UNIVERSITY OF ZULULAND

POLICY AND PROCEDURES

ON

RESEARCH ETHICS

POLICY NUMBER	**RI P4**	**POLICY OWNER**	Deputy Vice-Chancellor: Research and Innovation
OVERSEEING COMMITTEE(S)		Research Ethics Committee → Senate → Council	
APPROVAL DATE	23 June 2022	**REVISION DATE**	22 June 2025

POLICY STATEMENT

This Policy provides guidelines and direction to the University regarding the rules and procedures to be followed in ensuring compliance with researchers' ethical obligations when conducting research at or under the auspices of the University.

REVISION HISTORY

CURRENT RECOMMENDATION AND APPROVAL CYCLE	
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POLICY NUMBER	**COUNCIL APPROVAL DATE**
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RELATED POLICY	
POLICY NUMBER	**NAME OF POLICY**
RI P5	Policy and Procedures on Managing and Preventing Acts of Plagiarism

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SECTION A: POLICY

1 PREAMBLE

The University of Zululand ("the University") is committed to research that is scientifically rigorous, valid and reliable. In addition, it should be conducted with integrity and in a manner that protects the rights of all participants. The University aims to promote a culture of ethical conduct amongst all its stakeholders and, in particular, it wishes to create and maintain a research environment in which the underlying values of human dignity, equality, non-discrimination, social justice and fairness are respected. Staff, students and all other participants in the University's research endeavours are enjoined to conduct research that is socially and ethically relevant, to pursue truth, intellectual honesty and openness to ideas and to maintain the highest professional and ethical standards.

2 PURPOSE AND OBJECTIVES

The purpose and objectives of this policy are:

2.1 To set out principles that inform the University's quest to conduct research with integrity and respect for others.

2.2 To establish an institutional infrastructure that would assist in ensuring that ethical norms and standards, as well as regulatory provisions, are adhered to.

2.3 To set out processes and procedures to be followed in implementing the provisions of this policy.

3 SCOPE

This Policy applies to:

3.1 All staff and students of the University and its associated entities, as well as any person or organization not affiliated to the University, who conduct research, whether on university premises or off-site, using the University's infrastructure and/or, data, or the University's staff, 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.

All research and research-related activities, whether in pursuit of an undergraduate or postgraduate degree or for other purposes; and it is not restricted to activities aimed at human and animal 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.

3.2 Teaching-related activities such as class projects, assignments or tasks that involve the use of human or animal subjects.

4 ABBREVIATIONS

#	**Abbreviations**	**Definitions**
1.	UZREC	University of Zululand Research Ethics Committee
2.	FREC	Faculty Research Ethics Committee
3.	NHREC	National Health Research Ethics Council
4.	WHO	World Health Organisation
5.	DVC	Deputy Vice-Chancellor
6.	DD	Deputy Deans
7.	NDA	Non-Disclosure Agreement
8.	HDMS	Higher Degrees Management System
9.	POPIA	Protection of Personal Information Act
10.	SENATE	Academic highest statutory body

5. DEFINITIONS

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.

Class Project

A classroom demonstration or practical laboratory exercise, or a research project assigned by an instructor as part of a teaching-and-learning plan of a module. Research by thesis or dissertation does not fall within this category.

UNIZULU Geographical Area

The area of jurisdiction which is under uMhlathuze Local Authority, as set out in the University's Statute (The Institutional Statute of the University of Zululand, GN 843, GG No 35784 of 12 October 2012).

Informed Consent

A voluntarily confirmation by a participant in a research project signifying his or her

willingness to participate in that project, after having been informed of all aspects of the project that are relevant to making an informed, rational decision to participate.

Mentor

An academic staff member or any University associate who guides another person, usually a staff member, a postdoctoral fellow or a student, in the conduct of that person's research activities. A mentor is normally not a supervisor, principal investigator, project leader or co-author.

Principal Investigator

The principal investigator who is the lead researcher in respect of a research project, thesis or dissertation and who has sole or joint responsibility for the design, conduct, analysis and reporting of the trial or research act. (Find a general definition)

Project Leader

The person responsible for the administration of a research project and the delegation of responsibilities. The project leader may, but need not be a principal investigator or a supervisor.

Proposal

A document that provides the background, rationale and objectives of a research project and describes its design, methodology, organization and the conditions under which it is to be performed and managed.

Research Assistant

Students or other persons authorised by the University, a principal investigator or a project leader to participate in a research project.

Research Project

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 staff of UNIZULU, or by outside agencies but using UNIZULU-facilities, fall within this category.

Supervisor

A person, usually an academic staff member, who is supervising a student engaged in a research project, either solely or jointly with another person.

Research Ethics

Research ethics refers to the principles and practices that guide the ethical conduct of research. These should embody respect for the rights of others who are directly or indirectly affected by the research. Such rights include rights of privacy and confidentiality, protection from harm, giving informed consent, access to information pre- and post-research and due acknowledgement. Ethical conduct in research also includes the avoidance of inflicting animal suffering of any kind and protection of the environment.

Four Rs' Principles

The principle of Replacement, Reduction, Refinement and responsibility which the South African National Standard requires Animal Research Ethics Committees (ARECs) to use when verifying that animal use in a research project is justified.

Replacement of animals with non-sentient research models or systems, i.e., researchers should strive to avoid the use of animals if alternative methods can yield the data they need.

Reduction of the numbers of animals in experiments by design strategies that facilitate the use of the smallest number that will allow valid information to be obtained from the study and that will not be implemented at the expense of greater suffering of individual animals.

Refinement of animal sourcing, animal care practices and experimental procedures are to be adopted to minimise or remove physical and psychological distress and when this is not avoidable to counter those effects by the use of ataractics (tranquillisers), neuroleptics (dissociative agents), anaesthetics, analgesics and other effective strategies.

Responsibility, everyone using animals, whether for experimentation, testing diagnosis, teaching or sourcing of tissues or body fluids is responsible in their personal capacity for assuring that the animals

which they use are afforded the highest levels of welfare and protection from abuse, and violations of the interests accorded to them.

