University of Venda

POLICY ON RESEARCH ETHICS

VERSION NUMBER	DATE (DD.MM.YYYY)	AUTHOR	DESCRIPTION	REVIEWED AND APPROVED BY	APPROVAL DATE
01	04/09/2022	Prof VO Netshandama	Original Poicy	University Council	03 December 2021

University Registrar
(Secretary to Council)

Vice Chancellor and Principal

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LIST OF ABBREVIATIONS AND ACRONYMS

DHET.....Department of Higher Education and Training
DOH.....Department of Health
UNIVEN..... University of Venda

DVC..... Deputy Vice Chancellor

REC(S)..... Research Ethics Committees

UREC.....University Oversight Research Ethics Committee

AEBREC..... Animal, Environment and Biosafety Research Ethics Committee

HCTREC .....Human and Clinical Trails Research Ethics Committee

RESSC..... Research Ethics Social Sciences Committee

UNIVEN.....University of Venda

NHREC..... National Health Research Ethics Council

VC .....Vice Chancellor and Principal
SOP..... Standard Operating Procedures
TORs..... Terms of Reference

SECTION A: PREAMBLE

1. POSITION STATEMENT

The policy clarifies the ethical obligations for researchers

1.1 The core values of research are based on commitment to the principles and values enshrined in the Constitution of the Republic of South Africa of 1996.

1.2 The Research Ethics Policy protects the rights and dignity of human beings, animals, environment and culture.

1.3 The Research Ethics Policy seeks to establish principles and responsibilities for research involving humans, animals and risks to society and the broader physical environment.

1.4 The Research Ethics Policy augments awareness of ethical principles and issues involved in the conduct of all research activities.

2. POLICY SCOPE

This policy applies to all research activities under the auspices of the University of Venda, irrespective of whether they are employees, students or visiting scholars and researchers at the University, and irrespective of their funding sources in the respective fields in which they conduct research.

Any research undertaking by staff, students and external stakeholders must be subject to ethical review. The Policy should be interpreted in the context of the other relevant legislation, policies and regulations as stipulated in the legislative framework and statutes of the University of Venda. The University monitors research integrity through the independent Research Ethics Committees

(RECs) namely,

(a) Animal, Environment and Biosafety (AEBREC),
(b) Human and Clinical Trails (HCTREC),
(c) Human and Social Sciences Committee (RESSC) and

the University Research Ethics Committee (UREC) which provides oversight to the reviewing RECs.

SECTION B: POLICY STATEMENT

3. LEGISLATIVE FRAMEWORK

Constitution of the Republic of South Africa, of 1996

3.1 Animal Protection Act 71 of 1962

3.2 Hazardous Substances Act, No. 15 of 1973 (as amended)

3.3 Genetically Modified Organisms Act No 15 of 1997

3.4 National Nuclear Regulatory Act, No. 47 of 1999

3.5 Nuclear Energy Act, No. 46 of 1999

3.6 National Health Act No. 61 of 2003

3.7 National Environment Management: Waste Act, No.59 of 2008

3.8 Protection of Personal Information Act, No 4 of 2013

3.9 South African Medical Research Council (SAMRC) Act No. 58 of 1991

3.10 South Africa Bureau of Standards on the Handling and Disposal of Waste Material within Health Care Facilities (SABS 0248:1993)

3.11 Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (Book 3) South African MRC 2004

3.12 South African National Standard: The Care and Use of Experimental Animals Standards SA. SANS 10386:2008 (Under review)

3.13 Guide for the Care and Use of Laboratory Animals: Eighth Edition, Institute for Laboratory Animal Research, National Research Council of the National Academies, National Academies Press 2011 Guidelines on Ethics for Medical Research: Use of Biohazards and Radiation South African Medical Research Council 2002

