



University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR COMPLAINTS MANAGEMENT

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
11 July 2018	1	Newly formulated
31 January 2022	2	Updated

2. PURPOSE OF THE SOP

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

- Complaints from researchers about a member of the UFH HREC or the UFH HREC itself.
- Complaints from a member of the UFH HREC or the UFH HREC itself about a researcher.
- Complaints received from a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher.

The NHREC adjudicates complaints about the functioning of UFH HREC. It also institutes remedial measures and disciplinary action where warranted to facilitate compliance with legal, ethical and professional norms and standards as required for responsible conduct of research.

During any investigation of complaints, the Ethics Office and UFH HREC will adhere to the following principles:

- *Fairness*
- *Confidentiality*
- *Integrity*
- *Prevention of detriment (consequential harm)*

3. SCOPE

Notwithstanding this complaint procedure, processes will comply with National Regulations. The Chair of an Ethics Committee retains the right to immediately suspend or terminate any research study that violates National Regulations.

4. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/Definition	Description
HREC	Health Research Ethics Committee
REC	Research Ethics Committee
UFH	University of Fort Hare
Complaint	Refers to any action of HREC, an HREC 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.

5. RESPONSIBILITIES

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

6. PROCEDURE(S)

Procedure for complaints from researchers about a member of the HREC or the HREC itself. Should a researcher/postgraduate student experience a problem with a specific UFH HREC member's behaviour/attitude or the UFH HREC 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 Head of the Ethics Office (aokeyo@ufh.ac.za) as well as the Chairperson of UFH HREC (dgoon@ufh.ac.za).

Such a written complaint will initiate the following process:

A meeting will immediately be constituted with the complainant, the Head of the Ethics Office, the Chairperson of UFH HREC and the Vice-Chairperson of the applicable ethics committee, and the member to discuss the complaint in an attempt to find an amicable solution. If the complainant is a postgraduate student, the supervisor will be included in this discussion. The Ethics Office will compile a written report of this meeting. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached.

If not, the process will proceed to the next phase as described below:

A meeting will be called as soon as possible with the complainant, the Dean, the Head of the Ethics Office, the Chairperson and Vice-Chairperson of HREC, a member, and the Director of the applicable research entity to discuss the complaint about a possible resolution. The Ethics Office will compile a written report of this meeting. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached.

If not, the process will proceed to the next phase as described below:

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. The procedure is available on the webpage of the UFH HREC.

The complaint and its outcome will be reported during the following UFH HREC meeting.

Flow diagram 1: Procedure for complaints from researchers



6.1 Complaints from a member of UFH HREC about a researcher

Should a member of the UFH HREC experience a problem with a specific researcher’s behaviour or research actions, they have the opportunity to lodge a complaint.

The complaint should be lodged in writing to the Head of the Ethics Office (aokeyo@ufh.ac.za) as well as the Chairperson of the UFH HREC (dgoon@ufh.ac.za).

Such a written complaint will initiate the following process:

A meeting will immediately be called with the complainant, the researcher, the Head of the Ethics Office, as well as the Chairperson and the Vice-Chairperson of the UFH HREC to discuss the complaint about the researcher in an attempt to find an amicable solution, and to communicate the problem and consequences to the

researcher in the most appropriate way. A written report of this meeting will be compiled by the Ethics Office and kept on file.

A meeting will immediately be called with the complainant, the researcher, the Head of the Ethics Office, as well as the Chairperson and the Vice-Chairperson of the UFH HREC to discuss the complaint about the researcher in an attempt to find an amicable solution, and to communicate the problem and consequences to the researcher in the most appropriate way. A written report of this meeting will be compiled by the Ethics Office and kept on file. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

A meeting will be called as soon as possible between the complainant, the Head of the Ethics Office the Chairperson and the Vice-Chairperson of the UFH HREC, and the researcher to discuss the complaint in an attempt to find an amicable solution. A written report of this meeting will be compiled by the Ethics Office which will be kept on file.

A meeting will be called as soon as possible between the complainant, the Head of the Ethics Office, and the Chairperson and the Vice-Chairperson of the UFH HREC, and the researcher to discuss the complaint in an attempt to find an amicable solution. A written report of this meeting will be compiled by the Ethics Office which will be kept on file. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.

