
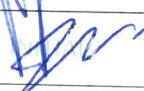




STANDARD OPERATING PROCEDURE

Title: Complaints involving the AEC and animal research		Page No.	Page 1 of 6
		SOP No.	MRU-SOP-ETH-005
Scope: Malelane Research Unit ETHICS		Version No.	02
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Approvals			
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Purpose

This SOP defines the avenues to handle complaints with regards to animal ethics by members of the AEC, the personnel at the Facility, and the owners of animals provided for research purposes, as well as complaints against the conduct of the AEC.

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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 (MRUAEC)
1.1.3	SOP	Standard Operating Procedure of the MRU
1.1.4	NHREC	National Health Research Ethics Committee

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	Researcher	Person recognized by the AEC as competent (including qualification, training, experience, and practical skills) to conduct research involving animals (including studies and projects).
1.2.4	Non-affiliated Researcher	Researcher not in the employ of Malelane Research Unit but complies to all the requirements of a Researcher.
1.2.5	Site/Study Veterinarian	Veterinarian responsible for the health and welfare of all animals at the Facility or animals in a study.
1.2.6	Research	Refers to all activities that involve the experimental use of animals, including studies/projects.
1.2.7	Animal owner	Gives consent for owned animals to be used for research purposes
1.2.8	MSD Global Ethics Office	Established to protect and promote the company's values and standards on a global basis by developing and overseeing initiatives designed to deter illegal, unethical, and improper behaviour related to the company's business.
1.2.9	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.
1.2.10	Committee	Refers to the Malelane Research Unit Animal Ethics Committee
1.2.11	Member	Person appointed to MRUAEC

2 Responsibilities

2.1 Management

- 2.1.1 Ensures that all involved parties are aware of the avenues available to them to lodge complaints involving the AEC or research activities conducted on behalf of the Facility. Involved parties include Researchers/Non-affiliated Researchers, personnel at MRU, animal owners, and the AEC.
- 2.1.2 Facilitates resolution of complaints lodged by any of the above-mentioned parties to the best of its abilities and liaises with the Chairperson regarding these matters, if indicated.
- 2.1.3 Ensures that Researchers/Non-affiliated Researchers inform all owners of animals to be purposed for research, of the avenues available to lodge complaints/concerns.

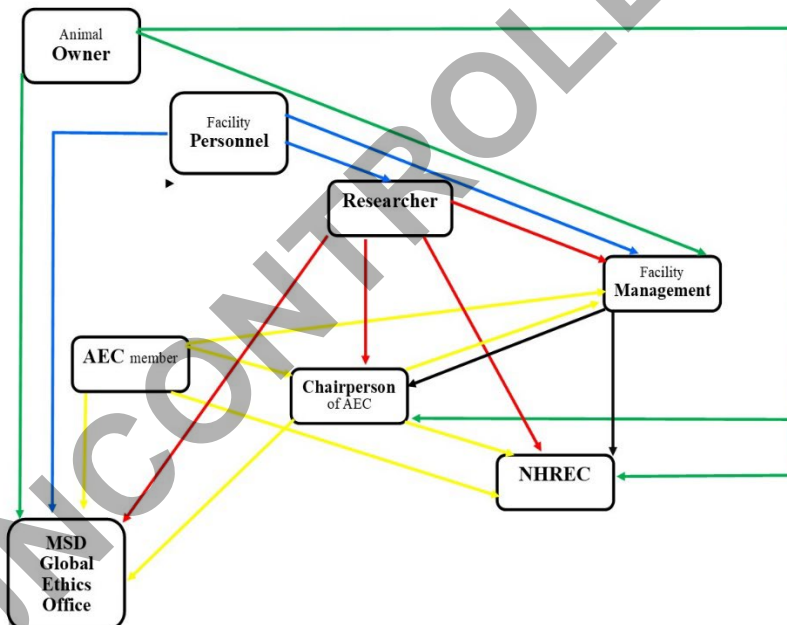
2.2 Chairperson of the AEC

- 2.2.1 Facilitates the resolution of all complaints addressed to the Chairperson of the AEC directly, or the AEC in general. Ensures all members of the committee are aware of the avenues available to them to lodge complaints. Re-direct any unresolved complaints or conflicts to Management, or to the National Health Research Ethics Committee.

3 Procedure

3.1 General

- 3.1.1 Complaints about AEC-related matters should be directed through internal channels in the first instance such as to the AEC Chairperson, or it may be escalated to Facility Management, and ultimately to external channels such as the NHREC.
- 3.1.2 The NHREC is empowered to adjudicate complaints about animal ethics committees and to hear a complaint from any Researcher, who believes that he has been discriminated against unfairly by an animal ethics committee.
- 3.1.3 A framework for the management of complaints and ethics related health research misconduct, has been developed by the Complaints and Advisory Disciplinary Committee (CADC) of the NHREC (<http://nhrec.org.za>).
- 3.1.4 MSD company has a Global Ethics Office, where complaints pertaining to misconduct may be lodged as an external channel if required: officeofethics@merck.com
- 3.1.5 Any complaints received will be noted on the minutes of the AEC meeting at the appropriate section and a complaints register is available in MRU-SOP-ADM-006 for completion.
- 3.1.6 Diagram below illustrates the avenues available for lodging complaints by the relevant parties:



