UNIVERSITY OF ZULULAND

A NODE FOR AFRICAN THOUGHT

HUMAN RESEARCH ETHICS POLICY

POLICY NUMBER	**(PN 2404010)**	**POLICY OWNER**	Deputy Vice-Chancellor: Research and Innovation
INITIATOR OF THE POLICY		Director: Research & Innovation	
OVERSEEING COMMITTEE(S)		Research Ethics Committee → Senate → Council	
APPROVAL DATE	23 June 2022	**REVISION DATE**	22 November 2023
POLICY NAME	Policy and Procedures for Managing Human Research Ethics		

POLICY STATEMENT
This Policy provides principles, procedures and guidelines for the University community and researchers *to* follow to ensure compliance with ethical obligations when conducting research involving human at or under the auspices of the University to ensure that the interest of human participants are protected in line with relevant legislations, standards, guidelines, and the University's high ethical values.

REVISION HISTORY

CURRENT RECOMMENDATION AND APPROVAL CYCLE		SIGNATURE
Date Of Recommendation by Ethics Committee	29 November 2021	
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RELATED POLICIES	
POLICY NUMBER	**NAME OF POLICY**
TBC	UNIZULU Code of Conduct for Staff and Students
TBC	UNIZULU Code of Conduct for Research Ethics Committee (REC) Members
TBC	Research Policy
TBC	Innovation Policy

TABLE OF CONTENTS

SECTION A: POLICY

1. POLICY RATIONALE AND PURPOSE[1]

1.1 The National Health Research Ethics Council (NHREC) is a statutory body established under the National Health Act No 61 of 2003. The National Health Act No 61 of 2003 has specified that all health research involving human beings are obligated to be reviewed and approved by a NHREC accredited the *Human Research Ethics Committee* before the start of the research process or activities. The force of the legislation is binding and it implies that any individual or institution (as juristic person) which acts outside of the abovementioned prescript would do so illegally. The University of Zululand ("the University" or "UNIZULU") needs a human ethics policy to ensure that its research endeavours involving human participants are guided by the tenets of the laws of the Republic of South Africa, and are in harmony with international obligations research ethics.

1.2 The establishment and accreditation of the *Human Research Ethics Committee* at the University is dependent on the institutionalisation of a Human Research Ethics policy, approved by the University Senate. Without a policy to guide practice, the HNREC will not validate the operations of this Committee. The NHREC relies on institutional ethics policy to guide and inform the auditing of its registered Research Ethics Committees, and to measure the level of governance compliance at the institution. This Human Research Ethics policy is therefore an important instrument for the NHREC to passively and actively monitor the activities of its registered research ethics committee structures at universities. Without the policy, the NHREC would not be in a position to determine if the University commits any infraction or infringement of the Act.

1.3 The University is committed to scientifically rigorous, valid and reliable research. Reliable research involving human participants is conducted with integrity, and in a manner that protects the legal and moral rights of all human beings. The policy is an important instrument to action and advance this commitment to scientific rigor (in research, innovation, and testing activities). Through the policy, the University can promote a *culture of ethical conduct* amongst all its researchers and research students and stakeholders, and create and maintain a scientific environment in which the underlying values of *respect* for research participants as human beings, the *dignity* of participants, the person's *privacy* and *confidentiality*, as well as the core ethical principles of *beneficence*, *non-maleficence, autonomy* and *justice* plus responsibility, are safeguarded at all times.

1.4 The policy gives the University Council the assurance that the University operations are not only governed through clearly stated guidelines that comply with the laws of the country, but also that, through the policy, there is a binding instrument which enjoins the staff, students and all other participants in the University's human research and innovation endeavours to maintain the highest professional and ethical standards. The tenets of the policy assure the Council that it is a legal and institutional requirement for all persons associated with the University of Zululand to obtain appropriate ethical approval from the *Human Research Ethics Committee* (HREC) before commencing any research activity involving human participants. The force of such commitment can only be available through this policy.

1.5 The purpose of this policy is therefore, broadly, to provide clear principles to guide human research ethics governance and operations, offer a framework for setup up the institutional infrastructure to support adherence to ethical norms, standards, and regulatory provisions, and to offer a set processes and procedures to guide policy implementation.

[1] It should be noted that this policy is subject to the provisions of the **POPI Policy** of the University of Zululand

2. ETHICAL VALUES AND GUIDING PROTOCOLS

2.1 Human research ethics is not just about risks. It is also about good practice in the conduct and reporting of research and innovation. Good or best practice is a standard, or set of guidelines, that is known to produce good outcomes if followed. Good practice is related to how to perform a task, or configure something. In the case of human research ethics best practice, there are distinct values associated with the practice.

