Standard Operating Procedures (SOPs)

MANCOSA HUMAN RESEARCH ETHICS COMMITTEE (M-HREC) SOPs

Version	M-HREC SOP V3
Type of document	Standard Operating Procedures
Purpose	Management of research ethics processes and review of humanities and social sciences research at MANCOSA
Managed by	Research Directorate
Approved by	Academic Exco
Approval date	11 July 2023
Implementation date	12 July 2023
Next review date	5 June 2025

MANCOSA
Member of HONORIS UNITED UNIVERSITIES

Dream it. We'll take you there.

Contents

M-HREC STANDARD OPERATING PROCEDURES (SOPs)

1. STANDARD OPERATING PROCEDURES

The M-HREC is committed to ensuring high-quality and ethical compliant research, thereby protecting the professional interests of the researchers as well. This SOP describes the mechanisms implemented for the effective evaluation of research protocols using humans. In formulating the protocols, the literature was widely consulted. The Department of Health (2015) guidelines, the World Health Organisation (2011) standards, and the Belmont Report (1979) provided the structured framework for the compilation of this SOP. Other references are cited in the text.

1.1 M-HREC MEETINGS

Meetings will be held at least six times in a year, and on the last Thursday on every second month, starting in February and ending in November. The schedule will be published on the M-HREC webpage. The final cut-off date for submission/applications is 17 days before a scheduled meeting. Submission/applications received after the cut-off date, will be scheduled for the processing at the next meeting. In addition, the schedule of meeting dates and deadlines for submission for any given year will be circulated to M-HREC members by the last week of January each year; with the minutes of meetings and the agenda being circulated to members at least ten (14) days prior to the meeting. A special meeting may be called at any time by the Chairperson of M-HREC.

1.2 CONFLICT OF INTEREST

A conflict of interest occurs when a member of the M-HREC 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. All members of the M-HREC 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. If a member of the M-HREC (academic or non-academic; staff of MANCOSA or from external organisation) has any reason to believe that some activity constitutes, or has the possibility of constituting a conflict of interest involving but not limited to research including:

1.2.1 Collaboration or co-investigation.

1.2.2 Reviewing of protocols.

1.2.3 Supervision.

1.2.4 Grant applications.

1.2.5 Funding (for the research) from agencies he/she is involved with.

1.2.6 Having any financial or material interest in the research.

1.2.7 Conducting classroom research where the effectiveness of his/her teaching methods or strategies are assessed.

1.2.8 The research is to benefit other interests that the researcher is committed to.

1.2.9 Committed to multiple positions/engagement that can possibility cloud his/her objectivity.

1.2.10 Authorship of research manuscripts or any publications arising from the research.

1.2.11 Patent applications, and

1.2.12 Conference presentations.

It is required that this is brought to the attention of the Chair (If there is a conflict of interest involving the Chair, the Deputy-Chair shall address the conflict of interest). In convened M-HREC meetings, the Chair shall determine whether the member be recused for items of discussion or be allowed to remain and address questions when asked to do so, but not vote or participate in final decision-making on the matter in question (the member is to be recused during these processes). Any conflict of interest must also be declared in the Letter of Information attached to the Ethical Clearance Application Form.

1.3 CONFIDENTIALITY

In order to assure the protection of confidential information **(Appendix A)**, all M-HREC members, support staff and observers shall sign a standard confidentiality agreement on appointment to the M-HREC **(see Appendix B)**.

1.4 QUORUM/VOTING

The Committee will make its decisions at scheduled or extraordinary meetings at which a quorum of members is present. Meetings will only be conducted when a quorum is present. Decisions will be determined by consensus (general agreement). In situations where consensus cannot be achieved, the decision will be arrived at by vote. Minutes taken at M-HREC meetings will be of sufficient detail to show attendance at the meetings; actions taken by M-HREC; if applicable, the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

1.5 RESEARCH REQUIRING ADDITIONAL ATTENTION

The M-HREC will pay special attention to protecting the welfare of participants from vulnerable populations **(Appendix A)** and/or participants requiring additional attention **(Appendix A)**, with the M-HREC needing to satisfy itself that consent obtained from such respondents is both adequately informed and voluntary.

