RESEARCH ETHICS POLICY

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RESEARCH ETHICS POLICY

Preamble

WHEREAS the North-West University (NWU) wishes to ensure that all research conducted under its auspices is conducted in accordance with national and international ethics standards and statutory requirements and in line with its Vision and Mission;

THEREFORE, against the background of the dream to be an internationally recognised university in Africa, distinguished for engaged scholarship, social responsiveness and an ethic of care, the council of the North-West University (NWU) has adopted this policy on 22 November 2018.

1 Policy statement

1.1 General principles

At the NWU research must be guided by the following general principles:

- ***Beneficence and non-maleficence***, signifying the signifying the maximizing of benefit and the minimizing of harm, and requires that the risks of harm posed by the research must be reasonable in light of anticipated benefits;
- ***Distributive justice (equality),*** a fair balance of risks and benefits amongst all role-players involved in research. It should reflect the principle of equality by no segment of the population being unduly burdened by harms of research or denied the benefits of knowledge derived from it;
- ***Respect (dignity and autonomy)*** *for research participants, signifying the opportunity for self-determination about their choices. It recognises the importance of dignity, well-being and safety interests of participants, as well as autonomy (DoH, 2015)*.

1.2 Specific principles

The nature and field of a research field may require the guidance of unique principles, to ensure the protection of human and animals involved in research or the prevention of negative environmental impact that must be formulated by every faculty for approval by the Faculty Board and Senate, to be managed and enforced by the relevant academic director and under the supervision of the Research Ethics Committee (REC) of the faculty concerned.

1.3 Shared research ethics standards

For the purposes of establishing shared research ethics standards, Senate must adopt a code of conduct for researchers to serve as a guide to ensure the integrity and ethical conduct of research undertaken under the auspices of the NWU, and for the accountability, professional courtesy and fairness of researchers when collaborating with others, and good stewardship.

2 Interpretation and application

The interpretation and application of this policy is subject to the provisions of –

- the Constitution and all relevant legislation and binding national and international regulatory requirements, standards, policies, and procedures relating to research;
- the Statute of the North-West University (2017), with specific reference to matters concerning research referred to in its preamble, paragraphs 14 and 20;
- the General Academic Rules of the North-West University (2018) (A-rules), with specific reference to rules 4.9.4 and 5.9.4, and
- resolutions taken by Senate in accordance with the Statute and the A-rules for the implementation of this policy.

3 Roles, responsibilities and accountability

3.1 In terms of the Statute of the NWU the Senate regulates all research and academic support functions of the NWU, and faculty boards are accountable to the senate for the monitoring and the oversight of research in the faculty concerned, and may advise the executive dean of the faculty on research, academic support and student matters pertaining to a faculty, as well as appropriate quality-assurance measures.

3.2 The Deputy Vice-Chancellor: Research and Innovation is responsible for the overall management of this policy and may delegate specific functions and assign duties in this regard to an officer or officers of the NWU.

3.3 The executive deans are responsible for the management of this policy in their faculties and may delegate specific functions and assign duties in this regard to a deputy dean and an academic director or directors/heads and an officer or officers of the faculty concerned.

3.4 A standing committee known as the Senate Committee for Research Ethics (SCRE) representative of all faculties and the university management must be appointed by Senate for the purposes of rendering advice on the NWU's management of research integrity and research ethics, on the state of which the RERC must report to Senate at least once annually.

3.5 Every faculty must establish at least one Research Ethics Committee (REC) to oversee and manage compliance with the requirements of ethical research of minimal risk studies in the various scholarly disciplines, subject to the oversight of the faculty board concerned.

3.6 Research with vulnerable participants or greater than minimal risk must be reviewed by one of the RECs specifically appointed for this purpose with expertise in the field of study.

3.7 In cases where considerations of research ethics involve more than one discipline, the responsible managers must take steps to activate all relevant REC's.

* Department of Health 2015. Ethics in Health Research. Principles, Processes and Structures. Second edition.

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Terms of Reference for the management of research ethics at the North-West University

1 Introduction

1.1 Motivation for a management process for research ethics

Research ethics deals with the way in which research is planned, conducted and executed, in order to ensure that the entire process conforms to rules, standards or norms for conduct as agreed upon by the research community at large. Naturally, this is dependent on the field of study and the research methodologies that are deemed acceptable within that field.

