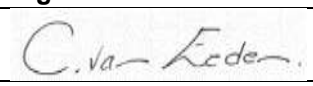
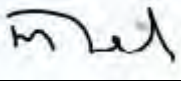
FACULTY OF HUMANITIES

Standard Operating Procedure: SOP_HSSREC_2.2

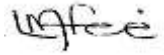
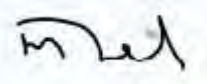
SOP for selection, appointment and functioning of the Human Social Sciences Research Ethics Committee of the Faculty of Humanities

	Standard Operating Procedure		
Title	SOP for selection, appointment and functioning of the Human Social Sciences Research Ethics Committee of the Faculty of Humanities		
SOP No	SOP_HSSREC_2.2	**Version No**	2
Date of approval		**Revision date**	April 2023
Web address		**Page No**	

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Revised by:	Prof. C. van Eeden		7 April 2021
Checked by:	Prof. J. Rothmann		22 April 2021
Authorised by:	Prof. M. Nel		28 Sep. 21

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
HSSREC	Prof. M. Heyns		27/4/21
Faculty of Humanities: Faculty Board	Prof. LM Fourie		29 Sept 2021
Committee for Research, Innovation and Higher Degrees	Prof. M. Nel		28 Sep 2021

3 DOCUMENT HISTORY

Date	Version No	Reason for revision
8 March 2018	1	Revision of 2015 SOP in line with NHREC audit of 30 November 2017. Based on the SOP of the NWU: HREC.
27 April 2021	2	Revision of 2018 SOP in line with NHREC requirements. Based on the SOP of the NWU: HSSREC: 2018.
29 October 2021	3	Final approval of HSSREC SOP documentation by Faculty Board and Deputy Dean Research and Innovation, Faculty of Humanities.

4 PURPOSE OF THE SOP

Quality assurance and legal compliance of research ethics within the Faculty of Humanities are administrated and managed by the Human Social Sciences Research Ethics Committee (HSSREC), registered with the National Health Research Ethics Council (NHREC): Reg No. REC-080615-047 and which focuses on research about human social functioning. The HSSREC reports to both the Senate Committee for Research Ethics (SCRE) of the North-West University and the Faculty Board of Humanities. The HSSREC of the Faculty of Humanities is registered with the National Health Research Ethics Council (NHREC): Reg. No. REC-080615-047 and functions 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), and 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 NHREC-registered HSSREC that provide operational management of research ethics processes within the Faculty.

5 SCOPE

Scope of research ethics evaluation and approval by the NWU-HSSREC:

- Studies within the broad field of humanistic disciplines that research human functioning in social, political, institutional, cultural and historical environments and developmental contexts (excluding health sciences);
- Other studies in the Faculty of Humanities that involve vulnerable populations or medium to high risk levels.
- Delegated power to consent to research involving minors: DELEGATION OF POWER TO CONSENT TO RESEARCH INVOLVING MINORS AS PRESCRIBED BY SECTION 71 (3)(a)(ii) OF THE NATIONAL HEALTH ACT No.61 OF 2003 TO HEALTH RESEARCH ETHICS COMMITTEES REGISTERED WITH THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL.

The NHREC-registered HSSREC makes recommendations, gives advice and reports to the Faculty Board of the Faculty of Humanities and the SCRE (as a subcommittee of the Senate) of the NWU. They also provide annual reports to both these aforementioned bodies.

The HSSREC is responsible for the review and approval of new research ethics applications, amendments and monitoring of research in the Faculty. No study referred to the HSSREC may begin before the HSSREC has provided written approval or may continue without the successful completion of the required monitoring reports.

The HSSREC is immediately notified of any incident or adverse event occurring during the research process which impacts on the safety of participants (see SOP_HSSREC_2.3).

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

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
HSSREC	Human Social Sciences Research Ethics Committee
NHREC	National Health Research Ethics Coguncil
NWU	North-West University
VTC	Vaal Triangle Campus
REC	Research Ethics Committee
SANS	South African National Standards
SCRE	Senate Committee for Research Ethics
HREC	Health Research Ethics Committee

7 RESPONSIBILITIES

The HSSREC is responsible for ensuring ethical research that is of a high quality, while the researchers should conduct research of the highest scientific and ethical standards.

8 PROCEDURE(S)

8.1 Aim

The aim of the HSSREC 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 researchers comply with the institutional, national and international requirements for research ethics in Humanity Sciences.

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

8.2 Objectives

To review research applications and amendments for ethical suitability within the Faculty of Humanities in order to ensure that:

- Research conducted will improve human social functioning within the broader framework of families, cultures, organizations and institutions;
- 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 is always protected;
- the research is valuable and scientifically responsible;
- written permission and informed consent are obtained at all times;
- approval is given to ethics applications based on research proposals that adhere to the scientific and ethical standards and requirements;
- 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 ongoing studies to ensure they adhere to the approved ethics criteria, the research protocol/proposal and relevant legal requirements.

