



STANDARD OPERATING PROCEDURE

Title: CODE OF CONDUCT FOR MRU ANIMAL ETHICS COMMITTEE MEMBERS	Page No.	Page 1 of 6
	SOP No.	MRU-SOP-ETH-004
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Approvals			
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Purpose

MRU AEC applies a set of principles, outlined in applicable guidelines, that govern the ethical conduct of people whose work involves the care and use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals, and incorporates the core ethical principles:

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 minimize or eliminate the impact on individual animals in terms of actual or potential pain, suffering, stress, and lasting harm.
4. The knowledge and acceptance of one's **Responsibilities**.

This Code of Conduct serves as a guide to members of the ethics committee to serve the interests of the Facility and that of the public generally, as well as protecting the safety and well-being of the animals used for research.

This Code of Conduct details conduct and integrity expectations of committee members, including regular and punctual attendance at meetings, diligent performance of responsibilities, maintenance of confidentiality, and consideration of potential conflicts of interest.

TABLE OF CONTENTS

1	Abbreviations/Definitions	3
1.1	Abbreviations	3
1.2	Definitions	3
2	Responsibilities.....	3
2.1	All AEC members	3
3	Procedure	3
3.1	Code of conduct	3
4	<i>Ad hoc</i> consultants and observers	5
4.1	General.....	5
5	Related Documents	6



5.1	Internal.....	6
5.2	References	6
6	Appendices	6
7	Distribution	6
8	Version History.....	6

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1 Abbreviations/Definitions

1.1 Abbreviations

1.1.1 MRU	Malelane Research Unit (The Facility)
1.1.2 AEC	The Animal Ethics Committee of the Malelane Research Unit (the committee)
1.1.3 SOP	Standard Operating Procedure of the MRU
1.1.4 GCP	Good Clinical Practice
1.1.5 GLP	Good Laboratory Practice

1.2 Definitions

1.2.1 Management	The Test Facility Manager as it pertains to GLP and the Site Manager as it pertains to GCP
1.2.2 Active Monitoring	A visit of an AEC member/person nominated by the AEC, with the intention to monitor approved proposal procedures. May include visual material for example photographs or videos.
1.2.3 Passive Monitoring	All the ethical review of data/documents/reports presented to the AEC in any format.
1.2.4 Oversight	A visit of an AEC member/person nominated by the AEC, to the Facility or off-site location, with the intention to inspect animal facilities and animal husbandry. May include visual material for example photographs or videos.
1.2.5 The Committee	Refers to the Animal Ethics Committee at Malelane Research Unit
1.2.6 The Facility	Malelane Research Unit
1.2.7 <i>Ad hoc</i> member	Member invited to meetings to provide specific feedback/insight but are not eligible to cast votes regarding AEC matters or proposal applications
1.2.8 Research	Refers to all activities that involve the experimental use of animals, including studies/projects.
1.2.9 Projects	Refers to all activities that involve the use of animals for other purposes than studies, such as teaching, parasite breeding etc.
1.2.10 Researcher	Person recognized by the AEC as competent (including qualification, training, experience, and practical skills) to conduct research involving animals.
1.2.11 Proposal Application	Study/Project/Major Amendment that requires ethical approval before commencement of any activities and is done via formal written application to the AEC.
1.2.12 Teaching Activity	Activity that involves animals and is performed to acquire, develop or demonstrate knowledge or techniques in any scientific discipline, including studies for the purposes of teaching and training in primary, secondary and tertiary institutions.
1.2.13 Member	Person appointed to the AEC

2 Responsibilities

2.1 All AEC members

- 2.1.1 All committee members have a fiduciary responsibility to serve the interests of the Facility (MRU) and that of the public generally. All decisions are to be made solely based on a desire to promote the best interests of the Facility and the public and, in the case of research ethics-related matters, the interests of the Researchers must be protected. The committee must endeavour to protect the best interests and welfare of all animals used in research, including the resident animals at the Facility, as well as consideration for the protection of the environment and people safety.
- 2.1.2 Details of AEC responsibilities, are outlined in the Terms of Reference MRU-SOP-ETH-001

3 Procedure

3.1 Code of conduct

- 3.1.1 Upon appointment to Malelane Research Unit Animal Ethics Committee, all committee members must commit to the set-out Code of Conduct and sign the applicable section

in the Appointment letter MRU-SOP-ADM-005F03. When the Code of Conduct is revised, all members will be required to complete the appropriate section on the Appointment letter subsequently to acceptance of the Code of Conduct.

3.1.2 Integrity

- 3.1.2.1 Must act in good faith and in the best interests of the Facility, without compromising the welfare of the animals used in research.
- 3.1.2.2 Set the tone for an ethical organizational culture
- 3.1.2.3 The primary responsibility of the AEC should ensure, on behalf of the Facility, that all activities relating to the care and use of animals are conducted in compliance with applicable guidelines and standards (SANS 10386).
- 3.1.2.4 Must refuse bribes for the benefit of any party involved in research.
- 3.1.2.5 All members should fulfil their responsibilities with integrity and respect towards all parties involved and not abuse their authority.

