University of Venda

UNIVEN Research Ethics Committees (RECs)

Terms of Reference (TORs)

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1. Introduction and Purpose

Independent review by RECs is one approach to ensure research is meaningful, valid, respectful and safe. It is generally, a legal, policy based and to in some cases a professional requirement that a research project undergoes such review.

The University has three specialist Research Ethics Committees (RECs): Research Social Sciences Ethics Committee (RESSC); Animal, Biosafety and Environmental Research Ethics Committee (AEBREC) and the Human and Clinical Trails Research Ethics Committee (HCTREC). They function directly under the auspices of the University Oversight Research Committee (UREC) where their respective chairs have representation and are responsible for effecting ethics approval of research proposals. Other specialist committees may be created by the UREC when the need arises.

The main purpose of the RECs is to conduct rigorous ethics review of research proposals to ensure that the welfare and other interests of participants, researchers and animals used in research are properly protected and that the research will be conducted in accordance with the required ethical norms and standards.

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2. UNIVEN Research Ethics Committee (UREC)

2.1. Terms of Reference

University Research Ethics Committee (UREC) is established to promote Research Ethics and Integrity and will take an oversight role of the RECs at the University of Venda.

1) To implement the university research ethics policy and make recommendations for any amendments to the policy;
2) To protect the interests of potential research participants and consider relevant risks;
3) When strict compliance is not possible, the UREC will ensure that the spirit of the codes and declarations are reflected in the research.
4) The UREC has the authority to appoint a standing or ad hoc subcommittee (that will comply with the applicable norms, rules and regulations of the UREC) to investigate or finalise any matter.
5) To approve arrangements for the delivery of training and advice on research ethics.
6) Collate and channeling matters from the RECs to Senate
7) Handling of complaints towards the RECs

- The UREC will align itself with the following guidelines:
  - The SA National Health Act No. 61. 2003
  - The SA Department of Health (2004) Ethics in health research: Principles, structures and processes and South African good clinical practice guidelines (2006).
  - Declaration of Helsinki (2013)
  - The Belmont Report
  - Animals Protection Act No. 71 of 1962
  - South African National Environmental Management Act
  - SOUTH AFRICAN NATIONAL STANDARD (SANS) 10386:2008. The care and use of animals for scientific purposes. Edition 1
  - South African Veterinary Association (SAVA)
  - South African Council of Natural Scientific Professionals (SACNASP)

2.2. Composition of the University Research Ethics Committee

The University Research Ethics Committee (UREC) is a committee of the SENATE housed in the Directorate of Research and Innovation. Membership will constitute of the following:

- Vice Chancellor and Principal – Ex officio
- DVC Academic – Ex officio
- Director Research and Innovation – Ex officio
- Chairperson of UREC
- Deputy Chairperson of UREC
- Community Engagement Representative
- Community Representative
- Legal and human rights Representative
- Provincial Representative
- Biodiversity Representative
- Veterinarian
- Chairperson Human and Clinical Trials Committee
- Chairperson Social Sciences Committee
- Chairperson Animal Environment and biosafety Research Committee
- The secretariat of UREC lies within the Directorate of Research and Innovation

A quorum is defined as 6 members'

2.3. Research Ethics Committees

The University Oversight Research Ethics Committee (UREC) will operate as an oversight committee to the RECs and is a committee of SENATE; this will allow sufficient independence RECs.

Three independent Research Ethics Committees (RECs) namely, Research Ethics Social Sciences Committee; Human and Clinical Trails Research Ethics committee; Animal, Environmental and Biosafety Research Ethics Committee which are aligned with the Department of Health (NHREC) guidelines and are responsible for effecting ethics approval of research proposals.

2.3.1. Terms of Reference and Compositions of RECs

The Committees adopted the terms of references with the assurance that proposals submitted to the Research Ethics Committees (RECs) will have to be checked by the faculties/department before submission to the RECs.

The Research Ethics Committees (RECs) two fundamental purposes are;

(i) to review and make recommendations on the University's Research Ethics Policies and Procedures;
(ii) to make decisions on applications for ethical approval that have been submitted by staff and students across the University.

The University of Venda offers Research Ethics committee members an indemnity in respect of claims which may be made against them in connection with work carried out in the course of their duties.

