Policy

Research Ethics

Version	RES-ETHV1	RES-ETHV2	
Managed by	Research Directorate		
Approved by	Academic Exco	Academic Exco	
Approval date	9 Dec 2020	11 July 2023	
Implementation date	1 Jan 2021	12 July 2023	
Review date	5 Jan 2023	5 June 2025	
Signed by Chair: Academic Exco			

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Contents

1. PREAMBLE

1.1 Policy Statement

The purpose of this Research Ethics Policy (henceforth referred to as the Policy) is to promote awareness of ethical principles and issues in the conduct of research activities and, in doing so, provide clarity for all researchers affiliated to MANCOSA on their ethical obligations. This Policy should be read and understood in parallel to the principles and values espoused in the Constitution of the Republic of South Africa (Chapter 2: The Bill of Rights). The Policy will empower the Research Ethics Committee of MANCOSA (henceforth referred to as M-HREC) to independently evaluate, approve and monitor research that involves humans, organisations, biological organisms, plants and the environment within a framework of generally accepted research ethics principles. The goal is to provide a framework that seeks to protect the integrity of the researchers and the research process but not compromise or limit the principles of academic freedom. MANCOSA is of the view that good research assumes ethical accountability according to internationally acceptable norms and that the responsibility for this lies with all stakeholders involved in research under the auspices of MANCOSA.

2. DEFINITIONS

i. **Academic freedom:** the right, without constriction by doctrine, to freedom of teaching and discussion, freedom in carrying out research and disseminating and publishing the results thereof, researchers' freedom to express freely their opinion about the institution or system in which they work, freedom from institutional censorship and freedom to participate in professional or representative academic bodies.

ii. **Anonymity:** a given response cannot be traced to a participant either by the researcher or the reader.

iii. **Anonymised data:** data that is coded or presented in such a way that the identity of the research participants cannot be established.

iv. **Biological organism:** any individual entity that embodies the property of life.

v. **Clinical trial:** a type of study that investigates new tests and treatments and evaluates their effects on human health outcomes.

vi. **Confidentiality:** treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission.

vii. **Environment research:** research which investigates the human interaction with the environment or research which investigate the interacting systems of physical, biological and cultural elements.

viii. **Ethics:** the rules of conduct recognised in respect of a particular class of human actions or a particular group, and are concerned with how morally accepted outcomes can be achieved in specific situations.

ix. **External research:** any research undertaken among staff and/or students of MANCOSA where the principal investigator is not a MANCOSA employee or student.

x. **Gatekeeper:** an individual who provides access to the research site; access to specified data at a research site; access to the participants; and identifies sites where the research may be carried out.

xi. **Health research:** any research that involves biological, clinical, psychological or social welfare matters; the causes and effects of diseases; the effects of environments on humans; methods of health care service delivery; new pharmaceuticals, medicines, health care products, devices or technologies to improve health and health care.

xii. **Human subject:** a human being about whom an investigator conducting research obtains data through intervention or interaction with the individual.

xiii. **Medical research:** research that involves fundamental scientific principles that may apply to a preclinical understanding.

xiv. **Minimal risk research:** projects in which the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

xv. **Online research methods:** any research or data collected via the Internet or using Web-based or social media methods.

xvi. **Organisation:** a social unit of people that is structured and managed to meet or to pursue collective goals.

xvii. **Principal investigator (PI):** the researcher, viz. the staff member, research associate, student or external researcher, who is responsible for implementing the research.

xviii. **Plant-based research:** any study involving plants of all types and species.

xix. **Privacy:** The right or expectation not to be interfered with or to be free from surveillance; the right to preserving bodily integrity; and the right to deny access to medical or research records.

xx. **Research:** the creative investigation, conducted systematically to validate previous research findings, to contribute to new knowledge and creative outputs, and to increase scientific and technological knowledge.

xxi. **Researcher:** any persons within MANCOSA (staff, undergraduate and postgraduate students) as well as collaborators/partners, research associates, and external researchers who undertake research at and/or through MANCOSA.

xxii. **Research Ethics Committee (REC)**: the subcommittee of the Senate delegated with the responsibility of ensuring that all research undertaken within MANCOSA meets statutory and ethical requirements. The REC is an independent review board constituted of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the ethics of proposed research studies.

xxiii. **Research for degree purposes:** all research undertaken by students and staff of MANCOSA towards attaining a qualification or degree.

xxiv. **Research for non-degree purposes:** research undertaken by individuals or collaboratively by groups of researchers and includes contract research, institutional research, and research by external bodies or individuals, not for the purpose of obtaining a qualification or degree.

xxv. **Research participant**: an individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information or documents.

xxvi. **Retrospective study**: research that is performed using information on events that have taken place in the past.

xxvii. **Staff:** all categories of employees of MANCOSA whether permanently appointed or appointed on contract.

xxviii. **Stakeholders:** all parties who have a material interest in the implementation and outcome of research and includes the MANCOSA community, the communities in which research is undertaken on behalf of MANCOSA, the specific participants in a study, sponsors and the broader research community.

xxix. **Student:** all *bona fide* undergraduate individuals and postgraduate individuals registered for Honours, Postgraduate Diplomas, Masters by coursework and treatise, Masters by research and Doctoral degrees.

xxx. **Supervisor:** a full-time or part-time staff member of MANCOSA, or an external person from industry or another university who, on account of his or her expertise or experience is directly involved in giving a student guidance in his or her studies, in respect of both technical and academic aspects, in the preparation of a dissertation or thesis to obtain a postgraduate qualification.

xxxi. **Vulnerable persons or groups:** individuals or groups who have "substantial incapacity to protect their own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical or psychological care or other necessities or being a junior or subordinate member of a hierarchical group". Vulnerable groups are defined by the Department of Health (2015) and Council for International Organizations of Medical Sciences (CIOMS) Guidelines (2016), as including, *inter alia*:

a. persons under the age of 18 years
b. institutionalised persons e.g., prisoners
c. the elderly
d. persons with mental or physical incapacity
e. persons from a stigmatised (e.g., HIV-positive) or minority group
f. groups or communities who are economically or socially disadvantaged
g. persons in a dependent relationship (e.g., employees, students, patients)
h. persons traumatised due to exposure to physical, psychological and/or emotional abuse or trauma
i. persons with only a basic/elementary knowledge of the language of the researcher

xxxi. **Wildlife:** undomesticated animal species or organisms that grow or live in the wild without being introduced by humans.

