

FACULTY OF HUMANITIES

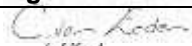

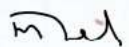
Standard Operating Procedure: ToR_HSSREC_1

**Terms of reference for the Human
Social Sciences Research Ethics
Committee of the Faculty of Humanities**


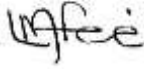

Faculty of Humanities

Terms of Reference			
Title	Terms of reference for the Human Social Sciences Research Ethics Committee of the Faculty of Humanities		
SOP No	ToR_HSSREC_1	Version No	2
Date of approval		Next 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 FOR FURTHER APPROVAL

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

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 ToR

These terms of reference provide guidelines and a minimum standard for the Human Social Sciences Research Ethics Committee's (HSSREC) operational management of the research ethics process within the Faculty of Humanities. It ensures the essential purpose of the HSSREC to protect the dignity, rights, safety, and well-being of all human participants in human social sciences research. This is done through

independent, prospective and ongoing ethics review of all human social sciences studies undertaken by *staff, registered students and affiliates* of the University.

Note: The terms of reference should be read in conjunction with all the other SOPs of the HSSREC, as well as national and international documentation (see section 9).

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.

Ethics approval must be obtained for all research proposals before a research study commences.

Note: The HSSREC will not consider research studies for approval if it is apparent that the data gathering research procedures has already been conducted (retrospective).

Registered REC's of the National Health Research Ethics Council (NHREC) and also the HSSREC (REC-080615-047) function according to: The requirements as stipulated by the National Health Act No. 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); national and international research ethics guidelines (see section 9), as well as the terms of reference provided by the Research Ethics Policy and Terms of Reference for the Management of Research Ethics at the North-West University, 2018.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
HSSREC	Human Social Sciences Research Ethics Committee
NWU	North-West University
VTC	VaalTriangle Campus
NHREC	National Health Research Ethics Council
SCRE	Senate Committee for Research Ethics
SOP	Standard Operating Procedures
ToR	Terms of Reference

7 RESPONSIBILITIES

The NHREC stipulates the responsibilities of the HSSREC as follows:

The main responsibility of the HSSREC is to conduct rigorous ethics reviews of human social sciences

research proposals to ensure that the welfare and other interests of participants and researchers used in research are properly protected and that the research will be conducted in accordance with the required ethical norms and standards.

The HSSREC must ensure that research proposals stand up to scientific and ethical scrutiny as is appropriate to the discipline concerned.

The review must ensure the maintenance of ethical and scientific standards to:

- Protect participants from harm by weighing the risk of harm against the likelihood of benefit;
- Hold researchers accountable for their research activities;
- Promote the highest scientific standards and best available techniques or approaches for optimal use of participating humans;
- Promote important social and ethical values.

The HSSREC must review research proposals prospectively (not retrospectively) to ensure that they meet the accepted ethical norms and standards before research commences, using the guidelines indicated in the “Ethics in Health Research: Principles, Processes and Structures” (2015) document as a minimum benchmark.

- The primary responsibility of each HSSREC member is to decide independently whether the proposed study protects the interests of participants adequately and upholds exemplary standards.
- Such responsibility regarding participant interest shall always take precedence over the interest of the scientific project.

The SCRE in its governance role further stipulates that the HSSREC of the Faculty of Humanities will:

- Function according to a strict code of conduct as appropriate for the Faculty of Humanities and approved by the SCRE (see 8.2 in this document).
- Formulate and seek approval from the SCRE for a set of operational rules for ethics applications in the Faculty of Humanities (SOP_Ethics_2.4).
- Formulate and seek approval for a set of research discipline-specific examples of Risk Level Descriptors, in line with the SCRE guidelines, to make a suitable classification of the risk levels of studies (see Risk Level Descriptor for research with human participants, and estimated environmental impact category).
- Provide feedback on specific matters as requested by the SCRE.
- Ensure confidentiality of all information revealed to it.
- Ensure that all researchers working in the Faculty of Humanities sign the NWU research ethics code of conduct.
- Ensure that researchers have a proper understanding of research ethics, as applicable to the specific research conducted in the Faculty of Humanities, by providing specific training.
- Receive applications for research ethics approval from researchers via the provided research management system.
- Consider these applications at its regular meetings, as well as minute discussions and decisions

and communicating the HSSREC decisions regarding applications to applicants.