6. GUIDING PROTOCOLS

The following international and national protocols and legislation govern and inform the conduct of research and research-related activity at the University:

6.1 International Protocols

6.1.1 The World Medical Association's Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (2002).

6.1.2 The Belmont Report, the US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US (The Report).

6.1.3 The US Office of Human Research Protections 45 CFR 461 (for non- exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56

6.1.4 The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite).

6.1.5 The Nuremberg Code (The Code).

6.1.6 The International Ethical Guidelines for Biomedical Research Involving Human Subjects, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2002). (The Guidelines).

6.1.7 Inter Academy Council Responsible Conduct in the Global Research Enterprise: A Policy Report (2012). (The Report)

6.1.8 NESH, Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology, Oslo (1993) 2016

6.2 National Protocols

6.2.1 The Constitution of the Republic of South Africa, 1996. (The Constitution)

6.2.2 SA National Health Act No 61 of 2003. (The Act)

6.2.3 Animals Protection Act No 71 of 1962. (The Act)

6.2.4 National Environmental Management Laws Act-14-of-2013 30 Veterinary & Para-Veterinary Prof No 19

6.2.5 Animal Protection No 71 (1962)

6.2.6 Societies for Prevention of Cruelty to Animals No 169 (1993))

6.2.7 Operational Health and Safety Act 85 of 1993

6.2.8 NEMBA 2004 Amendment Act10

6.2.9 The Department of Health Ethics in Health Research: Principles, Structures and Processes (2004). (The Guidelines).

6.2.10 The principles for animal research are governed by the South African National Standard (SANS 10386:200X, ISBN 978-0-626-22296-3 (2002)).

6.2.11 A Good Practice Guide for Quality Management of Research (HEQC), 2005. (The Guide

6.2.12 White Paper on Science and Technology, 1996. (The White Paper).

7. GUIDING PRINCIPLES FOR RESEARCH GENERALLY

7.1 Introduction

The National Health Research Ethics Council (NHREC) is a statutory body established under the National Health Act No 61 of 2003. The Act mandates the Minister of Health to establish the Council and it sets out NHREC's functions, which in short involves giving direction on ethical issues relating to health and to develop guidelines for the conduct of research involving humans and animals. The Council observes and advises on international developments in health ethics issues through liaison with relevant international organizations. The National Health Research Ethics Council (NHREC) is tasked to oversee all University Research Ethics Committees and other organization conducting research. All Ethics Committees are registered and audited by council in order to be able to review applications and give approval. The NHREC uses the 2015 Guidelines for auditing.

The following ethical principles govern the conduct of research and research-related activity at the University and will inform any compliance decisions and processes:

7.2 General Principles

7.2.1 Research shall be conducted with scholarly integrity and excellence.

7.2.2 Researchers shall disclose any conflict of interest.

7.2.3 Research results that have scientific merit shall be published, in a timely and competent manner, thereby recognising society's right to have access to research findings and information.

7.2.4 Potential benefits resulting from research shall be brought to the attention of participants and/or relevant communities.

7.2.5 Compliance standards and procedures shall be transparent and evenly applied.

7.2.6 Researchers should engage in research which falls within the Ambit of their expertise and which complies with acceptable ethical standards

7.2.7 Principal investigators must ensure that the design of their projects adheres to ethical guidelines.

7.2. 8 Principal investigators must ensure the safety of all those associated with the research.

7.2.9 Confidentiality must be observed and no confidential data gathered in the research process may be divulged to a third party without appropriate consent. However, parties authorized by the UZREC may scrutinize research data in the execution of their duties, provided that appropriate confidentiality is maintained.

7.2.10 Compliance oversight should be conducted in a spirit of promoting research endeavours, and not to hinder research.

7.2.11 The authority of regulatory authorities, professional bodies and codes shall be recognised and respected.

7.3 Research on Humans

7.3.1 The National Health Act (NHAs 72(6)(c)) gives authority to the NHREC for setting norms and standards for health and health-related research that involves humans. The NHREC gives authority to registered Research Ethics Committees (RECs) to review and approve all research protocols involving human participants

7.3.2 Ethical reviews shall be required from all research projects involving data collected from research participants.

7.3. 3 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.

7. 3.4 Consideration will also be given to culture, language, beliefs, perceptions, customs, age and gender.

7.3.5 Written informed consent from participants is a prerequisite for research to begin.

7.3.6 Declaration whether the research is on minors.

7.3.7 A participant's right to both privacy and confidentiality shall be protected.

7.3.8 Researchers are encouraged to give feedback on research findings to communities where data was sourced. This must be presented in a language that is

understandable to the community. Power relations with researchers working on vulnerable group must be outlined and clarified.

7.3.9 Research that relies exclusively on publicly available information or accessible through, legislation or regulation usually need not undergo formal ethics review. This does not mean that ethical considerations are irrelevant to the research.

7.3.10 Research involving observation of people in public spaces and natural environments usually need not undergo formal ethics review, provided that:

7.3.10.1 The researcher does not interact directly with individuals or groups

7.3.10.2 The researcher does not stage any intervention

7.3.10.3 The individuals or groups do not have a reasonable expectation of privacy

7.3.10.4 Dissemination of research findings does not identify individuals or groups

7.4 Research on Animals

7.4.1 The South African Bureau of Standards' South African National Standard (SANS 10386:2008 or latest version) for the Care and Use of Animals for Scientific Purposes and MRC Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (2004) provide the minimum benchmark to ensure ethical and humane care of animals used for scientific purposes as well as for teaching activities, in line with the fundamental principles of Replace, Reduce, Refine and Responsibility on animal use. ARECs and researchers are expected to familiarise themselves with the content of both documents in addition to these Guidelines, as appropriate. Trainings on RECs and researchers must be tailored to the SANS guidelines and policies aligned.

7.4.2 Researchers shall respect animals and be sensitive to the fact that they experience pain and stress, and that experimentation could have long lasting negative effects.

7.4.3 Animal experimentation shall be reduced and refined or ideally replaced with alternative testing methods.

7.4.4 All aspects of the international and national Animals Protection Acts shall be adhered to.

7.5 Research on the Environment

7.5.1 Researchers shall conduct their research and related activities in a manner that is not harmful to human health or wellbeing according to section 24 of the Bill of Rights of the Constitution of South Africa which requires that research should not produce an environment that is harmful to human health or well- being. Instead, researchers must seek the protection of the environment for the benefit of present and future generations.

