RHODES UNIVERSITY

Where leaders learn

RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

Approved by:	Name	Signature	Date
Human Research Ethics Committee	Dr Janet Hayward	JHayward	1/12/2023
VC Legal Unit	Mr Gordon Barker	G/Barker.	26/01/2024
DVC: RISP	Dr Kwezi Mzilikazi		27/04/2024

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

DOCUMENT HISTORY

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

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

RU-HREC TERMS OF REFERENCE

1. RHODES UNIVERSITY RESEARCH ETHICS COMMITTEE (RU-HREC)

1.1 At Rhodes University research ethics clearance relating to humans is conducted by the Rhodes University Human Research Ethics Committee (RU-HREC).

1.2 RU-HREC is an independent standing committee, not controlled by any superior University body in terms of its decisions regarding research ethics.

1.3 The functions of RU-HREC are supported by the Research Office, the Rhodes University Ethics Forum (RU-REF), the Rhodes University Education Faculty Research Ethics Committee (RU-EFREC) and the Rhodes University Humanities Faculty Research Ethics Committee (RU-HFREC).

1.4 Faculty Higher Degrees Committees may liaise with the RU-HREC, but they formally remain separate committees with their own Chairs or Coordinators. As scientific integrity is a principle of ethical research, dialogue across Higher Degrees Committees and the RU-HREC is useful in resolving any concerns relating to the ethics of methodology.

1.5 RU-HREC commits itself to national and international ethics principles and standards, to the Rhodes University Research Ethics Policy: Research Involving Human Participants (2021) and related documents and guidelines, and to Rhodes University rules and standards for all administrative matters.

1.6 RU-HREC's Terms of Reference (ToR) are aligned with the Rhodes University Research Ethics Policy, Research Ethics Procedures and Practices as well as with the National Health Act No. 61 of 2003 and the Department of Health's 'Ethics in Health Research' Guidelines (2015, 2023).

1.7 RU-HREC is accredited by Department of Health's National Health Research Ethics Council (NHREC) in terms of the National Health Act as per section 73 to independently conduct the transactional processes of research ethics clearances at Rhodes University.

1.8 RU-HREC reports directly to NHREC but submits reports, at least annually, to the Rhodes University Senate via the DVC: Research, Innovation and Strategic Partnerships (DVC: RISP) and the Senate Research Committee.

1.9 The RU-HREC NHREC Registration number is RC-241114-045.

2. AUTHORITY

2.1 RU-HREC is mandated to fulfil its function by the Rhodes University Senate through the Senate Research Committee, to which it reports at least annually in writing.

3. RELATIONS BETWEEN RU-HREC AND NON-NHREC REGISTERED ETHICS COMMITTEES

3.1 Rhodes University Research Ethics Forum (RU-REF) is not an accredited committee, but a strategic one, through which ethical research is supported at Rhodes University. It meets formally twice a year (with ad hoc meetings being called if necessary).

3.2 RU-REF is supported administratively by the Registrar's Office.

3.3 Without interfering with the ethics clearance decisions made by Rhodes University Animal Research Ethics Committee (RU-AREC), RU-HREC, or Faculty RECs, RU-REF provides the following supportive functions:

- advising on drafting ethics policies and guidelines
- receiving reports from the Research Ethics Committee Chairs and/or Ethics Coordinator
- assisting with the budgeting for and facilitating research ethics training and support
- reviewing reports from faculties and research units about their needs in relation to research ethics training and/or mentoring

- receiving annual reports from RU-HREC and RU-AREC to inform strategic directions regarding ethics
- facilitating resolution of disputes where necessary [Note: the role is facilitation and not arbitration: RU-REF may not overturn ethics clearance decisions]
- advocating to the Institutional Planning Committee and the Senate Research Committee about the resourcing needs of research ethics processes where necessary.

3.4 RU-REF's minutes will serve at the Research Committee. RU-REF should, where necessary, flag particular issues as Class A matters for onward reporting to Senate.

3.5 RU-EFREC and RU-HFREC are also not accredited committees, but support RU-HREC in its functions.

3.6 RU-EFREC and RU-HFREC were created to review low-risk applications in the Education and Humanities faculties, respectively

3.7 RU-EFREC and RU-HFREC screen all applications submitted to the committees, and go on to review, request changes and approve those which are low-risk.

3.8 All medium- and high-risk applications are returned to the applicant who will need to resubmit the application to RU-HREC.

3.9 Where there is any doubt as to the risk level of the application, the advice of the Chair of RU-HREC is to be sought.

