# McMaster University Logo.

# Animal Research Ethics Board (AREB)

**Health Research Services**

HSC 3H9, 1200 Main Street West Hamilton, Ontario L8N 3Z5

(905) 525-9140 X22465

# Terms of Reference

**McMaster University and Hamilton Teaching Hospitals**

# Animal Research Ethics Board

The President’s Animal Research Ethics Board (hereafter referred to as AREB or the Board) is a University Review Board, constituted by the President and responsible to the President, through the Vice-President, Research, for matters relating to the welfare of animals used in research, teaching and testing by members of the University community. As the welfare of animals is, in part, determined by the knowledge, competence and availability of trained people and quality of facilities for animal maintenance and research, the Board also assumes some responsibilities in these areas. The University will work with the Board to ensure that all animal researchers, educators and caregivers are informed of and comply with the institutional animal care and use policies.

The Board is specifically empowered by the President of the University to review each research, teaching or testing project in which it is proposed that living, non-human vertebrate animals will be used to assure that, in the view of the Board, the number and species of animals used, the procedures employed and levels of pain experienced by any animal are appropriate to the proposed project. The phrase “living, non-human vertebrate animals” is intended to include both animals that are living at the time the experiments are performed on them and animal tissue or tissue obtained from living animals.

McMaster University is responsible for supporting AREB and ensuring the members of the Board are provided with training opportunities to understand their work and role.

# Purpose

To fulfill the University’s legal and ethical responsibilities concerning the use of animals in research, teaching and testing. In general, the Board will ensure that the procurement, care and use of animals under its jurisdiction follow the legislation as presented in the *Animals for Research Act, Ontario (1980)* and administered by the Ontario Ministry of Agriculture and Food and Rural Affairs (OMAFRA) and the guidelines and policy statements established by the Canadian Council on Animal Care (CCAC). The Board is

empowered to make judgments on individual projects beyond the guidelines mentioned in order to ensure that appropriate ethical standards are met.

To provide appropriate policies to the University Veterinarian, Faculty and senior administration (Department Chairs, Deans, Vice-Presidents) and the President of the University. The Board will oversee the application of these policies to the operation of animal facilities and the maintenance of standards of animal care within the University and Hamilton teaching hospitals (St. Joseph’s Healthcare Hamilton and Hamilton Health Sciences).

To ensure that recommendations from appropriate committees within the University are followed so as to ensure the safety and security of both animals and those persons that may come into contact with the animals.

To make recommendations to the appropriate committees and individuals within the University and affiliated hospitals, to ensure adequate communication with the general public concerning animal welfare and experiments with animals.

# Responsibilities

AREB is responsible for ensuring appropriate use of animals for research or teaching at all McMaster University affiliated Animal Facilities and Laboratories including those located at Hamilton teaching hospitals (St. Joseph’s Healthcare Hamilton and Hamilton Health Sciences).

# Animal Welfare

AREB is responsible for:

* + 1. Ensuring that any research project or teaching program involving animals cannot commence without prior AREB approval of a written Animal Utilization Protocol (AUP), and that animals cannot be acquired or used before such approval.
    2. Ensuring that animals cannot be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior AREB approval of a written AUP, except where current CCAC guidelines provide for exemptions. The Board 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.
    3. Requiring all animal researchers complete an AUP form according to current *CCAC Guidelines on Animal Use Protocol Review*. As much as possible, the Board encourages the use of standard operating procedures (SOPs) in order to

facilitate the work of protocol authors, and details should be such that all members of the Board can readily understand. Approved AUPs and SOPs should be readily accessible.