- the suitability of the investigator(s) for the proposed study in terms of his/her availability,
- qualifications, experience, supporting personnel, and available facilities;
- the study rationale and the appropriateness of the inclusion/exclusion criteria in the South African context;
- the suitability of the study methodology in relation to the objectives of the study; i.e. the potential for reaching sound conclusions with the smallest possible exposure to risk of participants, and the justification of predictable risks and inconveniences weighed against the anticipated benefits for the participants and/or others;
- the suitability of the study population;
- whether participants constitute a vulnerable group, and if so whether the study is justified and whether sufficient measures to protect their interests are in place;
- that the number of participants to be recruited is appropriate in answering the research question;
- the risk-benefit analysis takes full cognisance of benefits and harms, also after the study itself, especially in relation to chronic life-threatening conditions;
- if a placebo is used, whether its use is adequately justified;
- that by their participation in a study the participants or other persons in the establishment or centre are not denied timely access to medical personnel, investigations, equipment or procedures;
- the means by which initial recruitment is to be conducted;
- the means and processes by which participants will be informed and informed consent be obtained;
- the adequacy and completeness of the written information to be given to the participants, their relatives, guardians and, if necessary, legal representatives;
- that the application allows the participants and/or their representatives adequate time to consider the patient information package before informed consent is sought;
- the content of any advertisements or public notices which will be used to recruit participants to a study;
- that the study protects participants' rights to privacy;
- the provision of compensation/treatment in the case of injury or death of a participant if attributable to a clinical study, and the insurance or indemnity to cover the liability of the investigator and sponsor;
- the involvement of payments and monetary transactions or financial matters and costs related to the research, researchers and research participants;
- whether results of the study are duly publicised and whether restrictions are required on the publication of results; (e.g., ensure there is a written commitment from investigators to publish the results of trials and there is no contractual clause which reserves the right of publication to the sponsor only);
- the scientific soundness of the study on which to base, among other things, the ethics approval (including for example the adequacy of the statistical methods proposed to evaluate the data generated);
- whether the study is advancing the body of knowledge on the subject and is worthy of execution considering risks, costs, and benefits

2.3.1.1. Research Ethics Social Sciences Committee (RESSC)

a) The RESSC ensures that all researches in the fields of Human and social sciences that utilize human subjects and/or informants is bound by specific ethical principles.
b) It has a monitoring function in respect of generally accepted scientific principles that underlie all research. The underlying rationale is to preserve and respect the rights, freedom and well-being of all people.
c) RESSC assumes that all researchers are ethically conscious and must take the responsibility for the protection of human subjects and/or informants/participants and control group.
d) The monitoring and control function is thus aimed at exercising impartial adjudication of the execution of research. This function is performed with due circumspection throughout so that the integrity of the University, is not jeopardized.
e) The Committee adopted the proposed terms of reference with the assurance that proposals submitted to the RECs will have to be checked by the schools/department before submission to the RESSC.
f) Furthermore, the first responsibility to ensure that the ethical considerations are met lies with the supervisors/promoters.

- Review proposals for research to be undertaken by staff and students or on the premises of the University or its affiliates, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines.
- Withhold ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
- Withdraw ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
- Monitor the conduct of approved research through the receipt of annual and completion reports.

Composition of RESSC

Chairperson
Deputy Chairperson
Secretariat
1 X Legal & Human rights
4 X Faculty of Humanities, Social Sciences and Education
4 X Faculty of Management, Commerce and Law
2 X Faculty of Health Sciences
1 X Provincial Health Department
1 X Statistician
1 X Emerging Researcher
1 X Layperson

2.3.1.2. Animal, Biosafety and Environmental Research Ethics Committee (AEBREC)

a) Review proposals for research to be undertaken by staff and students or on the premises of the University or its affiliates, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines.
b) Withhold ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
c) Withdraw ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
d) Monitor the conduct of approved research through the receipt of annual and completion reports.
e) The Animal Ethics Committee will consider all ethical and welfare aspects of proposed research involving animals, approving only those studies in which the use of animals is essential and fully justified, with special reference to these principles:
   - *replacing* animals wherever possible by research that does not use animals,
   - *reducing* the animals used to an extent that does not compromise experimental design or statistical significance of results, and
   - *Refining* techniques used in research so as to minimize the adverse impact on animal subjects.

