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RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

SOP 2.3 RU-HREC REVIEW PROCESSES

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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 (2023): 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 REVIEW PROCESSES

1. Purpose

The purpose of these guidelines is to outline the requirements for and processes of application for ethical review of research protocols involving research with human participants.

2. Definitions of Risk Categories

2.1 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.

2.2 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]

2.3 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.

2.4 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.

3. Projects exempt from RU-HREC Ethics Clearance

3.1. Risk category 1 research projects do not require ethics clearance. These are projects that involve 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 available in the public domain; literature review; studies based on theoretical or secondary analysis alone; use of open access digital texts that are in the public domain and use of human biological material that has not been collected from human subjects (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).

3.2. It is not necessary to apply for ethics approval in the case of Risk category 1 research projects, but if such an application is submitted, an Ethics Waiver letter will be issued.

3.3. A Rhodes researcher who has conducted a Risk category 1 research project may apply to the Chair of RU-HREC for an ethics waiver letter should this be required during the publication of their research findings.

4. Requirements for Research Ethics Clearance

4.1. All Rhodes University student and staff research projects that involve human participants must have obtained ethics approval before data collection begins.

4.2. With the exception of Science Faculty applications, all Masters and PhD research proposals must have received approval from the relevant Higher Degree Committees prior to submission for ethical clearance.

4.3. Normally, ethics approval must be obtained before data collection commences. RU-HREC will not provide clearance for retrospective applications, except where the activity being researched was not initially set up as a research project. For example, student assignments from past years; case notes taken by healthcare workers and therapists; administrative data collected by government or other agencies. These participants' data were collected for other intentions and their informed consent to have the material used for research purposes may, depending on the data, need to be sought.

5. Applying for Research Ethics Clearance

5.1. RU researchers who intend to perform research involving human participants shall obtain ethics clearance prior to data collection or, on rare occasions retrospectively (see Section 4.3 above).

5.2. An ethics protocol must be completed through formal channels, currently through the online Ethics Research Application System (ERAS): https://www.ru.ac.za/researchgateway/ethics/

5.3. Risk category 2 applications (low-risk) from Education and Humanities Faculties are to be submitted to the respective Faculty RECs for review.

5.4. Applications submitted to the Education and Humanities RECs that turn out to be Risk category 3 (moderate-risk) or 4 (high risk) are to be referred to RU-HREC for review.

5.5. Risk category 2 applications (low-risk) from all other faculties and all Risk category 3 (moderate-risk) and category 4 (high risk) applications are to be submitted to RU-HREC for review.

6. Expedited Review

6.1. On rare occasions, with valid reasons, expedited review may be effected through the following mechanisms:

1) Low-risk projects may be reviewed and decided by the appropriate REC Chair.
2) Medium and high-risk projects should only be expedited with very good reason and must be reviewed by at least two reviewers. If review recommendations align, ethics clearance can be decided upon in an ad-hoc meeting of RU-HREC or through RU-HREC Chair's circular.

7. Assigning Research Ethics Applications to Reviewers

7.1. The Coordinator will assign ethics reviewers in accordance with NRU-HREC guidelines.

7.2. For ethics reviews to be thorough, rigorous, and supportive, careful selection of reviewers is necessary. For an adjudged low risk study, at least one reviewer should be assigned, and for medium or high-risk levels, two reviewers should be assigned.

7.3. Ideally at least one reviewer should hold a PhD in the relevant or cognate discipline

7.4. Preferably both reviewers should:

1) hold a PhD.
2) be research active and/or supervise postgraduate research.
3) have submitted ethics clearance applications themselves.
4) completed reviewer induction training.
5) completed additional reviewer training.

7.5. For capacity development, a less experienced reviewer may be paired with a reviewer with the above requirements for ethics protocols at low or, at times, medium risk.

7.6. Reviewers should have no vested interest in the study being reviewed; they should not be a supervisor or co-supervisor, or research team member, or a family member of the applicants.

7.7. Where the Chair of RU-HREC is the applicant, or supervising a student applying for ethics clearance, the Deputy Chair should manage the review and discussion of the application. The Chair will recuse themselves from any committee discussions and voting.

8. RU-HREC Review Criteria:

8.1. Social and scientific value: The proposed research must demonstrate relevance to:

1) The community involved and/or the greater South African and/or African community
2) The advancement of knowledge/the scientific field in the proposed area of study and/or related areas of study.

8.2. The proposed research must be:

1) Well designed and conducted (e.g. clear aims, rigorous design, adequate sample, adherence to GCP, sound data analysis).
2) Not expose participants to inconvenience or risk of harm without possible benefit to society or where the research will not generate the intended knowledge.

