



RHODES UNIVERSITY

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RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE SOP 1.3 WRITING, REVISING AND MANAGING STANDARD OPERATING PROCEDURES

Approved by:	Name	Signature	Date
Human Research Ethics Committee	Janet Hayward		12/12/2023
Endorsed by:			
VC Legal Unit	G Barker		31/01/2024
DVC: RISP	N. Mzilikazi		31/01/2024

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DOCUMENT HISTORY

Version 1.0 (December 2023)

WRITING, REVISING AND MANAGING STANDARD OPERATING PROCEDURES

1. Purpose

The purpose of these guidelines is to clearly define the preferred method for preparing, writing, revising, updating and approving all Rhodes University Human Research Ethics Committee (RU-HREC) Standard Operating Procedures (SOPs).

2. Scope and responsibilities

- 2.1. All Rhodes University researchers and their collaborators, RU-HREC members and staff are responsible for working in accordance with approved SOPs.
- 2.2. All staff and affiliates to whom the RU-HREC SOPs apply, are responsible for identifying new SOPs that need to be written; or gaps and deficiencies in current SOPs that need to be revised. The committee must be informed by email (ethics-committee@.ac.za) of any requests to write or update SOPs.
- 2.3. The Chairperson of RU-HREC is responsible for the oversight of RU-HREC SOPs, as well as plans for writing and revising and implementation of RU-HREC SOPs.
- 2.4. The RU-HREC SOPs may be written by the Chairperson of RU-HREC, or Vice Chairpersons or persons delegated to write or revise SOPs.
- 2.5. The Chairperson and the Vice Chairperson, in collaboration with the office of the Deputy Vice Chancellor for Research Innovation and Strategic Partnerships (DVC: RISP), are responsible for ensuring that the SOPs remain accurate, current and compliant with any changes to national and international research ethics guidelines and /or regulatory requirements.
- 2.6. The RU-HREC SOPs are to be circulated to RU-HREC committee members for expert advice and feedback.

3. Identification of need for new SOP or Revision of existing SOP

- 3.1. All RU-HREC SOPs must be current and fit for purpose; and as such, must undergo regular review.
- 3.2. A review of each SOP must be carried out at least once every three years.
- 3.3. New or revised SOPs may be necessary and should be generated when:
 - 1) The need has been identified by consensus amongst RU-HREC committee members;
 - 2) New or revised national or international research regulations, ethics guidelines or procedures are introduced;
 - 3) Recommended by the National Health Research Ethics Council (NHREC);
 - 4) Clarification or additions are required to accommodate situations not well defined by the SOPs;
 - 5) Gaps in the Rhodes University policies and procedures become apparent.

4. SOP approval: new or revised

- 4.1. The Chairperson of RU-HREC and all the members of the committee are required to follow and to keep abreast of the latest development in the research ethics that involves human participants.
- 4.2. Any significant changes or updates are to be discussed at a regular quorate review meeting of RU-HREC.

- 4.3. If the meeting deems any such development significant enough to change the way research ethics is understood at Rhodes University, then a particular SOP must be updated to reflect the change, or a new one is to be drafted.
- 4.4. The chairperson will initiate and drive the review and re-drafting of SOPs.
- 4.5. Drafts are to be tabled at a regular quorate RU-HREC meeting for member feedback and change suggestions.
- 4.6. Once changes and suggestions have been incorporated, the updated version of the SOP is tabled at the next meeting of RU-HREC for adoption.
- 4.7. After adoption by RU-HREC, SOPs are published on the Rhodes University website and become operational.

5. Version Control

- 5.1. Modification history must be detailed in an SOP Version History Log as a prefix to the RU-HREC SOP content.
- 5.2. Version numbers in the format x.x must be assigned to every new issue of a SOP.
- 5.3. Minor changes (such as annual review that does not change the content of the SOPs or typographical changes) should result in an increment after the decimal point (e.g. 2.0 to 2.1).
- 5.4. Major changes should result in a change before the decimal point (e.g. 2.2 to 3.0).

6. Access and Record keeping

- 6.1. The Human Research Ethics Office will make finalised versions of all SOPs available on the Rhodes Research Ethics website.
- 6.2. The Human Research Ethics Office will notify Rhodes University researchers, RU-HREC members and staff when a new or updated version of a SOP is published.
- 6.3. A paper copy of each finalised SOP version must be stored in the 'SOP master folder' in the Human Research Ethics Office.

7. Effective date of this SOP

12 December 2023 with the next revision date being 12th December 2026, or as deemed necessary by a quorate meeting of RU-HREC.