3. PURPOSE OF THE RESEARCH ETHICS POLICY

The Policy is not intended to restrict or discourage research at MANCOSA but aims to:

i. inform all researchers of their ethical responsibilities in conducting research;
ii. promote understanding and adherence to all applicable ethical procedures;
iii. protect the rights of all stakeholders engaged in the research process.

4. INDEPENDENCE OF THE MANCOSA RESEARCH ETHICS COMMITTEE

4.1 The M-HREC is an independent body comprising members who have the ability to undertake thorough, competent and timely reviews of research proposals. The duties and terms of reference of the Committee shall apply to all matters associated with academic and research ethical practices and issues and shall apply to both staff and students conducting research.

4.2 The M-HREC is different from a scientific or technical review committee. While the M-HREC examines the adherence of the research to ethical principles, the scientific or technical review committee scrutinises its scientific and technical quality. Membership in committees may overlap but the ethics review must be independent of the scientific review. The deliberations and decisions of the M-HREC will be recorded in the minutes which will be kept by the Administrator or Secretary of the M-HREC. The minutes and reports of the M-HREC shall, however, be tabled by the Research Committee for noting.

4.3 It is beneficial for the work of the M-HREC to maintain active links with the scientific or technical committee, especially because some methodologies or research designs while technically sound, could involve ethical dilemmas. M-HREC members may seek the advice of experts of the scientific or technical committee if this facilitates the discharge of their functions.

4.4 Circumstances may arise that necessitate the use of other local and international ethics guidelines by the M-HREC in addition to this Policy.

4.5 The Chair of the M-HREC shall not be the Chair of the scientific or technical review committee or the Doctoral Research Committee of MANCOSA.

4.6 No committee or person/s shall override the decisions of the M-HREC.

5. ROLES AND RESPONSIBILITIES OF THE MANCOSA RESEARCH ETHICS COMMITTEE

5.1 To provide guidance to researchers on the ethical aspects of their work.

5.2 To develop and propose policies to enhance and facilitate ethical research and ethics review in MANCOSA, including those which are necessary for building capacity in ethical research and ethics review.

5.3 To provide advice to the Director: Research and/or the Research Committee, on matters pertinent to research ethics.

5.4 To maintain internationally-acceptable ethical standards of practice in research.

5.5 To protect research stakeholders from harm or exploitation.

5.6 To review all research proposals for ethical clearance.

6. COMPOSITION, TERM OF OFFICE AND MEETINGS

These are described in the Terms of Reference (ToR) of the M-HREC.

7. REVIEW OF RESEARCH, TRAINING OF RESEARCHERS, AND PROTECTION FOR THE MANCOSA RESEARCH ETHICS COMMITTEE MEMBERS

7.1 It is the responsibility of MANCOSA to ensure that there is an accredited structure for the ethical review of research in accordance with relevant legislation.

7.2 MANCOSA is further responsible for ensuring appropriate and relevant training in respect of the members who serve on M-HREC and its subcommittees and within the broader community of researchers (staff and students).

7.3 All M-HREC members are hereby protected vicariously by MANCOSA from incurring any personal liability whilst acting in the course and scope of their official duties as designated herein.

8. FULL AND EXPEDITED REVIEW OF RESEARCH

In the first phase of the review, all protocols will be triaged by the M-HREC Chair into one of three mutually exclusive categories: Exemption from ethical review, expedited review process and full committee review. M-HREC may grant exemption from ethical review for research which does not involve human participants.

8.1 Research studies that qualify for exemption from ethics review include those employing the method of review of materials available in the public domain such as:

i. Newspapers, websites, magazines, public reports, public statements, films, television programs, public performances, public exhibitions, public speeches
ii. Published works, systematic reviews, literature reviews, collective reviews
iii. Archived materials that are available in the public domain

The protocol for expedited review is described in the M-HREC SOPs. Under an expedited review procedure, the review may be carried out by the M-HREC chair or by one or more experienced reviewers designated by the chair from among members of the M-HREC.

8.2 The conditions for expedited review of research proposals include the following:

i. there is minimal risk to participants or organisations;
ii. no vulnerable persons or population are involved;

iii. informed consent is obtained from all participants;
iv. the researcher is using existing data or commonly available public data;
v. the researcher is using anonymous (not anonymised) data where the participants are not mentioned nor can any of the data be traced to any of the participants;
vi. minor revisions after previous conditional approval of all categories of research.

Research which is deemed to constitute at risk (minor or major) will be reviewed by the M-HREC. The protocol for expedited review is described in the M-HREC SOPs.

9. ETHICS GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

All research conducted at MANCOSA, involving human participants, must adhere to the ethical principles, viz.:

9.1 **Autonomy:** The right to make one's own decisions is the foundation of autonomy. The rules for respect of autonomy include:

i. the researcher telling the truth to the participants
ii. participants having the right to confidentiality and privacy
iii. participants providing informed consent
iv. proper communication between researcher and participants

9.1.1 Researchers should not infringe the autonomy of participants by resorting to coercion, undue influence or the promise of unrealistic benefits.
9.1.2 Coercion may include taking undue advantage of individuals or abusing their participation in the research.
9.1.3 Inducement may include a promise of material or financial gain, services or opportunities.
9.1.4 No financial or other inducement should be offered to research participants, whether children or adults, parents or guardians of children.
9.1.5 Reimbursement of expenses (e.g. transport costs, meals) or compensation for the time or effort expended or any opportunity that may be lost is allowed, on condition that all participants are offered similar reimbursement and that such reimbursement is only aimed at recompensing the participants.

9.2 **Beneficence:** The doing of good and active promotion of goodness define beneficence.

9.2.1 The researcher has an ethical obligation to protect and defend the rights of the participants.

9.2.2 The researcher should clearly state that the research is undertaken in pursuit of knowledge and/or the good of society.

