Terms of Reference (ToR)

MANCOSA HUMAN RESEARCH ETHICS COMMITTEE (M-HREC) - ToR

Version	M-HREC TOR V3
Type of document	Terms of Reference
Purpose	To describe the constitution and functions of the M-HREC
Managed by	Research Directorate
Approved by	Academic Exco
Approval date	11 July 2023
Implementation date	12 July 2023
	Amended 11 July 2024 -Section 1.1
Next review date	5 June 2025

MANCOSA
Member of
HONORIS UNITED UNIVERSITIES

Dream it. We'll take you there.

CONTENTS

TERMS OF REFERENCE - MANCOSA HUMAN RESEARCH ETHICS COMMITTEE (M-HREC) 2
1. TERMS OF REFERENCE 2
1.1 MANDATE 2
1.2 ROLE 2
1.3 REGULATORY AUTHORITY 2
1.4 PURPOSE 3
1.5 GUIDANCE 3
1.6 FUNCTIONS AND DUTIES 3
1.7 RESPONSIBILITY 4
1.8 THE COMMITTEE 4
1.8.1 Composition 4
1.8.2 Membership 5
1.8.3 Training 6
1.9 TERM OF OFFICE 6
1.10 REMUNERATION OF M-HREC MEMBERS 7
1.11 M-HREC SUB-COMMITTEE 7
1.12 REVIEW 7
REFERENCES 8

TERMS OF REFERENCE - MANCOSA HUMAN RESEARCH ETHICS COMMITTEE (M-HREC)

1. TERMS OF REFERENCE

1.1 MANDATE

MANCOSA is a private higher education institution registered in terms of the Higher Education Act (Act 101 of 1997) as amended. MANCOSA has eleven learning centres within South Africa and the Southern African Development Community (SADC) region, where the mode of delivery is primarily distant. The HREC is centralised and accepts all research applications for ethical approval from the range of MANCOSA campuses. However, the HREC cannot approve studies to be conducted external to South Africa. Ethics approval for research studies outside the borders of South Africa must be obtained through appropriate RECs in respective countries.

The Senate of MANCOSA has given the MANCOSA-Human Research Ethics Committee (henceforth "M-HREC") authority to carry out its duties.

1.2 ROLE

The role of the M-HREC is to advise the Research Committee (RC) on ethical issues and to evaluate and approve applications for ethical clearance. It is also to ensure that research studies at MANCOSA must be conducted in alignment with the MANCOSA Research Policy, and to review all research studies with human subjects.

1.3 REGULATORY AUTHORITY

The M-HREC will ensure that it is free from bias and outside influences that could compromise its independence when carrying out its functions. The M-HREC will abide by the principles and standards outlined in:

1.3.1 The National Health Research Ethics Council with regard to social science and humanities research;

1.3.2 The clauses of the National Health Act No. 61 of 2003 and its modifications, to the extent that they apply to research in the social sciences and humanities;

1.3.3 Department of Health, National Guidelines 2015: Ethics in Health Research: Principles, Processes, and Structures;

1.3.4 The requirements of the Protection of Personal Information Act 4 of 2013;

1.3.5 All applicable laws, rules, and regulations, as well as any international standards and guidelines that may be relevant to social science and humanities research;

1.3.6 Official publications from scientific and professional organisations to the extent that they are pertinent to social science and humanities study;

1.3.7 The MANCOSA Research Ethics Policy;

1.3.8 The M-HREC members' and/or researchers' code of conduct at the institution.

1.4 PURPOSE

The main purpose of the M-HREC is to protect the dignity, rights, safety and well-being of all human participants in non-biomedical, human participant research. This will be done through independent, prospective and ongoing ethics review of all management sciences and humanities research projects undertaken by members of staff, registered students and affiliates of MANCOSA. Research to be reviewed will be in accordance with the provisions of the National Health Act (Act No. 61 of 2003).

1.5 GUIDANCE

The overarching ethics guidance for the M-HREC will be the SA Department of Health: Ethics in health research: Principles, structures and processes (2015). Where relevant major international guidelines (including, but not restricted to: The Declaration of Helsinki, current version (2013); The Belmont Report (1979) and the CIOMS Guidelines (2016) will also apply. When strict compliance with the letter of a particular requirement of these declarations and codes is not possible, M-HREC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

1.6 FUNCTIONS AND DUTIES

The M-HREC functions as an independent Committee and reports to the NHREC. The duties and terms of reference of the Committee shall apply to all matters associated with academic research ethical practices and issues, and shall apply to both staff and students conducting research.

1.7 RESPONSIBILITY

The committee shall take all reasonable and appropriate steps to ensure:

1.7.1 The implementation of and compliance with ethical research conduct by staff, students and researchers external to MANCOSA in all research and relevant academic activities.

1.7.2 The formal evaluation and approval of the ethical aspects of proposed research prior to conducting the research.

1.7.3 Reviewing and approving applications for ethical clearance that meet research ethics criteria and standards of practice.

1.7.4 The issuing of the ethics approval letter.

1.7.5 Consultation with experts on ethical issues outside the expertise of the Committee members.

1.7.6 Referring or seeking advice from the RC and/or Senate in cases of ethical infringements which may be outside the scope of authority of the Committee.

1.7.7 The formal re-evaluation and approval of research or research projects, already granted ethical clearance, that have changed or been modified substantively in approach, methodology or focus during the process of conducting research.