- Approve the issuing of research ethics certificates (valid for a year) for approved projects.
- Consider and approve any amendments to the original approved research proposal.
- Manage a monitoring system for approved projects that includes an annual reminder system, the evaluation of the submitted reports, as well as providing written approval for continuation of the study.
- Consider and act appropriately (as described in SOP 2.5) in cases of ethical misconduct by researchers.
- Report all ethical matters to the Deputy Dean Research and Innovation and the Executive Dean of the Faculty of Humanities.
- Report to the SCRE on an annual basis using the NHREC template.

8 PROCEDURE(S)

8.1 Formal character of the HSSREC

The HSSREC of the Faculty of Humanities must always be a NHREC registered committee, as well as approved by the SCRE of the NWU. See detail for HSSREC member selection, appointment and functioning (SOP_Ethics_2.2).

8.2 Code of conduct for HSSREC members

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 (provide 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.

8.3 Relationship to non-affiliated researchers

Researchers with no affiliation to the North-West University can approach the NHREC-registered

HSSREC of the Faculty of Humanities to review and approve their human social sciences research proposals, where the HSSREC may, on a case-by-case basis, decide whether it is appropriate to deal with the matter and whether the HSSREC is willing and has proper expertise and capacity to evaluate the application. A fee will be levied for such a service.

8.4 Accountability responsibilities of the HSSREC

The NHREC-registered HSSREC functions within the legislative framework of Section 73 of the National Health Act No. 61 of 2003, which requires a University at which human social sciences research is being conducted to have an NHREC-registered REC. The HSSREC is a single body vested with the explicit authority and legal accountability for determination regarding the ethical acceptability of proposals within the Faculty of Humanities.

8.5 Mechanisms for reporting by the HSSREC

The HSSREC, managed and supported by the Faculty of Humanities, functions directly under the Executive Dean of the Faculty of Humanities responsible for research. The HSSREC works in close collaboration with the Research Committee and Scientific Committees of the Faculty of Humanities, as well as with other Faculties' structures involved in human social sciences research. The Faculty Board and SCRE also serve to internally audit the HSSREC in terms of their operational mandate and standards, and where applicable, to ratify the HSSREC's decisions. The HSSREC will submit progress reports to every meeting of the Faculty Board and the Committee for Research and Innovation, Ethics and Higher Degrees. The HSSREC must report annually on their activities to the NHREC and the SCRE

8.6 Mechanisms for remuneration of HSSREC members

HSSREC members who are on the payroll of the North-West University are not remunerated for their services as HSSREC members, in order to reduce conflict of interest and increase independence. Should the services of a member not on the payroll of the University be required (e.g. layperson, attorney, etc.), their services should be viewed as part of service delivery to their community.

However, they may be remunerated according to an honorarium negotiated before the appointment, where they are compensated for time, inconvenience and expenses (TIE principle) provided they are:

- 1) Not employed and might lose the opportunity to earn income for the day by attending to certain HSSREC duties;
- 2) Employed but have to add hours to their workday to serve on the HSSREC and do its work; or
- 3) In a private practice and their involvement as a member of the HSSREC will lead to a loss, as they are not able to earn an income during the HSSREC meeting.

8.7 Authority of the HSSREC

The National Health Act No. 61 of 2003 provides statutory authority for the governance of human social sciences research through the registered HSSREC, as well as the necessary ethics regulatory infrastructure through the NHREC.

The HSSREC further derive its authority from the minimum standards and guidelines for research ethics of the NHREC, as well as the governance rules formulated by the SCRE:

- The National Health Act No. 61 of 2003, section 73, which requires the University to establish RECs which are registered with the NHREC.
- The Department of Health's minimum national benchmark of norms and standards for conducting responsible and ethical human social sciences research in *Ethics in Health Research: Principles, Processes and Structures*, 2015 (chapter three and four).
- The North-West University Research Ethics Policy (2018).

In all instances the latest versions or amendments of the Act, regulations or standards, will take immediate effect as they are published or promulgated, where after this SOP will then be amended as soon as possible to reflect the latest changes.

The NHREC-registered and SCORE-approved HSSREC are managed by the Faculty of Humanities and function as a sub-committee of the Faculty Board of the Faculty of Humanities. If the HSSREC is dissolved by the Faculty, it must be reported to the NHREC and SCORE.

