



University of Fort Hare  
Together in Excellence

**TITLE:** Animal Research Ethics Committee TERMS OF REFERENCE

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**IMPLEMENTATION RESPONSIBILITY:** University Research Ethics Committee, SENATE

**STRUCTURE APPROVED BY:** AREC, UREC, Proposed to SENATE

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**COMPLIANCE OVERSIGHT BY:** University Research Ethics Committee, SENATE

**TO BE READ IN CONJUNCTION WITH THE FOLLOWING Documents:**

- University Research Ethics Policy;
- University Research Ethics Committee (UREC) Terms of Reference
- AREC Standard Operating Procedures

**APPROVED BY:**

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Name:

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Date

**DESIGNATION:**

**UNIVERSITY OF FORT HARE**

## 1. PURPOSE AND INTRODUCTION

The University of Fort Hare Animal Research Ethics Committee (UFH-AREC) is mandated to fulfil its functions by the Senate and University Research Ethics Committee (UREC) of the University of Fort Hare (UFH). The essential purpose of the UFH-AREC is to protect the dignity, rights, safety and wellbeing of all participants (animal and human) of animal research, teaching and husbandry. UFH-AREC will do this through independent, prospective and ongoing rigorous scientifically informed ethics review of all research projects and teaching on animals undertaken by members of staff, registered students and affiliates. The UFH-AREC functions in compliance with, but not limited to, the following documents and guidelines

- South African National Standard: 10386 (2008, Under revision for release in 2021)
- Department of Health 2015
- Animal Protection Act, 1962 (Act No. 17 of 1962), as amended
- Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982), as amended
- Animal Diseases Act, 1984 (Act No. 35 of 1984), as amended
- Animal Health Act, 2002 (Act No. 7 of 2002), as amended
- Animal Matters Amendment Act, 1993 (Act No. 42 of 1993), as amended
- Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), as amended
- Performing Animals Protection Act, 1935 (Act No. 24 of 1935), as amended
- SPCA Act No, 169 of 1993
- Professional Code of Ethics of the Association of Zoos and Aquaria

By fulfilling its mandate, the UFH-AREC will incorporate the core ethical principles of Replacement, Reduction and Refinement into its activities. More information on the core principles can be found in the SANS 2008 (or newer), but briefly;

- Replacement of the use of animals with alternative models where feasible
- Reduction of the number of individual animals used but ensuring scientific integrity
- Refinement of experimental design, procedures, care and husbandry, to minimise or eliminate the impact on individual animals in terms of actual or potential pain, suffering, stress, and lasting harm.

To advise the UFH Senate and designated authority (UREC) on all matters related to the ethics, wellbeing and care of animals. These matters include, are not limited to, all research, teaching and husbandry conducted at the UFH. The UFH-AREC will be mandated to investigate and take appropriate actions, in the event of the deviations from approved

protocols, and violations or allegations of unethical conduct concerning the use of animals in teaching and research. UFH-AREC is registered with the National Health Research Ethics Council (**Registration Number: AREC-150311-008**)

## 2. MEMBERSHIP OF THE ANIMAL RESEARCH ETHICS COMMITTEE

The UFH-AREC shall have a membership that will allow it to fulfil its terms of reference. The UFH-AREC membership shall include the following members.

### 2.1 Membership<sup>1</sup>

- One (1) category A member: Persons with qualifications in veterinary science, with experience relevant to the activities of the institution or, in special circumstances, a person with qualifications and experience to provide comparable expertise.
- Four (4) category B members: Persons with substantial recent experience in the use of animals in scientific or teaching activities. The chairperson shall be appointed from the category B members.
- Two (2) category C members: Persons with a demonstrable commitment to, and established experience in, furthering the welfare of animals, who are not employed by or otherwise associated with the institution, and who are not involved in the care and use of animals for scientific purposes. The person should where possible be selected based on active membership of and nomination by, an animal welfare organisation.
- Two (2) category D members: Independent persons who do not currently and have not previously conducted scientific or teaching activities using animals, and who are not an employee of the institution, except under defined circumstances. Two category D member types are recognised, an external member who is not an employee of the institution and an employee of the institution that has no interaction or association with animal research.
- Where required the following people can attend the meeting but will not have formal voting rights nor count towards the quorum or representation of various groups
  - A member of staff responsible for the procurement, production and daily care and maintenance of the animals
  - Where appropriate, specialists and other advisors may be invited to review protocols and attend meetings