8.3 Composition of the HSSREC

The composition of the HSSREC is determined by legal requirements, as set out by the NHREC in their guidelines titled, Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).

The HSSREC should be independent, multi-disciplinary, multi-sectoral and pluralistic.

8.3.1 The Human Social Sciences Research Ethics Committee (HSSREC) for research with human participants

HSSREC should consist of:

a. At least nine members, with a quorum being a simple majority;

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

c. at least one layperson who could represent the external community;

d. at least one member with knowledge of and current experience in the professional care, counselling or health-related treatment of people;

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

f. members with professional training and experience in quantitative methodologies;

g. a member with expertise in statistics;

h. a member with expertise in research ethics;

i. 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 of all HSSREC 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:

As soon as the HSSREC becomes aware of a vacancy in this position, the Faculty of Humanities' management (Deputy Dean of Humanities: Research and Innovation), in consultation with the HSSREC, suggests possible candidates based on their experience as HSSREC members and knowledge of research ethics. A qualification in research ethics is not a requirement but will, however, be advantageous. The Deputy Dean and an appropriate REC chairperson conducts interviews with candidates and make a recommendation to the Exco of Faculty for approval. The SCRE and the

Committee for Research, Innovation, Ethics and Higher Degrees are provided with the CV of the candidate and documentation of the Faculty of Humanities for ratification of the appointment. The SCRE is informed in order to finalise 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 (SOP's and NHREC documents); 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 HSSREC. This appointment must reflect in the annual task agreement of the HSSREC member, if applicable. The NHREC is also notified.

An acting chairperson can be appointed by the HSSREC, to act for a limited period.

8.4.2 The selection and appointment of the vice-chairperson:

As soon as the HSSREC becomes aware of a vacancy in this position, it nominates possible vice-chairpersons from the existing HSSREC members. The Deputy Dean of Humanities (Research and Innovation) and the chairperson have preliminary discussions with the nominated candidates on the roles and responsibilities of this position and makes a recommendation to the HSSREC. A final decision is taken during the next HSSREC meeting, confirmed at ExCo, ratified at the Faculty Board, and the SCRE is informed.

8.4.3 The selection and appointment of committee members:

As soon as the HSSREC becomes aware of a vacancy in this position, it makes it known within the Faculty and ask for nominations. The Deputy Dean Research and Innovation of the Faculty and the chairperson have preliminary discussions with the nominated candidates on the roles and responsibilities of this position. A final decision is taken during the next HSSREC meeting, confirmed at ExCo, ratified at the Faculty Board, and the SCRE is informed in order to finalise the appointment, as a subcommittee of the Senate. A formal letter of appointment is sent by the HSSREC, setting out the term of office; where to find the necessary information for new members (SOP's etc.); and the assurance that the members are indemnified from personal liability against claims that may arise in the course of ordinary business of the HSSREC. This appointment must reflect in the annual task agreement of the HSSREC member, where applicable. The NHREC is notified.

8.4.4 Sub-committees

The HSSREC can establish various sub-committees, from within the membership of the HSSREC, as per their needs and requirements e.g. executive committee, incident committee and/or serious adverse event committee (SOP_HSSREC_2.3).

8.4.5 Co-opted members, observers and visitors

The HSSREC co-opt members as and when needed. Observers and visitors will only be allowed in exceptional cases and for specific purposes. Researchers can be invited for the discussion of their applications and be present to clarify uncertainties.

8.5 Training

Training of all HSSREC members is critical. Training and refresher courses should be available and members will be expected to attend at least once every three years. HSSREC members should have documented proof of research ethics training.

8.6 Code of conduct

All HSSREC 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 committees 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 a timetable compiled at the beginning of the year and circulated to all relevant parties.

The agenda for these meetings close on the dates as indicated in the timetable.

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 ethics applications had been received at the closing of the agenda, except when urgent HSSREC related matters exist and the chairperson deems a meeting necessary.

Late ethics applications will stand over until the next meeting.

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

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

8.7.3 Proposed process for functioning

The HSSREC 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 approved applications.

The ethical review process should not be mechanical, but is a thorough consideration of all ethical aspects involved in the application of each unique study.

All applications reviewed by the HSSREC should have prior approval by a Scientific/Proposal Committee.

All applications are reviewed by the chairperson and/or deputy-chairperson and a minimum of two reviewers from the HSSREC. Expert reviews can also be requested when additional insights are needed.

HSSREC members should be encouraged to:

- be mindful of the basic ethical principles that should inform the planning, design and undertaking

of human social sciences research;

- be open-minded and not allow personal biases to cloud their application of ethical 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 ethics principles;
- be deliberate, reflective and thoughtful in discussions about how to balance ethical considerations.

Set timelines for review procedures to ensure an effective system:

- 5 – 8 working days for new applications; and
- 5 working days for corrections, smaller amendments and monitoring reports.

The HSSREC is also responsible for evaluation of incidents, adverse events (SOP_HSSREC_2.3) as well as passive and active monitoring (SOP_HSSREC_2.6) of approved studies.