If not, the process will proceed to the next phase as described below:

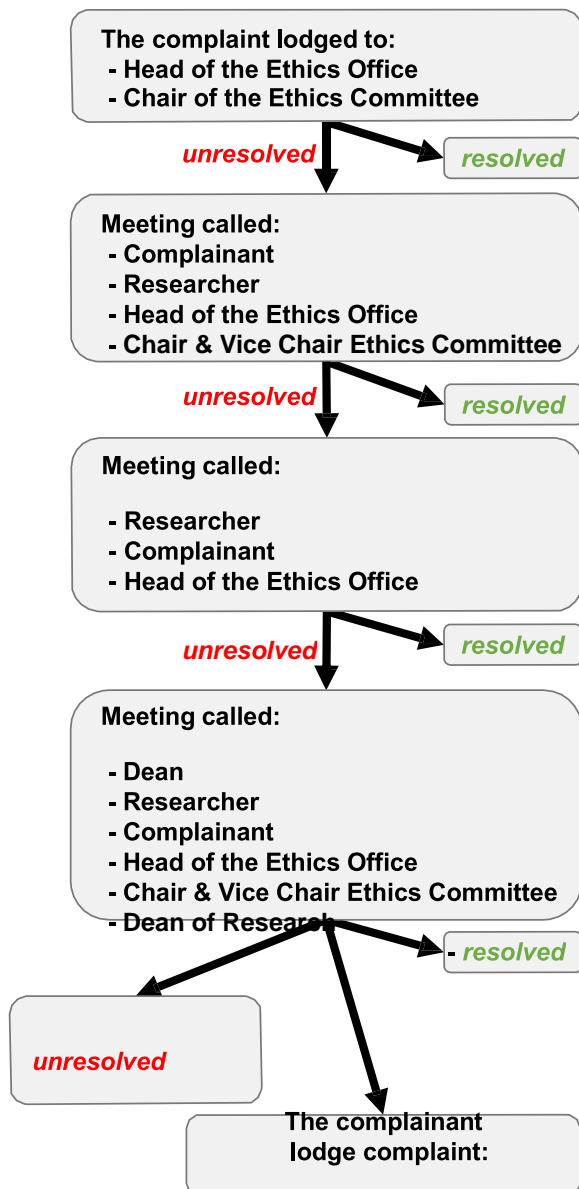
A meeting will be called as soon as possible with the researcher, the complainant, the Dean, the Head of the Ethics Office, the Chairperson and the Vice-Chairperson of the UFH HREC, and the Dean of Research to discuss the complaint in an attempt to find an amicable solution. A written report of this meeting will be compiled by the Ethics Office which will be kept on file. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached.

If not, the process will proceed to the next phase as described below:

The complainant may approach the NHREC to lodge the unresolved complaint, also providing proof that the aforementioned internal mediation process was followed and unsuccessful. The procedure is available on the webpage of the NHREC. Should the researcher feel unfairly treated he/she can follow the internal process, and if unresolved, also approach the NHREC.

The complaint and its outcome will be reported during the following UFH HREC meeting.

Flow diagram 2: Procedure for complaints from REC members



6.2. Procedure for complaints received from a research participant, co-researcher, research assistant, or interested community member about the conduct of the researcher and research process.

