POLICY ON THE STUDY AND CARE OF ANIMALS

Approved by the Executive Committee of Douglas Hospital Research Centre on February 13, 2023

1. Preamble

The purpose of this policy is to outline the basic principles for the care of animals involved in research, teaching or testing at Douglas Hospital Research Centre (DHRC). DHRC recognizes the importance of animal research in our efforts to further our knowledge of natural processes, health and diseases. DHRC also recognizes that animal models are a valuable component of teaching.

Research, educational and testing projects must be conducted with full commitment to the wellbeing of the animal subjects. In order to limit animal use to meritorious research or educational projects, DHRC relies on stringent peer review processes, along with assessment of ethical issues by the facility animal care committee (FACC). Decisions of FACC are of the utmost importance to the entire review process; the objective of FACC is to keep a balance between the need for high quality research, teaching and testing, and compassionate treatment of animal subjects.

DHRC recognizes that the use of animals in research, teaching and testing carries significant responsibilities. DHRC, along with its collaborating partner McGill University, will continue to develop and maintain guidelines and regulations, following the high standards established by the Canadian Council on Animal Care (CCAC).

DHRC is committed to conducting the highest-quality research and to providing animals with the best care. At DHRC, all research, teaching and testing involving animals is guided by the Russell-Burch tenet of Replacement, Reduction and Refinement (3Rs)[1]. A rigorous review by FACC ensures that animals are used only when necessary and under humane conditions.

DHRC regards the use of animals in research, teaching, and testing to be an integral component of continued progress in medicine, science and education, resulting in enormous potential benefits for human and animal health.

2. Policy Statement

All individuals involved in the oversight, care and use of animals:

a. Have a responsibility to the scientific community and society as a whole for the proper stewardship of the animals under their care;
b. Will be aware of their responsibilities in the use of animals in research, teaching and testing, as determined by public concerns, federal and provincial laws and regulations, and applicable policies.

3. Office and Committees Responsible for Monitoring the Care and Use of Animals

a. Scientific Director of DHRC
   - The Scientific Director of DHRC has executive responsibility for the Animal Care and Use Program;
   - The Scientific Director hears and decides appeals of administrative or FACC actions and/or decisions.

b. Facility Animal Care Committees (FACC)
   - The DHRC FACC is the local body responsible for ensuring the humane care and use of animals in research, teaching or testing, within its jurisdiction according to CCAC guidelines and policies;
   - The FACC is responsible for the ethical review and certification of Animal Use Protocols (AUPs). The FACC is also responsible for monitoring compliance with approved protocols;
   - The FACC, with the assistance of the Quality Assistants responsible for post-approval monitoring, has the authority to suspend any activity involving animals that does not comply with the applicable laws, regulations, policies and/or guidelines. The FACC has the right to inspect areas where animals are housed or used. When such inspections are deemed necessary by the FACC, reasonable efforts will be made to minimize the risks of compromising ongoing scientific investigations and whenever possible, a collaborative approach will prevail;
   - The FACC's specific composition, jurisdiction and function will accord with the requirements of the CCAC and are detailed in its Terms of Reference.
   - The FACC reports to the Scientific Director of DHRC.

In addition to these local instances, the Animal Care and Use Program of DHRC interacts with and harmonizes its policies with the following McGill University committees:

c. Animal Compliance Office (ACO)
   - The ACO is headed by its director who reports directly to the Vice Principal (Research & Innovation) of McGill University;
   - It works closely with the Animal Policy & Welfare Oversight Committee (APWOC) for establishing McGill University institutional policies on the care and use of animals;
   - It assists investigators, research staff, students, veterinary and animal care staff, Facility Animal Care Committees (FACCs), and administrators in remaining compliant with animal care and use regulations, policies and guidelines;
   - The ACO promotes University-wide understanding of the requirements for the ethical conduct of research, teaching, and testing involving animals.

d. Animal Policy & Welfare Oversight Committee (APWOC)
   - The APWOC is the McGill University body responsible for ensuring the humane care and use of animal in research, teaching and testing, and has final authority to suspend any activity involving animals, which does not comply with applicable laws, regulations, policies and guidelines, where the Facility Animal Care

Committee (FACC) refuses or fails to act. To that end, it has the right to investigate any area where animals are housed or used. When such inspections are deemed necessary by the APWOC, efforts will be made to minimize the risks of compromising ongoing scientific investigations, and whenever possible, a collaborative approach will prevail;

- APWOC works closely with the ACO;
- APWOC's specific composition and function will accord with the requirements of the CCAC and are detailed in its Terms of Reference.
- The Chair of DHRC's FACC is a standing member of APWOC.

