FACILITY ANIMAL CARE COMMITTEE
(FACC)

TERMS OF REFERENCE

Facility Animal Care Committees (FACCs) are established for each major McGill University campus involving animals in research, teaching or testing, in accordance with the Policies and Guidelines of the Canadian Council on Animal Care (CCAC). The purpose of each FACC is to ensure that all animals in research, teaching or testing activities within its mandate, are used and cared for in accordance with all applicable requirements.

All McGill FACCs operation is governed by the following Terms of Reference. Research Institutes may choose to follow these Terms of Reference or establish their own.

The McGill University FACCs are:

1. Downtown Campus A FACC - mandate includes all downtown campus-based projects (non-field study projects) and associated animal facilities. The review is mainly those of cell biology and tumour type projects;

2. Downtown Campus B FACC - mandate includes all downtown campus-based projects (non-field study projects) and associated animal facilities. The review is mainly those of behaviour, physiology, non-human primate and teaching projects;

3. Macdonald Campus FACC – mandate includes all Macdonald campus-based projects and associated animal facilities, including the farm as well as field study projects from all Faculties;

4. MNI FACC – mandate includes the Montreal Neurological Institute (MNI) and all associated animal facilities.

On the basis of CCAC certifications, the four McGill University’s FACCs report to the Vice-Principal (Research & Innovation) (VP(RI)). In the case of the MNI, the MNI FACC reports to the Director who reports to the VP-RI in matters related to animal care.

In addition, all FACCs have representation on the Animal Policy and Welfare Oversight Committee (APWOC).

1. Membership

FACC members are 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 and every effort will be made to find a replacement. This does not apply to FACC members who must be part of the FACC because of their role within the institution (ex officio members): the FACC coordinator, the veterinarian(s), the Animal Compliance Office representative (ACO) and the animal facility supervisor/manager.
The composition may vary according to the needs of each committee, but the membership includes:

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

b) at least one veterinarian experienced in laboratory animal medicine;

c) one institutional member whose normal activities 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 recent 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 FACC activities throughout the year;

e) technical staff representation (either an animal care, an animal facility or an animal research technician);

f) one animal facility supervisor/manager;

g) person(s) mandated to perform post-approval monitoring (also known as Quality Assistance Advisor);

h) at least one representative of the Animal Compliance Office (ACO) (only for McGill FACCs);

i) One graduate student representative; and

j) the FACC Coordinator.

2. FACC Chair

The Chairs of the McGill FACCs are appointed by the VP (RI). In the case of the MNI, the FACC Chair is appointed by the MNI Director and confirmed by the VP (RI).

The Chair represents the committee and as such, is expected to work with members at reaching consensus on decisions and action items. Quorum is 50% plus 1 of the FACC members. Where a matter cannot be resolved by consensus and where a vote would be appropriate in light of the issue before the Committee, a vote will be taken. The view of the simple majority will prevail. The Chair will cast the deciding vote in the event of a tie. Committee minutes must incorporate the dissenting opinion(s).

In order to avoid potential conflicts of interest, the FACC Chair must not be any of the following:

- Veterinarian or any other animal health or veterinary personnel member charged with ensuring compliance with CCAC guidelines;
- personnel directly involved in the management of the institutional animal facilities;
- researcher or individual involved in the preparation of a significant number of the protocols to be reviewed by the committee.

In the absence of the Chair, or when in conflict of interest, a Chair must delegate his/her authority and responsibilities, to another member of the committee, who is not in conflict of interest as listed above. This member is often referred to as Vice-Chair of the FACC and there can be more than one Vice-Chair.

3. Authority
The FACC has the authority, on behalf of the senior administrator responsible for animal care and use for the institution, to:

a) Stop any procedure if it concludes 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;
c) Have an animal euthanized humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated;
d) Order the withholding of research funds and/or animal ordering privileges for projects in non-compliance with the applicable requirements;
e) Revoke animal facility access privileges and take further action if appropriate; animal facilities must report revoking of privileges to the FACC with appropriate documentation justifying this action.

