TERMS OF REFERENCE
RESEARCH ETHICS COMMITTEE (HUMAN) (REC-H)

1. INTRODUCTION

1.1 The Nelson Mandela University Research Ethics Committee's Terms of Reference are aligned with the Nelson Mandela University Research Ethics Policy, Nelson Mandela University Code of Conduct for Researchers Policy as well as with the National Health Act No. 61 of 2003 and the Department of Health's 'Ethics in Health Research' Guidelines (March 2015). The National Health Act per s 73 requires institutions to establish Human Research Ethics Committees which are registered with the National Health Research Ethics Council (NHREC) and requires all research involving human participants to undergo prior ethics review by a registered research ethics committee. Committees are registered by the NHREC after an assessment of eligibility and compliance with the governing legal and ethics framework.

2. AUTHORITY

2.1 The Research Ethics Committee (Human) of the Nelson Mandela University hereafter referred to as REC-H (international equivalent titles: Institutional Review Board (IRB), Independent Ethics Committee) is established as a committee of the University Research and Engagement Committee and derives its authority from the Senate.

2.2 Administrative support is managed by the Department of Research Development (RD). The REC-H is registered with the National Research Ethics Council (NHREC) in accordance with the National Health Act No. 61 of 2003. Its registration number is REC-042508-025.

3. MANDATE

3.1 The REC-H is mandated to fulfil its functions in accordance with the National Health Act No. 61 of 2003 as outlined in the Department of Health 'Ethics in Health Research' Guidelines (2015). It reports annually to the National Research Ethics Council (NHREC) and to the Senate of the University via the University Research and Engagement Committee.

3.2 REC-H reviews human- and environmental-related research proposals to be conducted by staff, students and other officially affiliated members of the University. Researchers with no affiliation to the University may approach REC-H to review their research proposals. REC-H 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. In the case of REC-H reviewing a proposal from a non-affiliated applicant, an appropriate fee may be levied for such a service.

3.3 REC-H will, where applicable and upon request, consider external applications to conduct research using University staff and/or students as participants. 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 in order 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 3.2 above.

3.4 REC-H will, where applicable, consider external applications on the advice from appeals to the DVC Research and Engagement.

4. ETHICAL AND REGULATORY REQUIREMENTS

4.1 In order to adhere to the highest ethical standards, the REC-H, through the Terms of Reference and relevant Standard Operating Procedures (SOPs), functions in compliance with, but not limited to the following documents and guidelines:

- 4.1.1 Constitution of South Africa – Act 108 of 1996/Chapter 2: Bill of Rights – Section 12 C; Right to Dignity – Section 10 and Equality – Section 9.
- 4.1.2 South African National Health Act No. 61 of 2003 and by the National Health Research Ethics Council;
- 4.1.3 Ethics in Health Research: Principles, Processes and Structures 2nd Edition, Department of Health, Republic of South Africa, 2015;
- 4.1.4 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;
- 4.1.5 The Nuremberg Code (1946);
- 4.1.6 Declaration of Helsinki (as amended);
- 4.1.7 Belmont Report (1979);
- 4.1.8 The Singapore Statement on Research Integrity;
- 4.1.9 Guidelines for Informed Consent. H3Africa Working Group on Ethics and Regulatory Issues for the Human Heredity and Health (H3Africa) Consortium, H3Africa, 2013;
- 4.1.10 International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organisations of Medical Sciences (CIOMS) and WHO: Geneva, 2002;
- 4.1.11 International Council for Harmonisation of Technical Requirement for Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018;
- 4.1.12 ICH Harmonised Tripartite Guideline: Clinical Investigation of Medical Products in the Paediatric Population E11 2000;
- 4.1.13 ICH for Registration of Pharmaceuticals for Human Use (ICH Tripartite);
- 4.1.14 Final Framework for African genomics and biobanking (2017);
- 4.1.15 Guidelines of the South African Health Products Regulatory Authority (SAHPRA) as well as Laws and Regulations with regard to the Control of Medicines;
- 4.1.16 The Association of the British Pharmaceutical Industry (ABPI): Clinical Trial Compensation Guidelines;
- 4.1.17 Registration of Clinical Trials Undertaken in South Africa: http://www.sanctr.gov.za or http://www.practr.org/;

