



THE AGA KHAN UNIVERSITY

<i>Policy No. ORGS/011-2021</i> POLICY ON USE OF ANIMALS FOR SCIENTIFIC PURPOSES	
<i>Approval Date:</i>	April 8, 2021 ¹
<i>Contact Office:</i>	Office of Research and Graduate Studies (ORGS)
<i>Approving Authority:</i>	University Research Council (URC)
<i>Related Policies</i>	This document should be read in conjunction with the following AKU policy documents: <i>University policies:</i> <ul style="list-style-type: none">• <i>Policy on Research Ethics Review</i>• <i>Policy on Research Misconduct</i>• <i>Policy on Animal Laboratory Biosafety</i>• <i>Terms of Reference of Ethics Committee for Animal Care and Use</i>

This document is intended for all AKU faculty/staff, including persons with honorary positions, and students engaged in use of animals for research, teaching and medical services at, or on behalf of the University. The Aga Khan University, in this document means its schools, colleges and hospitals operating across all campuses around the globe.

1.0 BACKGROUND

The Aga Khan University recognizes the necessity of an Animal Care and Use Program for biomedical sciences to forward its mission of developing human capacities through the discovery and dissemination of knowledge, and application through service.

The purpose of this Policy is to express principles of governance for the use of laboratory animals for research, teaching and service at the Aga Khan University in its facilities for biomedical research, health sciences education and health care provision, and define the scope and operations of its Animal Care and Use Program.

2.0 PRINCIPLES AND OBJECTIVES

Animals are required for performing pre-clinical research and educational / training endeavors. The Aga Khan University offers undergraduate and graduate programs of international quality, which include M.B.B.S along with M.Phil and Ph.D in Biological Sciences It prioritizes teaching

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and research, which informs and underpins intellectual innovation and change while upholding core values such as building an environment that fosters intellectual freedom and distinction in scholarship. The Animal Care and Use Program intends to support the University in the above by catering to the need of laboratory animals for research and education to support biomedical and health sciences. The Program aims to achieve standards of animal care and use comparable to those described in the Guide for the Care and Use of Laboratory Animals (8th ed. 2011, National Research Council, National Academies Press)^A and the Guide for the Care and Use of Agricultural Animals in Research and Teaching (3rd ed. 2010, Federation of Animal Science Societies)^B and endorsed by the international accrediting agency for animal laboratories, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International, USA.

Emanating from these principles, the specific objectives of this policy are:

- 2.1 To define its Animal Care and Use Program for judicious use of animals for scientific purposes including but not limited to research and teaching, encompassing facility construction, maintenance and upgradation for animal-based research, development of standard operating procedures for the use of animals, review of operations, and overall governance.
- 2.2 To provide a framework for ensuring compliance in the use of animals at Aga Khan University with
 - a. internationally accepted guidelines and principles of animal welfare and ethics
 - b. local and national regulations governing the use of animals for educational and scientific purposes
 - c. international best practices regarding the use of animals and biological materials for medical services
- 2.3 To outline mechanisms to safeguard the highest standards of scientific integrity in the utilization of animals and dissemination of knowledge thus gained.

4.0 DEFINITION AND SCOPE

The Animal Care and Use Program, hereinafter called ‘the Program’, is defined as the policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by the Aga Khan University to achieve the humane care and use of animals in the laboratory and throughout the institution, in accordance with internationally accepted guidelines and applicable local laws and policies. It includes the establishment and support of committees for ethics review, approval and monitoring, and operations of the animal facility, and maintenance of an environment enabling these committees to function and carry out their responsibilities successfully. The scope of this Program at present is the Faculty of Health Sciences, Pakistan, where the respective committees are the Ethics Committee for Animal Care and Use – Pakistan (ECACU) and the Animal Facility Committee (AFC).

3.0 APPLICABILITY

This policy applies to all University employees (viz. faculty, residents, fellows and staff), students, and also those affiliated with the University (such as volunteers, trainees, technicians,

clinicians, visiting researchers, collaborators, and other staff members) who are engaged in the use of animals for research, education or service at or by the University, regardless of the source of funding.