The FACC must have access at all times to all areas where animals are or may be held or used. Upon request, the FACC will not be denied access to these areas.

Any FACC member who is, or appears to be, in conflict of interest must recuse themselves from discussions and decisions related to the matter.

The FACC works with the ACO, the Quality Assistance Advisor(s) (QAAs)(person(s) responsible for post-approval monitoring), members of the veterinary and animal care staff to ensure compliance with its decisions and with the conditions set out in approved protocols. The ACO personnel, the QAA, the veterinary and animal care staff must work in a collegial manner with animal users and attempt to correct deficiencies collaboratively.

The FACC is the body responsible for determining and working to correct breaches of compliance with approved animal use protocols and Standard Operating Procedures (SOPs). In the event of a major or serious animal welfare incident, the FACC must follow the McGill Policy on Reporting Serious and Major Incidents. The FACC Chair (or delegate) is responsible for reporting any persistent breaches of compliance or threats to the health and safety of personnel or animals to the senior administrator and to the CCAC, as necessary. In the event that the serious breaches of compliance are not addressed, the senior administration must inform all members concerned about sanctions that will be taken by the administration.

The veterinarian is designated by the Senior Administrator and must be a licensed veterinarian with authority and responsibility for supporting the overall institutional animal ethics and care program. This includes oversight for all related activities that are occurring at institutional sites and in the field. The veterinarian can delegate responsibilities to other individuals, including other veterinarians, who are qualified to perform those duties.

The Senior Administrator of the institution and its FACCs must acknowledge and define the responsibilities and authority of the veterinarian, including:

• The veterinarian or his/her designee is responsible for and has authority to ensure provision of a comprehensive veterinary care program that meets all regulatory and/or compliance requirements;
• The veterinarian or his/her designee must have access to all sites, at all times, where animals are maintained and worked with, as well as access to animal use protocols and medical records; and
• The veterinarian or his/her designee has the authority to treat, remove from a study or euthanize, if necessary, an animal based on their professional judgement.
4. Responsibility of higher administration:

The senior administrator responsible for the CCAC certificate, i.e., VP (RI) at McGill, appoints the FACC Chair and Vice-Chair(s). The selection is done in consultation with the current Chair of each FACC. The FACC Chair and/or the senior administration appoints its members.

The senior administrator also provides a FACC Coordinator. The coordinator supports the FACC Chair by ensuring that animal use protocols are well managed, that committee minutes and reports are promptly produced and distributed, that all exchanges between the FACC and animal users are well documented and filed in a timely manner, and that animal users and FACC members are provided with necessary information and software training. Minutes and reports must be made available to the senior administration.

For specifics on appointment of community representatives refer to APWOC Policy on Community Representatives.

The senior administration must also ensure that FACC members are provided with training opportunities to understand their work and role: these must include at least a formal orientation session, to introduce new FACC 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. Ongoing opportunities to better understand animal care and use in science are also provided.

The senior administration must also ensure that projects involving the use of animals are reviewed for their scientific merit via the source of funding or internal peer review or pedagogical merit via the ACO (for all FACCs), according to CCAC policies.

5. Responsibility of the FACC

It is the responsibility of the FACC to:

a) Ensure that no research or testing project or teaching program (including field studies) involving animals be commenced without prior FACC approval in the form of an Animal 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 breeding purposes, or for eventual use in research, teaching or testing projects, without prior FACC approval in the form of an Animal Use Protocol, except where current CCAC guidelines provide for exemptions.

c) Require all animal users to complete an Animal Use Protocol form in its entirety and ensure that the information therein includes the following points, clearly presented in a format that all members of the FACC can readily understand. To facilitate the work of both protocol authors and FACC members, appropriate SOPs are to be followed when applicable.

   i) project title and descriptive procedural keywords and brief description of the procedures to be conducted on animals;

