



STANDARD OPERATING PROCEDURE

Title:	Terms of Reference for the MRU AEC	Page No.	Page 1 of 7
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Purpose and scope

To consolidate in one document the Terms of Reference that guide the MRU AEC for the purpose of enabling public sharing.

Malelane Research Unit has an Animal Research Ethics Committee (MRU AEC) under the guidelines of SANS 10386:2021, EDITION 2. STANDARDS SOUTH AFRICA, PRETORIA, 2002 (or the latest edition) and the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 ("National Guidelines 2015").

The Terms of Reference ("ToR") are designed to ensure that MRU AEC is compliant with the requirements of the above-mentioned guidelines.

This document describes the formal character of the committee, how it complies with organizational and statutory requirements, affiliation of members to the organization (MRU), and how the members, chairperson and deputy chairperson of MRU AEC are appointed.

The Terms of Reference aim to outline the responsibilities of MRU AEC to ensure that animal care and use comply with SANS 10386:2021, incorporating the core ethical principles of

1. **Replacement** of the use of animals with alternative models where feasible
2. **Reduction** of the number of individual animals used
3. **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.

This document must be read in conjunctions with all the related documents listed 5.1

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1 Abbreviations/Definitions

1.1 Abbreviations

1.1.1	MRU	Malelane Research Unit
1.1.2	AEC	The Animal Ethics Committee of the Malelane Research Unit
1.1.3	SOP	Standard Operating Procedure of the MRU
1.1.4	PDA	Public Disclosure Act No. 26 of 2000

1.2 Definitions

1.2.1	Management	Test Facility / Site Manager of Malelane Research Unit
1.2.2	Line manager	The next in line manager to whom an employee reports according to the organogram or according to temporary reporting structures over weekends or during studies.
1.2.3	Routine complaint	A complaint handled as per complaint procedures. (See MRU-SOP-ETH-005, Complaints involving the AEC)
1.2.4	Whistleblowing	A way of reporting a complaint that brings the underlying information of the complaint out into the open.
1.2.5	Misconduct	Any action that is contrary to the MSD value of ethics and integrity. This action may be in the sphere of finance, marketing, research, human-resources, animal welfare and ethical integrity.
1.2.6	Prima facie evidence	Information that would lead the normal person to conclude that it presents strong evidence. Deeper investigation may reveal prima facie evidence not to present real evidence.
1.2.7	Ex officio	As a result of one's position held at the institution
1.2.8	Serious Adverse Event	Relates to an unforeseen harmful event related to all study / donor / resident animals (e.g. injury/death due to an experimental / VMP intervention).
1.2.9	Serious Incident	Relates to an unforeseen harmful event unrelated to a study itself (e.g. facility failure/pathogen outbreak) taking into account the effect on study and resident animals (Possibility to draw line at serious injury / death)
1.2.10	Active Monitoring	A visit of an AEC member to the MRU site with the intention to monitor approved procedures or studies.
1.2.11	Oversight	A visit of an AEC member to the MRU site with the intention to inspect animal facilities and animal husbandry.
1.2.12	Minor Amendment	An amendment with no impact on animal welfare or introduces a change that improves the welfare of the animals. Does not change the objectives of the study.

2 Responsibilities

The AEC shall, on behalf of the facility, ensure that all activities relating to the care and use of animals, are conducted in compliance with current standards and guidelines.

2.1 Composition of MRU AEC

New members for Malelane Research Unit Animal Ethics committee are appointed by the Chairperson in consultation with the committee. Factors to consider for appointment to the AEC are experience, expertise (knowledge), and availability to serve on the committee. Before appointment, all members of AEC should acknowledge their acceptance of the Terms of Reference and Code of Conduct of the committee, as well as requirements for the confidentiality required by the facility. Four categories of members are dictated by international and national standards (see 5). In keeping with these requirements, the AEC will consist of at least 9 members (with at least 2 members in each category).

Four categories of member are required:

A: Person with qualifications in veterinary science (Veterinarian). Experience in relevant activities at MRU would be advantageous.

