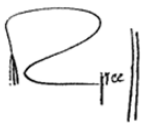



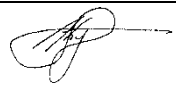
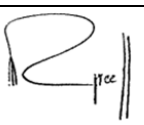


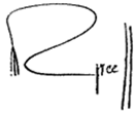




Faculty of Health Sciences Ethics Office

ETHICS OFFICE		Standard Operating Procedure	
Title	SOP for selection, appointment and functioning of the RECs of the Faculty of Health Sciences		
SOP no	2.2.4_SOP_Ethics_1.2	Version no	2
Date of approval	4 April 2018	Revision date	April 2021
Web address	http://health-sciences.nwu.ac.za/healthethics	Page no	Page 1 to 9

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Minrie Greeff		22 August 2016 4 April 2018
Checked by:	HREC		8 Sept 2016
	AnimCare		8 Sept 2016
	Ethics Office		8 Sept 2016
	Faculty Council		9 Nov 2016
Authorised by:	Prof Minrie Greeff as Head of the Ethics Office		9 Nov 2016 4 April 2018

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof Minrie Greeff		10 Nov 2016 4 April 2018
Chairperson on behalf of HREC	Dr GW Towers		10 Nov 2016 4 April 2018
Chairperson on behalf of AnimCare	Prof Tiaan Brink		10 Nov 2016 4 April 2018
Executive Dean of the Faculty of Health Sciences	Prof Awie Kotzé		10 Nov 2016 4 April 2018
Faculty of Health Sciences	Ms Leanie van Ronge		10 Nov 2016 4 April 2018

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2016	1	Procedure formulated as a SOP
4 April 2018	2	Change in university structure

4 PURPOSE OF THE SOP

Quality assurance and legal compliance of research ethics within the Faculty of Health Sciences are mainly administrated and managed by the Faculty's Ethics Office as well as its support of at least two National Health Research Ethics Council (NHREC) registered Research Ethics Committees (RECs), one over campus committee which focuses on research on humans (Health Research Ethics Committee – HREC) and the other over campus committee which focuses on research with animals with a human or animal health focus and environmental impact focus (The Ethics Committee on Animal Care, Health and Safety in Research – AnimCare). The number of these committees could increase should the workload for a specific REC increase and it is no longer able to handle the work. These RECs report to both the Research Ethics Regulatory Committee (RERC) of the North-West University (NWU), the Faculty Board and the Ethics Office of Health Sciences. All of the RECs of the Faculty are registered with the National Health Research Ethics Council (NHREC) and function according to the requirements as stipulated by the National Health Act 61 of 2003, the concomitant regulation (Regulations Relating to Research with Human Participants, 19 September 2014), the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015), as well as the South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008).

The purpose of this SOP is to provide a framework for the selection, appointment and functioning of members of the NHREC-registered RECs that provide operational management of the research ethics processes at Faculty level.

5 SCOPE

The NHREC-registered RECs as standing committees of the Faculty Board of Health Sciences make recommendations, give advice and report to the Faculty Board of the Faculty of Health Sciences and the RERC (as a standing committee of the Senate) of the NWU. They also provide annual reports to both these aforementioned bodies.

The RECs are responsible for the review and approval of all new research ethics applications, amendments and monitoring of research in the Faculty. No study may begin before a REC has provided written approval or may continue without the successful completion of the required monitoring reports (six-monthly for medium and high risk studies; annually for minimal risk studies).

The RECs are immediately notified of any incident or adverse event occurring during the research process which impacts on the safety of participants, or negatively influences the well-being of animals (see 2.2.4_SOP_Ethics_1.3).

The scope of these documents covers the selection, appointment and the functioning of members of the mentioned RECs. It covers the responsibilities and procedures to be followed for these aforementioned activities.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
AnimCare	The Ethics Committee on Animal Care, Health and Safety in Research
HREC	Health Research Ethics Committee
RERC	Research Ethics Regulatory Committee
NHREC	National Health Research Ethics Council
NWU	North-West University
REC	Research Ethics Committee
SANS	South African National Standards
FMC	Faculty Management Committee

7 RESPONSIBILITIES

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

8 PROCEDURE(S)

8.1 Aim

The aim of the RECs is to ensure that the dignity, rights, safety and well-being of the human beings and animals 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 RECs and researchers comply with the institutional, national and international requirements for research ethics in Health Sciences.

