



Faculty of Health Sciences Research Ethics Committee

Standard Operating Procedure: Processing of complaints and “whistle-blowing” regarding research or a researcher

1. Purpose of this document

The purpose of the SOP is to define complaints and describe the procedures for the consideration of complaints or “whistle-blowing” regarding research or a researcher. 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. Haden'.

_____ 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 or “whistle-blower”:** Any person or organisation that formally raises a complaint regarding research or researcher within the mandate of the Faculty of Health Sciences Research Ethics Committee. 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 **Research or researcher misconduct:** That research activity or conduct that the Faculty of Health Sciences Research Ethics Committee considers to be misconduct, which include but is not restricted to the following:
- 3.4.1 Failure to obtain ethics approval prior to commencing with research
 - 3.4.2 Failure to obtain ethics approval for amendments to research
 - 3.4.3 Conducting research without a valid ethics approval certificate
 - 3.4.4 Conducting research outside the terms and stipulations of the documents considered by the ethics committees in its approval of the study
 - 3.4.5 Failure to suspend research activities when so instructed by the ethics committee
 - 3.4.6 Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research
 - 3.4.7 Substantive deviation from or failure to adhere to the approved study protocol without prior formal approval from the ethics committee
 - 3.4.8 Any misrepresentation of data and/or interests and/or involvement
 - 3.4.9 Any falsification of credentials
 - 3.4.10 Any deception in documentation or in publication
 - 3.4.11 A false claim that ethics approval would have been granted
 - 3.4.12 Piracy of materials
 - 3.4.13 Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research personnel
 - 3.4.14 Failure to obtain voluntary and informed consent in writing unless this requirement has been waived by the ethics committee.

- 3.4.15 A breach of confidentiality
- 3.4.16 Negligent management of data security.
- 3.4.17 Conducting research in a way that is malicious or harmful to research participants
- 3.4.18 Conducting research that is negligent as researcher and/or professional
- 3.4.19 Conducting research that is in violation of standard codes and regulations pertaining to the researcher's profession
- 3.4.20 Any research activity that is in violation of the South African Constitution or in violation of a South African law.

4. Responsibilities

The REC has the responsibility to process complaints, establish prima facie evidence of misconduct, and formulate an opinion on the nature of the ethical misconduct, as well as identify potential mitigating or aggravating factors, and corrective actions. When there is prima facie evidence of a serious transgression, the matter must be referred to the dean of the FHS and the Executive Management including the Registrar of the University of Pretoria, for the issue of a warning, and/or instituting disciplinary and/or corrective procedures.

5. Procedures

- 5.1 Complaints should be made in writing to the chairperson of the REC and may be received from the complainant directly or through the complaints hotline of the University of Pretoria. The latter is managed independently and operates 24 hours a day, 365 days a year.
- 5.2 The chairperson may obtain further information from the complainant, researcher, or other person after receiving the complaint.
- 5.3 The chairperson may consult confidentially with experts in the field.
- 5.4 The REC will consider the complaint and obtain further information as it may see fit.
- 5.5 The REC will take all reasonable steps to prevent the disclosure of the complainant's identity, unless there is compelling reason for its disclosure.
- 5.6 The REC may invite the researcher to respond to the complaint in writing and/or at a meeting.
- 5.7 The REC will formulate an opinion on the nature of the alleged ethical misconduct.
- 5.8 Once sufficient information has been obtained, the REC will vote on whether there is *prima facie* evidence of a transgression;
- 5.9 If a simple majority vote supports *prima facie* evidence of a transgression, the REC will identify potential mitigating or aggravating factors, as well corrective actions.

- 5.10 If a simple majority vote supports *prima facie* evidence of a transgression, a letter will be written to the dean of the FHS and the executive management including the registrar of the University of Pretoria. The letter will describe the nature of the transgression, potential mitigating and aggravating factors, and suggested corrective actions. The letter may also contain suggestions regarding disciplinary action.
- 5.11 The REC will inform the researcher that a letter as described in 5.9 has been sent.
- 5.12 The REC will not participate in disciplinary processes other than providing the available documentation in the matter, or expressing an opinion or explanation on whether a specific action is unethical.
- 5.13 The chairperson may meet with the dean and/or a member of the executive management of the University of Pretoria, for purposes of clarification and procedural guidance.
- 5.14 All members of the REC must keep information regarding the complaint and its processing confidential.