3.1 Implementation of and compliance with this policy is a shared responsibility among:

- a) the people using laboratory animals for scientific purposes
- b) the Associate Vice Provost, Research
- c) the Ethics Committee for Animal Care and Use
- d) the Institutional Biosafety Committee
- e) the Animal Facility Committee
- f) the Office of Research and Graduate Studies
- g) external collaborators performing animal work at Aga Khan University

4.0 SPECIFIC RESPONSIBILITIES

4.1 Institutional Official

The Institutional Official (IO) is the designated individual with overall responsibility for the Animal Care and Use Program, the legal signatory on grants, contracts, and MOUs, and contact person for accreditation purposes.

- 4.1.2 The IO is expected to support the University in the humane care of laboratory animals for scientific purposes by providing administrative and financial oversight to the Program.
- 4.1.3 The Associate Vice Provost, Research (Health Sciences), will be the IO for Animal Care and Use Program.
- 4.1.4 Being a representative of the senior administration, the IO bears ultimate responsibility for the Animal Care and Use Program and is responsible for resource allocation in consultation with the Provost.
- 4.1.5 The overall direction of the Animal Care and Use Program is a shared responsibility among the IO, attending veterinarian (AV), and the Chair, ECACU.
- 4.1.6 The IO is authorized to plan budgetary needs of the Animal Care and Use Program to ensure the Program's overall effectiveness in consultation with the AV and the Chair, ECACU, and recommend to the Provost.
- 4.1.7 The IO relies on the AV and Chair, ECACU for the day-to-day oversight of the Animal Care and Use Program, to develop plans to correct program deficiencies, to address concerns that may arise regarding the institution's use of animals in science, and to make recommendations regarding the Program.
- 4.1.8 The IO receives updates and reports from both these officials on a periodic basis, including the mandatory semi-annual program evaluation comprising a program review and facilities inspection.
- 4.1.9 The IO may delegate responsibilities for the operations and implementation of the Animal Care and Use Program to the ECACU, the AV, the Director, Research Laboratories, animal care technicians, and relevant administrative staff from the Office of Research and Graduate Studies.

4.2 **Chair, ECACU**

The Chair, ECACU has a critical role in ensuring the success of the Animal Care and Use Program. The Chair:

- 4.2.1 sets the overall direction of the Program with the IO and the AV
- 4.2.2 ensures that all proposals for animal-based research projects are reviewed for scientific merit and ethics through a formal process of independent peer-review before their approval, with the support of members of ECACU and the administrative officer.
- 4.2.3 advises the IO for budgetary needs to ensure the Program's effectiveness
- 4.2.4 provides periodic updates and reports to the IO about the ongoing Program
- 4.2.5 leads the mandatory semiannual program evaluation
- 4.2.6 approves and facilitates training sessions on animal research and care while assuring appropriate pedagogical merit for provision to the University and external community.
- 4.2.7 working with the Manager, Ethics and Integrity, oversees compliance for ECACU approved projects, and
- 4.2.8 maintains open channels of communication with the IO, keeping the IO informed of the status of the Program, and alerting the IO to potential and actual non-compliance with ECACU approvals, institutional policies or any applicable regulations, and
- 4.2.9 prepares documents required by external agencies for review and approval by the IO before onwards submission.

4.3 **Attending Veterinarian**

The Attending Veterinarian (AV), designated as Specialist, Vivarium, is required to hold a degree in veterinary medicine and possesses experience of working with laboratory animals. The AV oversees all day-to-day operations of the animal facility is responsible for the overall health and well-being of animals. Thus, the AV:

- 4.3.1 is committed to providing support full-time, regardless of employment status as full- or part-time,
- 4.3.2 reports directly to the IO, keeping the IO informed of the status of the program, and alerting the IO to potential and actual non-compliance with ECACU approvals, institutional policies, or any applicable regulations,
- 4.3.3 heads the Animal Facility Committee,
- 4.3.4 coordinates finances, management, and procurements to ensure availability of resources required by the Program through the Office of Research and Graduate Studies,
- 4.3.5 is a member of ECACU,
- 4.3.6 provides veterinary care to all animals under the Animal Care and Use Program, including preventive health measures,

- 4.3.7 is responsible for maintaining animal colonies, overseeing daily requirements of animals, and managing assignments of the animal facility staff,
- 4.3.8 supports monitoring of compliance with ethics approvals, and
- 4.3.9 plans and contributes to educational activities related to laboratory animal use.