9.2.3 The researcher should, at an appropriate time and in an appropriate manner, disseminate publicly, information of the research undertaken as well as the findings and implications thereof.

9.2.4 Research undertaken should be sound in terms of methodology and scientific validity.

9.2.5 All researchers should be personally and/or professionally qualified and competent for the research that they undertake. Recommendations may be made by the M-HREC to the scientific or technical review committee with a view to strengthening the quality of a proposed study.

9.3 **Non-maleficence:** Non-maleficence is based on the principle of first doing no harm.

9.3.1 The fiduciary nature of the research-participant relationship is based on mutual trust and, as such, the researcher is obligated to disclose any potential adverse effects or outcomes to the participant.

9.3.2 Any disclosure must be done timeously and openly and when the participant is able to comprehend.

9.3.3 Researchers should ensure that the actual benefits to be derived by the participants or society generally from the research clearly outweigh any possible risks, and that participants are subjected only to those risks that are clearly necessary for the conduct of the research.

9.3.4 Researchers should identify potential risks to participants and make provision for avoiding them.

9.3.5 If during the course of the research it becomes evident that a participant has suffered harm in a way not foreseen by the researcher, this should immediately be reported to the M-HREC for immediate investigation and action. Such action may, for example, include the need to refer the participant for counselling.

9.3.6 There should be no exploitation of research participants, researchers (including students and junior members), communities, institutions or vulnerable people.

9.3.7 The researchers should ensure that the use of the participants' personal information is done in line with the requirements of the Protection of Personal Information Act 4 of 2013, and should ensure that the information is not used for unlawful and secondary purposes incompatible with the original purpose consented by participants.

9.4 **Justice:** Justice refers to the fair treatment of participants.

9.4.1 This is based on:

i. respect for morally-acceptable laws;
ii. respect for human rights as enshrined in the Constitution of South Africa; and
iii. fair distribution of limited resources.

9.4.2 The criteria for the selection of research participants should be fair, as well as being scientific.

9.4.3 Easily-accessible individuals or groups should not be inordinately burdened with repeated demands on their time and knowledge by the researcher.

9.4.4 Researchers should be transparent and honest about their own limitations, competence, belief systems, values and needs. The contribution of other researchers or members of the research team should be properly acknowledged.

9.4.5 Researchers should not abuse their positions or knowledge for personal power or gain.

The four ethical principles are not hierarchically ordered each one is binding unless it conflicts with another principle.

9.5 Organisational Ethics

9.5.1 In addition to the four principles of ethics described above, organisational ethics also require consideration.

9.5.2 Organisational ethics may be defined as an organisation's efforts to:

i. define it core values;
ii. identify areas of conflict;
iii. seek best resolution of the conflicts;
iv. manage its performance according to its own espoused values.

10. INFORMED CONSENT

10.1 All research participants: All relevant personal information should be collected in adherence to the Protection of Personal Information Act 4 of 2013.

10.1.1 The participation of individuals should be based on their voluntary, specific and informed consent.

10.1.2 Researchers should respect their right at any stage to refuse to participate in particular aspects of the research or to decide to withdraw their previous given consent without demanding reasons or imposing penalties.

10.1.3 Written information containing adequate details of the research, including any risks associated with the study, should be provided to all participants.

10.1.4 Participants should be informed that research-related personal information may be shared with individuals who are part of the research e.g. supervisors and co-investigators who have to abide by the terms of this Policy to maintain participant confidentiality.

10.1.5 Participants should give their express consent in writing and accompanied by their name and signature.

10.1.6 If participants refuse to provide their consent in writing, they must not be included in the study.

10.1.7 No research data shall be collected prior to obtaining informed consent of the participants.

10.2 **Recording of data:** Where the data collection entails video, audio or digital recording, this must be disclosed to the participants prior to the study. The express consent of the participants must be obtained in writing.

10.3 **Illiterate participants and participants who do not understand the language of the researcher:** Where a participant is illiterate or does not sufficiently understand the language of the researcher, consent should be obtained in the presence of a literate witness or translator who should verify and sign a document stating that informed consent had been given. The right thumb print of the participant should be taken where the participant cannot sign his/her name. The researcher should provide a validated letter of information and informed consent in the main or first language of the participant.

10.4 **Online or electronic-based research:** Where the research is done online or electronically, informed consent can be obtained electronically but in a format separate from the online research in order to protect the identity of the participants. A potential participant must click a button or type in a response which would indicate that he/she has read the information and consent information and agrees to participate. If IP addresses are collected by the survey tool, these should be deleted from the downloaded data. Due to privacy risks associated with online research, the following statement should be included in the informed consent:

"The possibility of tampering from external sources when using the Internet or social media for collecting data cannot be completely eliminated. Although efforts will be made to protect the confidentiality of your responses, there is the possibility of hacking or other security breaches during online data collection or downloading of data that may be beyond my or MANCOSA's control."

10.5 **Children:** Children should participate only when their participation is indispensable to the research. The protection and best interests of children are of prime importance. Non-therapeutic research may only be conducted on a child under the age of 18 years with the consent of the following persons:

i. the Minister responsible for social development;
ii. the parent or guardian of the child; and
iii. the child if he or she is capable of understanding.

10.5.1 All research involving children and adolescents shall comply with the relevant statutory Acts viz. the National Health Act 61 of 2003 and the National Children's Act 38 of 2005.

10.5.2 The Minister has delegated authority to provide consent for non-therapeutic research on minors to research ethics committees that have full registration with the National Health Research Ethics Council.

10.5.3 MANCOSA Services do not address anyone under the age of 13 (thirteen). MANCOSA does not knowingly collect personally identifiable information (PII) from anyone under the age of 13. If a parent or guardian becomes aware that his/her child has provided MANCOSA with PII, the institution should be contacted. If

MANCOSA becomes aware that it has collected PII from anyone under the age of 13 without verification of parental consent, MANCOSA will take reasonable steps to remove such information from its servers, tools and systems. Where MANCOSA is required to capture personally identifiable information of students who may be below the age of 18, MANCOSA will require informed consent to do so from the students' parent or legal guardian.