In keeping with these principles, the committee:

(i) examines all applications for the use of animals, and approves, modifies or rejects them in accordance with the principles (a) to (c) above;
(ii) withdraws approval for any project which fails to comply with the three principles (a) to (c) above;
(iii) establishes measures, develops appropriate policies, makes any recommendations and takes those actions needed to ensure that the standards implied by the three principles (a) to (c) are maintained;
(iv) maintains a register of all approved applications;
(v) monitors the acquisition, transport, production, housing, care of and research on animals;
(vi) determines and approves all policies and operating procedures relating to the purchase, transport, housing, use and disposal of animals;
(vii) ensures procedures are in place so that any unexpectedly suffering animal is treated or humanely killed, and that the matter is reported to the UREC;
(viii) examines and comments on all plans and policies of the University (or any other institution or body for which the committee has responsibility) which may affect the housing, care and welfare of animals used for scientific purposes;
(ix) receives reports from projects approved through the committee;

Composition of AEBREC

Chairperson
Deputy Chairperson
Secretariat
1 X Legal & Human rights
4 X Faculty of Science, Engineering and Agriculture
1 X Veterinarian
1 X Statistician
1 X Emerging Researcher
1 X Layperson

2.3.1.3. Human and Clinical Trials Research Ethics Committee (HCTREC)

a) Receive and review proposals for human research projects to determine whether they meet all relevant ethical standards;
b) Ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific merit and statistical validity, before deciding whether the proposal is both acceptable on ethical grounds and conforms with standards.
c) To ensure that all research involving human participants and clinical trials conducted by students and staff undergo review and prior to research initiation.
d) Decide whether participants in all reviewed and approved human research projects will be accorded the protection and respect that is due to them;
e) Withhold ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
f) Monitor the conduct of approved research through the receipt of annual and completion reports.
g) Receive reports from researchers on any changes related to the approved research proposals.
h) Withdraw ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.

Composition of HCTREC

Chairperson
Deputy Chairperson
Secretariat
1 X Legal & Human rights
4 X Faculty of Health Sciences
4 X Faculty of Science, Engineering and Agriculture
4 X Faculty of Humanities, Social Sciences and Education
1 X Provincial Health Department
1 X Statistician
1 X Emerging Researcher

1 X Layperson

2.4. Chair and Deputy Chair Responsibilities and Entitlements

The Chairperson and Deputy Chair(s) has a strategic role to play in representing the vision and purpose of the committee in addition to the responsibilities and entitlements as members, the Chair and Deputy Chair(s) will have the following responsibilities:

- The Chair must not have other responsibilities that will impair the REC's capacity to fulfil the obligations and fulfil roles and carry out the functions set out in these Terms of Reference.
- The Chair is responsible for ensuring that RECs decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration from some of those members who cannot be present.
- Provide support and supervision to members
- Ensure the management committee functions properly
- Represent the committee
- Achieving such decisions requires that the Chair:
  - To actively engages all members;
  - to elicits their views; and
  - To communicates their responses to other members.

Qualities and Skills Required of Chair and Deputy Chair

- Good leadership skills.
- Good communication and interpersonal skills.
- Impartiality, fairness and the ability to respect confidences.
- Ability to ensure decisions are taken and followed-up.
- Good time-keeping.
- Tact and diplomacy.
- Understanding of the roles/responsibilities of a management committee.
- Experience of organisational and people management.
- Knowledge of the operating environment.

2.5. Rights and responsibilities of researchers

2.5.1. Researchers have the fundamental right to academic freedom and freedom of scientific research.

2.5.2. Integrity in research

- It is the responsibility of the researcher to ensure that he or she does not undertake research without ethical clearance. Researchers may only undertake research that has been approved by an appropriate Research Ethics Committee.

- Researchers should be competent and accountable. They should act in a responsible manner and strive to achieve the highest possible level of excellence, integrity and scientific quality in their research.