2.2 Research involving human or human related participants at UNIZULU are informed, and guided, by the core moral and social values of respect, justice, beneficence, non-maleficence, scientific merit and integrity, and social responsibility.

2.2.1 **Respect**. This value requires that persons capable of deliberation about their choices must be treated with respect and permitted to exercise self-determination (DoH, 2015). Where someone lacks the capacity to, or has diminished capacity for, discussion or negotiation regarding his/her preferences, must be protected against harm from irresponsible choices (DoH, 2015). Respect obligates UNIZULU and its researchers to recognise as top priority the dignity, well-being, safety and interest of participants in the research process. The interests of the participants should outweigh the interests of science and society. Out of respect, all categories of participants in research must be justified in the research proposal. Respect for persons also means that the interests of the researchers must be considered – e.g., welfare and safety interests; authorship interests; intellectual property interests; and collegial and professional interests (DoH, 2015).

2.2.2 **Beneficence**. This value refers to the ethical obligation to maximize benefit but to minimize harm (non-maleficence) (DoH, 2015). Beneficence requires three things: (a) reasonable risks of harm, compared to anticipated benefits, posed by the research; (b) sound research design; (c) competence of the researchers to execute the planned research activities.

2.2.3 **Non-maleficence**. This value mandates that researchers do no harm to the participants in the research (DoH, 2015). In other words, non-maleficence sets three conditions for researchers at UNIZULU; they (a) shall not deliberately inflict any harm onto participants in the research, (b) shall minimize such harm to participants, or (c) the harm shall be reasonable in light of anticipated benefits. UNIZULU research shall seek to improve the human conditions.

2.2.4 **Justice**. Justice is about fairness and equity. UNIZULU researchers shall endeavour to achieve a fair balance of risks and benefits amongst the groups involved in the research (DoH, 2015). The groups may include the participants, the communities when the research is conducted, or the wider society. Equality in the research context is achieved when these groups are considered, or when no segment is unduly burdened by the harms of research, or denied the benefits of knowledge – present or future – derived from it (DoH, 2015).

2.2.5 **Dignity and autonomy**. All researchers are to ensure that they honour the dignity of participants in research by showing them respect. Respect for research participants includes the moral obligations to respect their autonomy. Participants' involvement in research shall be voluntary and based on their consent.

2.2.6 **Scientific merit and integrity**. All researchers are to ensure that, regardless of discipline, they plan and execute research with integrity and ensure that the *science* supports the research *ethics*. Poorly designed research, or inappropriate

research methods, expose participants to undue risk of harm, or little or no compensating benefits.

2.2.7 **Responsibility**. All individuals involved in the research process are to be aware of, accept, and take accountability for their responsibilities to implement the ethical values mentioned above, and to ensure compliance with relevant standards as set out in this policy.

2.3 Alongside the ethical values, the Policy is also informed by international and national protocols and legislations on the conduct of research involving human. These include:

2.3.1 National Laws and Regulations

(a) The Constitution of the Republic of South Africa, 1996. (the Constitution).
(b) The Cape Town Statement on Fairness, Equity and Diversity in Research
(c) South African National Health Act No 61 of 2003. (the Act).
(d) Operational Health and Safety Act 85 of 1993.
(e) National Environmental Management: Biodiversity Act 10 of 2004
(f) White Paper on Science and Technology, 1996. (the White Paper).

2.3.2 National Standards and Guidelines

(a) South African Ethics in Heath Research Guidelines: Principles, Processes and Structures (2024).
(b) The Department of Health, Ethics in Health Research: Principles, Structures and Processes (2015)
(c) Guidelines on Ethics for Medical Research, SA Medical Research Council (1993).

2.3.3 International Codes, Reports and Protocols

(a) *San Code of Research Ethics*. (2016).
(b) The Singapore Statement on Research Integrity. (2009).
(c) African Charter on Transformative Research Collaborations
(d) The *National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)*: Guidelines for Research Ethics in the Social Sciences and the Humanities, 2021 (5th edition).
(e) *Council for International Organizations of Medical Sciences.* Clinical Research in Resource-limiting Settings. (2021).
(f) The *TRUST Code*: A Global Code of Conduct for Equitable Research Partnerships. (2018).
(g) The *World Medical Association's Declaration of Helsinki* – Ethical Principles for Medical Research Involving Human Subjects. (2013).
(h) The *Belmont Report of the US Office of Human Research Protections* 45 CFR 461 for principles on conducting human participant research and non-exempt research with human participants conducted or supported by the US (The Report).
(i) The *International Conference on Harmonization and Technical Requirements* for Registration of Pharmaceuticals for Human Use (ICH Tripartite).
(j) The *Nuremberg Code* (The Code). (1947).
(k) *InterAcademy Council, Responsible Conduct in the Global Research Enterprise*: A Policy Report. (2012).

