

THE NEURO ANIMAL CARE COMMITTEE (THE NEURO ACC) Terms of Reference

Introduction

Facility Animal Care Committees (FACCs) are established for each major McGill University campus and affiliated institutions, including The Neuro, using animals in research, teaching or testing, in accordance with the Policies and Guidelines of the Canadian Council on Animal Care (CCAC). The purpose of the Neuro ACC is to ensure that all animals used in research, teaching or testing within its jurisdiction, are used and cared for in accordance with all applicable requirements and with the same degree of care and attention regardless of the species. The Neuro Animal Care Committee (ACC)'s operation is governed by the following Terms of Reference. The Neuro ACC reports to the Director of The Neuro. In addition, The Neuro ACC is part of the McGill University Animal Care and Use program and has representation on the Animal Policy and Welfare Oversight Committee (APWOC).

1. Membership

The Neuro ACC members are appointed for terms of no less than two years and renewable, usually up to a maximum of eight consecutive years of service. This does not apply to ACC members who must be part of the ACC because of their role within The Neuro (ex officio members): the ACC Administrator, The Neuro Compliance Officer, the Veterinarian(s), the Centre for Neurological Disease Models (CNDM) Associate Director, and the Colony Manager. At The Neuro, the membership of the ACC consists of:

1.a. A minimum of two scientists experienced in animal care and use, who may or may not be actively using animals during their term on the ACC; representation of the diverse animal-using units of The Neuro must be ensured;

1.b. An institutional member whose normal activities do not depend on or involve animal use for research, teaching or testing;

1.c. One or two graduate student(s) and/or research trainee representatives;

1.d. Full-time veterinarian(s) experienced in laboratory animal medicine;

1.e. The animal facility associate director, and colony manager;

1.f. Technical staff representation (either an animal health or an animal care technician);

1.g. At least one, and preferably two person(s), representing community interests and concerns, who has (have) had no affiliation with The Neuro or McGill, and who has (have) not been involved

in animal use for research, teaching or testing for at least one year; community representation must be ensured for all ACC activities throughout the year;

1.h. The Director of the McGill Animal Compliance Office or delegate and

1.i. The Neuro full-time ACC administrator and The Neuro compliance officer.

In order to avoid potential conflicts of interests, The Neuro ACC Chair must not be directly involved in the management of the institutional animal facilities, nor be the facility veterinarian(s), and should not be involved in the preparation of a significant number of the protocols to be reviewed by the committee.

The Neuro ACC administrator supports the ACC by ensuring that animal use protocols are well managed in the electronic protocol management system, Animal Management System (AMS) software, 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 Neuro compliance officer is responsible for The Neuro Post-Approval Monitoring Program (PAM) and all other Neuro compliance functions.

2. Authority

The Neuro ACC must have access at all times to all areas where animals are or may be held or used.

The ACC has the authority, on behalf of the Director of The Neuro, who is responsible for animal care and use at The Neuro, to:

2.a. Stop any procedure if it considers that unnecessary distress or pain is being experienced by an animal.

2.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.

2.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.

2.d. Have an animal(s) placed on Holding Protocol in the following circumstances:

2.d.i. When an Animal Use Protocol (AUP) approval is pending.

2.d.ii. When an AUP is terminated and there are remaining housed animals.

2.d.iii. In all other circumstances deemed appropriate by The Neuro ACC, such as:

2.d.iii.1. If animals are received prior to approval of a new AUP.

2.d.iii.2. If the AUP has expired and is still pending renewal submission to The Neuro ACC.

2.e. Order the withholding of research funds and/or animal ordering privileges for programs in non-compliance with the applicable requirements.

2.f. Supervise the Post-Approval-Monitoring (PAM) process and ensure that recommendations of The Neuro Compliance Officer are implemented.

2.g. Monitor Breaches of Compliance:

The Neuro ACC is the body responsible for identifying and working to correct breaches of compliance with approved animal use protocols and Standard Operating Procedures (SOPs). The ACC working with concerned animal users and veterinary / animal care staff will implement solutions to address the breach in compliance. Breaches of compliance that cannot be resolved by discussion of The Neuro ACC with the involved Principal Investigator (PI) must be referred to The Neuro Director. Animal research that has been performed and completed without an approved protocol will be referred to the Director of The Neuro as a major breach of compliance. All members of the animal care and use program will be informed about decisions that will be taken by The Neuro senior administration in the event of serious breaches of compliance.

The Neuro ACC collaborates with The Neuro Compliance Officer, The Neuro veterinarian(s), The Neuro facility animal care staff, and the McGill Animal Compliance Office, to ensure compliance with its decisions and with the conditions set out in approved protocols. The Compliance Officer, veterinarian(s), and animal care staff must work in a collegial manner with animal users and attempt to correct deficiencies collaboratively. In the event of a major or serious animal welfare incident, the FACC will follow the McGill Policy on Reporting Serious and Major Incidents. Where there are persistent breaches of compliance or threats to the health and safety of personnel or animals, these must be reported back to the Chair of The Neuro ACC, and the ACC must promptly address these issues, through communications with the animal user (s), meetings and site visits, and eventually communications with The Neuro Director, as necessary. Furthermore, if deemed necessary, the veterinarian can report major animal welfare compliance issues directly to The Neuro Director.