3.14 Ethics in Health Research: Principles, Structures and Processes 2nd Ed. of 2015

3.15 Research and Innovation Policy (as reviewed and approved in 2021)

3.16 Postgraduate Training Policy Guidelines of University of Venda (2012) (as reviewed and approved in 2021)

3.17 UNIVEN Joint Degrees Policy

3.18 UNIVEN Policy on Mentorship

3.19 South African Policy Framework on Internationalisation of Higher Education in South Africa of 2019

3.20 IPR Act, Act No. 51, 2008

3.21 The Children's Act Number 38 of 2005

3.22 National Environmental Management: Biodiversity Act 10 of 2004

3.23 Ethics in health research: Principles, processes and structures, 2015

3.24 UNAIDS Guideline Document: Ethical Considerations in HIV Preventive Vaccine Research, May 2000

3.25 International Conference on Harmonisation (ICH) Guideline: Choice of Control Group and Related Issues in Clinical Trials 2000

3.26 Intellectual Property Rights from Publicly Financed Research and Development Act: Regulations

3.27 Animal Protection Amendment Bill of 2017

3.28 The UN convention on biological diversity 1993

3.29 UN Global declaration on human rights of indigenous people 2007

3.30 2002 Bonn Guidelines

3.31 Report 1979

3.32 Singapore statement on research integrity (Singapore Statement) 2013

3.33 Montreal statement on research integrity in cross-boundary research collaborations 2013

3.34 AU strategic guidelines for coordinated implementation of the Nagoya Protocol 2015

4. PURPOSE

The purpose of the research ethics policy is to outline the:

4.1 Ethical standards within which all research should be conducted.

4.2 Ethical standards at the University of Venda and provide guidelines for seeking ethical approval from the relevant Research Ethics Committees (RECs).

4.3 Financial management, management of conflict of interest, intellectual property and the investigation of scientific misconduct.

4.4 Roles and responsibilities of researchers, departments and faculties, RECs and UREC.

4.5 Acknowledgement of existing codes of ethics from regional, national and international professional bodies

4.6 Promotion of the integrity of UNIVEN research and output.

5. DEFINITION

5.1. **Animal experiments:** Any procedure which includes the use of live animals with the aim of testing a hypothesis, collecting information, promoting, transferring or demonstrating knowledge, testing or collecting a product, or registering the effect of a certain procedure on animal.

5.2. **Biodiversity**: the variety of life in the world or in a particular habitat or ecosystem.

5.3. **Biosafety:** Biosafety is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. These prevention mechanisms include conduction of regular reviews of the biosafety in laboratory settings, as well as strict guidelines to follow. Biosafety is used to protect humans, animals and the environment from harmful incidents.

5.4. **Clinical research** –research intended to test safety (not harmful or dangerous to human health), quality (ingredients are of good quality), effectiveness (working to diagnose, treat, prevent or cure a disease condition) and efficacy (better/ best when compared with other treatment or medicine for a similar condition) of new and/or existing or old medicines, medical devices and/or treatment options, using human participants (South African Clinical Trials Registration)
http://www.sanctr.gov.za/Resources/Whatisaclinicaltrial/tabid/175/Default.asp
The Ottawa Statement defines **'trial'** as a prospective controlled or uncontrolled research study evaluating the effects of one or more health-related interventions related to prevention, health promotion, screening, diagnosis, treatment, rehabilitation, or organization and financing of care.

5.5. **Collaborative research**: is research that involves the cooperation of researchers from different academic institutions, organisations and/or communities.

5.6. **Confidentiality** – the responsibility to protect information entrusted to researchers for research purposes from unauthorized access, use, disclosure, modification, loss or theft.

5.7. **Conflict of interest** – incompatibility of duties, responsibilities or interests (personal or professional) of a person or an institution as regards ethical conduct of research so that one cannot be fulfilled without compromising another.

5.8. **Consent** – indication of agreement to participate in research, based on adequate knowledge and understanding of relevant information, and freely given.

5.9. **Environment**: the surroundings or conditions in which a person, animal, or plant lives or operates.

5.10. **Ethics review** – review of research proposals or protocols by RECs prior to commencement of the research.

