

Animal Care Committee - Terms of Reference

Preamble

The Animal Care Committee (ACC) derives its authority from Trent University as well as from federal and provincial legislation, notably The Animals for Research Act (Ontario). As a result, in matters concerning animal regulations, the ACC is answerable to the University as well as to government officials. As most of the Committee's activities have some bearing on animal care, it is often not possible (nor desirable) to determine where statutory authority and responsibility ends, and University jurisdiction begins. Members of the ACC should bear this in mind when reading these Terms of Reference and CCAC guidelines.

The ACC is responsible to the Vice-President (Research and Innovation) or designate and to the President.

A. Membership

All members of the ACC have voting privileges unless otherwise indicated.

Membership should include:

1. Up to two faculty members from Biology, preferably experienced in animal care and research;
 2. One faculty member from the Trent School of the Environment, preferably someone experienced in animal care and research;
 3. One faculty member from Psychology, preferably someone experienced in animal care and research;
 4. One other faculty representative who is a non-animal user;
 5. Up to two representatives of OPSEU local 365, preferably with a demonstrated interest and experience in animal care;
 6. One graduate student member, preferably from the Sciences;
 7. One undergraduate student member, preferably from the Sciences;
 8. One Veterinarian, preferably experienced in research-animal care (ex officio);
 9. The Manager of Animal Care (ex officio);
 10. One staff member from Animal Care;
 11. The Coordinator, Research Conduct and Reporting, from the Office of Research and Innovation (ex officio);
 12. Science Facilities Manager (ex officio);
 13. One or two persons representing community interests.
- The ACC Chair should be a member of faculty. Staff member can serve as an acting chair in the absence of the official chair (See section F5 for procedures to follow when a Chair, who is an animal user, has a protocol under consideration.)
 - The ACC may elect a Vice-Chair to serve the committee when the Chair is unavailable. The incumbent must fulfill all the same qualifications the Chair is required to have.
 - The Vice President (Research and Innovation) in consultation with the ACC, may nominate an ACC Chair to the Office of the Vice President Academic, who appoints faculty members to the committee and names the incumbent of Chair.
 - The committee may co-opt other (non-voting) persons as needed. This should be done in consultation with the Vice President (Research and Innovation) or designate.
 - Quorum shall consist of a simple majority of servng members, including a Chair, a Community Representative and the Veterinarian.
 - No protocol application will be approved without the expressed consent of the Veterinarian and the Community Representative(s).
 - For appointed university members, terms of service should be at least two years with no appointment being longer than four years. Consecutive appointments should not total to more than eight years.
 - If a faculty representative from a department is unavailable to serve, Trent faculty on contract appointments are acceptable from that department.
 - The Manager of Animal Care and Coordinator, Research Conduct and Reporting, fulfill the duties of an Animal Care Committee coordinator.

B. Authorities

The ACC has the authority:

1. To stop any objectionable procedure if it considers that unnecessary pain or distress is being experienced by the animal. On deciding that prompt action is necessary to change the condition or size of the animal population, informs the Chair of the ACC, Vice President of Research and Innovation, or designate as soon as is feasible.
2. To immediately terminate any use of animals which deviates from the approved protocol, any unapproved procedure, or any procedure causing unforeseen pain or distress to animals.
3. To order the humane killing of an animal if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.
4. To confiscate animals that are not being used for purposes specified in approved protocols or which have not been brought formally (through the protocol approval process) to the attention of the ACC.

The Veterinarian has the authority:

1. To stop any objectionable procedure if the Veterinarian considers that unnecessary pain or distress is being experienced by the animal.
2. To immediately terminate any use of animals which deviates from the approved protocol, any unapproved procedure or any procedure causing unforeseen pain or distress to animals.
3. To order the humane killing of an animal if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.
4. To order the administration of medical intervention or to medically intervene themselves if in the Veterinarian's professional judgement such intervention will alleviate unforeseen pain or distress in an animal.
5. To remove an animal suffering from unforeseen pain or distress from a study for the appropriate treatment.
6. In such cases the Veterinarian will inform the Manager of Animal Care and the Chair of the ACC immediately of the nature of the problem and the intervention action taken.

Note: Under normal circumstances this would be done in consultation with the principal investigator, however this in no way limits the Veterinarian's authority to act alone if the situation is deemed serious enough by the Veterinarian's professional judgement.