7.5.2 Pollution and ecological degradation must be avoided.

7.5.3 The environment must be protected by promoting conservation.

7.6 Research that does not require Ethics Review from UZREC

Desktop research can be reviewed by Faculty level by the Faculty Research Ethics Committee. If the research proposal owner is not at a Faculty, the proposal should be submitted to the research office.

Research that does not require ethical clearance, if your study involves:

7.6.1 Laboratory experiments where there is no use of animal or human biological materials, e.g., radio astronomy, cosmology, nuclear or solid-state research, research involving the synthesis of chemicals, microorganism isolation and culturing, molecular and morphological identification, enzymatic properties.

7.6.2 Geological and plant surveys.

7.6.3 Screening of test compounds against enzymes and biological targets/markers where the enzymes and target molecules are obtained from commercial sources.

7.6.4 The selection of sites and the establishment of a working relationship with interest groups (e.g., government departments and NGOs) prior to commencing with a specific project.

7.6.5 Data for a study is extracted from the public domain, e.g., data from national or international bodies such as the World Health Organisation.

7.6.6 Literature reviews.

7.6.7 Mathematical, theoretical research or computation programming or modelling where data is obtained from the public domain e.g., NCBI.

7.6.8 Mapwork using GIS and satellite imagery (provided no sensitive data is included)

7.6.9 Animal and insect cell lines obtained from commercial sources.

8 RIGHTS AND RESPONSIBILITIES OF THE UNIVERSITY

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

8.2 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 and within the field of their expertise.

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

8.3.1 Providing the resources necessary for the effective implementation of this policy. SENATE for oversight.

8.3.2 Administrative and other infrastructural support for such research ethics committees as may be required or established in accordance with the provisions of this policy.

8.3.3 Ensuring that all laboratory facilities and other physical resources used or made available for research at the University are suitable for the conduct of effective and ethical research in a safe and healthy environment and meet applicable regulatory requirements.

9 RIGHTS AND RESPONSIBILITIES OF RESEARCHERS

9.1 Researchers have the right to academic freedom, which includes the freedom to conduct scientific research of their choice.

9.2 Researchers must ensure that they undertake research work that falls within their fields of expertise and/or competence.

9.3 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.

9.4 Researchers are required to show commitment to 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,

animals and the environment generally, and to the Institution's credibility and reputation, in particular.

9.5 Primary responsibility for ensuring that these policies and procedures are adhered to rests with the principal researcher and/or project supervisor, or in the case of teaching-related activities, the lecturer setting the class project, assignment or task. In particular:

9.5.1 Where collaborative or team research is being conducted, the research project leader or principal investigator is obliged to ensure that members of the research team are aware of the provision of this policy and of any other applicable norms governing the conduct of research.

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

9.6 Notwithstanding the obligations that any other person might have, every person participating in a research or research-related activity must adhere to the provisions of this policy. Without derogating from the generality of this clause, researchers must refrain from:

9.6.1 Pursuing activities that are unsafe and/or do not comply with safety regulations and standards.

9.6.2 Falsifying, manipulating and fabricating data and/or other material.

9.6.3 Plagiarism.

9.6.4 Misuse of research funds.

Pursuing any other activities that might undermine the University's research integrity.

9.7 Notwithstanding the obligations that any other person might have, every person participating in a teaching and learning activity that involves human and/or animal subjects must adhere to the provisions of this policy. In appropriate instances, ethical clearance may be granted in respect of a class activity as a whole. It is incumbent upon lecturers to make student investigators aware of the policy, procedures and ethical guidelines applicable to the use of human and/or animal subjects in academic affairs, to ascertain that they are able to maintain the necessary standards, and to monitor compliance.

9.8 Where data of a confidential nature are obtained in the course of research, confidentiality must be observed and researchers must refrain from using such data for their own personal advantage or that of a third party. Although secrecy may be necessary for a limited period in the case of contract research or non- contractual research that is under consideration for patent protection, research results and methods should however be open to scrutiny by colleagues within the Institution and, through appropriate publication, by the profession at large.

9.9 Members of the research community must report ethical transgressions to the UZREC.

9.10 Nothing in this policy should be interpreted as relieving a researcher, lecturer 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.

10. PROTECTION OF RIGHTS AND DIGNITY IN HUMAN, MEDICAL OR CLINICAL RESEARCH AND HUMAN EXPERIMENTATION

10.1 Introduction

10.1.1 Research involving humans as subjects is important for the advancement of knowledge in the sphere of human welfare.

10.1.2 The general conduct of biomedical studies is guided by statements of internationally-recognized principles of human rights, including the Nuremberg Code and the World Medical Association's Declaration of Helsinki as revised (Helsinki IV). These principles also underlie the International Guidelines for Biomedical Research Involving Human Subjects, prepared by CIOMS and the WHO in 2002.

10.1.3 These and similar national codes are based on the model of clinical medicine, and often address interests of "patients" or individual "subjects". Epidemiological research concerns groups of people, and the above codes do not adequately cover its special features. Proposals for epidemiological studies should be reviewed independently on ethical grounds.

10.1.4 The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

10.2 Principles for all human or medical research

The principles enshrined by the Declaration of Helsinki include:

10.2.1 The design and performance of each research study involving human subjects must be clearly described in a research protocol.

10.2.2 The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must:

10.2.2.1 be independent of the researcher, the sponsor and any other undue influence.

10.2.2.2 take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in the Helsinki Declaration.

have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information *about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician, researcher or other health care professional and never the research subjects, even though they have given consent.*

10.3 Medical research involving a disadvantaged or vulnerable population or community is justified only if:

the research is responsive to the health needs and priorities of this population or community and *there is a reasonable likelihood that this population or community stands to benefit from the results of the research.*

10.4 Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

10.5 Every clinical trial must be registered in a publicly-accessible database before recruitment of the first subject. Research proposals shall be required to demonstrate compliance or be sent to the MRC where the need arises

10.6 Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

10.7 Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.