The Neuro ACC also recognizes that The Neuro veterinarian(s) have the authority to treat, remove from a study or euthanize, if necessary, an animal according to the veterinarian(s)'s professional judgment. The veterinarian(s) involved must attempt to contact the animal user whose animal is in poor condition before beginning any treatment that has not previously been agreed upon, and should also attempt to contact The Neuro ACC Chair, if deemed pertinent, but the veterinarian(s) has the authority to proceed with any necessary emergency measures, whether or not the animal user and ACC Chair are available. For life threatening emergencies where immediate action is needed, the veterinarian(s) may proceed with emergency procedures based on his/her professional judgment prior to contacting the animal user and The Neuro ACC Chair. In such case, the veterinarian(s) will inform the animal user and The Neuro ACC Chair of the actions that were taken as soon as possible. A written report should be sent by the veterinarian(s) to the animal user and to The Neuro ACC following any such event.

3. Responsibility of Higher Administration

The Director of The Neuro appoints the Chair, ACC Administrator, and Compliance Officer. The Neuro ACC Chair appoints the other committee members. For specifics on appointment of community representatives refer to APWOC Policy on Community Representatives.

The Neuro must also ensure that ACC members are provided with training opportunities to understand their work and role: these must include at least a formal orientation session, to introduce new ACC members to The Neuro'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 should also be provided.

The Director of the Neuro appoints the veterinarian, who 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. The veterinarian may delegate responsibilities to other individuals, including other veterinarians, who are qualified to perform those duties.

The Neuro Administration and its FACCs 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 ACC

It is the responsibility of the ACC to:

4.a. Ensure that no procedures 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. This includes internally funded projects.

4.b. Ensure that no animals be held for 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 personnel responsible for these activities to ensure that animal care and use is undertaken according to appropriate procedures.

4.c. Require all animal users to complete an electronic animal use protocol form in its entirety and ensure that the information therein includes the following points, clearly presented in a form that all members of the ACC can readily understand.

4.c.i. Project title and descriptive procedural keywords and brief description of the procedures to be conducted on animals.

4.c.ii. List of 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.

4.c.iii. If the study is to take place over more than one year, the work and numbers of animals for the first year only should be provided, and further work can then be approved in annual review(s), full review(s), or new protocol(s).

4.c.iv. For research or testing projects, funding source(s) and status of funding approval.

4.c.v. For research projects, an indication of whether the project has received peer review for scientific merit.

4.c.vi. For teaching programs, a course number and an indication of whether the course has been reviewed with respect to the pedagogical merit of using live animals.

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

4.c.viii. Lay summary.

4.c.ix. An indication of the use of biohazardous, hazardous chemical or radioactive agents in animal-based projects; and, if so, an indication of institutional approval of this use.

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

4.c.xi. Proof of awareness of the Three Rs (replacement, reduction and refinement alternatives) of animal use, to include:

4.c.xi.1. Awareness 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.

4.c.xi.2. Justification of the species and numbers of animals to be used over the course of the year, to emphasize minimization (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.

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

4.c.xi.3.1. Anesthesia and analgesia, including dosages and methods of use, for all invasive protocols.

4.c.xi.3.2. Other medical treatments as appropriate, as indicated through veterinary consultations.

4.c.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 ACC.

4.c.xi.3.4. Refinements to the procedures to be employed on the animals.

4.c.xi.3.5. Refinements to the length of time that animals will be held/used.

4.c.xi.3.6. Any other possible refinements.

4.c.xii. A clear description detailing the procedures that are carried out on the animals (referring to appropriate SOPs as much as possible).

4.c.xiii. A description of the endpoint(s) of the experimentation, selected according to the CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching and testing, (refer to The Neuro/McGill 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 all animals requiring treatment are treated and that animals are not simply kept indefinitely; relevant information for identifying and applying endpoints must be readily available, preferably posted, in the area where the animal-based work is taking place.

4.c.xiv. 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 guidelines on euthanasia.

4.c.xv. 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.

4.c.xvi. 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.

4.d. Ensure that each research project has been found to have scientific merit through independent peer review before approving the project; if such review is not carried out during the grant application review process it must be obtained according to the CCAC policy statement on: the importance of independent peer review of the scientific merit of animal based research projects. At The Neuro, in the case of protocols not so reviewed, the PI is required to contact The Neuro Associate Director, Academic Affairs, and request that an ad-hoc external peer review be performed according to the CCAC guidelines, to review the project for scientific merit.

