Guidelines for the Establishment and Functioning of Animal Ethics Committees
[Institutional Animal Care and Use Committees] in Africa

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2. Definitions

2.1. Animal: All live non-human vertebrates (i.e. fish, amphibians, reptiles, birds and mammals) and higher invertebrates (i.e. cephalopods and decapods), of all life-stages from half of gestation or being capable of independent feeding (whichever comes first), including but not limited to laboratory animals, farm animals, wildlife, free-living animals, domestic animals, feral animals and genetically altered animals.

2.2. Institutional Official: The authorised member of senior administration or management of the institution, who bears ultimate responsibility and accountability for the institutional animal care and use programme and compliance with animal ethics standards. This person should have the authority and budgetary means to ensure appropriate standards.

2.3. Protocol: A detailed written description of the proposed use of animals for scientific purposes, as submitted to an Animal Ethics Committee, in application for review and consideration for approval.

2.4. Reduction: Methods which minimise the number of animals used.

2.5. Refinement: Methods which minimise animal suffering and improve welfare.

2.6. Replacement: Methods which avoid or replace the use of animals.

2.7. Scientific purposes: Research, education (teaching and training), testing, safety and efficacy studies, the use of animals for diagnostic purposes, production of biological products or substances, validation, field trials, conservation studies, observation, environmental studies, regulatory studies to register a product, including animals that are produced to be used for scientific purposes.

2.8. Three Rs: The Replacement, Reduction and Refinement of the use of animals for scientific purposes.
3. Abbreviations

3.1. AEC: Animal Ethics Committee, alternatively termed an Institutional Animal Care and Use Committee (IACUC)
3.2. CIOMS: Council for International Organization for Medical Sciences
3.3. ICLAS: International Council for Laboratory Animal Science
3.4. OIE: World Organization for Animal Health

4. Introduction

4.1. In recognition of the common status in several African institutions, countries and regions, regarding:
   4.1.1. a scarcity of functional legal frameworks, guidelines, standards or ethical oversight systems for animal care and use for scientific purposes;
   4.1.2. limited availability of resources and expertise;
   4.1.3. the requirement for human resource development;
   4.1.4. the necessity for sustainable scientific capacity development;
   4.1.5. the responsibility to realise sound scientific practice and scientific integrity;
   4.1.6. the obligation to promote the welfare of animals;
   4.1.7. and the importance of harmonising practices to strengthen cooperation and collaboration;
4.2. In recognition of the African Union Commission’s Agenda 2063 – The Africa We Want⁴, Aspiration 1 “A prosperous Africa based on inclusive growth and sustainable development” and Aspiration 5 “An Africa with a strong cultural identity, common heritage, values and ethics”;
4.3. In recognition of the African Union’s Animal Welfare Strategy in Africa⁵, the vision of which is “an Africa where animals are treated as sentient beings, as a leading continent in implementation of good animal welfare practices for a competitive and sustainable animal resource sector” with the goal “to transform the animal resources sector through adoption of good animal welfare practices for human wellbeing, sustainable livelihoods, poverty reduction and economic growth”;
4.4. In acknowledgement of the significant role that the use of animals for scientific purposes plays in biological discovery and advancement of human and animal health and wellbeing in Africa;
4.5. In acknowledgement of the guiding principles that animals should only be used for scientific principles when necessary and when their use is scientifically and ethically justified, in which case the principles of the Three Rs should be incorporated into the design and conduct of activities that involve animals;
4.6. These guidelines are produced, as a recommendation for good practice, to be implementable and relevant in the African context, taking into account the cultural, religious, political and socioeconomic diversity in Africa;
4.7. These guidelines are intended as a practical guide to facilitate the establishment and functioning of Animal Ethics Committees (AECs) [Institutional Animal Care and Use Committees; IACUCs] in Africa, as fundamental instruments for the responsible oversight of animal care and use for scientific purposes.

