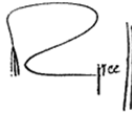




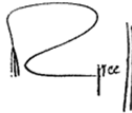






Faculty of Health Sciences Ethics Office for Research, Training and Support









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	3
Date of approval	1 November 2023	Revision date	November 2026
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 M Greeff		22 August 2016	
			4 April 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		9 Nov 2016 2 August 2023
Authorised by:	Prof Minrie Greeff as Head of the Ethics Office		9 Nov 2016 4 April 2018
	Prof Wayne Towers as Head of the Ethics Office		1 November 2023

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Ethics Office	Prof M Greeff		10 Nov 2016 4 April 2018
	Prof GW Towers		27 July 2023
Chairperson on behalf of NWU-HREC	Dr GW Towers		10 Nov 2016 4 April 2018
	Prof P Bester		27 July 2023
Chairperson on behalf of NWU-AnimCareREC	Prof CB Brink		10 Nov 2016 4 April 2018 27 July 2023
Executive Dean of the Faculty of Health Sciences	Prof A Kotzé		10 Nov 2016 4 April 2018 2 August 2023
Faculty of Health Sciences	Ms L van Ronge		10 Nov 2016 4 April 2018
	Ms L Sengati		27 July 2023

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
Xx July 2023	3	Revision of SOP

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 for Research, Training and Support (referred to as the Ethics Office) through its support of at least two National Health Research Ethics Council (NHREC) registered Research Ethics Committees (RECs). Currently, these include one over campus committee which focuses on health and health-related research on humans namely the North-West University Health Research Ethics Committee (NWU-HREC) and another over campus committee which focuses on research with animals with a focus on human, animal or environmental health, namely the North-West University Animal Care, Health and Safety in Research Ethics Committee (NWU-AnimCareREC). The number of these NHREC-registered RECs could increase, should the workload of a specific REC become too great for it to be handled by a single committee. All of the RECs within the Faculty are registered with the 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 10386:2021). These RECs further report to the Senate Committee for Research Ethics (SCRE) of the North-West University (NWU), as well as the Faculty Board (FB) and the Ethics Office of the Faculty of Health Sciences.

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 FB of the Faculty of Health Sciences, make recommendations, give advice and report to the aforementioned FB and the SCRE (as a standing committee of the Senate) of the NWU. They also provide annual reports to both these aforementioned bodies, as well as the NHREC.

The RECs are responsible for the review and approval of all new research ethics applications and amendments as well as the monitoring of research in the faculty. No study may begin before an appropriate REC has provided written approval or ethical clearance. Furthermore, no study may continue without the successful completion of the required monitoring reports (three-monthly for high risk studies, six-monthly for medium risk studies; annually for minimal risk studies in the case of the NWU-HREC and six-monthly for category 5 studies and annually for categories 0-4 in the case of the NWU-AnimCareREC).

Furthermore, the RECs must immediately be 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 this document covers the selection, appointment and the functioning of members of the aforementioned RECs. It covers the responsibilities and procedures to be followed for these activities.

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
NHREC	National Health Research Ethics Council

NWU	North-West University
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
NWU-HREC	North-West University Health Research Ethics Committee
REC	Research Ethics Committee
SANS	South African National Standards
SCRE	Senate Committee for Research Ethics
SOP	Standard Operating Procedure

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 The aims of the RECs in the Faculty of Health Sciences are:

- 8.1.1 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.
- 8.1.2 To ensure that the RECs themselves and researchers comply with the institutional, national and international requirements for research ethics in Health Sciences.
- 8.1.3 To ensure that research where people and animals are involved, is scientifically grounded and ethically responsible.

8.2 The main objectives of the RECs in the Faculty of Health Sciences are

- 8.2.1 To review all research applications and amendments within the faculty, for ethical suitability, to ensure that:
 - a. The research conducted will improve health within the broader framework of healthcare, prevent illnesses and disabilities and improve healing.
 - b. 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.
 - c. The health, safety and position of the researcher (potential exposure to chemicals and micro-organisms / liability) is always protected.
 - d. The research is valuable and scientifically responsible
 - e. Written permission and informed consent are obtained at all times
 - f. Approval is given to research proposals that adhere to the scientific and ethical standards and requirements
 - g. The research provides a favourable benefit-risk ratio, and in cases where this is not possible, sufficient motivation is provided.
- 8.2.2 To monitor and manage all incidents and adverse events.
- 8.2.3 To monitor all ongoing research studies to ensure they adhere to the approved proposal and legal requirements.
- 8.2.4 To review all health-related research applications and amendments from the other faculties of the university, for ethical suitability.

