



University of Fort Hare  
Together in Excellence

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

**AUTHOR(S):** Dr Tambling (Chair: Animal Research Ethics Committee)

**IMPLEMENTATION RESPONSIBILITY:** Senate Research Ethics Oversight Committee

**STRUCTURE APPROVED BY:** SREOC

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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;
- SREOC Committee Charter
- Ethics Committee Code of Conduct
- AREC Standard Operating Procedures

**APPROVED BY:**

Dr N Taole-Mjimba

Chair: SREOC

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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 Research Ethics Policy of the University of Fort Hare (UFH).

The institutional animal care and use program of UFH is defined as the policies, procedures, standards, organisational structure, staffing, animal facilities and practices put into place by UFH to achieve the humane care and use of animals throughout the institution. The Institutional Official, the individual who, as a senior administration representative, is responsible for resource planning and assuring alignment of program goals with the institution's mission, bears ultimate responsibility for the UFH animal care and use programs. The overall program direction is a shared responsibility between the Institutional Official, UFH-AREC and the attending veterinarian. The essential purpose of the UFH-AREC is to protect the dignity, rights, safety and well-being of all animals used for scientific purposes within the animal care and use program of UFH. This applies to animal research, teaching, and husbandry performed by members of the University (including staff, students, and other relevant persons) and/or performed in the University's facilities.

The UFH-AREC functions in compliance with, but not limited to, the following laws, standards and guidelines

- South African National Standard: 10386: 2021 - The Care and Use of Animals for Scientific Purposes
- National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed. National Department of Health of the Republic of South Africa.
- Animals 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, Refinement and Responsibility into its activities. More information on the core principles can be found in the SANS 10386: 2021, 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.
- Responsibility in that all parties involved in or authorising the use of animals in research take responsibility for the wellbeing and welfare of the animals to ensure that animals are not harmed or that harm is limited during research that involves animals. All persons involved should be adequately educated and trained so that they know and accept their responsibilities and are held accountable for them.

To advise the UFH Senate, designated authority, and institutional official on all matters related to the ethics, well-being, and care of animals. These matters include but are not limited to, all research, teaching, testing, other scientific purposes, and husbandry conducted at the UFH. To ensure this reporting, the animal care and use program needs should be clearly and regularly communicated to the Institutional official by the chairperson of the UFH AREC. The UFH-AREC will be mandated to investigate and take appropriate actions in the event of deviations from approved protocols and violations or allegations of unethical conduct or non-compliance 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**).

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 institution's Animal Ethics Committee through an application process. Formal agreements that outline responsibilities and expectations are required between the institutions and ARECs involved in compliance with NDoH 2024. 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.

## 2. Institutional Support.

The institution is responsible for ensuring that the AREC has sufficient financial support (and other resources) to meet its mandate under the research ethics policy and effectively implement its terms of reference. The institution is responsible for ensuring compliance with the entire animal care program. In addition, administrative support is provided by an ethics administrator, a staff member of the UFH based in the GMRDC at the UFH.

## 3. 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.

### 3.1. Membership<sup>1</sup>

- Minimum of nine members
- Chairperson – This member should hold a senior position at the Institution or is external to the institution. The chairperson is appointed in addition to the category A-D members mentioned below.
- Category A member: At least one veterinarian who is registered with the SAVC as a veterinarian or vet specialist who is legally permitted to practice as a veterinarian in South Africa.
- Category B members: At least two (2) members with substantial and recent experience using animals for scientific purposes.
- Category C members: At least one (1) member with an active membership in and enforcement of an independent animal welfare organisation and knowledge of the welfare and husbandry of the species used. If there is more than one category C member, they should come from different welfare organisations.
- Category D members: At least one (1) lay person who has no experience or past or present involvement with the care or use of animals for scientific purposes who is

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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)

independent of the life sciences, biological sciences or health sciences or any departments, faculties or schools or other units that use animals for scientific purposes.

- Additional required members: A member with daily hands-on contact with animals and responsibility for the daily care, procurement, production and maintenance of the animals. A member with expertise and experience in quantitative research methodologies. A member with knowledge and experience translating the relevant basic sciences to the corresponding applied sciences or practice. A member that is entirely independent of the institution. A member with expertise in biostatistics and competencies to confirm appropriate statistical methodologies and power analysis. A member with relevant expertise in animal research ethics. A legally qualified member. Should the expertise required above not be available in the members of categories A-D, they will need to be appointed as additional members.
- Members of categories C and D will make up no less than one-third of the UFH-AREC Committee.