   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;

   iii) 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;

   iv) for research or testing projects, funding source(s);
v) for research projects, an indication of whether the project has received peer review for scientific merit;

vi) for teaching and training projects, a course number (if applicable) and an indication of whether the project has obtained favourable pedagogical merit;

vii) for testing projects, an indication that the testing has been planned according to the most current regulatory requirements, using guidelines acceptable to the regulatory agency(ies) and which meet the requirements of the CCAC Policies; that the planned animal use not exceed the requirements of the regulatory authorities - if it does, justification for the additional animal use must be provided;

viii) lay summary;

ix) an indication and details as to the use of biohazardous, hazardous chemical or radioactive agents in animal-based projects;

x) category(ies) of invasiveness and Purpose of Animal Use (PAU) as defined in the CCAC Policies,

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

xi.1 Justification 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;

xi.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;

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

xi.3.1 anesthesia and analgesia, including dosages and methods of use, for all invasive protocols;

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

xi.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 FACC;

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

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

xi.3.6 any other possible refinements;

xii) a clear description detailing the procedures that are carried out on the animals (referring to appropriate SOPs as much as possible);

xiii) a description of the endpoint(s) of the experimentation (refer to institutional SOPs, if available and relevant); the person(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 and posted, in the area where the animal-based work is taking place;

xiv) a description of capture, restraint, transportation and/or housing of animals used in field studies, as well as any other information pertinent to field studies, such as capture of non-target species, ecological impacts and potential injuries or mortality during capture or transportation, if relevant;

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

xvi) a description of the fate of the animals if they are not to be euthanized, including the length of time that they are to be held;

xvii) any other information considered important or necessary and pertinent, 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 peer review is not carried out by an external funding agency, the scientific merit assessment must be obtained according to the CCAC policy on scientific merit review of animal-based research, and the mechanism in place is performed by the Associate Dean or Director’s Office and is valid for a maximum of 5 years;

Ensure that each teaching or training project has been found to have pedagogical merit through independent peer review before approving the project. Pedagogical Merit Reviews are administered by the ACO and are valid for 4 years.

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 FACC discussions with protocol authors can be very useful, but protocol authors and members of their teams must always clearly remove themselves from FACC 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. FACCs 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 to facilitate protocol management purposes and to expedite the submission and review of protocols. This is encouraged as long as FACCs continue to meet in person for protocol discussions and final approvals.

A FACC can 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 FACC. The interim review process, including exchanges between the FACC and protocol authors, must be documented and must then be subject to discussion and final approval at a full meeting of
the committee. Protocol authors requiring an interim approval must contact the Chair (or delegate) and justify the need for such a review.

f) Ensure that animal users update their approved protocols with any modifications they intend to make, and approve any amendments to a protocol before they are implemented. It is the prerogative of the FACC to decide if a protocol amendment is to be considered a minor or major change based on the context of the proposed modifications and the main protocol in question. The FACC Coordinator can review the amendment, consult with the Chair as needed, before submitting to either the full membership or a subset of the FACC.

i) For any major changes, a review by the full committee is required. Major changes are defined as, but not limited to: a change in the fundamental objective, an increase of 20% or more in the number of animals required, a change of species, use of more invasive or more frequent procedures.

ii) For minor modifications, a review by the Chair of the FACC or a delegate is required. Minor modifications are defined as: changing contact information, changing funding source, addition or removal of personnel, an increase of less than 20% in animal numbers, addition of a new strain, changing housing or procedure location, switching to less invasive, distressful or painful procedures, switching to a non-physical euthanasia method covered by an approved SOP. Minor modifications approved by the Chair (or delegate) are documented in the minutes of the following FACC meeting.

iii) 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 FACC.

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 representative and should be brought to the attention of the full FACC for its information. Protocol renewals must emphasize:

i) the number of animals used in the preceding year. The Principal Investigator must provide the number per species if not captured by the animal facility census system or supplied by the animal facility staff;

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 changes to the goals of 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.

v) any other changes from the original protocol.