8.3. Reasonable risk-benefit ratio: The potential risks to individual subjects in the proposed research must be outweighed by the benefits to the individual or society. Risks to participants are reasonable in relation to:

1) The anticipated benefits to participants and/or the broader community; and
2) The importance of the knowledge that may reasonably be expected to result.
3) ALL the following requirements must be satisfied:
    i. The potential risks to individual participants are identified and minimized.
    ii. The proposed research involves procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
    iii. Risk minimization measures are undertaken and stated in the protocol.
    iv. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
    v. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
    vi. The potential benefits of the research to participants and/or the wider community are identified and maximized. NOTE: Compensation for time and inconvenience, and reimbursement for expenses such as travel are not considered research benefits.
    vii. In evaluating risks and benefits, RU-HREC shall consider only those risks and benefits that may result from the research itself (as distinguished from risks and benefits of therapies participants would receive as standard clinical practice, even if not participating in the research). RU-HREC shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks and benefits that fall within the purview of its responsibility.

8.4. The selection of research participants for the proposed research must be fair and just. In making this assessment RU-HREC shall take into account the purpose of the research and the setting in which the research will be conducted and shall be particularly cognizant of the special challenges of research involving vulnerable populations, such as children, prisoners, pregnant women, intellectually impaired persons, or economically or educationally disadvantaged persons.

1) Participants must be selected:
    i. According to the scientific goals of the study (not for non-scientific reasons e.g. convenient, vulnerable, less able to protect their rights); and
    ii. To minimize risks (some participants may be eligible for scientific reasons, but at substantially higher risk of harm, e.g. impoverished and vulnerable to undue inducements);
    iii. To fairly distribute benefits and burdens. Research can provide direct and indirect benefits. Participants should be selected so that these benefits are fairly distributed;
    iv. Participants and/or communities should not be excluded without sound justification. Unfair exclusion from research may deny these participants and/or communities relevant knowledge/ health interventions.

v. Individuals and groups who bear the burdens of the research should share its benefits (new knowledge or products). Those who stand to benefit from research must contribute to its risks and discomforts. No group of persons should be asked to bear more than their fair share of the burdens of research; no group (e.g. impoverished) should be asked to bear research risks in order that others (e.g. the wealthy) enjoy benefits (new knowledge or products);
vi. The research should avoid vulnerable participants when less vulnerable persons could be involved.
vii. When some or all of the participants are likely to be vulnerable, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the applicant has:
- Justified why vulnerable individuals/communities are included;
- Clearly articulated, additional safeguards in the proposed research to minimize risks for, and protect the rights and welfare of, these participants.

8.5. The use of socially constructed categories, such as race, ethnicity, and gender: RU-HREC recognizes that human categories such as race, ethnicity and gender are social constructs:

1) The use of socially constructed categories, such as race, ethnicity and gender in research must be adequately justified;
2) The onus is on the research applicant to adequately justify to the RU-HREC the value and meaning of the use of such categories, inclusive of how it will be documented and reported on for the purposes of the study;
3) The researcher(s) must have the necessary expertise/ background to carefully navigate the contours of these complex constructs, and evidence of such expertise and/or support must be provided to RU-HREC;
4) Participants must retain the right to self-identification and preference not to answer;
5) Research proposing the use of socially constructed categories will warrant review by two reviewers and discussed at a full RU-HREC meeting. The discussion will be documented in RU-HREC meeting minutes;
6) When reviewing research protocols where human categories are included in the fabric of the study (e.g. in the aim, methodology, research instrument(s), ICF and or recruitment strategies) RU-HREC reviewers must carefully consider the rationale, justification and evidence of the careful unpacking of intricacies as provided by the researcher(s) for the inclusion of such variables(s) for data collection, analysis or reporting;
7) RU-HREC follows a structured and disciplined process as outlined by the SA Constitution, international and national guidelines, and the NDOH guidelines (2015), which state that: “Information about a person’s race or ethnic origin must be necessary (s 29(a)) or for affirmative action purposes (s 29(b))”; and that “Persons should not be excluded unreasonably or unfairly on the basis of any of the prohibited grounds for discrimination: race, age, sex, sexual orientation, disability, education, religious belief, pregnancy, marital status, ethnic or social

origin, conscience, belief or language (s 8 of the Constitution); and "Similarly, persons should not be unfairly targeted for research merely on the basis of one or other of these grounds."

9. Review and Approval of Research Protocols

9.1. All Ethics Applications will be reviewed with reference to the criteria outlined in Section 8 (above).

9.2. Reviewers are to review applications online in the ERAS system where they are to make detailed comments and suggestions.

9.3. A report on each application reviewed must be submitted either prior to or at the meeting (template provided to reviewers on appointment to the committee).

9.4. Unless expedited, all applications are to be deliberated on in a full RU-HREC meeting or RU-HREC EXCO and Chair's circular in the case of meetings being non quorate in which case absent committee members are given 48 hours to provide additional feedback to the Chair before decisions are communicated to applicants. (See RU-HREC Terms of Reference Section 10. Committee meetings and Quorum Rules, p 8 and SOP 2.2 RU-HREC Committee Meetings).

9.5. Decision-making at RU-HREC meetings is by consensus. At the Chairperson's discretion, voting may be decided by a show of hands**.**

9.6. Voting by proxy is not allowed.

9.7. Ad hoc/co-opted reviewers and ex officio members may not vote.

9.8. Procedures for running meetings including quorum and the management of conflict of interest and confidentiality are outlined in SOP 2.2 RU-HREC Committee Meetings.

