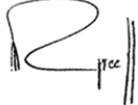


Faculty of Health Sciences Ethics Office

ETHICS OFFICE		Terms of References	
Title	Terms of reference for research ethics committees of the Faculty of Health Sciences		
ToR No	2.2.4_ToR_Ethics_1.1	Version no	2
Date of approval	6 June 2018	Revision date	June 2021
Web address	http://health-sciences.nwu.ac.za/healthethics	Page no	Page 1 to 7

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof Minrie Greeff		30 Aug 2016 6 June 2018
Checked by:	HREC		8 Sept 2016
	AnimCare		8 Sept 2016
	Ethics Office		8 Sept 2016
	ExCo		8 Sept 2016
Authorised by:	Prof Minrie Greeff as the Head of the Ethics Office		19 Sept 2016 6 June 2018

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of the HREC	Dr Wayne Towers		10 Nov 2016 6 June 2018
Chairperson on behalf of AnimCare	Prof Tiaan Brink		10 Nov 2016 6 June 2018
On behalf of the Ethics Office	Prof Minrie Greeff		10 Nov 2016 6 June 2018
ExCo FMC	Prof Awie Kotzé		10 Nov 2016 6 June 2018
Faculty of Health Sciences	Ms Leanie van Ronge		10 Nov 2016 6 June 2018

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
19 Sept 2016	1	Development of the document
6 June 2018	2	Change in university structure

4 PURPOSE OF THE ToR

These terms of reference provide guidelines and a minimum standard for the Research Ethics Committee's (REC's) operational management of the research ethics process within the Faculty of Health Sciences. It ensures the essential purpose of the RECs to protect the dignity, rights, safety, and well-being of all human and animal participants in *health* and *health-related* research. This is done through *independent, prospective* and *ongoing* ethics review of all health and health-related research 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 Ethics Office and RECs, as well as national and international documentation (see section 9).

5 SCOPE

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

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

The Faculty of Health Sciences National Health Research Ethics Council (NHREC) registered RECs 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), as well as the South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008), national and international research ethics guidelines (see

section 9), as well as the terms of reference provided by the Rules for the Management of Research Ethics at the North-West University, 2016.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
HREC	Health Research Ethics Committee
AnimCare	The Ethics Committee on Animal Care, Health and Safety in Research
REC	Research Ethics Committee
NWU	North-West University
RERC	Research Ethics Regulatory Committee
NHREC	National Health Research Ethics Council
SOP	Standard Operating Procedure/s
AREC	Animal Research Ethics Committee

7 RESPONSIBILITIES

The NHREC stipulates the responsibilities of RECs as follows:

- The main responsibility of a REC is to conduct rigorous ethics reviews of all health or health-related research proposals to ensure that the welfare and other interests of participants, researchers and animals used in research are properly protected and that the research will be conducted in accordance with the required ethical norms and standards.
- RECs 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;
 - Protect the safety and welfare of animals;
 - Hold researchers accountable for their research activities;
 - Promote the highest scientific standards and best available techniques or approaches for optimal use of participating humans and animals;
 - Promote important social and ethical values.
- RECs 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 HREC member is to decide independently whether the proposed research study protects the interests of participants adequately and upholds exemplary standards.
 - In the case of research with animals, the primary role of the AnimCare is to protect the welfare interests of animals used or to be used in research (see SANS 10386:2008 for the role and function of an AREC).

Such responsibility regarding participant interest and animal welfare shall always take precedence over the interest of the scientific project.