10.6 **Persons with a mental illness:** This refers to any person with a positive diagnosis of a mental health related illness in terms of accepted diagnostic criteria made by a mental health care practitioner authorised to make such a diagnosis. The requirements for the participation of mentally ill persons in non-therapeutic research shall be in accordance with the National Health Act 61 of 2003.

10.7 **Persons with diminished capacity or competence:** Capacity refers to a person's ability to make a clinical judgement while competence is the legal judgment of a person's ability to provide or decline consent. The requirements for the participation of persons with diminished capacity or competence in non-therapeutic research shall be in accordance with the National Health Act 61 of 2003.

10.8 The preferred format and structure of the Letter of Information and Informed Consent is shown in **Appendix 2**.

11. MEDICAL RESEARCH AND CLINICAL TRIALS

All clinical trials conducted under the auspices of MANCOSA, its affiliated organisations and research partners must abide by the principles of the Declaration of Helsinki (2013). In addition, the following must be taken into consideration by the researcher(s):

11.1 The design and performance of each research study involving human subjects must be clearly described in a research protocol. This includes the procedures and techniques of all experimental work.

11.2 Monitoring information especially any adverse effects must be provided by the researcher to the M-HREC on a regular basis or when the adverse effects are serious.

11.3 Sound justification must be provided by the PI for the use of placebo in any medical research or clinical trial and how the interests and health of the participants will be protected in such instances.

11.4 No change to the research protocol may be made without consideration and approval by the M-HREC.

11.5 Medical research involving human subjects must be conducted only by individuals with the appropriate scientific and/or medical training and qualifications.

11.6 Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

11.7 The responsibility for the protection of research subjects must always rest with the physician, researcher or other health care professional and never the research subjects, even though they have given consent.

11.8 Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

11.9 Every clinical trial must be registered in a publicly-accessible database before recruitment of the first subject.

11.10 The scheduling of all drugs and the approved status of all devices used in medical research and clinical trials must be reported in the research proposal and subsequent academic output e.g. thesis or research manuscript.

11.11 At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

11.12 All clinical trials conducted at State institutions require ethical approval by the National or provincial Department of Health Ethics Committee.

12. RETROSPECTIVE STUDIES

It is the responsibility of the researcher(s) to ensure that all data is anonymised before analysis and publication in any form. Additional ethical approval and/or permission may need to be obtained from the relevant ethics committees or authorities before data collection can commence.

13. MOLECULAR BIOLOGY AND CELL RESEARCH, AND BIOSAFETY

Care should be taken to ensure that all research that could potentially harm the environment, including research with genetically modified organisms (GMOs), is carried out with the necessary respect for the impact that it could have on the physical, biological and spatial environment. All researchers undertaking research with bio-hazardous material including GMOs that could potentially cause harm to the researcher and supporting staff, or other humans, animals or the environment must familiarise themselves with relevant biosafety and containment procedures. The Genetically Modified Organisms Act 15 of 1997 defines a *genetically modified organism* as “an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and ’genetic modification’ shall have a corresponding meaning”.

13.1 Any institution, laboratory or similar facility where any biological organisms, viruses, plant or chemical materials, will be developed, produced, used or applied, must be accredited with the necessary documentation submitted to the M-HREC as proof of accreditation.

13.2 A permit in terms of the Act has to be obtained in the case of importing, exporting, producing, using, applying, releasing and distributing GMOs.

13.3 The researcher or supervisor of the study must provide evidence of his/her qualifications and experience in the field of biological organism, plant- or laboratory-based study. In addition, all personnel must comply with the Hazardous Biological Agents Regulations of the Occupational Health and Safety Act No. 85 of 1993. Personnel must be appropriately trained to work with hazardous biological or chemical materials and be accredited as such.

13.4 A research proposal must contain a risk assessment in terms of the possible impact of the research on humans and the environment.

13.5 The liability for any possible damage caused by the use or release of biological organisms including GMOs, viruses and radiation in the environment should be addressed in the proposal.

13.6 All research proposals involving recombinant DNA molecules must be screened by the Institutional Biosafety Committee.

13.7 Waste management, safety and disposal procedures must be included in the proposal as part of the study.

13.8 Laboratories must have particular Standard Operating Procedures (SOPs) for the procedures that will be undertaken in the laboratory.

13.9 Molecular and cell research projects should be registered with the relevant laboratory manager and a laboratory log book should be kept of all processes in the experiment.

13.10 Researchers should adhere to all SOPs that apply in the laboratory they are utilising.

13.11 Managers of laboratories where hazardous biological or chemical material is used will need to inform the Occupational Health and Safety Practitioners of MANCOSA and/or of the relevant institutions.

14. ANIMAL AND PLANT-BASED RESEARCH

All research involving animals and wildlife will be subject to approval from an accredited Animal Ethics Review Committee. For plant-based research the following principles will apply:

14.1 All plant researchers abide by the stipulations of the National Environmental Management: Biodiversity Act 101 of 2004.

14.2 The South African National Biodiversity Institute (SANBI) red list of endangered species in South Africa will be followed to ensure the classification of the plant species in terms of whether they are endangered or not.

14.3 Indigenous plant species or the indigenous knowledge related to the plants will not be exploited.

14.4 Where required, permits should always be sought for obtaining and transportation of plant material nationally and internationally.

14.5 Only the quantity of plant material required to conduct scientific research should be harvested.

14.6 Collection of plant material should not endanger the existence of the species.

14.7 Experimental designs used in plant-based or agricultural research should not endanger the environment or the persons involved in the research.

14.8 Care should be taken to ensure that crop experimentation does not endanger future crops due to toxic residue in the ground caused by a particular experimental design.

14.9 The termination of an agricultural trial should be considered in terms of the toxicity of the remaining ground in which the crop or plant trials had been conducted.

14.10 If insects are bred or used during any crop- or plant-related research trials or experiments, all possible measures should be taken to ensure that the environment or any person, animal or living organism is not endangered in any way.