8.7.4 Conflict of interest

All conflicts of interest or potential conflicts of interest should be declared by committee members to the committee at the start of a HSSREC meeting. 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 committee. No information with regard to applications or research protocols will be distributed to a third party unless the HSSREC is legally required to do so.

8.7.6 Secretariat

The Faculty of Humanities will provide the secretariat for the HSSREC within the Faculty.

All meetings are recorded, transcribed and saved electronically.

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 Submission 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 either be referred back or stand over until all documents have been obtained.

8.7.8 The review procedure

When an application is received by the administration of the HSSREC, all documentation is checked within two working days for completeness, to ensure that all documents indicated in the checklist are attached.

All reviewers are provided with a code by the HSSREC Administrator to ensure anonymity of their reviewer reports.

The application is then sent to the HSSREC chairperson or deputy chairperson when necessary, who within three days decides on:

- The primary and secondary reviewers (HSSREC members) who, based on their 1) research ethics expertise; 2) methodological knowledge; 3) absence of conflict of interest, and 4) equitable distribution of review burden across the committee, will be requested to review the application and give written feedback at the next HSSREC meeting.

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 to the allocated reviewers within three working days.

The reviewers have 5 – 8 working days for review and provide their feedback on an approved template (see addenda 4 and 5).

Reviewer reports are received back before the forthcoming HSSREC meeting and made available for all HSSREC members' perusal.

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

- The chairperson and/or vice-chairperson are tertiary reviewers for quality control.
- Applications can also be assigned to the legal representative, and quantitative studies to the statistician, where necessary.
- If a study plans to undertake recruitment within a local community, a copy of the informed consent documentation could be sent to one of the community representatives for recommendations.
- If the nature of the study requires expertise not present in the REC, the application is allocated to an appropriate external reviewer.
- If there is any uncertainty on the distribution, it is discussed with the Deputy Dean of Humanities responsible for research or the Head of the SCRE.

8.7.9 Decision-making process

The process of decision making is based on aggregate feedback, followed by debate and the reaching of a 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 pertaining to people is always 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.

In cases where the HSSREC cannot come to a conclusion or some other conflict arises within the

HSSREC, the general rules for conflict resolution of the NWU will be followed.

9 AUTHORITY OF THE HSSREC

The HSSREC functions under the management of the Faculty of Humanities, the SCRE and in collaboration with the sub-committees of the Faculty Board (Research Committee and/or Scientific/Proposal Committees). The HSSREC 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 HSSREC is dissolved by the Faculty, this must be reported to the SCRE and the NHREC.

10 REVIEWING OF APPLICATIONS OF RESEARCHERS FROM OUTSIDE THE FACULTY OF HUMANITIES 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 will be levied 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 before the student may begin with the study. Approval for off-campus facilities where studies will take place should be organised by the chairpersons of the relevant committees. The person awarding approval should be an expert and should have the necessary experience with regard to the suitability of these facilities.

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)
- Research Ethics Policy and Terms of Reference for the Management of Research Ethics at the North-West University (2018).
- The Health Research Ethics Committee of the NWU: Standard Operating Procedures.

13 ADDENDA

No	Document name
1	Research Ethics Policy for the NWU
	Note: The above documents (1 and 2) have been NWU-reviewed and should be replaced by the latest approved documents.
2	Research ethics reviewer report (HSSREC)
3	Code of Conduct for Researcher (North-West University, 2016)
5	Appointment letter
6	Code of conduct for HSSREC members
7	Consent letter from the Minister of Health to HSSREC.

RESEARCH ETHICS POLICY

Reference number	9P/9.1.5
Policy owner	Deputy Vice-Chancellor: Research and Innovation
Policy administrator	Director: Research Support
Responsible division	Research Support Office
Status	Approved
Approved by	Council
Date of approval	22 November 2016
Date of amendments	2018
Accompanying documents	Terms of Reference for the management of research ethics at the North-West University
Review date	2021
Web address of this policy	http://www.nwu.ac.za/content/policy-rules
Address on the policy database	(10935746) H:\HSC\2. Management\2.1.3 Policy management\Beleide\Raad November2016\9P\9.1.5_e.docm

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 Senate Committee for Research Ethics (SCRE) 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.

* Department of Health 2015. Ethics in Health Research. Principles, Processes and Structures. Second edition.

Original details: (10830745) H:\HSC\2. Management\2.1.3. Policy management\Beleide\Raad November 2018\9P-9 _Research Ethics Policy_e.docm
29 November 2018

File reference: 9P/9.9.1.5

NWU®

NORTH-WEST UNIVERSITY
NOORDWES-UNIVERSITEIT
YUNIBESITI YA BOKONE-BOPHIRIMA

Terms of Reference 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 must be safeguarded, the relationship between researcher and participants must be considered;
- Data-intensive research: Aspects involving the collection, use, interpretation and safeguarding 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 to 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 in such a manner 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 research ethics standards, such as:

- Ensuring integrity 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 research 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 research ethics principles for research at the university. These principles were further expanded into an approved Code of Conduct for Researchers, 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 govern and manage the Research Ethics processes of the NWU. A **Senate Committee for Research Ethics (SCRE)** 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 and Innovation Committee. The REC will have the same status and reporting responsibility as the Faculty Research and Innovation Committee.