10. Prompt Notification of Decisions

10.1. Decisions made during quorate RU-HREC committee meetings are to be communicated to applicants within 48 hours of the meeting (Monday – Friday).

10.2. Decisions made during non-quorate meetings are to be communicated as soon as possible after the meeting once feedback has been received from absent reviewers and taken account of.

10.3. Notifications of decisions are communicated to applicants via email that must include:

1) The decision (Approved / Minor modifications required / Major modifications required / Rejected).
2) If modifications are required, a list of reviewer comments / required changes.

11. Annual Reports

11.1. Ethics clearance is valid for one year, after which application for extension is required. Extensions may be applied for through the automated annual report generated by the ERAS system and/or correspondence with the relevant chair.

11.2. Applicants must complete an online annual report on ERAS which:

1) Allows the applicant to request extension or close the project.
2) Report on any deviations from the original protocol.

11.3. The Ethics Coordinator will review annual reports monthly prior to the RU-HREC meeting:

1) Closures and extension requests with no protocol deviations are to be actioned.
2) Minor deviations are to be forwarded to the Chair for protocol amendment.

3) Major deviations are to be placed on the agenda of the next meeting for deliberation. The committee will decide whether to approve the amendment or require a new application.

12. Protocol Amendments

12.1. Should an applicant wish to amend the original protocol for which approval has been received, they should apply to the Chair of RU-HREC in writing, providing the following information:

1) The precise changes to be made in terms of research participants / research methods / other are to be explained; any supporting documents for example research instruments are to be attached.
2) The reasons for the proposed changes are to be outlined.

12.2. The Chair will review the protocol amendment request:

1) The Chair may grant minor or straight-forward protocol amendments in which case an approval of protocol amendment letter is to be forwarded to the applicant and filed for recording purposes. Amendments are to be placed on the agenda of the next meeting for noting.
2) Major or more complex amendments are to be placed on the agenda of the next meeting for deliberation. The original two reviewers will review the amendments and the committee will decide whether to approve the amendment or require a new application. In the case of the former, an approval of protocol amendment letter is to be forwarded to the applicant and filed for recording purposes.

13. Protocol deviations and protocol violations

13.1. A protocol deviation is when a researcher deviates slightly to moderately from the approved research protocol without requesting a protocol amendment (section 12 above).

13.2. A protocol violation is when a researcher significantly alters the approved research protocol without requesting a protocol amendment (section 12 above).

13.3. Reports of protocol deviation and/or violation may be submitted by internal or external parties via the whistleblowing procedures outlined in SOP 3.3 PROCEDURES FOR REPORTING ALLEGATIONS OF MISCONDUCT / NONCOMPLIANCE / UNETHICAL RESEARCH PRACTICE.

13.4. Reports of protocol deviations should be submitted as soon as possible, and within one month of the incident occurring.

13.5. Procedures for dealing with protocol deviations and protocol violations are dealt with in SOP 3.4 CONSEQUENCES FOR NON-COMPLIANCE.

14. Suspension and termination of projects

14.1. Where circumstances indicate that a project is non-compliant with the approved protocol and the interests of participants are at risk of harm, the REC may withdraw approval, after due process has been followed:

1) RU-HREC EXCO is to be constituted (EXCO comprises the Chairperson, the Deputy Chairperson and two other RU-HREC members with experience in research involving human participants).
2) The investigation process must be fair and transparent: RU-HREC EXCO will convene a meeting with the researchers concerned and any other interested parties.

3) After the investigation meeting, RU-HREC EXCO will deliberate and reach one of the following decisions:
   - The researcher/s satisfactorily defended allegations of non-compliance; no need for further action to be taken.
   - Suspension (temporary stoppage) of approval with recommended remedial action and reinstatement of approval once remedial actions have been taken to the satisfaction of RU-HREC EXCO.
   - Termination (permanent stoppage/withdrawal) of approval.

14.2. The decision is to be communicated to the principal investigator and other interested parties, including the institutional authorities.

14.3. In the case of suspension or termination, the principal investigator should comply with the recommendations and any special conditions imposed by the REC.

15. Compliance checks and audits

15.1. Passive monitoring of approved applications takes place via the Annual Report process described in section 11 (above).

15.2. Active monitoring of medium-risk applications:

1) Two – three medium-risk applications per year are to be randomly selected for active monitoring. The Chair / Deputy Chair / a senior RU-HREC committee member is to visit the research site, for inspection purposes.

15.3. Active monitoring of high-high-risk applications:

1) All high-risk applications are to be recorded in a data base compiled for this purpose.
2) Applicants will need to provide six-monthly reports, one of which being the online Annual Report described in section 10 (above).
3) The second will involve completion of a questionnaire and possible meeting with the Chair if deemed necessary by the Chair / Deputy Chair / any RU-HREC committee member.
4) Two – three high-risk applications per year are to be randomly selected for active monitoring. The Chair / Deputy Chair / a senior RU-HREC committee member is to visit the research site, for inspection purposes.

16. 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.