3. PURPOSE OF THE POLICY

3.1 This policy provides a set of principles to guide human research ethics governance and operations, and outlines a framework to setup up an appropriate institutional infrastructure

– including the University's Human Research Ethics Committee – to support adherence to ethical norms, standards and regulatory provisions. It also provides a set of processes and procedures to guide policy implementation. These collectively constitute its purpose.

4. SCOPE OF THE POLICY

4.1 This Policy applies to:

4.1.1 All staff and students of the University, as well as its associated entities (i.e., academic or support structures that the University has/may establish to supplement, complement and enhance its mainstream academic endeavours, and which forms part of the University in some way and is ultimately accountable to the University's Council) and which includes research fellows and other academic associates (UNIZULU Associate Academic Policy).

4.1.2 Any person or organisation not affiliated to the University, who conducts research, whether on university premises or off-site, using the University's infrastructure and/or data from human participants, or who uses the University's staff or students as participants, or who conduct research in the name of, under the auspices of, or in collaboration with the University and/or its staff and students.

4.1.3 All research and research-related activities, whether in pursuit of an undergraduate or postgraduate degree or for other purposes; including but not limited to activities aimed at human research, or the gathering of research information, such as the conduct of surveys or interviews, the processing and analyses of research data, and the reporting of research findings.

4.1.4 Teaching-related or training-related activities such as class projects, assignments or tasks that involve the use of human participants.

4.1.5 Any other person who undertakes research involving human beings for scientific purposes at the University.

5. DEFINITIONS AND ABBREVIATIONS

5.1.1 **Health research**: Health research, as per the National Health Act 61 of 2003, may be understood to include, but is not limited to research that contributes to knowledge of biological, clinical, psychological, or social welfare matters including: (a) processes as regards humans; (b) the causes and effects of and responses to disease; (c) effects of the environment on humans; (d) methods to improve healthcare service delivery; (e) new pharmaceuticals, medicines, interventions and devices; and (f) new technologies to improve health and healthcare.

5.1.2 **Research Study**: Research activity of whatever nature, including research conducted by undergraduate and postgraduate students, but excluding class projects. All research projects carried out by postgraduate students and/or employees of UNIZULU or by outside agencies but using UNIZULU facilities fall within this category.

5.1.3 **Principal Investigator:** The principal investigator is the person leading a research study. This is a university appointed person responsible for conceptualizing, planning, executing, and writing up the report on the study, or a student conducting research under the guidance of an appointed supervisor. The principal investigator has the primary responsibility to ensure the safety and well-being of participants, the scientific integrity of the protocol and responsible implementation of the protocol. For international multi-centre research, at least one (co-) PI must be based in South Africa.

5.1.4 **Project owner -** Where research is undertaken by a student, the owner of the research project shall be the university. As the project owner, the University assumes responsibility for the careful management of the research-innovation that students follow. The university assumes liability for all the risks associated with the management of the research-innovation projects. By virtue of this, the university is the owner of the intellectual property that emanates from the research-innovation project. As such, the university owns the project.

5.1.5 **Supervisor**: A person, usually an employee, or any contracted University associate, who is supervising a student engaged in a research study either solely or jointly with another person.

5.1.6 **Mentor**: An experienced and trusted person (e.g., employee, any University associate; others) who serves as an advisor to a less experienced person – guiding, motivating, inspiring, building confidence, and contributing toward the personal, emotional, and psychological development of the individual – who may be an employee, a postdoctoral fellow, or a student (See UNIZULU Mentorship Guide). A mentor is normally, but not necessarily, a supervisor, principal investigator, project leader or co-author.

5.1.7 **Research ethics**: refers to the principles and practices that guide the ethical conduct of research. These should embody respect for the rights of others directly or indirectly affected by the research. Such rights include rights to privacy, right to dignity and confidentiality, protection from harm, giving informed consent, access to information pre- and post-research and due acknowledgement.

5.1.8 **Informed Consent**: A voluntary confirmation by a prospective research participant, signifying his/her willingness to participate in that study after having been informed of all aspects relevant to making an informed, rational decision to participate.

5.1.9 **Associated Entity**: An academic or support structure that the University has established or may establish to supplement, complement and enhance its mainstream academic endeavours, and which forms part of the University in some way and is ultimately accountable to the University's Council.

5.1.10 **Risk***:* For the purpose of this policy, a *risk* is the *potential of harm occurring to a participant as a result of participating in a research project*. There is always the possibility that the research will expose the participant to a certain level of risk.

