



health

MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

A horizontal banner image showing a sunset over a field with a large tree in the foreground.

MPUMALANGA PROVINCIAL HEALTH RESEARCH ETHICS COMMITTEE (MPHREC) STANDARD OPERATING PROCEDURE (SOP) FOR COMPLAINTS MANAGEMENT

REF: SOP/01/06/2024: RESEARCH

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Abbreviations

Abbreviation/Definition	Description
1. COMPLAINT	Refers to any action of MPHREC, an MPHREC member, researcher, co-researcher, research assistant, research participant, or interested community member about dissatisfaction with research-related activities which they wish to take forward formally.
2. MPHREC	Mpumalanga Provincial Health Research Ethics Committee
3. NHREC	National Health Research Ethics Council
4. SOP	Standard Operating Procedure

1. INTRODUCTION

Creating a Standard Operating Procedure (SOP) for Research Ethics Complaints Management is crucial to ensure that research activities are conducted ethically, and that any concerns or complaints are addressed in a systematic and transparent manner. During any investigation of complaints, the Mpumalanga Provincial Health Research Ethics Committee (MPHREC) will adhere to the following principles: Fairness, Confidentiality, Integrity and Prevention of detriment.

2. PURPOSE OF THE SOP

The objective of this SOP is to provide guidelines for the management of research and ethics complaints to ensure ethical conduct in research activities and timely resolution of complaints.

3. SCOPE

This SOP applies to all research projects conducted within Mpumalanga Province and is designed to address concerns or complaints related to ethical issues in research. Notwithstanding this complaint procedure, processes will comply with National Regulations. The Chair of MPHREC retains the right to immediately suspend or terminate any research study that violates National Regulations.

4. REFERENCE DOCUMENTS

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).
- Regulations Relating to Research with Human Participants, 19 September 2014.
- South African Ethics in Health Research Guidelines, Principles, Processes and Structures, 3rd edition (National Department of Health, 2024).
- The Belmont Report, 1979.
- The Declaration of Helsinki, 2013.
- The National Health Act, No. 61 of 2003.

5. RESPONSIBILITIES

This SOP provides guidelines for MPHREC, researchers, co-researchers, research assistants, research participants, or interested community members regarding handling any dissatisfaction related to research-related activities.

6. PROCEDURE:

6.1. Reporting Concerns:

Should a researcher experience a problem with a specific MPHREC member's behaviour/attitude or MPHREC itself regarding meeting procedures, application management, or reviewer report(s), they have the opportunity to lodge a complaint. The complaint should be lodged in writing to the chairperson of MPHREC using an appropriate form (Annexure 1 / MPHREC SOP Annexure 16).

6.2. Complaint Procedure:

- 6.2.1 A meeting will immediately be constituted with the complainant, Chairperson, Vice Chairperson, MPHREC member, and the MPHREC Secretariat to discuss the complaint in an attempt to find an amicable solution. The MPHREC secretariat will compile a written report of this meeting. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached. Should the meeting fail to provide a mutual agreement regarding a workable solution, the process will proceed to the next phase (appeal committee, see annexure 2).
- 6.2.2 A meeting will be called as soon as possible with the complainant, the Head: Health (or representative), the MPHREC Chairperson, MPHREC Vice-chairperson, MPHREC member and MPHREC secretariat. The MPHREC secretariat will compile a written report of this meeting. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached. Should the meeting fail to provide a mutual agreement regarding a workable solution, the process will proceed to the next phase.
- 6.2.3 The complainant may approach the National Health Research Ethics Council (NHREC) to lodge the unresolved complaint, providing proof that the aforementioned internal mediation process was followed unsuccessfully (nhrec@Health.gov.za). The complaint and its outcome will be reported during the following MPHREC meeting.

6.3. Complaints from a Department's Responsibility Manager about a researcher:

Should the Department's Responsibility Manager experience a problem with a researcher's behaviour/attitude or research actions, they have the opportunity to lodge a complaint using an appropriate form (Annexure 1). The complaint should be lodged in writing to the Chairperson of MPHREC. The complaint will be handled as per procedure in Section 6.2.