Research involving children (i.e., individuals under the age of 18 years) may only be approved if:

1.5.1 The research involves no more than minimal risk.

1.5.2 The research involves more than minimal risk but provides direct benefit to the child which is commensurate with the level of risk (i.e., a favourable risk-benefit ratio).

1.5.3 The research involves no more than a minor increase over minimal risk, with no direct benefit to the child, but the research has a high probability of providing significantly generalisable knowledge (i.e., a favourable risk-knowledge ratio).

1.5.4 Permission for children to participate in research must be obtained from the parents or legal guardian. The M-HREC must ensure that adequate steps are outlined in protocols to obtain the child's assent when, in the opinion of the M-HREC, the child is capable of providing such assent.

1.5.5 In the event of 'therapeutic research' that includes interventions that may hold out the prospect of direct health related benefit for the participant, then parents or guardians who grant permission for their minor child to participate in research, will be provided a detailed description of all diagnostic and therapeutic interventions that will affect the child in the study. Furthermore, the informed consent documentation must explain whether results of tests will be made known to child-participants and their parents.

1.6 REVIEW PROCEDURES

1.6.1 Protocol submission

All the applications for ethics review and approval of the research proposal will be submitted to the M-HREC administration via email. The administrator will then check all the documents being submitted based on the below check list. If the submission is incomplete, i.e., any document is missing, then the administrator will communicate with the PI to submit the relevant documents. The Committee will obtain the following document/s from the administrator:

1.6.1.1 Completed M-HREC application form(s).

1.6.1.2 Study protocol (s).

1.6.1.3 Written informed consent form(s).

1.6.1.4 Information sheets.

1.6.1.5 Participant recruitment procedures (e.g., advertisements).

1.6.1.6 Written information to be provided to participants.

1.6.1.7 Safety information.

1.6.1.8 Research instrument (s).

Any other documents that the M-HREC may need to fulfil its responsibilities.

1.6.2 Protocol review

1.6.2.1 Ethical framework for review

The review of protocols will be informed by the ethical framework developed by Emanuel et al. (2008) which can be summarised in terms of eight ethical principles: collaborative partnership, social value, scientific validity, fair participant selection, favourable risk-benefit ratio, independent ethics review, informed consent and respect for informants. This framework has been adapted for social science research (Wassenaar and Mamotte, 2012).

1.6.2.2 Review procedures

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**, **expedite**d and **full review**.

1.6.2.2.1 Exemption from ethical review

The M-HREC may grant exemption from ethical review for research which does not involve human participants (**Appendix A**) and carries no risk for the well-being of individuals or groups of individuals (e.g. research which is restricted to the secondary analysis of data sources which are in the public domain or observations of behaviour which is in the public domain). 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

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 or the M-HREC Subcommittee.

a. 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.

1.6.2.2.2 Expedited review process

The M-HREC may use the expedited review procedure in the following circumstances:

i. The research is deemed to involve no more than minimal risk **(Appendix A).**
ii. To approve minor changes in previously approved research during the period for which approval is authorised; and/or
iii. The M-HREC will consider "Class approvals" for expedited review in circumstances where the usual criteria for expedited approval are met, in addition to the following: (a) where an investigator wishes to do exploratory research involving several lines of inquiry on retrospectively collected data, or (b) where an investigator needs to repeat a specified research exercise, for teaching or training purposes.

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. In reviewing the research, the reviewers will exercise all the authority of the M-HREC except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedures set out below. Members of M-HREC will be informed at committee meetings of all protocols that have been approved using the expedited review process since the last committee meeting (Adapted from: 45 CFR 46 110(b); M-HREC, 2010).