There are many aspects and challenges involved in different research fields, and hence many reasons to consider the ethical aspects of such research. The following is a small selection of examples to illustrate the point:

- Research involving human participants or animal subjects: The rights and welfare of such participants must be safeguarded, the relationship between researcher and participants must be considered;
- Data-intensive research: Aspects involving the collection, use, interpretation and safeguarding of data must be acceptable;
- Research plans: Aspects such as formulating, review, reporting, communication of findings, affordability to execute and complete research;
- Research teams: Competence and authorisation of team members to perform tasks and ability to take necessary responsibility;
- Relationships within research teams: Who will publish or co-publish, first-author agreements, travel and conference attendance, issues related to affiliation, conflict resolution.
- Relationship with the community: Responsibility to perform and communicate research in such a manner that it remains responsive to community needs and aspirations, keeping the community engaged, aware and informed.

From a normative perspective, there are several reasons to adhere to solid research ethics standards, such as:

- Ensuring integrity in all aspects of research;
- Ensuring that researchers can be held accountable when conducting research;

- Ensuring a high level of professional courtesy and fairness in working with others;
- Ensuring good stewardship of research on behalf of others.

It is, hence, imperative that all researchers at the NWU must agree on a shared set of research ethics guidelines, and that management measures be put in place to ensure that all research is conducted within the boundaries of these guidelines. These guidelines will be derived from the Research Ethics Policy of the NWU.

1.2 Overview of management process

1.2.1 Code of Conduct

The NWU has adopted a Research Ethics Policy which lays down the research ethics principles for research at the university. These principles were further expanded into an approved Code of Conduct for Researchers, which must be signed by all researchers to indicate their acceptance of these principles. All management structures of the NWU will ensure that all research conducted under the auspices of the NWU must adhere to these principles.

1.2.2 Structure

In order to give effect to the Research Ethics Policy of the NWU, a committee structure will be set up to govern and manage the Research Ethics processes of the NWU. A **Senate Committee for Research Ethics (SCRE)** will be responsible for the governance issues, and a number of **Research Ethics Committees (REC)** functioning within the faculties will be responsible for the operational management of the process. Each faculty will have at least one REC, but can have more than one such REC depending on discipline-specific needs.

Each REC will function in close alignment with the various research committees in the Faculty e.g. the research entity's Scientific/Proposal Committee and the Faculty Research and Innovation Committee. The REC will have the same status and reporting responsibility as the Faculty Research and Innovation Committee.

1.2.3 Statutory requirements for external registration of a REC

The National Health Act was first published in 2003. Chapter 9 of the Act deals with national health research and information. A large portion of that chapter is in fact dedicated to health research ethics. Section 72 mandates the establishment of the National Health Research Ethics Council (NHREC), and stipulates in section 73 that all RECs dealing with health research must be registered by the NHREC (a statutory body). The gazetted regulation relating to research with human participants of 2014 and the document Ethics in Health Sciences: Principles, Processes and Structures of 2015 expand on this and refer to *health and health-related research*. The latter document is intended to provide the minimum national benchmark of norms and standards for conducting responsible and ethical research involving humans or animals. In the latter case, the SANS 10386:2008 provides the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes.

It can be envisaged that other groupings can follow this example set by the Department of Health, i.e. that the research ethics within various contexts can in some form or way be governed by a statutory body. Hence, these rules must make provision for a variety of RECs that are registered with some statutory body, which prescribes guidelines that must be adhered to.

All RECs that are approved by the NWU, irrespective of it being registered with an external regulatory body or not, will have the same status within the NWU.

1.2.4 Risk Level Descriptors

A risk can be seen as "the probability of harm occurring as a result of participation in research" or "an unexpected negative consequence of unethical actions". Therefore, risk needs to be assessed prior to conducting research. A risk level descriptor (RLD) is therefore the specification of the probability and the magnitude of the risk and probability of such risk occurring. It forms the basis of any REC's decision-making regarding ethical approval of research.

