# Rules of the Research Ethics Committee

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<td>Accountable executive manager</td>
<td>Executive Director: Research and Innovation</td>
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<td>Policy owner</td>
<td>Director: Research</td>
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<td>Responsible division</td>
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Rules of the Research Ethics Committee (REC) of the North-West University

RULES

1 NAME
The name of the committee is the RESEARCH ETHICS COMMITTEE OF THE NORTH-WEST UNIVERSITY

2 STATUS
The Research Ethics Committee is a standing committee of the Senate of the North-West University. The Research Ethics Committee must report continuously to the member of the Institutional Management responsible for research, or as determined by the Senate.

3 COMPOSITION
The Research Ethics Committee consists of members who are nominated for a three-year term. All members and functionaries can be re-nominated for a three-year term. The composition of the Research Ethics Committee is such that a balance between male and female members is pursued (with the ideal that at least 40% of the members should be female). The Research Ethics Committee is composed in such a way that there is a main committee plus assessment panels, which are Research Ethics Subcommittees of the main committee. The assessment panels (Subcommittees) are also appointed for three-year terms and are composed in such a way that they consist of experts that are able to assess research projects in the various main areas of expertise (human sciences, animal experiments, medical-pharmacological, genetics, etc.). The involvement of members of the Main Committee and/or Subcommittees (those who are also North-West University staff members) with the activities of the Research Ethics Committee should also be reflected in their task agreements with their managerial heads. A quorum shall consist of 50% of the members plus one.

3.1 Main Committee
The Main Committee consists of at least the following members:
- The Chairperson appointed by Senate from the Research Ethics Committee.
- Vice-Rectors responsible for research from all three campuses (ex officio).
- The Director: Research Support from the Institutional Office (ex officio).
- The Head of the Animal Health Programme at Mafikeng Campus.
- The Head of the Laboratory Animal Centre at Potchefstroom Campus.
- A member of the Institutional Legal Office or an expert from one of the Law Faculties of the University.
- The representative(s) of the Research Ethics Subcommittee(s) from the Vaal Triangle Campus.
- The representative(s) of the Research Ethics Subcommittee(s) from the Mafikeng Campus.
- The Research Directors of the focus areas/research units at Potchefstroom Campus with own Research Ethics Subcommittees.
- One member from a registered Animal Welfare organisation.
A member nominated by the North-West Provincial Department of Agriculture, Conservation and Environment.

An independent medical practitioner.

An independent veterinarian.

A layperson from the North-West community.

- With no affiliation to the institution.
- Who is not currently involved in medical, scientific or legal work.

A member nominated by the North-West Provincial Department of Health.

The chairperson of the Executive Committee of the Committee for Occupational Health, Safety and Preparedness or his/her delegate from the Potchefstroom campus.

(1) A member of the Institutional Research Office acts as the Secretariat of the Research Ethics Committee.

(2) The Research Ethics Committee may co-opt additional members based on specific subject expertise needed.

(3)

3.2 **Subcommittees**

Each campus of the North-West University nominates Research Ethics Subcommittees where research is done for which ethical approval must be obtained. In particular, where focus areas/units require ethical approval for their research, such Subcommittees are to be formed. The Subcommittees must be approved by the campus Senate Committee of each campus as well as by the Main Committee.

Each Subcommittee consists of at least five members of which:

- one member should be an expert in the field of statistics/biostatistics.
- two or three members should be subject specialists in the particular field, and
- one member who should not be a staff member of the North-West University.
- one member should be the research director of the focus area in the case of focus areas/research units.

4 **FUNCTIONS OF THE COMMITTEE**

The Research Ethics Committee meets once a year, but can also be convened for special meetings, should the need arise.

Within the framework of the policy of the North-West University, the Research Ethics Committee formulates norms for the research ethical guidelines with which all research on humans, animals, human and animal material as well as genetic material from all living organisms should comply.

On the basis of these norms, the Research Ethics Committee develops the necessary documentation on which to apply for approval of protocols.

The Research Ethics Committee assesses the protocols through the campus Subcommittees and issues a letter of approval or makes recommendations for the improvement of the protocol.

No project may commence without such letter of approval, and if it does, the researchers and subjects/participants will not be covered by the North-West University's insurance.

The Research Ethics Committee oversees such research by requesting a written report from each current project at least once a year. Should a project leader fail to submit such a report, the Research Ethics Committee's approval for the project could be withdrawn.

The Research Ethics Committee has no disciplinary authority and non-observance of the approved procedures by a researcher is referred to the responsible member of the Institutional Management for further handling. Should a project leader fail to adhere to the stipulations of the protocol, the Research Ethics Committee's approval for the project could be withdrawn.
The Research Ethics Committee is responsible for the training of researchers and committee members regarding the ethical guidelines with which research should comply.

The Research Ethics Committee reports to the Senate and the Institutional Research and Innovation Committee on its activities once a year.

