


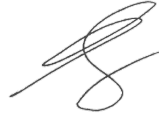


University of South Africa Ethics Review Committees	
Title	SOP for appeal against a decision of an Ethics Review Committee
SOP No	SOP 2_Appeal_ERCs_V1.17.05.18_SRIPCC
Date of approval	17/05/2017
Revision date	17/05/2020
Pages	5

COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled by:	Dr. Retha Visagie (Deputy Chairperson URERC)	13 November 2017	
Checked by:	URERC	23 April 2018	
Authorised /Approved by:	URERC Prof A Davis (Acting: Executive Director Research Administration)	23 April 2018	
Authorised/Approved by:	SRIPCC Prof A Davis (Acting: Chair)	17 May 2018	

DOCUMENT HISTORY

Date	Version no	Reason for revision
13 November 2017	1	Development of the document
17 May 2018	1	Approved by the SRIPCC

ABBREVIATIONS AND DEFINITIONS/DESCRIPTIONS

Abbreviation	Definition/description
APPEAL	Researchers have the right to apply for the review of a decision, in relation to significant amendments requested to or rejection of a research proposal for ethics approval, by a constituted ethics review committee provided that sufficient motivation for such an objection exists.
ERC	There are two categories of Ethics Review Committees in Unisa, namely the unit or college ERCs and the sub-unit or departmental ERCs: <ul style="list-style-type: none"> • The unit ERCs are attached to or based in a specific college/institute/centre. There is a minimum of one unit ERC per college. • The sub-unit ERCs are departmental committees affiliated to and reporting to the college/institute/centre ERC.
HREC/ERC	A Health Research Ethics Committee or Research Ethics Review Committee is duly registered to the National Health Research Ethics Review Council and reviews human research according to the National Health Act, No. 61 of 2003.
URERC	University of South Africa Research Ethics Review Committee refers to the university ERC that has Unisa-wide jurisdiction and is not attached to or based in a single unit in Unisa. It is a subcommittee of the Senate Research, Innovation, Postgraduate Degrees and Commercialisation Committee.
SOP	Standard Operating Procedure
SRIPCC	Senate Research, Innovation, Postgraduate Degrees and Commercialisation Committee

1 PURPOSE OF THE SOP

The purpose of this SOP is to provide a framework for the establishment of an appeal procedure to promote standard and uniform appeal practices based on integrity, dignity (fairness, transparency, care and respect) and accountability.

2 SCOPE

The scope of this document covers the establishment of a standardised appeal procedure with university-wide application to all ERCs. It covers the responsibilities and procedure(s) to be followed by the relevant ERCs.

3 RESPONSIBILITIES

The chairperson, deputy chairperson and administrative assistant/secretary of an ERC should be aware of the appeal procedure to ensure a standardised approach.

4 PROCEDURE(S)

4.1 Grounds for appeal

An applicant may appeal in writing against a decision concerning his/her application, including:

- Significant requested amendments/changes to the proposal/application documentation
- Rejection of the application

NOTE: Dissatisfaction with the decision of an Ethics Review Committee (ERC) is not alone a ground for an appeal.

4.2 Appeal process (general)

- (a) Where researchers are dissatisfied with an ERC decision, they have the right to obtain from the ERC written reasons for its decision and should exercise this right before launching an appeal.
- (b) An informal discussion with the relevant ERC chairperson and/or the research ethics and integrity advisor should be the first step before launching an appeal.
- (c) If an oral, informal resolution cannot be achieved, a formal appeal process is initiated which allows for the case to be escalated to the next level of research ethics review (departmental level up to the college ERC, college ERC to the URERC and URERC to the SRIPCC).
 - The researcher/appellant writes a memo stating the grounds for the appeal within three weeks of receiving the committee's decision. The appeal is directed to the Chairperson of the relevant ERC.
 - Departmental/sub-unit ERC chairpersons may escalate the appeal to the college/unit ERC.
 - College/unit ERC chairpersons may escalate the appeal to the URERC.
 - The URERC chairperson may escalate an appeal to the SRIPCC.
- (d) The URERC or SRIPCC will not engage with appeals until informal and college remedies have been exhausted.
- (e) A researcher retains the right to appeal or complain to the National Health Research Ethics Council, if the research falls under the jurisdiction of this council i.e. fulfils the definition of Health Research as defined in the National health Act No.61.2003.

NOTE: A researcher/appellant may not directly appeal to an ERC with higher authority without following the appropriate reporting channels.