1.2.3 Statutory requirements for external registration of a 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 in section 73 that all RECs dealing with health research must be registered by the NHREC (a statutory body). 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 research involving humans or 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 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 probability and the magnitude of the risk and probability of such risk occurring. It forms the basis of any REC's decision-making regarding ethical approval of research.

Research Ethics Risks for adult participants can be classified under the following four categories: (**Note:** The definitions given here, with minor changes, are quoted from the document "Regulations relating to research on human participants"[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 consequences as no participants are directly involved.
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 stable society). 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 minors and adults with mental incapacity refer to greater than minimal risk. For animals it 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 and classified as categories.

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[1] Regulations relating to research on human subjects, Department of Health, Government Gazette #36508, 29 May 2013.

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

1.2.5 Application for Ethics Approval

Before any research may be conducted scientific approval must be granted for a project by the relevant scientific/proposal committee. The process of application for research ethics approval will be based on the involvement with human participants, animals and possible environmental impact and RLDs applicable to the specific discipline and formulated by the relevant REC.

A typical ethics approval 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 level of the application, 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, or has a non-health related focus where vulnerable human participants are involved and/or medium and high risk levels exist, the application must be referred to a committee registered with the NHREC, in the format specified by the registered REC.

After an independent and proper review by the relevant REC, the committee will communicate their decision to the researcher and/or the SCRE for further action. The SCRE requires a signed approval letter, along with minutes of the REC meeting where an application was reviewed, before an official NWU-SCRE Ethical Approval Letter can be issued. This Ethics Approval Letter is to be signed by the Chairperson of the REC that has approved the application. Ethical approval will be valid for one year with an option to renew when necessary.

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 behaviour 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) and proof thereof provided to the REC.

1.2.7 Governance of research ethics at the North-West University

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 that have to register with external regulatory bodies, and which allow 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 research ethics planning, and the research ethics policy framework of the university. 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 financial, human and infrastructural 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 approval letters, in collaboration with the REC.
- Referring to the Research Data Gatekeeper Committee (RDGC), any request from an outside

entity to conduct research within the NWU, for review, and to also refer such requests to the appropriate REC, except where it meets criteria that precludes it from the requirement of ethical review.

- 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 SCRE 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 SCRI, 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: Research and Innovation *(ex officio)*
- The Director: Research Support of the NWU *(ex officio)*;
- A member of the Institutional Legal Office or an expert from the Faculty of Law 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 Governance and Secretarial Services.
- The SCRE may from time to time co-opt additional members as needed.
- The Head of the Faculty of Health Sciences Research Ethics Office for Research, Training and Support or similar individuals from any other similar Ethics Offices created in future.

All members of the SCRE have voting rights.

2.5 Meeting arrangements 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 members of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies all members, 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. The minutes of each meeting serves at Senatel 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 favour 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 the Department of 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
Policy and Rules for Research Ethics	Approved	Council	17 November 2016
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 RECs registered with an 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:

- 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;
- Will have, in the recommended format, the following documents, further guidelines will be provided as an appendix to this policy document[2]:
  - Terms of Reference (ToR) (*at least specifying how it complies with SCRE and other statutory requirements (including scope of authority, powers, and responsibilities, membership and quorum rules), relationship, communication and accountability responsibilities towards SCRE and other applicable statutory bodies, requirement for formal procedures and processes (e.g. types of SOPs), functions and responsibilities of*

[2] Recognition that these requirements have been adopted from the Annual Report Form for Health Research Ethics Committees of the National Research Ethics Council of South Africa, 2018, and modified to own needs.

the secretariat and/or administrative office, relationship with members and researchers, and financial compensation (if applicable)).

- Standard Operating Procedures in the appropriate format *(at least addressing in one or more documents aspects of the frequency of meetings, preparation of agendas and minutes, distribution of documentation prior to meetings, review and approval of proposals/protocols (including expedited), how final decisions are reached, prompt notification of decisions, how to address conflicts of interest and conflicts of commitment for REC members, how to address conflicts of interest and conflicts of commitment for researchers and teachers, informed consent, privacy and confidentiality regarding participants and their health care information, reporting of unanticipated problems/incidents/adverse events, protocol amendment procedures, protocol deviations and protocol violations, maintenance of records, reporting of allegations of misconduct/non-compliance, mechanisms for "whistle-blower" protection, complaints procedures, post-approval passive monitoring of proposals/protocols (as appropriate), post-approval active monitoring of proposals/protocols, continuing review and recertification procedures, suspension and termination, research involving minors and involving vulnerable persons (as applicable), biological materials collection and storage, as well as databases, registries and repositories (as applicable), development and management (review, monitor, approve) of SOPs).*
- Templates and/or application and report forms *(at least including ethics application form for approval of a study, ethics application for approval of sub-studies under a larger/umbrella/parent study, application form to amend an approved study, form for annual passive monitoring of an approved study, form for active monitoring of an approved study in progress, report form for serious adverse events or incidents, form for raising a query or complaint).*

- 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 REC's decision regarding applications to the applicants;
- Approve the issuing of research ethics approval letters for approved projects;
- In cases where the REC cannot reach consensus, 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 accordance with the approved SOP, 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;
- Report to the appropriate statutory body (if applicable) on an annual basis, as applicable.

