



# RHODES UNIVERSITY

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## RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

### SOP 2.1 HUMAN RESEARCH ETHICS COMMITTEE

| Approved by:                    | Name          | Signature    | Date       |
|---------------------------------|---------------|--------------|------------|
| Human Research Ethics Committee | Janet Hayward |              | 29/01/2023 |
| Endorsed by:                    |               |              |            |
| VC Legal Unit                   | Ismail Amajec |              | 05/02/2024 |
| DVC: RISP                       |               | N. Mzilikazi | 12/02/2024 |

COMPILED BY Dr Janet Hayward, Chair, Rhodes University Human Research Ethics Committee and Ms Paulina Nkosi, Research Ethics Intern.

#### DOCUMENT HISTORY

Version 1.0 (2014): Rhodes University Ethical Standards Handbook (comprising Institutional Policy, Terms of Reference and Standard Operation Procedures).

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

## **HUMAN RESEARCH ETHICS COMMITTEE**

### **1. Purpose**

The purpose of these guidelines is to outline the procedure for appointing the Rhodes University Human Research Ethics Committee (RU-HREC) Chairperson, Deputy Chairperson and Committee members, and to describe their roles and responsibilities. The policy further defines the composition of RU-HREC.

### **2. Chairperson: Appointment and Responsibilities**

- 2.1. The Chairperson performs a leadership, oversight and advisory role in the conceptualisation, management and conduct of Human research ethics at the institution. To be and to do such, the chairperson needs to be a respected academic, knowledgeable, and experienced in operationalizing research ethics, legal frameworks and enabling sound committee leadership practices.
- 2.2. The Chairperson is appointed by the Deputy Vice Chancellor: Research, Innovation and strategic Partnership (DVC: RISP) after nomination and voting by committee members. Nominations and brief motivations by any trained ethics reviewer or committee member of any of the Research Ethics Committees (RECs) or the Rhodes University Research Ethics Forum (RU-REF) will be called for by the DVC: RISP through the Ethics Coordinator.
- 2.3. The DVC: RISP will implement a formal voting procedure. Voting will be open to any trained ethics reviewer or committee member of any of the RECs or RU-REF. The successful candidate will be vetted by the DVC: RISP and appointed for a (renewable) period of three-years through a formal letter of appointment.
- 2.4. The Chairperson may serve a maximum of three consecutive terms.
- 2.5. The Chair or Deputy Chair may not be the Chair or Deputy Chair of Education or Humanities RECs, or the Chair or Deputy Chair of a Faculty Higher Degrees Committee.
- 2.6. The Chairperson's responsibilities are to:
  - 1) Conduct and direct the monthly RU-HREC meetings.
  - 2) With the assistance of the administrator, decide on review categorisation, for example expedited, meeting assigned or excluded from review.
  - 3) With the assistance of the administrator, select reviewers with necessary expertise to perform initial and ongoing protocol reviews.
  - 4) Advise and consult with researchers on research ethics-related issues.
  - 5) Conduct expedited reviews or delegate this task to a trained reviewer in the committee.
  - 6) Engage with researchers on research ethics-related issues.
  - 7) Compile an annual report on the activities RU-HREC for submission to the DVC: RISP, Senate and to the National Health Research Ethics Council (NHREC). The latter report is for the purpose of maintaining accreditation and registration as a compliant research ethics committee.
  - 8) Participate in non-compliance investigations.
  - 9) Contribute to the development of RU-HREC policies and procedures.
  - 10) Liaise with the DVC: RISP via the Department of Research Development regarding appropriate and sufficient administrative support and resources to function optimally.
  - 11) Liaise with and assist the RU-HREC administrator to prepare the agenda before meetings, and to review minutes after meetings.
  - 12) Review and sign letters to researchers conveying RU-HREC decisions relating to their submitted research protocols.

### **3. Deputy Chairperson: Appointment and Responsibilities**

3.1. The Deputy Chairperson is appointed by the DVC: RISP after nomination and voting by committee members for a (renewable) period of three-years through a formal letter of appointment.

3.2. The Deputy Chairperson's responsibilities are to:

- 1) Attend a minimum of 70% of the RU-HREC meetings scheduled for the year. 100% attendance is however preferable.
- 2) Perform duties delegated by the Chairperson.
- 3) Act as Chairperson in the absence of the Chairperson.
- 4) Provide active in-meeting support, for example meeting management, timekeeping, and conceptual and psycho-social support to the Chairperson and committee members.
- 5) Vote on protocols at the full committee meeting together with other RU-HREC members.
- 6) Act as a member of the RU-HREC Executive Committee (EXCO).
- 7) Advise and consult, as agreed, with researchers, RU-HREC members and members of the RU-HREC offices on research ethics issues.
- 8) Participate in non-compliance investigations.
- 9) Contribute to the development and implementation of RU-HREC policies and procedures.
- 10) Represent RU-HREC at the annual NRU-HREC meetings and other meetings at national level.
- 11) General responsibilities which accompany committee membership.

### **4. RU-HREC committee members: Composition, Appointment and Responsibilities**

4.1. According to the Department of Health requirements as stipulated in Ethics in Health Research: Principles, Processes and Structures 3rd Edition (2023) RU-HREC membership must meet the following requirements:

- 1) at least nine members with a quorum being a simple majority,
- 2) where the number of members is more than 15, the quorum may be 33%,
- 3) at least one layperson,
- 4) at least one member with knowledge of, and current experience in, the professional care, counselling, or health-related treatment of people. Such a member might be e.g., a medical practitioner, psychologist, social worker, or nurse,
- 5) at least one member with professional training and experience in qualitative research methodologies,
- 6) members with professional training and experience in quantitative research methodologies,
- 7) a member with expertise in biostatistics,
- 8) a member with expertise in research ethics,
- 9) at least one member who is legally qualified and has extensive knowledge of family law, health law and research ethics.