6.4. Complaints from a research participant, co-researcher, research assistant, or interested community member about the conduct of the researcher and research process.

6.4.1 In the informed consent documentation, clear reference is made to either the researcher or the applicable MPHREC secretariat that should be contacted if a research participant has any queries or complaints regarding the research conduct or the researcher.

6.4.2 Likewise, a complaint can be lodged by a co-researcher, research assistant, or interested community member about the research conducted itself and/or the researcher.

6.4.3 These complaints should be received in writing (Annexure 1). It should be clear on the nature of the complaint and provide the necessary facts.

6.4.4 When such a complaint is received, the MPHREC secretariat should be contacted immediately and a plan of action devised in agreement with the Chairperson of the MPHREC.

6.4.5 The minimum plan of action should include:

6.4.5.1 Immediately contact the complainant via telephone (preferred if available) plus e-mail if available (to have key deliberations on record).

6.4.5.2 The MPHREC secretariat must acknowledge receipt of the complaint by the MPHREC within 10 working days of receipt.

6.4.5.3 The MPHREC secretariat notifies the MPHREC Chairperson that a complaint has been received.

6.4.5.4 If possible, an immediate meeting should be set up between the complainant and the MPHREC secretariat.

- 6.4.5.5 The researcher is contacted immediately and requested to supply the MPHREC secretariat and the MPHREC Chairperson with a written report.
- 6.4.5.6 A separate meeting is set up between the MPHREC Secretariat, the MPHREC Chairperson, an MPHREC member and the researcher.
- 6.4.5.7 The outcome of the two meetings (one with the complainant and one with the researcher) will inform the necessity of a further meeting as soon as possible where the researcher, the complainant, the MPHREC secretariat, an MPHREC member and the MPHREC Chairperson will finalise the complaint.
- 6.4.5.8 Should this not be achievable, a final meeting between all parties mentioned previously, and the Head: Health (or representative) will be called as soon as possible in an attempt to find an amicable solution.
- 6.4.5.8.1 A detailed written report of the aforementioned processes and outcomes will be compiled by the involved persons and circulated for correctness and fairness. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached.
- 6.4.5.9 If not, the process will proceed to the next phase as described below:
- 6.4.5.10 The complainant shall be advised about his/her right to contact the NHREC. The procedure and all necessary contact information shall be provided to the complainant.
- 6.4.5.11 The complaint and outcome will be reported during the following MPHREC meeting.

6.5. Documentation:

- 6.5.1 All complaints, investigations, and resolutions should be documented, including:
- 6.5.1.1 The nature of the complaint.
 - 6.5.1.2 The individuals involved.
 - 6.5.1.3 Actions taken to investigate and resolve the complaint.
 - 6.5.1.4 Recommendations and decisions made by the MPHREC.
 - 6.5.1.5 Communication with the complainant.

7. REVIEW AND REVISION:

This SOP should be reviewed every five year period/ when a need arises to ensure that it remains current and effective in managing research and ethics complaints.

7. SOP APPROVAL

APPROVED/ NOT APPROVED



DR LK NDHLOVU
HEAD: HEALTH

12/6/2024
DATE

Effective date 12/06/2024



Annexure 1 MPHREC COMPLAINTS FORM

NHRD Ref. No:

Please fill in the first table, providing as much detail as you can. Please send this completed form to MPHREC secretariat: Tel: 0137663766

Your contact details		
Name:	Email:	Phone number:
Research project you wish to make a complaint about		
Name of researcher (if known):	MPHREC (non-medical) Clearance number (if known) :	
Title of research project (if known), or topic of the project:		
Nature of complaint (please be as specific as you can)		
Your signature:	Date:	

<i>Office use only</i>
Description of action taken



Annexure 2 MPHREC APPEALS FORM

NHRD Ref. No:

Please fill in the first table, providing as much detail as you can. Please send this completed form to MPHREC secretariat: Tel: 0137663766

Your contact details		
Name:	Email:	Phone number:
Research project you wish to make a complaint about		
Name of researcher (if known):	MPHREC (non-medical) Clearance number (if known):	
Title of research project (if known), or topic of the project:		
Reason for appeal		
Your signature:	Date:	

<i>Office use only</i>
Description of action taken