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 (proposals, 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 must be submitted to the relevant Scientific/Proposal Committee for review.
2. The Scientific/Proposal Committee will advise (based on the information in the research proposal) whether ethics approval is required and refers the application to the relevant REC if it involves human participants, animals or might have a negative environmental impact as well as other possible aspects of concern.
3. The REC will handle each application for ethics approval according to the rules and operating procedures of the involved REC.
4. If deemed necessary, or if required, a REC must refer an application to a suitable NHREC 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 and Innovation Committee and Scientific/Proposal Committee. Each REC functions within a predetermined research field of expertise within the structure of the RECs for the NWU.

The REC derives its authority from the governance rules formulated by the SCRE, as well as in the case of registered RECs, the governing statutory body. As such, the establishment of a REC must also be approved by the SCRE. If a REC is dissolved by its faculty, this must be reported to the SCRE.

3.4 Membership of the REC

Members of a 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 independence as well as their specific research ethics knowledge and expertise. Upon appointment, a formal Letter of Appointment will be issued by the SCRE. This appointment must reflect in and count towards the annual task agreement of the staff member.

3.4.1 Composition of the REC

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

- At least 7 members, with a quorum being a simple majority.
- Where the number of members is more than 15, the quorum may be 33%.
- A chairperson, being an academic staff member with appropriate experience, expertise and leadership skills to ensure efficient functioning of the committee.
- 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 or community representative).
- It is recommended that at least one member should be an expert in the field of statistics, if applicable, given the scope of applications the REC reviews.
- Ad hoc attendees with required fields of expertise may be nominated for meetings, such as a statistician, legal advisor, bioethicist, biosafety, clinical or procedure expert, etc.

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

The Faculty Management, in consultation with the appropriate REC, suggests possible candidates. Members are approved by the relevant Faculty board, and formally appointed by the SCRE, in its role as standing committee of Senate.

3.4.3 Appointment of Chairperson and Vice Chairperson

The Faculty Management, in consultation with the appropriate REC, suggests possible candidates for chairperson. The Faculty Board appoints a chairperson in consultation with the Faculty Management and the REC. The vice-chairperson is selected and appointed by the REC and need not be appointed by the Faculty Board.

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. In such cases a confidentiality agreement must be signed. Researchers may be invited to attend 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 minimum requirements apply for a meeting, in addition to any applicable statutory requirements when applicable to a particular REC:

Frequency	A **minimum** of four per annum, if there are matters to consider. These meetings should preferably be face-to-face meetings, but can also be held via interactive electronic media where practical. The timing of meetings should be such that research projects are not delayed unnecessarily while waiting for ethics approval.
Extraordinary meetings	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. Where the number of members is more than 15, the quorum may be 33%
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies the members of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies the members, provides the reason for an extraordinary meeting, as well as the time and venue. In

	exceptional cases, for urgent matters such as with serious adverse events with significant risk or potential harm to participants, animals, researchers, students and/or the environment, immediate action may be required which must then be ratified at the next meeting.
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 REC's 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 or agreed upon format in the case of NHREC registered RECs.
Decision-making process	Matters are decided by means of general debate and consensus. When consensus cannot be obtained, minor change that will allow consensus must be sought, or further consultation can be requested if the matter at hand is not urgent. When consensus is still not possible and a timely decision is required, the Chairperson should put the decision to a vote. The Chairperson may decide that voting must be by secret ballot, provided that voting by members 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. In such cases the member is required to declare conflict of interest and should abstain or obtain the leave of the meeting during such discussion and voting.
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. 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.[3] 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	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), or as otherwise specified as per approved SOP. Records management must be according to the file plan of the university's record management system.

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. A large portion of that chapter is in fact dedicated to health research ethics. Section 72

[3] In the case of NHREC registered RECs, there is a requirement that all meetings are to be held in a face-to-face environment.

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*[4] 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 research involving humans or animals, as specified in paragraphs 1.4.1 and 1.5.1 of the document in footnote 4. 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 ***research that*** *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*

Health-related research is defined as any research conducted by disciplines other than health disciplines about topics or participants within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.

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 RECs as stipulated by the SCRE, also comply with the rules of the NHREC. All health and health-related research, despite risk level can only be reviewed by an NHREC-registered REC that has experience with the review of such applications.

