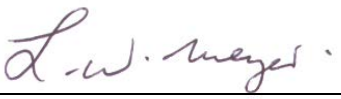
NWU-EMELTEN-REC

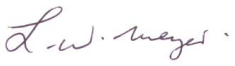
The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

ETHICS OFFICE	**Standard Operating Procedure**		
Title	SOP for the selection, appointment, functioning and quality assurance and legal compliance of research ethics within the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC)		
SOP no	SOP_EMELTEN_Ethics_1.2	**Version no**	4
Date of approval	22 September 2017	**Revision date**	22 September 2021
Email address	Ethics-EMELTEN@nwu.ac.za	**Page no**	Page 1 to 34

1 COMPILATION AND AUTHORISATION

Action	**Designated person**	**Signature**	**Date**
Compiled by: Prof Minrie Greeff and amended by Prof Lukas Meyer	Prof Lukas Meyer		6 December 2016
Revised and checked by:	NWU-EMELTEN Research Ethics Office: Prof Lukas Meyer		1 December 2018 4 September 2019
Approved by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		9 March 2020
	Faculty Board, Faculty of Education Chair: Prof Lloyd Conley		15 April 2020
	SCRE Chair:		27 August 2020
Authorised by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		28 August 2020

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of NWU-EMELTEN-REC	Prof Lukas Meyer		28 August 2020
Deputy Dean: Research and Innovation			
NWU-EMELTEN-REC: Administrator	Mrs Villera le Roux		31 August 2020

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
6 December 2016	1	Compiling of SOP for EMHS-REC
7 May 2018	2	Changing old NWU Logo to new NWU Logo
1 December 2018	3	Changing committee's name EMHS-REC to NWU-EMELTEN-REC
4 September 2019	4	Revision of document

4 PURPOSE OF THE SOP

Quality assurance and legal compliance of research ethics within the Faculties of Education, Economic and Management Sciences, Law, Theology, Engineering and Natural Sciences are mainly administrated and managed and supported by the NWU-EMELTEN-REC which evaluates research applications with a non-health related focus where vulnerable human participants are involved and/or the possibility of medium to high risk of potential harm to human participants due to research exist. The number of committee members could increase should the workload of the NWU-EMELTEN-REC increase and it is no longer able to cope with the work load. The NWU-EMELTEN-REC report to the Senate Committee for Research Ethics (SCRE) of the North-West University (NWU), the Faculty Board of the Faculty of Education, and further to the Deputy Deans and Directors of Research and Innovation of the six faculties. The NWU-EMELTEN-REC will apply for registration with the National Health Research Ethics Council (NHREC) and function according to the requirements as stipulated by the National Health Act 61 of 2003, the concomitant regulation (Regulations Relating to Research with Human Participants, 19 September 2014), the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015).The purpose of this SOP is to provide a framework for the selection, appointment and functioning of members of the NWU-EMELTEN-REC that provide operational management of the research ethics processes at Faculty level.

5 SCOPE

The NWU-EMELTEN-REC makes recommendations, gives advice and reports to the Faculty Board of the Faculty of Education and the SCRE (as a committee of the Senate) of the NWU. It also provides annual reports to both the NHREC and SCRE.

The NWU-EMELTEN-REC is responsible for the review and approval of new research ethics applications, amendments and monitoring of research in the six faculties that refers to vulnerable participants and involves greater than minimal risk studies. No study may begin before the NWU-EMELTEN-REC has provided written approval or may continue without the successful completion of the required monitoring reports (six monthly for medium risk studies, three monthly for high risk studies and annually for minimal risk studies).

The NWU-EMELTEN-REC is immediately notified of any incident or adverse event occurring during the research process which impacts on the safety of participants (see Addendum 3).

The scope of this document covers the selection, appointment and the functioning of members of the NWU-EMELTEN-REC. It covers the responsibilities and procedures to be followed for these aforementioned activities.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
NWU-EMELTEN-REC	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee
NWU-EMELTEN-REO	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Research Ethics Office
SCRE	Senate Committee for Research Ethics
NHREC	National Health Research Ethics Council
NWU	North-West University

7 RESPONSIBILITIES

The NWU-EMELTEN-REC responsible for ensuring ethical research within the six faculties where it refers to vulnerable participants and medium risk studies, while the researchers should conduct research of the highest scientific and ethical standards.

8 PROCEDURE/S

8.1 Aim

The aim of the NWU-EMELTEN-REC is to ensure that the dignity, rights, safety and well-being of the human beings involved in research, and teaching-learning, are protected, as well as ensuring that research integrity and the highest ethical standards are upheld.

To ensure that the NWU-EMELTEN-REC and researchers comply with the institutional, national and international requirements for research ethics.

To ensure that research projects where people are involved, are scientifically grounded and ethically responsible.

8.2 Objectives

To review research applications and amendments for ethical suitability and to ensure that:

- people involved in research are treated with respect and dignity and that their well-being is a higher priority than the research being done,
- the health, safety and position of the researcher (liability)is always protected,
- the research is valuable and scientifically responsible,
- written permission and informed consent are obtained at all times,
- approval is given to research proposals that adhere to the scientific and ethical standards and requirements,
- the research provides a favourable benefit-risk ratio, and in cases where this is not possible, sufficient motivation is provided.

To monitor and manage all incidents and adverse events.

To monitor all on-going research studies to ensure they adhere to the approved proposal and legal requirements.

8.3 Composition of the NWU-EMELTEN-REC

The composition of the NWU-EMELTEN-REC is in accordance with the legal requirements, as set out by the NHREC in their guidelines entitled, “Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)”

The NWU-EMELTEN-REC should be independent, multi-disciplinary, multi-sectoral and pluralistic.

8.3.1 The North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) for research with human participants

NWU-EMELTEN-REC members should consist of:

i. at least nine members, with a quorum being a simple majority

ii. where the number of members is more than 15, the quorum may be 33%

iii. at least one layperson

iv. at least one member with knowledge of, and current experience in, the counselling of people.

v. at least one member with professional training and experience in qualitative research methodologies

vi. members with professional training and experience in quantitative methodologies

vii. a member with expertise in statistics

viii. a member with expertise in research ethics

ix. at least one member who is legally qualified

8.4 Selection and appointment

Members are appointed for a term of *five years* (as per the SCRE rules) and may be re-appointed for another single term. A break of at least two years is needed before a member can be re-appointed after two terms.

Updated CVs, signed Code of Conduct and proof of research ethic training of all NWU-EMELTEN-REC members should always be on file in the applicable administrator's office.

Consideration should be given to succession planning.

8.4.1 The selection and appointment of the chairperson:

The chairperson of the NWU-EMELTEN-REC must always be selected form the Faculty of Education due to the fact that the Faculty of Education acts as the host faculty and a larger number of ethics applications are referred to the NWU-EMELTEN-REC due to the number of research studies conducted with minors. As soon as the NWU-EMELTEN-REC becomes aware of a vacancy in this position, the management of the Faculty of Education, in consultation with the NWU-EMELTEN-REC, suggests possible candidates, based on their experience and knowledge of research ethics. A qualification in research ethics is not a requirement but will, however, be advantageous. CV's are sent to the chairperson of the NWU-EMELTEN-REC. The chairperson having preliminary discussions with the suggested candidates on the roles and responsibilities of this position. A final decision is taken at the Faculty Management Committee (FMC) meeting, ratified at the Faculty Board of Education and the SCRE is informed in order to finalize the appointment, as a committee of the Senate. A formal letter of appointment is sent by the SCRE setting out the term of office; where to find the necessary information for new members; and the assurance that the members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the NWU-EMELTEN-REC. This appointment must reflect in the annual task agreement of the NWU-EMELTEN-REC member. The NHREC is also notified.

An acting chairperson can be appointed by the NWU-EMELTEN-REC, to act for a limited period.

8.4.2 The selection and appointment of the vice-chairperson:

As soon as the NWU-EMELTEN-REC becomes aware of a vacancy in this position, they nominate possible vice-chairpersons from the existing NWU-EMELTEN-REC members. The chairperson has the preliminary discussion with the nominated candidates on the roles and responsibilities of this position. A final decision is taken during the next NWU-EMELTEN-REC meeting, confirmed at FMC, ratified at the Faculty Board of Education and the SCRE is informed.