* + 1. Ensuring that an animal-based research project has merit based on independent scientific merit review before it is approved. If the review is not carried out by a funding agency that utilizes peer review, then this responsibility is delegated to the Office of the Associate/Vice Dean of Research of the appropriate Faculty (Faculty of Health Sciences, Faculty of Science or Faculty of Engineering) or his/her designate.
    2. Ensuring all animal-based teaching has been reviewed for pedagogical merit and that the 3Rs (ie: Replacement, Reduction, Refinement) have been considered, particularly replacement alternates. All animal-based teaching protocols must be reviewed by the Pedagogical Merit Review Committee according to its Terms of Reference (<https://fhs.mcmaster.ca/healthresearch/areb_policies.html>) prior to ethics review.
    3. Reviewing AUPs in accordance with CCAC policy statements and guidelines and, where necessary, require further supportive information from the investigator/teacher, or meet with the investigator/teacher to ensure that all members of the Board understand the procedures to be used on the animal(s). Communications are documented in writing. Review and assessment of all AUPs according to the following process can be found on the Faculty of

Health Sciences, Health Research Services website under “AUP Forms” and a “Guide for Preparation of AUPs” (<https://fhs.mcmaster.ca/healthresearch/areb_forms.html>).

* + - 1. If procedures are at variance with CCAC guidelines, then the Board requires scientific justification for the variance.
      2. Discussing protocols and arriving at consensus during full Board meetings. This may involve working with protocol authors until the content of the AUP and the conditions under which it will be implemented are acceptable to all members of AREB. All members of AREB may not be equally comfortable with the protocol, but all should be reasonably satisfied that the work has been refined as much as possible and that safeguards are in place for the animals. On rare occasions where consensus cannot be reached, members present will be asked to vote by a show of hands and the majority opinion will prevail.
      3. Reviewing live animal-based protocols involving McMaster University researchers collaborating at academic institutions or research facilities outside of McMaster University and its affiliated teaching hospitals and research facilities according to AREB’s Institutional Collaboration policy (<https://fhs.mcmaster.ca/healthresearch/areb_policies.html>). For research being conducted at facilities accredited and/or sanctioned by the regulatory organization in their jurisdiction, the approved animal protocol

from the outside facility must be submitted to AREB for discussion. The McMaster University researcher shall address any concerns raised by AREB. Any remaining concerns that AREB may have will be communicated by the Chair of AREB to the Chair of the Collaborating Institution’s animal care committee. For research being conducted in facilities not accredited by a regulatory organization, the AUP must undergo full review by AREB.

* + - 1. Decisions on AUPs reached by AREB include:

**Full Approval** – The AUP can proceed for a maximum of four (4) years, subject to Annual Review and Renewal at years 1, 2 and 3.

**Conditional Approval** – Given for AUPs where AREB is satisfied with the rationale, compliance with CCAC and McMaster University policies, etc., but requires revisions in order for the proposed AUP to reach full approval. The revisions that are required will be documented and communicated to the protocol author. Once the revisions are made, the AUP will be discussed to ensure that all AREB recommendations have been addressed.

**Decision Deferred** – Given for proposed AUPs where AREB 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 the protocol author. Once the revisions are made, the AUP will be discussed at the next scheduled AREB meeting.

**Rejected** – Given where AREB finds that there are fundamental inconsistencies 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 the protocol author.

* + 1. Ensuring that AUPs are reviewed annually during the annual review process. This is done through the Annual Review Form which is evaluated and considered for approval by AREB.

The dates for annual review of an AUP are set upon its initial approval. AUPs can be renewed three times (i.e. AUPs are active for a maximum of 4 years). If the protocol is a Category of Invasiveness D or greater a completed Endpoint Monitoring form must accompany the Annual Review form.

The annual AUP review process considers information including:

* + - 1. the number of animals used in the preceding year;
      2. the number of animals required for the upcoming year (must be consistent with the AUP and subsequent Amendments);
      3. complications encountered relative to animal use (i.e.: unpredicted outcomes, and any animal pain, distress or morbidity/mortality), amendments to the original protocol, adequacy of the endpoints for the

protocol, or refinements made relative to protecting animals from pain, distress or morbidity/mortality;

* + - 1. any progress made with respect to the Three Rs;
      2. other changes from the original protocol;
      3. academic outcomes over the past year.
    1. Ensuring that modification and changes to AUPs are reviewed and approved by AREB prior to start of the work. Application for change(s) to an AUP is made through the AUP Amendment form and most are reviewed by the Protocol Review Subcommittee of AREB, consisting at least a Veterinarian, one Community Representative of AREB, one scientist, and the AREB Chair, and supported by the AREB Ethics Officer and/or Administrative Assistant. The Protocol Review Subcommittee will determine if an AUP amendment is classified as a Minor or Major Amendment.