4.2. RU-HREC consists of:

- 1) The Chair and/or Deputy Chair of RU-HREC.
- 2) The Chair and/or Deputy Chair of the Education and Humanities RECs.
- 3) At least one further delegate from each of the Education and Humanities RECs (delegates may vary by meeting).

- 4) Elected members of faculties.
  - 5) Two Senate representatives.
  - 6) One representative of the Community Engagement Division.
  - 7) One external representative of a community-based organisation or non-governmental organisation.
  - 8) The Ethics Coordinator.
- 4.3. RU-HREC members are appointed by the DVC: RISP via an official letter of appointment for a period of three years. Re-nomination for one further term is possible.
- 4.4. On appointment, RU-HREC members are required to sign a statement undertaking that:
- 1) All matters of which they become aware during their tenure on the RU-HREC will be kept confidential.
  - 2) Any conflicts of interest, which exist or may arise during their tenure on the RU-HREC will be declared.
- 4.5. Members are not offered remuneration, except in exceptional cases lay members who may be reimbursed for traveling expenses to attend meetings.
- 4.6. The membership and composition of the RU-HREC will be continuously monitored to ensure appropriate representation. The Chairperson and Deputy Chairperson will perform an annual review of the composition, expertise, and contribution of members. When a member resigns from RU-HREC, the choice of a replacement considers the faculty from which the member was nominated, the overall balance of the RU-HREC and specific expertise that is needed.
- 4.7. The university will provide protection in respect of liabilities that may arise when members are acting in good faith whilst performing their RU-HREC responsibilities.
- 4.8. The Committee members' responsibilities are to:
- 1) Perform reviews in a timeous fashion and meet review deadlines communicated by the RU-HREC coordinator.
  - 2) Provide timeous written notice if unable to take on a particular review (within 3 working days of receiving review allocations) to the RU-HREC Chairperson and administrator.
  - 3) Attend meetings on a regular basis and not leave until meetings are adjourned.
  - 4) Attend a minimum of 7 meetings per year (excluding sabbatical or other leave periods).
  - 5) It is crucial for the primary reviewer to be present at the meeting to present their review to the committee. If this will not be possible, the reviewer should arrange with the Chairperson to take over these review duties in order not to delay the review process.
  - 6) Maintain strict confidentiality regarding protocol information, reviews, decisions, and all other matters discussed at committee meetings.
  - 7) Disclose potential conflicts of interest to the Chairperson and committee coordinator, and where a conflict does exist, not review the protocol, and leave the room during discussion of and voting on the protocol.
  - 8) Remain impartial and objective when reviewing protocols.
  - 9) Respect each other's views and the deliberative process.
  - 10) Serve as a primary reviewer for research in their area of expertise.
  - 11) Serve as a general reviewer of all research discussed at full committee meetings.

- 12) Decide independently if the design and conduct of proposed studies will protect participants' safety, rights, and welfare, and comply with relevant ethics guidance and regulations.
  - 13) Decide whether to approve, require revisions, defer, or reject studies following deliberation at full committee meetings.
  - 14) Keep up to date with national and international research ethics guidelines and regulations.
  - 15) Engage in continuous research ethics training refreshed at least once within the period of appointment and submit documented proof of such to the RU-HREC office.
- 4.9. RU-HREC may make use of co-opted members/*ad hoc* reviewers, when necessary. For example, colleagues from the same discipline as a committee member may be appointed to attend a specific meeting when that member is unable to attend.
- 4.10. Observer members and applicants may attend meetings with the prior agreement of the Chairperson of RU-HREC. Such members do not contribute to the quorum and as such are not eligible to vote.
- 4.11. Where appropriate, specialists and other advisers may be invited to attend meetings and/or give input. Such members do not contribute to the quorum and thus are not eligible to vote.
- 4.12. Co-opted and/or *ad hoc* reviewers:
- 1) must have access to the relevant study documentation, submitted to RU-HREC,
  - 2) must declare no conflict of interest in respect of the relevant study under review,
  - 3) must pledge confidentiality regarding the specific protocol and the meeting proceedings by signing a confidentiality and non-disclosure agreement, and
  - 4) may provide information about a specific study by written report, attending the meeting or both.
  - 5) must have a working knowledge of the Department of Health Research Ethics Guidelines (2023) and the Protection of Personal Information Act, 2013.
- 4.13. Co-opted reviewers and/or *ad hoc* reviewers are required to submit a written review on the studies they review for safe keeping by RU-HREC.

## **5. Executive Committee of RU-HREC (EXCO)**

- 5.1. Should an emergency arise in research involving human participants, and a decision about human participant ethics and its implications for the academic project of RU be required on short notice, the RU-HREC EXCO must be constituted swiftly to act on behalf of RU-HREC.
- 5.2. EXCO will be constituted in the case of non-quorate monthly committee meetings, as outlined in SOP 2.2 HUMAN RESEARCH ETHICS COMMITTEE MEETINGS, clause 3.4 – 3.7.
- 5.3. RU-HREC EXCO should comprise the Chairperson, the Deputy Chairperson and two other RU-HREC members with extensive experience in the ethics of research involving human participants.
- 5.4. All decisions of the RU-HREC EXCO must be tabled at the following meeting of the RU-HREC and these decisions must also be communicated to the DVC: RISP.

**6. Effective date of this SOP**

29th January 2024 with the next revision date being 29th January 2027, or as deemed necessary by a quorate meeting of RU-HREC.