5.11. **Human participant**: is generally a living person about whom a researcher obtains data through intervention or interaction with the person or through the use of her/his identifiable information. However, this definition may be extended for the purpose of this policy to protect the rights of deceased persons.

5.12. **Intellectual property:** is a patentable invention or any copyrightable subject matter such as a trademark, a design, a traditional work as defined in the Intellectual Property Amendment Act of 2010 and a trade secret or knowledge of how to do something.

5.13. **Research:** includes a range of activities conducted in various disciplines and areas of specialties that may use different methodologies and explanatory frameworks to extend knowledge through disciplined inquiry or systematic investigation within any given community within which such research may resonate to become a collectively owned community engagement activity.

5.14. **Researcher:** an individual and / or entity that carries out research, academic and / or scientific, under the aegis of UNIVEN as an employee, student, visiting scholar, adjunct scholar / researcher and / or collaborator.

5.15. **Research Integrity:** is fundamental to all forms of scientific research and is anchored in the values of "truth" and "honesty". Trust by peers and the public in the truth of research is exemplified by the responsible conduct of researchers, trust in their competence and trust in their devotion to do research according to internationally acceptable ethical norms and values.

5.16. **Research misconduct**: means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrications refer to the making up of data or results and recording or reporting them. (b) Falsifications refer

to the manipulating of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

5.17. **Risk** – function of the magnitude of harm and the probability that it will occur.

5.18. **Vulnerability** – diminished ability to fully safeguard one's own interests in the context of a specific research project; may be caused by limited capacity or limited access to social goods like rights, opportunities and power.

5.19. **Vulnerable participants:** include children, especially those individuals under the age of eighteen (18), the elderly, pregnant women, people with cognitive or mental impairment, prisoners or people on parole, students, people living with HIV/AIDS, people in dependent relationships, persons with disabilities, socio-economically disadvantaged people, indigenous people and indigents.

6. POLICY FRAMEWORK

This policy framework embraces the Standard Operating Procedures (SOPs) and Terms of Reference (TORs) of the respective REC's Policy documents which need to be read in conjunction with the following internal policies:

1) UNIVEN Research and Innovation Policy
2) UNIVEN Anti-Plagiarism policy
3) UNIVEN Intellectual Property Policy
4) UNIVEN Conflict of Interest policy
5) UNIVEN Community Engagement Policy
6) Guidelines for Classification of Prospective Research with Respect to Research Ethics

6.1. Research involving the use of human participants

All proposals seeking the intimate involvement of humans must apply for ethics approval from HCTREC. Research involving human beings as participants is important for the advancement of knowledge in the sphere of human welfare and University research has made a substantial contribution to the welfare of society. The protection of the rights and dignity of all participants by a policy statement of ethical standard and procedures is seen as an important aspect of research procedures.

Research and associated class projects must be conducted with extreme care with regard to the rights and welfare of the individuals who volunteer as participants. The institution where human research is conducted has direct responsibility to the participants of that research and this is also applicable to the University of Venda.

The rights and welfare of all participants in University research activities are of primary importance to the University, and their rights must be protected by conscientious scrutiny of each University research project and class projects to identify all foreseeable risks. All participants should also be afforded the opportunity to protect themselves and should participate only by express consent, freely given after having received adequate information about the project to evaluate risks that may be encountered as well as the legal limitations to anonymity and confidentiality. Participants should be able to rely on the researcher to respect their privacy, to maintain anonymity and to keep all data collected pursuant to participation in the project with legal limitations confidential.

All research activities involving human participants must comply with the following principles, before, during and after the research:

a) **autonomy** (the autonomy, rights and dignity of research participants should be respected)
b) **beneficence** (A positive contribution towards the welfare of people by

researchers)

c) **Informed Consent** (The medical or surgical procedure, or for research, are that the participant or subject (i) must be competent to understand and decide, (ii) receives full disclosure, (iii) comprehends the disclosure, (iv) acts voluntarily, and (v) consents to the proposed action)
d) **non-maleficence** (no harm to the participant(s) in particular or to people in general)
e) **justice** (the benefits and risks of research should be fairly distributed among people)

6.2. Research on Human, Social Sciences and Community Engagement

Research involving human participants in the collection or sourcing of information and is non-invasive, requires ethical clearance from the RESSC or from the relevant faculty as approved by the Office of Research Ethics and should also comply with the principles of autonomy, beneficence, informed consent, non-maleficence, and justice.