8.4.3 The selection and appointment of committee members:

As soon as the NWU-EMELTEN-REC becomes aware of a vacancy in this position, they make it known within the appropriate faculties and ask for nominations. The Dean and the Deputy Deans of Research and Innovation of the appropriate faculties are notified and asked for nominations. The DoH (2015) guidelines regarding the

composition of registered RECs should be followed to when candidates are nominated. The chairperson has preliminary discussions with the nominated candidates on the roles and responsibilities of this position. A final decision is taken during the next NWU-EMELTEN-REC meeting, confirmed at FMC, ratified at the Faculty Board of Education and the SCRE is informed in order to finalize the appointment, as a subcommittee of the Senate. A formal letter of appointment is sent by the SCRE, setting out the term of office; where to find the necessary information for new members; and the assurance that the members are indemnified from personal liability against claims that may arise in the course of ordinary business of the NWU-EMELTEN-REC. This appointment must reflect in the annual task agreement of the NWU-EMELTEN-REC member. The NHREC is notified.

8.4.4 Sub-committees

The NWU-EMELTEN-REC can establish various sub-committees, from within the membership of the NWU-EMELTEN-REC, as per their needs and requirements e.g. executive committee, incident and Serious Adverse Events (SAE) committee.

8.4.5 Co-opted members, observers and visitors

The NWU-EMELTEN-REC co-opts members as and when needed. Observers and visitors will only be allowed in exceptional cases and for a specific purpose. Researchers can be invited for the discussion of their applications and be present to clarify uncertainties.

8.5 Training

Training of all NWU-EMELTEN-REC members is critical. Training and refresher courses should be available and members will be expected to attend at least one research ethics training course once every three years. NWU-EMELTEN-REC members should provide documented proof of research ethics training to the research ethics office.

8.6 Code of conduct

All NWU-EMELTEN-REC members have to sign the code of conduct formulated by the NWU. This code of conduct indicates their acceptance of the ethical principles for research at the university.

8.7 Functioning of committees

8.7.1 Quorum for meetings

The quorum for the NWU-EMELTEN-REC is determined, according to the guidelines of the Department of Health and the NHREC, 2015, specifically according to section 4.4 as discussed under 8.3 of this document.

8.7.2 Frequency of meetings and agendas

Monthly: February to November with a minimum of ten scheduled meetings annually. No meetings will take place during January and December. These applications will be reviewed during the next meeting in February. No meetings will take place during recess periods.

Meetings will take place on the dates as indicated in the timetable of the Faculty.

The agendas for these meetings close on the dates as indicated in the timetable of the Faculties.

At least 5 days prior to the meeting, the Secretariat provides the complete agenda pack electronically to all members.

No meeting will take place if no applications where received at the closing of the agenda.

Late applications will stand over until the next meeting.

Notice of extraordinary meetings should reach members at least 2 days before the meeting.

8.7.3 Proposed process for functioning

NWU-EMELTEN-REC has Standard Operational Procedures (SOP) that indicate the functioning of the committee as well as the processes to be followed when ethical clearance is needed for both new applications or amendments to research proposals.

The ethical review process should not be mechanical.

All applications reviewed by the NWU-EMELTEN-REC should have prior approval by a Scientific/Proposal Committee.

All applications are reviewed by a minimum of two reviewers, preferably not from the same faculty and campus. Expert reviews can also be requested.

NWU-EMELTEN-REC members should be encouraged to:

- be mindful of the basic ethical principles that should inform the planning, design and undertaking of research
- be open-minded and not allow personal biases to cloud their application of these guidelines to the review of an application
- accept the consensus that ethical principles should be balanced, that this is difficult to achieve and that divergence enriches deliberations
- be mindful of the influence that the context has on how to prioritise principles
- be deliberate, reflective and thoughful in discussions about how to balance ethical considerations.

Set timelines for review procedures ensure an effective system:

- 5 working days for new applications
- 3 working days for corrections, smaller amendments and monitoring reports.

The NWU-EMELTEN-REC is also responsible for evaluation of incidents, adverse events (see Addendum 3) as well as passive and active monitoring (Appendix 5: SOP_EMELTEN Ethics_1.6) of research studies.

8.7.4 Conflict of interest

All conflict of interest or potential conflict of interest should be declared by committee members to the committee at the start of a NWU-EMELTEN-REC meeting (see Addendum 4). No committee member should be allowed to be part of the review of an application, if there is any conflict of interest present.

8.7.5 Confidentiality

The total process of review of the scientific and ethical integrity of research projects will be treated confidentially by all of the members of the committees. No information with regard to applications or research protocols will be distributed to a third party unless the NWU-EMELTEN-REC is legally required to do so (see Addendum 6)..

8.7.6 Secretariat

The NWU-EMELTEN-REO of the Faculty of Education will provide the secretariat for the NWU-EMELTEN-REC.

All meetings are recorded, transcribed and saved electronically and in hard copies.

Registers are kept for all meetings including:

- agendas;
- minutes;
- signed record of attendance;
- signed record of permission to record the meeting, confidentiality, as well as conflict of interest;
- digital recording of the meeting.

8.7.7 Submitting of applications and dates of meetings

- All of the complete applications submitted before the closing of the agenda, will be reviewed during the following meeting. Incomplete applications will stand over until all documents are obtained.
- An administrative fee could be levied for each application.

8.7.8 The review procedure

When an application is received by the administration of the NWU-EMELTEN-REC Ethics Office, all documentation is checked within two days for completeness, to ensure that all documents indicated in the checklist are attached.

All reviewers are provided with a code to ensure anonymity of their reviewer reports.

The application is then sent to the NWU-EMELTEN-REC chairperson to decide on the reviewer, within three days:

- The primary and secondary reviewers (NWU-EMELTEN-REC members) based on their 1) research ethics expertise; 2) methodological knowledge; 3) no conflict of interest, and 4) equitable distribution of review burden across the committee.
- The chairperson may assign a tertiary reviewer for quality control purposes.
- All applications are also assigned to the legal representative, as well as all quantitative studies are assigned to the statistician.
- If a study plans to undertake recruitment within a local community, a copy of the informed consent documentation is sent to one of the community representatives for review.
- If the nature of the study requires expertise not present in the NWU-EMELTEN-REC, the application is allocated to an external reviewer.
- If there is any uncertainty in the distribution, the chairperson of the NWU-EMELTEN-REC will decide.

The chairperson then compiles a distribution list according to the decisions made for reviewers and forwards it to the administrator who then sends it out within three days to the allocated reviewers.

The reviewers then have 5 working days for review and then provide their feedback on an approved template (see Addendum 5).

Reviewer reports are received back at least five working days before the NWU-EMELTEN-REC meeting and placed on an electronic storage system for all NWU-EMELTEN-REC members' perusal.

Note: The ethics review process should not be mechanical but based on a *case-by-case deliberation*.

8.7.9 Decision making process

The process of decision making is based on aggregate feedback, followed by debate and then reaching consensus. Only if no consensus can be reached, will a vote be called by the chairperson.

The chairperson may decide that voting must be by secret ballot, provided that voting for persons must always be by secret ballot.

The chairperson has an ordinary vote, but must in addition, exercise a casting vote in the event of an equality of votes on any matter.

The chairperson may electronically submit urgent matters for review, between scheduled meetings through a round robin approach. At least two thirds of members have to electronically confirm their involvement in the review process by giving feedback whether it be approval or non-approval. Such a resolution must be recorded in the minutes of the next meeting.

In cases where the NWU-EMELTEN-REC cannot come to a conclusion, or some other conflict arises within the NWU-EMELTEN-REC, the general rules for conflict resolution will be followed.

9 AUTHORITY OF THE NWU-EMELTEN-REC

The NWU-EMELTEN-REC functions under the management of the NWU-EMELTEN-REO in the Faculty of Education and in collaboration with the sub-committees of the Faculty Board (Research and Innovation Committee and Scientific/Proposal Committees). The NWU-EMELTEN-REC derives its authority from the governance rules formulated by the SCRE and the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015). If the NWU-EMELTEN-REC is dissolved by the Faculty of Education, this must be reported to the SCRE, the NHREC and the Deputy Deans of Research and Innovation and to the scientific committees of the respected faculties.