4.1.18 A Directory of Legal Rights of Minor Research Participants including Children and Adolescents compiled by the HIV AIDS Vaccine Ethics Group in collaboration with the Desmond Tutu HIV Centre and Perinatal HIV Research Unit;

4.1.19 Participant's Bill of Rights for preventive HIV Vaccine Trials compiled by the South African AIDS Initiative (SAAVI): http://www.saavi.org.za/billofrights.htm;

4.1.20 Nelson Mandela University Research Ethics Policy; and

4.1.21 Nelson Mandela University Code of Conduct for Researchers Policy.

4.2 When strict compliance with the letter of a particular requirement of these Declarations, codes and guidelines is not possible, REC-H will ensure that the proposed research is nonetheless in keeping with the spirit of the relevant documents.

5. PURPOSE

5.1 The primary purpose of the REC-H is to protect the dignity, rights, safety and well-being of all human participants in research, and to ensure the safety, health and wellbeing of humans affected by environmental related research. The REC-H will do this through independent, prospective and ongoing ethics review of all research projects submitted to this committee for review.

5.2 A secondary purpose of the REC-H 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.

6. SCOPE OF OPERATIONS

6.1 The directive of the REC-H is to:

6.1.1 Conduct rigorous ethics review, prospectively, 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. Retrospective review is not permitted;

6.1.2 Advise its appointing authority on all matters pertaining to the ethics of research involving humans;

6.1.3 Conduct rigorous ethics review, prospectively, of all submitted research proposals for human research 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;

6.1.4 Conduct rigorous ethics review, prospectively, of all submitted research proposals involving environment related aspects to ensure that the safety, health and welfare of humans are properly protected and that the proposed research is compliant with ethical norms and standards;

6.1.5 Ensure via University Faculty Postgraduate Studies Committees that research proposals are scientifically sound and feasible; and to advise on improvements when applicable;

6.1.6 Decide whether to approve, to require amendments or to reject the proposals for lack of compliance with ethics norms and standards and where applicable to advise on the scientific quality of proposals;

6.1.7 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;

6.1.8 Actively monitor the execution of approved research proposals on an ad hoc basis;

6.1.9 Conduct investigations into any reported allegations of misconduct in research involving human participants;

6.1.10 Ensure appropriate reporting occurs to fulfil the oversight obligation of the REC-H to monitor welfare interests of participants; and

6.1.11 Make an annual (or more frequent) report to the affiliated national ethics body and appointing authority, making the report available to other interested parties.

6.2 The REC-H EXCO comprising of the Chairperson, Vice-chairperson and the Director (Research Capacity Development) supported by the secretariat, is mandated to deal with matters between meetings, duly authorised by the full committee.

6.3 The REC-H has the authority, from time to time, to appoint standing or ad hoc reviewers to deal with specific aspects of the work of the REC-H, e.g. low/negligible risk undergraduate fourth year, low/negligible risk honours student ethics review applications as well as low/negligible risk postgraduate degree student and low/negligible risk staff ethics review applications. These reviewers are authorised to approve the applications in compliance with applicable norms, rules and regulations; and to report to the full REC-H for noting.

6.4 The following mechanisms operate to ensure that the quality of ethics review is consistent:

6.4.1 At least one representative per Faculty, usually a member of the relevant Faculty Postgraduate Studies Committee, serves on the REC-H as a formal committee member.

6.4.2 REC-H ratifies ethics applications approved by the various co-opted reviewers by means of passive reporting.

6.5 The REC-H expects of its members (nominated, co-opted, ex officio and otherwise) to subscribe to the conditions of appointment as stipulated in the letter of appointment. These conditions of appointment entail a description of the expectations of members, including, but not limited to, a Confidentiality Agreement and a Conflict of Interest Declaration, the latter being applicable to individual matters tabled at monthly meetings.

6.6 The REC-H does not act as a research-funding or grant-giving committee.

7. COMPOSITION AND MEMBERSHIP OF REC-H

7.1 The composition and function of the REC-H must meet the minimum standards and requirements as set out in:

7.1.1 Ethics in Health Research: Principles, Processes and Structures 2nd Edition, Department of Health, Republic of South Africa, 2015;

7.1.2 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.