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

h) Document all FACC discussions and decisions in the committee minutes and FACC recommendations made to the PI linked to the protocol forms;

i) Ensure that all FACC members and animal users have the opportunity to become familiar with CCAC guidelines and policy statements, federal, provincial or municipal statutes that may apply, as well as institutional requirements;

j) 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 with adequate expertise for the animals in question, 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 Standards of Veterinary Care of the Canadian Association for Laboratory Animal Medicine (CALAM/ACMAL), which define the roles and responsibilities of veterinarians involved in scientific animal care and use programs;

k) 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 FACC. 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;

l) 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;

m) In the case of projects involving proprietary or patentable research or testing, ensure that as much information as possible is provided to the FACC in terms of what effects to expect on animal health and welfare, and insist on close monitoring of animals;

n) Designating areas in which animals may be housed, cared for and used so as to ensure facilities and personnel are adequate to provide humane care and use;

o) Supports the Quality Assistance Program to ensure that all animal facilities and research laboratories where live animal work is conducted, are visited by the QA Advisor (QAA) on a regular basis to facilitate compliance to animal use protocols. In collaboration with the QAA, addresses pending and/or unresolved non-compliance issues in a timely manner.

p) For multi facility protocols, it is the home FACC to which the protocol is submitted and where it is reviewed. The home FACC is defined as the FACC mandated to oversee the location of the investigator's/instructor's main appointment. The home FACC will send a copy to the host FACC who will discuss it with the appropriate committee members as necessary and send comments back to the home FACC Coordinator. Comments from both FACCs will be incorporated into one set of recommendations to the Principal Investigator.

q) For construction and renovations of all proposed and current animal housing and research facilities, the FACC, a subcommittee thereof, or the veterinarian will participate in the facility planning with the involved units and reports to the APWOC on progress of major projects.

r) Ensure that assessment documentation is supplied to the CCAC by the deadline and that a response it given to the CCAC for recommendations made in assessment reports and requests for updates.

6. FACC Meetings and visits of animal facilities
Animal care committees should meet at least four times per year and as often as necessary to fulfill their mandate as described in this 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 FACC discussions, decisions and modifications to protocols must be produced for each meeting and made available to their senior administration.

Quorum is the majority of committee members but must include a veterinarian, a Community Representative and a researcher. Meetings should be scheduled at times that are convenient for all members, including community representatives. Protocol review comments should be submitted via the online software or by email for proposed decisions or significant changes to the FACC Coordinator by non-attending committee members.

Visits of the animal facilities and areas in which live animals are used must be conducted at least once a year and must be documented through the FACC minutes or written reports. Those responsible for the animal facilities and laboratories should respond to any FACC recommendations in writing, and site visit reports should be followed up by the FACC and/or Quality Assistance Advisor and/or facility Vets or staff, and if not resolved, involve the senior administration. Visits to animal care facilities and areas in which live animals are used may be divided between the various members of the committee. Each member of the FACC should participate in at least one of the facility visit(s) on an annual basis.

In addition, the FACC is encouraged to 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, appropriate management of controlled substances and documentation of use, and any other concerns) and to forward any recommendations or commendations to the person(s) responsible for the facilities and for animal use.

More frequent FACC 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 members of the FACC and/or the Quality Assistance Advisor and/or veterinary and/or animal facility staff.

7. General

a) For McGill FACCs (including the MNI FACC), the AUDF is completed by the ACO in collaboration with the animal facilities staff and submits to the CCAC by March 31.

b) Must ensure that a crisis management program is in place for the animal facilities and for the animal care and use program, in conjunction with any general institutional crisis management plan(s). 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 crisis, and must include a communications plan for addressing public and media inquiries on concerns related to animal use;

c) FACCs may, 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, FACC members and other interested parties to attend as possible.