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RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

SOP 1.1 MAINTENANCE OF RECORDS

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

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DOCUMENT HISTORY
Version 1.0 (December 2023)

MAINTENANCE OF RECORDS

1. Purpose

The purpose of this SOP is to formalise a procedure for record keeping and accessing meeting minutes and records of ethics applications and committee membership.

2. RU-HREC Meeting Minutes

- 2.1. The RU-HREC will hold at least ten meetings per year.
- 2.2. The RU-HREC meets every month face-to-face, normally during the fourth week of the months February – December.
- 2.3. The schedule of the meeting dates for the year is available on the Rhodes Research Ethics website.
- 2.4. Documenting the activities of RU-HREC is via minutes of Committee meetings.
- 2.5. Prior to a scheduled meeting, the agenda and supporting documents are prepared by the Administrator.
- 2.6. After being approved by the Chairperson, they are electronically circulated to RU-HREC members prior to every meeting.
- 2.7. Minutes should be:
 - 1) A reflection of the agenda of the meeting and must record the discussion and action taken on each agenda item.
 - 2) An accurate reflection of the matters considered and the justification for the subsequent decisions taken.
 - 3) Detailed enough to reconstruct its decisions at a later date if necessary to protect itself and the institution.
 - 4) Such that it shows concern for a participant's rights, safety and well-being.
- 2.8. The meeting minutes must also document committee members' attendance with respect to the following:
 - 1) Attendance at the meeting;
 - 2) Member's absence from discussion, deliberation, and vote on specific protocols because of financial or non-financial conflict of interest;
 - 3) The presence of a quorum at the meeting including the presence of one non-scientific member;
 - 4) The name of RU-HREC members who recused themselves and for which item, due to conflict of interest.
- 2.9. The draft of the minutes is reviewed by the Chairperson prior to distribution.
 - 1) The correction or comments on the minutes are made at the following convened meeting. If none is made, a motion to approve the minutes is made and voted on.
 - 2) After approval, the RU-HREC administrator files a copy of the minutes, copies of all documentation (agenda, minutes, protocols and approval letters) in the RU-HREC google drive folder.
- 2.10. For all protocols under review at the meeting, the minutes must reflect:
 - 1) The project reference number, names of the researcher and, study title.
 - 2) Deliberations, actions and votes (if applicable) on each study undergoing initial or continuing review, and each amendment or revision requiring full-committee review.

- 3) Actions taken are recorded as follows:
 - i. Approved
 - ii. Approved with minor modifications
 - iii. Approved with major modifications
 - iv. Not Approved
- 2.11. Minor modifications may be reviewed by the Chair and the application approved if revisions have been made to the satisfaction of the Chair.
- 2.12. Major modifications may be reviewed by the Chair or Deputy Chair, but the application must go before another RU-HREC meeting for deliberation.
- 2.13. The duration of ethical approval is 1 year. Once this period lapses, the researcher should apply for an extension of the ethics approval.
- 2.14. Minutes will not be made available to others outside the university administration unless otherwise required by law or external regulations.
- 2.15. Expedited approvals, external applications, protocol amendment approvals and any other matters handled by the Chair and/or Deputy Chair in between meetings will be captured in the minutes for noting.

3. Record-keeping: Ethics applications

- 3.1. Records kept by RU-HREC include the following:
 - a. Research Protocols;
 - b. The details of the investigator, supervisor, and / or collaborator(s);
 - c. The gatekeeper request and permission documents;
 - d. The informed consent documents;
 - e. The participant recruitment documents;
 - f. The records of continuing review activities;
 - g. The amendments to previously approved research and /or protocol deviations;
 - h. Extension of ethical clearance approval letters;
 - i. Project closure approval letters;
 - j. All correspondence between the RU-HREC and the researchers.
- 3.2. A RU-HREC reference number is allocated to all new applications. This number is recorded on all correspondence and additional attachments/amendments.
- 3.3. The meeting resolutions and relevant feedback on the studies are communicated to the researcher within three to six days working days of the RU-HREC meetings via the electronic application system known as ERAS.
- 3.4. The following information is included in the feedback to researchers upon the study serving at a meeting:
 - 1) If revisions are required, a list of panel comments with reasons will be outlined on ERAS.
 - 2) If not approved, the reason for the decision will also be communicated.
 - 3) If deferred, the reasons why the study had to be held over until the next meeting will be detailed in the minutes.
- 3.5. Upon approval of a protocol, a letter of approval, including any standard regulatory requirements and/or conditions that must be agreed to before approval, is clearly outlined in a letter drafted by the RU-HREC Administrator with the approval of the Chairperson.