1.7.8 Amendment or development of policy and practice related to all ethical aspects of research.

1.7.9 Contribution to increasing the levels of awareness of ethical aspects of research through the provision of education, opportunities for academic and professional growth, and the promotion of information, training and development opportunities appropriate to research and the responsible conduct of research, and

1.7.10 Provision of regular minutes of meetings of the M-HREC and reports to the RC.

1.8 THE COMMITTEE

1.8.1 Composition

The composition of the M-HREC will be in accordance with the provisions of the Department of Health (2015) Ethics in health research: Principles, structures and processes and the South African Good Clinical Practice Guidelines (2020). Members of M-HREC should collectively have the qualifications, experience and expertise to review and evaluate the scientific, legal, psychosocial and ethical aspects of research proposals. The total number of Committee members must be no less than twelve (12).

A M-HREC sub-committee convened by the Director, Research and consisting of five (5) to six (6) Research Directorate staff, reviews the research protocols submitted by Honours and Masters students.

1.8.2 Membership

The committee shall:

1.8.2.1 Be representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa;

1.8.2.2 Include members of both genders, with no more than 70% of members being of one gender;

1.8.2.3 A simple majority (50% + 1) constituting a quorum;

1.8.2.4 Have a Chair and a Deputy-Chair;

1.8.2.5 The Chair must have experience in Research Methodology and Research Ethics and will be supported by a least one Deputy-Chair;

1.8.2.6 The Deputy Chair should be elected by the members and be expected to assist the Chair with responsibilities and inter-meeting matters, as well as to step into the role of Chair when necessary.

1.8.2.7 Include at least one member of academic/research staff from each of the departments (i.e., Education, Management);

1.8.2.8 Include at least one member with knowledge of, and current experience in, areas of research that are likely to be regularly considered by the M-HREC;

1.8.2.9 Include at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people. Such a member might be, for example, a medical practitioner, psychologist, social worker or nurse;

1.8.2.10 Include at least one member who has experience in both qualitative and quantitative research methodologies;

1.8.2.11 Include at least one member who is legally trained;

1.8.2.12 Include at least one member who is a lay person;

1.8.2.13 Ensure that the membership is equipped to address all relevant considerations arising from the

categories of research likely to be submitted to it;

1.8.2.14 Ensure that it is adequately informed on all aspects of a research protocol, including its scientific and statistical validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document;

1.8.2.15 The M-HREC may co-opt expert members and other representatives as voting members as required by particular protocols. Voting status is to be confirmed by M-HREC in advance on a case-by-case basis;

1.8.2.16 On invitation or request, M-HREC meetings may be attended by bona fide students, researchers and other interested parties as non-voting observers, subject to the signing of a confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chair.

1.8.3 Training

The SOP, code of conduct and any other pertinent M-HREC documents will be sent to all new M-HREC members so they can become familiar with the requirements, inclusive of training.

Continuous personal development in research ethics will be required of all M-HREC members (at least once a year). By offering research ethics education to researchers and M-HREC members, the institution may support the ethical conduct of scholarly research.

The M-HREC webpage will also bear relevant training information.

1.9 TERM OF OFFICE

1.9.1 The term of office for the Chair, Deputy-Chair and members shall be five (5) years, renewable once.

1.9.2 The term of office for external members shall be five (5) years.

1.9.3 Should a member vacate their office before the expiry of their term, the Chair shall call for a replacement of the member.

1.10 REMUNERATION OF M-HREC MEMBERS

M-HREC members will be remunerated based on the MANCOSA remuneration policy.

1.11 M-HREC SUB-COMMITTEE

The M-HREC sub-committee is convened by the Director, Research and consists of five to six members of the Research Directorate, usually on a rotation basis. This enables members of Research Directorate to both share the review load and to develop ethics review capacity. The sub-committee reviews the research protocols submitted by Honours and Masters students. **A.** Low-risk projects can be directly approved by the sub-committee and do not need to be submitted to the M-HREC. Once the sub-committee has approved a project, the applicant may start data collection. Where applicable, the sub-committee must request the applicant to make certain changes to the project or informed consent form, etc., and should recommend an appropriate process for ensuring that these changes are made prior to the implementation of the project. A schedule of approved protocols is tabled and ratified at a convened quorate M-HREC meeting. The M-HREC reserves the right to suspend the sub-committee approval and request changes or clarifications, where required. **B.** Studies deemed to constitute a risk (minor to high) are referred to the M-HREC for full review.

1.12 REVIEW

The Terms of Reference of the Committee shall be reviewed, amended, varied or modified in writing after consultation and agreement by Committee members at least every three (3) years and recommendations made to the Research Committee, followed by tabling and approval by the Academic Exco.

REFERENCES

Council for International Organizations of Medical Sciences (CIOMS), 2016. International Ethical Guidelines for Health-related Research Involving Humans. Geneva. Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

Department of Health, 2015. Ethics in Health Research: Principles, Processes and Structures. Pretoria, South Africa. Available at: https://www.health.gov.za/wp-content/uploads/2022/05/NHREC-DoH-2015-Ethics-in-Health-Research-Guidelines-1.pdf

Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines Pretoria, South Africa. Available at: https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf

Department of Health, Education, and Welfare, 1979. Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Report of the National Commission for the protection of human subjects of biomedical and behavioural research. Washington. Available at: https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

Republic of South Africa: The Higher Education Act 101 of 1997. Available: https://www.gov.za/sites/default/files/gcis_document/201409/a101-97.pdf

Republic of South Africa: National Health Act No. 61 of 2003. Available at: https://www.gov.za/sites/default/files/gcis_document/201409/a61-03.pdf

Republic of South Africa: Protection of Personal Information Act 4 of 2013. Available at: https://www.gov.za/sites/default/files/gcis_document/201409/3706726-11act4of2013protectionofpersonalinforcorrect.pdf

World Medical Association, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 2013. Available at: https://www.up.ac.za/media/shared/6/files/declaration-of-helsinki_fortaleza_brazil-2013.zp158501.pdf