1.6.2.2.3 Full committee review

Research which is deemed to constitute at risk (minor or major) will be reviewed by the M-HREC. The review process for protocols categorised as for the M-HREC will be as follows:

i. Protocols received at least fourteen (14) days prior to a scheduled M-HREC committee

meeting will be tabled at the next committee meeting.

ii. Following the completion of the administrative check and corrections, the M-HREC administrator in consultation with the Deputy Chair will allocate reviewers, at least ten (10) days prior to the meeting.

iii. Each protocol/application will be discussed at a convened quorate M-HREC meeting, including at least one member whose primary concerns are in non-scientific areas.

iv. For all non-expedited reviews, all committee members will receive copies of the M-HREC application form and the protocol.

v. Each non-expedited application and protocol will be reviewed in advance of a convened M-HREC meeting by all M-HREC members. A primary and secondary reviewer, and where necessary, an expert reviewer will be allocated to review each such application.

vi. The primary and secondary reviewer (and expert reviewer, where applicable) will, at the M-HREC meeting, initially provide an evaluation of the positive and negative aspects of the proposed research, with other committee members present at the meeting subsequently being afforded an opportunity to provide their evaluations.

vii. Apart from the scientific input, opinions from members representing the community must also be taken into account.

viii. Decisions are reached either by consensus or by a vote.

ix. The M-HREC's review of a protocol will lead to written confirmation to the applicant of either:

    a. full approval.
    b. provisional approval with resubmission to the reviewers.
    c. major revision required prior to resubmission to the M-HREC for approval.
    d. rejection.

x. Reasons for provisional approval, revision and rejection will be furnished to the researcher in writing, at least ten (10) days after the meeting.

xi. The M-HREC must document its views in writing, clearly identifying the study, the documents reviewed, and the dates for the following:

    a. full approval.
    b. provisional approval with resubmission (in lieu of improving turn-around times, the M-HREC Deputy Chair, in consultation with the primary reviewer of that protocol will evaluate the re-submission).
    c. major revision required prior to resubmission.
    d. rejection; and

e. termination or suspension of any prior approval.

1.7 APPEALS PROCEDURE

Researchers have the ability to lodge an appeal against judgments made by the committee, and challenges or difficulties regarding the administration process for the M-HREC. The appeal must be submitted by the lead investigator directly to the Chairperson/ Deputy Chairperson of the M-HREC through the M-HREC Administrator. There needs to be a clear justification for the appeal, which should be backed up by the opinion of a subject matter expert who is not the primary investigator. The Chairperson of the M-HREC in consultation with the Deputy Chair or a delegated member may then seek consultation from outside sources regarding the research. Thereafter, this information, together with any suggestions regarding the appeal, will be reported back to the members of the M-HREC. The M-HREC committee will take into account the new motivations and evaluate the entirety of the protocol before reaching a conclusion. Following the conclusion of the appeals process, the decision at hand is final.

1.8 CONTINUING REVIEW PROCEDURES

1.8.1 Recertification and continuing review

The M-HREC should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research participants, to be done on either a bi-annual or not less than an annual basis. In conducting continuing review of research not eligible for expedited review, all M-HREC members should at least receive and review the M-HREC recertification application form containing essential study information including a protocol summary and status report on the progress of the research.

1.8.2 Post approval active monitoring (PAAM)

1.8.2.1 The three primary types of monitoring visits

i. Routine/Not-For-Cause Audits: The M-HREC will randomly select 5% of all studies that involves vulnerable participants, based on the level of risk of the study. This includes studies with and without a required continuing review. In addition, the M-HREC may opt to select specific topics for auditing across multiple protocols such as recruitment or informed consent procedures, participant procedures, or maintenance of study records.

Note: The M-HREC will make an effort not to select multiple studies from the same PI within the same calendar year for PAAM review.

ii. For-Cause Audits: Monitoring visits may also be conducted at the discretion of the M-HREC Chair, Director, Research, or the institutional office as deemed necessary. These reviews are performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the M-HREC. This includes review of any or all study-related activities.

iii. Investigator Initiated Audits: A PI may request an on-site review to audit records and procedures to ensure compliance with the M-HREC regulations, institutional policies, and/or to prepare for an external audit by a sponsor or any agency.