Research Ethics Risks for adult participants can be classified under the following four categories: (**Note:** The definitions given here, with minor changes, are quoted from the document "Regulations relating to research on human participants"[1] derived from the National Health Act of 2003, and **may not be directly applicable to all contexts**).

1. **No Risk**: There is no possible risk that the research may lead to any undesirable effects or unexpected negative consequences as no participants are directly involved.
2. **Minimal, Low or Negligible Risk**: The probability, magnitude or seriousness of unexpected negative consequences, harm or discomfort anticipated in the research is **negligible** and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a stable society). Research in which the only foreseeable risk is one of **minimal unexpected negative consequences, discomfort or inconvenience**.
3. **Medium Risk**: Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.
4. **High Risk:** Research in which there is a real and foreseeable risk of unexpected negative consequences, harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.

There are various other ways of classifying risk. For instance, risk for research with minors and adults with mental incapacity refer to greater than minimal risk. For animals it is usually classified according to the impact on animal wellbeing, ranging from *no impact* on animal wellbeing to *very severe impact*, requiring extraordinary motivation and control measures and classified as categories.

[1] Regulations relating to research on human subjects, Department of Health, Government Gazette #36508, 29 May 2013.

By their very nature, these RLDs are discipline-specific. Hence, each REC needs to formulate its own discipline specific examples for the various risk levels described above. These examples of RLDs must be reviewed and approved by the NWU SCRE.

1.2.5 Application for Ethics Approval

Before any research may be conducted scientific approval must be granted for a project by the relevant scientific/proposal committee. The process of application for research ethics approval will be based on the involvement with human participants, animals and possible environmental impact and RLDs applicable to the specific discipline and formulated by the relevant REC.

A typical ethics approval process would include that a research proposal with supporting documents as well as an ethics checklist (determined by discipline specific RLDs) first be submitted to a scientific/proposal committee for scientific review. This committee will make a preliminary assessment of the risk level of the application, and refer the application to an appropriate REC for a final review. The REC must also determine the context of the research: if the context is health or health-related, or has a non-health related focus where vulnerable human participants are involved and/or medium and high risk levels exist, the application must be referred to a committee registered with the NHREC, in the format specified by the registered REC.

After an independent and proper review by the relevant REC, the committee will communicate their decision to the researcher and/or the SCRE for further action. The SCRE requires a signed approval letter, along with minutes of the REC meeting where an application was reviewed, before an official NWU-SCRE Ethical Approval Letter can be issued. This Ethics Approval Letter is to be signed by the Chairperson of the REC that has approved the application. Ethical approval will be valid for one year with an option to renew when necessary.

1.2.6 Training

Knowledge regarding research ethics has evolved greatly over the course of the past few years. More specifically, in South Africa, research ethics, which originally focused on health research due to Chapter 9 of the National Health Act 61 of 2003, has developed to reveal other important ethical aspects within non-health disciplines, as motivated in 1.1 above. With this evolution, new research ethics issues have come to the fore as well as misconceptions with regard to what is ethical research behaviour and what is not. To stay informed and up to date with current developments within research ethics, training of researchers and research ethics committee members needs to be done on a continuous basis (at least once every three years) and proof thereof provided to the REC.

1.2.7 Governance of research ethics at the North-West University

In the sections following this introduction, this document makes provision for the following:

- Rules for the establishment of the SCRE, that provides governance leadership for research ethics at the NWU;
- Rules for the establishment of NWU RECs;
- Rules for the functioning of such RECs;

- Rules which makes provision for some of the NWU RECs that have to register with external regulatory bodies, and which allow these registered RECs to also satisfy the requirements of the external regulatory body;
- Rules to establish a mechanism and guidelines in order to ensure that research ethics applications are considered by the correct and appropriate REC.

2 Terms of Reference: Senate Committee for Research Ethics (SCRE)

2.1 Purpose of the SCRE

The SCRE is established for matters concerning research ethics. These matters include research ethics planning, and the research ethics policy framework of the university. This committee is meant to support the Senate in this regard.