10 REVIEWING OF APPLICATIONS OF RESEARCHERS FROM OUTSIDE THE FACULTY OF EDUCATION AND THE NWU

Ethical applications of researchers from outside the NWU will only be considered if:

- Researchers and/or students of the NWU are involved in the study.
- The research takes place on the campus/facilities of the NWU or if the facilities of the NWU are being used.
- Personnel of the NWU are involved in the study being performed at an off-campus facility.
- A contract has been signed with a designated group.

An administrative fee may be asked for each of these applications.

11 APPROVAL OF FACILITIES OUTSIDE OF THE NWU WHERE STUDIES ARE COMPLETED

All of the facilities where studies will be completed, should be approved by NWU-EMELTEN-REC before the student may begin with the study.

If studies will take place at other universities, ethical clearance will be awarded at the NWU and at the other university, except when mutual standards can be ensured and if a mutual agreement exists to provide mutual approval.

12 REFERENCE DOCUMENTS

- The National Health Act, No 61 of 2003.
- Regulations Relating to Research with Human Participants, 19 September 2014.
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Policy a rules for research ethics, 17 November 2016
- NWU-policy on research ethics (2018).

13 ADDENDA

No	Document name
1	Research Ethics Policy (SCRE, 2018)
2	Code of Conduct for NWU Researchers (North-West University, 2016)
3	NWU-EMELTEN-REC: Incident report form when conducting research with human participants
4.	Disclosure of conflict of interest at an NWU-EMELTEN-REC meeting
5	Research ethics reviewer report (NWU-EMELTEN-REC)
6	Confidentiality undertaking

ADDENDUM 1

RESEARCH ETHICS POLICY

Preamble

Whereas the North-West University (NWU) wishes to ensure that all research conducted under its auspices is conducted in accordance with national and international ethics standards and statutory requirements and in line with its Vision and Mission;

Therefore, against the background of the dream to be an internationally recognised university in Africa, distinguished for engaged scholarship, social responsiveness and an ethic of care, the council of the North-West University (NWU) has adopted this policy on 22 November 2018.

1 Policy statement

1.1 General principles

At the NWU research must be guided by the following general principles:

- ***Beneficence and non-maleficence***, signifying the signifying the maximizing of benefit and the minimizing of harm, and requires that the risks of harm posed by the research must be reasonable in light of anticipated benefits;
- ***Distributive justice (equality),*** a fair balance of risks and benefits amongst all role-players involved in research. It should reflect the principle of equality by no segment of the population being unduly burdened by harms of research or denied the benefits of knowledge derived from it;
- ***Respect (dignity and autonomy)*** *for research participants, signifying the opportunity for self-determination about their choices. It recognises the importance of dignity, well-being and safety interests of participants, as well as autonomy (DoH, 2015)*.

1.2 Specific principles

The nature and field of a research field may require the guidance of unique principles, to ensure the protection of human and animals involved in research or the prevention of negative environmental impact that must be formulated by every faculty for approval by the Faculty Board and Senate, to be managed and enforced by the relevant academic director and under the supervision of the Research Ethics Committee (REC) of the faculty concerned.

1.3 Shared research ethics standards

For the purposes of establishing shared research ethics standards, Senate must adopt a code of conduct for researchers to serve as a guide to ensure the integrity and ethical conduct of research undertaken under the auspices of the NWU, and for the accountability, professional courtesy and fairness of researchers when collaborating with others, and good stewardship.

2 Interpretation and application

The interpretation and application of this policy is subject to the provisions of –

- the Constitution and all relevant legislation and binding national and international regulatory requirements, standards, policies, and procedures relating to research;
- the Statute of the North-West University (2017), with specific reference to matters concerning research referred to in its preamble, paragraphs 14 and 20;
- the General Academic Rules of the North-West University (2018) (A-rules), with specific reference to rules 4.9.4 and 5.9.4, and
- resolutions taken by Senate in accordance with the Statute and the A-rules for the implementation of this policy.

3 Roles, responsibilities and accountability

3.1 In terms of the Statute of the NWU the Senate regulates all research and academic support functions of the NWU, and faculty boards are accountable to the senate for the monitoring and the oversight of research in the faculty concerned, and may advise the executive dean of the faculty on research, academic support and student matters pertaining to a faculty, as well as appropriate quality-assurance measures.

3.2 The Deputy Vice-Chancellor: Research and Innovation is responsible for the overall management of this policy and may delegate specific functions and assign duties in this regard to an officer or officers of the NWU.

3.3 The executive deans are responsible for the management of this policy in their faculties and may delegate specific functions and assign duties in this regard to a deputy dean and an academic director or directors/heads and an officer or officers of the faculty concerned.

3.4 A standing committee known as the Research Ethics Regulatory Committee (RERC) representative of all faculties and the university management must be appointed by Senate for the purposes of rendering advice on the NWU's management of research integrity and research ethics, on the state of which the RERC must report to Senate at least once annually.

3.5 Every faculty must establish at least one Research Ethics Committee (REC) to oversee and manage compliance with the requirements of ethical research of minimal risk studies in the various scholarly disciplines, subject to the oversight of the faculty board concerned.

3.6 Research with vulnerable participants or greater than minimal risk must be reviewed by one of the RECs specifically appointed for this purpose with expertise in the field of study.

3.7 In cases where considerations of research ethics involve more than one discipline, the responsible managers must take steps to activate all relevant REC's.

CODE OF CONDUCT FOR NWU RESEARCHERS

This code of conduct is applicable to all NWU researchers.

As a researcher of the North-West University (NWU), I subscribe to the rules of the NWU Research Ethics Regulatory Committee (RERC), all applicable policies of the NWU as well as all national and international laws and regulations applicable to my field of study. Furthermore, I commit myself to abide by the ethical principles and responsibilities as set out in the Singapore statement on Research Integrity (22 September 2010), in any and all research endeavors that I undertake as a researcher of the NWU.

The four major principles of research integrity to which I will adhere and that will guide my research are:

- Honesty in all aspects of research
- Accountability in the conduct of research
- Professional courtesy and fairness in working with others
- Good stewardship of research on behalf of others

Consequently, I will also adhere to the following ethical responsibilities:

1. I will take responsibility for the originality and trustworthiness of my research.
2. I will stay abreast of and adhere to all institutional, national, and international laws, regulations, and policies applicable and related to my research.
3. I will at all times employ appropriate research methods, base my conclusions on critical analysis of the evidence and report my findings and interpretations fully and objectively.
4. I will keep clear and accurate records of all research that I have conducted in a manner that will allow verification and replication of my work by others, if applicable.
5. I will, where applicable, share my data and findings openly and promptly, in line with external funding rules. This will be done as soon as possible after I have had an opportunity to establish priority and ownership claims.
6. I will take responsibility for my own contributions to publications, funding applications, reports and other representations of my research. I will also and only include authors who meet valid authorship criteria.
7. I will acknowledge the names and roles of those who made significant contributions to my research in publications, including writers, funders, sponsors, and others, but do not meet authorship criteria.
8. In my peer reviews, I will provide fair, prompt and rigorous evaluations and I will respect confidentiality when I review others' work.
9. I will disclose all conflicts of interest (financial and other) that could compromise the trustworthiness of my work in research proposals, publications, public communications, and in review activities.
10. When I publically address a community in the spirit of academic freedom, I will in all stages base my professional comments on research findings (if applicable) and my expertise. I will distinguish between professional comments and opinions based on personal views.
11. Should any irresponsible research practices and/or research misconduct become known to me or brought under my attention, I will report such irresponsible research activities to the appropriate authorities.
12. I will respond to irresponsible research practices or conduct, by taking prompt actions as set out in the procedures of the university. I will also protect those who report misconduct in good faith, to the best of my abilities.
13. I will endeavor to create and sustain an environment that encourage research integrity through education of students, research teams and peers, as well as abide by policies, and reasonable standards for advancement.
14. I will at all times weigh societal benefits against the risks inherent in my work.

Name: Signature:

Date

Rules for the management of research ethics at the North-West University

1 Introduction

1.1 Motivation for a management process for research ethics

Research ethics deals with the way in which research is planned, conducted and executed, in order to ensure that the entire process conforms to rules, standards or norms for conduct as agreed upon by the research community at large. Naturally, this is dependent on the field of study and the research methodologies that are deemed acceptable within that field.