B: Scientists with substantial and recent experience in the use of experimental animals. Preferably such experience should be similar in nature to the research conducted at MRU.



C: A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with MRU, and who is not involved in the care and use of animals for scientific purposes.

D: An independent person who does not currently, and has not previously conducted scientific or teaching activities using animals, and who is not an employee of MRU

Composition of the AEC is described below.

2.1.1 Affiliated members of the AEC

- The Test Facility Manager at MRU (*ex officio*)
- The Site Veterinarian at MRU (*ex officio*)
- Animal Researcher/s at MRU

Depending on the requirements to fulfil the need for two members per category, the three members above shall be appointed in either Category A or Category B (provided also that they meet the requirements of that category).

2.1.2 Non-affiliated members

- Two persons representing animal welfare organisations – Category C
- Two lay persons – Category D
- Additional members as required regardless of category.
- Where appropriate, specialists and other advisers may be appointed *ad hoc* to attend meeting and/or give input. Such members are not eligible to vote.
- Observer members and applicants may be invited to the meetings. Such members are not eligible to vote.



2.1.3 Appointments and resignations are described in 5.1.1.1

2.2 Special positions within the AEC

2.2.1 Persons appointed in these positions will need to declare all conflicts of interest for each proposal, and this will affect the voting process. Where the position is fulfilled by an *ex officio* member this person will not be allowed to vote where there is a conflict of interest. This person will however fulfill all other responsibilities required by the procedures.

2.2.2 Chairperson of the AEC

2.2.2.1 The Chairperson of the AEC is appointed by the Test Facility Management.

2.2.2.2 The Test Facility Management itself may assume the role of the Chairperson (as prescribed by the SANS 10386 guideline), to facilitate easy compliance by the facility. Otherwise, a non-affiliated member of the AEC may be elected to promote independence.

2.2.2.3 The Chairperson is elected for a period of 2 years (with the option to renew).

2.2.3 Deputy Chairperson of the AEC

2.2.3.1 Any member of the AEC may be elected as the Deputy Chairperson. However, it is recommended that should the Chairperson be a non-affiliated member, the Deputy Chairperson should be part of MRU management (and vice versa). This is to facilitate optimal cooperation between the facility and the AEC at the highest levels of the AEC and the facility.

2.2.3.2 The Deputy Chairperson is elected democratically by the members of the AEC for a term of 2 years (with the option to renew).

2.3 Executive committee

The Executive Committee (EXCO) comprises the Chairperson, Deputy Chairperson, Test Facility manager, the Site Veterinarian of MRU and one Category C/D member. If one person fulfils more than one of the four roles defined above, an additional person shall not be appointed to the EXCO provided that the EXCO has at least 4 members of which at least 2 are non-affiliated members. The EXCO may on an *ad hoc* basis invite input from additional members.

The EXCO has been established to streamline the animal ethics process, to increase the efficiency of the AEC and to reduce workload on the AEC, thus allowing additional time for discussion of ethical considerations.

The EXCO deals with urgent matters that arise between routine meetings of the AEC. Minor Amendments may be approved by the EXCO, as the need arises, between routine meetings of the AEC. All decisions of the EXCO must be tabled at the following routine meeting of the AEC.

2.4 Quorum rules

75% of members, which must include a member from each category A, B, C, and D constitute a quorum.

2.5 Absenteeism

Where committee members are not able to attend any committee meeting/commitment, they should notify the Chairperson of their expected absence.

If a committee member is absent for two consecutive meetings without first notifying the Chairperson of their absence, or if a committee member is absent for three consecutive meetings having notified the Chair of their absence, that committee member is in breach of their obligations and is liable for removal from the committee, subject to the decision and endorsement by the Chairperson.



2.6 Terms of office

Animal Ethics Committee members are generally appointed for a period of up to two years (with the option to renew).