2.2 Responsibilities of the SCRE

Governance: Formulates the Research Ethics Policy of the NWU, and ensures that all research conforms to this policy by

- Formulating a research ethics code of conduct to be signed by all researchers;
- Formulating generic minimum rules for all RECs at the NWU;
- Facilitating the establishment of appropriate research ethics committees (REC) within the NWU;
- Approving the specific operational rules, RLDs and codes of conduct where applicable for each REC;
- Ensuring that every REC performs its duties in line with its approved operational rules;
- Ensuring that the members of each REC are appropriately trained and qualified;
- Being co-responsible for ensuring that, when appropriate, registered RECs comply with the rules of the external governing body.

Support: Provides the necessary support (via the Research Support office) to RECs, in terms of:

- Providing and maintaining an efficient research ethics management system (InfoEd);
- Providing a research ethics awareness program for new staff;
- Creating awareness with line managers to ensure that RECs are provided with the necessary financial, human and infrastructural resources in the normal budgeting process in order to fulfil its Terms of Reference;
- Recordkeeping (via the research ethics management system) of all activities of each REC, including the recording of ethics approval numbers and the issuing of ethics approval letters, in collaboration with the REC.
- Referring to the Research Data Gatekeeper Committee (RDGC), any request from an outside

entity to conduct research within the NWU, for review, and to also refer such requests to the appropriate REC, except where it meets criteria that precludes it from the requirement of ethical review.

- Reviews the activities of each REC annually, by considering the annual report of the REC in consultation with the Chairperson of the REC. The SCRE will also conduct regular on-site reviews of all RECs. This review must satisfy the SCRE that the proper procedures as approved by the NWU are followed by the REC. In cases where the REC is registered with some external body, this review will be combined with external reviews conducted by the external body, and will serve to ensure that the conditions of that body are satisfied;
- Requests an appropriate REC to comment on particular ethics aspects if requested by an outside entity;
- Through SCRI, provide Senate with an annual report on research ethics matters.

2.3 Authority of the SCRE

The SCRE is a standing committee of the Senate of the NWU, and advises Senate on research ethics governance matters. The SCRE must report continuously to the DVC: Research and Innovation, or as determined by the Senate.

2.4 Membership of the SCRE

The SCRE consists of:

- A Chairperson **appointed by Senate** for an appropriate period from the ranks of the DVCs;
- The DVC: Research and Innovation *(ex officio)*
- The Director: Research Support of the NWU *(ex officio)*;
- A member of the Institutional Legal Office or an expert from the Faculty of Law of the University, **appointed by Senate**;
- The Chairperson(s) or his/her delegate of each REC of the NWU *(ex officio)*;
- A member of the Research Support Office, who provides support as specified in 2.2 above *(ex officio)*;
- A committee secretary from the department of Governance and Secretarial Services.
- The SCRE may from time to time co-opt additional members as needed.
- The Head of the Faculty of Health Sciences Research Ethics Office for Research, Training and Support or similar individuals from any other similar Ethics Offices created in future.

All members of the SCRE have voting rights.

2.5 Meeting arrangements of the SCRE

Frequency	Twice per annum; the first meeting of the year will deal mainly with reports from RECs, while the second will deal mainly with governance matters.
Extraordinary meetings	If and when necessary
Quorum	The quorum of the meeting will be half (50%) plus one of all the members, excluding vacant positions.
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies members of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies all members, provides the reason for an extraordinary meeting, as well as the time and venue.
Agenda	At least 7 days prior to the meeting, the Secretariat provides the complete agenda pack electronically to all members.
Reporting	The SCRE reports to Senate. The minutes of each meeting serves at SenateI for discussion and approval.
Decision-making process	Matters are decided by means of general consensus. The Chairperson might, however, decide when a decision should be taken by means of a voting procedure. The Chairperson may decide that voting must be by secret ballot, provided that voting for persons must always be 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 number of votes in favour of or against any proposal is not recorded in the minutes, unless the Chairperson so decides.
Conflict of Interest	A member may not take part in the discussion of or vote on any matter in which the member has a direct financial or other interest, unless the members first discloses the nature and extent of the interest and obtains the leave of the meeting to take part in the discussion or to vote.
Point of Order	A point of order, clarification or information may be raised against any member, in which instance the ruling of the Chairperson is