6.3. Research Involving Animals, the Environment and Biosafety

University staff, intending to make any use whatsoever of animals in their work, whether in research or for teaching purposes, are required to apply to ABREC for approval. The term "Animals" in this policy refers to all animals having the power of sense, perception or sensation. The use of animals in scientific research can only be justified if the benefits to both humans and animals outweigh the potential harm to the animal subject. "Justification for causing psychological or physical distress, illness or pain to animals should not be based on any explicit or implicit assumption that non-human animals experience these conditions in qualitatively different ways to humans" (Medical Research Council

guidelines).

All animal research conducted under the auspices of this university should uphold the "Four R" principles for humane animal research, namely:

a) Replacement of so-called "sentient" animals wherever possible, with "non-sentient" research models or systems to eliminate the use of animals that can experience unpleasant sensations.
b) Reduction of the numbers of animals in experiments by design strategies that facilitate use of the smallest number that will allow valid information to be obtained from the study.
c) Refinement of animal sourcing, animal care practices and experimental procedures to eliminate physical and psychological distress within limitation imposed by the objectives of the research.
d) Responsibility: Individuals or institutions involved in any aspect of the care and use of animals for scientific purposes should be aware of and accept their responsibilities and act following local and international accepted standards.

Researchers have a mandate and responsibility to oversee and monitor the care and use of all laboratory and other animals kept for teaching and research purposes at, or under the auspices of the University of Venda.

All vertebrate animals are protected in South Africa by the Animal Protection Act 71 of 1962. UNIVEN stipulates that the use and care of animals for research must adhere to this Act. Accordingly, the Animal Protection Act 71 of 1962 (***As amended)*** will guide researchers, staff and students to:

6.3.1. Ensure that the use of animals is justified.

6.3.2. Ensure that optimal standards in terms of animal health, care and welfare are observed.

6.3.3. Only use animals when alternative techniques and research methods for a certain project do not exist.

6.3.4. Only use the number of animals absolutely required by the study.

6.3.5. Refine methods and procedures to minimise or avoid pain or distress in animals.

6.4. Research involving environment and biosafety

Care should be taken to ensure that all research is carried out with the necessary respect for the impact that it could have on the physical, biological and spatial environment. All researchers undertaking research with bio-hazardous material that could potentially cause harm to humans, animals or the environment or the researcher and supporting staff must be trained in appropriate biosafety and containment procedures.

Researchers are also responsible for registering the use of biological, radio-active, and chemical materials as required by the relevant acts and regulations. The evidence of registration should be filed at the Research and Innovation Office.

6.5 Research involving other ethical concerns

Certain research projects may not fall under any of the three categories mentioned above but may still be regarded as ethically sensitive such as research involving deceased persons, certain historical archives, and research that needs to be 'covert' in some respect in order to fulfil its objectives. It remains the responsibility of the researcher to conduct a self-critical ethical appraisal of their own research and to obtain ethical approval from an appropriate university research ethics committee when necessary.

Formal ethics review and approval is mandatory in all instances where obtaining prior informed consent from individuals or permission from organisations or institutions would be an obstacle to fulfilling the objectives of the research.

7. Submission of research for ethical review proposals

7.1 Project leaders or Principal Investigators must submit applications for ethical clearance on the prescribed forms

7.2 The faculty research ethics committees or any authorized committee at the faculty level will review certain categories of applications for ethical clearance as delegated by the respective REC based on the assessed inherent risk of the proposed activities.

7.3 The Secretariat of the Office of Research Ethics is responsible for directing research proposals to the appropriate REC for those applications which the faculties are not authorized to review.