C. Responsibilities

It is the responsibility of the Animal Care Committee through its protocol approval policy to:

1. Ensure that all its members receive a copy of every animal use protocol submitted for approval and ensure the information therein is complete, clearly presented and understandable to all members.
2. Ensure that no research, testing project, teaching program, field study or educational display involving live vertebrates or cephalopods be commenced without prior approval of the ACC. The ACC should communicate this responsibility to the Research Policy Committee, the University Undergraduate Studies Committee and Graduate Studies annually.
3. Review and assess all animal use protocols, with particular attention to the CCAC's Guide to the Care and Use of Experimental Animals and Ethics of Animal Experimentation and, where necessary, require further supportive information from the investigator or meet with the investigator to assure that all members of the Committee understand the procedures to be used on the animal. The ACC must also assure that all procedures comply with CCAC guidelines, and if at variance with those guidelines, require justification for the variance on scientific grounds.
4. Assure that all animal users have the opportunity to become familiar with CCAC's Ethics statement, federal, provincial or municipal statutes that may apply, and institutional requirements for animal use.
5. Ensure appropriate care of animals in all stages of life and provide veterinary assistance (in some cases for a fee) in case of sickness, injury and elective procedures.
6. Undertake inspections as a Committee of all animal care facilities and experimental laboratories from time to time, but at least once a year, followed by a written report.
7. The ACC shall establish procedures to ensure that:
 - unnecessary pain or distress to animals in its care is avoided;
 - anaesthesia and analgesia are properly and effectively used where indicated;

- painful studies requiring exemption from the use of either anaesthetics or analgesia are subject to particular scrutiny, not only prior to approval, but throughout;
 - post-operative care commensurate with current veterinary concepts is provided;
8. The ACC shall support Trent policies which provide a program of animal care that will meet the needs of the University and that will include:
 - establishment of standards of animal husbandry, animal care and testing facilities and equipment (see the Trent Animal Care Standards Policy and associated procedures).
 - the requirement that all animal care and animal experimentation are conducted within the guidelines set by the CCAC and applicable federal, provincial and institutional regulations (see Procedure for Animal Care Committee Concern Identification and Response);
 - the training and qualification of animal users and animal care personnel;
 - procedures for euthanasia.
 9. The ACC will establish a process that provides an applicant the ability to appeal if their protocol is rejected (see section G). An appeal may involve an external review process.
 10. Protocols must either arise from research that has been successfully externally peer reviewed for its scientific merit through the Tri-Council process or by similar agencies (NSF, NIH, etc.) that include peer review in the approval process or these protocols must be accompanied by the names of at least two individuals who have no vested interest in the research and are qualified to review the work scientifically. Reviews must address the competence of the researcher, the appropriateness of the proposed methods and the scientific merit of the research.
 11. The ACC will promote the use of currently acceptable standards of care and best practices by ensuring that researchers and students have access to such information.
 12. The ACC will establish a process that provides post approval monitoring (PAM) either assigned to specific projects or randomly performed. Members of the ACC will work with the Coordinator, Research Conduct and Reporting, to provide PAM checks where necessary.

D. Meetings

The Animal Care Committee should meet at least six times a year and otherwise as often as necessary to fulfill its Terms of Reference and be satisfied that all animal use within its jurisdiction is in compliance with institutional, municipal, federal and provincial regulations, and the CCAC Guidelines. Minutes of meetings are forwarded to the Vice President of Research and Innovation. A verbal report by the Manager of Animal Care and the Veterinarian on the state of operations should be an agenda item for each meeting.

E. Protocol and Amendment Submissions

The Office of Research and Innovation will accept applications for Animal Use Protocols from the following personnel:

1. Principal investigators who are employed by the University in a teaching or research capacity or who have Emeritus or Adjunct status in a Trent academic program and who are qualified to use animals in research and/or teaching. Graduate and undergraduate students must relay their animal care protocols or amendments to their course or thesis to the Supervisor who will submit them to the ACC. Graduate and undergraduate students named on protocol applications must be adequately trained in the use of animals for research.
2. Research Assistants, University Support Staff, or Teaching Assistants/Demonstrators who have been designated by Principal Investigators, Course Co-ordinators or Departmental Chairs and who have been adequately trained in the use of animals for research and/or teaching.