5. Rationale for the Guidelines

5.1. Humans have a moral imperative and ethical responsibility to limit the suffering of animals and recognize the intrinsic value of animal life. The humane care and use of animals create awareness of animal welfare and a culture of care;
5.2. Ethical review and oversight of animal care and use is a key component of the responsible conduct and quality-assurance of science, impacting on the quality, reproducibility and reliability of scientific data;
5.3. Appropriate ethical and scientific standards promote global acceptance, thus enhancing international collaboration, scientific publication, grant funding, conferring of degrees, international rankings of educational institutions, career progression and promotion of scientists, mitigation of reputational and legal risk, and accreditation of animal care and use programmes;
5.4. Appropriate ethical standards encourage the national advancement of science and technology, human and animal health, as emphasised by the requirement by regulators for animal ethics approval for the registration of medicines, vaccines and medical devices;
5.5. Harmonisation with established international codes and guidelines (e.g. those of the OIE⁶, CIOMS and ICLAS⁷) impacts positively on international trade, economy, scientific recognition and exchange.
6. Scope of the Guidelines

6.1. These guidelines are intended to be used in conjunction with applicable national legislation. In cases of inconsistencies, national legislation takes precedence over the guidelines;

6.2. These guidelines apply to all live non-human vertebrate animals (i.e. fish, amphibians, reptiles, birds and mammals) and higher invertebrates (i.e. cephalopods and decapods), of all life-stages from half of gestation or being capable of independent feeding (whichever comes first), including but not limited to laboratory animals, farm animals, wildlife, free-living animals, domestic animals, feral animals and genetically altered animals;

6.3. These guidelines apply to all care and use of animals for scientific purposes, including for research, education (teaching and training), testing, safety and efficacy studies, the use of animals for diagnostic purposes, production of biological products or substances, field trials, conservation studies, observation, environmental studies, regulatory studies to register a product, including animals that are produced to be used for scientific purposes;

6.4. Animal ethics committees may choose to extend the scope of these guidelines to also include other species (e.g. invertebrates), uses of animals (e.g. non-scientific uses), or other aspects (e.g. the use of animal tissues) to meet their specific situational needs.

7. Foundation for the Guidelines

7.1. These guidelines were developed with reference to international recommendations, primarily the World Organization for Animal Health (OIE) Terrestrial animal health code: Use of animals in research and education⁴; and the Council for International Organization for Medical Sciences (CIOMS) and the International Council for Laboratory Animal Science (ICLAS) International guiding principles for biomedical research involving animals⁴;

7.2. The guidelines were produced with consideration of known existing legal frameworks, standards and policies relating to the care and use of animals for scientific purposes in Africa, and with regard for the cultural, religious, political and socioeconomic diversity in Africa;

7.3. The guidelines were composed to be relevant to the African context, by incorporating the experience and expertise of 32 African delegates from 12 African countries in a collaborative democratic process, in the Workshop for Developing Guidelines for the Establishment and Functioning of Animal Ethics Committees in Africa, convened at the Ecole Nationale de Médecine Vétérinaire de Sidi Thabet, Tunisia, 4-8 March 2019.

8. The Institutional Official and Institutional Responsibilities

8.1. Institutional Official: The authorised member of senior administration or management of the institution, who bears ultimate responsibility and accountability for the animal care and use programme and compliance with animal ethics standards. This person should have the authority and budgetary means to ensure appropriate standards;

8.2. The Institutional Official should provide the required resources to enable the AEC to function effectively and fulfil its responsibilities, including administrative support, office space, training of committee members, etc.;

8.3. The Institutional Official should appoint the chairperson of the AEC and the AEC members, in consultation with the chairperson of the committee;

8.4. The institution should ensure the independence of the committee in terms of decision-making and functioning, including the authority of the committee and upholding of committee decisions;

8.5. The institution should enable mechanisms for smooth and efficient communication between researchers and the committee, conflict resolution, appeals and adjudication of complaints;

8.6. The institution should ensure that appropriate internal and external quality-assurance assessment of the committee’s functioning is undertaken;

