1. PREAMBLE

Animal Facilities are controlled environments designed for the housing and use of animals ensuring optimal lighting, temperature, air quality, and sanitation. Procedures involving animals are typically conducted within these facilities or the use of animals outside the facility is approved by the Facility Animal Care Committee (FACC).

2. PURPOSE

To outline the regulations pertaining to animal-related work with animals outside the Animal Facility and to specify the responsibilities of the Principal Investigator, the FACC, Veterinarian, and Quality Assistance Advisor* (QAA*) in relation to the ALPHA location.

3. DEFINITIONS

3.2 A.L.P.H.A (Alternative Locations for Procedures and Housing of Animals):
   - Locations dedicated to animal use and/or housing not under direct supervision of Animal Facility staff (e.g., Research labs or spaces shared among multiple researchers in a workgroup or department).
   - A.L.P.H.A Locations are characterized based on the location, species, purpose, and the amount of time the animals spend outside the Animal Facility (procedure vs. housing):
     2.3.1 Procedure Location: Any location where live vertebrate animals are held for less than 12 hours.
     2.3.2 Housing Location: Any location where live vertebrate animals are held for 12 hours or more.

3.3 Memorandum of Understanding to Use Animals Outside the Facility:
   - Outlines the terms and details of an agreement reached between the FACC and the Principal Investigator, indicating the requirements to maintain the use of A.L.P.H.A locations.
   - Adherence to the Memorandum of Understanding to Use Animals Outside the Facility is essential to ensure compliance with standards related to animal health, stress reduction, safety, welfare, security, and environmental considerations.

3.4 Justification: There must be scientific justification to demonstrate that the work in the Animal Facility is not feasible.

N.B. *Quality Assistance Advisor is used as a generic reference to define the person mandated for post-approval monitoring in the McGill University and Affiliated Hospitals Research Institutes and does not reflect the actual position title.
4. POLICY CONTENT

4.1 Animals remain inside the Animal Facility unless a clear justification is provided in the Animal Use Protocol (AUP) and approved by the (FACC).

4.2 Principal Investigators must ensure compliance with institutional and CCAC policies and guidelines when using alternative locations.

4.3 The infrastructural, mechanical, and environmental aspects of the A.L.P.H.A housing locations must conform to the standards specified in the CCAC Guidelines for Laboratory Animal Facilities and the species-specific regulations set forth by CCAC. Note that potential delays in the approval of housing locations may occur due to the time required for the evaluation of environmental parameters and infrastructure.

4.4 Principal Investigators must provide the necessary details required in the Animal Husbandry/Housing section of the AUP.

4.4.1 The AUP must contain:

4.4.1.1 A clear justification for working with animals outside the Animal Facility.
4.4.1.2 A thorough completion of all sections relevant to A.L.P.H.A location within the AUP.
4.4.1.3 The specific location for the animal use.
4.4.1.4 The duration during which animals will be outside the Animal Facility.
4.4.1.5 A description of the activities related to animals in each location, such as surgery, catheter placement, euthanasia, tissue collection, gavage, imaging, and other relevant procedures.

4.4.2 Modifications to the use of A.L.P.H.A locations must be documented in an AUP via amendments and may prompt a re-evaluation process involving inspections.

4.4.3 Justifications for the use of animals outside the Animal Facility will be evaluated by the FACC at each protocol renewal.

4.5 A comprehensive animal care plan for monitoring, treatments, and husbandry must be developed and implemented in collaboration with the Veterinarian and/or Facility Management.

4.6 Approved requests are applicable only for the designated purposes, locations, and species.

4.7 A.L.P.H.A certificates are valid for one year, contingent on annual and routine inspections by the FACC, QAA*s and/or veterinarians and their delegates.

4.8 The QAA*, Veterinarian, and their delegates must have unlimited access to the alternative locations, with their authority to manage all animal welfare issues as per institutional and CCAC policies and guidelines.

4.9 The Principal Investigator is required to maintain and ensure the accessibility of all records, including Standard Operating Procedures (SOP), veterinary records, and experimental records.

4.10 The Principal Investigator must understand and adhere to the Memorandum of Understanding to Use Animals Outside the Facility.

5. RESPONSIBILITIES

6.1 FACILITY ANIMAL CARE COMMITTEE (FACC):

6.1.1 Reviews and approves alternative use/housing requests in the context of research protocols, considering the specific limitations of the Animal Facility, including space and equipment, and ensuring the application of institutional and CCAC policies and guidelines.