The Office of Research and Innovation will also accept amendment forms for Animal Use Protocols as described above. Additionally, amendments can be submitted by the students who have been designated by Principal Investigators. Definitions for what constitutes a minor or major amendment follow.

"MINOR" AMENDMENTS

A minor amendment provides a relatively modest amount of specific information that corrects one or more deficiencies in the parent protocol. The nature of a minor amendment does not alter the assigned invasiveness, goal or scope of the parent protocol. Minor amendments may be approved through the Manager of Animal Care. Approved changes are

communicated to the full ACC via the Animal Care report, a standing agenda item. Feedback from the full ACC through the Chair may follow minor amendments that are more complex and may need to be considered major.

Examples of common minor amendments include the following (this list is not exhaustive):

- protocol extensions up to three months
- addition or removal of personnel working with the animals
- simple additions or changes in minor procedures; surgery lesion coordinates, drug refinements where the effects on the animals are commonly thought to be equivalent or better, common behavioural testing, common capture or handling methods, injection routes
- reasonable additions to approved animal numbers with adequate justification (no more than 30% of the original number of animals requested)
- addition of similar species within reasonable and justifiable numbers
- providing simple revisions to correct deviations or errors in the original protocol that do not change the invasiveness and end goals of the study

"MAJOR" AMENDMENTS

A major amendment contains new information that significantly alters the characterization of the invasiveness of the parent protocol. More insight to what necessitates the change should be provided by the principal investigator to justify a major amendment. Major amendments will be put before the ACC in full. Approval by the Chair of the ACC must be granted in writing prior to changes taking effect.

Examples of common major amendments include the following (this list is not exhaustive):

- a change in species with substantially different welfare, husbandry or handling needs
- protocol extensions greater than three months
- a change in the principal investigator
- inclusion of novel or complex changes in protocol procedures; surgery, capture techniques, or invasive testing not commonly done by the lab
- a significant addition of approved animal numbers (greater than 30% of the originally approved total).
- substantial modifications to parent protocols (e.g. more than one of the example major amendments below on a single parent protocol) may require a completely new protocol.

Proposed changes that constitute a new protocol submission include:

- A change in the main objective of the study 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.
- Multiple major amendments to the original approved parent protocol (>2 per year)
- Addition of a level E category of invasiveness procedure. (This will generally require the submission of a pilot protocol).

F. Protocol Review

Each application for an Animal Use Protocol will normally be reviewed in the following manner:

1. A completed animal use protocol application, renewal or amendment shall be submitted by the principal investigator, or authorized designate, to the Coordinator, Research Conduct and Reporting, in the Office of Research and Innovation to be distributed to the ACC
2. For renewals and major amendments, the Coordinator, Research Conduct and Reporting, will ensure documents are on the ROMEO portal and ACC members have access to that portal. A reminder email alerting the ACC to new materials posted on ROMEO and an impending meeting will also be sent to members.
3. For new protocols, the Coordinator, Research Conduct and Reporting, will appraise the protocol for satisfactory external peer review – i.e. that the protocol is consistent with a grant from an external granting agency such as NSERC, or an independent external peer review is favourable prior to the Animal Care Committee review (see Procedure for Obtaining External Peer Review.)
4. Each member of the ACC will review the application and major amendments. Minor amendments will be communicated to the ACC in full at the next Committee meeting.
5. At the next meeting of the ACC, each application will be reviewed and discussed by the Committee. Any member of the ACC may request that any visitor or ACC member who may be involved in the research protocol

being assessed, leave the room for part or all of this discussion. (If the applicant is the ACC Chair, the Vice Chair or another faculty member of the committee will be asked to take the Chair temporarily.) Decisions will normally be by consensus. If consensus cannot be achieved, a formal vote will be held, and the Chair will vote in the event of a tie.