3.1.3 Competence

- 3.1.3.1 Should take steps to ensure that they have sufficient working knowledge of the Facility and context in which it operates as precondition to fulfil their responsibilities. This is achieved by regular Facility oversight and active/passive monitoring of research conducted. Further insight to Facility is gained by reviewing of standard procedures pertaining to animal care, use and welfare.
- 3.1.3.2 Must act with due care, diligence and take reasonable diligent steps to become informed about matters and decisions. This is achieved by timeous responses to email communications, preparing for meetings, reviewing of material shared with committee and attending meetings regularly.
- 3.1.3.3 Continuously develop their competence to participate in all matters effectively. Reference documentation is provided to all members by the Facility to assist with self-development and training for effective membership in the committee. Regular training is provided by the Facility to develop members. Basic training requirements for AEC members are outlined in the Terms of Reference, MRU-SOP-ETH-001.

3.1.4 Responsibilities

- 3.1.4.1 Attend meetings punctually and in person on a regular basis and, as far as possible, to remain until the meeting is adjourned.
- 3.1.4.2 Devote sufficient time and attention to prepare for meetings or other matters pertaining to the committee
- 3.1.4.3 Review all matters independently, impartially, and objectively
- 3.1.4.4 Serve as a main reviewer in his/her area of expertise.
- 3.1.4.5 Serve as a general reviewer of all matters discussed at committee meetings.
- 3.1.4.6 Keep up to date with research ethics and regulatory guidance.
- 3.1.4.7 Contribute to ethics-related continuing education.
- 3.1.4.8 Ensure that applications involving the use of animals, undergo rigorous scientific and ethical review processes
- 3.1.4.9 Ensure appropriate monitoring of approved studies/projects.

3.1.5 Conflict of interest

- 3.1.5.1 Each member must declare all perceived or actual conflicts of interest involving matters pertaining to the AEC, including proposal applications. Members with a conflict of interest should remove themselves from the AEC's decision making on matters that relate to the conflict of interest.
- 3.1.5.2 Conflicting interests include but is not limited to any personal involvement or participation in the research or in competing research, and, in the event of such a conflict with respect to a proposal application, not to review the application, and to recuse him/herself during the discussion and decision-making process.

3.1.6 Confidentiality

- 3.1.6.1 AEC matters are confidential, 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. All members must commit to this policy which is affirmed by signing of the confidentiality document during appointment to the committee.
- 3.1.6.2 Confidential documentation shared with members must be treated as such, and may be brought to the Facility for destruction if no longer required.

3.1.7 Disciplinary actions

- 3.1.7.1 Disciplinary actions may be taken against members that repeatedly or intentionally fail to follow the Code of Conduct. These disciplinary actions will vary depending on the violation.
- 3.1.7.2 Disciplinary proceedings will at a minimum, involve Management, Chairperson of the AEC, and the member in question. Possible consequences include:
- Reprimand
 - Suspension
 - Termination of membership for more serious offenses
 - Legal action in cases of unlawful behaviour.

3.2 **Ad hoc consultants and observers**

3.2.1 General

- 3.2.1.1 Ad hoc consultants/reviewers might from time to time be called upon to assist with application reviews or other matters pertaining to the AEC. The obligation to maintain confidentiality, where necessary according to company guidelines, should be made known to these reviewers and confidentiality agreements put in place. This Code of Conduct will apply to such members. Other animal ethics committees or authorities may be consulted to assist with reviews or other matters pertaining to the AEC.
- 3.2.1.2 Observers or guests may attend committee meetings at the Chairperson's discretion or invitation. Such persons have an interest in research ethics and the review process but are not committee members. Observers and guests must maintain confidentiality, where necessary according to company guidelines, regarding the business of the committee. Confidentiality agreements will be in place for observers/guests.

3.2.1.3 All persons attending AEC meetings, are free to make observations, ask questions but only AEC members may vote on decisions. Anyone without a vote, who disagrees with the resolution of the issues, under discussion and/or the outcome of the vote, should take the matter up with the Chairperson of the AEC in the first instance. The Chairperson may call a special meeting to discuss the substance of the disagreement, or to debate more fully issues raised in this way.

4 Related Documents

4.1 Internal

- 4.1.1.1 MRU-SOP-ADM-005, Animal Ethics
- 4.1.1.2 MRU-SOP-ETH-002, Role of MRU in the Ethics Process
- 4.1.1.3 MRU- SOP- ETH-003, Role of the AEC in the Ethics Process
- 4.1.1.4 MRU-SOP-ETH-001, Terms of Reference
- 4.1.1.5 MRU-SOP-ETH-005 Complaints involving the AEC and animal research
- 4.1.1.6 MRU-SOP-ETH-006, Whistle-blower

4.2 References

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

5 Appendices

None

6 Distribution

Refer to MRU-SOP-QA-02-F01 for distribution details of SOPs. This SOP is available on the public platform for MRUAEC marked as an uncontrolled copy. (<https://www.msd-animal-health.co.za/malelane-research-unit-ethics-documentation>)

7 Version History

Version	Effective date	Short description of changes
1.0	01APR2022	NEW. Collates information previously contained in MRU-SOP-ADM-005.
		Incorporate minor comments from MRU AEC at last endorsement cycle. Update related documents section. Elaborate on the integrity and competence of AEC members. Added section on Disciplinary actions
2.0	14AUG2023	Include acceptance of the Code of Conduct by signing the appropriate section in MRU-AOP-ADM-005F03.