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<sup>1</sup> The categories used here are taken from the South African National Standard: The care and use of animals for scientific purposes (SANS 10386:2008)

2.2 Chairperson: The chairperson of the UFH-AREC will be appointed by UREC via an official signed letter. UREC shall in its capacity as designated authority decide on the approach that will be used for the appointment of the chairperson, be it through an election of standing members or direct appointment. The chairperson should, however, be an academic at the UFH and have experience working with animals for research or teaching purposes as well as an understanding of animal ethics through formal training (Category B Member). The chairperson drives the formulation and maintenance of animal ethics policy and standard operating procedures for animal-related activities within the UFH.

2.3 Deputy Chairperson: The deputy chairperson will be elected from the standing members of the UFH-AREC. The deputy chairperson will assume responsibilities for the chairperson should the chairperson be unable to fulfil their duties. Deputy chairperson term of office will be for one calendar year and will be rotated amongst members on the committee.

2.4 Members of category C and D will make up no less than one-third of the UFH-AREC Committee. All members are appointed by UREC via an official letter which contains the terms in office and indemnified the members for actions conducted while on the UFH-AREC. The appointment must be ratified by Senate.

### 3. EXECUTIVE COMMITTEE

The UFH-AREC Executive Committee (EXCO) will be comprised of the chairperson, a category A member and a category C member. The EXCO will have the power to act on behalf of the UFH-AREC for the following decisions

- 3.1. pertaining to emergencies (where swift action and decisions need to be made on animal-related aspects that are time-sensitive)
- 3.2. minor amendments to approved protocols or activities where the change is not likely to cause harm to the animals, including pain, suffering or distress. This includes the final decision on biological sample collection studies where no interaction with animals is proposed.
- 3.3. the final assessment of protocols that have been through a full quorate meeting of the UFH-AREC and been given the approved pending clarification of comments from the committee.

The EXCO cannot approve protocols where animal use takes place and all decisions made by the EXCO need to be ratified at the next quorate meeting of the UFH-AREC.

#### 4. QUORUM RULES

A meeting quorum will be achieved when at least one of each category (A-D) is present as stipulated in the SANS10386 5.2.3 and when 50% of the committee is present.

#### 5. TERMS OF OFFICE

As per the DoH 2015, terms of office will be for three (3) years and will be stated on the appointment letter provided to each member. Terms of office can be renewed for subsequent terms but all effort will be made to rotate members to ensure continuous training and continuity of membership. This continuity is important in ensuring the longevity of the committee and ensuring turn-over with trained committee members. Post-Doctoral Fellows can be appointed for one calendar year, with possible renewal for extra year's should their contracts be extended.

#### 6. FUNCTIONS AND RESPONSIBILITIES

All functions and responsibilities are based on the guidelines listed in the SANS 10386: 2008 (or newer).

- 6.1. The UFH-AREC will review proposals that have been submitted. Proposals should be accompanied by the appropriate UFH-AREC protocol form, be fully completed, and should place before the UFH-AREC sufficient information to satisfy the UFH-AREC that the proposed use of animals is justified and complies with the principles of Replacement, Reduction and Refinement (3 R's). Following a fair and balanced review that considers the harms-benefit analysis, 3 R's and animal welfare, proposals will be approved, sent back for modification, deferred or rejected.
- 6.2. Only those scientific or teaching proposals that conform to the requirements of all relevant sections of this Code and of legislation may be approved. Proposals shall be considered and approved only at Quorate meetings of the UFH-AREC and a record of all approved projects will be maintained.
- 6.3. Scientific or teaching activities involving the use of animals shall not start before written approval is given. Failure to obtain such permission shall result in projects not being recognized. Pilot studies, where proposed or considered preferable, by the UFH-AREC, should be regarded as integral to the overall project(s). These enable the assessment of the feasibility and value of the project and the potential for Refinement and Reduction. Pilot studies should similarly receive clearance from the UFH-AREC

