

<b>POLICY NAME</b>	<b>POLICY ON ANIMAL WELFARE CONCERNS AND NON-COMPLIANCE</b>
<b>Approving Body</b>	Animal Policy and Welfare Oversight Committee (APWOC)
<b>Original Approval Date</b>	-
<b>Last Revision Date</b>	-
<b>Next Review Date</b>	July 31, 2025
<b>Related Documents</b>	Policy on the Care and Use of Animals in Research, Testing and Testing

## 1. PREAMBLE

This policy is a supporting document to accompany McGill’s Policy on the Study and Care of Animals and is a Unit-Level Document as defined by the University’s Policy Framework.

## 2. PURPOSE

2.1 The purposes of this Policy are:

- To meet the requirements set out by the Tri-Agencies, and the Canadian Council of Animal Care (CCAC);
- To articulate the responsibilities and standards required of Members of the University Community who work with animals; and
- To provide a process for dealing with animal welfare concerns and allegations of non-compliance.

## 3. DEFINITIONS

- 3.1 “Animal Care and Use Program” means all activities conducted by and at the University that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management, occupational health and safety, animal care committee function and animal facility design and management.
- 3.2 “Animal Compliance Office” (“ACO”) means the University office that assists with regulatory compliance in animal research, teaching and testing projects.
- 3.3 “Animal Use Protocol” (“AUP”) means a form that describes any animal related research, teaching or testing activity that must be approved by a Facility Animal Care Committee/Animal Care Committee before the activity can commence.
- 3.4 “Animal Welfare” means the physical and mental state of an individual animal and how the animal is experiencing the conditions in which it lives.
- 3.5 “Animal Welfare Concerns” means, as it relates to this Policy, anything communicated to any Member of the University Community regarding Animal Welfare, human safety, AUP-related issues or other allegations of possible Non-Compliance as defined in this policy.
- 3.6 “Canadian Council on Animal Care” (“CCAC”) means the national organization responsible for setting and maintaining standards for the ethical use and care of animals used in science (research, teaching and testing) in Canada.

- 3.7 “Animal Care Committees” (“ACC”) means the committees established for each major McGill University campus involving animals in research, teaching or testing in accordance with the Policies and Guidelines of the CCAC.
- 3.8 “Images” means, but is not limited to, any means of recording images or likeness, including photography, audio or video recordings, and/or images obtained during virtual meetings.
- 3.9 “Non-Compliance” means any conduct that breaches the requirements and expectations regarding the care and use of animals as set out in the applicable laws, policies, procedures, guidelines and contractual obligations. Non-Compliance can also include administrative issues with limited or no animal health and welfare concerns.
- 3.10 “Principal Investigator” (“PI”) means the researcher who is so identified to a funding agency or, in the absence of such identification, the researcher who has primary responsibility for the design, conduct and supervision of research, teaching or testing. The PI is the person responsible for submitting an AUP and oversight of the work conducted under the AUP.
- 3.11 “Reportable Animal Welfare Incident” (“RAWI”) means an event that leads to significant mortality or a serious noncompliance with CCAC standards that must be reported to the CCAC within 14 days of occurrence.
- 3.12 “Research Integrity Officer” means the member of the academic staff of the University appointed to the position of the Research Integrity Officer or as required by the context, a Deputy Research Integrity Officer.
- 3.13 “Use of Animals” means all research, teaching or testing involving animals by Members of the University Community, or governed by the McGill Certificate of GAP – Good Animal Practice®.

#### **4. POLICY CONTENT**

- 4.1 Research processes are dynamic and animal use in research poses particular challenges. Concerns may arise for a number of reasons, including knowledge gaps, protocol drift, inadequate record-keeping, equipment failures, communication problems and human error. Many of these concerns can be resolved quickly and effectively by the veterinary and animal care staff, Quality Assistance Advisor/Compliance Officer (QAA/CO), who work in a collegial manner with animal users and attempt to correct deficiencies collaboratively. Concerns can be reported through multiple channels including:
- 4.2 If an animal welfare concern a) can’t be resolved through collaborative work; b) reflects serious non-compliance and/or c) nature of the concern warrants additional consideration, it is reported to the Animal Care Committee (ACC) for further review. This includes situations where a (QAA)/CO has identified a concern as needing “Significant” or “Major” non-compliance findings, as defined in the Policy on the Post-Approval Monitoring (PAM) Program. If there are “Major”, non-compliance findings, they are brought immediately to the attention of the ACC Chair and will follow the requirements of the CCAC and APWOC’s Policy on Reporting Significant and Major Animal Welfare Incidents.
- 4.3 The ACC follows the principles of procedural fairness in conducting any review of possible non-compliance. The nature of the investigation is decided by the ACC on a case-by-case basis and may include formation of a subcommittee. Investigations include:
- review of the approved AUP.

