



# Terms of Reference for Lakehead University's Animal Care Committee

**Jurisdiction:** Vice President, Research and Innovation;

**Approval Authority:** Executive Team;

**Established on:** August 2008;

**Amendments:** January 2022.

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## Preamble

This document sets standards of care and foundations for use of animals by Lakehead University. The University will work with the Animal Care Committee (ACC) to ensure that all ACC members, animal users and technical staff are informed of and comply with the institutional animal care and use policies. The University will ensure that all members of the ACC are provided with training opportunities to understand their work and role.

The Terms of Reference for Lakehead University's ACC are prepared in accordance with the Canadian Council on Animal Care (CCAC) guidelines (revised in March 2006) and comply with legislation including the Animals for Research Act (Ontario, 1990). The terms described herein will ensure the humane care and use of animals in Lakehead University programs, both in facilities managed by the University and, insofar as the animals are subject to the control of the University or the investigator, in other facilities or jurisdictions. The ACC is also empowered to make judgments in exceptional situations where individual projects raise issues that fall outside of these terms, in order to ensure that appropriate ethical standards are met.

The Terms of Reference are implemented by the Lakehead University ACC, and its operation is governed by these Terms of Reference.

The Lakehead University ACC is responsible directly to the Vice-President, Research and Innovation. Its purpose is to fulfill the University's legal and ethical responsibilities concerning the use of animals in research, teaching and testing.

The University will work with the ACC to ensure that all animal users and technical staff are informed of, and comply with, institutional animal care and use policies and procedures.

The University is supportive of the committee's work and will maintain the appointment of an ACC coordinator who will work part-time for the ACC. The Manager, Research Ethics & Contracts is the ACC coordinator. The ACC coordinator will 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 Research Ethics Coordinator is responsible for the minutes which detail ACC discussions, decisions, and modifications to protocols and must be produced for ACC meetings and forwarded to the Vice-President, Research and Innovation. The ACC coordinator will also inform the CCAC Secretariat of any important changes to the Animal Care and Use Program, such as membership changes to the ACC, changes in the veterinarian or senior animal care personnel, or changes to the reporting structure.

The University will work with the ACC to ensure that all ACC members, animal users, and technical staff are informed of, and comply with, the University standards for animal care as outlined in the Terms of Reference. It will ensure that ACC members are provided with training opportunities to understand their work and role. These will include a formal orientation session to introduce new ACC members to the institution's animal care and use program, the other ACC members, the CCAC guidelines and policies, the University's policies and procedures, and the University's animal facilities. ACC members are encouraged to access material on the CCAC website (and other relevant websites), such as the Training Modules. Ongoing opportunities to better understand animal care and use in science will also be provided, such

as time spent with animal technical staff and users, access to relevant journals and materials, and meetings/workshops related to animal care and use, including the CCAC National Workshop.

The Vice-President, Research and Innovation and senior administrators must ensure that the ACC is well respected within the institution, and that all ACC members and the ACC Chair are valued and recognized.

The University will assume full responsibility, including legal and other resulting costs, associated with legal matters and/or litigation involving the University, its animal care facilities, or the ACC.

## **1. Membership**

ACC members will be appointed by the Vice-President, Research & Innovation 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. The terms should be staggered to ensure continuity of membership. This does not apply to ACC members who must be part of the ACC because of their role within the institution, such as the ACC coordinator, the veterinarian(s) and the animal facility manager(s).

The complement of the committee will vary and should be determined by the ongoing needs of the University, but should include:

1. Faculty or representatives of the University, upon recommendation by the Deans, 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 three such members, and representation from all the major animal-using divisions of the institution must be ensured;
2. A veterinarian, experienced in experimental animal care and use, and laboratory animal medicine;
3. A minimum of one faculty or staff whose normal activities, past or present, do not depend on or involve animal use for research, teaching or testing;

4. 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;
5. One technical staff representative, preferably the manager with overall responsibility, from each animal use facility;
6. One graduate student engaged in animal research but preferably not supervised by an ACC member; and
7. A representative of Health & Safety;
8. The Director of the Office of Research Services and representative of senior administration, non-voting member.
9. The Manager, Research Ethics & Contracts who is the ACC coordinator (the institutional employee who provides support to the ACC), non-voting member.
10. The Research Ethics Coordinator (the institutional employee who records the minutes), non-voting member.

The ACC Chair will be appointed by the Vice-President, Research and Innovation 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. The Chair 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.

Other persons may be appointed to the ACC by the Vice-President, Research & Innovation as the need arises.

A quorum for meetings will be a majority of the members, and the quorum must include the Chair, a community member and the veterinarian.

## 2. Authority

The ACC is authorized by the Vice-President, Research and Innovation to review each research, teaching or testing protocol that proposes to use living, non-human vertebrate animals, including both living animals used in experiments and field research, and animals that arrived live on University property and from which tissue was taken after application of humane methods of euthanasia.