There are many aspects and challenges involved in different research fields, and hence many reasons to consider the ethical aspects of such research. The following is a small selection of examples to illustrate the point:

- Research involving human participants or animal subjects: The rights and welfare of such participants/subjects must be safeguarded, the relationship between researcher and participants must be considered;
- Data-intensive research: Aspects involving the collection, use and interpretation of data must be acceptable;
- Research plans: Aspects such as formulating, review, reporting, communication of findings, affordability to execute and complete research
- Research teams: Competence and authorisation of team members to perform tasks and ability take necessary responsibility;
- Relationships within research teams: Who will publish or co-publish, first-author agreements, travel and conference attendance, issues related to affiliation, conflict resolution.
- Relationship with the community: Responsibility to perform and communicate research such that it remains responsive to community needs and aspirations, keeping the community engaged, aware and informed.

From a normative perspective, there are several reasons to adhere to solid ethics standards, such as:

- Ensuring honesty in all aspects of research;
- Ensuring that researchers can be held accountable when conducting research;
- Ensuring a high level of professional courtesy and fairness in working with others;
- Ensuring good stewardship of research on behalf of others.

It is hence imperative that all researchers at the NWU must agree on a shared set of ethics guidelines, and that management measures be put in place to ensure that all research is conducted within the boundaries of these guidelines. These guidelines will be derived from the Research Ethics Policy of the NWU.

1.2 Overview of management process

1.2.1 Code of Conduct

The NWU has adopted a Research Ethics Policy which lays down the ethics principles for research at the university. These principles were further expanded into an approved Research Code of Conduct, which must be signed by all researchers to indicate their acceptance of these principles. All management structures of the NWU will ensure that all research conducted under the auspices of the NWU must adhere to these principles.

1.2.2 Structure

In order to give effect to the Research Ethics Policy of the NWU, a committee structure will be set up to manage the Research Ethics processes of the NWU. A **Research Ethics Regulatory Committee (RERC)** will be responsible for the governance issues, and a number of **Research Ethics Committees (REC)** functioning within the faculties will be responsible for the operational management of the process. Each faculty will have at least one REC, but can have more than one such REC depending on discipline-specific needs.

Each REC will function in close alignment with the various research committees in the Faculty e.g. the research entity's Scientific/Proposal Committee and the Faculty Research Committee. The REC will have the same status and reporting responsibility as the Faculty Research Committee.

1.2.3 Statutory requirements for external registration of REC

The National Health Act was first published in 2003. Chapter 9 of the Act deals with National health research and information. A large portion of that chapter is in fact dedicated to health research ethics. Section 72 mandates the establishment of the National Health Research Ethics Council (NHREC), and stipulates that all RECs dealing with health research must be registered by the NHREC. The gazetted regulation relating to research with human participants of 2014 and the document Ethics in Health Sciences: Principles, Processes and Structures of 2015 expand on this and refer to *health and health-related research*. The latter document is intended to provide the minimum national benchmark of norms and standards for conducting responsible and ethical health and health-related research, including research with animals. In the latter case, the SANS 10386:2008 provides the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes.

It can easily be envisaged that other groupings can follow this example set by the Department of Health, i.e. that the research ethics within various contexts can in some form or way be governed by a statutory body. Hence, these rules must make provision for a variety of RECs that are registered with some statutory body, which prescribes guidelines that must be adhered to.

All RECs that are approved by the NWU, irrespective of it being registered with an external regulatory body or not, will have the same status within the NWU.

1.2.4 Risk Level Descriptors

A risk can be seen as "the probability of harm occurring as a result of participation in research" or "an unexpected negative consequence of unethical actions". Therefore, risk needs to be assessed prior to conducting research. A risk level descriptor (RLD) is therefore the specification of the magnitude of the risk and probability of such risk occurring. It forms the basis of RECs' decision-making regarding ethical clearance of research.

Research Ethics Risks can be classified in the following four categories: (**Note:** The definitions given here, with minor changes, are quoted from the document "Regulations relating to research on human subjects"[1] derived from the National Health Act of 2003, and **may not be directly applicable to all contexts**).

1. **No Risk**: There is no possible risk that the research may lead to any undesirable effects or unexpected negative consequence.
2. **Minimal, Low or Negligible Risk**: The probability, magnitude or seriousness of unexpected negative consequences, harm or discomfort anticipated in the research is **negligible** and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country). Research in which the only foreseeable risk is one of **minimal unexpected negative consequences, discomfort or inconvenience**.
3. **Medium Risk**: Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.
4. **High Risk:** Research in which there is a real and foreseeable risk of unexpected negative consequences, harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.

There are various other ways of classifying risk. For instance, risk for research with animals is usually classified according to the impact on animal wellbeing, ranging from no impact on animal wellbeing to very severe impact, requiring extraordinary motivation and control measures.

By their very nature, these RLDs are discipline-specific. Hence, each REC needs to formulate its own definitions and examples for the various risk levels described above. These examples of RLDs must be reviewed and approved by the NWU RERC.

1.2.5 Application for Ethics Clearance

Before any research may be conducted scientific clearance must be granted for a project by the relevant scientific/proposal committee. The process of application for ethics clearance will be based on the RLDs applicable to the specific discipline and produced by the relevant REC.

A typical ethics clearance process would include that a research proposal with supporting documents as well as an ethics checklist (determined by discipline specific RLDs) first be submitted to a scientific/proposal committee for scientific review. This committee will make a preliminary assessment of the risk levels of the application based on an ethics checklist, and refer the application to an appropriate REC for a final review. The REC must also determine the context of the research: if the context is health or health-related, the application must be referred to a committee registered with the NHREC, in the format specified by the registered REC.

After proper review by the relevant REC, the committee will communicate their decision to the researcher and/or the SCRE for further action.

1.2.6 Training

Knowledge regarding research ethics has evolved greatly over the course of the past few years. More specifically in South Africa research ethics, which originally focused on health research due to Chapter 9 of the National Health Act 61 of 2003, has developed to reveal other important ethical aspects within non-health disciplines, as motivated in 1.1 above. With this evolution new research ethics issues have come to the fore as well as misconceptions with regard to what is ethical research behavior and what is not. To stay informed and up to date with current developments within research ethics, training of researchers and research ethics committee members needs to be done on a continuous basis (at least once every three years).

In the sections following this Introduction, this document makes provision for the following:

- Rules for the establishment of the SCRE that provides governance leadership for research ethics at the NWU;
- Rules for the establishment of NWU RECs;
- Rules for the functioning of such RECs;
- Rules which makes provision for some of the NWU RECs to register with external regulatory bodies, and which allows these registered RECs to also satisfy the requirements of the external regulatory body;
- Rules to establish a mechanism and guidelines in order to ensure that research ethics applications are considered by the correct and appropriate REC.

2 Terms of Reference: Senate Committee for Research Ethics (SCRE)

2.1 Purpose of the SCRE

The SCRE is established for matters concerning research ethics. These matters include ethics planning, and the ethics policy framework. This committee is meant to support the Senate in this regard.

2.2 Responsibilities of the SCRE

Governance: Formulates the Research Ethics Policy of the NWU, and ensures that all research conforms to this policy by

- Formulating a research ethics code of conduct to be signed by all researchers;
- Formulating generic minimum rules for all RECs at the NWU;
- Facilitating the establishment of appropriate research ethics committees (REC) within the NWU;
- Approving the specific operational rules, RLDs and codes of conduct where applicable for each REC;
- Ensuring that every REC performs its duties in line with its approved operational rules;
- Ensuring that the members of each REC are appropriately trained and qualified;
- Being co-responsible for ensuring that, when appropriate, registered RECs comply with the rules of the external governing body.

Support: Provides the necessary support (via the Research Support office) to RECs, in terms of:

- Providing and maintaining an efficient research ethics management system (InfoEd);
- Providing a research ethics awareness program for new staff;
- Creating awareness with line managers to ensure that RECs are provided with the necessary resources in the normal budgeting process in order to fulfil its Terms of Reference;
- Recordkeeping (via the research ethics management system) of all activities of each REC, including the recording of ethics approval numbers and the issuing of ethics certificates.
- Referring to the appropriate REC, any request from an outside entity to conduct research within the NWU, for review.

Reporting and Monitoring: Considers the annual reports of RECs, and reports on ethics activities to ICRI and Senate.