9 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)

The Declaration of Helsinki, 2013. The Belmont Report, 1979.

The Singapore Statement on Research Integrity, 2010.

The Code of Federal Regulations of the USA (Title 45 Part 46).

The International Conference on Harmonisation – Good Clinical Practice (ICH-GCP), 1997.

The Rules for the Management of Research Ethics included in the North-West University Research Ethics Policy (2018).

10 ADDENDA

No	Document name
1	NWU Code of conduct for researchers
2	Risk level descriptors for human participants
3	Code of conduct for HSSREC members
4	Appointment letter; Adapted
5	Consent letter from the Minister of Health to HSSREC.



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:

ETHICAL RISK LEVEL DESCRIPTORS ADAPTED FROM THE NWU ETHICAL RISK LEVEL DESCRIPTORS – RESEARCH

RISK LEVELS	DESCRIPTIONS	PRACTICAL EXAMPLE
<p><u>High risk</u></p> <p>Please complete the NWU Ethics application form and send all relevant documentation with the application</p>	<ul style="list-style-type: none"> ○ Research with human participants. ○ Any research with children. ○ Research with people suffering from psychological conditions that affect their cognitive, behavioural, or social functioning so that they cannot take informed decisions. ○ Any research done that is outside of the researcher's field of expertise can be seen as high risk. The competence of the researcher within this specific field will be a determining factor for the risk assessment of the research. ○ Research involving human participants with research-related medical or psychopathology ○ Research involving vulnerable human participants. ○ Research involving sensitive ethical dilemmas in society ○ Research that may affect public or environmental safety or sensitive ecosystems ○ Research budget higher than R1 million per annum ○ Any research deemed to present potential high risk for whatever reason by any applicant or committee 	
<p><u>Medium risk</u></p> <p>Please complete the NWU Ethics application form and send all relevant documentation with the application.</p>	<ul style="list-style-type: none"> ○ Collaborative human social sciences research involving people. ○ Multi-centre human social sciences studies involving people. ○ Long-term human social sciences studies exceeding one year in duration. ○ Umbrella human social sciences projects involving human participants ○ Research involving face-to-face psycho-social contact with participants e.g. interviews, focus groups. ○ Any human social sciences intervention studies individually or in communities. ○ Non-clinical Research/Research with vulnerable communities/people (older persons and their care givers, patients and health-care professionals, students and teachers, persons with life-threatening diseases and their care givers, people living with HIV, wards of the state and guardians or care-givers, employees and employers, prisoners and the relevant prison authorities, members of the SA Defence Force and their supervisors, children, mentally ill persons own direct students) 	

	<ul style="list-style-type: none"> ○ Research budget not higher than R999 999 per annum and not lower than R250 000.00 per annum <p><u>All research not described under high risk, but where the following criteria applies:</u></p> <p>Human human social sciences projects involving:</p> <ul style="list-style-type: none"> ○ Collaborative research ○ Multi-centre studies ○ Long-term studies exceeding one year in duration ○ Umbrella projects 	
<p>Low risk (Minimal risk to human participants)</p> <p>Please complete the NWU Ethics Checklist together with the project/research proposal/protocol</p>	<p><u>All research not described under high risk or medium risk, but where the following criteria applies:</u></p> <ul style="list-style-type: none"> ○ Surveys by means of validated interview schedules ○ Documented data or analyses with identifiable human participants ○ Simple questionnaire or instrument development ○ Questionnaire or instrument development ○ Research involving retrospective data. ○ System research using structured survey forms. ○ Interventions based on professional, scientific base protocols. ○ Research budget under R250 000 but higher than R100 000 	
<p><u>No ethical approval needed</u> (if you need ethical approval for funding opportunities/journal publications, you will have to follow the low risk process)</p>	<p><u>All research not described under high risk, medium risk or low risk, including the following:</u></p> <ul style="list-style-type: none"> ○ Systematic reviews/Literature reviews ○ Postal / surveys with validated questionnaires ○ Document/artefact analyses without identifiable human participants ○ Unidentifiable electronic surveys ○ Public observation without interaction or intervention 	



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

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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: 17/3/2019


Aids Helpline
☎ 0800-0123 22