3.10 Allocation of risk level is determined according to the definitions included in the Rhodes University Research Ethics Policy: Research Involving Human Participants (see 12. Risk Categories below).

4. MANDATE

4.1 The mandate of RU-HREC is to ensure that research activities involving human participants at Rhodes University comply with, but are not limited to, all the standards listed in 1.5 – 1.8 (above) and with the following core principles of research ethics:

- Respect for persons: Protection of the dignity, rights, safety, and well-being of all human participants in research.
- Respect for autonomy: control over one's own life and body;
- Beneficence: Obligation to take positive steps to prevent harm, remove harm or promote good;
- Non-maleficence: Obligation not to inflict harm;
- Justice: Being fair and act with sense of equity;
- Truthfulness & honesty: The concept of informed consent.

4.2 This will be achieved by ensuring that research proposals involving the use of human participants undergo rigorous scientific processes and ethical review.

4.3 RU-HREC will review research proposals submitted by staff, students, and other officially affiliated members of the university where the research involves human participants.

4.4 RU-HREC may, at the discretion of the Chairperson or delegated member, consider external applications to conduct research using University staff and/or students as participants.

4.5 Where applicable, reciprocal recognition of research ethics committees at other institutions, such as universities and other science councils accredited by the NHREC, will be considered to facilitate and expedite ethics clearance of projects. In cases where reciprocal approval is not possible, such applications will be considered external applications by researchers with no affiliation to the University and treated as such as per clause 4.4 above.

5. ETHICAL AND REGULATORY REQUIREMENTS

5.1 RU-HREC is guided by ethical principles laid down in the following documents and guidelines:

- Chapter 2 of the Constitution of the Republic of South Africa (1996), particularly the right to dignity (section 9), and the right to equality (section 10) and the right of freedom and security of person (section 12);
- The SA National Health Act No.61 of 2003;
- South African Children's Act No. 38 of 2005;
- Ethics in Health Research: Principles, Processes and Structures (published by the National Department of Health of South Africa, 2nd ed, Pretoria, 2015, 2023);
- Ethics in Health Research: Principles, Processes and Structures (published by the National Department of Health of South Africa, 3rd ed, Pretoria, 2023);
- South African Medical Research Council (2004): Guidelines on Ethics in Medical Research: General Principles;
- SA Department of Health (2006). South African clinical trial guidelines: Good practice for clinical trials with human participants 3rd ed. Department of Health: Pretoria, South Africa;
- World Medical Association (1965-2013): Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (as amended);
- National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (1978): Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research;
- The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services (HHS), 21 CFR 50, 21 CFR 56; ICH-GCP-E6 Sections 1-4).
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018) (Canada).

5.2 RU-HREC and the Faculty RECs commit themselves to national and international ethics principles and standards, to the RU Research Ethics Policy and related documents and guidelines, and to Rhodes University rules and standards for all administrative issues.

6. PURPOSE OF RU-HREC

6.1 The primary purpose of RU-HREC is to protect the dignity, rights, safety, and well-being of all human participants in research. RU-HREC will do this through independent, prospective, and ongoing ethics review of all research projects undertaken by members of staff, registered students, and affiliates of the University.

6.2 A secondary purpose of RU-HREC is to protect the dignity, rights, safety and well-being of university researchers conducting research on human participants, at the same time affording due consideration to the interests of the community from where participants are recruited and the reputation of the University during the course of conducting the research.

7. FUNCTIONS AND ROLE OF RU-HREC

7.1 The directive of RU-HREC:

- To advise the Vice-Chancellor and DVC: RISP, as well as RU Senate on all matters pertaining to the ethics of research involving human participants.
- To ensure that committee members attend an Induction Course on research ethics at the start of their term of office, and the continuous professional development of its members in terms of ethical principles of research involving human participants through accredited courses that are run by an NHREC accredited provider(s) and/or by RU.

- To conduct rigorous ethics review of all submitted research proposals involving human participants to ensure that welfare and other interests of participants, researchers, the community, and the University are properly protected and that the proposed research is compliant with ethical norms and standards.
- To conduct rigorous ethics review of all submitted research proposals involving human participants to be conducted at the institution or in places away from the institution by staff and/or students and/or other stakeholders associated with the institution.
- To examine and authorise, subject to modification, or reject all proposals for research involving human participants to be carried out within the ambit of RU, in accordance with current standards and guidelines.
- To review progress reports of already approved research projects after one year of implementation with the view to either approve the project for an extended period upon application or in the case of unethical conduct to suspend or terminate re-approval depending on the nature of the problem identified.
- To review and request modifications to any protocol revisions to already approved research projects requested by applicants and authorise such amendments provided they do not deviate extensively from the original protocol.
- To conduct investigations into any reported allegations of misconduct in research involving human participants.
- To perform active and passive monitoring of all medium and hight risk- studies in accordance with SOP 2.3 RU-HREC REVIEW PROCESSES, SECTION 15.
- To submit annual reports to the NHREC, to the DVC: RISP of RU, as well as Senate of RU, without compromising confidentiality of the individual applications for ethical clearance that had been submitted to RU-HREC for consideration during a particular reporting period.