- Reviews the activities of each REC annually, by considering the annual report of the REC in consultation with the Chairperson of the REC. The SCRE will also conduct regular on-site reviews of all RECs. This review must satisfy the RERC that the proper procedures as approved by the NWU are followed by the REC. In cases where the REC is registered with some external body, this review will be combined with external reviews conducted by the external body, and will serve to ensure that the conditions of that body are satisfied;
- Requests an appropriate REC to comment on particular ethics aspects if requested by an outside entity;
- Through ICRI, provide Senate with an annual report on research ethics matters.

2.3 Authority of the SCRE

The SCRE is a standing committee of the Senate of the NWU, and advises Senate on research ethics governance matters. The SCRE must report continuously to the DVC: Research and Innovation, or as determined by the Senate.

2.4 Membership of the SCRE

The SCRE consists of:

- A chairperson **appointed by Senate** for an appropriate period from the ranks of the DVCs;
- The DVC: RIT *(ex officio)*
- The Director: Research Support of the NWU *(ex officio)*;
- A member of the Institutional Legal Office or an expert from one of the Law Faculties of the University,
  - **appointed by Senate**;
- The Chairperson(s) or his/her delegate of each REC of the NWU *(ex officio)*;
- A member of the Research Support Office, who provides support as specified in 2.2 above *(ex officio)*;
- A committee secretary from the department of Institutional Governance and Secretarial Services.
- The SCRE may from time to time co-opt additional members as needed, such as the Head of the Faculty of Health Sciences Research Ethics office.

All members of the SCRE have voting rights.

2.5 Meeting arrangements of the SCRE of the SCRE

Frequency	Twice per annum; the first meeting of the year will deal mainly with reports from RECs, while the second will deal mainly with governance matters.
Extraordinary meetings	If and when necessary
Quorum	The quorum of the meeting will be half (50%) plus one of all the members, excluding vacant positions.
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies of the time and place where the meeting is to be held.

	At least 2 days before an extraordinary meeting, the Secretariat electronically notifies, provides the reason for an extraordinary meeting, as well as the time and venue.
Agenda	At least 7 days prior to the meeting, the Secretariat provides the complete agenda pack electronically to all members.
Reporting	The SCRE reports to Senate via the ICRI. The minutes of each meeting serves at ICRI for discussion and approval.
Decision-making process	Matters are decided by means of general consensus. The Chairperson might however decide when a decision should be taken by means of a voting procedure. The Chairperson may decide that voting must be by secret ballot, provided that voting for persons must always be by secret ballot. The Chairperson has an ordinary vote, but must in addition exercise a casting vote in the event of an equality of votes on any matter. The number of votes in favor of or against any proposal is not recorded in the minutes, unless the Chairperson so decides.
Conflict of Interest	A member may not take part in the discussion of or vote on any matter in which the member has a direct financial or other interest, unless the members first discloses the nature and extent of the interest and obtains the leave of the meeting to take part in the discussion or to vote.
Point of Order	A point of order, clarification or information may be raised against any member, in which instance the ruling of the Chairperson is binding. The ruling of the Chairperson is binding and cannot be challenged. Should the above point of order, clarification or information be immediately challenged by a member, the ruling is put to the meeting for determination – without it being discussed, and the decision of the meeting is final.
Disrespectful Disorderly conduct	Anyone attending a meeting who, after having been requested to refrain from disrespectful or disorderly conduct, continues to disobey a ruling from the Chairperson, must be requested to leave the meeting. If that person does not leave the meeting immediately, such a person could be removed from the meeting with the assistance of Protection Services.
Apology	Members absent from the meeting, with apology prior to the meeting, are allowed to participate. The views of a member who is unable to attend a meeting may be submitted in writing.
Round Robin Process	The Chairperson may electronically submit urgent matters in between scheduled meetings. The Secretariat will assist in this process. At least two thirds of the members have to electronically confirm their involvement in the process by giving feedback, approval or non-approval. When a majority of members reaches agreement it is taken as a resolution. Such resolution is equivalent to a resolution of the committee and must be recorded in the minutes of the next meeting.
Resources and Budget	A centralised budget regarding the matters of this committee is managed within Institutional Research Support.
Records management	All records of the committee (terms of reference, membership list, agendas, attendance register, correspondence, etc.) will be kept electronically (on *Share*)

2.6 Approval and Review

The following documents guide the operations of the SCRE:

Document	Status	Authority	Date
Research and Innovation Policy	Approved	Council	20 September 2013
Research Ethics Policy	To be approved		
Policy for the Management of Research and Innovation Contracts and External Investment/Stake holding	Approved	Council	23 November 2012
Policy on Joint and Double Degrees at Masters and Doctoral Level with Foreign Universities	Approved	Council	31 July 2015
Rules for the Classification of Thesis and Dissertations	Approved	Council	20 June 2014

3 Terms of Reference: Research Ethics Committees (RECs)

These terms of reference provide a minimum standard for the operational management of the research ethics process within the NWU. All RECs approved by Senate, including REC registered with some external regulatory body, will function within these terms of reference.

3.1 Purpose of the REC

The REC provides operational management of the research ethics process at faculty level within its field of research expertise.

3.2 Responsibilities of the REC

The SCRE, in its governance role, stipulates that each REC will, within its specific field of research expertise:

- The REC will function within a strict code of conduct as appropriate for the specific research field and approved by the SCRE, and will ensure confidentiality of all information revealed to it;
- Ensure that researchers have a proper understanding of research ethics as applicable to the specific research field of expertise by providing subject-specific training;
- Ensure that all researchers working within its research field of expertise sign the NWU research ethics code of conduct;
- Formulate and seek approval from the SCRE for a set of operational rules for ethics applications within the specific research field of expertise;
- Formulate and seek approval for a set of research field-specific examples of Risk Level Descriptors, in line with the SCRE guidelines, to make a suitable classification of research ethics proposals.
- Provide feedback on specific ethics matters as requested by the SCRE;
- Receive applications for research ethics approval from researchers via the provided research management system;
- Consider these applications at its regular meetings, and communicate and minute the RECs decision regarding applications to the applicants;
- Approve the issuing of research ethics certificates for approved projects;
- In cases where the REC cannot come to a conclusion, or some other conflict arises within the REC, follow the general NWU rules for conflict resolution;
- Consider and act appropriately on the annual reports of approved projects;
- Consider applications to change any of the details of the research project as specified in the original proposal;
- Consider and act appropriately in cases of ethical misconduct by researchers
- Report via the approved Faculty structures to the relevant Dean;
- Report to the SCRE on an annual basis, using the prescribed reporting template.

3.2.1 Minimum standard for the ethics application procedure:

The SCRE will, with the support of the Research Support Office, maintain and manage the research ethics

management system (e.g. InfoEd). All ethics applications (ethics checklist, relevant application forms and supporting documents) must be captured and managed on this research management system, where after all decisions regarding applications must be captured on this system.

The ethics application procedure shall include at least the following steps:

1. A completed research proposal as well as an ethics checklist (as developed by the relevant ethics committee in line with its RLD) must be submitted to the relevant Scientific/proposal Committee for review.
2. The Scientific/Proposal Committee decides (based on the information in the research proposal and checklist) whether ethics clearance is required and refers the application to the relevant REC if necessary.
3. The REC will handle each application for ethics clearance according to the rules and operating procedures of the involved REC.
4. If deemed necessary or if required a REC may refer an application to a suitable registered committee.

3.3 Authority of the REC

The REC functions as a sub-committee of the Faculty board and in close collaboration with the Faculty Research Committee and Scientific/Proposal Committee. Each REC functions within a specific research field of expertise. Hence, any faculty could establish one or more RECs, depending on factors such as the number of research fields active within the faculty or statutory requirements.

The REC derives its authority from the governance rules formulated by the SCRE. As such, the establishment of an REC must also be approved by the SCRE. If an REC is dissolved by its faculty, this must be reported to the SCRE.

3.4 Membership of the REC

Members of an REC are recommended to, and approved by the relevant Faculty board for a period of five years, in accordance with the governance rules of the SCRE. Members are recommended based on their expertise within the specific research field, as well as their general research ethics expertise. Upon appointment, a formal Letter of Appointment will be issued by the SCRE. This appointment must reflect in the annual task agreement of the staff member.

3.4.1 Composition of the REC

The REC will consist of ***at least*** the following:

- A minimum of two members who are specialists in the particular research field,
- One member who is not a staff member of the North-West University (lay person).
- The research director of the research entity responsible for the research field of expertise (if practical; in large faculties this may not be the case).
- One member should be an expert in the field of statistics if applicable to the application;
- Ad hoc attendees can be nominated for meetings.