It can 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.

In lieu of such statutory bodies, however, the NHREC does make the provision in the aforementioned document that RECs that review research involving humans, that is not health-related, can also find guidance in this document. This is highlighted in the following two verbatim extracts from *Ethics in Health Sciences: Principles, Processes and Structures*[5] document (derived from section 1.1.12 and 1.1.13 of the aforementioned guideline document):

"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

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[4] See: Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015, published by the Department of Health, Republic of South Africa.
[5] See: Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015, published by the Department of Health, Republic of South Africa.

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."

"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."

4.2 Exclusions

RECs that are registered with the NHREC have very clear guidelines related to the type of research that generally does not require ethical approval. These exclusions can also be applied in RECs that are not registered with the NHREC, however, there may also be context-specific exclusions which should be decided upon by the REC itself. The ethical approval exclusion guidelines are described under section 1.1.8 - 1.1.11 of the guideline document and are to be applied in consultation with the REC and with reference to "The National Health Act (NHAs 72 (6)(c))".

4.3 Referring an ethics application to a registered REC

Although most of the discussion in this section is related to health and health-related research involving humans, it must be emphasized that research involving human participants, that is not health-related must also have ethical approval from a REC. If the risk level for this type of research is greater than minimal or involves vulnerable groups of people, the ethics application should be referred to the appropriate NHREC-registered REC.

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 Institutional Research Ethics Regulatory Committee (IRERC), 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 endeavours 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 endeavour 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:

Applicant name: Ethics #:

Reviewer: Date of Review:

This guidance is offered to remind reviewers about important ethical issues in research. Where a reviewer makes a comment about a **methodological** issue, please indicate whether the change is required or merely recommended.

1. Aims, Background and Significance

1.1. Are the study aims and objectives clearly specified?
1.2. Why is this research important to conduct? Will it add important knowledge to the field?
1.3. Why is it worth doing in this particular setting?
1.4. Is there a mechanism for those affected by the study to express their views, clarify their needs and contribute to the research?

Comments or Questions for Researchers

2. Scientific Design

2.1. Is the scientific design adequate to answer the study's questions?
2.2. Is the scientific design adequately described and justified?
2.3. Does the study involve a control/comparison group?
  2.3.1. If so, why is a control/comparison group needed?
2.4. Are study aims and objectives achievable in the given time frame?
2.5. Do the principal and co-investigators (including students and/or fieldworkers collecting the data) have appropriate academic and clinical credentials and experience to conduct this study?
2.6. In the case of qualitative research, does the researcher:
  2.6.1. Demonstrate an understanding of the qualitative paradigm and method chosen?
  2.6.2. Have experience in conducting qualitative research?

Comments or Questions for Researchers

3. Inclusion and Exclusion Criteria

3.1. Is the selection of participants appropriate for the question being asked?
3.2. Is the rationale for the proposed number of participants reasonable?
3.3. Are inclusion and exclusion criteria clearly stated and reasonable?
3.4. Does the study include vulnerable groups such as (but not limited to) children, psychiatric patients, individuals with impaired decision-making capacity, persons in dependent relationships (e.g. lecturers doing research with students), persons with physical disability, persons in prison?
  3.4.1. If yes, are adequate safeguards included to protect their rights and welfare?
  3.4.2. Is the inclusion of vulnerable populations justified?
  3.4.3. Can the study be done without involving vulnerable populations?
3.5. Will the study target or exclude a particular ethnic or language group? Is there a feasible motivation for this?
3.6. In the case of qualitative research:

3.6.1. Is the method of sample selection appropriate and clear as to how the researcher will determine when adequate sampling has occurred?
3.6.2. If the sample size cannot be delineated before the study begins, are a rationale and plan provided?

Comments or Questions for Researchers

4. Recruitment and Enrolment

4.1. How and by whom will individuals be identified for recruitment into the study?
4.2. Are the location, setting, and timing of recruitment acceptable?
4.3. What recruitment methods materials will be used e.g. flyers, posters, or advertisements? Are these attached to this application (they should be)?
4.4. Are procedures for screening participants prior to recruitment acceptable?
4.5. Will any potential participants be in a dependent relationship with the researchers or persons recruiting for the study, e.g. student/lecturer, doctor/patient, and employer/employee? If so, has the researcher taken steps to ensure that the participants' decision to enrol will not be influenced by the relationship?
4.6. Has the study population been involved in previous research to the extent that the proposed research may present a significant additional burden? (e.g. an existing cohort of participants already in research)

Comments or Questions for Researchers

5. Research Procedures

5.1. Are the rationale and details of research procedures adequately described and acceptable?
5.2. Are the proposed tests or measurements appropriate, valid and reliable to answer the scientific question in the local context?
5.2.1. If this point is part of the aim of the study, then justify and motivate.
5.3. Are there adequate plans to inform participants about specific research results, e.g. incidental findings, clinically relevant findings, personally important findings?
5.4. Are individuals who are performing procedures adequately trained? For example, in conducting focus group, or implementing specific intervention programs?

