

MCGILL UNIVERSITY

Policy on the Quality Assistance Program for McGill University Facility Animal Care Committees

1. Purpose

The purpose of this Policy is to describe the components and processes of the Quality Assistance Program (QAP) as well as the roles and responsibilities of all stakeholders and participants.

2. Scope

The primary goals of the QAP are to ensure animal welfare and assure the integrity of McGill University's Animal Care and Use Program. The QAP validates that animal-related research, teaching and housing activities under the oversight of the three Facility Animal Care Committees (FACCs) of McGill University comport with the parameters set by the approved Animal Use Protocols (AUPs) and conform to institutional and [Canadian Council on Animal Care \(CCAC\)](#) policies, guidelines and procedures.

The QAP aims to further improve the University Animal Care Program as well as to provide education to investigators and instructors regarding their responsibilities in the conduct of ethical research and teaching with animals. It aims to work in collaboration with, and in support of, researchers, instructors, veterinarians and animal facility staff members to review procedures, provide knowledge on best practices, and facilitate the needs of the research and teaching community. In addition to ensuring animal welfare, the QAP also provides guidance on safe work practices, , and controlled substance regulations.

3. Responsibility

3.1. Quality Assistance Advisor (QAA):

- 3.1.1. Under the oversight of the FACC, is responsible for monitoring all aspects of animal-related activities, provides recommendations as per the Definitions of Recommendations for McGill Quality Assistance Program, and reports to the appropriate FACC. The FACC is the body responsible for determining and correcting breaches of compliance with approved AUPs and SOPs as per [FACC Terms of Reference](#).
- 3.1.2. Plans, coordinates, and conducts assessment visits to observe and validate that animal-based procedures comply with the approved AUP; and that animal housing and use areas and the University Animal Care and Use Program comply with institutional and CCAC policies and guidelines. Assesses competency and provides consultation and guidance on techniques, personnel safety, animal facility infrastructure and activities, and legal requirements (e.g., Health Canada controlled substances exemptions) to ensure compliance with regulatory guidelines.
- 3.1.3. Communicates findings and recommendations of post-approval review visits with researchers, instructors, and animal facility staff members. Validates and reinforces response to recommendations and ensures that any findings of non-compliance are addressed in a timely manner.
- 3.1.4. Participates in FACC annual site visits (on request) and follows up on recommendations arising from inspections (for serious, major, and recurrent findings).

- 3.1.5. Reports animal-based activities, identifies risks and concerns to the Downtown Campus A and B (DOW A and DOW B) and Macdonald Campus (MAC) FACCs and participates in protocol review and meetings.
- 3.1.6. Provides recommendations to the Animal Policy and Welfare Oversight Committee (APWOC) via the Quality Assistance Working Group, for the refinement of processes and for the development/revision of policies within the Animal Care and Use Program as a proactive measure to address non-compliance.
- 3.1.7. Provides advice and assistance on protocol development.
- 3.2. The Principal Investigators/Instructors and their research/teaching personnel (hereafter referred to as researchers unless otherwise specified) and Animal Facility staff members:
 - 3.2.1. Responsibly follow the above requirements corresponding to AUP-related activities as well as institutional and CCAC policies and guidelines and provide the FACC with additional information (follow-up reporting) as warranted.
 - 3.2.2. Work in collaboration with the QAA to facilitate observation of procedures, answer QAA questions to the best of their knowledge, and provide all documents needed to complete the quality assistance assessment successfully.
 - 3.2.3. Respond to QAA recommendations and implement corrective measures within the assigned timelines.
- 3.3. The Animal Compliance Office Director:
 - 3.3.1. Provides operational oversight of the QAA and his/her execution of the QAP, ensuring that the relevant FACC receives reports and that all FACC members have the opportunity to discuss these reports.
 - 3.3.2. As Chair of the Quality Assistance Working Group, ensures membership of the QAA on the working group to share resources, discuss emerging trends, and help refine the QA program. Serves as the liaison between the Quality Assistance Working Group and the APWOC.
- 3.4. Veterinarian(s):
 - 3.4.1. Operate(s) with the responsibility and authority as described in the [FACC Terms of Reference](#).
 - 3.4.2. Provide(s) consultation to the QAA on matters of animal health, and procedures.
 - 3.4.3. Participate(s) in QA assessment visits by request, especially when more invasive or novel procedures are involved.
 - 3.4.4. Has the authority to terminate a procedure if animal welfare is compromised and pain cannot be alleviated.
- 3.5. The Facility Animal Care Committees:
 - 3.5.1. Ensure the humane care and use of animals in research, teaching or testing, according to institutional and CCAC guidelines and policies, and are responsible for monitoring compliance with approved protocols. FACCs have the authority to suspend any activity involving animals that do not comply with applicable laws, regulations, policies, and/or guidelines ([McGill University Policies and Guidelines](#)).
 - 3.5.2. Are committed to the QAP and support the QAA.