The composition of RECs registered with an outside regulatory body might be prescribed by that body. Even if this is the case, the minimum membership will be as described above.

3.4.2 Appointment of members

Members are approved by the relevant faculty board, and formally appointed by the SCRE, in its role as subcommittee of Senate.

3.4.3 Appointment of Chairperson and acting Chairperson

The Faculty Board appoints a chairperson in consultation with the REC. An acting chairperson can be appointed by the REC, to act for a limited period.

3.4.4 Co-opted members, observers and visitors

The REC co-opts members as and when needed. Since the REC functions within a strictly confidential environment, observers and visitors will only be allowed in exceptional cases and for a specific purpose.

Researchers can be invited for the discussion of their application and to be present to clarify any uncertainties.

3.4.5 Voting rights

All members will have voting rights, while co-opted members, observers and visitors will not have such rights.

3.4.6 Secretariat

The relevant Faculty will ensure that appropriate secretarial services are provided.

3.5 Meeting arrangements

The following meeting arrangements apply:

Frequency	A **minimum** of twice per annum preceding the two meetings of the SCRE. These meetings should preferably be face-to-face meetings, but can also be held via electronic media where practical. The timing of meetings should be such that research projects are not delayed unnecessarily while waiting for ethics clearance.
Extraordinary	If and when necessary
Quorum	The quorum of the meeting will be at least half (50%) plus one of all the members, excluding vacant positions.
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies, provides the reason for an extraordinary meeting, as well as the time and venue.
Agenda	At least 5 days prior to the meeting, the Secretariat provides the complete agenda pack electronically to all members.
Reporting	A report of the RECs activities, excluding confidential information, serves at the appropriate faculty board for discussion and approval. An annual report must be submitted to the SCRE in the prescribed format.
Decision-making process	Matters are decided by means of general debate and consensus. The Chairperson might however decide when a decision should be taken by means of a voting procedure. The Chairperson may decide that voting must be by secret ballot, provided that voting for persons must always be by secret ballot. The Chairperson has an ordinary vote, but must in addition exercise a casting vote in the event of an equality of votes on any matter.
Conflict of Interest	A member may not take part in the discussion of or vote on any matter in which the member has a direct financial or other interest, unless the members first discloses the nature and extent of the interest and obtains the leave of the meeting to take part in the discussion or to vote.
Point of Order	A point of order, clarification or information may be raised against any member, in which instance the ruling of the Chairperson is binding. The ruling of the Chairperson is binding and cannot be challenged. Should the above point of order, clarification or information be immediately challenged by a member, the ruling is put to the meeting for determination – without it being discussed, and the decision of the meeting is final.
Disrespectful / Disorderly conduct	Anyone attending a meeting who, after having been requested to refrain from disrespectful or disorderly conduct, continues to disobey a ruling from the Chairperson, must be requested to leave the meeting. If that person does not leave the meeting immediately, such a person could be removed from the meeting with the assistance of Protection Services.

Apology	Members absent from the meeting, with apology prior to the meeting, are allowed to participate. The views of a member who is unable to attend a meeting may be submitted in writing.
Round Robin Process	The Chairperson may electronically submit urgent matters in between scheduled meetings. The Secretariat will assist in this process.2 At least two thirds of the members have to electronically confirm their involvement in the process by giving feedback, approval or non-approval. When a majority of
Resources and Budget	The Chairperson submits a budget to the appropriate faculty as part of the annual budgeting process.
Records management	All records of the committee (terms of reference, membership list, agendas, attendance register, correspondence, etc.) will be kept electronically on the research ethics management system (InfoEd).

4 RECs registered with external regulatory bodies

There is currently only one such external regulatory body, namely the National Health Research Ethics Council.

4.1 Registration with the NHREC

The National Health Act was first published in 2003. Chapter 9 of the Act deals with National health research and information. A large portion of that chapter is in fact dedicated to health research ethics. Section 72 mandates the establishment of the National Health Research Ethics Council (NHREC), and stipulates that all RECs dealing with health research must be registered by the NHREC. The gazetted regulation relating to research with human participants of 2013 (See footnote 1 above) and the document *Ethics in Health Sciences: Principles, Processes and Structures*[3] of 2015 expand on this and refer to *health and health-related research*. The latter document is intended to provide the minimum national benchmark of norms and standards for conducting responsible and ethical health and health-related research, including research with animals, as specified in paragraphs 1.4.1 and 1.5.1 of the document in footnote 3. In the latter case, the SANS 10386:2008 provides the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes.

Health research is defined as

Health research *– contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care*

Each REC dealing with research that complies with this definition of Health or Health-Related Research must be registered with the NHREC. After registering with the NHREC, the REC must, in addition to the minimum rules for REC as stipulated by the SCRE, also comply with the rules of the NHREC.

It can easily be envisaged that other groupings can follow this example set by the Department of Health, i.e. that the research ethics within various contexts can in some form or way be governed by a statutory body. Hence, these rules must make provision for a variety of RECs that are registered with some statutory body, which prescribes procedures that must be adhered to.

4.2 Exclusions

The importance of ethical behavior in all scientific endeavors cannot be denied. This is especially true when the health and well-being of humans and animals are at stake. There is a general school of thought that the National Health Act and its associated publications provide a minimum national benchmark of norms and standards for conducting responsible and ethical research in **all** research fields. This school of thought is based on statements made in the Foreword of the document referred to in footnote 3.

The following ***verbatim extract*** from *Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015,* provide guidelines to better understand the context within which the document must be interpreted, and hence where the principles as specified in the document are applicable. (See also Appendix 1 of the document for definitions. Where any confusion or misinterpretation can arise, the definitions are also given here in footnotes.)

1.4.1 The National Health Act (NHAs 72(6)(c)) gives authority to the NHREC for setting norms and standards for ***health and health-related*** *research that involves humans.* (Authors emphasis)

*1.5.1 The National Health Act (NHA) gives authority to the NHREC for setting norms and standards for **health research** that uses animals (NHA s 72(6)(c)).* (Authors emphasis)

1.1.6 These guidelines do not advocate the so-called 'medical model' of ethics review, especially not for social science, behavioral or humanities research.

1.1.7 The core ethical principles outlined in these guidelines apply to all forms of research that involve living human participants and use of animals, placing their safety, welfare and interests of both humans and animals as paramount. The principles also apply to research that involves use of human biological materials and data collected from living or deceased persons, including human embryos, foetuses, foetal tissue, reproductive materials, and stem cells.

1.1.8 Research that relies exclusively on publicly available information or accessible through legislation or regulation usually need not undergo formal ethics review. This does not mean that ethical considerations are irrelevant to the research.

1.1.9 Research involving observation of people in public spaces and natural environments usually need not undergo formal ethics review, provided that

- the researcher does not interact directly with individuals or groups
- the researcher does not stage any intervention
- the individuals or groups do not have a reasonable expectation of privacy
- dissemination of research findings does not identify individuals or groups

1.1.10 Research that relies exclusively on secondary use of anonymous information[4] or anonymous human biological materials usually need not undergo formal ethics review, provided that no identifiable information is generated. See 3.3 below for further information regarding human biological materials.

1.1.11 Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews usually do not constitute research and thus usually do not undergo formal ethics review. It should be noted, however, that if publication of such studies is desirable, it is prudent to obtain ethics approval before the study begins. RECs may not grant retrospective ethics approval.

1.1.12 These guidelines express the view that the core ethical principles apply to all forms of research that involve humans or use of animals, insofar as the welfare and safety interests of both humans and animals are paramount. Health and safety issues include those that may arise in the environment of research e.g. viruses, parasites, bacteria, as well as the air, water and land.

1.1.13 This document is intended to be as inclusive as possible, so that all researchers who involve human participants or use animals in their research will find assistance in these guidelines. In other words, although this document derives its authority from the National Health Act, the National Health Research Ethics Council (NHREC) intends it to address research more broadly to achieve the specific goal of providing guidance for researchers so that all research involving human participants or animals may be conducted in accordance with the highest ethical norms and standards.