4.4 **Researchers/Educators**

The researcher/educator intending to use animals for biomedical research is expected to:

- 4.4.1 hold a full-time faculty appointment at the University, or collaborate with a full-time faculty;
- 4.4.2 develop their research protocols by following the principles of ‘Replacement, Reduction and Refinement’ and
 - a) avoiding the use of animals if a replacement alternative is available, feasible, and appropriate for the objective/s of the study; this may include in vitro experiments, use of non-vertebrates, and computer simulation, among other alternatives,
 - b) keeping the number of animals at the minimum by using appropriate planning/sample size calculations,
 - c) refining the protocol to reduce animal pain and distress as much as possible
- 4.4.3 develop the study/training program while upholding scientific/pedagogical merit,
- 4.4.4 consult the Animal Care and Use Committee while developing the protocols to ensure availability of the facilities, equipment, and consumables,
- 4.4.5 apply for ECACU approval well before the start date of the project/training and comply with ECACU recommendations upon approval,
- 4.4.6 assume responsibility for all persons, whether students, visiting scientists or others, who will be working on approved projects under their supervision, ensure that such persons are competent, and seek prior authorization by ECACU to do so,
- 4.4.7 follow the standard operating procedures of the Animal Facility.

4.5 **Health Service Provider**

The individual working on animals for any aspect related to services provided by the Aga Khan University Hospital for clinical care provision, including but not limited to diagnostics, prevention, and therapeutics, is expected to:

- 4.5.1 hold a full-time appointment at the University, or collaborate with a full-time employee,
- 4.5.2 develop their protocols to reduce the number of animals to the minimum and refine the protocols to cater for the maximum well-being of animals,
- 4.5.3 consult the Animal Care and Use Committee while developing the protocols to ensure availability of the facilities, equipment, and consumables, and
- 4.5.4 obtain ECACU approval and extensions in a timely manner.

4.6 **Animal facility staff**

- 4.6.1 The animal facility staff are responsible for the provision of care to animals according to established standards of such care, including breeding, housing, feeding, and veterinary care, and services to animal users according to their specific needs.
- 4.6.2 They are responsible for monitoring compliance of staff and users with ECACU approvals and health and safety protocols, and in this role, they may assume responsibilities as delegated by the IO and ECACU. For this purpose, they are authorized to access any area within and outside the animal facilities on campus where animal work is being done.

5.0 **COMMITTEES**

5.1 **Ethics Committee for Animal Care and Use (ECACU)**

- 5.1.2 Working under the Aga Khan University Ethical Review Board (ERB), which reports to the University Research Council (URC), ECACU is mandated to provide guidance and create awareness about the humane care and use of animals at Aga Khan University, and to ensure that the use of animals, including but not limited to research, education, diagnostics, and therapeutics, is justified from a legal and ethical perspective.
- 5.1.3 ECACU is authorized to permit the use of animals, for which a formal process is defined, and to stop animal work in case of non-compliance for which mechanisms to monitor animal usage are in place.
- 5.1.4 ECACU also provides training relevant to animal use and guidance in the form of standard operating procedures.
- 5.1.5 *Membership* of ECACU is multidisciplinary, with the composition according to international norms including the AV, two scientists experienced in animal research, a representative from the Clinical Laboratories, and an independent member.