The ACC has the authority, on behalf of the Vice-President, Research and Innovation, to:

1. Stop any objectionable procedure if it considers that unnecessary distress or pain is being experienced by an animal;
2. 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
3. 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.

To ensure effective post-approval monitoring, 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 Animal Use Protocols. The veterinary and animal care staff must work in a collegial manner with animal users and attempt to correct deficiencies collaboratively.

To this end, it is imperative that the ACC obtains timely feedback on all Animal Use Protocols (AUPs) in the form of post approval monitoring (Post Approval Collaborative Review Program), renewal requests, and regular reporting from the veterinary staff.

Working collaboratively, the ACC, with assistance from the veterinarian, facility managers, and researchers, will monitor all animal use activities. This monitoring aims to prevent

unanticipated distress and/or to quickly and properly address unanticipated distress. The ACC will also seek to ensure that, where necessary, AUPs Standard Operating Procedures (SOPs) are revised accordingly.

At bi-monthly ACC meetings, reports will include information about compliance issues, welfare issues, and any unexpected protocol events. The technicians will always report, in a timely fashion, any animal illness or welfare problems to the facility manager(s) and veterinarian.

Where there are persistent breaches of compliance or threats to the health and safety of personnel or animals, these must be reported to the Chair of the ACC. The ACC must promptly address these issues through communications with the animal users, meetings and site visits and eventually communications with the Vice-President, Research and Innovation as necessary. Breaches of research integrity will be dealt with in accordance with the Lakehead University Research Integrity Policy.

The ACC delegates to the veterinarian 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. However, the veterinarian has the authority to proceed with any necessary emergency measures, whether or not the animal user is available. A written report will be sent by the veterinarian to the animal user and to the ACC following any such event.

The veterinarian and ACC may, in some circumstances, 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 animal use protocol; further to this, that no animals be acquired or used before such approval; it will also ensure that the procurement, care, and use of animals under its jurisdiction

follow the guidelines and policy statements established by CCAC, and the Animals for Research Act (Ontario). 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 is clearly presented in a form that all members of the ACC can readily understand. 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 for all researchers and teachers in the areas where animal-based work is taking place, and on the institutional Animal Care website;
- 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: scientific merit and ethical review of animal-based research (March 2013).

The Office of Research Services, will ensure that peer reviews are conducted. Reviews should be conducted by at least two independent experts with no links to the researcher, at least one of whom will not sit on the ACC. Reviewers will be selected based on their expertise in their field and the nature of the AUP to be reviewed. This requirement exists for past protocols which have not been adequately reviewed and will be required at the time of renewal. The ACC will generally accept peer reviews provided by funding agencies (i.e. Tri-Agency reviews) though, in some cases, may

require additional peer review.

Teaching courses involving live animals require departmental pedagogical and scientific review only (2 members or a departmental committee attesting to the values of pedagogical and scientific merit). The ACC discourages the use of live animals in situations where there are viable alternatives and investigators are asked to substantiate the use of live animals. Undergraduate student projects require similar departmental review. The ACC discourages undergraduate student projects past level C invasiveness unless they are very well justified, closely monitored and subject to a full independent peer review.

- 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.

Ensure that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, require justification for the variance on scientific grounds. The ACC should discuss protocols and make decisions on them during full committee meetings, rather than through individual reviews, and should attempt to reach decisions by consensus.

The 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.

Before any research or teaching concerning animals is initiated (including ordering of animals) the animal use protocol must be reviewed and approved by the ACC. The basic philosophical principle is that total responsibility and accountability is the price the individual researcher pays for the privilege of animal experimentation. The protocol review process is as follows:

- i. The protocol must address the issues that are stated the University AUP forms and are based on CCAC guidelines on: animal use protocol review (1997);
- ii. Protocols must be submitted through the Romeo Researcher Portal at least 14 days before the next ACC meeting. Veterinary pre-review is recommended. Providing it is completed properly, the ACC coordinator will send, through Romeo, the application to each member of the committee. The ACC reviews and assesses all animal use protocols, with emphasis on the CCAC's Guide to the Care and Use of Experimental Animals, Ethics of Animal Investigation, Animal Use Protocol Review, and their Terms of Reference for Animal Care Committees;
- iii. AUPs are considered during meetings. The decision for approval or non-approval is determined by the ACC giving consideration to CCAC guidelines and OMAFRA regulations and by the clarity of the protocol. The researcher can be invited to answer specific questions and help clarify aspects of the AUP but not be present during the final discussion and voting to avoid conflicts of interest;
- iv. Committee members shall not participate in the review of their own AUPs or the AUPs submitted by persons with whom they are in direct academic collaboration or conflict. If a Committee member is unsure whether a conflict of interest exists, he/she must disclose the nature of the potential conflict to the Committee and abide by the Committee's decision as to whether he/she should participate in the proposal review;
- v. Every effort will be exercised to obtain a consensus. If a protocol is not accepted unanimously, discussions of the concerns will focus upon solutions;
- vi. Approval of a protocol is defined by simple majority at the meeting where quorum