7.2 RU-HREC Terms of Reference and Standard Operating Procedures (SOPs) must be reviewed and updated, and any updates implemented, in response to changes in the respective South African legislation, NHREC guidelines or notices published in the government gazette, and/or response to any changes in the RU policies which have implications in terms of ethics involving human participants.

7.3 RU-HREC ToR must be reviewed every five years. Any changes must be ratified by a majority of all RU-HREC members in a properly constituted and quorate meeting of RU-HREC, by all faculty boards of RU, as well as Academic Senate of RU and the RU Council. After which, the respective changes take effect.

7.4 RU-HREC SOPs must be reviewed every three years. Any changes must be ratified by a majority of all RU-HREC members in a properly constituted and quorate meeting of RU-HREC, after which, the respective changes take effect.

7.5 RU-HREC SOPs must deal with (among other things) non- compliance with current standards and guidelines, allegations of research misconduct, appeals and any other grievance related to the RU-HREC process. Such procedures must clearly define the reporting mechanisms and responsibilities of all parties to ensure fair and effective processes.

7.6 Protocol deviations and violations, plus human participant welfare issues and alleged unethical treatment of research human participants are detailed in SOP 3.3 CONSEQUENCES OF NON-COMPLIANCE, PROTOCOL VIOLATION OR UNETHICAL RESEARCH PRACTICE.

7.7 The RU-HREC Chairperson, supported by the Ethics Coordinator, is mandated to deal with matters between meetings, duly authorised by the full committee.

7.8 RU-HREC has the authority, from time to time, to appoint a standing or ad hoc subcommittee to investigate or finalise certain matters under its jurisdiction, in compliance with applicable norms, rules and regulation.

8. CONSTITUTION OF RU-HREC

8.1 The DVC: RISP's Office will provide, through the Chair of RU-HREC, an outline of the roles and responsibilities of RU-HREC members to the Community Engagement Division, Senate, and Faculties that conduct research involving human participants to guide them in their nomination of members. Each of these entities has the obligation to ensure that their nominees have the necessary background and experience to contribute constructively to RU-HREC and are willing to undergo training.

8.2 The Directors/Heads of Departments (HoDs) will provide the Chairperson and/or Ethics Coordinator with the names of the nominated person(s) with brief reasons for their nomination. They should be drawn from academic and research staff based on their experience in research, and the related ethical considerations. They should have substantial and recent experience in research involving human participants.

8.3 Members of RU-HREC and Education and Humanities RECs may overlap with Faculty Higher Degrees Committees. The committees must meet separately as they play different, albeit complementary, roles.

8.4 All new members to RU-HREC will undergo a formalised set of induction requirements, including:

1) Successful completion of an online Research Ethics programme such as TRREE or TCPS 2.
2) Receive a full set of the RU-HREC Guidelines and SOPs as well as the relevant National Guidelines and core reading material.
3) Orientation / Induction session to go through RU-HREC SOP's, guidelines and processes as coordinated and offered by the RU-HREC Chairperson and/or Coordinator.
4) Training in the use of the relevant software application used (Infonetica) as arranged by the RU-HREC Chairperson and/or Coordinator.
5) Attendance of at least one (preferably three) full RU-HREC meetings as an observer

8.5 After selection, RU-HREC members are formally appointed by the DVC: RISP and the RU-HREC Chairperson via official letters.

8.6 Members of RU-HREC will be appointed for a period of three years. Re-nomination for one further term is possible.

8.7 Conditions of appointment entail a description of the expectations of members, including, but not limited to their signing a Confidentiality Agreement and declaring a Conflict-of-Interest where applicable to individual matters tabled at monthly meetings.

8.8 The Chair and Deputy Chair are appointed by the 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 RECs will be called for by the DVC: RISP through the Chairperson and/or Ethics Coordinator. 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. The successful candidate will be vetted by the DVC: RISP and appointed for a (renewable) period of three-years through formal letter.

8.9 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.