### 3.2. Appointment of members

- All members are appointed by the Senate Research Ethics Oversight Committee (SREOC) via an official letter which contains the terms in office and indemnify the members for actions conducted while on the UFH-AREC.
- The term of office for UFH-ARREC is five years per term renewable once.
- Where possible appointments of members should overlap to ensure that not more than half of the committee will be replaced at a time.
- Appointments will need to be accepted (by signing) by members and the appointment letter will include the nature of appointment (category or other member status), the length of the term of office and the relevant indemnity statement.
- All new members need to accept the institutional ethics code of conduct prior to their appointment which covers issues related to conflict of interest and confidentiality.
- Once appointed, member will be informed where to locate the relevant policies, terms of reference and standard operating procedures.
- All members must meet the training requirements as laid out in the SANS10386:2021 and NDOH 2024. Training with assessments will be preferred over those without.
- No committee members will receive remuneration for their service on the committee. However, where travel and incidental expenses are incurred by external committee members, these will be reimbursed to the committee members.

### 3.3. Confidentiality

- Committee business is confidential to protect intellectual property and 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.
- 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. The AREC should have appropriate methods to manage perceived, potential or actual conflicts of interest involving the AREC members and external reviewers/experts consulted.

### 3.4. Conflict of interest

- Members will sign confidentiality agreements on appointment and at the start of each meeting the attendance register will contain a declaration of confidentiality.

## 4. MEETING PROCEDURES

- Meetings are held on a monthly basis and are scheduled for the third Friday of each month.
- Meetings will be virtual or hybrid.
- Fully quorate meetings will discuss full applications where animals are being handled and thus where the potential harms are deemed more significant than minimum.
- Applications that are classified as minimum harms will be discussed as per the expedited process.
- A meeting quorum will be achieved when at least one of each category (A-D) is present as stipulated in the SANS10386:2021, with categories D and C making up at least one third of sitting voting members and when 50% +1 of the committee present. All members must be present throughout the meeting for a quorum to be maintained.
- Decisions reached at meetings shall be made through a process that is fair, consistent, transparent to investigators and teachers, and acceptable to all UFH-AREC members.
- Decisions will be made based on consensus. Where consensus cannot be reached after a reasonable effort to resolve the difference, the UFH-AREC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved, the UFH-AREC should only proceed to a majority vote

after members have been allowed a period of time to review their positions, followed by further discussion.

- Voting can only be done by the four categories (A-D), with each category receiving one vote, and there is no conflict of interest in any of the voting categories. In the case of a split vote within a category, the majority vote within that category becomes the category vote. If there is a tie within a category then the category's vote is zero. The chairperson will not usually vote, but in cases where of a tie across categories, the chairperson has a deciding vote.

## 5. EXECUTIVE COMMITTEE

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

- 5.1. pertaining to emergencies related to approved projects (where swift action and decisions need to be made on animal welfare-related aspects that are time-sensitive)
- 5.2. may consider minor amendments to approved protocols or activities where the change is not likely to cause harm to the animals, including pain, suffering or distress.
- 5.3. may consider the final assessment of protocols that have been conditionally approved through a full quorate meeting of the UFH-AREC and clarification has been requested by 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 monthly meeting of the UFH-AREC.

## 6. FUNCTIONS AND RESPONSIBILITIES AS DELEGATED BY THE RESEARCH ETHICS POLICY

The UFH-AREC is mandated to implement the Research Ethics Policy as defined in the Policy, including all functions and responsibilities as defined by the SANS 10386: 2021, NDoH 2024 and relevant laws and regulations.

- 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, Refinement and Responsibility (4 R's). Following a fair and balanced review

that considers the harms-benefit analysis, 4 R's and animal welfare, and the governing principles of the SANS 10386:2021 (i.e., respect for animals, promoting the dignity of animals, high standards of scientific integrity, appropriate justification, limiting harms to animals, promoting animal wellbeing, the 4Rs), 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 the Policy, this Terms of Reference document, the relevant UFH-AREC SOPs and of legislation, relevant standards and Guidelines 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 considered 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, approve and monitor all standard operating procedures (SOPs) for animal care and use, including scientific procedures, in all animal facilities associated with UFH (including all farms, dairies and breeding centres and other facilities where animals are held under the banner of 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. Monitor all approved protocols to maintain the appropriate standards and approval conditions. Monitoring will take the form of active (site visits, post-approval monitoring [PAM]) and passive (reports) approaches. Passive monitoring will take the form of annual and final reports and any other reports requested by the UFH-AREC. Active monitoring will include ongoing PAM through site visits, or other means possible if site visits are not possible. Approved projects of extended duration (> one year in length) and the long-term continuous use or reuse of individual animals shall be reviewed at least annually by the UFH-AREC or more frequently if considered desirable. The continuation of the project will only happen if it is renewed by the UFH-AREC. Any project can be reviewed if warranted by the emergence of new information (whether scientific or about 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 to, and review and approval by the AREC, of satisfactory written annual reports that should advise on:
  - What progress has been achieved



- Problems that may have interfered with project progress
- Animal welfare incidents, severe adverse events, unanticipated problems, illness or death of animals, or other challenges encountered during the reporting period
- Number of animals used to date or in total
- The well-being 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.