4. Use of Animals in Research, Teaching and Testing.

The use of animals in research, teaching and testing must be described in an Animal Use Protocol (AUP).

At DHRC, all AUPs:

a. Are peer-reviewed for scientific or pedagogical merit;
b. Are approved by the Facility Animal Care Committee (FACC) before animals are purchased and/or used in laboratory;
c. Comply with the CCAC policies and guidelines;
d. Ensure that work with animals is performed in an area approved by the FACC and/or a CCAC certified institution's facility, which will consistently ensure the appropriate care of animals and the safety of staff through high standards of animal care and management.

In addition, all AUPs conducted outside Canada by DHRC individuals:

a. Are ideally performed in an institution or facility accredited by the CCAC, the International Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) or other national or international accreditation organizations;
b. Failing the existence of any official accreditation policy in the relevant location, it is the responsibility of the DHRC researcher to obtain reasonable assurance that all work will be conducted in an environment where animals are treated humanely to the satisfaction of the FACC.

The AUP will contain detailed explanations on:

a. The 3Rs – Replacement, Reduction and Refinement: On an annual basis and whenever compatible with research, teaching or testing objectives, alternative methods for replacement (non-animal use), reduction in the number of animals, and refinement in procedures and husbandry will be applied for the proposed project;
b. Animal numbers: Animal numbers will be minimized and justified based on a clear description of the objectives, the study design and on a statistical rationale, when applicable;

c. Endpoints: Any anticipated signs of morbidity will be clearly outlined and will warrant appropriate monitoring by trained individuals. Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals, or death and moribundity as clinical endpoints or study goals are not permitted.
d. Pilot Project: The FACC may require a pilot study if the clinical signs, and their severity or frequency, are unknown. Results from this pilot study will be reported to the FACC before approval of the complete protocol. Animals will be removed from the study, treated or euthanized at the earliest possible endpoint consistent with the objective(s) of the proposal, and in accordance with the endpoints in the AUP accepted by the FACC;
e. Long term housing and reuse of animals: These matters will be carefully considered by the FACC, taking into account the general welfare of the animals;
f. Research, teaching, testing and husbandry procedures: These will be performed in conditions that consider both the welfare of the animals and the success of the procedures. They will be performed by trained individuals who are capable of ensuring appropriate care;
g. Euthanasia: The method used will follow the recommendations of the CCAC. The euthanasia will be carried out by trained individuals and be performed in conditions which avoid unnecessary pain or distress to the animal;
h. Source of animals: The source of animals will be legal, recognized and reputable. The FACC will approve the source of the animals before they are ordered or used;
i. Hazardous materials: The use of hazardous agents (radioactive materials, recombinant DNA/RNA, human/plant/animal pathogens, toxins, chemical carcinogens, etc.) must be described in detail including the potential health risks to humans and animals, special animal care and containment requirements, precautions for individuals, animal disposal and related waste requirements as well as applicable emergency procedures. Individuals working with hazardous material must adhere to applicable environmental and safety guidelines.

5. Animal Care

Animals will be maintained in an environment and using practices that will promote their health and psychological wellbeing in terms of housing, social, dietary and behavioural needs unless approved otherwise by the FACC for a specific AUP.

6. Veterinary Care

a. The veterinarians have the authority and responsibility to make determinations concerning animal wellbeing and to assure that this is appropriately monitored and promoted;
b. The veterinarians participate in the development of policies and procedures for animal care, animal study, the training and qualification of animal users and animal care personnel, standards of husbandry, facilities and equipment, procedures for alleviation of unnecessary pain or distress; procedures for the proper and effective use of anesthesia and analgesia; standards for post-operative care and procedures for euthanasia;