5.1.11 **Harm:** is anything that has a negative effect on the participant's welfare. All research with humans must be preceded by an assessment of potential risk of harm, or inconvenience, and possible benefits for the potential participant. An expectation, when conducting a risk-benefit analysis, is a critical reflection on, and deliberation about, the risks and the benefits by both the researcher and the ethics committee.

5.1.12 **Benefit:** is any reward, direct or indirect, or outcome from research that positively affects the interest or welfare of the participant or community.

5.1.13 **Intellectual Ownership**: The University is the owner of the research study undertaken by a Principal Investigator or any other researcher . As the owner of the study, the University is responsible for carefully managing the research innovations of researchers. The University assumes liability for all the risks of managing the research and innovation studies and projects. By this, the University owns the intellectual property that emanates from all research and innovation studies carried out under the auspices of the University.

5.1.14 **Research proposal**: Is a scientific research blueprint, developed around a research problem, providing the theoretical background, rationale and research questions,

objectives or hypotheses to guide the investigation and describing the philosophical orientation, design, approaches and methods, and the ethical and safety conditions, among other things, under which it will be performed and managed.

5.1.15 **Researcher's conflict of interest**. Refers to where a researcher's personal interests or responsibilities have the potential to interfere with the execution of his or her institutional/professional obligations in the research. A conflicted researcher increases the risk level of the research. As such, the conflict should be disclosed in writing as soon as it arises

5.1.16 **Vulnerability**: Refers to the diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited capacity or limited access to social good like rights, opportunities and power; limited freedom to make choices; or one's inability to protect his/her own interest. *Adverse event:* Refers to any undesirable or unintended response by, or occurrence in a research participant during research (related or not related to the research).

5.1.17 **Personal information**: Personal Information means information relating to an identifiable, living, natural person, and, where it is applicable, an identifiable, existing juristic person (see POPIA)[2]. Identifiable information: Information reasonably expected to identify an individual alone or in combination with other information.

5.1.18 **REC Grievances, Appeal and Advisory Panel:** The structure responsible for good governance and administration of grievances and appeals arising from the registered Human Research Ethics Committee (HREC). The HREC is the committee registered with the NHREC to consider and approve the ethics of research involving human participants.

5.1.19 **Research Ethics Review:** An objective appraisal by a university approved Research Ethics Committee of the likely effect that a proposed-research may have on the wellbeing of potential human participants, communities, and /or institutions.

ABBREVIATIONS

HREC	Human Research Ethics Committee
NHREC	National Health Research Ethics Council
WHO	World Health Organisation
DVC	Deputy Vice-Chancellor
DD	Deputy Deans
NDA	Non-Disclosure Agreement
HDMS	Higher Degrees Management System
POPIA	Protection of Personal Information Act No 14 of 2013
SENATE	Academic highest statutory body
UNIZULU	University of Zululand

6. POLICY PRINCIPLES AND GOVERNANCE

6.1 The Institutional Official

[2] *As defined in the Protection of Personal Information Act. 4 of 2013, including, but not limited to: (a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person; (b) information relating to the education or the medical, financial, criminal or employment history of the person; (c) any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the person; (d) the biometric information of the person; (e) the personal opinions, views or preferences of the person; (f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence; (g) the views or opinions of another individual about the person; and (h) the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person.*

6.1.1 In compliance with the DoH Guidelines, and the SANS 10386:2021, the University has appointed an Institutional Official. The Institutional Official is the Deputy Vice-Chancellor (DVC): Research and Innovation.

6.1.2 The Institutional Official is the person who, as a representative of senior and executive management, bears ultimate responsibility for the institutional protection of participants in research involving human, their risk assessment program, and is responsible for resource mobilisation, planning and ensuring alignment of the risk assessment and management plan with the mandate of the University.

6.1.3 The needs of the program to protect participants in research involving human program shall be clearly and regularly communicated to the Institutional Official by the institutional Human Research Ethics Committee (HREC), and others associated with the program (e.g., research ethics manager, human researchers, health and safety administrators, and so forth).

6.1.4 There shall be clear lines of communication established to promote and foster this communication.

6.1.5 Serve as complainant in instances where ethics policy violation occurs.

6.1.6 To maintain independence from the institutional senior and executive management structures, the Institutional Official shall *not* ordinarily be a member of the UNIZULU HREC.

6.2 The Institutional Human Research Ethics Committee (HREC)

6.2.1 To comply with the minimum national standards set by the National Health Act, the DoH Guidelines under the NHREC, and related ethics codes, the University has established the institutional Human Research Ethics Committee (the “HREC”) as the official University body to oversee the entire institutional protection of participants in research involving human program.

6.2.2 The HREC is a Senate-level, university-wide committee, whose functions shall span all Faculties and Departments, and shall derive its authority from the University’s Senate.