- 6.6. Monitor all animal facilities and animal care and use areas 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 regularly at the time of formally scheduled meetings of the AREC. All Categories of UFH-AREC members should take part in facility and site visits. The UFH-AREC shall ensure through monitoring that adequate records are kept on the acquisition, transport, breeding, health, care, housing, use, euthanasia or killing, and disposal of animals.
- 6.7. Communicate with and educate the animal use community at UFH about the ethical use of animals, the harms-benefits analysis and the 4 Rs. The UFH-AREC will also ensure the practical competence of researchers, animal care staff and other personnel who are in contact with animals before they are permitted to work with animals, and will only permit personnel with confirmed competence to interact with, capture, handle, restrain, or perform procedures on animals.
- 6.8. Ensure that all researchers, teachers, students, staff members, and other personnel who design projects or activities (including principal investigators), work with animals, care for animals, kill animals, or perform procedures on animals (including capture, handling or restraint) are adequately educated and trained in their responsibilities under the SANS 10286:2021 and NDoH 2024 and understand these responsibilities.
- 6.9. The UFH-AREC might need to put in place procedures to deal with rapid review with the immediate use of animals to diagnose unexplained and severe disease outbreaks.
- 6.10. The UFH-AREC shall ensure that any activity that constitutes a major breach of the policies, Terms of Reference, Standard Operating Procedures and guidelines (i.e. a breach with immediate negative implications for animal welfare) ceases immediately and

appropriate action is taken. This may include a referral to SREOC. 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 an investigation into any suspected or alleged non-compliance with policies, Terms of Reference, Standard Operating Procedures and guidelines.

- 6.11. The UFH-AREC shall report to the SREOC in writing at least annually. The UFH-AREC will submit an annual report to the National Health Research Ethics Council (NHREC) to maintain its registration through the NHREC.
- 6.12. The UFH-AREC will ensure that the annual and 4-yearly external reviews of UFH-AREC and institutional functioning are performed in accordance with SANS 10386:2021 requirements.
- 6.13. To review, approve, require modification, reject or withdraw approval for ongoing research, teaching and other scientific purposes related to the use, care and husbandry of animals
- 6.14. To require annual (or more frequent) 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
- 6.15. To authorise the humane euthanasia of any animals deemed to be suffering or harmed as a result of the approved protocol or activity
- 6.16. To monitor the animal facilities (defined as all animal care and use areas) at UFH and other study sites and facilitate the monitoring of said facilities by animal welfare organisations (eg.. National Society for the Prevention of Cruelty to Animals - NSPCA) and South African Veterinary Council (SAVC) inspectors
- 6.17. To review and investigate concerns or reported irregularities involving the care, husbandry and use of animals in accordance with the SANS 10386: 2021 and to take appropriate action if deemed necessary.

## 7. STANDARD OPERATING PROCEDURES

The following Standard Operating Procedures should be developed by the UFH-AREC to govern and streamline operations. This list is not exhaustive and more SOPs to enhance the functionality of the UFH-AREC can be developed.

- 7.1. 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. The AREC must compile SOPs to meet its mandate and responsibilities in line with SANS 10386:2021 and NDoH 2024.
- 7.2. Standard Operating Procedures related to communicating decisions will be developed. 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 depends. 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 arise.
- 7.3. 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 Institutional Operating Procedure for Whistle Blowing will be available.
- 7.4. Standard Operating Procedures for monitoring approved projects will be developed to ensure compliance with approved protocols.
- 7.5. Standard Operating Procedures for the effective processing of applications will be developed to ensure that the UFH community understand the time frames that are associated with ethical review processes.
- 7.6. Standard Operating Procedure for maintaining records and documentation will be developed. Records related to the UFH-AREC business will be kept by the secretariat for a minimum of 5 years but preferably longer, including
  - 7.6.1. a register of all applications, including outcomes
  - 7.6.2. minutes that record the decisions and aspects of the UFH-AREC operations
  - 7.6.3. records of all inspections conducted by the UFH-AREC
  - 7.6.4. outcomes of all investigations conducted by the UFH-AREC
  - 7.6.5. reports submitted to the SREOC and National Health Research Ethics Council
  - 7.6.6. Reports of annual reviews of the AREC (SANS 10386:2021)
  - 7.6.7. Reports of the external independent review of institutional functioning every four years (SANS 10386:2021)

## 8. References

SANS 10386:2021. South African National Standard: The Care and Use of Animals for Scientific Purposes.

NDoH 2024. National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed. National Department of Health of the 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