- 6.4. The UFH-AREC will review and monitor all standard operating procedures (SOPs) for animal care and use, including scientific procedures, in all animal facilities and breeding centres belonging to UFH. SOPs shall not be used until approved by the UFH-AREC and will lapse if not reviewed on a three-year cycle. All approved SOPs will be readily available to all relevant people.
- 6.5. Decisions reached at meetings shall be made through a process that is fair, consistent and transparent to investigators and teachers, and acceptable to all UFH-AREC members. Decisions will be reached through majority voting. Irreconcilable differences between the UFH-AREC and an investigator or teacher shall be referred to UREC for review.
- 6.6. Monitor all approved protocols to ensure the appropriate standards and approval conditions are being maintained. Monitoring will take the form of active (site visits) and passive (reports) approaches. Passive monitoring will take the form of annual and final reports in addition to any other reports requested by the UFH-AREC. Active monitoring will include ongoing Post-Approval-Monitoring (PAM) through site visits or other means possible if site visits are not possible. Approved projects of long duration (> 1 year in length) and the long-term continuous use of individual animals shall be reviewed at least annually by the UFH-AREC or more frequently if considered desirable. Continuation of the project will only happen if renewed by the UFH-AREC. Any project can be reviewed if warranted by the emergence of new information (whether scientific or pertaining to the scientific or teaching activities or investigator). Regardless of the duration of the approval, the continuation of all projects shall be subject to the submission of written annual reports that should advise on:
- What progress has been achieved
  - Problems that may have interfered with project progress
  - Number of animals used to date or in total
  - The wellbeing and animal welfare status of all animals during the study
  - Unexpected mortalities
  - Envisaged modifications, amendments, or additions
  - Whether the project has or will be able to, achieve the stated objectives
  - Whether the project is continuing, has been completed, or discontinued, and
  - What publications have been produced

Following a review of the annual report, the UFH-AREC may determine, based on the report and further consultation with the researcher that a project may continue, be suspended, require modification or be terminated.

- 6.7. Monitor all animal facilities to ensure appropriate standards and conditions are met. This monitoring will take the form of active monitoring where animal facilities are inspected

no less than once a year and passive monitoring where animal facility reports are submitted to the UFH-AREC. The UFH-AREC shall ensure through monitoring that adequate records are kept on the acquisition, breeding, health, care, housing, use and disposal of animals.

- 6.8. Communicate with and educate the animal use community at UFH about the ethical use of animals, the harms-benefits analysis and the three Rs. The UFH-AREC will also ensure the practical competence of researchers, animal care staff and other personnel who are in contact with animals.
- 6.9. Ensure that all members of the UFH-AREC have received appropriate training, including induction training and ongoing training. If possible, training with assessments will be preferred over those without.
- 6.10. The UFH-AREC might need to put in place procedures to deal with the immediate use of animals for the diagnosis of unexplained and severe disease outbreaks.
- 6.11. The UFH-AREC shall ensure that any activity that constitutes a major breach of this Code (i.e. a breach that has immediate negative implications for animal welfare) ceases immediately and appropriate action is taken. This may include referral to UREC. For non-compliance that has infrastructural dimensions, a reasonable time shall be given for correction, but the UFH-AREC shall be assured and kept informed that the problem is being addressed. The UFH-AREC shall initiate investigation into any suspected or alleged non-compliance with this Code, institutional policies or the Animals Protection Act, 1962 (Act 71 of 1962).
- 6.12. The UFH-AREC shall report in writing at least annually to the UREC as Senate Committee of the University which will report to Senate. The UFH-AREC will submit an annual report to the National Health Research Ethics Council (NHREC) to maintain its registration through the NHREC.
- 6.13. Where projects are to be conducted at more than one institution, UFH-AREC approval should be sought from each institution unless responsibility has been formally delegated to one institutions Animal Ethics Committee through an application process.
- 6.14. The UFH-AREC may be approached by individuals, or organisations, which do not have direct access to an institutional Animal Ethics Committee, yet require Animal Ethics approval before proceeding to use animals for scientific purposes. The UFH-AREC shall decide, on an individual case basis, whether it is prepared to assess the proposal and oversee the project. In such cases, proposals for non-institutional applicants shall address the points below, in addition to all information normally required by the UFH-AREC. This arrangement should enable the institution to withdraw from the agreement if the non-institutional applicant fails to comply with directions of the UFH-AREC.