9. COMPOSITION OF RU-HREC

9.1 The composition of RU-HREC must meet the minimum standards and requirements set out in:

- Ethics in Health Research: Principles, Processes and Structures 2nd ed, Department of Health, Republic of South Africa, 2015, 2024;
- Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Department of Health, Republic of South Africa, 2006.

9.2 RU-HREC consists of at least 9 members including:

- The Chair of RU-HREC.
- The Deputy Chair of RU-HREC
- The Chair and/or Deputy Chair of the Education and Humanities RECs.
- At least one further delegate from each of the Education and Humanities RECs (delegates may vary by meeting).
- Elected members of faculties.
- Two Senate representatives.
- One representative of the Community Engagement Division.
- One external representative of a community-based organisation or non- governmental organisation.
- The Ethics Coordinator.

9.3 Each of the above categories should be represented in the membership of the committee (given that one individual may represent more than one category).

9.4 RU-HREC members are selected by their respective faculties and serve on a voluntary basis without financial compensation.

9.5 RU-HREC may co-opt members when necessary, for example:

- For capacity building: colleagues from the same discipline as a committee member may be appointed to attend a specific meeting when that member is unable to attend.
- Where appropriate, specialists and other advisers may be invited to attend meetings and/or give input. Such members are not eligible to vote.
- Observer members and applicants may attend meetings with the prior agreement of the Chairperson of RU-HREC. Such members are not eligible to vote.

9.6 Should an emergency arise in research which involve human participants, and a decision about human participant ethics and its implications for the academic project of RU be required on short notice, the **Executive Committee of RU-HREC (EXCO)** must be constituted swiftly to act on behalf of RU-HREC. EXCO comprises the Chairperson, the Deputy Chairperson and two other senior RU-HREC members with experience in the ethics of research involving human participants.

9.7 All decisions of the EXCO must be tabled at the following meeting of the RU-HREC and these decisions must also be communicated to the DVC: RISP.

9.8 Documenting the activities of RU-HREC is via minutes of Committee meetings and comprehensive record keeping of protocols reviewed by the Committee. Minutes should be:

- A reflection of the agenda of the meeting and must record the discussion and action taken on each agenda item;
- An accurate reflection of the matters considered and the justification for the subsequent decisions taken;
- Detailed enough to reconstruct its decisions at a later date if necessary, to protect itself and the institution;
- Show concern for participant's rights, safety, and well-being.

9.9 The above-mentioned mechanisms operate to ensure that the quality of ethics review is consistent across all committees, and specifically RECs as subcommittee of RU-HREC.

10. COMMITTEE MEETINGS AND QUORUM RULES

10.1 At least 10 meetings will be held per year, monthly between January and November.
10.2 Meeting dates will be available on the University website, on the Research Ethics webpage.
10.3 Except when an expedited procedure is used, RU-HREC must review initial and continuing studies at quorate committee meetings.
10.4 The Chair may invite applicant researchers to meetings if this is deemed to facilitate the clearance process.
10.5 Where RU-HREC comprises 15 or more members there is quorum if one third of the appointed RU-HREC members, including either the Chairperson or Deputy Chairperson, are in attendance.
10.6 Where RU-HREC comprises less than 15 members there is quorum if a simple majority of members, including either the Chairperson or Deputy Chairperson, are in attendance.
10.7 Should the meeting be non-quorate, RU-HREC Executive Committee (EXCO) should be constituted if possible. EXCO comprises the Chairperson, the Deputy Chairperson and two other RU-HREC members with experience in the ethics of research involving human participants.
10.8 Provided it is possible to constitute EXCO, the meeting may go ahead, but all recommendations made, together with PDFs of the applications deliberated on must be forwarded to all Committee members via Chair's Circular the next working day after the meeting. Committee members have 48 hours to give their input and assessment of the recommendations, after which the committee's decisions will be ratified / amended accordingly and then communicated to applicants.
10.8 If it is not possible to constitute EXCO, the meeting should be postponed to a later date.

11. COMMITTEE DECISIONS

11.1. The final recommended decision will be by consensus or, where this is not possible, by majority vote of the committee.
11.2. If minor modifications are required, the researcher will be invited to effect these changes on the online system (ERAS). The researcher may upload a covering letter on the ERAS system outlining how the changes have been effected. The Chair may review these changes and issue an ethics clearance letter if satisfied. The Chair may also elicit the opinion of one or more other members of RU-HREC if uncertain that the changes have been effected satisfactorily.
11.3. If major modifications are required, the researcher will be invited to effect these changes on the online system (ERAS). The researcher may upload a covering letter on the ERAS system outlining how the changes have been effected. Major modified applications must go before a second Committee meeting and be deliberated on again before a decision is made.
11.4. In either case (major and minor modifications) the researcher may upload a letter outlining substantive reasons for disagreeing with certain recommendations (where these apply). These will be considered by the Chair who may elicit the opinion of one or more other members of RU-HREC.