PAAM visits are not designed to "catch" individuals. Rather, they are conducted to verify that research is being carried out as approved. The PAAM process may involve site visits to observe data collection procedures being performed, evaluation of record keeping, confirmation of proper personnel training, and discussions related to approve activities. The process is meant to facilitate dialogue and education between the M-HREC and researchers.

1.8.2.2 Protocol of the PAAM process

i. When a protocol is identified for PAAM, the Monitor (M-HREC member or MANCOSA staff) will send an initial notice to the Principal Investigator (PI) of the M-HREC protocol. This message will notify the PI of the PAAM selection and explain preparations for the visit.

ii. Prior to the visit, a pre-visit questionnaire will be sent to the PI via email and should be completed and returned to the Monitor within five business days. If the pre-visit questionnaire is not completed, the visit will still occur, but the Monitor will need to gather additional information from the PI during the monitoring visit.

iii. The visit will be scheduled for a mutually agreeable time for the PI and the Monitor. The PI may ask for additional laboratory/teaching/research staff to assist with the visit, but during the visit, the PI will discuss the activities of the protocol. Whenever feasible, the Monitor will observe data collection of the protocol and research/teaching activities.

iv. The Monitor will complete the PAAM form during the visit. Problems or deficiencies noted on these visits will be corrected at the time the deficiency is noticed and further training/education provided, if needed. General observations will be discussed with the PI/personnel at the conclusion of the visit.

v. A summary of PAAM visits, will be reported to the M-HREC chair by the Monitor. The Monitor (if not a M-HREC member) may attend any M-HREC meetings in a non-voting capacity to clarify any matters from the report. The final report will become part of the M-HREC protocol record.

1.8.2.3 Reporting of the monitoring visit

i. The M-HREC monitoring representative will prepare a written report of the outcome of the site visit which will be sent to the PI within 10 business days from the date of the site visit via email.
ii. If necessary, the M-HREC monitoring representative will meet with the PI and the study team to provide a brief summary of any findings.
iii. Within 10 business days of receiving the written summary report the PI will respond in writing to the M-HREC addressing each indication of non-compliance and providing a plan of corrective action.
iv. Once sufficient corrective actions have been taken by the PI and communicated in writing to the M-HREC, the M-HREC will send a PAAM close-out email to the PI.

1.8.2.4 Appeals process following PAAM reporting

If PIs disagree with M-HREC findings from the PAAM visit or required corrective actions, they are invited to address these concerns with the M-HREC monitoring representative who conducted the review within 10 business days of being sent the findings report. If a satisfactory resolution cannot be determined, the PI may then contact the M-HREC Chair within five business days of speaking with the M-HREC monitoring representative. If at that point no satisfactory resolution is agreed upon, the PI may address to the Director, Research directly. If at that point a satisfactory resolution is still not agreed upon, the PI may address any concerns with the Academic Exco within five business days of the full-board meeting. The decision of the Academic Exco is final.

1.8.2.5 Post approval passive monitoring (PAPM)

All PIs of the M-HREC approved protocols will be required to submit a yearly report regarding the status of the proposal until the project is complete (PAPM form). This will be followed by a review of the monitoring report by the M-HREC followed by permission granted to continue the study for a further year. Studies which do not meet the anticipated progress targets set in the approved protocol will be reported to the M-HREC for review and intervention.

1.9 AMENDMENTS TO RESEARCH PROTOCOL

A study protocol approved by the M-HREC, is to ensure that the research will be carried out in accordance with sound ethical standards. Before being put into effect, any amendment must be filed to the M-HREC using the "**Application for Amendment to Approved Proposal** form". The amendment's implication to the study and its participants will be determined by the chairperson. If the modification is minimal, it might go through expedited review; if it's important, it will be discussed at a seating of the entire committee.