From the above, it is clear that the aim of the document is to **provide guidelines** to ensure the **welfare and safety interests** of human participants or animals used in **health or health-related research** (section 1.1.12). The document states clearly that it **does not wish to enforce** a "medical model" of ethics review for research in **social science, behavioural or humanities research.** Sections 1.1.8, 1.1.9 and 1.1.10 makes it clear that in cases where **anonymous data** is collected through means **not involving direct contact** with live humans, ethics clearance as specified for health or health-related research is not necessary. It also **excludes quality assurance** and quality improvement studies, **program reviews** and **performance reviews** from ethical clearance.

Section 1.4.1 also states that the NHREC derives its authority from the National Health Act, and hence can set norms and standards for health and health-related research that involves humans. In other contexts, the NHREC can provide guidelines, but cannot be prescriptive.

4.3 Referring an ethics application to a registered REC

It must be emphasized that research involving live humans or vulnerable groups of people must be done with the utmost care and consideration of ethical principles. Therefore, if any doubt exists, applications for ethical clearance involving live humans must be referred to an REC registered with the NHREC.

However, it is also clear that the NHREC regulations could be interpreted in a way that seriously complicates and sometimes even compromises research projects. The REC must therefore give careful consideration to such applications before referring it to a NHREC-registered REC. In the deliberations of the REC, the following two questions must be considered:

1. If the research project involves live humans or animals, is the research done in the health or health- related context?
    a. If YES, do any of the exclusions above apply? If yes, the REC may proceed to question 2 below, otherwise the application is referred to a registered REC qualified to deal with the application.
    b. If NO, the REC may proceed to question 2 below.
2. Is there any possibility of unexpected negative consequences, harm or discomfort as a result of unethical behaviour? Based on the RLD's as approved for this specific REC, a risk classification is made and the application is dealt with in terms of the rules as approved for this REC.

The answer to question 1 above is not a simple matter, and requires the members of the REC to apply their minds. A simple statement like "If it involves humans, it is health" is obviously not the answer. Turning to the definition of health research given above, one must consider whether the research will contribute towards a better understanding of

- biological, clinical, psychological, or social welfare matters.
- causes and effects of and responses to diseases;
- effects of environment on humans;
- methods to improve health care delivery;
- new pharmaceuticals, medicines, interventions and devices;
- new technologies to improve health and health care

If the answer is YES, then it is research within the health or health related context. If one of the exclusions as discussed above applies, then it is not required to get ethical clearance. Otherwise, ethical clearance from a registered REC is compulsory.

To answer the second question is again not a simple matter. A simple statement like "there is no risk, since the research does not involve live humans" is again not conclusive. There is for instance a serious risk of harm to the reputation of the NWU due to unethical behaviour in virtually every research project.

The final message here is that a very careful assessment of each research project in in the context of its field of research must be made to decide on the appropriate REC.

ADDENDUM 2

CODE OF CONDUCT FOR RESEARCHERS

This code of conduct is applicable to all NWU researchers.

As a researcher of the North-West University (NWU), I subscribe to the rules of the NWU Research Ethics Regulatory Committee (RERC), all applicable policies of the NWU as well as all national and international laws and regulations applicable to my field of study. Furthermore, I commit myself to abide by the ethical principles and responsibilities as set out in the Singapore statement on Research Integrity (22

September 2010), in any and all research endeavors that I undertake as a researcher of the NWU.

The four major principles of research integrity to which I will adhere and that will guide my research are:

- Honesty in all aspects of research
- Accountability in the conduct of research
- Professional courtesy and fairness in working with others
- Good stewardship of research on behalf of others

Consequently, I will also adhere to the following ethical responsibilities:

15. I will take responsibility for the originality and trustworthiness of my research.
16. I will stay abreast of and adhere to all institutional, national, and international laws, regulations, and policies applicable and related to my research.
17. I will at all times employ appropriate research methods, base my conclusions on critical analysis of the evidence and report my findings and interpretations fully and objectively.
18. I will keep clear and accurate records of all research that I have conducted in a manner that will allow verification and replication of my work by others, if applicable.
19. I will, where applicable, share my data and findings openly and promptly, in line with external funding rules. This will be done as soon as possible after I have had an opportunity to establish priority and ownership claims.
20. I will take responsibility for my own contributions to publications, funding applications, reports and other representations of my research. I will also and only include authors who meet valid authorship criteria.
21. I will acknowledge the names and roles of those who made significant contributions to my research in publications, including writers, funders, sponsors, and others, but do not meet authorship criteria.
22. In my peer reviews, I will provide fair, prompt and rigorous evaluations and I will respect confidentiality when I review others' work.
23. I will disclose all conflicts of interest (financial and other) that could compromise the trustworthiness of my work in research proposals, publications, public communications, and in review activities.
24. When I publically address a community in the spirit of academic freedom, I will in all stages base my professional comments on research findings (if applicable) and my expertise. I will distinguish between professional comments and opinions based on personal views.
25. Should any irresponsible research practices and/or research misconduct become known to me or brought under my attention, I will report such irresponsible research activities to the appropriate authorities.
26. I will respond to irresponsible research practices or conduct, by taking prompt actions as set out in the procedures of the university. I will also protect those who report misconduct in good faith, to the best of my abilities.
27. I will endeavor to create and sustain an environment that encourage research integrity through education of students, research teams and peers, as well as abide by policies, and reasonable standards for advancement.
28. I will at all times weigh societal benefits against the risks inherent in my work.

Name: Signature:

Date

ADDENDUM 3

NWU-EMELTEN-REC

INCIDENT REPORT FORM WHEN CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS

Note: An incident is seen as an unanticipated situation or issue that arises while conducting your research and that has no direct cause/effect due to an intervention.

Please complete the form according to the following guidelines:

- Researchers need to complete Sections A to C.
- The Chairperson of the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) will complete Section D.

SECTION A: GENERAL INFORMATION

1. Project Leader/Principal Investigator/Study leader Details						
Surname			**Initials**		**Title**	
School/ Research unit						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
2. Student Details (if applicable)						
Surname			**Initials**		**Title**	
School/ Research unit						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
3. Details of approved research						
Title						
Ethics Approval Number						
Approval date			**Expiry date**			
Last submission of a monitoring report			**Date:**			

Please describe the progress to date of the project (not more than 500 words):
Please describe the incident that is being reported in detail (please ensure that you respond to what, where, who, how, when of the incident):
Please describe the action that has been taken to date in detail in order to contain the incident:
Please indicate a possible strategy/action plan for correcting the incident:
Please indicate a possible strategy/action plan for ensuring that it will not occur again:

SECTION B: INCIDENT REPORT

	Yes	No	NA
Will this incident require that the proposal will have to be changed? **If yes, please ensure that an amendment request is submitted to the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) as soon as possible.**			

SECTION C: SIGNATURE

By signing this document, I certify that the information provided is accurate and complete.			
Signature by the principal investigator		**Date**	

SECTION D (for office use only):

14. North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) report	**Yes**	**No**	**NA**
Has the incident been satisfactorily reported?			
Has the incident been satisfactorily addressed?			
If yes, please explain the manner in which the incident was managed with the project leader/principle investigator/study leader and participant/s:			

NWU-EMELTEN-REC Chairperson	**Signature**	**Date**

ADDENDUM 4

NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

DISCLOSURE OF CONFLICT OF INTEREST AT AN NWU-EMELTEN-REC MEETING ON THE…… (DATE) FROM …….. (TIME).

I.....

(Full name and surname)

hereby disclose conflict of interest in that:

.....

.....

.....

.....

.....

.....

.....

.....

.....

Signed on ……(date) at an NWU-EMELTEN-REC meeting held at the NWU Potchefstroom Campus, Building C6 Room G01.

.....

SIGNATURE

.....