4.3 Appeal process (Departmental and College ERC level)

- (a) The receipt of an appeal is acknowledged within two working days by the administrative assistance/secretary of the ERC. If an appeal is escalated to college ERC level, the principal researcher should be notified of this decision, as well as the Executive Dean of the college.
- (b) The basis of the appeal and all the relevant documentation must be submitted in writing to the chair of the ERC.
- (c) Composition of the appeal panel:
 - The chairperson of the relevant ERC appoints an appeal panel made up of 3 – 5 members to review the substance of the application together with any additional information put forward by the researcher.
 - The panel must obtain at least one independent, external, expert review of the research and the substance of the appeal.
 - The independent, external review can be obtained either internally from a member of any UNISA ERC that is not directly affiliated to the ERC dealing with the appeal, or externally from a person with the necessary expertise from another university.
 - Additional reviews should be obtained if deemed appropriate i.e. in case where special expertise might be needed.

- If the appeal is lodged on a departmental level, the chairperson of the College ERC or a person acting on behalf of the chairperson must form part of the panel.
 - If the appeal is lodged on a college level, a member representing the URERC must form part of the panel.
- (d) Members of the appeal panel signs a conflict of interest and confidentiality agreement on acceptance of membership to the panel.
- (e) The chairperson responsible for the appointment of the appeal panel draws up timelines for the submission of documentation, for the hearing of the appeal and for delivery of the panel's decision.
- (f) After deliberation of all the information placed before it, the panel must either
- (i) Uphold the appeal;
 - (ii) Reject the appeal; or
 - (iii) Refer the matter to the ERC on the next level.
- (g) In the event of an (a) or (b) outcome, the decision of the ERC is final. However, researchers conducting 'health research' retain the right to complain or appeal to the National Health Research Ethics Council in the event that they remain dissatisfied with the outcome of the appeal¹.
- (h) The appeal panel is authorised to:
- request further information if needed;
 - interview the parties; but if it does so, it must be in the presence of both parties, failing which, it must report to the other party the substance of the submissions or answers given and allow an opportunity to rebut;
 - require the parties to seek to resolve the matter through mediation or seek some other route as to a possible resolution of the dispute; and to recommend to the ERC that the appeal be upheld; or
 - to recommend to the ERC to dismiss the appeal.
- (i) If a college ERC refers the matter to the URERC it undertakes to adhere to any decision taken by the URERC, regarding the matter.
- (j) If the URERC refers a matter to the SRIPCC it undertakes to adhere to any decision taken by the SRIPCC, regarding the matter.
- (k) The outcome of the appeal committee deliberation will be provided in writing, normally within five working days of the meeting.
- (l) In case of a departmental ERC, the outcome of the appeal is reported to the college ERC.
- (m) In case of a college ERC, the outcome of the appeal is reported to the URERC.
- (n) In case of an appeal lodged at URERC, the outcome of the appeal is reported to the SRIPCC.

4.4 Appeal process (URERC)

- (a) The receipt of an appeal is acknowledged within two working days by the administrative assistant/secretary of the URERC. The principal researcher is notified of this decision, as well as the Executive Director: Research.
- (b) The matter is usually heard on the basis of written submissions only, that is, no oral evidence is led. It is therefore important that the chair of the ERC ensure that all the information that is relevant is before the Appeal Panel of the URERC. The principal researcher, the ERC and other interested parties may make submissions to augment the existing record, in accordance with the time lines set out by the Chair of URERC.
- (c) Composition of Appeal Panel:

¹ The National Health Research Ethics Council has been given the mandate by the National Health Act No.61. 2003 (NHA) to investigate and manage complaints related to the review and approval of 'health research' as defined in the NHA, by research ethics committees.

- The appeal will be heard by an independent panel made up of 3 – 5 members, who will ordinarily be members of the URERC, but may be other persons if deemed necessary by the Chair of the URERC.
 - The members of the panel must include one member from the college concerned.
 - In the case where special expertise might be needed to deal with technical aspects of the substance of the appeal, then such expertise should be sought without compromising the independence of the panel.
- (d) The members of the panel is appointed by the chairperson or deputy chairperson of the URERC who must draw up timelines for the submission of documentation, for the hearing of the appeal and for delivery of the panel’s decision.
- (e) The appeal panel is authorised to:
- request further information if needed;
 - interview the parties; but if it does so, it must be in the presence of both parties, failing which, it must report to the other party the substance of the submissions or answers given and allow an opportunity to rebut;
 - require the parties to seek to resolve the matter through mediation or seek some other route as to a possible resolution of the dispute; and to recommend to the URERC that the appeal be upheld;
 - to refer the appeal to the SRIPCC, or to
 - recommend to the URERC to dismiss the appeal.
- (f) As previously stated, researchers conducting ‘health research’ as defined by the SA National Health Act No.61.2003, retain the right to submit an appeal or complaint to the National Health Research Ethics Council if unsatisfied with the outcome of the process.

8 REFERENCE DOCUMENTS

- 8.1 University of Stellenbosch. (2016). Standard Operating Procedures and Guidelines, V4: Health Research Ethics Committee 1 & 2.