- Minor modification (expedited review) - does not alter the study's risk-benefit profile, such as a title change, administrative changes, the addition of an investigator, modifications to the study's design and results, and minor modifications to the letter of information and consent, such as editorial adjustments.
- Major amendment – Substantial amendments that modify the risk-benefit profile of the study, such as revisions to the study's aims and objectives, its process, its inclusion criteria, and its information and consent letter.

1.10 ADVERSE EVENTS

Reports on adverse events and serious adverse events (AEs and SAEs) should be reported in writing to the M-HREC, the study sponsors, and any regulatory authority (where appropriate), within seven (07) working days of the occurrence for the study sites.

1.11 SUSPENSION/TERMINATION OF APPROVAL

The M-HREC may suspend or terminate approval of a study that is not being conducted in accordance with prevailing M-HREC or the South African Department of Health's 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/Deputy Chair in minuted consultation with a M-HREC subcommittee and/or other co-opted parties as soon as possible but not more than seven (7) days after receipt of relevant information by the Chair/ Deputy Chair. Such action must be reported to the M-HREC at the next quorate meeting, and to the Director, Research.

1.12 RECORDS

All M-HREC documentation and communication is dated, filed and archived. All records (electronic) are stored securely to safeguard the information and ensure confidentiality. A document repository will be granted via DataSTOR. The back-up facility will be gained via our disaster recovery site. Training will be provided via our IT Directorate on how to use the DataSTOR, and access will be granted only to designated research ethics members. Staff will also be appropriately trained to ensure optimal record-keeping, retrieval and confidentiality. Documents will be stored for a period of fifteen (15) years.

1.13 COMPLAINTS BY INVESTIGATORS

Investigators are encouraged to initially address complaints regarding M-HREC procedures or decisions informally by contacting the Deputy Chair, who may consult with the Chair, or escalate accordingly. In the event that complaint is unresolved, investigators have the option to formally submit a complaint to the Director, Research. Should the complaint continue to be unresolved, it may be escalated to the Chief Academic Officer. If the matter remains unresolved even at this stage, investigators may consider submitting a complaint to the National Health Research Ethics Council at the National Department of Health. For further information, please visit the website: http://www.doh.gov.za/nhrec/

1.14 RESEARCH MISCONDUCT (See MANCOSA Research Ethics Policy)

Research misconduct encompasses *inter alia*:

i. Failure to submit a protocol for ethics approval in term of this document.
ii. Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research.
iii. Deviation from or failure to adhere to the approved protocol without prior formal approval from M-HREC.
iv. Misrepresentation of data and/or interests and/or involvement.
v. Falsification of credentials.
vi. Deception in the research proposal.
vii. Non-approved deception in the carrying out of research.
viii. Piracy of materials.
ix. Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research staff.
x. Failure to obtain voluntary and informed consent.
xi. Breach of confidentiality.

xii. Negligent management of data security.

Incidents of research misconduct will be reported to the Director, Research and managed in accordance with applicable MANCOSA rules and procedures. Protocol violations are to be tabled and discussed at quorate meetings of M-HREC.

1.16 APPOINTMENT OF M-HREC MEMBERS

The institution's notice system is used to place a call for membership in the M-HREC. For external members the call is placed on the LinkedIn platform. After receiving the applications, the selection committee comprising the Chair and at least two other M-HREC members, evaluate them for suitability and shortlists the applicants for interviews. Members of the Committee make recommendations of community members who have access to rural communities for possible appointment for the role of lay person on the M-HREC.

Following the interviews and panel decision, the appointment is made by the Chair. Each member is appointed for a term of five years, after which they are eligible to have it renewed. Each member is required to submit a streamlined version of their curriculum vitae to the M-HREC administrator at the start of their term of office. Each and every member is required by the Terms of Reference to be in good standing and to have a complete awareness of the pertinent ethical standards and guidelines.

Each member of the committee, as well as the support staff, must sign a confidentiality agreement before being assigned to the M-HREC. A copy of this agreement shall be sent to each member of the M-HREC, and the original will be kept in the organisation's administrative records file. A member's membership will be terminated if they do not attend three consecutive meetings without submitting a formal written apology that the committee would accept. The administrator of the M-HREC must get the committee member's feedback if they are unable to attend the meeting.