8.3 The composition of the RECs

- 8.3.1 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 10386:2021).

- 8.3.2 All RECs should be independent, multi-disciplinary, multi-sectoral and pluralistic.
- 8.3.3 All members of the RECs must have evidence of undertaking an appropriate form of assessed training in research ethics i.e. proof of ethics training, that is not older than three years.
- 8.3.4 The **NWU-HREC** for health and health-related research with human participants should consist of:
 - 8.3.4.1 At least nine members, where a quorum will be a simple majority i.e. 50% plus one, or if the number of members is more than 15, then the quorum will be 33%.
 - 8.3.4.2 A chairperson, being an academic staff member with appropriate experience, expertise and leadership skills to ensure efficient functioning of the committee
 - 8.3.4.3 At least one layperson
 - 8.3.4.4 At least one member with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people.
 - 8.3.4.5 At least one member with professional training and experience in qualitative research methodologies
 - 8.3.4.6 Members with professional training and experience in quantitative methodologies
 - 8.3.4.7 A member with expertise in bio-statistics
 - 8.3.4.8 A member with expertise in research ethics
 - 8.3.4.9 At least one member who is legally qualified
- 8.3.5 The **NWU-AnimCareREC** for research on animals for the purpose of human, animal or environmental health should consist of:
 - 8.3.5.1 At least one member from each of the following four categories as dictated by SANS (10386:2021):
 - a. Category A: Veterinarians (with experience in the type of research the NWU is involved in)
 - b. Category B: Scientists with substantial and recent experience in the use of experimental animals
 - c. Category C: Animal welfare organisation representatives
 - d. Category D: Representatives not involved in animal experimentation
 - 8.3.5.2 At least nine members, where a quorum will be a simple majority i.e. 50% plus one, or if the number of members is more than 15, then the quorum will be 33%. Over and above

these quorum requirements, it is also required that, of the members attending a specific meeting:

- a. At least one representative is present from each of the four categories indicated under 8.3.4.1,
- b. At least 33% of the members present, are representatives of Categories C and D, as indicated under 8.3.4.1.

- 8.3.5.3 A chairperson, being an academic staff member with appropriate experience, expertise and leadership skills to ensure efficient functioning of the committee.
- 8.3.5.4 A member with expertise in bio-statistics
- 8.3.5.5 The size of the REC may depend on the number of animal users in the University.

8.4 Selection and appointment of REC members

- 8.4.1 Members are appointed for a term of *five years* (as per the SCRE Terms of Reference) 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.
- 8.4.2 Updated CVs, appointment letters, signed Code of Conduct for REC members, proof of induction attendance, proof of ethics training, any Personal Development documentation in regard to ethics and membership documentation applicable to ethics of all REC members should always be on file in the applicable administrator's office.
- 8.4.3 Consideration should be given to succession planning.
- 8.4.4 The selection and appointment of the **chairperson**:
- 8.4.4.1 As soon as the RECs become aware of a vacancy in this position of chairperson, the Faculty Management Committee (FMC), 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.
- 8.4.4.2 CVs of potential candidates are sent to the Head of the Ethics Office, after which the Head and Academic Advisor of the Ethics Office and the applicable chairperson currently in the position, have preliminary discussions with the suggested candidates on the roles and responsibilities of this position.
- 8.4.4.3 A final decision is taken at an FMC meeting, ratified at the FB, and the SCRE, as a standing committee of the Senate, is informed in order to finalise the appointment.
- 8.4.4.4 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; 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. The NHREC is also notified.
- 8.4.4.5 This appointment must reflect in the annual task agreement of the new REC chairperson.
- 8.4.4.6 An acting chairperson can be appointed by the REC, to act for a limited period.
- 8.4.5 The selection and appointment of the **vice-chairperson**:
- 8.4.5.1 As soon as the RECs become aware of a vacancy in this position, they nominate possible vice-chairpersons from the existing REC members.
- 8.4.5.2 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.
- 8.4.5.3 A final decision is taken during the next REC meeting, confirmed at FMC, and the SCRE is informed.
- 8.4.6 The selection and appointment of **committee members**:
- 8.4.6.1 As soon as the RECs become aware of a vacancy in this position, they make it known to the FMC and within the Faculty and ask for nominations to replace the specific gap the resignation