10.8 In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.

10.9 Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

10.10 Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or

mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician or researcher should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

11 PROTECTIONS OF RIGHTS AND DIGNITY IN ANIMAL CLINICAL RESEARCH AND EXPERIMENTATION

11.1 Introduction

11.1.1 This section covers basic assessment of experimental animal health and welfare, ethical consideration for the use of animals in scientific research as well as implementing assessment techniques for pain management and humane endpoints.

11.1.2 Such research is governed by the South African National Standard which encompasses all aspects of the care and use of, or interaction with, animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching. It includes their use in research, teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies.

11.1.3 The purpose of this policy is to ensure the ethical and humane care of animals used for scientific purposes, including teaching. Its aims are to:

11.1.3.1 emphasise the responsibilities of investigators, teachers and institutions using animals.

11.1.3.2 ensure that the welfare of animals is always considered.

that the use of animals is justified.

vent or minimize pain or distress where possible for each animal used in scientific and teaching activities, minimum uniform national standards of animal care and use.

Minimise the number of animals used in projects in such a way that it will not jeopardise the validity of the study.

Note the development and use of techniques which refine, reduce or replace animal use in scientific and teaching activities.

11.1.4 The South African National Standard requires that Animal Research Ethics Committees (ARECs) verify that animal use in a research project is justified and to ensure adherence to the principle of Replacement, Reduction and Refinement and responsibility ("the four R's").

11.1.4.1 The ability of an animal to cope with the environment and exert controls over its life is critical for animal welfare. The overriding ethical and legal constraints on invasive, potentially harmful and exploitative studies on humans sometimes necessitate a limited use of animal subjects, provided that this does not cause unnecessary suffering in the form of deprivation, fear, stress, distress and pain which may be endured. Such conditions are addressed by refinement strategies to ameliorate them as far as it is possible to do so.

11.1.4.2 Animal experiments should only be performed when no alternative is available and when the benefit of the experiment outweighs the suffering of the animal. When animals are used, there is a legal and moral obligation to safeguard welfare and minimize discomfort, since this is generally beneficial for both the animal and the experimental outcome. Discomfort and stress both before, and during the experiment can lead to non-specific effects, thus jeopardizing results. Where possible, they should be anticipated, and in the event of any observed adverse reaction, animal studies should be terminated at the earliest time so as to avoid unnecessary discomfort or suffering.

11.2 Principles for animal research

11.2.1 Researchers who use animals and institutional management should strive for the best regulation of laboratory animal use. They should ensure that animal welfare regulations and operational codes and practices are properly adhered to.

11.2.2 The availability to the public of regularly updated and good quality information on what animal experiments are undertaken and why they are undertaken is vital to

create circumstances in which the issue of animal experimentation can be productively discussed and debated.

11.2.3 It must be recognized that the ethical imperative of the 'replacement' component of the three Rs principle is a primary challenge in every animal use procedure, and forms a critical part of the analysis in the ethical review process.

11.2.4 Sensitivity and respect for the sentience of non-human animals demands that they should be treated as organisms fully worthy of moral concern, under the stewardship of institutions and their staff.

11.2.5 Animal users should respect the interests of animals and not subject animals to intentions and motives which are not directly concerned with research or teaching project, its objectives and its methodology.

11.2.6 Animal care staff, researchers and educators must be personally and professionally qualified.

11.2.7 Researchers and educators who use laboratory animals and the staff who procure, breed and care for them are personally responsible for the proper care and use of these animals. They should uphold professional standards in accordance with their academic training and their professions.

11.2.8 Integrity should be promoted by honesty and fairness. In particular, researchers, educators, animal care personnel and AREC members should be honest about their own limitations, competence, belief systems, values and needs, and be prepared to respect views contrary to their own.

11.2.9 Sensitivity in animal experimentation requires balancing scientific or teaching interests with general values and norms supporting the interests and welfare of the animal subjects.

11.2.10 Special care should be taken not to treat animals as mere objects.

This includes:

11. 2.10.1. Moral philosophy

11.2.10.2 Animal interests

11.2.10.3 Humaneness

11.2.10.4 Animal protection

11.2.10.5 Relevance

11. 2.11 Research objectives shall always be subordinate to the humane treatment of animals.

11.2.12 Researchers must apply safety rules and guidelines for the preservation and protection of the health and welfare of laboratory animals when hazardous substances, micro-organisms or parasites are being worked with in experimental situations.

11.2.13 The responsible researcher, educator and animal care staff are to be appropriately qualified and experienced and to have facilities to ensure that all procedures conducted on laboratory animals will be undertaken with due discretion and precautions to protect the welfare of the animals.

11.2.14 Adequate preliminary studies of the literature pertaining to the proposed work should be undertaken to define as far as possible the risks inherent in the animal studies.

11.2.15 The users of laboratory animals have a responsibility to their professions, to the animals which they use, and to the public to ensure that an animal experiment is likely to yield information worth knowing, and that such information is well supported by valid experimental data and analysis of that data.

12. PUBLICATION

12.1 General principles

12.1.1 Peer assessment of research outcomes is important in validating research and researchers are expected to subject their research to peer review.

12.1.2 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.

12.1.3 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.

12.1.4 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.

12.1.5 University staff and students must indicate their affiliation to the University and acknowledge that the work was carried out at the University.

12.1.6 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 form of research 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.

12.2 Multiple outputs

12.2.1 Publication of multiple outputs based on the same set(s) or subset(s) of data by the same author could be classified as self-plagiarism and would accordingly be unacceptable; except where there is full cross- referencing within the outputs (for example, in a series of closely- related works, or where a complete work grew out of a preliminary publication such as a thesis or dissertation, or a conference paper, and this is fully acknowledged).

12.2.2 An author who submits substantially similar work to more than one publisher must disclose this to the publishers at the time of submission and point out the extent of the overlap.

12.2.3 Although not advisable, it is not unethical to submit a previously- delivered conference paper to a journal for publication, since it is accepted academic practice that conference papers constitute work in progress aimed at soliciting comments from one's peers in order to clarify and refine issues before a final product is submitted for publication. However, it would be unacceptable to submit a paper that was published in the conference proceedings to another publisher without full disclosure of the prior publication.

12.2.4 Is similarly not unethical to deliver a previously-delivered conference paper at another conference, where there is evidence that input received at the previous conference has been incorporated into the subsequently-delivered paper. The document should however indicate that the paper had been delivered elsewhere and has been revised.