	binding. The ruling of the Chairperson is binding and cannot be challenged. Should the above point of order, clarification or information be immediately challenged by a member, the ruling is put to the meeting for determination – without it being discussed, and the decision of the meeting is final.
Disrespectful / Disorderly conduct	Anyone attending a meeting who, after having been requested to refrain from disrespectful or disorderly conduct, continues to disobey a ruling from the Chairperson, must be requested to leave the meeting. If that person does not leave the meeting immediately, such a person could be removed from the meeting with the assistance of Protection Services.
Apology	Members absent from the meeting, with apology prior to the meeting, are allowed to participate. The views of a member who is unable to attend a meeting may be submitted in writing.
Round Robin Process	The Chairperson may electronically submit urgent matters in between scheduled meetings. The Secretariat will assist in this process. At least two thirds of the members have to electronically confirm their involvement in the process by giving feedback, approval or non-approval. When a majority of members reaches agreement it is taken as a resolution. Such resolution is equivalent to a resolution of the committee and must be recorded in the minutes of the next meeting.
Resources and Budget	A centralised budget regarding the matters of this committee is managed within the Department of Research Support.
Records management	All records of the committee (terms of reference, membership list, agendas, attendance register, correspondence, etc.) will be kept electronically (on *Share*)

2.6 Approval and Review

The following documents guide the operations of the SCRE:

Document	Status	Authority	Date
Research and Innovation Policy	Approved	Council	20 September 2013
Policy and Rules for Research Ethics	Approved	Council	17 November 2016
Policy for the Management of Research and Innovation Contracts and External Investment/Stake holding	Approved	Council	23 November 2012
Policy on Joint and Double Degrees at Masters and Doctoral Level with Foreign Universities	Approved	Council	31 July 2015
Rules for the Classification of Thesis and Dissertations	Approved	Council	20 June 2014

3 Terms of Reference: Research Ethics Committees (RECs)

These terms of reference provide a minimum standard for the operational management of the research ethics process within the NWU. All RECs approved by Senate, including RECs registered with an external regulatory body, will function within these terms of reference.

3.1 Purpose of the REC

The REC provides operational management of the research ethics process at faculty level within its field of research expertise.

3.2 Responsibilities of the REC

The SCRE, in its governance role, stipulates that each REC will, within its specific field of research expertise:

- function within a strict code of conduct as appropriate for the specific research field and approved by the SCRE, and will ensure confidentiality of all information revealed to it;
- Will have, in the recommended format, the following documents, further guidelines will be provided as an appendix to this policy document[2]:
    - Terms of Reference (ToR) (*at least specifying how it complies with SCRE and other statutory requirements (including scope of authority, powers, and responsibilities, membership and quorum rules), relationship, communication and accountability responsibilities towards SCRE and other applicable statutory bodies, requirement for formal procedures and processes (e.g. types of SOPs), functions and responsibilities of*

[2] Recognition that these requirements have been adopted from the Annual Report Form for Health Research Ethics Committees of the National Research Ethics Council of South Africa, 2018, and modified to own needs.

the secretariat and/or administrative office, relationship with members and researchers, and financial compensation (if applicable)).

- Standard Operating Procedures in the appropriate format *(at least addressing in one or more documents aspects of the frequency of meetings, preparation of agendas and minutes, distribution of documentation prior to meetings, review and approval of proposals/protocols (including expedited), how final decisions are reached, prompt notification of decisions, how to address conflicts of interest and conflicts of commitment for REC members, how to address conflicts of interest and conflicts of commitment for researchers and teachers, informed consent, privacy and confidentiality regarding participants and their health care information, reporting of unanticipated problems/incidents/adverse events, protocol amendment procedures, protocol deviations and protocol violations, maintenance of records, reporting of allegations of misconduct/non-compliance, mechanisms for "whistle-blower" protection, complaints procedures, post-approval passive monitoring of proposals/protocols (as appropriate), post-approval active monitoring of proposals/protocols, continuing review and recertification procedures, suspension and termination, research involving minors and involving vulnerable persons (as applicable), biological materials collection and storage, as well as databases, registries and repositories (as applicable), development and management (review, monitor, approve) of SOPs)*.
- Templates and/or application and report forms *(at least including ethics application form for approval of a study, ethics application for approval of sub-studies under a larger/umbrella/parent study, application form to amend an approved study, form for annual passive monitoring of an approved study, form for active monitoring of an approved study in progress, report form for serious adverse events or incidents, form for raising a query or complaint)*.