6. All multiyear protocols will undergo an annual review for renewal each calendar year. The renewal application for multiyear protocols shall include the following:
 - i. a justification of the number of animals to be used in the next year based on the progress made in the previous year and on the work yet to be done
 - ii. the number of animals used in the previous year
 - iii. a summary of any animal incidents
 - iv. a description of the adequacy of endpoints as applied in practice
7. An application will have one of four possible outcomes:
 - A. Approved – work may start as of the ACC approved start date on the application. No changes are necessary.
 - B. Revision(s) required – Certain information is missing in the application or a question(s) has been raised where a satisfactory answer is required prior to work commencing. To receive full approval, the applicant must supply the requested information to the Chair (or designate) who, if satisfied, is authorized by the Committee to issue full approval. When the ACC deems a protocol needs revisions, it must supply the Chair with acceptable responses to assist the Chair in determining whether or not concerns have been addressed adequately. The principal investigator has 30 days in which to send in the revisions requested or the application will be deemed “withdrawn”. These timelines can be extended at the request of the ACC or the principal investigator, due to unforeseen circumstances with the submission.
 - C. Denied – The work as outlined in the application may not proceed because it does not meet applicable best practices or ethical standards. The ACC will provide the reasons for issuing a denial.
 - D. Decision deferred – This may apply to a protocol that is acceptable in principle but that requires clarifications or additional information beyond the scope that the Chair could approve (as in the revisions required category). Protocols for which the decision has been deferred must come back to the Committee or the Sub-committee for approval.

The Chair, on behalf of the ACC, will notify the principal investigator/designate or supervisor of studies of the decision and the reasons for rejection or conditional or deferral, if applicable. The Coordinator, Research Conduct and Reporting maintains all copies and ACC work with the Office of Research and Innovation database.

Under circumstances or at times when the Committee cannot or does not meet (lack of quorum, summer months), or urgent attention is required, protocol applications will be reviewed by an ACC Subcommittee in the following manner:

1. A completed animal use protocol application, renewal or amendment shall be submitted by the principal investigator or their authorized designate through the normal submission process.
2. In the case of major amendments or renewals the Coordinator, Research Conduct and Reporting will provide a copy or a notification of its availability, to each member of the ACC Subcommittee consisting of the ACC Chair, Veterinarian, Community Member, and the Manager of Animal Care. Additional input of a subject matter expert could be sought at any time.
3. In the case of new protocols, their scientific merit will be secured by the Coordinator, Research Conduct and Reporting (following step #3, Protocol Review process, above). In the case of satisfactory peer review, the Coordinator, Research Conduct and Reporting will provide the protocol, or a notification of its availability, to each member of the ACC Subcommittee.
4. All protocols or major amendments reviewed by the Subcommittee are provided with interim approval only. The ACC in full will review all interim approvals for a final decision and revisions may be required.

All annually repeating animal work will require a full protocol every four years. This allows for a submission (year 1), and up to three renewals (years 2, 3, and 4). Following that period a new submission must be made in lieu of the Annual Progress Report to ensure the work evolves with the program.

G. Appeals

Appeals of an unfavourable decision may be made through the following procedure:

1. The principal investigator or supervisor of studies may request to attend a meeting of the ACC to discuss the ruling. Discussion may result in clarifications acceptable to the ACC in which case a change in the status of the protocol may result.
2. If the result of the above meeting is not acceptable to the principal investigator or supervisor of studies, it may be appealed to the Vice President (Research and Innovation) or designate. The Vice President (Research and Innovation) or designate will convene an appeal committee consisting of, if possible, a former Chair of the ACC, a former faculty member of the ACC and Vice President (Research and Innovation), to review the decision. This appeal committee will meet with both the principal investigator and the ACC to discuss the issue. This appeal committee may or may not request additional information from external sources to assist in its deliberations.
3. The decision of the appeal committee is final.

H. General

1. The Animal Care Committee should regularly review (at least every three years):
 - its Terms of Reference;
 - the concerns of animal welfare organizations, particularly within the Peterborough area;
 - the security of the animals and research facilities;
 - standard operating procedures;
 - policies and procedures for monitoring animal care and experimental procedures within the university.
2. The ACC should maintain liaison with the CCAC Secretariat and with the Provincial Veterinary Inspector.
3. The ACC should develop and maintain liaison with reputable animal welfare organizations, particularly those recognized by and affiliated with the Canadian Federation of Humane Societies (CFHS), and try to foster transparency with such groups.
4. The ACC should sponsor seminars or workshops on animal science and the ethics of animal experimentation.
5. The ACC should be aware that the general public has a legitimate interest in animal care at Trent and should make every effort to allay public concerns regarding animal use.
6. The ACC must develop a crisis management plan for the animal facilities and for the animal care and use program.
7. The ACC submits animal use data for all protocols annually to the CCAC and OMAFRA, and as part of the CCAC pre-assessment document.

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