12.2.5 Where substantially the same paper, without significant revision, were to be delivered more than once a real danger of unethical practices in the form of financial "double dipping" and "CV padding" arises. Such practices should preferably be avoided and are justified only if input is sought from a target audience that is substantially

different from the initial audience to avoid mere lip-service being paid to the accepted rationale for duplicate presentations. Where such repeat presentations do occur, steps should be taken to ensure that funding parties are aware of the situation, that any document states clearly that it is a repeat presentation and that CVs and/or similar documents clearly note the repetition and do not represent those different papers have been delivered.

13 DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

13.1 Ethical practice in conducting research requires the disclosure of any actual or potential conflict of interest and all researchers must comply with the statutory and institutional requirements as contained in the University's code of conduct.

13.2 Without derogating from the generality of the previous clause, a conflict of interest may arise in the following particular instances:

13.2.1 Where researchers are affiliated with, or have a financial involvement in, any organization or entity with a direct interest in the research subject-matter or materials.

13.2.2 If any organization or entity with a direct interest in the subject-matter provides direct benefits to the researchers that are not stipulated in a formal agreement with the University, such as a sponsorship of an investigation.

13.2.3 If any organization or entity with a direct interest in the subject-matter provides indirect benefits to researchers that are not stipulated in a formal agreement with the University, such as a gift to a researcher or a relative, the provision of materials or facilities or the support of individuals in the form of travel or accommodation expenses to attend conferences.

13.2.4 Where the terms of a new grant from a funding agency require disclosure of project data from a related project and the terms of the related project grant prevent that disclosure.

13.2.5 Where a researcher (or a family member) has a financial interest (equity, directorship, consultant) in a funding agency or in an agency being paid from the grant funds.

13.2.6 Where a researcher employs, for benefit, a family member or close friend to provide services in connection with the research undertaken.

13.2.7 Where a researcher allocates funds in the form of remuneration or expenses himself or herself out of research or departmental funds.

This section should be read in conjunction with the University's Postgraduate Guide.

13.3 Researchers have an obligation to disclose to the Chairperson of the UZREC any affiliation with, financial involvement in, and/or any direct or indirect benefit received from any organization or entity with a direct or indirect interest in the research subject-matter or materials.

13.4 When an actual or potential conflict of interest arises at the time of reporting or proposing research, and this conflict of interest has the potential to influence research and investigations, publication and media reports, grant applications, and applications for appointment and promotion, the researcher must disclose the details "in confidence" to the Chairperson of the UZREC, who must decide whether a conflict of interest exists and if so, what further action should be taken.

13.5 Before deciding upon the appropriate way forward, the Chairperson of the UZREC must consult with the researcher and may also consult with the funding agency or any other party to ensure that the conflict of interest does not compromise the research or the University's interests.

13.6 Without restricting the discretion of the Chairperson of the UZREC to decide upon an appropriate course of action, such action may be to reject or terminate a research project, or to disclose the conflict of interest to the editors of journals or the readers of published work arising from the research.

13.7 The provisions of this section apply equally to members of research ethics committees in the conduct of their work.

14 STRUCTURES FOR OVERSEEING COMPLIANCE

14.1 Senate has overall oversight in respect of research ethics, but has delegated this function, in terms of this policy, to the Research Ethics Committee and other committees that are accountable to that Committee. However, UZREC should report to NHREC and comply to its regulations.

14.2 The University's research ethics compliance structures consist of the following:

14.2.1 The University of Zululand Research Ethics Committee (UZREC), which is registered with NHREC and reviews both Human subjects and Animal research.

14.2.2 Faculty Research Ethics Committees (FRECs), the sub-committees of UZREC.

14.3 The structures mentioned in Clause 14.2.2 operate as a collective and the UZREC may, without derogating from its overall responsibilities, perform certain of its functions and obligations through one of the other committees.

14.4 The committees established to implement this policy have discretion to deviate from strict application of the relevant ethical guidelines where exceptional circumstances or common-sense dictate, provided that the basic principles underlying this policy are not compromised.

14.5 To be recognized by the relevant regulatory authorities, the University's research ethics compliance structures must:

14.5.1 In matters involving human health:

14.5.1.1 Be equipped to address all relevant issues arising from the categories of research likely to be submitted to it.

14.5.1.2 Include representative of the communities in which the University is located and reflect the demographic profile of the South Africa's population.

14.5.1.3 Include members of both sexes, although not more than 70% should be either male or female.

14.5.1.4 Include at least one member with knowledge of, and current experience in, areas of research that are likely to be regularly considered by the ethics committee.

14.5.1.5 include at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people.

14.5.1.6 Include at least one member who has professional training in both qualitative and quantitative research methodologies.

14.5.1.7 *Include at least one member who is legally trained*

14.5.1.8 Include at least two lay persons who have no affiliation to the institution, preferably from the community in which the research is to take place, and who are not currently involved in medical, scientific or legal work.

14.5.1.9 At least 50% + 1 attendance constituting a quorum

14.6 In matters involving animals:

14.6.1 Include a person with qualifications in veterinary science, or with qualifications and experience to provide comparable expertise.

14.6.2 Include a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the Institution, and who is not involved in the care and use of animals for scientific purposes. The person should where possible be selected on the basis of active membership of and/or nomination by, an animal welfare organization. When choosing this member, a minimum of two nominees, nominated by separate animal welfare organizations, should be considered.

14.6.3 A scientist with substantial and recent experience in the use of experimental animals.

15 THE UNIVERSITY OF ZULULAND RESEARCH ETHICS COMMITTEE (UZREC)

15.1 Introduction

15.1.1 The University of Zululand Research Ethics Committee (UZREC) is a SENATE committee that reports to NHREC and gives feedback to SENATE. It is charged with oversight of research ethics matters.

15.1.2 The UZREC is registered with the National Health Research Ethics Council (NHREC) and until such time as a separate Health Research Ethics Committee (HREC) becomes necessary, shall function in that capacity.

15.1.3 Until such time as a separate Animal Research Ethics Committee (AREC) is warranted, the UZREC shall function in that capacity.

