





STANDARD OPERATING PROCEDURE

Title:	Complaints involving the AEC	Page No.	Page 1 of 4
		SOP No.	MRU-SOP-ETH-005
Scope: Malelane Research Unit ETHICS		Version No.	01
		Supersedes	NEW
		Effective	01APR2022

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 employees of MRU and the owners of animals provided for research purposes.

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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 |

1.2 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 | Misconduct | Any action that is contrary to the MSD value of ethics and integrity. For the purpose of this SOP the sphere of such misconduct is restricted to matters involving animal welfare and/or research ethics. |

2 Responsibilities

2.1 Management

Ensures that all involved parties are aware of the avenues available to them to lodge complaints.
Facilitates complaints lodged by MRU personnel.

2.2 Chairperson of the AEC

Facilitates all complaints addressed to the Chairperson of the AEC directly or the AEC in general.

3 Procedure

3.1 Complaints by animal owners

- 3.1.1 Should the owner feel that he/she was misled about the fate of the animals, a complaint can be lodged with the AEC chairperson.
- 3.1.2 Should the animal owner feel that their complaint was not handled appropriately, a complaint can be lodged The National Health Research Ethics Committee: nhrec@health.gov.za

3.2 Complaints by employees of MRU

- 3.2.1 Where personnel feel that a member of the AEC was guilty of unprofessional conduct or made unreasonable requests, a complaint can be lodged with Management.
- 3.2.1.1 Avenues are available to all employees or contracted personnel to 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, Whistle-blowing)
- 3.2.2 Should management feel the complaint of the employee has merit, the complaint can be forwarded to the chairperson of the AEC.

3.3 Complaints by members of the AEC

- 3.3.1 Where members of the AEC feel aggrieved, they can lodge a complaint. Depending on the nature of the complaint the AEC member can use one of several avenues:
- The Chairperson of the AEC
 - The global ethics office of MSD: officeofethics@merck.com
 - Management of MRU.

3.3.2 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

3.4 Empowerment

3.4.1 The AEC shall have the details of the avenues for ethical complaints printed on the agenda and minutes of every routine meeting.

3.4.2 Animal owners that provide animals for research purposes sign an informed consent. The informed consent form shall contain the contact details of the AEC to enable lodging of a complaint. See 4.1.1.1

3.5 Whistle-blowing

3.5.1 The nature of some complaints may be better suited for whistleblowing. See 4.1.1.2

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, Whistle-blowing

4.1.1.3 MRU-SOP-ADM-005, Animal Ethics

4.2 References

4.2.1 SANS 10386:2008, 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

No controlled

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.