14.11 Spraying of crops or any plants should follow strict health and safety procedures.

15. CONSENT FROM GATEKEEPERS OR ORGANISATIONAL STRUCTURES

15.1 It is the responsibility of the researcher to ensure compliance with the research policy or directives of gatekeepers or organisational structures.

15.2 There may be a need to obtain written permission from the "gatekeeper" to access the participants, relevant data or information and/or research sites.

15.3 Care should be taken in the following situations:

i. Permission obtained from the gatekeeper may not be substituted for the need to obtain separate and informed consent from the participants. The rights of participants in such a situation are the same as in all other cases.

ii. In the process of research or data collection, care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardised.

15.4 If gamekeeper permission is refused, the researcher shall not proceed with the study in the environment or organisation under the authority of the gamekeeper or organisation structure**.**

16. COMMUNITY ENGAGEMENT IN RESEARCH

16.1 Community engagement within academia is understood as the scholarly activity of partnering and engaging with communities to exchange mutually beneficial knowledge and resources to the benefit of all.

16.2 It blends more traditional forms of knowledge production with "lived experience".

16.3 Community engaged research can involve quantitative, qualitative, or combined data gathering methods depending on the research questions under investigation. This orientation emphasises ownership, participation, access, control and possession by non-academic researchers or communities as values in the process of creating knowledge and change.

16.4 Permission for research may require authorisation from community bodies and relevant state authorities. If the research involves a particular community, a functional community advisory board or a community committee should be involved in each research project. This can be an existing body or one created for the specific purpose of the project. At the minimum, the community should be consulted during the planning stage of the research, should be consulted on an *ad hoc* basis while the research is being done, and should be informed in a structured manner at the end of the research about the results.

16.5 Researchers must negotiate the method and particulars (i.e. authorship and co-authorship) of the release or dissemination of data (i.e. scientific journals) with the community researchers.

16.6 Researchers must consider the potential repercussions to the community if data (sensitive or not) is released prematurely or in an insensitive or any other manner.

16.7 Community participation needs to be ensured and it is important to be realistic about time and resource constraints.

16.8 A mutually beneficial agreement should be in place if a community or research setting is used as a continuous and long-term resource for collecting data to be used for curricular research or training.

17. USE OF INTERPRETERS AND TRANSLATORS

17.1 Where the participants are insufficiently familiar with the language in which research is to be conducted, the PI should ensure that reputable interpreters or translators are used so that the participants understand the nature of the study and their involvement in the research.

17.2 Interpreters or translators must be present during discussions with the participants.

17.3 Interpreters must be independent (i.e. not related to the researcher or the participants) except for low-risk research where a friend or a family member of the participant be used.

17.4 All interpreters must sign a confidentiality statement where they agree to keep all research-related discussions and research data confidential.

17.5 Where appropriate, the interpreter or translator must also sign the informed consent on the same occasion as the participant.

17.6 Interpreters or translators are not to be used to collect the research data on behalf of the researcher(s).

18. MANAGEMENT OF RESEARCH DATA AND RECORDS

In the interests of transparency and fairness, all research data must be available for evaluation by the broader research community. Agreements, under which data is kept confidential for a period in order to protect intellectual property rights, must conform with this code.

Data storage and maintenance

i. It is the responsibility of the researcher to arrange for safe storage of all data related to the research. The hardcopy and electronic data should be stored in the department in which the project is based. The intention of this is to ensure safety and integrity of the data set. The overall responsibility for this rests with the Director: Research. The costs of such storage should be included in the budgets of the Research Office.

ii. Electronic data sets should be password-protected and adequate arrangements for back-up need to be provided by the researcher. The password should be disclosed to the Director: Research or to a person designated by the Director. Ensuring this is the responsibility of the researcher.

iii. Data on which any research publication is based should be retained in the department for a minimum of five (05) years after publication. However, any data obtained from clinical research must be retained in the department for a minimum of fifteen (15) years.

iv. If a researcher leaves MANCOSA, the institution and the researcher are jointly responsible for ensuring that satisfactory arrangements are made for maintenance of the data set. If there is no contractual arrangement to determine what is to be done with the data, then possible arrangements are:

   a. The data set is retained at MANCOSA. The researcher has access to the original data set and may keep copies.
   b. The data set is transferred to the research institution to which the researcher is moving, provided that adequate facilities are available for conservation and storage.
   c. If no publications based on the data set have appeared within the last five (05) years, it may be destroyed.

18.1 Confidentiality, Privacy and Anonymity

i. All personal information and records provided by participants should remain confidential. It should be made clear during data collection that confidentiality and anonymity will be safeguarded unless waived by the research participant in writing. Whenever it is methodologically feasible, participants should be allowed to respond anonymously or under a pseudonym to protect their identity and privacy.

ii. All personal information obtained directly or indirectly on or about the participants (e.g. names obtained by researchers from human resource records), as well as information obtained in the course of research which may reveal the identity of participants, should remain confidential and anonymous. This guarantee should also be given when researchers request consent to use data which is not already available within the public domain (e.g. classified data on salaries held by human resources departments of organisations).

iii. In the case of observation studies, steps should be taken to ensure that the information will not be used or published in a form in which the individuals could be identified.

iv. Researchers should maintain privacy, anonymity, and confidentiality of information in collecting, creating, storing, accessing, transferring and disposing of personal records and data under their control, whether these are written, automated or recorded in any other medium, including computer equipment, graphs, drawings, photographs, films or other devices in which visual images or audio recordings are embodied.

v. Codes or other identifiers should, where possible, be used to de-link obvious connections between data and participants/stakeholders. Where there is a mixture of information obtained from the public domain and that obtained with the participants' informed consent, there should be no traceable link between the two sets of information.

vi. Research findings published in the public domain (e.g. theses and articles) which relate to specific participants (e.g. organisations or communities) should protect their privacy. Identifiers which could be traced back to the participants in the study should not be included. However, public interest may outweigh the right to privacy, and may require that participants be named in reports (e.g. unfair labour practices by an organisation).

vii. The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers at MANCOSA, MANCOSA administrative employees and students and all stakeholders and persons (from or outside MANCOSA) not directly associated with the research who may possibly have access to the information.

viii. Researchers are entitled to keep data sets confidential before publication. Researchers should ensure the protection of the interests of co-researchers and participants, including the participants' right to privacy and confidentiality, when sharing data or making it public in any form. After publication, when the research is in the public domain, the data should, upon request, be available to other researchers by the PI. It is recognised that there may be technical or cost difficulties which prevent it being freely available, but the principle is that there should be the opportunity for checking any data on which material in the public domain is based.

ix. Data may be shared with other researchers for future studies or for future publications provided that all data is anonymised and the participants have provided consent to the PI for doing so.

x. In no way do the requirements for data availability override the right to confidentiality and privacy of individuals or organisations who are the subjects of research.