Comments or Questions for Researchers

6. Risks and Benefits

6.1. Are risks and benefits adequately identified, evaluated and described, including physical, psychological, social, and economic?
6.2. Are risks to the community or a particular group of individuals, e.g. stigmatisation, adequately identified?
6.3. Are there any specific risks to the researcher (e.g. safety concerns)?
6.4. Do risks stated in the protocol match the risks described in the informed consent form?
6.5. Are risks reasonable in relation to anticipated benefits?

6.6. Are risks reasonable in relation importance of knowledge to be gained?
6.7. Are there clear explanations of how potential risk will be minimised/managed?
6.8. Is the location of the study adequate to assure participants' safety and comfort (e.g. appropriate equipment for monitoring and emergencies, a child-friendly setting for paediatric research)?
6.9. Will counselling or support services be available, if required? Are sufficient details of these provided?
6.10. Is the population from which study participants will be drawn likely to benefit from the research?

Comments or Questions for Researchers

7. Process of Obtaining Informed Consent and Assent

7.1. Is the process well-explained?
7.2. Does the process minimise the possibility of undue influence/coercion?
7.3. Does the process provide sufficient time, privacy and an adequate setting for participants to decide?
7.4. Who will obtain consent or assent? Is the individual obtaining consent or assent adequately trained?
7.5. Are issues relating to participants' comprehension considered?
7.6. How will a researcher decide if a participant has decision-making capacity to choose to enrol in a study?
7.7. Is there appropriate justification for the use of proxy consent in the event that the researcher cannot obtain direct consent from the participant?
7.8. Is the language used in the assent and consent forms appropriate for participants' level of understanding?
7.9. Are jargon, acronyms and abbreviations explained or defined in ordinary language?
7.10. Are terms such as 'randomisation' clearly defined and illustrated (e.g. like flipping a coin)?
7.11. Will an interpreter be necessary to obtain assent or consent?
7.12. Does the protocol state if consent forms will be translated into other languages?
7.13. Does the consent form state that participants can contact the HSSREC chairs if they have a complaint or questions about their rights and welfare as research subjects?
7.14. Does the consent process meet South African legal and regulatory requirements?
7.15. In general, is the consent form consistent with the protocol?

Comments or Questions for Researchers

8. Privacy and Confidentiality

8.1. Does the protocol describe site-specific measures to protect participants' privacy?
8.2. Are provisions to protect confidentiality of data during and after research adequate?
8.3. Does the protocol describe how written records, video or audiotapes will be secured, for how long and who will be responsible for storage or final disposal?
8.4. In the case of focus groups and/or visually explicit research (e.g., DITL or Community-based Participatory Video), are participants told that confidentiality cannot be guaranteed as group members may disclose what was discussed outside the research setting/others may recognise them?
8.5. Are activities that could potentially result in notification/duty to disclose (e.g. deliberate abuse or neglect) addressed in the protocol and consent form?

Comments or Questions for Researchers

9. Data Analysis and Monitoring

9.1. Are the plans for data and statistical analysis defined and justified?
9.2. Are there adequate plans for monitoring data, e.g. stopping rules?
9.3. Is a data safety monitoring board part of the study? Is it independent?
9.4. In the case of non-interventional or qualitative research is there a mechanism, such as a reference or event monitoring group, to provide ongoing oversight and impartial analysis of unanticipated incidents?

Comments or Questions for Researchers

10. Reimbursement

10.1. Are there adequate plans to avoid out-of-pocket expenses and costs incurred by participants (e.g. travel expenses, parking costs, and lost wages? Participants cannot be expected to carry any study-related expenses)?
10.2. Is the compensation to participants reasonable?
10.3. If the participant does not complete the study, will compensation be pro-rated?
10.4. If children or adolescents are involved, who receives the compensation? Is this appropriate?

Comments or Questions for Researchers

11. Insurance

11.1. Is there provision for insurance for research-related injuries, if applicable?
11.2. In the case of investigator-initiated research, is there cover in terms of NWU's no-fault insurance policy?

Comments or Questions for Researchers

12. What Happens at the End of the Study?

12.1. Will post-intervention care be available?
12.2. Who will supply this care/intervention and for how long?
12.3. How will participants and communities be informed of important findings?
12.4. How will findings be disseminated to the wider research community (e.g. peer-reviewed scientific journals, conference presentation, and internal report)?

Comments or Questions for Researchers

13. Conflicts of Interest

13.1. Will any research staff receive incentives for recruiting participants or for any other purpose directly related to the study?

13.2. Do any personnel involved in the design, conduct or analysis of the research have any proprietary interests (e.g. royalties, patents, trademarks, copyrights or licensing agreements) involving any agent, device or software being evaluated in the study?

Comments or Questions for Researchers

14. Additional Comments or Questions for Researchers

None.