- is met. If more than one meeting elapses when quorum is not met, a special meeting may be called by the Chair for interim approval by a sub-committee of the veterinarian, community representative, the coordinator and the Chair. An interim approval would then need subsequent approval at the next full meeting of the ACC. AUP's always require all content to be acceptable according to current veterinary standards;
- vii. When an AUP is approved it is made "active" in the Romeo Portal. Where animals are held at an animal use facility, the Romeo number must appear on the cage/tank card involved with this AUP. Correspondence, clarifications and additional protocol information are kept with the protocol file in the Romeo Portal;
  - viii. If approval of an AUP is postponed, the Chair will communicate the concerns of the ACC to the researcher. The researcher can re-submit the protocol through Romeo addressing specific issues as well as attend the following meeting;
  - ix. It is recommended that AUPs be first sent to the university veterinarian for content review prior to the ACC meeting in order to expedite the process. A meeting or email/phone interaction can be held to discuss veterinary details and procedures involved in the experiment and assist with overall planning of the project. After AUP approval, further meetings with the veterinarian and/or the facility manager are encouraged in order to facilitate implementation details.
- f. Ensure that animal users update their protocols. Minor modifications to an AUP must be submitted through the Romeo Portal and approved 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 (see *When to Submit a Modification or New Protocol* on the animal ethics webpage).

Major changes to a protocol require that a new one be submitted.

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

Reporting Form on the animal ethics webpage.

It is recommended that modifications be first sent to the university veterinarian for content review prior to the ACC meeting.

- g. Review all protocols annually, i.e., within a year of commencement of the project; researchers must request the renewal of ongoing protocols on an annual basis through the Romeo Portal; annual renewals should be approved by at least a scientist, a veterinarian and a community representative and should be brought to the attention of the full ACC for its information. Renewal information must contain at a minimum (See Renewal Application on the Romeo Portal):
  - i. The number of animals used in the preceding year;
  - ii. a brief progress report, describing any complications encountered relative to animal use (unpredicted outcomes, and any animal pain, distress or mortality), and steps taken by the investigator to address the problem; any amendments to the original protocol; and, any progress made with respect to the Three Rs of replacement, reduction and refinement of animal use;
  - iii. 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
  - iv. any other changes from the original protocol.

The ACC requires the submission of a new protocol after a maximum of three consecutive renewals.

- h. Document all ACC discussions and decisions in the committee minutes;
- i. Ensure that AUP authors can appeal decisions in the event that proposed animal use is not approved by the ACC. This mechanism involves:
  - i. An oral presentation to the committee by the applicant; if issues are not resolved then;
  - ii. A review by an appeals committee established by the Vice-President, Research and Innovation. Members of this committee should have appropriate expertise

- and ensure an appropriately separate, fair, and impartial process that is overseen by the Vice-President, Research and Innovation. Individual(s) with expertise from outside of the ACC may be assigned to the appeals committee;
- iii. The CCAC may be called upon for information purpose; 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 on an ongoing basis. Formal arrangements must be made to obtain the services of a veterinarian. These formal arrangements must be based on the elements contained in the CALAM/ACMAL Standards of Veterinary Care, 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: training of personnel working with animals in science (2015), either within the institution or through the programs of other institutions. The ACC will be involved in reviewing training programs;
- 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;
- v. standards of husbandry, facilities and equipment;
- vi. standard operating procedures (SOPs) 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; SOP's are to be readily available through the Office of Research Services and the University website; researchers should refer to SOPs as much as possible when filling out the AUPs. These SOP's need to meet current appropriate veterinary and animal health standards to ensure that:
  1. Unnecessary pain or distress is avoided;

2. Anesthesia and analgesia are properly and effectively used. Painful studies requiring exemption from the use of analgesia must be subject to particular scrutiny prior to approval and during the experiment;
  3. Appropriate post-operative care is provided.
- 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 3 (l).

#### **4. Meetings**

Animal care committee meetings will normally be held bi-monthly and more frequently if necessary to fulfill their Guidelines 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 will be produced for each meeting, and will be forwarded to the Vice-President, Research and Innovation.

In addition, the ACC should have the opportunity to visit annually 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 ensure that facilities are within CCAC standards, to monitor animal-based work according to approved protocols and SOPs, to consider cleanliness and animal health, that all necessary records are in compliance as required by the CCAC and to

ensure continuous registration under the Animals for Research Act, 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 and written reports to the Vice-President, Research and Innovation that outline findings. The ACC shall, when appropriate, make recommendations to the Vice-President, Research and Innovation relating to the development, maintenance, and use of the animal facilities in their charge.

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 Vice-President, Research and Innovation and the ACC.

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. Will 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. Will 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. Will 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; and will report animal use numbers to OMAFRA as required annually by February 28 of the following year.
  - d. Will 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. Will, 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 care technicians, students, ACC members and other interested parties to attend as possible;
  - f. Will 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. Will be open to developing and maintaining communication with animal welfare organizations.