6.2.3 As per the provisions of the National Health Act, the HREC shall maintain its registration with the NHREC, but where such registration is disrupted by virtue of non-compliance, the committee shall continue to exist and operate, under the University registration, as a body and arm of Senate, while it rectifies the non-compliance.

6.2.4 The HREC shall be sufficiently independent, i.e., be able to take decisions without undue institutional, political, or other interference, and able to make decisions without fear of intimidation or fear of prejudice. The HREC membership shall be composed to manage potential conflicts of interest.

6.2.5 The HREC’s composition, appointment, responsibilities, authority, reporting, and functioning are described in the committee’s Terms of Reference.

6.2.6 The University indemnifies HREC members from personal liability and shall ensure that adequate public liability insurance exists at institutional level. The institution shall take legal responsibility for the decisions and advice of the HREC, if members act in good faith.

6.2.7 The Chairperson of the HREC shall report directly to the University's Institutional Official.

6.3 Guidance for Research Practice

6.3.1 In compliance with the DoH Guidelines, and the SANS 10386:2021, the University has committed itself and its researchers to the principles stated below. It shall be a violation of this policy to practice otherwise:

(a) Conduct research with scholarly integrity and excellence.
(b) Conduct risk level assessment of the research prior to commencement, and report such risks as part of the research proposal for ethical approval.
(c) Align the science with the ethics by anchoring the research problem, methodology and reporting on the established ethical values specified in this policy and related ethical Codes.
(d) Disclose any conflict of interest its researchers may have.
(e) Publish research results that have scientific merit in a timely and competent manner – recognising intellectual property rights, but also the society's right to access research findings and related information.
(f) Bring the potential benefits resulting from research to the attention of participants and/or the relevant communities (Beneficence).
(g) Be transparent with, and evenly applied, compliance with standards and procedures.
(h) Monitor research planning and practice to ensure researchers engage in research which falls within ambit of their expertise and which complies with acceptable ethical standards.
(i) Ensure that the design of the research adheres to ethical guidelines, regardless of the level of experience of the researcher.
(j) Ensure that the safety of all those associated with the research is a top priority.
(k) Observe confidentiality. No confidential data gathered in the research process shall be divulged to a third party without appropriate consent. Notwithstanding, members authorised by the HREC shall scrutinize research data in the execution of their duties, provided that appropriate confidentiality is maintained.

6.3.2 As part of promoting science and good research governance, the University shall conduct compliance oversight but in a spirit of supporting research endeavours, and not to hinder research.

6.3.3 The University commit to recognise and respect the authority of all regulatory authorities, professional bodies, and codes of ethics.

6.3.4 Ethical reviews shall be required from all research projects involving data collected from research participants. The primary concern of research involving human participants shall be respect for the dignity and self-esteem, safety and well-being as well as basic human rights of the participants such that communities are not exploited. Participants shall be treated with respect; honesty; justice and fairness; and care to minimize harm (non-maleficence). Respect for person shall include all factors defined encompassed in the DoH (2024).

6.3.5 Written informed consent is a prerequisite for research involving human participants to begin.

6.3.6 The right of participants to both privacy and confidentiality shall always be protected.

6.3.7 All research shall declare whether the research project includes minors. And where minor(s) is involved, all the relevant ethical measures shall be fulfilled before the research commences.

6.3.8 Researchers shall conduct research and related activities in a manner that is **not** harmful to human health or wellbeing. To comply with Section 24 of the Bill of Rights of the Constitution of the Republic of South Africa, researchers shall seek to the protection the environment for the benefit of the present and future generations.

6.4 Ethical Review, Approval and Monitoring

Review

6.4.1 The NHREC gives authority to its registered Research Ethics Committees (RECs) to review and approve all research protocols involving human participants.

6.4.2 The sole Committee responsible for formal ethical review and valid ethical approval shall be the Senate-level HREC, registered with the NHREC. Work in all other committee structures at Faculty level (e.g., FREC) shall be for purposes of screening and supporting the proper documentation and presentation of the research proposal to the Senate-level HREC.

6.4.3 The institutional HREC shall perform all review responsibilities and shall have full oversight of the entire institutional program for the protection of participants in research involving human, including the review, approval and monitoring of all projects, research process, and activities that involve human subjects for scientific purposes, as stipulated herein.

6.4.4 The University requires prior review and written ethical approval from the HREC before **any** research project or activity that directly or indirectly involves human participants for scientific purposes, can be initiated. In other words, **no research project shall be exempted** from ethical approval. However, depending on the level of risks associated with a research project, the review and approval process may take any of the following forms:

(a) Full review
(b) Expedited review
(c) Rapid review

6.4.5 The HREC shall establish and maintain clear procedures for the execution of full, expedited and rapid reviews. The nature of the research that may be given expedited or rapid review shall be described in the procedures. In principle, expedited or rapid review shall apply only to research that poses no more than minimal or no risk of harm (See **Appendix 1**).