- Ensure that researchers have a proper understanding of research ethics as applicable to the specific research field of expertise by providing subject-specific training;
- Ensure that all researchers working within its research field of expertise sign the NWU research ethics code of conduct;
- Formulate and seek approval from the SCRE for a set of operational rules for ethics applications within the specific research field of expertise;
- Formulate and seek approval for a set of research field-specific examples of Risk Level Descriptors, in line with the SCRE guidelines, to make a suitable classification of research ethics proposals.
- Provide feedback on specific ethics matters as requested by the SCRE;
- Receive applications for research ethics approval from researchers via the provided research management system;

- Consider these applications at its regular meetings, and communicate and minute the REC's decision regarding applications to the applicants;
- Approve the issuing of research ethics approval letters for approved projects;
- In cases where the REC cannot reach consensus, or some other conflict arises within the REC, follow the general NWU rules for conflict resolution;
- Consider and act appropriately on the annual reports of approved projects;
- Consider applications to change any of the details of the research project as specified in the original proposal;
- Consider and act appropriately, in accordance with the approved SOP, in cases of ethical misconduct by researchers;
- Report via the approved Faculty structures to the relevant Dean;
- Report to the SCRE on an annual basis, using the prescribed reporting template;
- Report to the appropriate statutory body (if applicable) on an annual basis, as applicable.

3.2.1 Minimum standard for the ethics application procedure:

The SCRE will, with the support of the Research Support Office, maintain and manage the research ethics management system (e.g. InfoEd). All ethics applications (proposals, relevant application forms and supporting documents) must be captured and managed on this research management system, where after all decisions regarding applications must be captured on this system.

The ethics application procedure shall include at least the following steps:

1. A completed research proposal must be submitted to the relevant Scientific/Proposal Committee for review.
2. The Scientific/Proposal Committee will advise (based on the information in the research proposal) whether ethics approval is required and refers the application to the relevant REC if it involves human participants, animals or might have a negative environmental impact as well as other possible aspects of concern.
3. The REC will handle each application for ethics approval according to the rules and operating procedures of the involved REC.
4. If deemed necessary, or if required, a REC must refer an application to a suitable NHREC registered committee.

3.3 Authority of the REC

The REC functions as a sub-committee of the Faculty board and in close collaboration with the Faculty Research and Innovation Committee and Scientific/Proposal Committee. Each REC functions within a predetermined research field of expertise within the structure of the RECs for the NWU.

The REC derives its authority from the governance rules formulated by the SCRE, as well as in the case of registered RECs, the governing statutory body. As such, the establishment of a REC must also be approved by the SCRE. If a REC is dissolved by its faculty, this must be reported to the SCRE.

3.4 Membership of the REC

Members of a REC are recommended to, and approved by, the relevant Faculty board for a period of five years, in accordance with the governance rules of the SCRE. Members are recommended based on their independence as well as their specific research ethics knowledge and expertise. Upon appointment, a formal Letter of Appointment will be issued by the SCRE. This appointment must reflect in and count towards the annual task agreement of the staff member.

3.4.1 Composition of the REC

The REC will consist of ***at least*** the following:

- At least 7 members, with a quorum being a simple majority.
- Where the number of members is more than 15, the quorum may be 33%.
- A chairperson, being an academic staff member with appropriate experience, expertise and leadership skills to ensure efficient functioning of the committee.
- A minimum of two members who are specialists in the particular research field.
- One member who is not a staff member of the North-West University (lay person or community representative).
- It is recommended that at least one member should be an expert in the field of statistics, if applicable, given the scope of applications the REC reviews.
- Ad hoc attendees with required fields of expertise may be nominated for meetings, such as a statistician, legal advisor, bioethicist, biosafety, clinical or procedure expert, etc.

The composition of RECs registered with an outside regulatory body might be prescribed by that body. Even if this is the case, the minimum membership will be as described above.

