



Faculty of Health Sciences Research Ethics Committee

Standard Operating Procedure: Processing of an appeal against a resolution made by the Faculty of Health Sciences Research Ethics Committee

1. Purpose of this document

The purpose of the SOP is to describe the procedures for the consideration of an appeal against a resolution made by the REC. 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 blue ink, appearing to read 'A. Staden'.

_____ Date: 27 September 2023

Signed by the Chairperson

2. Scope of this SOP

The SOP is intended to inform and guide appellants, 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, the SOP for complaints against the REC and other SOPs that may be relevant.

3. Definitions

3.1 **Appellant:** Any person or organisation that formally lodged a written appeal against a resolution made by the REC. 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, declined, 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 **Appeal:** An appeal may arise when the principal investigator or another stakeholder formally objects to a specific resolution of the REC and the outcome of the complaints procedures was not satisfactory in the view of the appellant.

3.5 **Appellant:** The person who makes the appeal.

4. Purpose and scope of the appeal procedures

These appeal procedures provide an appellant a final recourse within the institution, i.e. the University of Pretoria, to formally object against a specific resolution of the REC. Before accepting an appeal for its consideration, the procedures for complaints (see SOP to this end) should have been followed first, thus utilising those procedures in seeking potential remedies.

The appellant may appeal against a specific resolution by making a case that the REC in making this resolution was not procedurally fair and/or that it was mistaken in its resolution. The appeal will concern prior documentation, but not oral submissions nor new revised documents. In addition, the appeal will require and concern a document that expresses the grounds for the appeal.

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 appeals against its resolutions, consider the appeal, and make a final resolution whether the appeal is upheld or dismissed. Following a resolution by the REC that the appeal is dismissed, the appellant may choose to escalate his or her appeal to the National Health Research Ethics Council.

5. Procedures

5.1 An appeal should be lodged in writing to the chairperson of the REC.

5.2 The chairperson may obtain further information from the appellant or another relevant person..

5.3 The REC will consider all appeals and obtain further information as it may see fit.

5.4 The REC or chairperson may invite the appellant to clarify in writing and/or discuss the appeal at a meeting of the REC.

5.5 The REC will consider each of the grounds (or reasons) for appeal in the case made by the appellant that the REC was not procedurally fair and/or that it was mistaken in making a specific resolution.

5.6 After careful deliberation regarding an appeal, the REC will vote on whether the appeal is upheld or dismissed.

5.7 The appellant will be informed in writing of the resolution in 5.6.