APPEAL TO ETHICS IN RESEARCH COMMITTEE

STANDARD OPERATING PROCEDURE

[Last updated August 2012]

1. INTRODUCTION

Appeals may arise because a Faculty-level Research Ethics Committee (REC) rejects a research proposal, adjudges a protocol deviation or violation to be sufficiently serious to merit calling a halt to the research, or requires additional protections or conditions before approving a protocol and the Principal Investigator (PI) or Primary Researcher objects to the decision of the Faculty-level REC and wishes to appeal to a higher body.

Note that it is expected that Faculty-level mechanisms should be used before lodging an appeal with EiRC.

- 1. Where a PI is dissatisfied with a Faculty-level REC decision, he or she has the right to obtain from the REC written reasons for its decision and should exercise this right <u>before</u> launching an appeal.
- 2. Each Faculty-level REC is expected to have a mechanism whereby a contested REC decision may be revisited at Faculty-level. If, having received written reasons for the REC decision, the PI is still dissatisfied, he or she may make representations in person to the REC to revisit the substance of the application together with any additional information not previously before the REC. This opportunity may prevent unnecessary misunderstandings. In the event of a failure to reach resolution, the PI may proceed in terms of the appeal process outlined below.
- 3. An external PI (i.e. someone not affiliated to UCT) who has applied for ethics clearance may use this appeal process.

2. PROCEDURE

- Notice in writing of the intention to appeal the decision must be given by the PI to the Chair of the Faculty-level Research Ethics Committee (REC) and the Chair of the (Senate) Ethics in Research Committee (EiRC).
- 2. The Chair of the EiRC must notify the Registrar and the DVC responsible for Research of receipt of the notice of intention to appeal.
- 3. The basis of the appeal and all the relevant documentation must be submitted in writing to the Chair of the EiRC by the PI within seven (7) days of the notice in 1) above.
- 4. The Chair of the EiRC must forthwith make the appeal documents available to the Chair of the Faculty-level REC, who must submit a written response to the Chair of the EiRC within seven (7) days of receipt by him/her.

- 5. The Chair of the EiRC must make a copy of the Chair of the Faculty-level REC's response available to the PI.
- 6. The appeal is usually heard on the basis of written submissions only, that is, no oral evidence is led. It is therefore important that both the PI and the Chair of the Faculty-level REC ensure that all the information that is relevant from their respective points of view is before the Appeal Panel of the EiRC. The PI, the Faculty-level REC and other interested parties may make submissions to augment the existing record, in accordance with the time lines set out by the Chair of EiRC (see below under Appointment of Appeal Panel).

3. COMPOSITION OF APPEAL PANEL

The appeal will be heard by an independent panel made up of 3-5 members, who will ordinarily be members of the EiRC, but may be other persons if deemed necessary by the Chair of the EiRC.

The members of the panel must include one member from the Faculty concerned. The members of the panel must not be members of the Faculty-level REC.

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.

4. APPOINTMENT OF APPEAL PANEL

The panel must be appointed by the Chair of EiRC who must draw up timelines for the submission of documentation, for the hearing of the appeal and for delivery of the panel's decision.

5. POWERS OF APPEAL PANEL

The appeal panel is empowered

- to request further information if needed;
- to 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;
- to 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 uphold the appeal; or
- to dismiss the appeal.

The Appeal Panel must keep careful minutes of the appeal proceedings and must draw up a report to support its finding at the conclusion of proceedings. The decision of the Appeal Panel is final and can only be taken on review to a Deputy Vice Chancellor nominated by the Vice Chancellor in the case of a procedural irregularity.

Diagram of Appeal to Ethics in Research Committee Standard Operating Procedure