- has created i.e. someone from a specific research entity and/or with specific skills as per requirement of the NHREC.
- 8.4.6.2 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.
- 8.4.6.3 A final decision is taken during the next REC meeting, confirmed at FMC, ratified at the FB, and the SCRE is informed in order to finalise the appointment, as a subcommittee of the Senate.
- 8.4.6.4 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; 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. The NHREC is also notified.
- 8.4.6.5 This appointment must reflect in the annual task agreement of the REC member.
- 8.4.7 The selection and appointment of **administrative staff supporting the REC:**
- 8.4.7.1 All administrative support is provided to the RECs by the Faculty's Ethics Office. As such the selection and appointment of administrative staff members falls under the ambit and responsibility of the Head of the Ethics Office.
- 8.4.7.2 As soon as the Head becomes aware of a vacancy in one of the administrative positions, they will proceed with assigning an interim administrative staff member to assist the REC, to ensure continuation of processes, until the position can be filled.
- 8.4.7.3 The Head of the Ethics Office will contact the appropriate representative from People & Culture and will proceed with the advertisement of the position as per the standard processes of the NWU. The Head will also inform the FMC, at its next meeting that an administrative position has been vacated and is in the process of being advertised.
- 8.4.7.4 Following advertisement, the Head of the Ethics Office will set up an appropriate interview panel as per the processes of the NWU and will include either the chairpersons or the vice-chairpersons of the RECs. The Head, in collaboration with the interview panel will be responsible for the short-listing of candidates, the arrangement of the interviews, and the finalisation of the offer to the candidate decided upon by the interview panel.
- 8.4.7.5 Upon acceptance of the position by the candidate, the Head of the Ethics Office will proceed with handling the induction of the new administrative staff member. This process will include discussion and acceptance of their specific performance agreement, so that there is a clear understanding of what will be required.
- 8.4.7.6 The new administrative staff member will undergo specific one-on-one induction training within the different sections of the Ethics Office, to ensure that they have oversight of the functioning of the Ethics Office, as well as that of both the RECs.
- 8.4.7.7 The new administrative staff member will be required to review all SOPs within the Ethics Office as well as the administrative SOPs pertinent to their functioning.
- 8.4.7.8 The administrative staff members within the Ethics Office, that are specifically responsible for the administration related to a REC e.g. part of the secretariat or as a minute-taker, will also undergo the research ethics induction and training pertinent to that specific REC, as provided by the Ethics Office.
- 8.4.7.9 The administrative staff member is in turn, introduced during the next REC meeting, after which their appointment is agreed upon by the REC, confirmed at the FMC, ratified at the FB,

and the SCRE is informed in order to finalise the appointment, as a subcommittee of the Senate.

8.4.8 Resignation of committee members

- 8.4.8.1 If a committee member wants to resign from a REC, it is requested that they notify the Head of the Ethics Office and the applicable chairperson of the REC of their intent to resign, via email.
- 8.4.8.2 Based on this notification, the Head and the Academic Advisor of the Ethics Office and the applicable chairperson, will undertake a discussion with the person within a week, to discuss the reasoning for the resignation, to determine if there is anything that can be done to assist and/or support the REC member and/or to negotiate the handling of any outstanding aspects assigned to the member. If the member wants to retract their resignation following this meeting, they are welcome to do so, by informing the Head of the Ethics Office and the applicable chairperson.
- 8.4.8.3 Following this discussion, if the member still wants to resign, then the Head of the Ethics Office will communicate the resignation to the Secretariat of the applicable REC. The member will be requested to still serve for an additional month (or as negotiated with the member), so that there is sufficient time to find a new member. The resignation will be discussed at the next REC meeting, after which it will be confirmed at the FMC, ratified at the FB, and communicated to the SCRE. The NHREC is also notified of the resignation.
- 8.4.8.4 The Head of the Ethics Office will then proceed with the process of selecting and appointing a new REC member as indicated under 8.4.6, to select and appoint a new committee member.

8.4.9 Sub-committees

- 8.4.9.1 All RECs in the Faculty of Health Sciences 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.

