



## STANDARD OPERATING PROCEDURE

Title:	<b>Whistle-blowing</b>	Page No.	Page 1 of 4
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Approvals			
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### Purpose and scope

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 employees or contracted personnel (included the 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. In addition, the SOP ensures the protection of whistleblowers.

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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 4.1.1.5).
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. (Means that there might initially be enough evidence based on basic facts, but it may be refuted after investigation of all the facts.)

## 2 Responsibilities

### 2.1 Management

Direct practices that promote animal welfare and ethics. Ensure that personnel are trained on corporate policies. Ensure that all staff are aware of avenues to report misconduct, actions with questionable integrity or ethical concerns.

Ensures the protection of whistle-blowers.

### 2.2 Line managers

Be available to receive complaints. Escalate or address as appropriate the complaints put before them.

### 2.3 All personnel and contracted staff

Report any action that might be classified as misconduct.

## 3 Procedure

### 3.1 Appropriateness of blowing the whistle

3.1.1 Before choosing to blow the whistle, all personnel (contracted or otherwise) should preferably handle complaints as per site procedure for complaints. (See 4.1.1.5).

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:

- Where the nature of the complaint involves alleged misconduct of the people that would receive a routine complaint.
- Where the misconduct involves a corrupt system (as opposed to an individual).
- Where threats are made about the sharing of information relating to misconduct.

- 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 Whistle blowing disclosures shall be made to either 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 whistleblower 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 one of the 3 identified parties in 3.2.1.
- 3.2.3 The whistle blower can disclose information through any communication means that he/she is comfortable with.
- 3.2.4 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
- 3.2.5 Whistle-blowers enjoy the full protection afforded by the Public Disclosure Act No. 25 of 2000.
- 3.2.6 Notwithstanding 3.2.5, 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 avenue 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 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

4.1.1.6 MRU-SOP-ADM-005 Animal Ethics

4.1.2 Forms/Templates

4.1.2.1 Complaint register.

## 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, 2<sup>ND</sup> ed. 2015 (or the latest edition).

## 5 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.