Prof Lukas Meyer

NWU-EMELTEN-REC Chairperson

ADDENDUM 5

NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

NWU-EMELTEN–REC: REVIEWER REPORT

Title of the study	
Ethics Application nr.	**NWU-**
Applicant's Name	
Reviewer Code	
Date of Review	

	Element	Yes No NA	Comment
1	Is the title appropriate to the content of the research?		
2	Has the research proposal been evaluated by a scientific/research proposal committee?		
3	Is the study relevant and of value? • Responsive • Contributes to knowledge • Worth doing		
4	Does the study show scientific integrity? • Knowledge of relevant literature • Sound and valid design and methodology • Was open to peer review and scrutiny • The ethical implications of the design and method clearly stated • Rationale of methodology		
5	Are the aims and/or objectives achievable and will it produce outcomes?		
6	Is the selection of the study population fair and just? • Method clear and complete • Fair distribution of burden and likelihood of benefit • No groups are deprived of an opportunity		

7	Are the inclusion and exclusion criteria clearly stated, appropriate and justified? • Rationale for the planned number reasonable • Rationale for inclusion and exclusion criteria clear and reasonable • Inclusion of vulnerable participants is justified		
8	Is the process of recruitment and enrolment clear and in detail? • Recruitment strategies neutral • Recruitment method (including screening) clear • Roles of gatekeepers and mediators clear • Recruitment materials appropriate (e.g. advertisement) • Done by an independent person • Location, context and timing appropriate and privacy and confidentiality protected • Participants not over researched		
9	Has a risk-benefit ratio analyses been done? • Risks identified • Precautions mentioned • Direct and indirect benefit stated • Risk benefit ratio analyses favourable		
10	Will the participants be appropriately reimbursement? • Time • Inconvenience • Expenses • No coercion or undue influence		
11	Is the participant's privacy and confidentiality protected? • Personal information and records protected • Identity protected		
12	Is the process of obtaining informed consent/permission/assent clear? • Informed and voluntary • Written and verbal • Obtained by an independent person • Confirmed by the researcher • Sufficient time given to consult and make an informed decision before signing • Can withdraw • Without coercion, undue influence or inappropriate incentives • Understandable and valid informed consent form • Need for translation		
13	Are the researchers professionally competent? • Academic qualifications suitable • Scientific and technical competence adequate • Proof of research competence (education, knowledge and experience) • Appropriate skills • Mentoring		
14	Is respect for participants clear throughout? • Dignity • Voluntary • Safety • Well-being		

	• Interest of the participant		
15	Are the facilities where the research will be conducted appropriate and suitably resourced?		
16	Is data-collection well managed? • What data is being collected? • Why is the data being collected? • What will happen to the data? • How long will data be retained? • Will the data identify the participant? • Will it be shared with others and why? • Will it leave the country?		
17	Is the process of sample storage clear (if applicable)? • For how long? • Where will it be stored? • Is there informed consent for the analyses? • Who will manage it? • Will it be shared with others and why? • Will it leave the country?		
18	Was a statistician included or consulted/proof of expertise?		
19	Are all the additional legal documents/requirements applicable, included and correctly completed? • What is the current status thereof? • To what extent has it been operationalized? ▪ International contractual agreements/sub agreements ▪ National contractual agreements/sub agreements ▪ Collaboration agreements (other universities, individuals etc.) ▪ Written permission (National/provincial Departments, hospitals, clinics, universities etc.) ▪ Written goodwill permission (Traditional leaders, managers etc.) ▪ Confidentiality agreements (fieldworkers, mediators, participating clinicians or professionals etc.) ▪ Export/import permits ▪ Sponsorship agreements ▪ Service agreements (with sponsors, other entities etc.)		
20	Is the researcher and project covered by insurance?		
21	Is it clear how results will be disseminated? • How will participants be informed? • Is there a sure dissemination plan? • Will it be done in an ethical manner?		
22	Is conflict of interest clearly stated and how it will be handled?		
23	Is the process of data management and storage clear? • How will electronic data and hard copies be stored? • How will audio and video data be stored? • Who will store the data? • Who will have access?		

	• How will the data be protected? • For how long will data be stored? • How will it finally be disposed of?		
24	Are there clear monitoring and safety measures in place?		
25	Is it a realistic time schedule?		
26	Has a budget been included and has it been stated how it will be covered?		
27	Specifically, for secondary use of data or samples (if applicable): • Is there a permission letter from the project head stating what can be done? • Is the documentation of the original study included (e.g. proposal, ethics certificate etc.)? • Does the sub-study match the larger study? • Was permission given in the signed informed consent for the planned sub-study? • Is it clear that the initial data set or samples were collected in an ethical manner? • Is it clear how data/sample integrity was ensured through safe storage? • Has a clear methodology been presented on how the data/samples will be used in the present sub-study?		

Recommendation for status of the application

Approved	
Approved with minimal changes	
Approved with several changes	
Deferred	
Disapproved	

Recommendation for potential risk level of the application in the case of adult participants

No risk	
Minimal risk	
Medium risk	
High risk	

Recommendation for potential risk level of the application in case of children or incapacitated adults

No risk	
No more that minimal risk of harm	
Greater than minimal risk but provides prospect of direct benefit	
Greater that minimal risk with no prospect of direct benefit	

Date **Reviewer signature**

ADDENDUM 6

NWU-EMELTEN-REC

CONFIDENTIALITY UNDERTAKING

entered into between:

I, the undersigned

Prof / Dr / Mr / Ms _____

Identity Number:_____

Address:_____

hereby undertake in favor of the **NORTH-WEST UNIVERSITY**, a public higher education institution established in terms of the Higher Education Act No. 101 of 1997

Address: Office of the Institutional Registrar, Building C1, 53 Borcherd Street, Potchefstroom, 2520

(hereinafter the "NWU")

1 Interpretation and definitions

1.1 In this undertaking, unless inconsistent with, or otherwise indicated by the context:

1.1.1 "Confidential Information" shall include all information that is confidential in its nature or marked as confidential and shall include any existing and new information obtained by me after the Commencement Date, including but not be limited in its interpretation to, research data, information concerning research participants, all secret knowledge, technical information and specifications, manufacturing techniques, designs, diagrams, instruction manuals, blueprints, electronic artwork, samples, devices, demonstrations, formulae, know-how, intellectual property, information concerning materials, marketing and business information generally, financial information that may include remuneration detail, pay slips, information relating to human capital and employment contract, employment conditions, ledgers, income and expenditures and other materials of whatever description in which the NWU has an interest in being kept confidential; and

1.1.2 "Commencement Date" means the date of signature of this undertaking by myself.

1.2 The headings of clauses are intended for convenience only and shall not affect the interpretation of this undertaking.

2 Preamble

2.1 In performing certain duties requested by the NWU, I will have access to certain Confidential Information provided by the NWU in order to perform the said duties and I agree that it must be kept confidential.

2.2 The NWU has agreed to disclose certain of this Confidential Information and other information to me subject to me agreeing to the terms of confidentiality set out herein.

3 Title to the Confidential Information

I hereby acknowledge that all right, title and interest in and to the Confidential Information vests in the NWU and that I will have no claim of any nature in and to the Confidential Information.

4 Period of confidentiality

The provisions of this undertaking shall begin on the Commencement Date and remain in force indefinitely.

5 Non-disclosure and undertakings

I undertake:

5.1 to maintain the confidentiality of any Confidential Information to which I shall be allowed access by the NWU, whether before or after the Commencement Date of this undertaking. I will not divulge or permit to be divulged to any person any aspect of such Confidential Information otherwise than may be allowed in terms of this undertaking;

5.2 to take all such steps as may be necessary to prevent the Confidential Information falling into the hands of an unauthorised third party;

5.3 not to make use of any of the Confidential Information in the development, manufacture, marketing and/or sale of any goods;

5.4 not to use any research data for publication purposes;

5.5 not to use or disclose or attempt to use or disclose the Confidential Information for any purpose other than performing research purposes only and includes questionnaires, interviews with participants, data gathering, data analysis and personal information of participants/research subjects;

5.6 not to use or attempt to use the Confidential Information in any manner which will cause or be likely to cause injury or loss to a research participant or the NWU; and

5.7 that all documentation furnished to me by the NWU pursuant to this undertaking will remain the property of the NWU and upon the request of the NWU will be returned to the NWU. I shall not make copies of any such documentation without the prior written consent of the NWU.

6 Exception

The above undertakings by myself shall not apply to Confidential Information which I am compelled to disclose in terms of a court order.

7 Jurisdiction

This undertaking shall be governed by South African law be subject to the jurisdiction of South African courts in respect of any dispute flowing from this undertaking.

8 Whole agreement

8.1 This document constitutes the whole of this undertaking to the exclusion of all else.

8.2 No amendment, alteration, addition, variation or consensual cancellation of this undertaking will be valid unless in writing and signed by me and the NWU.

Dated at Potchefstroom this _____ 20____

Witnesses:

1 .....

2 ....

(*Signatures of witnesses*) (*Signature*)