



STANDARD OPERATING PROCEDURE

Title:	Whistleblowing	Page No.	Page 1 of 5
		SOP No.	MRU-SOP-ETH-006
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Scope: Malelane Research Unit ETHICS		Supersedes	New
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Approvals			
Owner:	<i>E. York</i>	<i>[Signature]</i>	<i>07 Aug 2023</i>
Approver:	<i>J. Kotze</i>	<i>[Signature]</i>	<i>7 Aug 2023</i>

Purpose

The Malelane Research Unit (MRU) is committed to live by the values and standards of MSD. One of the 4 values is "ethics and integrity".

This SOP defines the avenues available to all Facility personnel as well as the Malelane Research Unit Animal Ethics Committee, to blow the whistle (to speak up) on practices that are unethical or have questionable integrity in the sphere of animal welfare and ethics, when the routine avenues of complaints do not suffice using internal and external channels.

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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
1.1.3 SOP	Standard Operating Procedure of the MRU
1.1.4 PDA	Public Disclosure Act No. 26 of 2000
1.1.5 NHREC	National Health Research Ethics Council
1.1.6 SAVC	South African Veterinary Council

1.2 Definitions

1.2.1 Management	Test Facility / Site Manager of Malelane Research Unit
1.2.2 Chairperson	Chairperson of MRU AEC
1.2.3 Facility	Malelane Research Unit
1.2.4 The Company	MSD
1.2.5 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.
1.2.6 Routine complaint	A complaint handled as per complaint procedures. MRU- SOP- ETH- 005
1.2.7 Whistleblowing	Complaints involving the AEC and in Research Involving Animals A way of reporting a complaint that brings to light information about activities within an organization that is deemed unethical, illegal, immoral, illicit, unsafe or fraudulent by using internal or external channels available to the whistleblower.
1.2.8 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.
1.2.9 <i>Prima facie</i> 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. (Means that there might initially be enough evidence based on basic facts, but it may be refuted after investigation of all the facts.)
1.2.10 MRU personnel	Employees and contracted staff members
1.2.11 Animal owner	Gives consent for owned animals to be used for research purposes
1.2.12 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.
1.2.13 Committee/member	Committee as it pertains to the AEC and the members

2 Responsibilities

2.1 Management

- 2.1.1 Directs practices that promote animal welfare, ethics, and integrity as part of the MSD's Code of Conduct and Compliance. Ensures that all personnel are aware of channels to report misconduct both internally at the Facility as well as externally. Ensures the protection of whistleblowers by maintaining confidentiality.

2.2 Line Managers

- 2.2.1 Be available to receive complaints. Escalate or address, in the appropriate manner, the complaints brought before them and maintaining confidentiality if appropriate.

2.3 All personnel at MRU, animal owners and the AEC

- 2.3.1 Report any action that might be considered as misconduct by lodging a formal complaint as described in MRU- SOP- ETH- 005 or by using external channels such as reporting to the Global ethics office or the NHREC if deemed more appropriate.



3 Procedure

3.1 Appropriateness of blowing the whistle

- 3.1.1 Before choosing to blow the whistle, all Facility personnel and AEC members should preferably report any misconduct as per site procedure for complaints using internal channels as far as possible. Internal channels relate to appropriate Facility reporting or AEC channels. Should internal channels not suffice, external channels may be pursued by reporting to the NHREC, SAVC or MSD Global Ethics Office.
- 3.1.2 Several situations may arise where an individual may feel that whistleblowing is a more appropriate action to pursue rather than routine complaints. Some examples are mentioned below:
- 3.1.2.1 Where the nature of the complaint involves alleged misconduct of the people that would receive a routine complaint.
- 3.1.2.2 Where the misconduct involves a corrupt system (as opposed to an individual).
- 3.1.2.3 Where threats are made about the sharing of information relating to misconduct.
- 3.1.2.4 Where the AEC feels that the veterinary care provided by the Site Veterinarian constitutes negligence.
- 3.1.2.5 Where Management attempts cover-ups to hide misconduct.
- 3.1.3 A whistleblower should have *prima facie* evidence of misconduct before blowing the whistle.

3.2 The act of blowing the whistle

- 3.2.1 Ultimately whistle-blowing disclosures shall be made to either Management, the Chairperson of the AEC, the MSD global office of ethics, or the NHREC. The choice of who to report to, is for the discretion of the whistle blower, and may be impacted by the nature of the alleged misconduct.
- 3.2.2 All MRU employees, contractors and AEC members are bound by confidentiality agreements signed on appointment. Such agreements have the primary purpose to protect intellectual property of MSD. In addition, it also aims to prevent the sharing of information regarding research procedures that has the potential to be construed as unethical when viewed without the proper context. For this reason, whistle-blowing disclosures in terms of animal ethics shall only be made to identified parties in 3.2.1.
- 3.2.3 Occasionally whistle-blowing may be appropriate to other external entities such as the South African Veterinary Council with regards to misconduct of veterinary professionals.
- 3.2.4 The whistleblower may disclose information through any communication means that he/she is comfortable with.
- 3.2.5 If the whistle-blower chooses to disclose information by e-mail, the following e-mail addresses are provided:
- The Chairperson of the MRU AEC: tessadrew@yahoo.co.uk
 - The National Health Research Ethics Committee: nhrec@health.gov.za
 - The Global Ethics Office of MSD: officeofethics@merck.com
 - The South African Veterinary Council: complaints@savc.org.za
- 3.2.6 Whistle-blowers enjoy the full protection afforded by the Public Disclosure Act No. 25 of 2000.
- 3.2.7 Notwithstanding 3.2.6, whistle-blowers may choose to make disclosures anonymously.



3.3 Empowerment

- 3.3.1 Management shall inform all personnel of the avenues available to them to make complaints. This shall be done through posters and training. The posters shall include the various contact details of all the different avenues mentioned in 3.2.
- 3.3.2 The AEC shall have the details of the avenues for ethical complaints printed on the agenda and minutes of every routine meeting.
- 3.3.3 All contracted personnel (permanent or semi-permanent) shall be made aware of the avenues available to them through a training session.
- 3.3.4 All Facility employees shall complete the training scheduled by the MSD Compliance and Ethics offices through the MyLearning platform. Periodic refreshers will be required as determined by the global team. Topics shall include but not be limited to ethics, anti-bribery, speaking-up and the code of conduct.

4 Related Documents

4.1 Internal

4.1.1 SOPs/Policies/Guidelines/Manuals

- 4.1.1.1 Corporate Policy 05: Prevention of Bribery and Corruption
- 4.1.1.2 Corporate Policy 09: Financial Integrity
- 4.1.1.3 Corporate Policy 10: Conflicts of Prevention of Bribery and Corruption
- 4.1.1.4 Corporate Policy 15: Reporting and Responding to Misconduct
- 4.1.1.5 MRU-SOP-ETH-005 Complaints involving the AEC and in Research Involving Animals
- 4.1.1.6 MRU-SOP-ADM-005 Animal Ethics
- 4.1.1.7 MRU-SOP-ADM-006, Complaints
- 4.1.1.8 MRU-SOP-ORG-002, Organizational structure and authorization procedure

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	1 Apr 2022	NEW. Replaces the joint SOP for complaints and whistle-blowing on all matters MRU-SOP-ADM-006.
2.0	14JUG2023	Minor grammatical changes as suggested by MRU AEC. Include the procedure for organizational structure at MRU in reference section Better definition for whistleblowing and the internal and external channels available. Correct the reference in the footer of the document

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