1. **Minor Amendments** are defined as those involving changes in minor procedures including (but not limited to) blood collection, injection routes, or type of anesthesia used, etc., or relatively minor changes in numbers of animals to be used (generally 10 percent or less of the initial approved number), minor changes in methodologies, and changes to personnel. Minor amendments will be reviewed by the Protocol Review Subcommittee and reported to AREB at the next AREB meeting and are accessible at anytime on AREB’s secure website.
2. **Major Amendments** are defined as those involving significant changes to methodologies, procedures, species used, or significant changes to animal numbers (generally greater than 10 percent of the initial approved numbers). Major amendments are to be reviewed by AREB at the full AREB meeting in the same manner as proposed AUPs (see section 2.1 e above). In exceptional circumstances, direct interim approval can be given by the Protocol Review Subcommittee. The exceptional circumstances (e.g. unforeseen circumstances that arise under a research or teaching protocol that require immediate consideration) must be documented and reported to AREB at the next AREB meeting and are accessible at anytime on AREB’s secure website.
   * 1. Documenting all AREB discussions and decisions in the Board minutes and on attachments to the AUP. Minutes of Board meetings are sent to the Vice- Presidents, Research for McMaster University and its affiliated hospitals (St. Joseph’s Healthcare Hamilton and Hamilton Health Sciences) and the Associate/Vice Deans, Research for the Faculty of Health Sciences, Faculty of Science and Faculty of Engineering.
     2. Ensuring that animal users have access to clarification from AREB regarding decisions as to proposed AUPs. In the event that an AUP or Amendment is not given approval, the applicant can appeal the decision to AREB. An outline of the AREB internal appeal process is found on the AREB Policies website (<http://fhs.mcmaster.ca/healthresearch/areb_policies.html>).
     3. Ensuring that all persons engaged in animal use and AREB members become familiar with OMAFRA’s regulations and CCAC’s guidelines and policy statements, applicable federal, provincial or municipal statutes as well as institutional requirements.
     4. Ensuring appropriate care of animals in all stages of their life and in all experimental situations, through the availability of veterinary care. Veterinary care will be provided according to the guidelines outlined in the current *Canadian Association for Laboratory Animal Medicine’s Standards of Veterinary Care*

(<https://www.calam-acmal.org/resources/Pictures/StandardsVetCare.pdf>)

* + 1. Establishing procedures commensurate with current veterinary standards to ensure that:
       1. Unnecessary pain or distress is avoided, and animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters.
       2. Anaesthesia 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 AREB. Painful studies requiring exemption from the use of either anaesthetics or analgesics must be subject to particular scrutiny, not only prior to approval, but also during the experiment.
       3. Appropriate post-operative care is provided.
       4. All due consideration is given to animal welfare, including environmental enrichment.
    2. Ensuring that policies to provide for a system of animal care that will meet the needs of the institution are established and implemented, and include:
       1. 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;
       2. ensuring adequate animal care and management of the animal facilities, in particular through the University Veterinarian who is designated to be in charge of animal care and management of the animal facilities, and is a member of AREB (see Section 4 Membership), and who should keep the other AREB members updated on the activities within the animal facilities;
       3. 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 must receive appropriate training according to the current “*CCAC Guidelines on: training of personnel working with animals in science”*, either within the institution or through the programs of other institutions;
       4. those involved in animal care and use, adhere to an occupational health and safety program 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 current CCAC guidelines;

* + - 1. standards of husbandry, facilities and equipment;
      2. 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); AREB has access to all SOPs and reviews animal welfare and procedures;
      3. procedures for euthanasia of animals are both humane and in accordance with relevant legislation and current *“CCAC guidelines on: euthanasia of animals used in science”*. <http://www.ccac.ca/Documents/Standards/Guidelines/Euthanasia.pdf>
    1. Encouraging the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Ensuring 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.
    2. In the case of projects involving proprietary or patentable research or testing, ensuring that as much information as possible is provided to AREB in terms of what effects to expect on animal health and welfare, and AREB will insist on close monitoring of animals in order to respect the elements outlined above.
    3. Ensuring that adequate administrative procedures are in place to ensure proper and humane treatment of all animals used for research, testing or teaching. “Humane treatment” will include the provision of appropriate space and facilities, as defined by the CCAC Guidelines <https://www.ccac.ca/en/standards/guidelines/>
    4. The Board and all members shall take all reasonable efforts to protect the confidentiality of the nature and purpose of the research it oversees.
    5. The Board shall ensure that accurate and complete animal use information is submitted annually as required by OMAFRA and the CCAC, and liaison with the CCAC is maintained.