15. Reviewer's Final Assessment (check ✕)

Risk level	**Comment on magnitude and probability, as well as risk-benefit ratio. Motivate your answer**
	Approved: No changes. There is an acceptable risk: benefit ratio and the protocol is acceptable as submitted.
	Approved, but editorial changes needed: Minor *editorial* changes needed to consent form or other study materials.
	Minor changes needed: Minor editorial changes needed to consent form or other study materials; minor clarifications regarding specific aspect(s) of study or additional information requested from PI. Both reviewers should reach consensus that revisions can be approved; HSSREC chairs to sign and stamp final consents before research may commence.
	Deferred with major changes: Major changes needed as protocol is poorly written, lacking information relating to scientific and/ or ethical aspects, and/or sections need to be rewritten and resubmitted. ***Revised protocol must be sent to reviewers***
	Deferred with major changes: : Major changes needed as protocol is poorly written, lacking information relating to scientific and/ or ethical aspects, and/or sections need to be rewritten and resubmitted. ***Revised protocol must be tabled at a full committee meeting***
	Disapproved: Risks significantly outweigh the benefit or value of the knowledge to be gained; there are significant ethical concerns or questions that make the study unacceptable.

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Research and Innovation

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 Institutional Research Ethics Regulatory Committee (IRERC), 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 endeavours 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 endeavour 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:

Original details: (1664754) P:\9. Research and Post-graduate Education\9.1 Implementation of the research strategy\9.1.5 Ethics\9.1.5.1.3_Code_Conduct_2017.docm
18 July 2017

File reference: 9.1.5.1.3

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
INSTITUTIONAL OFFICE

NWU Senate Committee for Research Ethics (SCRE)

Dear

NWU HUMAN SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE (HSSREC) APPOINTMENT

We hereby confirm your appointment as member of the NWU **Human Social Sciences Research Ethics Committee (HSSREC)** as approved by the Faculty of Humanities on _____ and the NWU Senate Committee for Research Ethics Committee on _____.

Appointment date: **Appointment expiry date**:

NWU has Public Liability Insurance cover in terms of which the aforementioned committee member is indemnified in respect of any claim related to his/her activities as a member of the committee.

Please see the attached Terms of Reference for the HSSREC and the Standard Operating Procedures 1.1 – 1.8 of the HSSREC. You will be provided with copies of these documents.

The attached Code of Conduct for HSSREC members and the Confidentiality Undertaking of the NWU, are to be signed by you and returned to the Administrator of the HSSREC.

Yours sincerely

Prof. Mirna Nel
Deputy Dean Faculty of Humanities

Prof. Frans Waanders
Chairperson: SCRE

Code of conduct for members of the Human Social Sciences Research Ethics Committee (HSSREC)

All HSSREC members will be expected to sign the NWU code of conduct for researchers.

Over and above this code of conduct it will be expected of HSSREC members to:

- Agree to a term of office of five years;
- Familiarise themselves with the institutional documentation as well as national and international research ethics guidelines;
- Attend research ethics training sessions to keep abreast with the latest changes in this field (proof of evidence at least once every three years);
- Always act with integrity;
- Regularly attend HSSREC meetings;
- Be punctual in the attendance of these meetings;
- Diligently perform all responsibilities delegated to them;
- Maintain all of these responsibilities in compliance with national and international ethical and regulatory requirements;
- Consider and declare any prior interest and/or involvement in any matter being discussed at a HSSREC meeting to avoid potential conflict of interest (personal or financial);
- Keep all matters coming to their attention during HSSREC meetings confidential.

I _____ will adhere to the terms set out above.

Signature: _____

Date: _____

MINISTRY OF
HEALTH
REPUBLIC OF SOUTH AFRICA

PRETORIA
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Chair: Prof C van Eeden
Chair: North West University Human Social Sciences Research Ethics Committee
Vaal Triangle Campus (NWU-VTC)
PO Box 11 74
VANDERBIJLPARK
1900

REC-080615-047

Dear Prof C van Eeden

DELEGATION OF POWER TO CONSENT TO RESEARCH INVOLVING MINORS AS PRESCRIBED BY SECTION 71 (3)(a)(ii) OF THE NATIONAL HEALTH ACT No.61 OF 2003 TO HEALTH RESEARCH ETHICS COMMITTEES REGISTERED WITH THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

I, Dr A Motsoaledi, in my capacity as the Minister of Health, for the Republic of South Africa, do hereby **delegate** in terms of section 92(a)(ii) of the National Health Act, 2003 (Act No. 61 of 2003) **the power to consent to research involving minors** vested in me in terms of Section 71 (3)(a)(ii) to the North West University Human Social Sciences Research Ethics Committee **on condition** that the HREC:

(i) complies with Section 73 of National Health Act, 2003 (Act No. 61 of 2003) by being registered with the NHREC;
(ii) is in possession of a current registration certificate; and
(iii) adheres to the norms and standards of research ethics guidelines as advocated by the NHREC.

Kind regards

DR. A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 17/3/2015