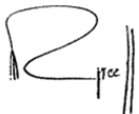



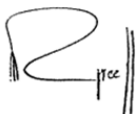

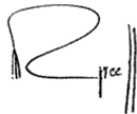



## Faculty of Health Sciences Ethics Office for Research, Training and Support





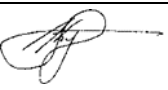


ETHICS OFFICE		Terms of Reference	
<b>Title</b>	Terms of reference for research ethics committees of the Faculty of Health Sciences		
<b>ToR No</b>	2.2.4_ToR_Ethics_1.1	<b>Version no</b>	3
<b>Date of approval</b>	1 November 2023	<b>Revision date</b>	November 2026
<b>Web address</b>	<a href="http://health-sciences.nwu.ac.za/healthethics">http://health-sciences.nwu.ac.za/healthethics</a>	<b>Page no</b>	Page 1 to 7

### 1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof M Greeff		30 Aug 2016
			6 June 2018
Updated by:	Prof GW Towers		27 July 2023
Checked by:	NWU-HREC		8 Sept 2016
			27 July 2023
	NWU-AnimCareREC		8 Sept 2016
			27 July 2023
	Ethics Office		8 Sept 2016
			27 July 2023

	Faculty Management Committee		8 Sept 2016 2 August 2023
Authorised by:	Prof M Greeff as the Head of the Ethics Office		19 Sept 2016 6 June 2018
	Prof GW Towers as the Head of the Ethics Office		1 November 2023

## 2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of the NWU-HREC	Dr GW Towers		10 Nov 2016 6 June 2018
	Prof P Bester		27 July 2023
Chairperson on behalf of NWU-AnimCareREC	Prof CB Brink		10 Nov 2016 6 June 2018 27 July 2023
On behalf of the Ethics Office	Prof M Greeff		10 Nov 2016 6 June 2018
	Prof GW Towers		27 July 2023
ExCo FMC	Prof A Kotzé		10 Nov 2016 6 June 2018 2 August 2023
Faculty of Health Sciences	Ms L van Ronge		10 Nov 2016 6 June 2018
	Ms L Sengati		27 July 2023

## 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
1 November 2023	3	Updating of document

## 4 PURPOSE OF THE ToR

These terms of reference provide guidelines and a minimum standard for the operational management of the research ethics process in the Research Ethics Committee's (REC's) 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 participants and animals involved 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 i.e. starting of actual data collection.

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

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: 2021 2<sup>nd</sup> ed), national and international research ethics guidelines (see section 9), as well as the terms of reference provided by the Research Ethics Policy and the Terms of Reference for the management of research ethics at the North-West University, 2018.

## 6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
DD: R&I	Deputy Dean: Research and Innovation
DVC: R&I	Deputy Vice Chancellor: Research and Innovation
FB	Faculty Board
FMC	Faculty Management Committee
NWU-HREC	North-West University Health Research Ethics Committee
NWU-AnimCareREC	North-West University Animal Care, Health, and Safety in Research Ethics Committee
NWU-AnimProd REC	North-West University Animal Production Research Ethics Committee
REC	Research Ethics Committee
NWU	North-West University
SCRE	Senate Committee for Research Ethics
NHREC	National Health Research Ethics Council
SOP	Standard Operating Procedure/s
AREC	Animal Research Ethics Committee
SAVC	South African Veterinary Council

NSPCA	the National Society for the Prevention of Cruelty to Animals
SANS	South African National Standard

## 7 RESPONSIBILITIES

The NHREC stipulates the responsibilities of RECs as follows:

- a. 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.
- b. RECs must ensure that research proposals stand up to scientific and ethical scrutiny as is appropriate for the discipline concerned.
- c. 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.
- d. 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 NWU-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 NWU-AnimCareREC is to protect the safety and welfare interests of animals used or to be used in research (see SANS 10386:2021 2<sup>nd</sup> ed. 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 SCRE in its governance role further stipulates that the RECs of the Faculty of Health Sciences will:

- a. Function according to a strict code of conduct as appropriate for the Faculty of Health Sciences and approved by the SCRE (see 8.2 in this document).
- b. Formulate and seek approval from the SCRE for a set of operational rules for ethics applications in the Faculty of Health Sciences (2.2.4\_SOP\_Ethics\_1.4).
- c. 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 research studies (see Risk level descriptor for research with human participants, estimated animal experience category (well-being), and estimated environmental impact category).
- d. Provide feedback on specific matters as requested by the SCRE.
- e. Ensure confidentiality of all information revealed to it.
- f. Ensure that all researchers working in the Faculty of Health Sciences sign the NWU research ethics code of conduct.
- g. 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.
- h. Receive applications for research ethics approval from researchers via the provided research management system.
- i. Consider these applications at its regular meetings, as well as minute discussions and decisions and communicating the RECs decisions regarding applications to applicants.