8.4.10 Co-opted members, observers and visitors

- 8.4.10.1 The RECs can co-opt members as and when needed e.g. expert reviewers.
- 8.4.10.2 Observers and visitors will be allowed in exceptional cases or for specific purposes e.g. as a learning opportunity for research interns or junior staff members.
- 8.4.10.3 Researchers can be invited for the discussion of their applications and be present to clarify uncertainties.

8.5 Training

- 8.5.1 Training of all REC members is critical, both in the principles of ethics as well as in the 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.
- 8.5.2 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

- 8.6.1 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

- 8.7.1.1 The quorum requirements for both committees are determined, according to the guidelines of the Department of Health, 2015, as set out by the NHREC (specifically according to section

4.4 of the DoH 2015) and the SANS (10386:2021) document, as discussed under Section 8.3 of this document.

8.7.2 Frequency of meetings and agendas

- 8.7.2.1 Meetings will be held monthly from February to November with a minimum of ten scheduled meetings annually. No meetings will take place during January and December. Applications received during these times will be reviewed during the next meeting in February. No meetings will take place during recess periods.
- 8.7.2.2 Meetings will take place on the dates as indicated in the timetable of the Faculty.
- 8.7.2.3 The agenda for these meetings closes on the dates as indicated in the timetable of the Faculty.
- 8.7.2.4 At least 5 days prior to the meeting, the Secretariat will provide the complete agenda pack electronically to all members.
- 8.7.2.5 No meeting needs to take place if no applications had been received at the closing of the agenda.
- 8.7.2.6 Late applications will stand over until the next meeting.
- 8.7.2.7 Notice of extraordinary meetings should reach members at least 2 days before the meeting.

8.7.3 Proposed process for functioning

- 8.7.3.1 Committees should have Standard Operating Procedures (SOP) that indicate the functioning of the committees as well as the processes to be followed when ethical approval or clearance is needed for both new applications or amendments to research proposals.
- 8.7.3.2 The ethical review process should not be mechanical.
- 8.7.3.3 All applications reviewed by the RECs should have prior approval by a Scientific/Proposal Committee.
- 8.7.3.4 All applications are reviewed by a minimum of two reviewers. Expert reviews can also be requested.
- 8.7.3.5 REC members should be encouraged to:
 - a. Be mindful of the basic ethical principles that should inform the planning, design and undertaking of health research
 - b. Be open-minded and not allow personal biases to cloud their application of these guidelines to the review of an application
 - c. Accept the consensus that ethical principles should be balanced, that this is difficult to achieve and that divergence enriches deliberations
 - d. Be mindful of the influence that the context has on how to prioritise principles
 - e. Be deliberate, reflective and thoughtful in discussions about how to balance ethical considerations.
- 8.7.3.6 The RECs should have set timelines for review procedures to ensure an effective system:
 - a. **5 working days** for new applications
 - b. **3 working days** for corrections, smaller amendments and monitoring reports.

8.7.3.7 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

8.7.4.1 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.

8.7.4.2 All conflicts of interest will be recorded on an appropriate template during the meeting, which will be co-signed by the chairperson and the academic advisor of the Ethics Office. This signed document will form part of the register as discussed under 8.7.6.3.

8.7.5 Confidentiality

8.7.5.1 The total process of review of the scientific and ethical integrity of research projects must 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

8.7.6.1 The Ethics Office for Research, Training and Support of the Faculty of Health Sciences will provide the secretariat for the RECs within the Faculty.

8.7.6.2 All meetings are recorded, transcribed and saved electronically.

8.7.6.3 Registers are kept for all meetings including:

- a. agendas;
- b. minutes;
- c. signed record of attendance;
- d. signed record of permission to record the meeting, confidentiality, as well as conflict of interest;
- e. digital recording of the meeting.

8.7.7 Submission of applications and dates of meetings

8.7.7.1 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.

8.7.7.2 An administrative fee may be levied for each application.

8.7.8 The review procedure

8.7.8.1 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.

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

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

- a. 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.
- b. The chairperson and academic advisor(s) are randomly assigned as tertiary reviewers for quality control.
- c. Any additional reviewers are also assigned, based on the requirements as stipulated by 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) e.g. a veterinarian, a reviewer not involved in animal research and an animal welfare representative in the case of research involving live animals or the bio-statistician in the case of quantitative studies that make use of statistical analyses.