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

8.2 Objectives

To review all research applications and amendments for ethical suitability within the Faculty of Health Sciences to ensure that:

- the research conducted will improve health within the broader framework of healthcare, prevent illnesses and disabilities and improve healing
- people and animals 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 (potential exposure to chemicals and micro-organisms / liability) is always protected
- the research is valuable and scientifically responsible
- written permission and informed consent are obtained at all times
- approval is given to research proposals that adhere to the scientific and ethical standards and requirements
- the research provides a favourable benefit-risk ratio, and in cases where this is not possible, sufficient motivation is provided.

To monitor and manage all incidents and adverse events.

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

To review all health-related research applications and amendments for ethical suitability within the other Faculty of the university.

8.3 Composition of the RECs

The composition of the RECs is determined by legal requirements, as set out by the NHREC in their guidelines entitled, "Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)" as well as the South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008).

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

8.3.1 The Health Research Ethics Committee (HREC) for research with human participants

HREC should consist of:

- I. At least nine members, with a quorum being a simple majority
- II. Where the number of members is more than 15, the quorum may be 33%
- III. At least one layperson
- IV. At least one member with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people.
- V. At least one member with professional training and experience in qualitative research methodologies
- VI. Members with professional training and experience in quantitative methodologies
- VII. A member with expertise in bio-statistics
- VIII. A member with expertise in research ethics
- IX. At least one member who is legally qualified

8.3.2 The Ethics Committee on Animal Care, Health and Safety in Research (AnimCare) for research on animals

Various members are dictated by SANS (10386:2008). Four categories of member are required:

A: Veterinarians (with experience in the type of research the NWU is involved in)

B: Scientists with substantial and recent experience in the use of experimental animals

C: Animal welfare organisation representatives

D: Representatives not involved in animal experimentation

The size of the REC may depend on the number of animal users in the University.

Quorum rules should be adjusted to reflect the size of the committee but should always include at least one member from each category of member as previously indicated.

8.4 Selection and appointment

Members are appointed for a term of *four years* (as per the RERC 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 REC members should always be on file in the applicable administrator's office.

Consideration should be given to succession planning.

8.4.1 The selection and appointment of the chairperson:

As soon as the RECs become aware of a vacancy in this position, the Faculty management, in consultation with the appropriate REC, suggests possible candidates, based on their experience as REC members and knowledge of research ethics. A qualification in research ethics is not a requirement but will, however, be advantageous. CVs are sent to the Head of the Ethics Office followed by the Head and Academic Advisor of the Ethics Office and the applicable chairperson having preliminary discussions with the suggested candidates on the roles and responsibilities of this position. A final decision is taken at a Faculty Management Committee (FMC) meeting, ratified at the Faculty Board and the RERC is informed in order to finalise the appointment, as a standing committee of the Senate. A formal letter of appointment is sent by the RERC setting out the term of office; where to find the necessary information for new members; and the assurance that the members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the REC. This appointment must reflect in the annual task agreement of the REC member. The NHREC is also notified.

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

8.4.2 The selection and appointment of the vice-chairperson:

As soon as the RECs become aware of a vacancy in this position, they nominate possible vice-chairpersons from the existing REC members. The Head and Academic Advisor of the Ethics Office and the applicable chairperson have preliminary discussions with the nominated candidates on the roles and responsibilities of this position. A final decision is taken during the next REC meeting, confirmed at FMC, and the RERC is informed.

8.4.3 The selection and appointment of committee members:

As soon as the RECs become aware of a vacancy in this position, they make it known to Faculty Management and within the Faculty and ask for nominations to replace the specific gap the resignation has created e.g. someone from a specific research entity and/or with specific skills as per requirement of the NHREC. The Head and Academic Advisor of the Ethics Office and the applicable chairperson have preliminary discussions with the nominated candidates on the roles and responsibilities of this position. A final decision is taken during the next REC meeting, confirmed at FMC, ratified at the Faculty Board, and the RERC is informed in order to finalise the appointment, as a subcommittee of the Senate. A formal letter of appointment is sent by the RERC, setting out the term of office; where to find the necessary information for new members; and the assurance that the members are indemnified from personal liability against claims that may arise in the course of ordinary business of the REC. This appointment must reflect in the annual task agreement of the REC member. The NHREC is notified.