6.4.6 The cost-benefit analysis of the research shall be monitored in the HREC review process. The involvement of human participant in research for scientific purposes can only be justified if the benefits to society are considered to outweigh the potential harm to the participants. The appropriately constituted and functioning HREC shall be the institutional structure that undertakes a formal evaluation of the potential harm/benefit analysis before the research commences.

Approval

6.4.7 All research project given ethical approval shall carry such approval for a fixed duration, and it shall be linked to a specific Principal Investigator (PI). The ethical approval shall be null and void if the PI leaves the project before the project is completed, or before the duration of the approval period elapses. An application

for an amendment to the approved protocol shall be made when a new PI is appointed.

6.4.8 When planning timelines for research project that involves human participants, all researchers shall take account of the turnaround time to obtain prior ethics approval in order to accurately forecast the project duration.

6.4.9 Under this policy, retrospective ethical review and approval, or clearance, shall **not** be permitted.

Monitoring

6.4.10 To ensure that all relevant regulatory, ethical, and human protection safeguards are being met on an ongoing basis, the University requires the HREC to provide sufficient oversight and to monitor all scientific activities that involve humans.

6.4.11 Beyond the measures to monitor participant's beneficence, non-maleficence, dignity and autonomy, respect, justice, and the scientific merit in a research proposal submitted for ethical approval, *HREC members shall also judge a research project to be unethical* if:

(a) Sources are improperly cited.
(b) Cited sources are improperly referenced.
(c) The work is plagiarised above acceptable levels defined in the UNIZULU Plagiarism Policy and Guidelines.
(d) The grammatical errors in the research are overbearing and lead to conceptual and methodological uncertainly in the science.
(e) There is falsification of information or misuse of research funds.

6.5 Reciprocal recognition of review decisions and expert consultation

6.5.1 The UNIZULU HREC may, at its discretion, recognize prior review and approval of a research proposal by another NHREC registered REC to avoid duplication of effort. Reciprocal recognition means that two or more registered RECs decide to recognize each other's prior review. The HREC shall determine the nature of the documents that should accompany applications for reciprocal recognition, but at a bare minimum, it shall include a copy of the approval letter from the other REC.

6.5.2 Notwithstanding the provision to recognise prior reviews, the UNIZULU HREC reserves the right to revise its decision, and may choose instead not to recognise a prior review and approval by another NHREC registered REC if justifying circumstances arise. The rationale supporting non-recognition, or a reversal of such recognition, shall be documented.

6.5.3 Where it is necessary, the HREC may consult with experts outside of the committee, provided that: (a) a signed agreement of strict confidentiality is put in place; and (b) the experts are not conflicted in the research proposal or project that is under consideration.

6.6 Consents and other Permissions

6.6.1 All required permits and other relevant permissions, including informed consent of participants and consent to access an organisation or community (if relevant), must be obtained, prior to initiating any research activities involving humans.

6.6.2 Details of all required consents and other relevant permissions, must be provided by the Principal Investigator during the HREC application for thics approval process. **NB.** If research activities involving humans are undertaken in

collaboration with external (i.e., non-University, e.g., SAMRC) persons on the basis of their consent and permit or other permissions, the details of those consents, permits and other permissions must be provided during the HREC application process.

6.6.3 All consents and other permission requirements and stipulations must always be adhered to.

SECTION A: IMPLEMENTATION

7. RESPONSIBILITIES AND ACCOUNTABILITY

7.1 The University

7.1.1 The University has a right to a sound research and innovation reputation and to take steps to maintain and promote such reputation.

7.1.2 While the University has a right to promote, develop and support particular areas of research or research projects, it shall respect the principle of academic freedom, and the autonomy of researchers to conduct research of their choice within the field of their expertise, as long as this meets ethical norms and standards.

7.1.3 The University shall create and maintain an enabling environment in which researchers are able to conduct ethically sound research, and which includes but is not limited to:

(a) Providing the resources necessary for the effective implementation of this policy, and ensuring that this is monitored by the University Senate.
(b) Administrative support, education and training, and other infrastructural support for the HREC membership as may be required in accordance with the provisions of this policy and to enable the HREC to meet its Terms of Reference.
(c) Ensuring that all research laboratory, related facilities and other physical resources used or made available for research or innovation at the University are suitable for the conduct of effective and ethical research and innovation in a safe and healthy environment and meet applicable regulatory requirements.