c. The veterinarians have the authority to remove an animal from a study, test, or teaching activity that is adversely affecting its wellbeing beyond a level reviewed and approved by the FACC;
d. The veterinarians have the authority to use appropriate treatment or control measures, including euthanasia if indicated, following diagnosis of an animal disease or injury. Whenever possible, the veterinarian will explain the situation to the principal investigator (PI) or designate to determine a course of action consistent with the study goals and animal welfare standards. However, if the PI or designate is not available, or if agreement cannot be reached in a timely manner, the veterinarian has the authority to act to protect the health and wellbeing of the animals;
e. The veterinarian has the right to inspect areas where animals are being used or housed. Efforts will be made to minimize the risks of compromising ongoing scientific investigations and whenever possible, a collaborative approach will prevail that guarantees maintaining animal welfare standards;
f. Veterinarians providing professional services to DHRC will have an appropriate certification and training or experience. They will be knowledgeable in the care of the species being used or capable of identifying appropriate sources of expertise and be cognizant of concepts involved in animal-based research;
g. External providers of veterinary services will have a contractual agreement in which their responsibilities and obligations are clearly outlined, according to the Canadian Association for Laboratory Animal Medicine (CALAM) Standards of Veterinary Care.

7. Education and Training

a. Before undertaking a procedure or using and caring for animals, all individuals involved will have appropriate training and preparation in accordance with APWOC policies;
b. All classroom projects involving animals must be approved by an FACC. Students who are part of such projects and work under the direct and constant supervision of a certified animal user, will be instructed on the ethical care and use of animals but are not required to obtain individual training certification.

8. Occupational Health

a. Individuals who are exposed to animals, tissues, body fluids, wastes, bedding, living quarters or equipment involved in the care and use of animals are strongly encouraged to participate in the occupational health program for animal related activities. For individuals working with non-human primates, participation in the program is mandatory. Any costs related to mandatory compliance with this policy shall be borne by DHRC.
b. All individuals working with or exposed to non-human primates will be tested for tuberculosis and measles for their own safety and the safety of the animal colonies.

9. Record Keeping

a. The Principal Investigator is responsible for maintaining research records which must include pertinent information such as the number of animals used, date of inoculations,

history of procedures, post-operative care, monitoring logs, information on study procedures and any information requested by the FACC;

b. Records documenting such activities as the provision of appropriate veterinary care and occupational safety as it pertains to animal research must conform to the recommendations of the CCAC and with commonly accepted standards;
c. All records must be readily available for inspection by regulatory authorities, the FACC, veterinary staff and animal care staff.

10. Animal Facility

a. All housing and procedure facilities for animals involved in research, testing and teaching must be conducive to the wellbeing and safety of the animals, provide an appropriately appointed and safe workplace for personnel, and establish an appropriate research environment. All facilities will be maintained, managed and operated in compliance with all pertinent laws and regulations, including CCAC guidelines and policies. All of the institution's facilities (including animal facilities and laboratories where live animals are studied) and their operations will be inspected and reviewed at least annually by the appropriate FACC;
b. All major proposals, plans, and construction documents which are developed in order to create facilities, to accommodate or house new species, or to renovate existing animal facilities, must be developed in compliance with all applicable laws and regulations, including CCAC guidelines and policies, and will be reviewed and approved by the veterinarian, FACC as appropriate.

11. Procedure for Reporting Violations of this Policy

a. Any individual who is aware of possible violations to existing animal care and use regulations must report this concern to the Chair of DHRC FACC or the Scientific Director of DHRC, or the Animal Facility Manager. If so desired, his/her name will be kept confidential.
b. The DHRC FACC Chair will be responsible to evaluate the situation, and, if warranted, will further investigate.
c. If the charges are substantiated, the FACC may suspend a previously approved protocol, or a portion thereof. In addition, disciplinary measures may be taken, in accordance with applicable regulations. These actions will be reported and discussed at FACC meetings.
d. All individuals who are involved in any reporting and/or investigation process are obliged to maintain confidentiality of the proceedings. At the request of a party to the complaint, after the investigation has concluded and if warranted by the circumstances, the Scientific Director of DHRC may release publicly and/or to the appropriate committees a summary notice of the case, the issue, and the resolution.
e. Attempts by individuals to discredit others through inappropriate use of this policy are not permitted; such individuals will be considered for disciplinary action.
f. For those not wishing to use the procedures outlined above, consult the McGill University Policy on Safe Disclosure (https://www.mcgill.ca/secretariat/files/secretariat/safedisclosure-policyon.pdf).

g. All individuals are to refer to the McGill University APWOC's Policy on Animal Welfare and Compliance Concerns posted on the APWOC Web site for information on resolution guidelines, authority and reporting (https://www.mcgill.ca/research/research/compliance/animals/animal-research-practices/guidelines).

1 RUSSELL, W.M.S. and BURCH, R.L. The principles of humane experimental technique. Springfield, Charles C. Thomas, 1959.