7.2 Membership should be representative of active research disciplines including both clinical and non-clinical fields of research.

7.3 The term of membership is 3 years, which is renewable for a maximum of 3 consecutive cycles.

7.4 REC-H members are appointed by their respective faculties and serve on a voluntary basis without financial compensation.

7.5 The REC-H must comprise of at least 9 formal members. Additional members may be co-opted as deemed necessary. New formal members and/or alternate members may be appointed as required by shifts in research directions or new strategic research partnerships.

7.6 Each of the following categories should be represented in the membership of the committee (given that one individual may represent more than one category) and include those as specified by the Department of Health in 'Ethics in Health Research: Principles, Processes and Structures 2nd Edition, Department of Health, Republic of South Africa, 2015':

7.6.1 At least one layperson

7.6.2 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

7.6.3 At least one member with professional training and experience in qualitative research methodologies

7.6.4 At least one member with professional training and experience in quantitative research methodologies

7.6.5 At least one member with expertise in bio-statistics

7.6.6 At least one member with expertise in research ethics

7.6.7 At least one member who has a qualification in Law

7.6.8 Ethnically and culturally diverse members and an appropriate mix of males and females

7.6.9 At least one scientific member with expertise in areas of research regularly reviewed by the committee.

7.6.10 At least one representative from each Faculty Postgraduate Studies Committee.

7.7 Consultants or ad hoc reviewers may be used where additional expertise is needed to review specific protocols. Reasons for seeking additional or specialised competence may include but are not limited to:

7.7.1 Additional scientific, clinical or scholarly expertise.

7.7.2 Particular knowledge about potentially vulnerable populations.

7.7.3 Broader understanding of gender or cultural issues.

7.7.4 Greater sensitivity to community perceptions.

7.7.5 A statistical opinion.

7.8 Permanent ex-officio representatives on REC-H are:

7.8.1 The DVC Research, Innovation and Internationalisation, or a nominated representative;

7.8.2 A representative from Research Development;

7.8.3 The Committee Officer nominated by the Registrar acts as secretary to the RECH.

7.9 Documenting the activities of REC-H is via minutes of Committee meetings and comprehensive record keeping of protocols reviewed by the Committee. Minutes should be:

7.9.1 A reflection of the agenda of the meeting and must record the discussion and action taken on each agenda item;

7.9.2 An accurate reflection of the matters considered and the justification for the subsequent decisions taken;

7.9.3 Detailed enough to reconstruct its decisions at a later date if necessary to protect itself and the institution;

7.9.4 Such that it shows concern for participant's rights, safety and well-being.

8. MEETINGS

8.1 At least 10 meetings will be held per year, one per month from February to November.

8.2 Meeting dates will be available on the University website, under the specific webpage of the Research Ethics Committee (Human).

8.3 Except when an expedited procedure is used, the REC-H must review initial and continuing studies at committee meetings at which a quorum is present. A quorum is considered to be upheld if 50% + 1 of appointed REC-H members, including the Chair- and Deputy Chairperson, are in attendance. A quorum must be maintained for each vote. If a quorum fails at any point during a meeting, further studies cannot be approved and must be held over until the next convened meeting.

9. REC-H POLICIES AND PROCEDURES

9.1 In order to ensure transparency and inclusivity, a manual depicting the following will be made publicly available to staff, students and affiliates of the University:

9.1.1 The recruitment and appointment process for members of the REC-H

9.1.2 Standard Operating Procedures (SOPs) that systematically describe all the processes and procedures involved in the work of REC-H including its institutional arrangements and reporting obligations and which will be

systematically reviewed every three to four years, or more frequently as necessitated by research ethics changes.

9.1.3 Documentation (for example application forms, guidance documents, review guidance, information and consent document guidance as well as report templates amongst others) to facilitate appropriate processing of applications and to assist researchers to comply with requirements.

10. AMENDMENTS TO THE TERMS OF REFERENCE

10.1 All proposals for amendments to the REC-H Terms of Reference must be considered and recommended by the REC-H.

10.2 Final approval of or recommended changes to the REC-H Terms of Reference is the authority of Senate.

Last updated January 2023. Approval Pending.