- d. All applications are also assigned to the legal representative unless they are either a sub-study of an already approved larger study or an affiliated single study that forms part of an overarching study that has been previously approved by the REC.
- e. 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.
- f. If the nature of the study requires expertise not present in the REC, the application is allocated to an external reviewer.
- g. If there is any uncertainty on the distribution, it is discussed with the Head of the Ethics Office.

8.7.8.4 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.

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

8.7.8.6 Reviewer reports are received back at least two 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

8.7.9.1 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.

8.7.9.2 The chairperson may decide that voting must be by secret ballot, provided that voting for persons is always by secret ballot.

8.7.9.3 The voting process to be followed between the two committees is slightly different based on the requirements as stipulated by 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).

- a. In the case of the NWU-HREC, each committee member has an individual ordinary vote which they are able to cast while the NWU-HREC chairperson also has an ordinary vote but must in addition exercise a casting vote in the event of an equality of votes on any matter.
- b. In the case of the NWU-AnimCareREC, the reviewers do not have individual vote, but rather all of the members in each specific reviewer category must reach a consensus vote for that specific category i.e. each reviewer category e.g. A, B, C and D has a single vote to cast, for a total of four votes. The NWU-AnimCareREC chairperson does not have their own individual ordinary vote but must exercise a casting vote in the event of an equality of votes on any matter.

8.7.9.4 The chairpersons 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.

- 8.7.9.5 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

- 9.1 The RECs function under the management of the Faculty's Ethics Office and in collaboration with the standing committees of the FB (Research and Innovation Committee, FMC and Scientific/Proposal Committees).
- 9.2 The RECs derive their authority from the governance rules formulated by the SCRE i.e. the Research Ethics Policy and the Terms of Reference for the management of research ethics at the North-West University as well as 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). If an REC is dissolved by the Faculty, this must be reported to the SCRE.

10 REVIEWING OF APPLICATIONS OF RESEARCHERS FROM OUTSIDE THE FACULTY OF HEALTH SCIENCES AND THE NWU

- 10.1 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.
- 10.2 An administrative fee will be levied for each of these applications.

11 APPROVAL OF FACILITIES OUTSIDE OF THE NWU WHERE STUDIES ARE COMPLETED

- 11.1 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.
- 11.2 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 ADHERENCE TO THE SANS 10386:2021 2nd ed. REQUIRED REVIEWS OF THE AREC

12.1 Required internal review of the NWU-AnimCareREC

- 12.1.1 The Terms of Reference (2.2.4_ToR_Ethics_1.1) section 8.8 refers to the SANS 10386:2021 2nd ed. required internal review of ARECs to be conducted on an annual basis.
- 12.1.2 This section details the process to be followed during the annual review:
- 12.1.3 Annually, on the *last day of February* (starting 2024), the Head of the Ethics Office and the Chairperson of NWU-AnimCareREC will submit:
- the required annual report to the NHREC (serving as the *external reviewer* for the purpose of the internal review), as well as,

- b. the required annual report to be sent to the Deputy Dean: Research and Innovation (DD: R&I), the Deputy Vice-Chancellor: Research and Innovation (DVC: R&I) and SCRE (serving as the *internal reviewers* for the purpose of the internal review).
- 12.1.4 The discussion of the annual report at the annual meeting of the SCRE, which is dedicated for the purpose of discussing annual reports of RECs, will then *serve as the meeting* with the Head of the Ethics Office and the NWU-AnimCareREC Chairperson as required by the SANS 10386:2021 2nd ed.
- 12.1.5 Due to the SANS 10386:2021 2nd ed, requiring the reporting of certain additional information, than is indicated in the NHREC annual report, and until such time as the NHREC required report has been adjusted, the following information must be added as an addendum to the report submitted to the DD: R&I and the DVC: R&I using the template:
- 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
- 12.1.6 Should the SCRE require further discussions with the Head of the Ethics Office and the Chairperson of the NWU-AnimCareREC, a meeting(s) can be arranged.
- 12.1.7 Annually by *mid-June*, the Head of the Ethics office will send a summative report that will serve at the FMC, the FB, the SCRE and then Senate.
- 12.1.8 The following will be included in this report, set up on a specific template:
- a. Main trends and status of the functioning of the NWU-AnimCareREC
 - b. Findings of the NHREC
 - c. Findings of the SCRE

Note: Should changes be required to section 12.1, then this should be coordinated with North-West University Animal Production Research Ethics Committee (NWU-AnimProd REC) at the NWU to ensure total alignment of processes.