12. RISK CATEGORIES

12.1. Risk category 1: No ethics clearance required

Definition: No contact with human participants. For example: Use of previously-collected data that received ethics clearance; use of anonymized human datasets; document analysis of documents firmly in public domain; literature review; studies based on theoretical or secondary analysis alone; use of human biological material (e.g. human cells lines from a commercial source(s) or established cell lines, where the results or the sourcing of such materials definitely do not lead to social risks); use of open

access digital texts that are in the public domain. A letter confirming Research Ethics Waiver will be issued by the Chair of RU-HREC should this be required for publication purposes.

12.2. **Risk category 2: Low (Minimal) risk**

Definition: The risk of harm is no greater than those imposed by daily life under stable social conditions, or in undertaking routine educational, psychological, health or social interventions or tests; or where the only foreseeable risk is minimal discomfort. For example: Market research; non-sensitive questions about people's everyday lives, and opinions; review of non-sensitive privileged information (e.g. documentation not publicly available); research on usual classroom or educational activities, routine psycho-social interventions (e.g. empowerment programmes). [Note: usual classroom, educational or psycho-social activities may include minors; where minors are not expected to do anything more than participate in usual activities associated with these activities, the study may be assigned low risk status]

12.3. **Risk category 3: Medium risk**

Definition: Where risk to participants, researchers and/or institutions is greater than those imposed by daily life under stable social conditions, but where appropriate steps can be taken to mitigate or reduce overall risk; the risk of harm is reasonable in relation to anticipated benefits or knowledge gained. For example: Research concerning topics that have the potential to evoke negative feelings; research involving groups with vulnerabilities; research conducted in a locality that may contain potential risks to the participants and/or researchers.

12.4. **Risk category 4: High risk**

Definition: Where there is significant and likely risk of harm to researcher, participant(s) and institutions which may lead to serious adverse consequences if not managed in a responsible manner; remedial interventions might be possible should harm occur, including by external professional intervention. The absence of remedial measures does not automatically disqualify the study where the risk of harm is reasonable in relation to anticipated benefits or knowledge gained. For example: Research on highly sensitive topics such as experiences of violence, rape, illegal activities; research involving groups with significant vulnerabilities or multiple vulnerabilities; research conducted in a locality that definitely contains risks to the participants and/or researchers; research involving deception of the participants; research involving illegal activities; research activities in which the participants may place themselves at risk of harm if they participate; research activities in which the researcher may place themselves at risk of harm; where the researcher may place themselves at risk of breaking the law.

13. ROLE AND RESPONSIBILITIES OF ETHICS COORDINATOR

13.1. The Ethics Coordinator occupies a full-time, permanent post. They report administratively to the Director of Research. They support the Chairs and committees of RU-REF, RU-HREC, RU-AREC, RU-EFREC and RU-HFREC.

13.2. Responsibilities of the Coordinator:

- Co-ordinate administer and develop the administrative aspects of the ethical application and review processes.
- Provide support, education, and training in relation to research ethics.
- Assist RU researchers in their ethics application process.
- Provide administrative and operational support in the research ethics application process, including prompt processing of research ethics submissions to the relevant REC through all stages of review, clearance, and monitoring.

- Maintain the Rhodes University Ethics website and online submission platform.
- Support the work of the Chairs, Faculty Representatives, and ethics committee members.
- Assist with coordinating the Rhodes University strategic approach that contributes to the University's research strategy, including the REC's roles in the intellectual health, growth, and reputation of ethical research
- Provide an outline of the roles and responsibilities of RU-HREC members to the Community Engagement Division and Senate to guide them in their nomination of members.

14. NON-AFFILIATED RESEARCHERS

14.1. Researchers with no affiliation to the University may approach RU-HREC to review their research proposals for non-medical research with human participants.

14.2. RU-HREC may exercise its discretion on a case-by-case basis to decide whether to review the proposal or whether to refer the applicant elsewhere to access appropriate expertise and capacity to evaluate the application.

14.3. In the case of RU-HREC reviewing a proposal from a non-affiliated applicant, an appropriate fee may be levied for such a service.

15. EFFECTIVE DATE OF THESE TERMS OF REFERENCE

27 April 2024 with the next revision date being 27 April 2029, or as deemed necessary by a quorate meeting of RU-HREC.