19. RIGHTS AND RESPONSIBILITIES OF SPONSORS AND FUNDERS

19.1 Researchers should ensure that they have an explicit written research mandate from the sponsor or funder in which the conditions, scope and terms of the research are set out clearly (e.g. research problem, expected deliverables, financial commitments and time frames).

19.2 The acceptance of a mandate should be sealed by a legally binding, written contract between the parties. This contract should specify the terms agreed on, including the rights and obligations of the parties involved, the publication of the findings and the ownership of intellectual property rights and benefits.

19.3 Interference from sponsors or funders that may jeopardise the academic and ethical integrity of the study or the interests of the research participants may oblige MANCOSA to cancel the contract.

19.4 Sponsors and funders should be made aware of the MANCOSA Policy on Research Ethics. They have the right to receive a copy of the Policy and to expect that the research proposal submitted for funding or sponsorship by researchers and MANCOSA contains the necessary information on ethical issues and complies with the Policy.

19.5 Sponsors and funders should respect the MANCOSA Policy on Research Ethics and should not expect researchers or MANCOSA to undertake research or conduct which is in any way contrary to the Policy, other related MANCOSA policies or legislative frameworks.

19.6 Where sponsors or funders act, directly or indirectly, as gatekeepers and control access to the participants, researchers should not devolve onto the gatekeepers their responsibility to obtain separate and informed consent from participants and to protect their rights.

20. COLLABORATIVE RESEARCH

20.1 In national and international collaborative research, the parties are host institutions, collaborating institutions, researchers from both institutions, research participants and/or communities.

20.2 There should be clear justification for the need for and benefit of collaborative research.

20.3 Before submission of a collaborative research proposal to the M-HREC, agreement should as far as practically possible be reached between the host research institution and the collaborating institution on all aspects of the research. These include the ownership of intellectual property, management of the research process, data management, the fate of data, division of responsibilities, finances, research output, publication strategy, sharing of benefits and burdens, development of infrastructure and research capacity in the host country and an ombudsman to settle disputes.

20.4 Intellectual property rights of institutions, researchers, participants and communities shall be respected, shared and acknowledged according to clear agreements before commencement of research.

20.5 Research involving human participants must not commence without ethics approval by the Ethics Review Committees of all collaborating institutions.

20.6 Research cannot commence without informed consent from participants and/or communities.

20.7 There shall be no exploitation of institutions, researchers, research participants or communities.

20.8 Researchers involved in international collaborative research should have some understanding of, and be sensitive to, the social, cultural, economic and political conditions in which the research is carried out.

20.9 There shall be equitable compensation of institutions, researchers, participants and communities. This shall extend beyond pure financial compensation.

21. CONFLICT OF INTEREST

21.1 A conflict of interest occurs when a member of MANCOSA has an opportunity, whether real, potential, or perceived, to place his or her personal interests, or the interests of external organisations, ahead of the interests of MANCOSA.

21.2 In the academic environment there are many opportunities for conflicts of interest to occur. Not all can be covered by formal procedures. All members of MANCOSA are expected to conduct their affairs in such a way that they can stand close scrutiny and are in accordance with scrupulous ethical and moral standards. In cases of doubt, advice should be sought before proceeding.

21.3 If a member of MANCOSA has any reason to believe that some activity constitutes, or has the possibility of constituting, a conflict of interest involving research, it is required that a disclosure statement be lodged with the Director: Research. The disclosure statement involves:

i. a statement of the nature of the conflict;

ii. a proposal from the staff member of how the conflict of interest is to be managed;

iii. a procedure for the management or elimination of the conflict agreed with the Head of Department, or line manager as appropriate. This procedure may demand public disclosure, varying levels of oversight, and may include prohibition of the activity.

21.4 Failure to disclose the existence of a conflict of interest may constitute and could lead to disciplinary action in accordance with MANCOSA's policy.

22. RESPONSIBILITY FOR OBTAINING ETHICAL CLEARANCE

22.1 Ethics clearance is required for all research through M-HREC prior to the commencement of data collection and cannot be issued retrospectively.

22.2 All research proposals/protocols and treatises/dissertations/theses should include a section on ethical considerations, where appropriate.

22.3 The responsibility for the submission of an ethics application rests jointly with the student and supervisor or the PI.

22.4 The supervisor bears responsibility for making the student (as PI) aware of the policy and procedures for obtaining the necessary ethics clearance for research to be undertaken, and for ensuring that the student is deemed competent to undertake the proposed research.

22.5 An ethical clearance certificate shall be valid for a period of three (03) years for all doctoral studies; two (02) years for all Masters studies and one (01) year for all Honours and non-degree studies. In the event of the research extending beyond the minimum ethical clearance time frame, it is the responsibility of the supervisor and student to reapply for ethical clearance which shall be valid for a period of one (01) year. Reapplication for ethical clearance is mandatory for each year thereafter.

22.6 In the event of any deviation from the approved protocol, it is the joint responsibility of the student and supervisor or the PI to bring such amendments to the attention of the M-HREC or the relevant scientific or technical committee. Failure to do so would constitute misconduct.

22.7 A copy of this Policy shall be provided to all researchers who engage with degree- or non-degree research, including external research, under the auspices of MANCOSA. All researchers and relevant stakeholders shall sign a declaration acknowledging their acceptance of the terms in this Policy.