15.1.4 The primary purpose of the UZREC is to protect the dignity, rights, safety and wellbeing of human participants in research; to protect the health and welfare of animals used in scientific research and teaching; and to monitor the ethical conduct of research and teaching undertaken by and within the University, particularly in respect of:

(a) animals used for teaching and experimentation.

(b) human subjects in research as individuals, groups or communities.

(c) biotechnology and genetic engineering.

(d) occupational hazards including biohazards which may have an effect on animals, plants and humans as well as the environment.

15.1.5 In addition, the UZREC will:

(a) consider all ethical matters pertaining to research at the University including, but not limited to, conflicts of interest, authorship, relationships between researchers, and the role of the scientist in society.

(b) deal with any ethical issues brought to the attention of the UZREC.

(c) screen and approve, or otherwise, research protocols that impact on humans, animals or the environment, conducted by the University staff, students or outside affiliates, who may approach the Committee from time to time.

15.1.6 Members of research ethics committees will not be remunerated for work done in that capacity, but, where appropriate, ad hoc external experts may be compensated at professional rates.

15.2 Membership

15.2.1 The UZREC comprises the following members:

15.2.1.1 The Deputy Vice-Chancellor Research and Innovation (Chairperson).

15.2.1.2 Committee shall appoint two deputy chairs to fulfil the duties of the chair in the absentia among the Deputy Deans/ chairs of FRECs as sub-committees to UZREC.

15.2.1.3 The Executive committee (EXCO) of UZREC shall comprise of the Chair, deputy chairs and two members of UZREC.

15.2.1.4 The Deans/Deputy Deans Research & Internalization of Faculty or their nominees.

15.2.1.5 At least three, but no more than five, persons appointed by Senate, after having considered the regulatory compliance requirements stipulated in Clause 9 above.

15.2.1.6 Staff member who has knowledge of and experience in professional care, counselling or treatment of people; alternatively, someone with such knowledge and experience who is a not a staff member.

15.2.1.7 Two members who are not researchers, drawn from the communities in which the University is located or conducts its research and who are not currently involved in medical, scientific or legal work.

15.2.1.8 ad hoc co-opted members for dealing with particular protocols. Without derogating from the generality of this clause, and in the absence of the required expertise among standing members, the following persons shall be co-opted when any matter involving animals is being considered:

15.2.1.9 A person (who may be a staff member) with qualifications in veterinary science, or with qualifications and experience to provide comparable expertise.

15.2.1.10 A person with substantial recent experience in the use of animals in scientific or teaching activities.

15.2.1.11 A member of an animal welfare organization, appointed by the Chairperson of the UZREC after having solicited nominations from animal welfare organizations within the University's geographic area.

15.2.1.12 A person with expertise in research ethics

15.2.1.13 A person with expertise in stats/biostats

15.2.1.14 Two staff members from the Research Office tasked with the administration of this policy. One must be a member and one Officer in attendance.

15.2.1.15 Ordinary membership of the UZREC will be for an initial two-year term, but members may be re-appointed for one additional two-year period. The provisions of this clause may be waived where a person serves on the UZREC in order to fulfil regulatory requirements.

15.2.1.16 All committee members will be required to sign a confidentiality agreement and non-discloser agreements (NDA) as well as a code of conduct part of their appointment process.

15.2.1.17 The University shall indemnify all committee members in respect of any legal consequences arising from bona fide decisions made as committee members.

15.3 Terms of Reference

15.3.1 The UZREC shall promote an environment in which researchers strive to comply with universal standards regarding ethical research and, when and where appropriate, shall advise Senate on matters involving research ethics.

15.3.2 The UZREC shall protect the dignity, rights, safety, and wellbeing of all participants in research and research-related activities through independent ethics-focused review of proposals and research methods, and the monitoring of all research projects within or related to the University.

15.3.3 The UZREC may accept for review research protocols submitted to it by researchers from institutions that are not affiliated to the University.

15.3.4 The UZREC shall ensure that the provisions of this policy are implemented and adhered to.

15.3.5 The UZREC shall have the power to co-opt ad hoc members to deal with particular protocols.

15.3.6 The UZREC shall have the power to assign some of its review tasks to specialist committees established in terms of this policy, but shall at no time abrogate its responsibility to ensure ethical compliance and shall, in particular, not abrogate its responsibility to make the final decision regarding ethical clearance and compliance in any matter.

13.3.7 The UZREC shall oversee the activities and decisions of all Faculty Ethics Committees.

15.3.8 The UZREC may recommend disciplinary measures where ethical Rules and principles are violated.

15.3.9 When strict compliance with the letter of a particular ethical requirement or guideline is not possible, the UZREC shall ensure that the proposed research is nonetheless in keeping with the spirit of the relevant requirement or guideline and the provisions of this policy.

15.4 Functions and Responsibilities

15.4.1 The UZREC is responsible for implementing ethics policy and procedures and will, where necessary, clarify and interpret policy, procedures and ethical guidelines and provide information to staff.

15.4.2 The UZREC assesses protocols submitted for research projects and class projects and, if approved, issues an ethical clearance certificate under the signature of the Chairperson of the UZREC. A certificate constitutes confirmation that the University is satisfied that the proposed research and research methods meet the ethical standards that the University requires.

15.4.3 The UZREC may require a project to be monitored in such manner as it deems appropriate.

15.4.4 The UZREC monitors the implementation of the policy in respect of all projects that it has approved and may amend the ethical clearance certificate in light of new information at its disposal.

15.4.5 The UZREC considers annual reports and reports submitted at the end of projects for ethical compliance in respect of the completed research and, if satisfied that the research had been conducted in an ethically sound manner, issues a Certificate of

Ethical Compliance in respect of the research under the signature of the Chairperson of the UZREC.

15.4.6 The UZREC will investigate, and attempt to satisfy, objections concerning ethical standards in any ongoing or completed project which was subject to review by that UZREC. Where a dispute cannot be resolved the UZREC will refer the matter to Senate.

15.4.7 The UZREC must refer the matter to Senate where:

15.4.7.1 The project supervisor is not prepared to alter the research protocol in order to conform to the suggestions of the UZREC, and the project supervisor wishes the decision of the UZREC to be reviewed.