The RERC in its governance role further stipulates that the RECs of the Faculty of Health Sciences will:

- Function according to a strict code of conduct as appropriate for the Faculty of Health Sciences and approved by the RERC (see 8.2 in this document).
- Formulate and seek approval from the RERC for a set of operational rules for ethics applications in the Faculty of Health Sciences (2.2.4_SOP_Ethics_1.4).
- Formulate and seek approval for a set of research discipline-specific examples of Risk Level Descriptors, in line with the RERC guidelines, to make a suitable classification of the risk levels of research studies (see Risk level descriptor for research with human participants, estimated animal experience category (well-being), and estimated environmental impact category).
- Provide feedback on specific matters as requested by the RERC.
- Ensure confidentiality of all information revealed to it.
- Ensure that all researchers working in the Faculty of Health Sciences 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 Health Sciences by providing health-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 RECs 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 in cases of ethical misconduct by researchers.
- Report all ethical matters to the Deputy Dean Research and Innovations of the Faculty of Health Sciences via the Faculty of Health Science's Ethics Office.
- Report to the RERC on an annual basis, using the NHREC template.

8 PROCEDURE(S)

8.1 Formal character of the RECs

The RECs of the Faculty of Health Sciences must always be NHREC registered committees, as well as approved by the RERC of the NWU. See detail for REC member selection, appointment and functioning (2.2.4_SOP_Ethics_1.2).

8.2 Code of conduct for REC members

All REC 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 REC 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 REC 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 REC meeting to avoid potential conflict of interest (personal or financial);
- Keep all matters coming to their attention during REC meetings confidential.

8.3 Relationship to non-affiliated researchers

Researchers with no affiliation to the North-West University can approach any of the NHREC-registered RECs of the Faculty of Health Sciences to review and approve their health or health-related research proposals, where such an REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application. A fee (see the predetermined HREC/AnimCare fee structure) will be levied for such a service.

8.4 Accountability responsibilities of RECs

The NHREC-registered RECs function within the legislative framework of Section 73 of the National Health Act No. 61 of 2003, which requires a University at which health and health-related research is being conducted to have an NHREC-registered REC. The REC is the single body vested with the explicit authority and legal accountability for the final determination regarding the ethical acceptability of the proposal.

8.5 Mechanisms for reporting by RECs

The RECs, managed and supported by the Faculty of Health Sciences Ethics Office, function directly under the Executive Dean of the Faculty of Health Sciences. The Ethics Office consists of a Head, an Academic Advisor and several support staff members. The RECs work in close collaboration with the Deputy Dean Research and Innovations, the Research and Innovations Committee and Scientific Committees of the Faculty of Health Sciences, as well as with other Faculties' structures involved in health-related research. The Faculty Board and RERC also serve to internally audit RECs in terms of their operational mandate and standards, and where applicable, to ratify the REC's decisions. RECs must report annually on their activities to the NHREC and the RERC.

8.6 Mechanisms for remuneration of REC members

REC members who are on the payroll of the North-West University are not remunerated for their services as REC 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, veterinarian), 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 REC duties;
- 2) Employed but have to add hours to their workday to serve on the REC and do its work; or
- 3) In a private practice and their involvement as a member of the REC will lead to a loss, as they are not able to earn an income during the REC meeting.

8.7 Authority of the RECs

The National Health Act No. 61 of 2003 provides statutory authority for the governance of “health research” through the registered RECs, as well as the necessary ethics regulatory infrastructure through the NHREC.

The RECs further derive their authority from the minimum standards and guidelines for research ethics of the NHREC, as well as the governance rules formulated by the RERC:

- 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 health and health-related research *Ethics in Health Research: Principles, Processes and Structures*, 2015 (chapter three and four).
- The 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 (RERC).

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 this SOP will then be amended as soon as possible to reflect the latest changes.

The NHREC-registered and RERC-approved RECs are managed by the Faculty of Health Sciences Ethics Office and function as sub-committees of the Faculty Board of the Faculty of Health Sciences. If an REC is dissolved by the Faculty, it must be reported to the NHREC and RERC.

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)
- South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008).
- 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.
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).
- The Rules for the Management of Research Ethics at the North-West University, 2016.

10 ADDENDA

No	Document name
1	NWU Code of conduct for researchers
2	HREC/AnimCare fee structure
3	Risk level descriptors for human participants
4	Estimated animal experience category (well-being)
5	Estimated environmental impact category
6	2.2.4_SOP_Ethics_1.2
7	2.2.4_SOP_Ethics_1.4

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