2.7 Terms of Reference of the AEC

- To advise its appointing authority (Test Facility Management of MRU), on all matters pertaining to the ethics of research, parasite lifecycle maintenance and teaching involving animals.
- To review and approve, subject to modification, or reject all proposals for research, and parasite lifecycle maintenance involving animals to be carried out within the ambit of MRU, in accordance with current standards and guidelines
- Monitor activities associated with the care, use, housing and management of animals at the facility, including the review of procedures applicable to these functions.
- Provide advice and recommendations to the facility in terms of animal husbandry.
- To confirm that animal users are adequately qualified/trained to perform research activities involving animals.
- To monitor protocol deviations and amendments for ethical impact.
- Take appropriate actions regarding unexpected Adverse Events, Serious Incidents or non-compliance to current guidelines and regulations, to ensure that animal wellbeing is not compromised. The issues are addressed promptly and activities that have potential to adversely affect the wellbeing of the animal cease immediately. Actions may include consulting with the relevant people, and where necessary, suspending or withdrawing approval for the project or activity.
- To attend to any animal welfare issues and alleged unethical treatment of research animals through the mechanisms detailed in the appropriate SOP.
- To report on its operations annually to NHREC (with registration) and this report will be shared with Management at MRU.
- To comply to the Code of Conduct for Ethics

3 Procedures

The Committee meets at least quarterly to examine proposals for research and other matters pertaining to the AEC.

The AEC will provide competent, fair, consistent and timely review of applications and reports related to the care and use of animals

The Committee must communicate to, and require implementation by, MRU via the Test Facility Manager, measures needed to ensure that the current standards and guidelines are implemented and maintained, including facility plans and policies that might affect animal welfare.

The Committee must approve only those studies/projects for which animals are essential, and which conform to the current standards and guidelines, taking into consideration ethical and welfare aspects as well as the scientific and educational value of the proposed research.

The Committee must maintain a register of approved projects.

The Committee receives reports via the Chairperson from the Site Veterinarian and the Researchers at MRU, concerning regular monitoring, inspections and assessment of the acquisition, transport, production, husbandry, care, use and disposal of animals used in research, parasite breeding or



teaching. All of these aspects must be in accordance with current standards and legislation relating to the ethics, welfare and use of animals. The Committee is expected to act on the reports as necessary.

The Committee must receive annual progress reports and a final report for every protocol approved, and these records must be maintained.

The Committee must establish procedures and processes:

- to address conflicts of interest for committee members and researchers
- to address allegations of non-compliance and allegations of research misconduct, and to hear appeals.

4 Confidentiality

Committee business is confidential so as to protect the intellectual property, researchers' interests, and to permit the committee members to speak freely and frankly, as well as to protect the public image of the facility. This policy is affirmed by signing of the confidentiality document during appointment to the committee. Breaches in confidentiality should be raised in the first instance with the Chairperson, and if not addressed to the satisfaction of the complainant, thereafter with Test Facility Management.

5 Related documents

5.1 Internal

- 5.1.1.1 MRU-SOP-ADM-005, Animal Ethics
- 5.1.1.2 MRU-WI-ADM-001, Role of MRU in the Ethics Process
- 5.1.1.3 MRU-WI-AMD-002, Role of the AEC in the Ethics Process
- 5.1.1.4 MRU-SOP-ETH-004, Code of conduct
- 5.1.1.5 MRU-SOP-ETH-005 Complaints
- 5.1.1.6 MRU-SOP-ETH-006, Whistleblower

5.2 References

- 5.2.1 SANS 10386:2021, EDITION 2. STANDARDS SOUTH AFRICA, PRETORIA, 2002 (or the latest edition).
- 5.2.2 ETHICS IN HEALTH RESEARCH: PRINCIPLES, PROCESSES AND STRUCTURES, DEPARTMENT OF HEALTH, 2ND ed. 2015 (or the latest edition).

6 Appendices

None

7 Distribution

No controlled distribution

8 Version History

Version	Effective date	Short description of changes
1.0	01APR2022	NEW. Collates information previously contained in MRU-SOP-ADM-005.