23. CODE OF CONDUCT FOR RESEARCH

23.1 All researchers working at MANCOSA must complete a statement confirming that they are familiar with the Code of Conduct for Research and undertake to observe it.

23.2 Contracts of affiliation between MANCOSA and independent researchers and institutes should ensure that the independent researchers and institutes adhere to a comparable code of ethics.

23.3. Researchers in particular disciplines/professions should also comply with any research ethics guidelines set out by their professional associations.

24. AUTHORSHIP

All researchers are encouraged to publish the results of their research in journals (preferably Department of Higher Education- (DHET) accredited) or in accredited conference proceedings or at the very least in some recognised academic media. In order to minimise conflict in cases of two or more authors for a research manuscript, or other academic output, the following principles of authorship would apply:

24.1 All authors must meet the following conditions:

i. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
ii. drafting the article or revising it critically for important intellectual content; and
iii. final approval of the version to be published.

24.2 Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

24.3 An administrative relationship to the investigation does not of itself qualify a person for co- authorship.

24.4 The order of the names in a publication is decided according to the extent of the contribution towards the academic work. Notwithstanding this, the responsibility and accountability for the results, the custom of the discipline and requirements of the journal are also other factors that may determine the order of the names in a publication.

24.5 The attribution of authorship is not affected by whether researchers were paid for their contributions or by their employment status.

24.6 The author who submits a manuscript for publication accepts the responsibility of having included as co-authors all persons who are entitled to co-authorship, and none who are inappropriate.

24.7 The submitting author should send each co-author a draft copy of the manuscript and should make a reasonable attempt to obtain consent to co-authorship, including the order of names; other contributions should be indicated in a footnote or an "Acknowledgements" section, in accordance with the standards of the discipline and the publisher prior to submission of the manuscript.

24.8 A student should be listed as the principal or first author on any multiple-authored publication that substantially derives from the student's dissertation or thesis.

25. ACKNOWLEDGEMENT SUPPORT OF RESEARCH

Research support by MANCOSA or any other organisation or person must be appropriately acknowledged in any publication, including a dissertation or thesis, resulting from the research.

26. PLAGIARISM AND ACADEMIC DISHONESTY

This is addressed by the Academic Honesty and Plagiarism Prevention Policy of MANCOSA.

27. DISPUTES BETWEEN CO-RESEARCHERS

27.1 Disputes between co-researchers must be resolved in accordance with MANCOSA's policies on dispute resolution.

28. ETHICAL CLEARANCE APPLICATION OF STUDIES WHERE THE PRINCIPAL INVESTIGATOR IS EXTERNAL TO MANCOSA

28.1 The M-HREC may accept studies for ethical clearance application where the PI is external to MANCOSA.

28.2 The M-HREC may levy a fee in lieu of reviewing external such applications.

28.3 The M-HREC may refuse to award ethical clearance if the PI does not agree to abide by the terms in this Policy.

29. REQUIREMENTS FOR SUBMISSION OF NON-DEGREE RESEARCH FOR ETHICS APPROVAL

29.1 A proposal of the research which includes the names and academic affiliation of all investigators, the Title, Aim, Objectives, Research Questions, Background to the Study, Rationale for the Study, brief Literature Review (800-1000 words) comprehensive Methodology, Statistical Analyses, Ethical Considerations, List of References (Harvard style).

29.2 An abbreviated CV of all investigators (researchers) involved in the study (not more than 3 pages each).

29.3 Completed Ethics Clearance Application (the Title, Aim, Objectives, Research Questions and Methodology must be exactly the same as that in the proposal). Contact details and relevant signatures, where required, must be completed.

29.4 The research instrument e.g. questionnaire, interview schedule (the methodology must include how the instrument was designed, adapted or permission was granted by the original authors for its use in the current research).

29.5 Letter of Information and Informed Consent (as per the Preferred format of the Letter of Information and Informed Consent)

29.6 Data collection sheet template

29.7 Gatekeeper letter – this must be submitted if the organisation has already provided permission to the investigator/s of the study. The letter or email must include the organisation's logo and the person providing the permission must be authorised to do so. Some organisations require an ethics approval before issuing a gatekeeper letter; in this instance the M-HREC may issue a provisional ethics approval letter to the principal investigator (PI) to submit to the organisation. Once the gatekeeper letter is obtained, this is submitted by the PI to the M-HREC, and if all is in order, a full ethics clearance letter is then issued. No data collection may commence until a full ethics clearance letter has been obtained by the PI. If there

are multiple organisations involved e.g., Bank X, Y, Z, then a gatekeeper letter is required from Bank X, Y, and Z before full ethics approval is issued.

29.8 Additional documents may be required by the M-HREC, and the PI will be informed

30. POST-APPROVAL ACTIVE MONITORING (PAAM), POST APPROVAL PASSIVE MONITORING (PAPM) AND REPORTING OF REPORTING OF ADVERSE EFFECTS DURING THE STUDY

These will be in accordance with the M-HREC Standard Operating Procedures (SOPs)

31. WHISTLE-BLOWING AND WHISTLE-BLOWER PROTECTION

This will be in accordance with the M-HREC Standard Operating Procedures (SOPs)

32. SUSPENSION OR TERMINATION OF ETHICS APPROVAL FOR A STUDY

The M-HREC may suspend or terminate approval of a study that is not being conducted in accordance with prevailing M-HREC or South African Department of Health (2015) ethical requirements. The primary justification for suspension or termination of approval should be the safety of participants or others. Such suspension or termination of approval must be authorised by the M-HREC chair in minuted consultation with a M-HREC subcommittee and/or other co-opted parties as soon as possible but not more than seven (07) days after receipt of relevant information by the chair. Such action must be reported to the M-HREC at the next quorate meeting, and to the Director: Research.

33. DISCIPLINARY ACTION

In the event of a researcher contravening the research ethics principles and practices as espoused in this Policy, any necessary disciplinary action will be dealt with by MANCOSA's existing disciplinary structures and procedures.

34. REVIEW

This Policy 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, following by tabling and approval by the Academic Exco.