15.4.7.2 Minority of consisting of at 50% +1 UZREC members participating in the decision at a meeting of the UZREC registers dissent from a majority decision.

16. FUNCTIONS AND RESPONSIBILITIES OF THE UZREC IN ITS CAPACITY AS THE INSTITUTIONAL ANIMAL RESEARCH ETHICS COMMITTEE (AREC)[4]

The following functions and responsibilities provide guidelines towards the operational requirements of an Animal Research Ethics Committee (AREC) and to which the UZREC, until such time as a separate AREC is warranted, must adhere:

16.1 Written proposals accompanied by the appropriate AREC protocol form, fully completed, should place before the AREC sufficient information to satisfy the AREC that the proposed use of animals is justified and complies with the Three R's principle.

16.2 Meetings should be scheduled as frequently as the volume of business demands, but not less than quarterly.

16.3 The process by which decisions are made shall be fair, consistent and transparent to investigators and teachers, and acceptable to all AREC members.

16.4 Irreconcilable differences between the AREC and an investigator or teacher shall be referred to the governing body of the institution for review.

16.5 AREC membership should be such that absenteeism will not result in failure to reach a quorum or lack of balance within the Committee.

16.6 The AREC might need to put in place procedures to deal with the immediate use of animals for the diagnosis of unexplained and severe disease outbreaks.

16.7 Only those scientific or teaching proposals that conform to the requirements of all relevant sections of this policy and of legislation may be approved.

16.8 Proposals shall be considered and approved only at meetings of the AREC and, where possible, by consensus.

16.9 Investigators and teachers shall be informed of decisions in writing.

16.10 A record of all approved projects shall be maintained.

16.11 Scientific or teaching activities involving the use of animals shall not start before written approval is given. Failure to obtain such permission shall result in projects not being recognized.

16.12 Pilot studies could be integral to an overall project. These enable the assessment of the feasibility and value of the project, and the potential for Refinement and Reduction.

16.13 AREC shall ensure through monitoring that adequate records are kept on the acquisition, breeding, health, care, housing, use and disposal of animals.

16.14 With due consideration of bio-safety requirements, announced and unannounced inspections of all animal housing and laboratory areas shall be conducted regularly by members of the AREC and appropriate records shall be maintained to ensure compliance with the Code17.

16.15 AREC shall ensure that any activity that constitutes a major breach of this policy (i.e., a breach that has immediate negative implications for animal welfare) ceases immediately and appropriate action is taken. This may include referral to the Deputy Vice-Chancellor Research and Innovation or the Vice- Chancellor. For non-compliance that has infrastructural dimensions, a reasonable time shall be given for correction, but the AREC shall be assured and kept informed that the problem is being addressed. The AREC shall initiate investigation into any suspected or alleged non-compliance with this policy, institutional policies or the Animals Protection Act, Act 71 of 1962.

16.16 Approved projects of long duration and the long-term continuing use of individual animals shall be reviewed at least annually by the AREC or more frequently if considered desirable.

16.17 Any project can be reviewed if warranted by the emergence of new information (whether scientific or pertaining to the scientific or teaching activities or investigator.)

16.18 The AREC shall make provisions to audit scientific and teaching activities in relation to an investigators or teacher's compliance with a submitted protocol.

16.19 Where two or more members oppose a proposal, it should not be approved until the AREC has explored ways of modifying the project that might lead to consensus.

16.20 The AREC shall report in writing at least annually to the UZREC as Senate Committee of the University which will report to the Senate of the University.

16.21 Regardless of the duration of the approval, the continuation of all projects shall be subject to the receipt of written annual reports that should advise on:

16.21.1 What progress has been achieved.

16.21.2 Problems that may have interfered with project progress.

16.21.3 Number of animals used to date or in total.

16.21.4 The wellbeing and animal welfare status of all animals during the study.

16.21.5 Unexpected mortalities.

16.21.6 Envisaged modifications, amendments, or additions.

16.21.7 Whether the project has, or will be able to, achieve the stated objectives.

16.21.8 Whether the project is continuing, has been completed, or discontinued.

16.21.9 What publications have been produced;

16.22 Following a review of the annual report, the AREC may determine, on the basis of the report and further consultation with the researcher that a project may continue, be suspended, require modification or terminated.

16.23 The AREC shall adopt or develop a system to categorize proposals, to help identify areas of special concern.

16.24 Where projects are to be conducted at more than one institution, AREC approval should be sought from each institution unless responsibility has been formally delegated to one AREC.

16.25 When responsibility has been formally delegated to another institution, the investigator should notify the AREC in writing at his/her own institution that there is approval elsewhere for a project.

16.26 AREC may be approached by individuals, or organizations, which do not have direct access to an institutional AREC, yet require AREC approval before proceeding to use animals for scientific purposes.

16.27 The AREC shall decide, on an individual case basis, whether it is prepared to assess the proposal and oversee the project. In such cases proposals for non-institutional applicants shall clearly address the points below, in addition to all information normally required by the AREC. This arrangement should enable the institution to withdraw from the agreement if the non-institutional applicant fails to comply with directions of the AREC.

17 THE FACULTY RESEARCH ETHICS COMMITTEE (FREC)

17.1 Introduction

17.1.1 Each Faculty Board must establish a Faculty Research Ethics Committee (FREC), which shall be a sub-committee of the Faculty Board, charged with ensuring and expediting ethical compliance of research projects within the faculty, and which shall make recommendations regarding ethics applications direct to the UZREC.

17.1.2 The FREC shall function in accordance with the framework set out in this policy.

17.2 Membership

17.2.1 The FREC comprises the following members:

17.2.1.1 The Dean (ex officio).

17.2.1.2 Deputy Dean Research & Internationalization person designated by Faculty (Chairperson).

17.2.1.3 At least four senior academic staff members, appointed by Faculty, who shall normally be experienced researchers' representative of the type of research conducted within the faculty.

17.2.1.4 ad hoc members as may be appointed by the FREC to deal with particular protocols.

17.2.1.5 A research office staff member for minute taking and administration processes

17.2.1.6 Membership of the FREC will be for an initial three-year term, but

17.2.1.7 Members may be re-appointed for one additional three-year period.

17.3 Functions and Responsibilities

17.3.1 The FREC reports to the UZREC and makes recommendations regarding the issuing or non-issuing of a research clearance certificate for a particular research project, or the manner in which the project should be monitored.