3.2 Complaints by animal owners

- 3.2.1 Should the owner feel that he/she was misled about the fate of the animals purposed for research or any other concern/complaint about the animals' welfare, a complaint can be lodged with the AEC Chairperson or Management. Relevant information of communication avenues is available on the informed consent form, MRU- SOP- TS-001. The Chairperson's email is shared with the relevant consent.
- 3.2.2 Should an owner of animals purposed for research off-site, the owner must be assisted by Management or the Chairperson of the AEC to address the concerns or complaints appropriately.
- 3.2.2.1 Should the animal owner feel that their complaint was not handled appropriately, a complaint may be lodged using external channels such as The National Health Research Ethics Committee: nhrec@health.gov.za or alternatively with the MSD Global Ethics Office: officeofethics@merck.com

3.3 Complaints by personnel of MRU

3.3.1 Researchers

- 3.3.1.1 Where any Researcher is of the opinion that a member of the AEC was guilty of unprofessional conduct, or made unreasonable requests/decisions, a complaint should be lodged following internal channels firstly with the Chairperson of the AEC, or directly with Management. Complaints will be investigated by Management and/or Chairperson, discussed and resolutions will be sought. If the Researcher is of the opinion that the resolution is unsatisfactory, a complaint may be lodged using an external channel such as the National Health Research Ethics Committee: nhrec@health.gov.za.

3.3.2 Other personnel at MRU

- 3.3.2.1 Where any personnel at the Facility is of the opinion that a member of the AEC was guilty of unprofessional conduct or made unreasonable requests, a complaint may be made directly with Management. Management will investigate the complaint and liaise with the Chairperson if further discussion/investigation is warranted.
- 3.3.2.2 Avenues are available to all personnel to lodge complaints or blow the whistle (to speak up) on practices that are unethical or have questionable integrity in the sphere of animal welfare and ethics (refer to MRU-SOP-ETH-006, Whistleblowing).
- 3.3.2.3 Animal welfare/research complaints or concerns may also be directly brought to the attention of the Facility Manager/Site Veterinarian/Study veterinarian/Researcher and subsequently escalated to Management. Refer to MRU MRU-SOP-ORG-002, Organizational structure and authorization procedure for Facility reporting structures. Management will conduct the appropriate investigation into the complaint. Should Management feel the complaint has merit, the complaint will be directed to the Chairperson of the AEC for further discussion, investigation, and resolution.
- 3.3.2.4 A further external channel such as the Global Ethics Office of MSD is available to report misconduct officeofethics@merck.com

3.4 Complaints by members of the AEC

- 3.4.1 Where members of the AEC feel aggrieved or have complaints of non-compliance against the Facility or Researcher, they can lodge a complaint. Depending on the nature of the complaint, the AEC member can use one of several channels:
- 3.4.1.1 The Chairperson of the AEC
 - 3.4.1.2 The global ethics office of MSD: officeofethics@merck.com
 - 3.4.1.3 Management of MRU.
- 3.4.2 When complaints involve immediate animal welfare such as projects/studies that are non-compliant with the approval conditions the AEC shall ensure that
- 3.4.2.1 Action is taken to ensure animal well-being is not compromised by addressing the issue promptly and that the activities, that have the potential to adversely affect the animal wellbeing, cease immediately. Actions may include suspending or withdrawing approval for the project/study. All complaints of non-compliance must be followed up appropriately.
- 3.4.3 Should the AEC member feel that the complaint was not handled appropriately, a complaint can be lodged The National Health Research Ethics Committee: nhrec@health.gov.za

3.5 Complaints by the Facility

- 3.5.1 The Facility may lodge complaints against members of the AEC, or the committee. These complaints might be due to non-compliance of the AEC or members to the standard procedures or responsibilities of the AEC. Such complaints will be firstly directed to the Chairperson of the AEC and subsequently may be escalated to the NHREC.

3.6 Empowerment

- 3.6.1 All Researchers, personnel at MRU and AEC members will have access to this procedure to give clear guidelines for lodging complaints
- 3.6.2 The AEC shall have the details of the avenues for ethical complaints printed on the agenda and minutes of every routine meeting.
- 3.6.3 Animal owners that provide animals for research purposes, sign an informed consent detailing avenues to follow to lodge complaints.

3.7 Whistleblowing

- 3.7.1 The nature of some complaints may be better suited for Whistleblowing, MRU-SOP-ETH-006

4 Related Documents

4.1 Internal

- 4.1.1 SOPs/Policies/Guidelines/Manuals
- 4.1.1.1 MRU-SOP-TS-001, Informed consent
 - 4.1.1.2 MRU-SOP-ETH-006, Whistleblowing
 - 4.1.1.3 MRU-SOP-ADM-005, Animal Ethics
 - 4.1.1.4 MRU-SOP-ADM-006, Complaints.
 - 4.1.1.5 Corporate Policy 05: Prevention of Bribery and Corruption
 - 4.1.1.6 Corporate Policy 09: Financial Integrity



4.1.1.7 Corporate Policy 10: Conflicts of Prevention of Bribery and Corruption

4.1.1.8 Corporate Policy 15: Reporting and Responding to Misconduct

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 as a watermarked uncontrolled copy.

7 Version History

Version	Effective date	Short description of changes
1.0	1 Apr 2022	NEW. Separated ethical complaints from the general complaints SOP (MRU-SOP-ADM-006). Updated the reference to SANS 10386. Added complaints by animal owners.
2.0	14AUG2023	Include complaint avenues for owners of animals purposed for research. Diagram included to facilitate the understanding of different avenues available to which relevant parties.