8.7. The institution should ensure compliance with relevant legislation; and

8.8. The institution should establish appropriate institutional grievance procedures.

9. Composition of the Animal Ethics Committee

9.1. The composition of the committee should ensure competent animal ethics review and oversight;
9.2. The impartiality and independence of members should be appropriately considered, including consideration that at least one member should be independent of the institution;
9.3. The chairperson of the committee should report regularly to the Institutional Official;
9.4. The committee’s composition should have fair representation in terms of gender;
9.5. The membership of the committee should enable the committee to fulfil its functions and meet its responsibilities, as outlined in this guideline;
9.6. Membership of the committee should consist of the following:
   9.6.1. At least one veterinarian with the relevant expertise and knowledge;
   9.6.2. At least one scientist with relevant experience in animal research and use;
   9.6.3. At least one public member to represent general community interests, who is independent of the science and care of the animals in the institution, who is not involved in the care or use of animals for scientific purposes;
   9.6.4. Additional members may be included as committee members in order to meet the needs of the committee (e.g. animal care staff, persons with knowledge of animal welfare, statisticians, ethicists, persons with knowledge of biosafety, persons with legal training, etc.);
   9.6.5. Additional persons may be co-opted as required;
9.7. The overall membership of the committee, including additional members, should be representative of the institutional environment, considering the needs of relevant stakeholders. An institutional analysis of animal care and use, including identification of relevant parties, can be beneficial to identify key stakeholders.

10. Responsibilities of the Animal Ethics Committee

10.1. Oversight of the entire institutional animal care and use programme, including animal acquisition, breeding, transport, husbandry and care, restraint, clinical procedures, euthanasia and safe disposal;
10.2. Ethical review of all protocols involving the care and use of animals for scientific purposes;
10.3. Post-approval monitoring of approved protocols to ensure compliance with approval conditions;
10.4. Inspection of animal facilities and areas to advise on changes needed to improve animal welfare;
10.5. Report all needs and deficiencies in the animal care and use programme to the Institutional Official;
10.6. Ensure that appropriate mechanisms are created for reporting and investigation of concerns regarding animal welfare or non-compliance;
10.7. Ensure appropriate veterinary care of animals;
10.8. Keep records of the use of animals for scientific purposes in the institution;
10.9. Provide a forum of discussion to promote a culture of care in the institution;
10.10. Ensure that all AEC members are adequately trained and competent, with reference to international guidelines;
10.11. Ensure that systems are established to confirm that all relevant animal care and use personnel are adequately trained and competent (refer to Section “Oversight of Training and Competence”);
10.12. Report on a regular (usually annual) basis to the institution, including the composition of the committee, meetings held and attendance, challenges faced by the committee, details of protocols reviewed, details of animals bred and used including the severity of studies, unanticipated problems and adverse events encountered including actions taken, details of non-compliance or misconduct, protocols withdrawn or suspended, challenges encountered in the animal care and use programme with recommendations for improvements, details of facility inspections and other relevant aspects identified by the committee.

11. Functioning of the Animal Ethics Committee

11.1. AECs should establish formal documentation and standard operating procedures to describe all relevant aspects of their functioning, including decision-making processes;
11.2. In the interest of transparency, relevant committee documentation should be publicly available;
11.3. The AEC should set timelines for submission and review of protocols, which should be communicated to applicants;
11.4. Adequate records should be kept of AEC activities, including attendance registers and minutes of meetings;
11.5. Committee members should sign an appropriate confidentiality agreement;
11.6. Conflicts of interest of AEC members should be appropriately declared and managed;
11.7. Establish mechanisms for complaints and concerns relating to the care and use of animals to be raised and investigated.

12. **Authority of the Animal Ethics Committee**

12.1. Evaluate and approve protocols and amendments to protocols (when all relevant requirements are met) for animal care and use;
12.2. Monitor the care and use of animals in approved protocols, to establish compliance with approval conditions (i.e. post-approval monitoring);
12.3. Inspect any facilities or areas where animals are kept or used, including breeding establishments for compliance on animal welfare aspects;
12.4. Investigate suspected non-compliance or misconduct, or refer investigation of non-compliance or misconduct to the Institutional Official or to a regulatory body, as may be appropriate;
12.5. Suspend or withdraw approval for previously approved protocols in cases of established non-compliance;
12.6. Instruct that an animal(s) is euthanized or receives appropriate treatment in cases of welfare concerns;
12.7. It is essential that the authority of the committee and that of the chairperson, as well as any additional authorities delegated by the Institutional Official, is clearly specified in the formal documentation of the committee, which should be approved by the Institutional Official.