1.17 M-HREC's CAPACITY BUILDING AND SUCCESSION PLANNING

The Training and Resources in Research Ethics Evaluation (TRREE) training will be completed by every member of the M-HREC. Induction and research ethics training will be provided at the start of each academic year, to new and existing members. Members are expected to undertake online research ethics training courses, available at: https://www.health.gov.za/wp-content/uploads/2022/05/NHREC-DoH-

2015-Ethics-in-Health-Research-Guidelines-1.pdf (Appendix 2), and provide proof of recent training at least once in the period of office.

The M-HREC is served by MANCOSA staff who hold doctoral degrees as well as other early career academics who have already established themselves as leaders in their fields. These academics are excellent candidates for successional planning, and they will be mentored to lead the M-HREC in the important ethics leadership roles as these become vacant.

Collaborative and collegial relationships have been created with other RECs in the region. As a result, we consult with Professor Clarke, who is the Chair of the Umgungundlovu Health Ethics Research Board (UHERB), in addition to other ethics experts from the University of KwaZulu-Natal. These individuals will have already delivered seminars and offered research ethics training for our members.

The time frames for capacity building and succession planning to commence in 2023 and continue thereafter. Persons responsible include: The current Chair and Co-chair, with final approval from the Director: Research.

1.18 CHANGES TO STANDARD OPERATING PROCEDURES, AND/OR MEMBERSHIP

Any changes to M-HREC Standard Operating procedures will need to be approved by the Research Committee, the Senate of MANCOSA, and the SA National Health Research Ethics Council (NHREC).

1.19 REVIEW

The SOPs 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

Code of US Federal Regulations: 45 CFR 46. Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

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, 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 behavioral research. Washington. Available at: https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

Emanuel, EJ., Wendler, D., & Grady C. 2008. An ethical framework for bioethical research. In: Emanuel et. al., The Oxford textbook of clinical research ethics (pp. 123-135), New York: Oxford University Press.

Wassenaar D. R., & Mamotte N. 2012. Ethical issues and ethics reviews in social science research. The Oxford Handbook for international psychological ethics. (pp. 268- 282). New York: Oxford. Available at: https://doi.org/10.1093/oxfordhb/9780199739165.013.0019

World Health Organization. 2011. Standards and operational guidance for ethics review of health-related research with human participants. Available at: https://www.who.int/publications/i/item/9789241502948

APPENDIX A: CONFIDENTIAL INFORMATION

Confidential Information means certain proprietary, personal, clinical or protocol- specific information which the M-HREC member acknowledges to be confidential. Such information includes all protocols relating to research with human participants and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, patient requirements, biological materials, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software.

Human subject means:

a) "A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual; with the term intervention including both physical procedures whereby data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes, and the term interaction including communication or interpersonal contact been researcher and subject; or

b) A living, or deceased, individual about whom an investigator (whether professional or student) conducting research obtains information that is both identifiable and private; with information being identifiable if the identity of the individual is, or may readily be, ascertained by the investigator, or associated with the information, and private information including information about behaviour that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)" (Adapted from 45 CFR 46.102).

Minimal risk means "the probability and magnitude of harm or discomfort anticipated in the research are 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" (45CFR 46.101).

Participants requiring additional attention means "participants who fall into one or more of the following categories:

- Minors: Children and adolescents.
- Women: Women and Pregnancy.
- Persons with mental disabilities.

- Persons with substance abuse related disorders.
- Persons in dependent or subservient relationships (e.g., students where the investigator is directly involved in their training; employees where the investigator has line authority over them).
- Prisoners.
- Persons highly dependent on medical care: Intensive care, Neonatal intensive care Terminal care.
- Persons with impaired capacity to communicate.
- Unconscious persons.
- Specific social collectivities.
- Persons in indigenous medical systems.
- Emergency care research.
- Innovative therapy or intervention.
- HIV/AIDS clinical and epidemiological research" (SA GCP Guidance, DoH, 2006).

