



Faculty of Health Sciences Research Ethics Committee

Standard Operating Procedure: Processing of complaints against the Faculty of Health Sciences Research Ethics Committee and/or its resolutions

1. Purpose of this document

The purpose of the SOP is to describe the procedures for the consideration of a complaint against the Faculty of Health Sciences Research Ethics Committee (REC) and/or a resolution that it made. This SOP was approved by resolution of the Faculty of Health Sciences Research Ethics Committee on 27 September 2023 and replaces all previous SOPs in this regard. It should be reviewed within 3 years after this date of approval.

A handwritten signature in black ink, appearing to read 'E. Waden'.

_____ Date: 27 September 2023

Signed by the Chairperson

2. Scope of this SOP

The SOP is intended to inform and guide complainants, members of the Research Ethics Committee (REC), and the REC in its deliberations. It gives effect to the Ethics Guidelines of the Department of Health (2015), especially section 4.5.1.12. This SOP should be interpreted within the Terms of Reference of the REC and other SOPs that may be relevant.

3. Definitions

3.1 **Complainant:** Any person or organisation that formally raises a complaint against the REC or a resolution that it made. A complainant may be, but is not restricted to, an employee of the University of Pretoria or its affiliated institutions, professional societies, affected organisations, and members of the public.

3.2 **Research:** Any research that the Faculty of Health Sciences Research Ethics Committee considered, approved, rejected, or that is within the remits of the Faculty of Health Sciences Research Ethics Committee as captured in its Terms of Reference.

3.3 **Researcher:** Any person who does research that is within the remits of the Faculty of Health Sciences Research Ethics Committee as captured in its Terms of Reference.

3.4 **Complaints:** An alleged unacceptable resolution that the REC made or an event that may include, but is not restricted to, a procedural or administrative irregularity or inadequacy, breach of confidentiality, an unacceptable delay, or in case of a conflict of interest.

4. Responsibilities

The REC is an independent legislatively-mandated and internationally- and nationally-accredited body,

- a) which independently reaches decisions and issues resolutions;
- b) on which no pressure or undue influence from outside the REC may be exerted on the REC or its members to effect a particular resolution; and
- c) the resolutions of which may not be overturned or overruled by any office-bearer of the University of Pretoria or any other party.

The REC has the responsibility to process complaints against it and/or its resolutions. It should process complaints in ways that potential remedies, if attainable, are facilitated first. A complaint against a resolution of the REC may result in the REC rescinding or sustaining that resolution. If a resolution is sustained, the complainant will have final recourse within the institution (University of Pretoria) to the appeal procedures (see the SOP for appeals).

5. Procedures

- 5.1 Complaints should be lodged formally in writing to the chairperson of the REC. For a complaint against a resolution made by the REC, the complaint should be supported by a document that provides reasons for the resolution to be rescinded or revised.
- 5.2 The chairperson may obtain further information from the complainant, researcher, or another relevant person after receiving the complaint.
- 5.3 The REC will welcome that potential remedies to a complaint, if attainable, be sought.
- 5.4 The REC or chairperson may tender an explanation if such is appropriate and resolves the complaint.
- 5.5 The REC or chairperson may tender an apology if such is appropriate and resolves the complaint.
- 5.6 The REC or chairperson may invite the complainant to clarify in writing and/or discuss the complaint at a meeting of the REC.
- 5.7 For a complaint against a resolution made by the REC, the REC may request opinions of suitable experts who are not members of the REC and/or not affiliated to the University of Pretoria. The expertise may be required regarding any aspect of a proposed study, and is limited neither to scientific nor ethical aspects. An expert may choose to remain anonymous.
- 5.8 For a complaint against a resolution made by the REC, the REC may request any standing committee at the University of Pretoria for a review on the scientific integrity of a proposed study regardless of whether they have reviewed or approved the study before. Alternatively, the REC may appoint an *ad hoc* committee to this end, comprising no less than two experts that are not members of the REC. The REC will be bound to consider the recommendations by these committees. However, the REC will not be bound to follow the recommendations as these recommendations may not absolve the REC from making resolutions independently.
- 5.9 After careful deliberation regarding a complaint against a resolution made by the REC, the REC will vote on whether the resolution is sustained or rescinded.
- 5.10 The complainant will be informed in writing of the resolution the REC has taken, supported by the reasoning of the REC in reaching this resolution.