13. **Applications for Animal Ethics Review**

13.1. Applications for the use of animals for scientific purposes should be submitted and approved by the AEC, before any of the animals are used for the specified purposes;
13.2. Applications for animal use should be by completion of the relevant AEC protocol application form;
13.3. The minimum details to be included in the protocol application form, should enable the AEC to conduct the ethical review, as outlined in the Section “The Ethical Review Process”;
13.4. Applications should provide the rationale for animal use in lay language (i.e. non-specialised terms) so that it is understandable by persons who are not subject experts;
13.5. The Principal Investigator, i.e. the person who takes primary responsibility for compliance with the approved conditions of the protocol, should be clearly specified.

14. **The Ethical Review Process**

14.1. The ethical review conducted by the AEC should include consideration of the following: Appropriate justification for the use of animals where there are no relevant alternatives, appropriate application of the Three Rs (i.e. Replacement, Reduction and Refinement of the use of animals), a clear valid scientific question building on previous knowledge, clear description of benefits arising, sound experimental design including estimation of sample size, relevant experience and expertise of involved personnel, training and competence of involved personnel in all animal care and use procedures, species-appropriate animal care and husbandry, suitable environmental enrichment, exercise in relevant species, a clear description of the procedures performed, a clear description of severity and cumulative harms to the animals (i.e. detrimental impacts on animal wellbeing, including fear, discomfort, pain, suffering, distress or lasting harm), the clinical progression of the animal’s condition over time, welfare monitoring (i.e. frequency, signs to be monitored, the persons responsible), humane endpoints (i.e. the maximum level of suffering that will be permitted), methods for euthanasia and confirming death, appropriate disposal of biological materials, the availability of appropriate facilities and acceptance by the principal investigator of full primary responsibility for the protocol;
14.2. The AEC should perform a harm-benefit assessment, in order to ensure that the likely benefits of the study will outweigh the total cumulative life-time harms to the animals;
14.3. The AEC may use a check-list for reviewers, to harmonize the ethical review process;
14.4. The AEC should ensure that appropriate scientific review of all protocols is conducted, as well as appropriate review of biosafety and occupational health and safety.

15. **Oversight and Monitoring of Animal Care and Use**
15.1. Post-approval monitoring of approved protocols, to ensure compliance with the conditions of the approval, including the competence of personnel in procedures;
15.2. Inspect facilities or areas where animals are kept and used;
15.3. Progress reports from PIs (annual and final) – issues identified can help improve institutional practice;
15.4. Review and approval of standard operating procedures for animal care and use.

16. Oversight of Training and Competence

16.1. All AEC members should be appropriately trained in relevant animal ethics review processes;
16.2. At least three levels of training should be provided for AEC members, i.e. introductory training for new members, in-depth training and continuing professional development;
16.3. Training should include the ethical evaluation process, regulations and guidelines, the 3Rs (Reduction, Refinement and Replacement), animal welfare, humane endpoints, the harms-benefit assessment, the culture of care, animal facility inspection, the standard operating procedures of the AEC, knowledge and understanding of the key research areas undertaken in the institution, training in committee functioning skills and relevant biosafety and occupational health and safety training;
16.4. All persons who come into contact with animals used for scientific purposes, or who have an impact on the welfare of these animals, should receive appropriate education and training in applicable scientific and animal welfare aspects relevant to their role, with reference to international guidelines.
16.5. Relevant introductory and continued education training should be provided to persons who perform procedures on animals (including researchers, students and staff), persons who care for animals (including breeders and suppliers of animals that are used for scientific purposes), persons who euthanize animals and persons who design projects and procedures;
16.6. The practical competence of persons who perform procedures on animals, euthanize animals or care for animals, should be assessed and confirmed by a person who is competent in the relevant techniques and who is trained in assessing competency. Standards for competence may be as determined by a national body or competent authority, or by reference to international guidelines for good practice. Systems should be established to ensure that persons remain competent;
16.7. Veterinary and para-veterinary professionals should receive education and training relevant to their role, including knowledge of the applicable species and procedures.

17. Quality-Assurance of the Animal Ethics Committee’s Functioning

17.1. Oversight of the AEC’s functioning is an essential quality-assurance mechanism;
17.2. The chairperson of the AEC should report regularly to the Institutional Official;
17.3. Internal oversight should include institutional assessment of AEC functioning. This can increase the efficiency and performance of the AEC and may contribute to recognition of the AEC and its authority within the institution;
17.4. External (to the institution) oversight may include auditing and/or registration of AECs by non-institutional bodies, to confirm appropriate composition and functioning of the committees. This could include national and/or regional oversight mechanisms and may include the compilation of national statistics of animal use for scientific purposes. National competent authorities may also play a role in terms of external oversight of facility standards and competence in procedures.