Vulnerable communities means "communities which have some or all of the following characteristics:

- Limited economic development.
- Inadequate protection of human rights and discrimination on the basis of health status.
- Inadequate community or cultural experience with the understanding of scientific research.
- Limited availability of health care and treatment options.
- Limited ability of individuals in the community to provide informed consent.
- Culturally marginal groups.
- Persons involved in illegal activities or livelihoods" (Adapted from: SA DoH, 2015; UNAIDS, 2000; 2007).

APPENDIX B: CONFIDENTIALITY AGREEMENT FOR MEMBERS OF THE MANCOSA HUMAN RESEARCH ETHICS COMMITTEE (M-HREC)

I the undersigned …… (herein referred to as "the M-HREC Member") with physical address at

……

……

HEREBY AGREE TO THE FOLLOWING:

a. The M-HREC is a body constituted by appropriately qualified professionals tasked with the reviewing of novel proposals for research which is to be conducted on/or with human participants and/or animals.
b. The work of the M-HREC is the scientific evaluation and systematic review of the ethical status of the research related actions of researchers and/or clinicians within the framework of health care.
c. The Members of the M-HREC, supporting administrative staff and ad hoc attendees hereby agree to be bound by the provisions of this Agreement for the duration of their service to and on the M-HREC as well as beyond the confines of the M-HREC member's obligations to the M-HREC and without limit in time.

1. INTERPRETATION

Unless the context indicates the contrary:

a. "Confidential Information" shall mean certain proprietary or confidential information which the M-HREC member acknowledges to be confidential. Such information relates to all trial protocols relating either to research on human participants, and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, know-how, processes, inventions, techniques, formulae, products, business operations, patient requirements, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, biological materials, and/or software.
b. "Results" shall mean all results obtained and conclusions reached during the contingency of the Project and the Main Agreement.

2. CONFIDENTIALITY

2.1 The M-HREC Member undertakes in favour of the others that he/she will treat as confidential all information labelled as confidential information including all results generated from any proposal and/or project, including any and all information whether of a technical or scientific nature or otherwise relating to all research proposals reviewed by the M-HREC as a whole or communicated to him/her hereunder or otherwise in connection with the M-HREC Member's role on the M-HREC. The M-HREC member agrees that he/she will not disclose such information to any person, any legal entity, or to the media, and will not use such information other than for the purposes of this Agreement, subject to any prior specific written authorization by the other members to such disclosure or use.

2.2 Confidential information shall not include:

i. Information which at the time of disclosure is published or otherwise generally available to the public, or later becomes generally available to the public otherwise than through any act or omission on the part of the M-HREC Member; or

ii. Information which the M-HREC Member can show by written records and to the satisfaction of the Disclosing Party, was in his/her possession at the time of disclosure and which was not acquired directly or indirectly from the Disclosing Party; or

iii. Information rightfully acquired from a bona fide third party who did not obtain it under pledge of secrecy to the disclosing Party; or

iv. Information which is or had been independently generated or developed by the M-HREC which can be shown by written records and to the satisfaction of the Disclosing Party; or Information which is required to be disclosed by law or a valid order of a court of competent jurisdiction or the request of any governmental or other regulatory authority, in which event the parties hereto shall use their best endeavours to seek confidential treatment of such information.

v. Information released to specified parties by or after consultation with the Chair of M-HREC and any other relevant parties (e.g., Director Research, Chief Academic Officer).

2.3 The confidentiality obligations contained in this Agreement shall endure beyond the confines of the M-HREC Member's obligations to the M-HREC and without limit in time.

3. GOVERNING LAW

3.1 This Agreement shall be governed by the law of the Republic of South Africa. Any disputes under this Agreement shall be resolved in a court of competent jurisdiction in Durban, South Africa.

Thus read, signed and agreed:

Signed at _____on the _____ day of _____ 20____

Full names: _____

Signed: _____ (M-HREC Member)