4.e. Review and assess all animal use protocols and amendments, 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 the final ACC decision-making on their own protocols.

The committee must also ensure that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, require justification for the variance on scientific grounds. 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.

4.e.i. New protocols, fourth year renewals, and annual renewals are reviewed by the full committee.

4.e.ii. Amendments:

It is the prerogative of The Neuro ACC 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 Neuro ACC Coordinator can review the amendment, consult with the Chair as needed, before submitting to either the full membership or a subset of The Neuro ACC.

4.e.ii.1. For any major changes, a review by the full committee is required. Major changes are defined as: 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.

4.e.ii.2. For minor modifications, a review by the Chair of The Neuro ACC 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 Neuro ACC meeting, with exceptions to changes to the AUP title, funding, personnel contact information or additional personnel.

4.f. Ensure that animal users update their protocols with any modifications they intend to make and approve any amendments to a protocol before they are implemented.

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

4.h. Review all protocol short reviews annually and all protocol full reviews every fourth year;

4.i. Document ACC discussions and decisions in the committee minutes.

4.j. Ensure that appropriate care of animals in all stages of their life and in all experimental situations is provided by The Neuro CNDM Veterinary services.

4.k. Establish procedures, commensurate with current veterinary standards, to ensure that;

4.k.i. Unnecessary pain or animal stress and injuries are avoided, whether during transfers of animals or in their normal quarters.

4.k.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.

4.k.iii. Appropriate post-operative care is provided and documented.

4.k.iv. All due consideration is given to animal welfare, including environmental enrichment.

4.I. 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.

4.m. 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.

4.n. In the case of projects involving collaboration with investigators from other institutions, ensure that appropriate Neuro committees have access to the approved Animal Use Protocol from the other institution, if only technological services are provided and animals never enter The Neuro CNDM. When other procedures and/or housing of animals at the ACF are also to be carried out at The Neuro, the home principal investigator has to submit an amendment to his/her approved protocol if available or submit a new AUP for review. A copy of the approved protocol from the collaborator's home ACC should be attached to the protocol.

4.o. In the case of The Neuro PIs who have animals housed and/or perform survival procedures in areas outside of the facility, the ACC applies the McGill APWOC approved, Policy on permission to use animals in laboratories outside of the animal facility, by:

4.o.i. The Compliance Officer, or if additional expertise is required, a subcommittee composed of the Compliance Officer and Veterinarian, or CNDM Associate Director inspecting the area in question.

4.o.ii. All comments from the inspection are summarized in a report by The Neuro Compliance Officer and the report is reviewed and approved by all subcommittee members (if applicable) before sending it to the PI.

4.o.iii. The PI responds to the recommendations(s) of the report and is then issued an Alternate Laboratory Animal Procedure, Housing or Holding (A.L.P.H.A.) certificate to be posted in the area inspected, and the area is re-inspected annually.

5. Meetings

The Neuro ACC meets at least ten times per year and as often as necessary to fulfill their Terms of Reference and be satisfied that all animal use within their jurisdiction complies with institutional and CCAC guidelines. Minutes detailing ACC discussions are forwarded to The Neuro Director.

Quorum is the majority of the members, but under most circumstances it must include a Community Representative, one researcher, and a Veterinarian. Meetings should be scheduled at times that are convenient for all members, including Community Representatives. If the Community Representative cannot be present due to an unforeseen last-minute event, the meeting may proceed but her/his review provided in AMS should be discussed by the committee. Unavoidably absent members are nevertheless encouraged to review all documents in AMS by the previously set due date.

Visits of the animal facilities and areas in which live animals are used (A.L.P.H.A.) must be conducted at least once a year and must be documented through the ACC minutes or written reports. Those responsible for the animal facility and laboratories should respond to any ACC recommendations in writing, and site visit reports should be followed up by the ACC and /or Compliance Officer and/or facility Vets or staff, and if not resolved, involve the Neuro 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 ACC is encouraged to visit the animal care facility in order to better understand the work being conducted within the institution, to meet with those working in the animal facilities and discuss their needs, 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 visits by the ACC should be made as necessary to follow up on any protocols that have raised significant concern during the protocol review and/ or PAM process or with some aspect of animal facility operation. These visits may be carried out by the Chair of the ACC or delegate, accompanied or not by other members or animal care staff.

6. General

The Neuro Animal Care Committee:

6.a. Must submit the Animal Use Data form for the past year (CCAC report) to the Animal Compliance Office prior to March 31 of every year.

6.b. Should submit an annual PAM Report to The Neuro Director of the Institution and should have a representative on the Quality Assistance Subcommittee to participate in the refinement of the PAM program at an institution-wide level. The Chair of the ACC attends meetings of APWOC and reports any Reportable Animal Welfare Incident (RAWI) that have been submitted to the CCAC.

6.c. 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 The Neuro/McGill/MUHC 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.

6.d. 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, ACC members and other interested parties to attend as possible.

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