- j. Approve the issuing of research ethics approval letters (valid for a year) for approved projects.
- k. Consider and approve any amendments to the original approved research proposal.
- l. 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.
- m. Consider and act appropriately in cases of research noncompliance, violation of good research practice, or research misconduct by researchers by channelling it to the Institutional Research Integrity Management System (IRIMS) as per SOP\_NWU Research Integrity \_1 to 3.
- n. Report all ethical matters to the Deputy Dean Research and Innovation (DD: R&I) of the Faculty of Health Sciences via the Faculty of Health Science's Ethics Office.
- o. Report to the SCRE on an annual (or as otherwise stipulated) basis, using the NHREC template.
- p. Adhere to the internal review of the operations of the NWU-AnimCareREC as required in the SANS 10386:2021 2<sup>nd</sup> ed. (section 5.3.3.6).
- q. Adhere to the independent external review of the operations of the NWU related to ARECs as required by the SANS 10386:2021 2<sup>nd</sup> ed. (Section 9).

## **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 SCRE 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:

- a. Agree to a term of office of five years;
- b. Familiarise themselves with the institutional documentation as well as national and international research ethics guidelines;
- c. Attend research ethics training sessions to keep abreast with the latest changes in this field (proof of evidence at least once every three years);
- d. Always act with integrity;
- e. Regularly attend REC meetings;
- f. Be punctual in the attendance of these meetings;
- g. Diligently perform all responsibilities delegated to them;
- h. Maintain all of these responsibilities in compliance with national and international ethical and regulatory requirements;
- i. 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);
- j. 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 and/or health-related research proposals, where such a 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 NWU-HREC/NWU-AnimCareREC 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 for Research, Training and Support, 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 DD: R&I, the Research and Innovation Committee and the Scientific Committees of the Faculty of Health Sciences, as well as with other Faculties' structures, that undertake health-related research. The Faculty Board (FB) and SCORE 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 SCORE.

## 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, 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 their appointment (to be based on an agreed upon hourly rate for the time spent in the actual REC meeting i.e. not including the preparation time for the meeting), where they are compensated for time, inconvenience, and expenses (TIE principle), provided that they are:

- a. Not employed and might lose the opportunity to earn income for the day by attending to certain REC duties;
- b. Employed but have to add hours to their workday to serve on the REC and do its work; or
- c. 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 SCORE:

- a. The National Health Act No. 61 of 2003, section 73, which requires the University to establish RECs which are registered with the NHREC.
- b. 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).
- c. The South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2021 2<sup>nd</sup> ed).
- d. Research Ethics Policy and the Terms of Reference for the management of research ethics at the North-West University, 2018 (SCORE).

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 SCRE-approved RECs are managed by the Faculty of Health Sciences Ethics Office and function as sub-committees of the FB of the Faculty of Health Sciences. If a REC is dissolved by the faculty, it must be reported to the NHREC and SCRE.

### **8.8 Adherence to the SANS 10386:2021 2<sup>nd</sup> ed. required internal review of the AREC**

To adhere to the requirements of the SANS 10386:2021 2<sup>nd</sup> ed. (section 5.3.3.6), the following procedures and processes will be followed:

An annual internal review of the NWU-AnimCareREC will be conducted to review the operations of the NWU-AnimCareREC, to ensure its compliance to the set standards of the SANS 10386:2021 2<sup>nd</sup> ed., as well as institutional policies.

- a. This review will include the annual report prepared by the Head of the Ethics Office and the chairperson of NWU-AnimCareREC, being sent to the NHREC, who will act as the *external reviewer*.
- b. The review will also include the aforementioned annual report being sent to the DD: R&I and the Deputy Vice-Chancellor: Research and Innovation or DVC: R&I (or his/her delegates) as the *internal reviewers*.
- c. The annual meeting set aside for the discussion of all the annual reports by the Senate Committee for Research Ethics (SCRE) will serve as the *meeting with the NWU-AnimCareREC chairperson*, where the Head of the Ethics Office is also present.
- d. The Head of the Ethics Office will furthermore formulate a summative report presented to the Faculty Management Committee (FMC), FB, the SCRE, as well as the Senate by no later than mid-year.
- e. Should further discussions be required a meeting(s) can be arranged.