7.4 The Secretariat of the Office of Research Ethics has the responsibility to advice on the appropriateness for the review of an application by more than one REC.

7.5 All research proposals must obtain ethical clearance from the appropriate REC, and all required permits prior to commencement of research activities.

7.6 The Project Leader or Principal Investigator is responsible for the ethical and responsible conduct of the research for which she or he is in charge.

7.7 The project Leader or Principal Investigator must ensure compliance with all the relevant National Acts and Regulations, as indicated in Section 4 of this policy, and any other regulation that may come into force.

7.8 Project Leaders or Principal Investigator must ensure the necessary registrations, permits, and authorizations are obtained from the relevant government departments or regulatory bodies for the research training activities carried out, and for the facilities used. This includes compliance on the use of organisms,

biologicals, chemicals, and radioactive agents.

7.9 The RECs will not provide retrospective approval.

8. Data Acquisition and Management

The acquisition and management of data particularly within an international collaborative research environment is often very complex. Data management as per Protection of Personal Information Act, 2013 (Act 4 of 2013). Please refer to the Research and Innovation policy.

9. Validity of the ethical approvals

Validity of the ethical approval will be determined by the nature of the project and duration as outlined on the proposal.

10. Continual review and recertification

All research approved by the RECs will be subject to substantive, meaningful and focused continuous review to determine if the risks and benefits of the study have changed. This is also to ensure that there are no unanticipated findings involving risks to participants and/or others, and that any new information regarding risks and benefits are provided to the participants. The review will occur every year, unless the level of risk requires more frequent review. The RECs may withdraw approval of a protocol previously approved.

11. Ethics training

All researchers should have relevant ethics training. All REC members will be required to have continuous personal development in research ethics. The institution should facilitate

ethical conduct of scholarly research by providing research ethics training for researchers and members of the REC.

12. Appeals

Researchers have the right to appeal decisions made by the committee or may have concerns regarding RECs process. The appeal must be submitted by the principal investigator to the Chairperson of the RECs through the RECs secretariat. There must be a clear motivation for the appeal which should be supported by a subject specialist/Executive Dean of Faculty other than the principal investigator. The RECs Chairperson or delegated member may then seek outside consultation about the research.

13. Financial aspects, conflict of interest and intellectual property

13.1 Financial Aspects

All research projects involve some financial cost and require sound financial management. University of Venda expects all researchers to uphold the highest standards of financial integrity and transparency when dealing with all financial, budget related and contractual aspects of research. Researchers are required to familiarise themselves and comply with applicable institutional and funder-specific policies.

13.2 Conflict of Interest

Conflict of interest arises when the individual's private or personal interests and professional obligations are divergent to such an extent that an independent observer may have doubt as to whether the individual's professional actions are influenced by personal considerations, financial or otherwise. Any conflict of interests should be avoided, and all researchers must make known any potential conflict of interests. Interference by clients or funders that could compromise the integrity of the research is unacceptable.

Possible conflict of interests:

13.2.1. Financial relationships of any kind by the researcher e.g., equity, stock
13.2.2. Proprietary interests e.g., patents, intellectual property
13.2.3. Sponsorship/donations e.g., conferences, equipment
13.2.4. Funding e.g., for additional staff or facilities, payments to departments
13.2.5. Co-authorship of articles
13.2.6. Positions on various boards e.g., Pharmaceutical Advisory board
13.2.7. Grants and retainers: Conflict of interests that are not disclosed may have a negative impact on the well-being of the research participants. Accordingly, the RECs must be duly informed in order to protect the participants. All principal investigators are required to sign a conflict-of-interest form.

13.3 Intellectual Property

Researchers must familiarise themselves with the University's Policy in respect of Exploitation of Intellectual Property and ensure that all research related activities that may give rise to issues surrounding intellectual property are in compliance with this policy.

