



RHODES UNIVERSITY

Where leaders learn

RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

SOP 3.3 CONSEQUENCES FOR NON-COMPLIANCE / PROTOCOL VIOLATION / UNETHICAL RESEARCH PRACTICE

Approved by:	Name	Signature	Date
Human Research Ethics Committee	Dr Janet Hayward (Chair)		26/02/2024
Endorsed by:			
VC Legal Unit	Mr Ismail Amojee		08/03/2024
DVC: RISP	Dr Kwezi Mzilikazi		12/03/2024

COMPILED BY Dr Janet Hayward, Chair, Rhodes University Human Research Ethics Committee

DOCUMENT HISTORY

Version 1.01 (November 2014): Rhodes University Ethical Standards Handbook (comprising Institutional Policy, Terms of Reference, and Standard Operation Procedures).

Version 2.0 (February 2024): Derived from division of previous version into separate documents and revised to align with RU Research Policy (2021) and DoH Guidelines (2015; 2024).

CONSEQUENCES FOR NON-COMPLIANCE / PROTOCOL VIOLATION / UNETHICAL RESEARCH PRACTICE

1. Purpose

The purpose of this policy is to outline procedures for dealing with non-compliance, protocol deviation/violation, culpability in unanticipated incidents and/or adverse events on the part of researchers during the course of research with human participants.

2. Scope

- 2.1. Any changes to an approved protocol (no matter how minor) must receive prior Rhodes University Human Research Ethics Committee (RU-HREC) approval before implementation. Thus, any alteration or modification to the approved research protocol without prospective RU-HREC approval and any willful violation of procedures of a research protocol must be reported to RU-HREC.
- 2.2. The procedures outlined below are to be followed in consequence of the following alleged infringements:
- 2.3. Report of unexpected problem, incident or adverse event by the researcher concerned or another party (internal or external) as outlined in SOP 3.1 REPORTING OF UNANTICIPATED PROBLEMS / INCIDENTS / ADVERSE EVENTS.
- 2.4. Report of protocol deviation/violation (see SOP 2.3 HUMAN RESEARCH ETHICS COMMITTEE REVIEW PROCESSESS, section 12) by internal or external party.
- 2.5. Complaint of suspected misconduct, non-compliance, or unethical conduct via one of the procedures outlined in SOP 3.2 PROCEDURES FOR REPORTING ALLEGATIONS OF MISCONDUCT / NON-COMPLIANCE / UNETHICAL RESEARCH PRACTICE.
- 2.6. Any other evidence of misconduct, protocol violation or unethical conduct that becomes known to RU-HREC.

3. Dealing with alleged non-compliance / protocol violation / unethical research practice

- 3.1. All research activities in the context of the project must stop until an investigation into the alleged infringement has been concluded.
- 3.2. Given the negative impact that this may have on the research, the investigation must be concluded speedily.
- 3.3. Within 24 hours of the receipt of the report, the Chairperson of RU-HREC must commence an investigation into the merits of the report:
 - 1) RU-HREC Executive Committee (RU-HREC EXCO) must be constituted (comprising a minimum of four members: the Chairperson, the Deputy Chairperson and two other senior RU-HREC members with experience in the ethics of research involving human participants).
 - 2) If either / both the Chairperson or Deputy Chairperson or other members of RU-HREC have a conflict of interest, they are required to recuse themselves from RU-HREC EXCO and other experienced committee members be delegated as Acting Chairperson / Deputy Chairperson.
 - 3) RU-HREC EXCO appoints one of their members to oversee investigations into and handling of the alleged infringement.

- 4) The (possibly anonymised) complainant's report is to be circulated to the members of RU-HREC EXCO for perusal, along with reference to the initial ethics protocol and reviews.
 - 5) Simultaneously, the affected party(ies) are to be given a chance to respond to the report.
- 3.4. After the documents have been studied by all members of the committee and affected parties, a meeting must be scheduled expeditiously, preferably within one week.
- 1) The strictest level of confidence must be maintained during the meeting and deliberations.
 - 2) Deliberations in the meeting must examine the merits of the alleged infringement.
 - 3) The affected party(ies) must be given a chance to present their case to the committee.
 - 4) If necessary, the advice of internal or external experts should be sought, and further investigations performed, including following up with affected parties.
 - 5) In its deliberations, RU-HREC EXCO must consider the reports and other information in relation not only to this policy, but also to all other relevant policies at Rhodes University, including (but not limited to) the staff and student disciplinary policies.
 - 6) After deliberations, RU-HREC EXCO should reach a consensus decision about the way forward and the way to resolve the complaint.
- 3.5. The outcome can include one of the following options but RU-HREC EXCO may agree on alternative measures, depending on the context and circumstances:
- 1) RU-HREC EXCO takes note of the report of alleged infringement but sees no reason to take any action.
 - 2) RU-HREC EXCO finds that the researcher(s) did commit the infringement and makes recommendations as to how things may be remedied, redressed, or sanctioned. Such measures must be appropriate to the severity of the infringement and may include temporary suspension or permanent withdrawal of approval (see SOP 2.3 HUMAN RESEARCH ETHICS COMMITTEE PROCESSES, Section 13).
 - 3) The matter is too severe to be dealt with by RU-HREC EXCO and must be referred to another relevant Rhodes University stakeholder according to conditions laid out in the Rhodes University Code of Conduct.
- 3.6. Once the investigation is completed, the appointed RU-HREC EXCO overseer shall compile a draft investigation report, verdict and recommendation based on the information accumulated during the investigation. This report must be finalised with input from the RU-HREC EXCO committee members and where applicable, the Faculty Ethics Committee members.
- 3.7. The report is then to be emailed to the DVC: RISP. The text of the investigation report must clearly outline the process that RU-HREC EXCO followed in reaching its conclusion(s), the information and/or evidence considered, the final recommendations arrived at, including any recommended remedial action to be taken by Rhodes University and/or the researcher(s) involved.
- 3.8. The DVC: RISP may return the report to RU-HREC EXCO for further investigation or clarification.
- 3.9. The DVC: RISP or their appointee must communicate the outcome of the investigation to all affected parties.

- 3.10. The text of the communication must also indicate that the affected parties have 7 days to appeal the findings of the investigation report, and the remedial and/or disciplinary action to be taken.
- 3.11. Affected parties can appeal the findings of an investigation report within 7 days of the receipt of the communication from the DVC: RISP:
- 1) The DVC: RISP or their designate must within 7 days of the receipt of the appeal appoint a panel of no less than 3 and no more than 5 suitably qualified members of the Rhodes University community as members of the appeals panel (these individuals will be designated as appointees).
 - 2) This panel must convene within 7 days of the appointment by the DVC. They must re-examine all the materials that formed the basis for the original report by RU-HREC.
 - 3) A report by the panel must be finalised and submitted to the DVC: RISP within 1 month. The DVC should communicate with all affected parties within 1 week of the submission of the panel's report. The decision of the appeal panel will be seen as binding.
- 3.12. Any further recourse must take place outside of Rhodes University, e.g. in a court of law of the Republic of South Africa.
- 3.13. The RU-HREC EXCO member delegated to oversee investigation of the alleged infringement must communicate the result to the next full quorate meeting of RU-HREC without compromising anonymity of the complainant / whistleblower or alleged perpetrator.
- 3.14. The report and all communication must be securely stored for five years for any future audits and/or other purposes.

4. Effective date of this SOP

26th February 2024 with the next revision date being 26th February 2027, or as deemed necessary by a quorate meeting of RU-HREC.