Additional items that should be included in the summative report, will include aspects not covered at present under either of the abovementioned annual reports:

- a. Reporting on the numbers of the type or model of research e.g., toxicology, safety etc., being reviewed by the NWU-AnimCareREC.
- b. The certification of the animals as specified by the relevant national departments.
- c. The confirmation of personnel that are certified or authorized by the relevant national council.
- d. The number of genetically modified animals produced.
- e. Number of animals per project

### **8.9 Adherence to the SANS 10386:2021 2<sup>nd</sup> ed. required independent external review of the operations related to the AREC.**

**Note:** To adhere to the requirements of SANS 10386:2021 2<sup>nd</sup> ed. (section 9) the NWU will ensure that both ARECs (NWU-AnimCareREC and North-West University Animal Production Research Ethics Committee (NWU-AnimProd REC)) at the NWU, will use the same external reviewers for the four yearly independent external review.

The following procedures and processes will be followed:

- a. The DD: R&I, FHS and the Head of the Ethics Office in collaboration with the DD: R&I, FNAS and the Chairperson of the NWU-AnimProd REC must on a *four yearly basis*, identify at least *two external reviewers* not affiliated with the NWU (who may be chairpersons of NHREC-registered Animal Research Ethics Committees from other South African Universities, or other experts knowledgeable about animal ethics and the SANS 10386:2021 2<sup>nd</sup> ed.).

- b. The identified external reviewers should be approached by the Head of the Ethics Office and the Chairperson of the NWU-AnimProd REC in collaboration with the DDs: R&I of the two mentioned Faculties to ensure their availability.
- c. The identified external reviewers must then be approved at the FMC, FB, the SCRE, as well as the Senate.
- d. On approval, the external reviewers will be requested to sign confidentiality agreements and declare any potential conflict of interest.
- e. The following documents will be provided to the external reviewers:
  - All NWU institutional policies and related governance documents on its animal care and use programme.
  - The annual reports sent to the NHREC for the past four years.
  - The annual reports sent to the DD: R&I and DVC: R&I for the past four years.
  - Facility inspection reports of all facilities inspected by the AREC for the past four years.
  - Active monitoring reports of the past four years.
  - A sample of the conclusion letters of serious adverse events that have occurred.
  - Sampled agendas and minutes of NWU-AnimCareREC meetings.
  - Any other relevant documents as requested by the external reviewers.
- f. The external reviewers will be granted the authority and resources to perform a further independent on-site review, should they deem it necessary. This could include:
  - Meetings with staff involved in the governance and execution of the animal care and use programme (institutional officers and administrators, animal research ethics committees (ARECs), researchers/investigators, animal facility management, veterinary and paraveterinary professionals, animal care takers).
  - Access to relevant premises, including the applicable SAVC registration certificates and other relevant accreditation or permits, any SOPs, registers, monitoring tools and/or other documentation.
  - Any other relevant matters as requested.
- g. A final report provided by the external reviewers, should cover all aspects as specified in the Standard:
  - Whether and how the NWU, via its ARECs, complies with the Standard.
  - Adequacy of support.
  - Resources and educational programmes for all staff with responsibilities within the animal care and use programme.
  - Effectiveness of institutional strategies and governance.
  - Effective monitoring of animal wellbeing.
  - Management and appropriateness of research animal facilities.
  - Any recommendations requiring response (non-compliance, strategies for improvement and positive findings).
- h. The NWU must ensure that the findings and recommendations of the external review are made known widely within the NWU and ensure that timely actions are taken to address the recommendations.
- i. As per recommendation of the Standard, the NWU may consider publishing an executive summary of the external review report, which can be made available to the National Health Research Ethics Council (NHREC), the South African Veterinary Council (SAVC), the National Society for the Prevention of Cruelty to Animals (NSPCA), other relevant regulatory authorities and funding bodies of the University.

## 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 10386:2021 2<sup>nd</sup> ed).
- 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).
- Research Ethics Policy and the Terms of Reference for the management of research ethics at the North-West University, 2018 (SCRE).

## 10 ADDENDA

No	Document name
1	NWU Code of conduct for researchers
2	NWU-HREC/NWU-AnimCareREC 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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