6.1.2 Upon approval, the FACC will issue an A.L.P.H.A certificate.
6.1.3 Uses the following criteria to evaluate exemptions annually:

6.1.3.1 There must be a clear justification to demonstrate that the work in the Animal Facility is not feasible.

6.1.3.2 The designated area must be suitable for the intended purpose of the study.

6.1.4 Inspects A.L.P.H.A locations before the initiation of animal studies to ensure compliance with institutional and Canadian Council on Animal Care (CCAC) policies and guidelines. The inspections must be conducted, with participation from a veterinarian and QAA*.

6.1.5 The use of these locations will undergo annual re-evaluation.

6.1.6 Assesses and grants approval for the inspection reports required for the issuance of A.L.P.H.A certificates.

6.1.7 Communicates recommendations following the site visit inspection to ensure compliance with institutional and CCAC policies and guideline.

6.1.8 The FACC possesses the authority to withdraw A.L.P.H.A certificates in the event of non-compliance.

6.2 PRINCIPAL INVESTIGATOR:

6.2.1 Completes the Husbandry and Housing section of the AUP at the initial application, annual renewal, and/or by amendment.

6.2.2 Understands and signs the Memorandum of Understanding.

6.2.3 Reevaluates and updates the reason for the use of animals outside the Animal Facility at each protocol renewal.

6.2.4 Requests changes related to the use of the A.L.P.H.A location (location, species, purpose) via amendments.

6.2.5 Displays A.L.P.H.A certificates visibly within locations.

6.2.6 Ensures that the care provided to laboratory animals in the A.L.P.H.A location aligns with institutional and CCAC policies and guidelines and the Memorandum of Understanding.

6.2.7 Where applicable, provide a plan for the monitoring, treatment, and care of animals.

6.2.8 Grants access to the QAA* and veterinarians and their delegates.

6.2.9 Promptly notifies Veterinary Care staff regarding any concerns related to the health and welfare of animals.

6.2.10 Maintains the appropriate sanitation and upkeep of the location, ensuring the correct operation, repair, and regular calibration/certification of equipment.

6.2.11 Establishes a working environment that is both safe and secure.

6.2.12 Ensures the comprehensive completion, maintenance, and accessibility of all essential documentation and records, including those related to husbandry, surgery, and environmental parameters for the activities within the approved ALPHA location.

6.2.13 Addresses any concerns or recommendations issued by the FACC, veterinarian and/or QAA* within the specified deadlines.

6.3 VETERINARIAN:

6.3.1 Participates in yearly FACC site visit inspections and compulsory engagement in the assessment of new location proposals.
6.3.2 Conducts regular rounds of the A.L.P.H.A housing location, ensuring ongoing communication with the researcher to ensure animals receive the necessary care and supervision.

6.3.3 Offers guidance and assistance to researchers on best practices for the care and use of animals in their studies.

6.3.4 Notifies the FACC of any concerns related to animal health and well-being.

6.3.5 Carries out their responsibilities and exercises their authority as outlined in the FACC Terms of Reference.

6.4 QUALITY ASSISTANCE ADVISOR*

N.B *Quality Assistance Advisor is used as a generic reference to define the person mandated for post-approval monitoring in the McGill University and Affiliated Hospitals Research Institutes and does not reflect the actual position title.

6.4.1 Participates in yearly FACC site visit inspections and compulsory engagement in the assessment of new location proposals.

6.4.2 Conducts regular visits of the A.L.P.H.A locations to ensure compliance with institutional requirements, SOPs and CCAC policies and guidelines.

6.4.3 Provides researchers with guidance and support in implementing optimal practices for the care and use of animals.

6.4.4 Collaborates with various stakeholders (e.g., Veterinary Care, Facility managers, Building directors).

6.4.5 Communicates any concerns or recommendations to the researcher and specifies deadlines for corrective measures.

6.4.6 Ensures a follow-up on corrective actions.

6.4.7 Reports instances of non-compliance and/or concerns regarding animal welfare to the FACC.

6.4.8 Carries out their responsibilities as outlined in the FACC Terms of Reference and the Policy on the Quality Assistance Program.

6. REVIEW

7.1 Mandatory review periods: every 3 years.