5.2 **Animal Facility Committee (AFC)**

- 5.2.1 Working under the Office of Research and Graduate Studies, this Committee is mandated to manage the animal facility, including procurement, housing, feeding, breeding, screening, day-to-day care, health care, dispensing to users, and monitoring of use of laboratory animals.
- 5.2.2 AFC reports to the Head of the Office of Research and Graduate Studies while working closely with ECACU for compliance monitoring function, to ensure that all animal related work is in line with protocols approved by ECACU.
- 5.2.3 The Committee is headed by the Attending Veterinarian and assisted by a coordinator.
- 5.2.4 The Committee periodically informs and updates ECACU about the functioning of the animal facility.
- 5.2.4 *Membership*: The Committee includes the AV, coordinator of the animal facility, and a representative from the Institutional Biosafety Committee. A representative

from the Clinical Laboratories is an invited member, called when required matters pertaining to animal use by the Laboratories. Director Laboratories, and Chair ECACU, are ex-officio members.

5.3 **Institutional Biosafety Committee (IBC)**

- 5.3.1 The IBC reviews and approves protocols entailing potential biological hazards. ECACU and Animal Facility Committee work in accordance with guidelines and relevant operating procedures of the IBC, to ensure safety of personnel and animals.
- 5.3.2 Specific occupational health and biosafety precautions pertaining to laboratory animal-related work are addressed within the umbrella of institutional biosafety.

6.0 **EMPLOYEE HEALTH**

Working closely with the IBC, this section within the Department of Family Medicine is responsible for employee health screening, incident / exposure reporting, and health maintenance, including vaccinations and medical treatment.

7.0 **IMPLEMENTATION**

Faculty, students, staff, and all other persons who use or handle animals for research or teaching at Aga Khan University have the responsibility to:

- a) avoid using animals if a replacement alternative is available, feasible, and appropriate for the objective of their usage,
- b) use animals after approval by ECACU, by complying with the approved protocol and any additional recommendations by ECACU,
- c) work with animals after receiving mandatory training offered by ECACU,
- d) inform ECACU in case of any change in protocol or unexpected/adverse event,
- e) work with the animal facility staff in a collegial and respectful manner,
- f) ensure the physical and emotional well-being of animals by handling/treating them with compassion, respect, and dignity,
- g) follow the standard operating procedures of the Animal Facility,
- h) respect this Policy and other related policies, standard operating procedures, and guidelines applicable to relevant animal use, and
- i) publish data related to animal research as per the highest standards of scientific integrity.

References:

1. Policy on Research Ethics Review, ORGS/008-2018, March 29, 2018. AKU Research Policies <https://www.aku.edu/research/policies/Pages/home.aspx>

2. Policy on Research Misconduct, ORGS/002-2018, Oct 11, 2018. AKU Research Policies <https://www.aku.edu/research/policies/Pages/home.aspx>
3. Policy on Animal Laboratory Biosafety [of The Aga Khan University].
4. Terms of Reference for Ethics Committee for Animal Care and Use [of The Aga Khan University].
5. Guideline on Compliance with Ethics in Laboratory Animal Use [of The Aga Khan University]
6. Terms of Reference for Animal Facility Committee [of The Aga Khan University].

Acknowledgement:

The following sources were consulted while drafting this Policy:

1. Guide for the Care and Use of Laboratory Animals, 8th ed. 2011, National Research Council, National Academies Press. Available from <https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf> accessed June 8, 2021.
2. Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd ed. 2010, Federation of Animal Science Societies. Available from <https://www.aaalac.org/pub/?id=E900BDB6-CCCF-AB13-89B6-DA98A4B52218> accessed June 8, 2021
3. University of Ottawa Policy 31, on Animals Used in Research and Teaching. Available from <https://www.uottawa.ca/administration-and-governance/policy-31-animals-used-research-and-teaching-university-ottawa> accessed June 27, 2020.
4. Institutional Animal Care and Use Committee Guidebook, , 2nd ed. 2002, Office of Laboratory Animal Welfare, NIH. Available from <https://grants.nih.gov/grants/olaw/guidebook.pdf> accessed June 27, 2020.

ORGANOGRAM

Aga Khan University, Karachi

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