- Researchers have a right, as well as an obligation, to refrain from undertaking or continuing any research that contravenes the Policy on Research Ethics, violates the integrity and/or validity of research and/or compromises their autonomy in research. If they feel that the policy or ethical principles are being violated, or that the study is unethical, they must make all possible efforts either to correct or to terminate the research. These would include reporting to the relevant Research Ethics Committee. In the event of failure of remedial measures they must terminate the study or end their involvement in it.

- Researchers should only undertake research that will contribute to knowledge on the subject. They should use resources judiciously and to avoid the unnecessary duplication of research.

- Researchers have a right and a duty to make all necessary efforts to bring the research and its findings or results to the public domain in an appropriate manner and at an appropriate time. The publishing of research findings should be done in a manner that will not harm research participants or their communities.

- Researchers who undertake secret or classified research must comply with all UNIVEN policies, other relevant policies and legislative frameworks.

- Researchers have a responsibility towards those involved in or affected by their work. They should make reasonable efforts to anticipate and to guard against the possibility of their research having undesirable or harmful consequences. They should take reasonable corrective steps when they come across misuse or misrepresentation of their research. They must be prepared to take responsibility

and to be held accountable for all aspects and consequences of their research activities.

- Researchers should be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research, including generating and analysing data, publishing results, and acknowledging the direct and indirect contributions of colleagues, collaborators and others.

- Researchers may not commit plagiarism, piracy, falsification or the fabrication of results at any stage of the research. The research findings should be reported accurately and truthfully, and historical records and study material should be preserved and protected.
- Plagiarism, falsification, the fabrication of results, and scientific misconduct in general are regarded as serious offences. These will be investigated by the relevant Research Ethics Committee and relevant actions taken.

- Researchers may be required to report regularly to the relevant Research Ethics Committee. Any researcher who experiences unexpected adverse events or changes in the research design should inform this committee within 48 hours.

- Researchers should adhere to relevant requirements arising in respect of data curatorship and data management. Whereas the first-mentioned refers to the collection, validation and preservation of data for various purposes, the last-mentioned refers to a broad range of data applications such as data design, re-use, storage and security.

2.6. Rights and responsibilities of Faculties/departments

- Faculty/Departments shall classify the prospective research accordingly.
- Research classified as Category 1 is exempt from RECs review however ethical review must still take place but at the Faculty level. Faculties are charged with the responsibility of reviewing and approving research classified as category 1 and a record of approved research should be submitted to the relevant RECs on a quarterly basis. It is thus imperative that committee members at the Faculty level are trained in research ethics and the South African requirements in this regard e.g. requirements for informed consent.

2.7. Membership

- Membership of the RECs is through nomination and co-option. Each member is appointed for three years with the option of renewing his/her term. All members are required to supply the RECs Administrator with their abbreviated CV at the beginning of their term of office. All members should be in good standing, with a working knowledge of ethical codes and guidelines as per the Terms of Reference.
- All members and support staff are required to sign a confidentiality agreement prior to appointment to the RECs. A copy of this agreement will be given to the RECs member, with the original being kept in the REC administration file.
- Should a member not attend three consecutive meetings, without an apology acceptable to the committee, their membership may be terminated. In the instance where a committee member cannot attend, he/she must send their comments to the RECs Secretariat/Administrator.

2.8. Training

All new REC members will be issued with the SOPs and any other relevant documentation of the UREC for them to familiarise themselves with the policies and procedures. They will be introduced to the administrative staff and should they require contact details of other REC members it will be made available to them.

All REC members will be required to have continuous personal development (at least once a year) in research ethics. The institution may facilitate ethical conduct of scholarly research by providing research ethics training for researchers and members of the REC. Researchers are encouraged to have ethics training when conducting research.

2.9. Conflict of interest

Members of the UREC are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence. UREC members (and members of their immediate families) maybe involved in activities that could be perceived as conflicting with their UREC responsibility. The integrity of the UREC review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided.

A standing item will be included in the meeting agenda regarding conflict of interests (appendix). A declaration of interests is placed at the beginning of the agenda of all meetings.

This always enables UREC members to perform their duties as diligently and honestly as possible and maintain the highest standards of integrity and propriety within the domain of their mandate.