8.4.4 Sub-committees

All RECs can establish various sub-committees, from within the membership of the RECs, as per their needs and requirements e.g. executive committee, incident and SAE committee.

8.4.5 Co-opted members, observers and visitors

The RECs co-opt members as and when needed. Observers and visitors will be allowed in exceptional cases or 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 REC members is critical, both in the principles of ethics as well as functioning as a REC member. Training in ethics principles, induction to the functioning of the REC and refresher courses should be available and members will be expected to attend at least once every three years. REC members should have documented proof of research ethics induction and training. REC members who review clinical trials should additionally have good clinical practice (GCP) training, as evidenced by a certificate of training.

8.6 Code of conduct

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

8.7 Functioning of committees

8.7.1 Quorum for meetings

The quorum for both 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 the timetable of the Faculty.

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

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

No meeting need to take place if no applications had been received at the closing of the agenda.

Late applications will stand over until the next meeting.

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

8.7.3 Proposed process for functioning

Committees have Standard Operational Procedures (SOP) that indicate the functioning of the committees as well as the processes to be followed when ethical clearance is needed for both new applications or amendments to research proposals.

The ethical review process should not be mechanical.

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

All applications are reviewed by a minimum of two reviewers. Expert reviews can also be requested.

REC members should be encouraged to:

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

Set timelines for review procedures ensure an effective system:

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

The RECs are also responsible for evaluation of incidents, adverse events (2.2.4_SOP_Ethic_1.3) as well as passive and active monitoring (2.2.4_SOP_Ethics_1.6) of research 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 REC 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 committees. No information with regard to applications or research protocols will be distributed to a third party unless the REC is legally required to do so.

8.7.6 Secretariat

The Ethics Office for Research, Training and Support of the Faculty of Health Sciences will provide the secretariat for the RECs 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 stand over until all documents have been obtained.
- An administrative fee may be levied for each application.

8.7.8 The review procedure

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

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

The application is then sent to the Academic Advisor who, in negotiation with the applicable REC chairperson, within three days decides on:

- The primary and secondary reviewers (REC members) 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.
- The chairperson and academic advisor(s) are randomly assigned as tertiary reviewers for quality control.
- All applications are also assigned to the legal representative, and quantitative studies are assigned to the biostatistician.
- If a study plans to undertake recruitment within a local community, a copy of the informed consent documentation is sent to one of the community representatives for review.
- If the nature of the study requires expertise not present in the REC, the application is allocated to an external reviewer.
- If there is any uncertainty on the distribution, it is discussed with the Head of the Ethics Office.

The Academic Advisor then compiles a distribution list (see addendum 3) according to the decisions made for reviewers and forwards it to the administrator who then sends it out to the allocated reviewers within three days.

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

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

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

8.7.9 Decision-making process

The process of decision making is based on aggregate feedback, followed by debate and 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 for persons 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.

The chairperson may 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.

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

9 Authority of the RECs

The RECs function under the management of the Ethics Office of the Faculty and in collaboration with the standing committees of the Faculty Board (Research and Innovation Committee and Scientific/Proposal Committees). The RECs derive their authority from the governance rules formulated by the RERC and the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015), as well as the South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008). If an REC is dissolved by the Faculty, this must be reported to the RERC.

10 Reviewing of applications of researchers from outside the Faculty of Health Sciences 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 chairperson of the 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)
- South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008).
- The Rules for the Management of Research Ethics at the North-West University, 2016.

13 ADDENDA

No	Document name
1	Rules for the Management of Research Ethics at the North-West University (IRERC, 2016)
2	Code of Conduct for Researcher (North-West University, 2016)
3	Template for the distribution list for reviewer allocation
4	Research ethics review report (HREC)
5	Research ethics review report (AnimCare)
6	2.2.4_SOP_Ethics_1.3
7	2.2.4_SOP_Ethics_1.6