



# WHISTLE BLOWER SOP, OCTOBER 2023, V1

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Research Ethics  
Committee



Final Version	Reason for Amendment	Effective Date
1	Developed and published for implementation	October 2023
	Administrative changes	March 2024

# REPORT FORM FOR RAISING A COMPLAINT.

## 1. INTRODUCTION

SAMAREC has developed a report form to allow individuals involved in research, such as researchers, participants, or even observers, to report any ethical violations, misconduct, or concerns related to the research. Whistleblower mechanisms help safeguard the rights and well-being of research participants by allowing them to report any mistreatment, breaches of confidentiality, or other issues that may arise during the research process.

## 2. PURPOSE OF THE SOP

This SOP provides guidelines for the management of three types of complaints:

- 2.1 Complaints from Researchers about the conduct of a member of an SAMAREC, meeting procedures, application management and reviewer reports.
- 2.2 Complaints from a member of SAMAREC about a researcher or a member of a research team, meeting procedures or application management.
- 2.3 Complaints received from a research participant, co-researcher, a member of a research team, or an interested community member or public member about research conduct and the researcher or a member of the research team.

During the investigation of a complaint, SAMAREC shall be guided by the following principles:

- Fairness
- Confidentiality
- Human dignity
- Honesty/Integrity

## 3. SCOPE

- 3.1 The scope of this SOP covers establishing the procedure to follow for managing complaints. The document also covers the responsibilities and procedures for the complaint process. Notwithstanding this complaint procedure, all RECs registered at the National Health Research Ethics Council will comply with National Regulations.
- 3.2 All SAMAREC members, researchers, research ethics administrators should know the procedures for dealing with complaints.
- 3.3 The chair of the SAMAREC retains the right to suspend or terminate a research study that violates the SAMAREC ToR or National Regulations.

## 4. RESPONSIBILITIES

THE SAMA governance department within SAMA plays a crucial role in overseeing and managing various aspects of corporate governance, compliance, and ethics. When it comes to whistleblowing, the SAMA governance



department has several important responsibilities to ensure that whistleblowers are protected, ethical concerns are addressed, and the organization operates in a transparent and responsible manner.

**Whistleblower Protection:** The governance department should work to establish a culture that protects whistleblowers from retaliation or adverse actions. This includes ensuring that individuals who report concerns are not subjected to any form of discrimination or harassment.

**Receiving and Managing Reports:** The governance department typically serves as the central point for receiving whistleblower reports.

**Investigation Oversight:** The governance department may play a role in overseeing the investigation of whistleblowing reports. They ensure that investigations are conducted impartially and in accordance with established procedures.

**Follow-Up and Resolution:** The governance department is responsible for tracking the progress of investigations and ensuring that reported concerns are appropriately addressed and resolved.

**Data and Reporting:** Responsible for maintaining records of whistleblower reports, investigations, and outcomes. This information can be used to identify trends, assess the effectiveness of the whistleblowing program, and report to the organization's leadership or relevant authorities as required by law.

**Compliance with Regulations:** The governance department must stay informed about relevant laws and regulations related to whistleblowing and ensure that the committee complies with them. This includes adhering to reporting requirements and protecting the rights of whistleblowers.

**Continuous Improvement:** The governance department should regularly review and assess the effectiveness of the whistleblowing program and make improvements, as necessary. This might involve soliciting feedback from whistleblowers and others involved in the process.

**Legal Counsel:** The governance department may work closely with the organization's legal team to ensure that whistleblowing policies and procedures comply with applicable laws and regulations.

Overall, the governance department is responsible for creating and maintaining a robust and transparent whistleblowing program that encourages all parties involved with SAMAREC and stakeholders to report ethical concerns without fear of reprisal and ensures that those concerns are appropriately addressed

## 5. PROCEDURES

Whistleblowing procedures are designed to provide a structured and transparent process for individuals to report ethical concerns, misconduct, or wrongdoing within an organization while protecting their identity and ensuring a fair investigation.

Whistleblowers should provide a clear and detailed account of the ethical concern or wrongdoing, including names of individuals involved, dates, times, locations, and any supporting evidence or documents.



SAMA and SAMAREC are committed to protecting the identity of the whistleblower. However, in non-anonymous reporting, the whistleblower's identity may be known to those conducting the investigation but should still be treated confidentially.

Upon receiving the whistleblower report, the governance department will acknowledge the receipt of the report and provide the whistleblower with a unique reference number or code for future communication.

The SAMA governance department will conduct an initial assessment of the report to determine its credibility and seriousness. This may involve gathering additional information or evidence.

If the initial assessment indicates that the report warrants further investigation, a formal investigation is launched. This investigation should be impartial, objective, and conducted by individuals who are not directly implicated in the alleged wrongdoing.

Throughout the process, SAMA governance department will maintain open communication with the whistleblower, providing updates on the status of the investigation and any relevant findings. In cases of anonymous reporting, this communication may be challenging but should still be managed using the reference number provided.

If the investigation reveals wrongdoing, SAMA will take appropriate corrective actions. This may involve disciplinary measures, policy changes, or other remedial actions to address the issue.

A final report summarizing the investigation's findings, actions taken, and any recommended changes to prevent similar issues will be prepared.

Whistleblowers will be protected against retaliation or adverse actions taken against them because of their report. Legal protections may also be in place depending on the jurisdiction.

If the whistleblower believes that SAMA has not adequately addressed the concern or that their identity has been compromised, they may have the option to escalate the matter to external authorities, regulatory bodies, or legal entities.



# ANNEXURE A:

## COMPLAINT/REPORT FORM:

Please provide the following details for any suspected serious misconduct or any breach or suspected breach of law or regulation that may adversely impact patient or participant safety.

REPORTER'S CONTACT INFORMATION (This section may be left blank if the reporter wishes to remain anonymous)	
Name	
Designation	
Company	
Contact Number	
Email Address	
SUSPECT'S/EVENT INFORMATION	
Name	
Designation	
Company	
Contact Number	
Email Address	
WITNESSES'S INFORMATION (if any)	
Name	
Designation	
Company	
Contact Number	
Email Address	
<p><b>COMPLAINT:</b> Briefly describe the misconduct / improper activity and how you know about it. Specify what, who, when where and how. If there is more than one allegation, number each allegation and use as many pages as necessary.</p>	
1. What misconduct / improper activity occurred?	
2. Who committed the misconduct / improper activity?	
3. When did it happen and when did you notice it?	
4. Where did it happen?	



5. Is there any evidence that you could provide us?
6. Are there any other parties involved other than the suspect stated above?
7. Do you have any other details or information which would assist us in the investigation?
8. Any other comments?
Date:
Signature:
<ul style="list-style-type: none"><li>• Please submit the complaint to <a href="mailto:samarec@samedical.org">samarec@samedical.org</a></li><li>• Should the complaint be against the SAMA Research Ethics Committee please submit the complaint to <a href="mailto:governance@samedical.org">governance@samedical.org</a></li></ul>

Approved by:

A handwritten signature in black ink, appearing to read "Naidoo", enclosed within a hand-drawn oval.

Dr N Naidoo SAMAREC Chairperson

Date Signed: 23 Aug 2024

A handwritten signature in black ink, appearing to read "M Nodikida", written in a cursive style.

Dr M Nodikida SAMA CEO

Date Signed: 10 October 2024