UREC members must disclose any relationship, interest or other circumstances, which could reasonably be perceived as creating a conflict of interest – including the following:

- *Personal relationship*: If the UREC member has a personal relationship with the principal investigator or key personnel of a research protocol under review by the UREC.
- *Relationship to the research study*: If the UREC member (his/her spouse or immediate family member) is the principal investigator or co-investigator of the research protocol under review by the UREC.
- *Business relationship or affiliation*: If the UREC member serves as a trustee, director, officer, owner or partner of an entity that could be affected by the outcome of the research protocol under review by the UREC.
- *Financial interest*: If the UREC member has a financial interest that could be affected by the outcome of the research protocol under review by the UREC. Included in the definition of financial interest are equity interests e.g. stock, stock options or other ownership interests, payment or expectation of payment derived from intellectual property rights (e.g. patent royalties); and payments received from an entity for consulting or other services.

UREC members are required to disclose only those interests that may be affected by the research, which is the subject of the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the UREC's review of the protocol or related matters.

UREC members should make disclosures to the Chairperson. The Chairperson and the committee shall determine whether a conflict exists. The final outcome of such determination shall be reflected in the minutes.

Should the situation arise where the Chairperson finds his/herself in a situation of potential conflict of interest, the committee will appoint the Deputy Chairperson or in the absence of the Deputy Chairperson another member as acting Chairperson. The acting Chairperson will conduct the meeting for the remainder of the discussion on the item in question.

UREC members who have a conflict of interest related to any research protocol that the UREC is about to consider should refrain from participating in any discussion of the protocol or related matters, except where it is necessary to provide relevant factual information requested by the Chairperson. Unless requested by the Chairperson to provide such information to the UREC, the UREC member with a conflict of interest will leave the meeting during the discussion and voting process.

The outcome of the committee decision in the absence of the recused member will NOT be discussed upon return of the member concerned but may be conveyed after closure of the meeting.

All UREC reviewers assigned to review a protocol or related matter must notify the Chairperson so that the protocol can be re-assigned, should a conflict of interest be identified.

2.10. Code of conduct for UNIVEN Research Ethics Committee members

NOTE: this Code of conduct applies to all Ethics committees at UNIVEN

All committee members at UNIVEN have a responsibility to serve the interests of the university and of the public generally.

All decisions are to be made solely on the basis of a desire to promote the best interests of the university and the public and, in the case of research ethics related matters, the interests of research participants and researchers must be protected. Upon appointment to a Research Ethics or Animal Ethics Committee, all committee members, including external members (e.g. lay persons) have responsibilities, including:

- To attend meetings on a regular basis and, as far as possible, to remain until the meeting is adjourned.
- To maintain confidentiality, where necessary according to department guidelines, regarding research proposal or protocol information, reviews and decisions and all matters discussed at committee meetings.
- To disclose conflicting interests, including any personal involvement or participation in the research or in competing research, and, in the event of such a conflict with respect to a proposal, not to review the proposal and to recuse him or herself during the discussion and decision-making process.
- To review independently, impartially and objectively whether the proposed design and conduct of research is likely to protect participants' safety, rights and welfare.
- To serve as a main reviewer in his or her area of expertise.
- To serve as a general reviewer of all research discussed at committee meetings.
- To keep up to date with research ethics and regulatory guidance.
- To contribute to ethics-related continuing education.

Consultants or ad hoc reviewers might from time to time be called upon to assist with research proposal reviews. The obligation to maintain confidentiality, where necessary according to department guidelines, should be made known to these reviewers. Observers or guests may attend committee meetings at the Chair's discretion or invitation. Such persons have an interest in research ethics and the review process but are not committee members.

Observers and guests must maintain confidentiality, where necessary according to guidelines, regarding the business of the committee.

All persons who attend UREC or RECs meetings are free to make observations, ask questions but only UREC or RECs members may vote on decisions. Anyone without a vote who disagrees with the resolution of the issues under discussion and/or the outcome of the vote should take the matter up with the Chair of the UREC or RECs in the first instance. The Chair may call a special meeting to discuss the substance of the disagreement or to debate more fully issues raised in this way. Note: Members should confirm that they will conform to guidelines on the confidentiality of application and proceedings. When non-members attend, they should confirm that they will maintain confidentiality.