# Animal Care Facilities

Representatives of the Board shall annually inspect McMaster University affiliated animal facilities and laboratories where experiments are performed using live animals, document such visits and report back to AREB. All AREB members are required to attend at least one facility and laboratory audit each year. AREB shall monitor animal care procedures to ascertain:

1. that facilities comply with OMAFRA and CCAC standards;
2. that there is continuous registration under the OMAFRA *Animals for Research Act* and that all necessary records are in compliance as required by the CCAC. Those responsible for animal facilities shall respond in writing to any recommendations made by AREB during site visits, and site visit reports will be followed up jointly by senior administration and AREB;

AREB shall, when appropriate, make recommendations to the Deans of the Faculty of Science, the Faculty of Engineering and the Faculty of Health Sciences, through their Associate/Vice Deans of Research relating to the development, maintenance and use of the animal facilities in their charge, as they relate to animal welfare. This will be in addition to, and separate from, any recommendations made by other institutional bodies struck to assess planning/allocation of resources/infrastructure.

# Authority

The Board will take necessary steps to ensure that measures are taken to prevent unnecessary pain and distress to animals specifically as detailed in the current edition of the CALAM/ACMAL *Standards of Veterinary Care of the Canadian Association for Laboratory Animal Medicine* and the OMAFRA *Animals for Research Act*. In particular:

1. AREB will establish procedures to ensure that, when possible, in any experiment likely to result in pain, the animal shall be anaesthetized or given pain management so as to prevent unnecessary pain and suffering. Studies requiring exemption from the use of either anaesthetics or analgesics must be closely scrutinized by AREB and, like all other protocols, such use must be approved prior to initiation. Endpoint definition and monitoring procedures are expected to be included in such protocols.
2. AREB, if it determines that proper and humane procedures are not being followed or that unnecessary pain is being experienced by any animal, shall be empowered:
   1. To stop any procedures which AREB, acting in accordance with appropriate guidelines, finds objectionable. This includes the responsibility to halt any unapproved work or work that deviates from approved protocols. If investigation demonstrates willful or repeated neglect of responsibilities by a researcher, AREB may advise that the privilege of conducting research with animals at McMaster University be withdrawn from that researcher. In the event of this, the AREB Chair, on behalf of AREB, shall so inform relevant officers of the University including the Associate/Vice Dean of Research of the individual’s Faculty (Faculty of Health Sciences, Faculty of Science or Faculty of Engineering), his/her Departmental Chair and the appropriate research administration office (Health Research Services, Faculty of Health Science or Research Office of Administration and Development Services, Faculty of Science and Faculty of Engineering).
   2. Where such procedures have caused distress to the animal which cannot be alleviated (e.g. by stopping the procedure(s) or providing analgesia), to humanely euthanize it.
   3. All cases of willful or repeated neglect of animal care or use will be referred to the Office of the Associate/Vice Dean of Research of the appropriate faculty (Faculty of Health Science, Faculty of Engineering, or Faculty of Science). The Board recognizes that the University Veterinarian is often the major operational figure in the work of the Board. Therefore, the Board delegates to the University Veterinarian the ongoing authority to act on behalf of the Institution and the Board to ensure proper care and treatment of animals, and is given the authority to intervene whenever necessary following procedures outlined in the current *CALAM/ACMAL Standards of Veterinary Care* of the Canadian Association for Laboratory Animal Medicine. The University Veterinarian will advise the Chair in writing of emergency actions taken on behalf of the AREB and report to AREB at the next AREB meeting.
   4. The Board shall review at least annually animal welfare regulations and guidelines that may affect animal research or animal maintenance at McMaster University and at the Hamilton teaching hospitals. When appropriate, AREB shall make changes in its procedures to facilitate compliance with said regulations or guidelines.