- informing the PI of the allegation of non-compliance and the process the ACC intends to follow.
  - interviewing the PI to allow a response to the concerns/allegations. The person may have representatives/advisor with them if requested.
  - confidentiality of all parties, including the PI.
- 4.4 The Investigation may also include, but is not limited to:
- obtaining documentation.
  - conducting a quality assistance assessment.
  - consulting with other university offices (e.g., Occupational Health and Safety, legal counsel, Research Integrity Officer) or seeking expert opinions/advice.
  - interviewing relevant parties.
- 4.5 The ACC may refer the concern/non-compliance to the Research Integrity Officer to conduct their own investigation regarding whether there was research misconduct.
- 4.6 Upon completion of the investigation, the findings are discussed by the ACC, who decides what course of action to take. A quorum of ACC members will make the final determination concerning the seriousness of the incident and of subsequent courses of action. In their decision, the ACC may consider:
- consideration of intentionality.
  - impact on animal and human welfare.
  - the nature of the non-compliance.
  - whether there is previous/chronic non-compliance.
  - involvement of others.
- 4.7 The course of actions recommended by the ACC can include but are not limited to:
- reporting to CCAC as required.
  - implementing measures to correct the problem and prevent recurrence.
  - counseling, such as meeting with the PI and research team.
  - mandating specific animal user training aimed at preventing future incidents.
  - monitoring by the QAA/CO and/or veterinary care staff.
  - temporary or permanent suspension of access to the animal facility.
  - temporary or permanent suspension of one or all of a PI's AUPs. In recommending this course of action, the ACC will also outline the steps that must be taken for the AUP to be reinstated.
- 4.8 If permanent suspension of the AUP is the course of action, the ACC informs the Office of Sponsored Research so that research funding is managed appropriately, and funding agencies can be notified as needed.
- 4.9 If the problems are determined to be largely due to the actions of animal support services staff not supervised by the PI, the QAA/CO will report the problem to the responsible staff, who can take appropriate action to correct, re-train or remove the staff member(s) responsible.

- 4.10 Decisions of the ACC are documented in a letter and then forwarded to the PI. Depending on the nature of the decision, the letter may also be forwarded to the Chair of the PI's Department, the Associate Dean (Research) of the Faculty, Dean and/or the academic unit head. (MNI – also sent to the Director of the Neuro. The letter may include:
- information on the nature of the allegation/concern.
  - a statement of determination as to whether non-compliance occurred and if so, the impact.
  - a summary of the information reviewed during the course of the investigation.
  - the key findings of fact based on the information gathered during the investigation.
  - the course(s) of action decided upon by the FACC/ACC.
  - the remedial action(s) required to avoid similar situations in the future.
  - consequences of non-adherence to the remedial action(s).
- 4.11 If a letter is provided to the PI, the ACC will follow up to ensure that the stated course(s) of action and/or remedial action(s) have been completed.
- 4.12 The PI has the right to appeal the ACC decision.
- 4.12.1 The first line of appeal for a decision made by The Neuro ACC is to appeal to the Director of The Neuro. If the PI is not satisfied with the decision, they have the option to appeal the decision to APWOC, as per the process below.
- 4.12.2 On behalf of the Vice-President (Research and Innovation), the APWOC Chair receives the appeal and will address the appeal in a timely manner by ensuring a separate, fair and impartial process, which may include expertise from appropriate external institutions.
- APWOC may set up a sub-committee for the appeal, as appropriate, in order to avoid any conflict of interest.
  - The written decision of the APWOC Chair in response to the appeal is considered final, and copied to the:
    - ACC
    - the PI and their academic unit head
    - University Veterinarian
    - VPRI and;
    - the Director of The Neuro (when applicable)

## **5. REVIEW**

- 6.1 Mandatory review periods: every 3 years.