7.2 The Institutional Official

7.2.1 The University's Institutional Official, in consultation with the governance structures of the University, is responsible for the implementation of this Human Ethics Policy, and ensuring compliance with relevant regulations, guidelines and standards.

7.2.2 The Institutional Official bears ultimate responsibility for the institutional program to protect participants in research involving human, and is responsible for resource planning, as well as program goals and institutional mission alignment.

7.2.3 The Institutional Official shall duly appoint the HREC membership, ensuring that the HREC has sufficient independence and authority to fulfil its mandate, and is sufficiently resourced to fulfil its Terms of Reference, and ensure compliance with this policy and its requirements.

7.3 The Institutional Human Research Ethics Committee

7.3.1 The UNIZULU HREC is responsible for the implementation of, and compliance with, this Huamn Ethics Policy, as per the detailed stipulations in the committee's Terms of Reference.

7.4 Researchers, Innovators and Students

7.4.1 Researchers are responsible for their academic freedom, which includes the freedom to conduct ethical scientific research of their choice.

7.4.2 Researchers must ensure that they undertake research work that falls within their fields of expertise and competence. The DoH Guidelines require researchers to be suitably qualified and technically competent to carry out the proposed research. Competence is demonstrated mainly by academic qualifications, credentials, scientific and technical competence, as evidenced in previous publications or testimonials.

7.4.3 All researchers and related practitioners are responsible for familiarising themselves with any relevant discipline-specific ethical principles and ensuring that their knowledge is up to date.

7.4.4 Researchers are required to ensure high standards of ethical and professional conduct and have an *obligation to ensure that their research activities and methodologies are scientifically and ethically sound* and not harmful to people, or the environment generally, and to the University's credibility and reputation, in particular.

7.4.5 The Principal Investigator and/or project supervisor, or in the case of innovation activities, the innovator developing the project, have primary responsibility for ensuring that this policy and procedures are adhered to.

7.4.6 The research project leader or Principal Investigator is obliged, where collaborative or team research is being conducted, to ensure that members of the research team are aware of the provision of this policy, the HREC conditions of approval, and any other applicable norms governing the conduct of research.

7.4.7 Researchers must comply with their reporting obligations to the Research Ethics Committee. Any researcher who experiences unexpected adverse event, or make changes, in the research design should inform the HREC.

7.4.8 Where the researcher is a student conducting the particular research for academic credits, the *supervisor shall be responsible for informing the student of her/his obligations in respect of the ethical conduct of research*, and for ensuring that the student's research project is conducted in accordance with the provision of this policy, and the HREC conditions of approval.

7.4.9 It is the responsibility of the relevant faculty /department to ensure that staff and students receive the necessary *training*.

7.4.10 In reporting findings, research shall adhere to the principles of honesty, clarity, comprehensiveness, accountability, and openness to public scrutiny.

7.4.11 Research Assistant and other participants in research activities that involve human must recognise and meet their responsibility for:

(a) Adherence to the applicable University policies, including this policy, and HREC standard operating procedures.
(b) Ongoing compliance with requirements of the UNIZULU HREC.

(c) The appropriate design, methodology, execution, and publication of any research.
(d) Planning so that the research findings have a high degree of validity.
(e) Appropriate management and declaration of potential conflicts of interest.

7.5 Research and Innovation division and Clients

7.5.1 Although secrecy may be necessary for a limited period in the case of contracted /commissioned research, or non-contractual research that is under consideration for patent protection, research results and methods shall however be open to scrutiny by colleagues within the University, as necessary, through appropriate committee and the Research and Innovation division.

7.5.2 Where data of a confidential nature is obtained in the course of research, confidentiality must be observed and Research and Innovation division shall monitor practices to ensure researchers refrain from using such data for their own personal advantage or that of a third party. The Research and Innovation division shall issue appropriate Research Data Management Guidelines. Researchers should adhere to relevant requirements arising in respect of data curatorship and data management.

7.5.3 The Research and Innovation division shall ensure that provision is made for research ethics training for all members of the HREC and the University research community. The division shall maintain records of training.

7.5.4 The Research and Innovation division shall promote whistleblowing to encourage members of the research community to report ethical transgressions to the Human Research Ethics Committee or the Research and Innovation division.

7.5.5 Nothing in this policy should be interpreted as relieving a researcher, or research assistant of any obligations imposed upon him or her as a result of membership of a professional association; and conversely, adherence to a professional code of ethics does not in itself override the obligations that this policy imposes on persons.

8. BREACHES AND VIOLATIONS

8.1 Breaches or violations of the University's policies (including this policy), codes (including the Code of Conduct for University personnel or HREC members, as applicable), or the conditions or requirements for ethical approval (as defined by this UNIZULU HREC), shall be dealt with in accordance with the relevant University procedures.