3.4.2 Appointment of members

The Faculty Management, in consultation with the appropriate REC, suggests possible candidates. Members are approved by the relevant Faculty board, and formally appointed by the SCRE, in its role as standing committee of Senate.

3.4.3 Appointment of Chairperson and Vice Chairperson

The Faculty Management, in consultation with the appropriate REC, suggests possible candidates for chairperson. The Faculty Board appoints a chairperson in consultation with the Faculty Management and the REC. The vice-chairperson is selected and appointed by the REC and need not be appointed by the Faculty Board.

3.4.4 Co-opted members, observers and visitors

The REC co-opts members as and when needed. Since the REC functions within a strictly confidential environment, observers and visitors will only be allowed in exceptional cases and for a specific purpose. In such cases a confidentiality agreement must be signed. Researchers may be invited to attend the discussion of their application and to be present to clarify any uncertainties.

3.4.5 Voting rights

All members will have voting rights, while co-opted members, observers and visitors will not have such rights.

3.4.6 Secretariat

The relevant Faculty will ensure that appropriate secretarial services are provided.

3.5 Meeting arrangements

The following minimum requirements apply for a meeting, in addition to any applicable statutory requirements when applicable to a particular REC:

Frequency	A **minimum** of four per annum, if there are matters to consider. These meetings should preferably be face-to-face meetings, but can also be held via interactive electronic media where practical. The timing of meetings should be such that research projects are not delayed unnecessarily while waiting for ethics approval.
Extraordinary meetings	If and when necessary
Quorum	The quorum of the meeting will be at least half (50%) plus one of all the members, excluding vacant positions. Where the number of members is more than 15, the quorum may be 33%
Notice	At least 14 days before the meeting date, the Secretariat electronically notifies the members of the time and place where the meeting is to be held. At least 2 days before an extraordinary meeting, the Secretariat electronically notifies the members, provides the reason for an extraordinary meeting, as well as the time and venue. In

	exceptional cases, for urgent matters such as with serious adverse events with significant risk or potential harm to participants, animals, researchers, students and/or the environment, immediate action may be required which must then be ratified at the next meeting.
Agenda	At least 5 days prior to the meeting, the Secretariat provides the complete agenda pack electronically to all members.
Reporting	A report of the REC's activities, excluding confidential information, serves at the appropriate Faculty board for discussion and approval. An annual report must be submitted to the SCRE in the prescribed or agreed upon format in the case of NHREC registered RECs.
Decision-making process	Matters are decided by means of general debate and consensus. When consensus cannot be obtained, minor change that will allow consensus must be sought, or further consultation can be requested if the matter at hand is not urgent. When consensus is still not possible and a timely decision is required, the Chairperson should put the decision to a vote. The Chairperson may decide that voting must be by secret ballot, provided that voting by members must always be 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.
Conflict of Interest	A member may not take part in the discussion of, or vote on any matter in which the member has a direct financial or other interest. In such cases the member is required to declare conflict of interest and should abstain or obtain the leave of the meeting during such discussion and voting.
Point of Order	A point of order, clarification or information may be raised against any member, in which instance the ruling of the Chairperson is binding. Should the above point of order, clarification or information be immediately challenged by a member, the ruling is put to the meeting for determination – without it being discussed, and the decision of the meeting is final.
Disrespectful / Disorderly conduct	Anyone attending a meeting who, after having been requested to refrain from disrespectful or disorderly conduct, continues to

	disobey a ruling from the Chairperson, must be requested to leave the meeting. If that person does not leave the meeting immediately, such a person could be removed from the meeting with the assistance of Protection Services.
Apology	Members absent from the meeting, with apology prior to the meeting, are allowed to participate. The views of a member who is unable to attend a meeting may be submitted in writing.
Round Robin Process	The Chairperson **may** electronically submit urgent matters in between scheduled meetings. The Secretariat will assist in this process.[3] At least two thirds of the members have to electronically confirm their involvement in the process by giving feedback, approval or non-approval. When a majority of members reaches agreement it is taken as a resolution. Such resolution is equivalent to a resolution of the committee and must be recorded in the minutes of the next meeting.
Resources and Budget	The Chairperson submits a budget to the appropriate faculty as part of the annual budgeting process.
Records management	All records of the committee (terms of reference, membership list, agendas, attendance register, correspondence, etc.) will be kept electronically on the research ethics management system (InfoEd), or as otherwise specified as per approved SOP. Records management must be according to the file plan of the university's record management system.