- 3.6. The Chairperson, or in his/her/their absence, the Deputy Chairperson reviews and signs the approval letter which is then forwarded to the researcher. The following information is included in each letter of approval:
 - 1) Protocol reference number.
 - 2) Title of the study.
 - 3) If approved, the duration of approval and date of approval.
- 3.7. The final approval letter reminds the researchers of ethical and regulatory requirements governing their research and these may include:
 - 1) The study must be conducted in strict accordance with the protocol approved by RU-HREC.
 - 2) Any changes to the protocol or relevant consent documents must be approved by RU-HREC before implementation.
 - 3) Adverse events or unanticipated problems must be reported promptly to RU-HREC.
 - 4) Participants must receive a copy of the consent form.
- 3.8. All records, research instruments and documents related to ethics applications or approvals must be stored for 5 years upon the completion of all project activities (for approved projects), or after the rejection/suspension of ethical approval.
- 3.9. The storage must be electronic and a designated upload link for the Rhodes University staff and students (via the RU internet) must be set up. The link is to be shared with applicants on the ethics approval letters that are issued by the Chairperson of RU-HREC, after quorate meeting deliberations and granting of approval.
- 3.10. The storage should be allocated on an internal Rhodes University server and the ERAS system can be used for this purpose.
- 3.11. Uploading of documents and access to them should be password protected, with the password only available to the RU-HREC Chairperson and Ethics Coordinator. A logbook should be set up to monitor and record every access of the storage space and the reason for the access.
- 3.12. An electronic backup should also be put in place.

4. Record-keeping: Active Monitoring

- 4.1. A data base of all high-risk projects and dates of their approval will be maintained by the Coordinator and updated after each meeting.
- 4.2. The high-risk data base will be uploaded to a password protected University data server that only RU-HREC Committee Members will have access to.
- 4.3. Applicants of high-risk projects will be required to complete a questionnaire six months after project approval, and every twelve months thereafter for the duration of the project. The purpose of the questionnaire will be to assess whether / what adverse events have occurred during data collection.
- 4.4. If the questionnaire indicates that adverse events might have occurred, or if additional information is required, the Chairperson of RU-HREC must call a meeting with the applicant to discuss the matter further.
- 4.5. Where a meeting is called with the researcher of a high-risk project, it is to be attended by two RU-HREC committee members: Chair and Deputy Chair or Chair/Deputy Chair and one other committee member. The Ethics Admin Assistant will also attend and take minutes.

- 4.6. Completed questionnaires and Meeting Minutes are to be stored in the same password protected University data server as the high-risk data base.
- 4.7. Applicants of high-risk projects will also complete automatically generated ERAS annual reports to further monitor their projects, thereby being monitored twice a year.
- 4.8. Information regarding high-risk applications will be stored on the University server for 5 years after initial approval OR expiry of the final renewal, as appropriate.

5. Access of the information on the ethics storage space by stakeholders from outside of Rhodes University

- 5.1. If a party outside of Rhodes University wants to access the RU-HREC storage space server, they must submit an electronic email request to the RU-HREC Chairperson, stating the reason for access, the ethics protocol approval number and the extent of information sought.
- 5.2. Upon receipt of this request, the RU-HREC Chairperson sends an email back to the applicant, acknowledging receipt of the access request. This must normally take place within 72 hours of receipt of the applicant's email.
- 5.3. Next, the Chairperson is to contact the Registrar of Rhodes University, as well the DVC for Research, Innovation and Strategic Partnerships (DVC:RISP). These three internal stakeholders discuss and devise a strategy for how to deal with the ethics data access request.
- 5.4. Legal advice can be sought, and the applicant's request must be processed expeditiously. Fiduciary and other responsibilities of The Registrar, the DVC:RISP and the Chairperson, as well as the common good, must drive their handling of the applicant's request.
- 5.5. An electronic email reply about the resolution of the applicant's request must be communicated within 30 days of the original date of the access request submission.

6. Record of RU-HREC membership

- 6.1. An up-to-date list of RU-HREC members identified by name; earned degrees; representative capacity; indication of experience sufficient to describe each member's chief anticipated contributions to deliberations; and any employment or other relationship between each member and the institution will be retained in the RU-HREC google drive database.
- 6.2. A record of all committee members' declaration forms (containing a strict confidentiality non-disclosure clause) will be retained on record in the RU-HREC google drive database.

7. Effective date of this SOP

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