18. Other Responsible Parties

18.1. Veterinarians: In addition to membership of the AEC, the role of veterinarians should include evaluation of animal health and welfare (including preventative care, health monitoring, diagnosis, treatment, post mortem examination), training and evaluation of competence of personnel in animal procedures, evaluation of standards of animal facilities and consultation during the design of protocols and needed. The veterinarian should liaise with the AEC chairperson and the Institutional Official;
18.2. Researchers, teachers, students, staff and other persons with responsibility for the humane care for and use animals for scientific purposes;
18.3. Institutional bodies with oversight of biosafety and occupational health and safety;
18.4. Institutional bodies responsible for the scientific review of proposals for animal use;
18.5. National competent authorities may regulate standards of facilities and competence;
18.6. National bodies may regulate standards of animal ethics review and oversight.
19. References


20. Acknowledgements

The guidelines were drafted by the *Technical Experts Committee in Scientific Animal Ethics*, during the *Workshop for Developing Guidelines for the Establishment and Functioning of Animal Ethics Committees [IACUCs] in Africa*, at the Ecole Nationale de Médecine Vétérinaire de Sidi Thabet, Tunisia, 4-8 March 2019.

The *Technical Experts Committee in Scientific Animal Ethics* was composed of the following members – Chairperson: Dr Bert Mohr (South Africa); Prof Sohair Fahmy (Egypt), Prof Francis Fakoya (Nigeria), Prof Khadiga Gaafar (Egypt), Dr Josiah Kantiyok (Nigeria), Prof Farida Khammar (Algeria), Dr Sarrah Mbarek (Tunisia), Dr Lawrence Mugisha (Uganda), Dr Hany Sleem (Egypt), Prof Ouajdi Souilem (Tunisia), Dr Alemayehu Toma (Ethiopia), Ms Maricel van Rooyen (South Africa) and Dr Henry Zakumumpa (Uganda).

The draft guidelines were written and revised in collaborative sessions over the course of 4-8 March 2019, with the input of all participants at the broader *Train the Trainer Course in International Best Practice in the Care and Use of Animals for Scientific Purposes*, at the Ecole Nationale de Médecine Vétérinaire de Sidi Thabet. The following delegates reviewed the guidelines: Dr Abdussamad Abdussamad (Nigeria), Dr Kamel Barhoumi (Tunisia), Dr Imène Ben Salem (Tunisia), Dr Abdelouafi Benmouloud (Algeria), Dr John Chipangura (Zimbabwe and South Africa), Mr Moses Egesa (Uganda), Prof Ahmed El Marghani (Libya), Dr Tamsyn Fourie (South Africa), Dr Nawfal Hdadech (Morocco), Dr Ngalla Jillani (Kenya), Dr Sara Kassouri (Algeria), Dr Médhia Khamassi Khbou (Tunisia), Dr Soumaya Kouidhi (Tunisia), Dr Dave Lewis (United Kingdom), Dr Asma Louati (Tunisia), Dr Zivanai Makoni (Zimbabwe), Dr Louise Martin (Switzerland), Dr Mokganedi Mokopasetso (Botswana), Dr Atunga Nyachieio (Kenya), Dr Carter Thanda (Botswana) and Dr Manal Zaki (Egypt).

The final version of the guidelines was approved on 8 March 2019 by all 34 delegates in the above meeting.

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Signatories to the Guidelines for the Establishment and Functioning of Animal Ethics Committees / Institutional Animal Care and Use Committees in Africa

These guidelines were developed and approved in the Workshop for Developing Guidelines for the Establishment and Functioning of Animal Ethics Committees in Africa, co-sponsored by the International Council for Laboratory Animal Science (ICLAS), convened at the École Nationale de Médecine Vétérinaire de Sidi Thabet, Tunisia, 4-8 March 2019. The guidelines were developed in a collaborative process, including 32 delegates from 12 African countries.

Signatories to the Guidelines (Friday 8 March 2019)

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</tbody>
</table>