REFERENCES

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32. APPENDICES

APPENDIX 1 - Categories of research for ethical review

Ethics Category **Note:** Ethics requirements are discipline-specific.							
Tick as appropriate:							
Humans		**Organisations**		**Environment (including plants)**		**Animals**	
Yes	No	Yes	No	Yes	No	Yes	No
Indicate Category (X)							
1.	Negligible risk to participants, organisations, or the environment. Expedited by subcommittee of Research Ethics Committee e.g. collection of publically-available data on the Johannesburg Stock Exchange or theoretical mathematical or financial models.						
2.	Minimal risk to humans, organisations, or the environment. Expedited review by subcommittee of Research Ethics Committee e.g. a survey-based study or document analysis study.						
3.	Possible risk to humans, organisations, or the environment or a sensitive research area. Full Research Ethics Committee review recommended e.g. collection of sensitive information or research procedures that may cause anxiety to participants.						
4.	Increased risk to humans, organisations or the environment or a sensitive research area. Full Research Ethics Committee review required e.g. research involving vulnerable groups.						

APPENDIX 2 - Preferred format of the Letter of Information and Informed Consent

LETTER OF INFORMATION

Date: INSERT
Title of the Research Study: INSERT
Principal Investigator/s/researcher/s and affiliation: e.g. John Smith, DBA student, MANCOSA
Co-Investigator/s/supervisor/s: e.g., Prof AT Thabede, School of Education, MANCOSA

Dear INSERT name of participant,

You are being invited to consider participating in a study that involves research. **The aim and purpose of this research is to** (describe in lay terms). **The study is expected to enrol** (how many participants in total, how many in each arm, how many other sites, and where**). It will involve the following procedures** (describe). **The duration of your participation if you choose to enrol and remain in the study is expected to be** (provide). **The study is funded by** (provide details if relevant).

Conflict of interests:

INSERT: Is there any conflict of interests for the researcher, supervisor or other co-investigators? Details must be provided.

Risks or Discomforts to the Participant:

INSERT: Description of foreseeable risks or discomforts to participants if applicable e.g. disclosure of sensitive information.

Benefits:

INSERT: How will the participants benefit from taking part in the study? How will the study benefit the wider community? What will the researcher get out of this study? (e.g. The researcher will graduate with a Doctor of Business Administration).

Reason/s Why the Participant May Be Withdrawn from the Study:

INSERT reasons: e.g. non-compliance, illness, etc. The researcher should state that there will be no adverse consequences for the participant should they choose to withdraw.

Remuneration:

INSERT: Will there be any remuneration for any participant e.g. any monetary or other types of remuneration e.g. gift? The researcher has to take into consideration the tax implications to the participant and the participants' employers' policy on employees receiving gifts or remuneration.

Costs of the Study:

INSERT: Will the participant be expected to cover any costs towards the study? e.g. transport costs to get to the venue for interviews. How will participants be compensated for out of pocket expenses (e.g. taxi fare) (if applicable)?

Anonymity and Confidentiality:

INSERT: Description of the extent to which anonymity or confidentiality will be maintained and how will this be maintained.

Research-related Injury or Adverse Effect:

INSERT: What will happen should there be a research-related injury or adverse effect? An adverse effect could be anxiety attack following participating in an interview for research. Will there be any compensation? Declare that any adverse reaction will be reported to the Research Ethics Committee.

Online/Internet-based/social media research:

The possibility of tampering from external sources when using the Internet or social media for collecting data cannot be completely eliminated. Although efforts will be made to protect the confidentiality of your responses, there is the possibility of hacking or other security breaches during online data collection or downloading of data that may be beyond my or MANCOSA's control.

Storage of Data and Duration:

INSERT: Insert where the hardcopy and electronic data will be stored and for how long. Who will have access to the data while it's in storage? Describe how the data will be eventually disposed.

Sharing of Data and Utilisation for Future Studies or Publications:

INSERT: Declare if the data is going to be shared with another researcher or is going to be used for future studies or publications. (Note such data must be anonymised prior to sharing or use in future studies or publications).

Notification of research findings:

Each participant has the right to be informed of the findings of the study. INSERT: How will the participants be made aware of the findings of the study? Merely stating that the thesis will be available in the MANCOSA library or on-line is not sufficient.

Research Ethics Approval:

This study has been ethically reviewed and approved by the MANCOSA Research Ethics Committee (REC) (Approval Number: to insert).

Person to Contact in the Event of Any Concerns or Queries:

Should you have any concerns or questions or you wish lodge a complaint regarding your involvement in the research study, please contact the Chair of the REC at MANCOSA: XXXX; Email address: XXXX@mancosa.co.za

If you have any questions, or concerns about the study, please do not hesitate to ask me.

Thank you

INFORMED CONSENT

I, (full name of the participant), hereby confirm that I:

1. Have been informed by the researcher, (name of the researcher), about the nature, conduct, benefits and risks of this study;
2. Have also received, read and understood the Letter of Information regarding the study;
3. Have also been informed that the results of the study, including personal details required by the study will be anonymously processed into a study report;
4. Agree that the data collected during this study can be processed in a computerised system by the researcher;
5. Agree that the data may be utilised or shared with another researcher for a future study or publication provided that the data is anonymised (i.e. cannot be traced to me);
6. Am aware and understand that I may, at any stage, without prejudice, withdraw my consent and participation in the study. Where I have had questions regarding the study, these have been answered by the researcher to my satisfaction;
7. Understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

Additional consent, where applicable
I hereby provide consent to:

- Audio-record my interview / focus group discussion YES / NO / NOT APPLICABLE
- Video-record my interview / focus group discussion YES / NO / NOT APPLICABLE
- Use of my photographs or images for research purposes YES / NO / NOT APPLICABLE
- Permission to edit, alter and copy the pictures that I have provided by the participant. YES / NO / NOT APPLICABLE

I declare that my participation in this study is entirely voluntary.

Full Name of Participant	**Date**	**Signature / Right Thumbprint**
Full Name of Witness (If applicable)	**Date**	**Signature**
Full Name of Legal Guardian (If applicable)	**Date**	**Signature**
Full Name of Translator (If applicable	**Date**	**Signature**