maintaining communication with animal welfare organizations.

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This policy statement supersedes all previous CCAC policies/guidelines on terms of reference for animal care committees.

For more information on these and other policies contact:

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