14. Collaboration, Visiting students, Mentorship and Authorship

14.1 Collaboration

The University supports and encourages research collaboration. Researchers (including visiting students and scholars) have a responsibility to ensure that a clear understanding of respective roles and responsibilities is developed at the beginning of the research collaboration and jointly have a duty to adequately fulfil their respective research obligations. Researchers should formalize their research collaborations with a 'Memorandum of Understanding' at the initiation of the collaboration. Faculties and/or

departments should develop their own guidelines for effective research collaboration in consultation with the Technology Transfer Unit in the Research Office.

14.2 Visiting students

Research activities involving visiting students should have sufficient oversight to ensure compliance with the principles established in this policy, particularly with respect to the protection of human or animal research participants. In addition, visiting students conducting research in affiliation with University of Venda, but who are registered at another institution should obtain ethics approval for their research from their home institution and from University of Venda. They must also comply with any specific requirements for research oversight as determined by the UREC. Furthermore, if the research involves University of Venda staff or student's additional approval is required from the UREC. Faculties and Departments hosting visiting students thus have the responsibility to ensure that students complete all necessary approval processes, prior to the commencement of their research projects.

14.3 Mentorship

Mentors should ensure that the research relationship or project is begun with a clear understanding of mutual responsibilities, a commitment to maintain a supportive research environment, proper supervision and review and an understanding that the main purpose of the relationship is to prepare trainees to become successful researchers.

Emerging researchers that are being mentored, in turn, have a responsibility to complete assigned work conscientiously, respect the authority of others working in the research setting, follow research regulations and protocols and abide by agreements established for authorship and ownership.

Mentors or supervisors should apply the principles of authorship described below towards publications of their research, where a student has made a significant contribution.

14.4. Authorship

Researchers are expected to make a reasonable effort to publish the results of their research in an accredited academic media. The following principles apply to authorship:

14.4.1. Authorship credit should be based on substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; and final approval of the version to be published. Authors should meet all the above conditions.

14.4.2. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

14.4.3. The order of the names in a publication is decided according to the quality of the contribution, the extent of the responsibility and accountability for the results, and the custom of the discipline.

14.4.4. The attribution of authorship is not affected by whether researchers were paid for their contributions or by their employment status; an author who submits a manuscript for publication accepts the responsibility of having included as co-authors all persons who are entitled to co-authorship.

14.4.5. The correspondence author should send each co-author a draft copy of the manuscript and should make a reasonable attempt to obtain consent to co-authorship, including the order of names; other contributions should be

indicated in a footnote or an "Acknowledgements" section, in accordance with the standards of the discipline and the publisher.

15. Reporting

The various chairpersons of the Research Ethics Committees report on the activities of the particular Research Ethics Committee to Senate. The Chairperson of the University Research Ethics Committee reports to SENATE as per the TOR and complaints of research misconduct within the University. This should also include the subsequent steps taken to ameliorate the challenges faced. Faculties reports on approved research classified as category 1 and a record should be submitted to the relevant RECs on a quarterly basis.

16. Acknowledgment of consulted policy

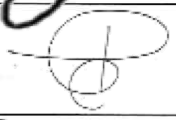
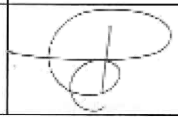
University of South Africa Policy on research ethics
University of Pretoria Policy and guidelines on Research Ethics and Integrity and Code of ethics for scholarly activities
University of Western Cape Research Policy
Stellenbosch University Research Ethics Policy

SECTION C: POLICY APPROVAL AND GOVERNANCE AUDIT TRAIL

17.REVIEW DATE

The University reviews this policy after three years or as and when the need arises.

18. AUDIT TRAIL

NAME	SIGNATURE	POSITION
Policy Owner		Director Research and Innovation
Policy Due Process Owner		University Registrar (Secretary to Council)
Chairperson		Research Ethics
Chairperson		Executive Committee
Chairperson		University Senate

Chairperson		University Council
Communication:		Director: Marketing, Branding and Communication
Published on Intranet	Date:	
Council Communication Issued	Date:	