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RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE SOP 2.2 HUMAN RESEARCH ETHICS COMMITTEE MEETINGS

| Approved by: | Name | Signature | Date |
|---------------------------------|---------------|-----------|------------|
| Human Research Ethics Committee | Janet Hayward | | 29/01/2023 |
| Endorsed by: | | | |
| VC Legal Unit | Ismail Amjec | | 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 (November 2014): Rhodes University Ethical Standards Handbook (comprising Institutional Policy, Terms of Reference and Standard Operation 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).

HUMAN RESEARCH ETHICS COMMITTEE MEETINGS

1. Purpose

The purpose of these guidelines is to outline the procedure for running meetings including quorum and the management of conflict of interest and confidentiality.

2. Meetings

- 2.1 At least 10 meetings will be held per year, one per month from January to November.
- 2.2 Meeting dates will be available on the University website, on the Research Ethics webpage.
- 2.3 Generally, decision-making at RU-HREC meetings is by consensus. At the Chairperson's discretion, voting may be decided by a show of hands.
- 2.4 Any member with a conflict of interest with respect to a specific study (see definitions below) must leave the room during deliberations and decision-making relating to the study. This member may not vote on the application.
- 2.5 Voting by proxy is not allowed.
- 2.6 Ad hoc/co-opted reviewers and ex officio members may not vote

3. Quorum

- 3.1. Except when an expedited procedure is used, the RU-HREC must review initial and continuing studies at committee meetings.
- 3.2. Where RU-HREC comprises 15 or more members a quorum is upheld if one third of the appointed RU-HREC members, including either the Chairperson or Deputy Chairperson, are in attendance.
- 3.3. Where RU-HREC comprises less than 15 members a quorum is upheld if a simple majority of members, including either the Chairperson or Deputy Chairperson, are in attendance.
- 3.4. 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 extensive experience in the ethics of research involving human participants.
- 3.5. 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.
- 3.6. 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.
- 3.7. If it is not possible to constitute EXCO, the meeting should be postponed to a later date.

4. Conflict of Interest

- 4.1. RU-HREC members are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence.
- 4.2. RU-HREC members and/or immediate family i.e. spouse or dependents may be involved in activities that could be perceived as conflicting with their RU-HREC responsibility. The integrity of the RU-HREC review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided.
- 4.3. Conflict of interest of a RU-HREC member generally includes the following:

- 1) Relationship to the research study: The RU-HREC member (his/her spouse or immediate family member) is listed as –
 - i. one of the research team members of the study,
 - ii. one of the supervisory team of a postgraduate student's study,
- 2) **Personal relationship:** The RU-HREC member has an immediate family relationship or other close relationship with one of the researchers (immediate family' means the RU-HREC member's domestic partner and dependent children).
- 3) **A financial interest:** The RU-HREC member holds significant equity or stock options, receives, or expects to receive compensation with a value that may be affected by the outcome of the study, has an ownership interest (including patent, trademark or copyright interest) in the drug, product or technology that is the subject of the research, or receives a significant amount annually as a salary, consulting income or other compensation from the sponsor.
- 4) **A fiduciary relationship to the sponsor:** The RU-HREC member serves as an executive to a company sponsoring the research or serves on the company's board of directors, or is a consultant to the company.
- 5) **Other examples of conflicting interests** include but are not limited to the following-
 - i. Committee member has an interest that he/she believes conflicts with the member's ability to review a protocol objectively.
 - ii. Committee member is in direct competition with the investigators for limited resources, funding, sponsorship or research participants, or the Committee member is considered a personal or professional adversary of the investigator. Since such situations may depend on the circumstances, the Committee member should raise such a situation as soon as possible with the Chairperson. The standard used by the Chairperson is whether an independent observer could reasonably question whether the individual's actions or decisions would be based on factors other than the rights, welfare, and safety of participant.
 - iii. Any other reason for which the Committee member believes he/she has a conflicting interest with the research.

5. The procedure to follow when a conflict of interest is identified:

- 5.1. The RU-HREC member discloses those interests that pertain to the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the review of the protocol or related matters.
- 5.2. The RU-HREC member should not accept the relevant protocol for review and should return it for assignment to another reviewer.
- 5.3. The Chairperson must ensure that the relevant RU-HREC member leaves the room when the protocol comes under discussion so that they do not participate in the discussion or vote on the protocol.
- 5.4. In a case where the Committee needs further information on the study from the member with a conflicting interest, the member may remain in the meeting room during the presentation of the study, but must then leave/recuse themselves from the meeting room during the deliberative discussion and voting on the protocol.

- 5.5. The RU-HREC member's absence will be documented in the minutes with the indication that a conflict of interest was the reason for the absence. The outcome of the committee decision in the absence of the recused member will not be discussed upon return of the member concerned but may be conveyed after closure of the meeting.
- 5.6. If the conflict of interest involves the Chairperson, he/she will appoint the Deputy Chairperson, or another member as acting chairperson (with approval of the RU-HREC). The acting chairperson will conduct the meeting, for the remainder of the discussion of the item in question.

6. Confidentiality

- 6.1. **Confidential information** shall mean certain proprietary, personal, or protocol-specific information, which the RU-HREC member acknowledges to be confidential. Such information includes all protocols relating to research with human participants and associated documentation.
- 6.2. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, patient requirements, biological materials, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software.
- 6.3. All RU-HREC members and support staff shall sign a standard confidentiality and non-disclosure agreement on appointment to RU-HREC.
- 6.4. The chairperson reminds members about this condition at every meeting.

7. 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.