4. Policy

- 4.1. The QAA must recognize potential issues in diverse areas relating to animal care and use, including animal housing conditions, procedural techniques, personnel safety (e.g., biosafety- related) concerns, and occupational hazards. The QAA must use judgment, knowledge, experience, consultation when needed, and good decision-making abilities to suitably resolve the issue(s).
- 4.2. The following are subjected to a QAP assessment.
 - 4.2.1. Procedure, holding, and housing locations on McGill campuses.
 - 4.2.2. AUPs under the jurisdiction of the DOW A, DOW B, and MAC Campus FACCs, including field-type studies.
 - 4.2.3. All animal-related activities conducted on McGill University facilities and campuses.
 - 4.2.4. N.B. Procedures deriving from collaborating institutional protocols will undergo the same processes herein described and in accordance with the Policy on Inter-Institution Collaborations.
 - 4.2.5. Investigation of reported concerns from the community (whistleblowing) and the Animal Ethics Working Group.
- 4.3. SELECTION:

The selection of procedures/locations for QA assessment cases is based on:

 - 4.3.1. Risk assessment (category of invasiveness, hazard level, species).
 - 4.3.2. At the request of the FACC, the Animal Ethics Working Group, and/or veterinarian, usually following protocol review (e.g., pilot projects, novel procedures, concerns).
- 4.4. CLASSIFICATIONS:
 - 4.4.1. The QAP Assessment type is classified by the rationale for the review:
 - For Cause: Investigations of procedures, protocols, or locations due to assumed or confirmed complications, reported non-compliance, or validation (e.g., pilot study).
 - Random: Procedures, protocols, or locations randomly selected by risk assessment (e.g., level of procedural intervention, impact on welfare, etc.).
 - 4.4.2.1. QAA recommendations are labeled according to the significance of the non-compliance on animal and human welfare as per the Definitions of Recommendations for McGill Quality Assistance Program
 - 4.4.2.2. Minor and Regular recommendations are communicated to both the participant and, in writing, to the Principal Investigator/Manager
 - 4.4.2.3. Serious recommendations are communicated, in writing, to the participant, Principal investigator/Manager and corresponding FACC.
 - 4.4.2.4. Major recommendations are immediately brought to the attention of the supervisor, FACC Chairperson, and will follow the directives of the CCAC on [Reporting Major Animal Welfare Concerns, and on McGill University's Policy on Reporting Serious and Major Animal Welfare Incidents](#)
 - 4.4.2.5. Repeat breaches of compliance will result in the escalation of the recommendations level, with more rigorous demands to address the matter.

4.5. POST-APPROVAL ASSESSMENTS:

- 4.5.1. Communication (verbal and written) between individuals must be professional and based on mutual respect and trust. Emails and letters may be reviewed by higher administration if there is no resolution at the local level.
- 4.5.2. The Researcher/Manager will provide all documentation (e.g. breeding records, surgery logs, permits, etc.) requested by the QAA to complete an assessment without undue delay.
- 4.5.3. The QAA must have access to all procedure, holding, and housing locations.
- 4.5.4. The QAA may use photos or record videos for the purpose of demonstration to the FACC and for reference. The data are maintained on a secure server accessible only to the QAA and Animal Compliance Office Director.
- 4.5.5. The Quality Assistance Advisor (QAA) has the authority to intervene in or to end any procedure where the welfare of the animal and/or individual performing the procedure is deemed, by the QAA, to be significantly/seriously compromised and/or the criteria for humane intervention indicated in the approved protocol are not followed. The QAA will expeditiously report the incident to the veterinarian and appropriate FACC.