# Membership

1. A Chair, who shall not be involved in the management of the animal facilities or be a Clinical Veterinarian or be involved in a significant number of the protocols to be reviewed by the Board.
2. At least three representatives of the Faculty of Health Sciences.
3. At least one representative of the Faculty of Science, Department of Psychology.
4. At least one representative of the Faculty of Science, Department of Biology.
5. Other members drawn from the Faculty of Health Sciences, Faculty of Engineering and/or Faculty of Science.
6. At least one member of the University faculty or staff not engaged in research, teaching or testing with animals.
7. At least one representative from faculty or staff based at the Hamilton teaching hospitals.
8. At least one member of technical staff actively involved in the care and/or use of animals within the institution.
9. At least two persons representing community interests and concerns (one of which is a community representative mentor), and who are not affiliated with the University and are not involved in animals used for research, teaching or testing.
10. At least one Veterinarian specializing in the field of laboratory animal medicine.
11. One person responsible for the management of the animal facilities.
12. At least one or more graduate students engaged in animal research.
13. The University Veterinarian.

Faculty representatives must include scientists and/or teachers experienced in animal care and use, who may or may not be actively using animals during their term on the Board.

# Board Resources and Administrative Staff

1. Training and Regulatory Coordinator
2. Biosafety Representative.
3. Health Physics Representative.
4. Health and Safety Representative.
5. FHS Corporate Services Representative.
6. Representative Administrator, Health Research Services.
7. AREB Ethics Officer.
8. AREB Administrative Assistant.

# Terms of Appointment

1. The Chair is appointed by the President of the University for a period of three years, renewable. The Chair may serve up to a maximum of eight consecutive years of service in any AREB role. The Chair shall not be involved in the management of the animal facilities, be a Clinical Veterinarian or be involved in a significant number of the protocols to be reviewed by the Board.
2. The members are appointed by the President on the advice of the Vice President, Research and the Associate/Vice Dean, Research, Health Sciences, in consultation with the appropriate Deans of the Faculties, Departmental Chairs and the teaching hospital Directors of Research.
3. The Chair of the Board may appoint additional members to serve as resource persons and may form subcommittees at his/her discretion.
4. The term of appointment for members of the Board shall be four years, renewable once, up to a maximum of eight (8) consecutive years of service, and should be staggered to ensure continuity of membership and prevent significant changes in membership over short periods of time.
5. Term limits outlined above do not apply to members who must be part of AREB because of their role within the institution including the AREB Ethics Officer, AREB Administrative Assistant, Community Representative Mentor, University Veterinarian, the Representative for the Management of the Animal Facilities, the Representative Administrator of Health Research Services, the Biosafety, the Health and Safety and the Health Physics Representatives.

# Frequency of Meetings

1. Once per month or as necessary.
2. Meetings to be called by the Chair.
3. Quorum for meetings consists of fifty percent (50%) plus one (1) members, and must include community, veterinary representation and minimum of two (2) scientists.
4. Decisions shall be made by consensus.

# General

1. AREB must regularly review (at least every three years) and revise if necessary:
   1. 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;
   2. the security of the animals and research facilities;
   3. SOPs and institutional animal care and use policies; AREB delegates SOP review to AREB members with the appropriate expertise, but SOPs will be accessible to all AREB members, and the full AREB will review all SOPs that involve procedures that may result in effects to animal health or welfare;
   4. 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 AREB to conduct monitoring.
2. AREB must maintain liaison with OMAFRA and the CCAC Secretariat, and inform the Secretariat of any changes to the animal care and use program in a timely manner; and at the same time inform the senior administrators for McMaster responsible for the animal care and use program, the Chair of AREB, and the veterinary or senior animal care personnel of any changes to the animal care and use program;
3. AREB must submit complete and accurate animal use information as required for OMAFRA and the CCAC on the 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;
4. AREB maintains 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 includes a communications plan for addressing public and media inquiries on concerns related to animal use.

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