12.2 Required independent external review of the operations related to the NWU-AnimCareREC

- 12.2.1 The Term of Reference (2.2.4_ToR_Ethics_1.1) section 8.9 refers to the SANS 10386:2021 2nd ed. required independent external review of the AREC, to be conducted on a four yearly basis. Note: *To adhere to the requirements of SANS 10386:2021 2nd ed. (section 9), the NWU will ensure that both ARECs (NWU-AnimCareREC and NWU-AnimProd REC) at the NWU, will use the same external reviewers for the four yearly independent external review, to ensure continuity and consistency.*
- 12.2.2 This section details the process to be followed during the four-yearly external review:
- 12.2.3 The following procedures and processes will be followed:
- a. The Head of the Ethics Office and the Chairpersons of NWU-AnimCareREC as well as the NWU-AnimProd REC, in negotiation with the co-ordinator of the Research Ethics and Research Integrity Program, will on a *four yearly basis (starting 2024), in February* of the applicable year, decide on the *two potential external reviewers* e.g. Chairpersons from other NHREC registered ARECs or other experts knowledgeable about animal ethics and the SANS 10386:2021 2nd ed., to be approved and appointed by Senate for the independent external review of the two ARECs.
 - b. The two potential independent reviewers will informally be approached by the Head of the Ethics Office, FHS and the chairperson of NWU-AnimProd REC to establish their availability to be nominated as independent reviewers for the two ARECs.
 - c. Once they have indicated their availability, their names and contact details will be forwarded to the two DD: R&I (FHS and FNAS) to write a formal letter together to the two

- potential reviewers, to get their formal agreement to be available to be nominated for the task.
- d. The letter will include:
 - The date of the review (by August) as well as the date by which to expect all the documentation.
 - The names of the two ARECs involved.
 - The tasks expected of the reviewers.
 - The documents they will be receiving for review.
 - Two separate reviewer reports will be expected from them.
 - That should they want to do a further on-site review, all arrangements will be made for them to do so, on request.
 - How costs will be covered e.g. travel, accommodation, subsistence etc.
 - e. Once their availability has been formally confirmed, the names of the two potential independent reviewers are presented to both FMCs, the FBs and then sent to SCRE, as well as the Senate by not later than June of the year for evaluation, for approval.
 - f. On approval by Senate, the external reviewers will be requested to sign confidentiality agreements and declare any potential conflict of interest.
 - g. 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 the ARECs meetings.
 - Any other relevant documents as requested by the external reviewers.
 - h. 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.
 - i. A final report for each of the two ARECs should be provided by the external reviewers, which should cover all aspects as specified in the Standard, via completion of the appropriate template:
 - 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).

- j. On receipt of the reports, they will be reviewed by the two Faculty's management structures and forwarded to SCRE and then Senate.
- k. Both faculties are to ensure that timely actions are taken to address the recommendations.
- l. The Faculties must ensure that the findings and recommendations of the external review are made known widely:
 - within the NWU by publishing it on the webpage of NWU Research Support, under the Research Ethics section (URL: <https://services.nwu.ac.za/research-support/research-ethics>)
 - externally sent to the National Health Research Ethics Council (NHREC), the South African Veterinary Council (SAVC), and the National Society for the Prevention of Cruelty to Animals (NSPCA),
 - can also be made available to other relevant regulatory authorities and funding bodies of the University.

Note: Should changes be required to section 12.2 coordinate with the NWU-AnimProd REC at the NWU to ensure total alignment of processes.

13 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).
- The North-West University Research Ethics Policy and the Terms of Reference for the management of research ethics at the North-West University, 2018.

14 ADDENDA

No	Document name
1	The North-West University Research Ethics Policy and the Terms of Reference for the management of research ethics at the North-West University, 2018.
2	Code of Conduct for Researcher (North-West University, 2016)
3	Template for the distribution list for reviewer allocation
4	Research ethics review report (NWU-HREC)
5	Research ethics review report (NWU-AnimCareREC)
6	2.2.4_SOP_Ethics_1.3
7	2.2.4_SOP_Ethics_1.6