(1)

5 EXECUTIVE COMMITTEE

The Chairperson and at least one member from each campus act as the Executive Committee to deal with urgent matters if the full committee cannot be convened. The Executive Committee has the right to co-opt in terms of specialised knowledge needed. In case of uncertainty about protocols or other matters, the Chairperson may provide finality. All decisions of the Executive Committee as well as decisions made by the Chairperson must be submitted in writing to the Research Ethics Committee at the following meeting.

6 WORKING METHOD

(1) All protocols are submitted in writing to the Research Ethics Committee’s secretariat at least six weeks before the planned start of the project and are referred to the relevant Sub委员会 for assessment.

(2) Approved protocols receive a written letter of approval plus a Research Ethics Committee reference number. No project may commence before such a number has been issued. Where practical, verbal feedback on projects can also be given.

(3) Leaders of projects that are carried out jointly by researchers from different institutions and where the approval of another ethics committee is involved, must submit proof that such approval was obtained before the necessary certificate of approval will be issued.

(4) The Research Ethics Committee oversees research projects in that a report on the status and progress of each project must be submitted to the committee at least once a year, in May, in writing on the appropriate forms – in this context the term “oversee” means nothing more than the annual feedback; the Research Ethics Committee assumes no further responsibility for the research. Should a research leader fail to do this, the certificate of approval will be withdrawn, and in which case the project must be discontinued. The certificate of approval can be re-issued if a satisfactory report with reasons for the failure to report is provided.

The Executive Committee will monitor the work of the Subcommittees through regular meetings. The Executive Committee will ensure coordination between the various Subcommittees on the campuses and will deal with cases where a decision could not be made in relation to the approval of research protocols by a Subcommittee.

(1) Any changes to the original protocol must be brought up for consideration (in writing) to the Secretariat of the Research Ethics Committee for assessment by the Executive Committee and approval by the Research Ethics Committee. The work covered by the changed protocols may not start until a new certificate of approval has been issued.

(2) Any problems experienced during a research project must be reported to the Research Ethics Committee, who will bring it to the notice of the chairperson of the relevant Subcommittee and member of the Institutional Management.

(3) The process for submission of applications is attached as Appendix A.

7 DISPUTES, REFERENCES AND APPEALS

(1) The Subcommittee is in the first instance responsible for the consideration of all protocols. If a protocol is referred back by the Subcommittee due to a lack of information or wrong procedures, the applicant should amend the protocol and re-submit it to the sub-committee for consideration within the time frame agreed upon by the parties.

(2) If a Subcommittee cannot reach a final decision on the protocol and if the applicant is not able to amend the document, the protocol must be referred to the Research Ethics Committee. The Subcommittee must give written reasons for the failure to come to a final decision. These reasons
must be communicated to the applicant in writing. The applicant must be given a reasonable time to respond to the reasons in order for the Research Ethics Committee to consider the protocol together with the Subcommittee’s and applicant’s written responses. Where a Subcommittee cannot reach a final decision it is deemed that they rejected the protocol. The final decision rests with the Research Ethics Committee.

(3) If the Research Ethics Committee approves or rejects an application, the decision is final. The Research Ethics Committee can decide to refer a protocol back with certain recommendations to the applicant. Protocols that have been referred back must be re-submitted for consideration to the Subcommittee. The applicant should indicate that the recommendations had been considered.

(4) If the Research Ethics Committee rejects a protocol, written reasons for the decisions must be given to the applicant within ten days after the decision was reached.

(5) The applicant can give notice of intention to appeal within 10 days after receipt of the written reasons. This notice must be given in writing to the secretariat of the Senate and the Chairperson of the Research Ethics Committee.

(6) The Senate will constitute an ad hoc three person committee to hear the appeal on the date, place and manner determined by them. The rules of natural justice and stipulations of the Promotion of Administrative Justice Act (Act 3 of 2000) should always be taken into consideration.

8 BUDGET

No member of the Research Ethics Committee or its Subcommittees is remunerated for his/her services. Remuneration will only be payable for real costs incurred in the execution of duties, such as travel and subsistence costs. In order to cover these costs and to cover the administrative costs of the Research Ethics Committee’s activities, a budget is submitted annually via the Director of Research Support

Approved by Council on 16 March 2006.
Applications submitted to REC Secretariat

REC Secretariat captures Application in Database, assign number and distributes it to Chairperson of relevant panel

Subcommittee evaluates proposal

Subcommittee approves and informs REC Secretariat

Secretariat issues certificate and submits report to REC

Subcommittee proposes revision and informs REC Secretariat and applicant

Applicant resubmits reworked application to Subcommittee

Subcommittee rejects application and provides feedback to REC Secretariat and applicant

Secretariat submits report to REC EXCO

REC EXCO makes final decision on behalf of REC

Secretariat submits final report to REC