## 7. PROCEDURES

- 7.1. Declaration and management of conflict of interests: Members will on appointment and at the start of each meeting be expected to disclose conflicts of interest and recuse themselves from involvement in matters where they may have a conflict of interest
- 7.2. Confidentiality: Members will sign confidentiality agreements on appointment and at the start of each meeting the attendance register will contain a declaration of confidentiality.
- 7.3. Administrative procedures: Standard Operating Procedures for the submission, receipt and processing of applications and reports to the UFH-AREC will be developed and these will be readily available.
- 7.4. Meeting procedures
  - 7.4.1. At least one member of categories A, B, C and D shall be present throughout a meeting to establish a quorum for the conduct of the meeting (See section 4 above). Members are permitted to be present in a digital format, thus ensuring a quorum.
  - 7.4.2. Categories C and D shall represent one-third of those members present (See section 2 above)
  - 7.4.3. Meeting documents will be distributed to UFH-AREC members promptly before the scheduled meeting
  - 7.4.4. Any conflict of interest should be disclosed at the start of the meeting and that member should recuse themselves from discussions and voting on the item where the conflict of interest exists
  - 7.4.5. Meetings should be scheduled as frequently as the volume of business demands, but not less than quarterly.
  - 7.4.6. The meeting business will include new and ongoing business as presented in the agenda circulated.
- 7.5. Communication: All decisions reached by the UFH-AREC will be communicated to the applicants, explaining the reasons for its decisions and any conditions on which approval is dependent. Communication will be in written format through e-mail. Face to face meetings between nominated committee members and applicants will be arranged should the need exist.
- 7.6. Complaints and non-compliance: Standard Operating Procedures for dealing with complaints (related to the UFH-AREC process), non-compliance (to the UFH-AREC approved protocols) and irreconcilable differences between the UFH-AREC and



applicants will be developed. A Standard Operating Procedure for Whistle Blowing will be available. All Standard Operating Procedures will be readily available.

- 7.7. Records and documentation Records related to the UFH-AREC business will be kept, including
- 7.7.1. a register of all applications including outcomes
  - 7.7.2. minutes that record the decisions and aspects of the UFH-AREC operations
  - 7.7.3. records of all inspections conducted by the UFH-AREC
  - 7.7.4. outcomes of all investigations conducted by the UFH-AREC
  - 7.7.5. reports submitted to the UFH Senate, UREC and National Health Research Ethics Council

## 8. CODE OF CONDUCT

- 8.1 Animal users and institutional managements should strive for the best regulation of laboratory animal use at both an institutional and statutory level. They should see that animal welfare regulations and operational codes and practices are properly adhered to.
- 8.2 The availability to the public of regularly updated and good-quality information on what animal experiments are undertaken and why they are undertaken is vital to create circumstances in which the issue of animal experimentation can be productively discussed and debated.
- 8.3 It must be recognised that the ethical imperative of the 'replacement' component of the three Rs principles is a primary challenge in every animal use procedure, and forms a critical part of the analysis in the ethical review process.
- 8.4 Sensitivity and respect for the sentience of non-human animals demand that they should be treated as organisms fully worthy of moral concern, under the stewardship of institutions and their staff.
- 8.5 Animal users should respect the interests of animals and not subject animals to intentions and motives which are not directly concerned with a research or teaching project, its objectives and its methodology.
- 8.6 Animal care staff, researchers and educators must be both professionally and personally qualified.
- 8.7 Researchers and educators who use laboratory animals and the staff who procure, breed and care for them are considered to be personally responsible for the proper care and use of these animals. They should uphold professional standards in accordance with their academic training and their professions.