4.6. QA RECOMMENDATIONS AND NONCOMPLIANCE:

- 4.6.1. The Researcher/Manager must provide timely responses to QAA correspondence (notification of assessments, reports, requests for information, etc.). Failure to respond or significantly delayed replies will be brought to the attention of the FACC Chairperson for his/her intervention.
- 4.6.2. The actions taken or planned by the Researcher/Facility Manager in response to these recommendations must be addressed within the timeline specified by the QAA and in accordance with the Definitions of Recommendations for McGill Quality Assistance Program and/ or in conjunction with the FACC decision. Failure to take such actions would further jeopardize animal welfare and/or personnel health and safety.
- 4.6.3. Breaches of compliance that cannot be corrected with the involvement of the FACC, the QAA responsible for post-approval monitoring, and veterinary/animal care staff, must be referred to senior administration. The senior administration must inform all involved individuals about sanctions that will be taken in the event of serious breaches of compliance.
- 4.6.4. The Principal Investigator/Manager may dispute QAA recommendations by communicating directly with the QAA. If a resolution cannot be reached, the Principal Investigator/Manager is to be invited to meet the local FACC (or subcommittee of the FACC) to ensure a good dialog benefitting both sides and agreement on the course of action. Further disagreement will follow the *Process for Reporting and Resolutions of Animal Welfare and Compliance Concerns* as described in the [Guidelines for Animal Welfare and Compliance Concerns](#) (under "Guidelines").

4.7. REPORTING ANIMAL WELFARE CONCERNS:

- 4.7.1. Reported concerns about a procedural or ethical breach by the public, research or teaching community (whistleblowing) will be discreetly investigated by the QAA as per the [Guidelines for Animal Welfare and Compliance Concerns](#)

- 4.7.2. A person reporting a concern is protected by the [Safe Disclosure Policy](#).
- 4.8. The FACC works with the QAA to ensure compliance with its decisions and with the conditions set out in approved protocols and may request a QA assessment of any animal-based activity or protocol, which may be a cause for concern to animal or human welfare.
- 4.9. The FACC makes decisions and addresses persistent and/or significant breaches of compliance or threats to the health and safety of personnel or animals as described in the [FACC Terms of Reference](#).
- 4.10. REPORTS:
- 4.10.1. The QAA reports findings and outcomes of post-approval review visits to the corresponding FACC(s).
- 4.10.2. A copy of the report will be sent to the Principal Investigator. Verbal reports for Level Serious and Major recommendations or trending non-compliance are verbally reported to the respective FACC.
- 4.10.3. The FACC reports breaches of compliance that cannot be corrected and major animal welfare incidences to the Senior Administration and CCAC.
- 4.10.4. Participant identity, assessment reports, and any other information of a sensitive nature is considered confidential. Confidential information will only be disclosed to essential personnel.
- 4.10.5. In the event of alleged research misconduct, the McGill Research Integrity Officer will be assigned and proceed with the investigation as per the [Regulations concerning the investigation of research misconduct](#).
- 4.11. EXTERNAL RESEARCHERS:
- 4.11.1. Researchers from collaborating institutions that are conducting animal-based procedures at McGill University facilities and campuses are subjected to post-approval assessments by the McGill QAA in accordance with the standards of this policy and with the [Policy for inter-Institution Collaborations](#).
- 4.11.2. In addition to the corresponding local FACC, the results/outcome of the post-approval review is also reported to the home institution's QAA (if applicable) and Animal Care Committee.
- 4.12. RECORDKEEPING
- 4.12.1. All QA assessment records, including reports will be maintained in the associated protocol file in the QAA's office.
- 4.12.2. Observations reported at the FACC will be recorded in the FACC meeting minutes.
- 4.12.3. Non-compliance information will be entered in the QA database for follow-up and reference.
- 4.12.4. All information obtained via the QAP will be treated in a confidential manner.
- 4.13. FACC ANNUAL SITE VISITS:
- 4.13.1. The QAA will follow up on all concerns resulting in serious and major FACC recommendations, recurring non-compliance, or observed non-compliance trends arising from the annual site visit inspections.
- 4.14. ASSISTANCE: In collaboration with the Training Advisor, The QAA assists with teaching and

refining techniques and promotes best practices with the use of animals in research and has the capacity to certify an individual via proficiency evaluation.

- 4.15. The QAA is available to assist with protocol review and protocol development and to address general inquiries.

*Approved by Downtown Campus A, Downtown Campus B and Macdonald Campus FACCs on June 19 2020.
Rev.3 reviewed and approved by DOW A, DOW B and MAC FACCs on July 26, 2023*