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

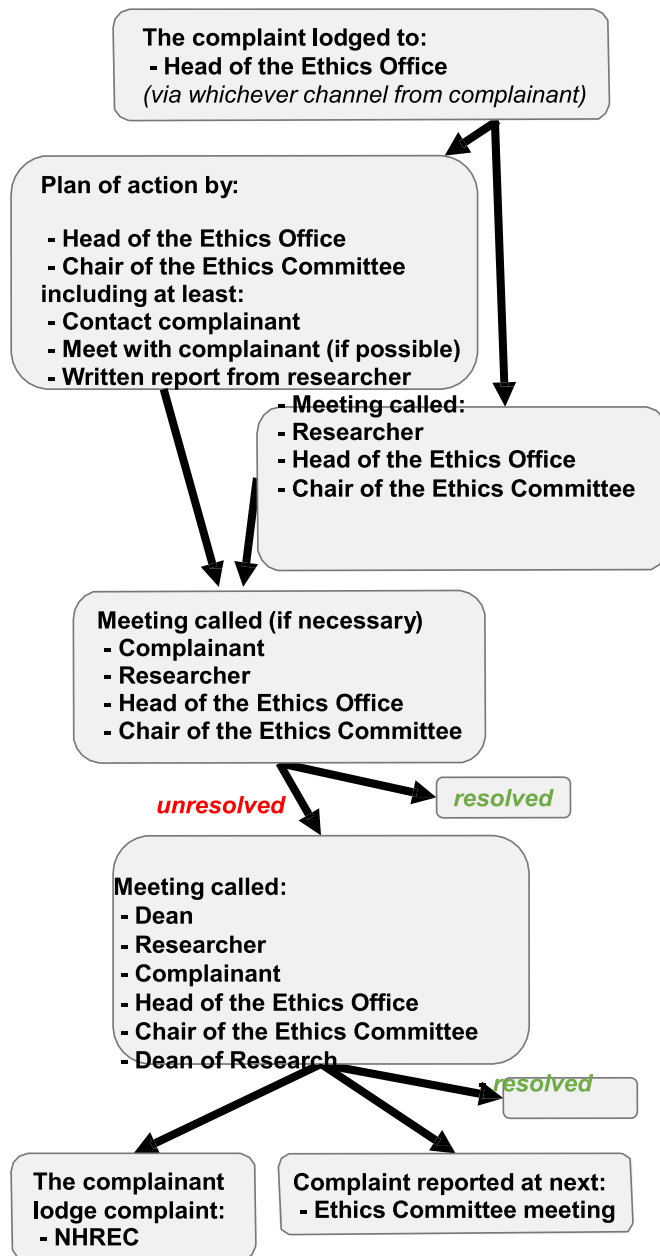
Likewise, a complaint can be lodged by a co-researcher, research assistant, or interested community member about the research conducted itself and/or the researcher.

These complaints should be received in the form of a written letter, e-mail or phone call. It should be clear on the nature of the complaint and provide the necessary facts. When such

a complaint is received, the Head of the Ethics Office should be contacted immediately and a plan of action devised in agreement with the Chairperson of the UFH HREC.

The minimum plan of action should include:

- Immediately contact the complainant via telephone (preferred if available) plus e-mail if available (to have key deliberations on record).
- The administration officer must acknowledge receipt of the complaint by the UFH HREC within 10 working days of receipt.
- The administration officer notifies the Chairperson of UFH HREC that a complaint has been received.
- If possible, an immediate meeting should be set up with the complainant.
- The researcher is contacted immediately and requested to supply the Head of the Ethics Office and the Chairperson with a written report.
- A separate meeting is set up between the Head of the Ethics Office, the Chairperson of the UFH HREC and the researcher.
- 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 Head of the Ethics Office and the Chairperson of the UFH HREC will finalise the complaint.
- Should this not be achievable, a final meeting between all parties mentioned previously, and the Dean of Research will be called as soon as possible in an attempt to find an amicable solution.
 - A detailed written report of the aforementioned processes and outcomes will be compiled by the involved persons (head of the Ethics Office or Chairperson of the UFH HREC) and circulated for correctness and fairness. The matter will be considered resolved if a mutual agreement regarding a workable solution is reached.
- If not, the process will proceed to the next phase as described below:
- The complainant shall be advised about his/her right to contact the NHREC. The procedure is available on the webpage of the NHREC and all necessary contact information shall be provided to the complainant.
- The complaint and outcome will be reported during the following UFH HREC meeting.



Flow diagram 3: Procedure for complaints about research conduct

8 REFERENCE DOCUMENTS

The UFH HREC adopts as its guiding reference the following documents:

- Guideline for the Management of Complaints, Complaints and Advisory Disciplinary Committee (CADC), NHREC, February 2015.
- The Rules for the Management of Research Ethics at the North-West University, 2016.
- The Rules for the Management of Research Ethics at the University of South Africa, 2016.
- The Rules for the Management of Research Ethics at the University of Cape Town, 2015.
- The National Health Act, No. 61 of 2003.
- Regulations Relating to Research with Human Participants, 19 September 2014.

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- The Declaration of Helsinki, 2013.
- The Belmont Report, 1979.
- The Singapore Statement on Research Integrity, 2010.
- The Code of Federal Regulations of the USA (Title 45 Part 46).
- The International Conference on Harmonisation – Good Clinical Practice (ICH-GCP), 1997.
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).