- 8.8 Integrity should be promoted by honesty and fairness. In particular, researchers, educators, animal care personnel and Animal Ethics Committee members should be honest about their limitations, competence, belief systems, values and needs, and be prepared to respect views contrary to their own.
- 8.9 Sensitivity in animal experimentation requires balancing scientific or teaching interests with general values and norms supporting the interests and welfare of the animal subjects.
- 8.10 Special care should be taken not to treat animals as mere objects. Research objectives shall always be subordinate to the humane treatment of animals.
- 8.11 Researchers must apply safety rules and guidelines for the preservation and protection of the health and welfare of laboratory animals when hazardous substances, micro-organisms or parasites are being worked within experimental situations.
- 8.12 The responsible researcher, educator and animal care staff are to be appropriately qualified and experienced and to have facilities to ensure that all procedures conducted on laboratory animals will be undertaken with due discretion and precautions to protect the welfare of the animals.
- 8.13 Adequate preliminary studies of the literature pertaining to the proposed work should be undertaken to define as far as possible the risks inherent in the animal studies.
- 8.14 The users of laboratory animals have a responsibility to their professions, to the animals which they use, and to the public to ensure that an animal experiment is likely to yield information worth knowing and that such information is well supported by valid experimental data and analysis of that data.

## 9. DELEGATED AUTHORITY

The UFH-AREC has the power to act on behalf of the Senate and UREC. These powers include;

- 9.1 To review, approve, require modification or withdraw approval for ongoing research and teaching activities related to the use, care and husbandry of animals
- 9.2 To request progress reports and final reports on any approved animal usage. These progress reports can be at any interval deemed sufficient by the UFH-AREC and may include details of animal use, animal welfare, adherence to approved protocols, achieved results, details of non-utilized animals, and any additional information that may be deemed necessary by the UFH-AREC
- 9.3 To authorise the humane euthanasia of any animals deemed to be suffering or harmed as a result of the research, teaching or husbandry practices of an approved protocol

- 9.4 To monitor the animal facilities at UFH and facilitate the monitoring of said facilities by animal welfare organisations (i.e. National Society for the Prevention of Cruelty to Animals - NSPCA) and South African Veterinary Council (SAVC) inspectors
- 9.5 To review and investigate concerns or reported irregularities involving the care, husbandry and use of animals in accordance with the SANS 10386: 2008 (or newer) and to take appropriate action if deemed necessary.

## 10. Confidentiality

Committee business is confidential to protect intellectual property, researchers interests, and to permit committee members to speak freely and frankly, as well as to protect the public image of the University. This confidentiality policy is confirmed by committee members at the start of each committee meeting by signing the attendance register. Concerns about breaches of confidentiality should be raised with the chair of the UFH-AREC (in the first instance), and if not satisfactorily addressed, with the designated authority for the UFH, University Research Ethics Committee.

## 11. Servicing Officers

The UFH-AREC gets financial support from the Goven Mbeki Research and Development Center (GMRDC) through the office of the Dean of Research. In addition, administrative support is provided by an ethics administrator, who is a staff member of the UFH based in the GMRDC at the UFH.

## 12. References

SANS 10386:2008. South African National Standard: The Care and Use of Animals for Scientific Purposes.

DoH 2015. Ethics in Health Research: Principles, Processes and Structures. Second Edition. Department of Health, Republic of South Africa.

Nelson Mandela Metropolitan University Research Ethics Committee (Animal) (REC-A).

Terms of Reference and Standard Operating Procedures. 05.11.19 v080311

Rhodes University AREC Terms of Reference