4 RECs registered with external regulatory bodies

There is currently only one such external regulatory body, namely the National Health Research Ethics Council.

4.1 Registration with the NHREC

The National Health Act was first published in 2003. Chapter 9 of the Act deals with national health research. A large portion of that chapter is in fact dedicated to health research ethics. Section 72

[3] In the case of NHREC registered RECs, there is a requirement that all meetings are to be held in a face-to-face environment.

mandates the establishment of the National Health Research Ethics Council (NHREC), and stipulates that all RECs dealing with health research must be registered by the NHREC. The gazetted regulation relating to research with human participants of 2013 (See footnote 1 above) and the document *Ethics in Health Sciences: Principles, Processes and Structures*[4] of 2015 expand on this and refer to *health and health-related research*. The latter document is intended to provide the minimum national benchmark of norms and standards for conducting responsible and ethical research involving humans or animals, as specified in paragraphs 1.4.1 and 1.5.1 of the document in footnote 4. In the latter case, the SANS 10386:2008 provides the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes.

Health research is defined as ***research that*** *contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care*

Health-related research is defined as any research conducted by disciplines other than health disciplines about topics or participants within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.

Each REC dealing with research that complies with this definition of health or health-related research must be registered with the NHREC. After registering with the NHREC, the REC must, in addition to the minimum rules for RECs as stipulated by the SCRE, also comply with the rules of the NHREC. All health and health-related research, despite risk level can only be reviewed by an NHREC-registered REC that has experience with the review of such applications.

It can be envisaged that other groupings can follow this example set by the Department of Health, i.e. that the research ethics within various contexts can in some form or way be governed by a statutory body. Hence, these rules must make provision for a variety of RECs that are registered with some statutory body, which prescribes procedures that must be adhered to.

In lieu of such statutory bodies, however, the NHREC does make the provision in the aforementioned document that RECs that review research involving humans, that is not health-related, can also find guidance in this document. This is highlighted in the following two verbatim extracts from *Ethics in Health Sciences: Principles, Processes and Structures*[5] document (derived from section 1.1.12 and 1.1.13 of the aforementioned guideline document):

"These guidelines express the view that the core ethical principles apply to all forms of research that involve humans or use of animals, insofar as the welfare and safety interests of both humans and

[4] See: Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015, published by the Department of Health, Republic of South Africa.
[5] See: Ethics in Health Research: Principles, Processes and Structures (Second Edition), 2015, published by the Department of Health, Republic of South Africa.

animals are paramount. Health and safety issues include those that may arise in the environment of research e.g. viruses, parasites, bacteria, as well as the air, water and land."

"This document is intended to be as inclusive as possible, so that all researchers who involve human participants or use animals in their research will find assistance in these guidelines. In other words, although this document derives its authority from the National Health Act, the National Health Research Ethics Council (NHREC) intends it to address research more broadly to achieve the specific goal of providing guidance for researchers so that all research involving human participants or animals may be conducted in accordance with the highest ethical norms and standards."

4.2 Exclusions

RECs that are registered with the NHREC have very clear guidelines related to the type of research that generally does not require ethical approval. These exclusions can also be applied in RECs that are not registered with the NHREC, however, there may also be context-specific exclusions which should be decided upon by the REC itself. The ethical approval exclusion guidelines are described under section 1.1.8 - 1.1.11 of the guideline document and are to be applied in consultation with the REC and with reference to "The National Health Act (NHAs 72 (6)(c))".

4.3 Referring an ethics application to a registered REC

Although most of the discussion in this section is related to health and health-related research involving humans, it must be emphasized that research involving human participants, that is not health-related must also have ethical approval from a REC. If the risk level for this type of research is greater than minimal or involves vulnerable groups of people, the ethics application should be referred to the appropriate NHREC-registered REC.