8.2 Student thesis or dissertation supervisor(s) shall bear responsibility for the ethical compliance of the research proposal before the work is submitted to HREC for approval.

8.3 Where a supervisor breaches this policy provision by failing to discharge this (clause 8.2) duty, he or she shall be guilty of an offense, and shall be dealt with in accordance with the relevant University procedures.

9. DISCLOSURE OF CONFLICT OF INTEREST

9.1 All researchers shall disclose any actual or potential conflict of interest and all researchers shall comply with the statutory and institutional requirements on disclosure of conflict of interest, as contained in the University Code of Conduct.

9.2 Where an actual, or potential, conflict of interest arises during the proposing or reporting of research in an HREC meeting, the HREC member shall disclose the details of the conflict, and shall recuse him/her-self from the meeting.

9.3 Members of the committee shall sign a non-disclosure agreement, which shall remain in effect even after their tenure ends.

10. POLICY REVIEW, MONITORING AND EVALUATION

10.1 The University's Institutional Official is responsible for conducting a comprehensive review of this policy every **five years** or sooner, if warranted. Nothing in this clause prevents the University Council from reviewing this policy at any time.

10.2 The review shall serve the purpose of updating the policy to stay current with applicable legislation, ethical standards and guidelines, and the University's strategic objectives.

APPENDIX 1
Rapid or expedited ethics review

1. Research that does not involve human participants, and carries no risk to the well-being of individuals, groups, communities, or the environment. All rapid or expedited research must address the relevant ethical measures or considerations

2. Examples of studies than can be rapid or expedited in review include but not limited to:

    - Duly authorized routine data gathering activities necessary for efficient administration and operations at the university, and standard educational practices and programme evaluation activities. **NB**. if the publication of such data in an article or studies is desirable, it is prudent to obtain ethics approval before the study begins.

    - Literature review and desktop research, which relies exclusively on publicly available information / data from national, continental, or international bodies; public documents such as legislations, policies, reports, listed company financial statements; mathematical formula or freely available computation programming or modelling, etc. This does not mean that *ethical considerations are irrelevant to the research*.

    - Non-sensitive data

    - Research involving non-deceptive observation of people in public spaces, and the natural environments. The condition of this is that:
        (a) the researcher does not interact directly with the people, individuals or groups;
        (b) the researcher does not stage any intervention;
        (c) the individuals or groups do not have a reasonable expectation of privacy; and
        (d) dissemination of research findings does not identify individuals or groups.

APPENDIX 2
PUBLICATION ETHICS

1. Peer assessment of research outcomes is important in validating research and researchers are expected to subject their research to peer review.
2. It is similarly important that research is communicated to peers and the public at large. While this should ideally occur after peer appraisal, where research is reported in the public media prior to peer review, such reporting should be based on the research data and findings.
3. All reasonable steps must be taken to ensure that published reports, statistics and public statements about research activities and performance are complete, accurate and unambiguous.
4. Publications should normally acknowledge sources of financial support for the research and sponsorship that carries an embargo on such naming of a sponsor should be avoided.
5. University employees and students must indicate their affiliation to the University and acknowledge that the work was carried out at the University.
6. Deliberate inclusion of inaccurate or misleading information relating to research activity in curriculum vitae, grant applications, job applications or public statements, or the failure to provide relevant information, is a misconduct. Accuracy is essential in describing the state of publication (in preparation, submitted, accepted), research funding (applied for, granted, funding period), and always conferred as well as where any of these relate to more than one researcher.
7. Research results should be reported irrespective of whether they support or contradict the expected outcome(s).
8. The following guidelines should be followed for giving authorship credit while reporting the research in any form:

    (a) Authorship, and its sequence in case of more than one author, should be based on discipline-specific and negotiated best practices. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere.

    (b) All other individuals not satisfying the criteria for authorship, such as communities or community members in the case of community engaged research, but whose contribution made the conduct and completion of research or publication possible should be properly acknowledged.

    (c) A student should be listed as principal or first author on any multiple-authored publication that substantially derives from the student's dissertation or thesis.

    (d) When data or information from other studies or publications is quoted or included, appropriate credit should be given.

9. Publication of multiple outputs based on the same set(s) or subset(s) of data by the same author should be written in a manner to avoid self-plagiarism. Self-plagiarism is unacceptable. There should full cross- referencing within the outputs.
10. It is unacceptable to submit a paper that was published in a peer-reviewed conference proceedings to another publisher without full disclosure of the prior publication.
11. Where a paper was delivered at one conference, then improved, before presented at another conference, it is good practice to acknowledge and indicate that the paper had been delivered elsewhere and has been revised.
12. The use of academic papers for financial “double dipping” and “CV padding” should be avoided.

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