17.3.2 The FREC is responsible for promoting compliance with research ethics policy and procedures within its faculty and will, where necessary, clarify and interpret policy, procedures and ethical guidelines and provide information to staff.

17.3.3 The FREC serves as an initial clearing house for research ethics clearance applications emanating from its faculty and ensures that applications contain the information necessary for making an informed decision.

18 CONTINUED PROFESSIONAL DEVELOPMENT IN RESPECT OF RESEARCH ETHICS

18.1 The Research Office shall ensure that provision is made for research ethics training for all members of the University's research community, including academic and administrative staff involved in research, undergraduate and postgraduate students and members of research ethics committees; and where appropriate, among other stakeholders.

18.2 All research ethics committee members shall receive the training necessary for them to execute their duties.

18.3 All members of research ethics committees shall engage in continuous professional development, especially after regulatory changes are made, whether in the form of special training events or presentations and discussions at committee meetings.

18.4 The Research Office shall prepare and disseminate accessible educational material to the University's research community.

18.5 The Research Office shall keep records of all formal and informal training activities undertaken.

19 INTERPRETERS

19.1 To ensure that research is conducted with full knowledge and informed consent, data collection and related instruments must be available in a participant's home language or a language in which a participant is fully conversant.

19.2 Where participants are insufficiently familiar with the language in which research is to be conducted, principal investigators must ensure that:

19.2.1 Participant information sheets have been translated into the participant's mother tongue.

19.2.2 Reputable interpreters are used to ensure the participants understand the relevant research instruments

19.2.3 Reputable interpreters are present during discussions with the participants.

19.2.4 Interpreters are independent; provided that in low-risk incidences, a family member or friend of the participant may be used.

SECTION B: PROCEDURES

20 THE ETHICAL CLEARANCE PROCESS

20.1 Introduction

20.1.1 All research conducted at the University shall be approved by the Research Committee or by the Higher Degrees Committee of Senate.

20.1.2 In those instances where an ethical clearance certificate is not submitted together with the research proposal documentation, such approval will be conditional upon ethical clearance for the research having been obtained.

20.1.3 No experimental research, empirical research or data collection by any staff member or student affiliated to the University, or at the University, in its name, or associated with the University in any way, may commence without a UZREC ethical clearance certificate indicating that such research may commence. This clause does not prevent the undertaking of preliminary research for proposal or research instrument development or literary reviews from being conducted.

20.1.4 The UZREC will normally not consider projects for approval where the data has already been collected. Exception may include instances where a researcher has relocated to the University subsequent to the collection of data or where data was collected prior to the establishment of a fully-functional ethics regime within the Institution.

20.1.5 While decision-making processes are to be transparent, it is also imperative that all research ethics committee members adhere to the necessary confidentiality and privacy requirements that might be associated with particular research projects.

20.2 The Application Documentation

20.2 .1 Applications will be loaded and processed through an online system called the Higher Degrees Management System (HDMS) that would require the following application process:

20.2.1.1 The person seeking ethical approval for proposed research shall prepare the following documentation, as appropriate:

(a) A completed Research Ethics Protocol/Application form.

(b) A fully-motivated project/research proposal stating and/or containing:

(i) A description of the research, including a clear statement on whether or not the research involves any of the following: human health, animals, vulnerable people, therapeutic research involving children and/or sensitive issues regarding rights, beliefs, perceptions, customs and cultural heritage issues.

(ii) The research methodology should be appropriate and ethical to the study, bad research is unethical, the criteria for selecting participants should be clear.

(iii) Plans for consulting participants and/or communities on their involvement, for keeping them informed.

(iv) How the research will be published and the nature of the report backs to participants and/or communities on the results of the research.

(v) Whether there are any special health and safety considerations that need to be considered, for participants as well as researchers.

(c) A participant's informed consent form.

(d) Informed consent from parent/guardian form for minors (below 18 yrs. of age).

(e) All data collection/survey instruments, e.g., questionnaires, with translation into the appropriate language(s).

(f) A description of any other research material that will be used, , e.g. information sheets, advertisements and letters.

(g) Copyright clearance or permission to use survey instruments.

(h) Proof of permission to access sites/information/participants.

(i) Conflict of interest form, whether in respect of researchers, funders, or participants.

(j) Data storage and time frame

(k) Whether the research interview will be conducted online or on site.

(j) Section on knowledge dissemination

20.3 **Ethics Applications: Determining the Level of Risk**

NHREC requires all RECs to include a risk-based approach when reviewing applications according to categories, low, medium and high risk. This means that an effective review process for all research projects/applications needs to be applied to ensure that low risk or medium research projects can be expedited and approved where required and noted in the next meeting. Higher risk research projects are reviewed and discussed in more detail, at a scheduled and convened in a formal meeting.

20.3.1 Low Risk

Research in which the only foreseeable risk is one of discomfort or inconvenience

a. The potential risk that would be experienced by the participant during the interview or survey is not greater than what they experience in their normal lives; the questions would not require them to divulge personal/sensitive information or experiences that they would not normally share with a stranger. The questions would not stir any emotional distress or increase the risk of discomfort or harm.

b. The participants are adults and not considered to be a vulnerable research population. Children are generally considered to be a vulnerable research population; however, this rule is not absolute and certain projects involving children may also be considered 'low risk'.

c. The research will collect information that would generally be regarded as non-sensitive, such as opinion rather than personal information.

d. The information can generally be collected anonymously. "A respondent may be considered anonymous when the researcher cannot identify a given response with a given respondent. This means an interview-survey respondent can never be considered anonymous, since an interviewer collects the information from an identifiable respondent. An example of anonymity would be the mail survey in which no identification numbers are put on the questionnaires before their return to the research office". (Babbie & Mouton, 2001)

e. Study of a social setting, a network, a set of activities, etc. that are not controversial and involve ethnographic methods (participant observation and interviews). A study of informal trade or of public life in a tourist destination could be examples. Much of the knowledge is of a public nature. (Sociology and Social Anthropology)

f. Post-hoc analysis of large sample of student essays/exam papers where anonymity of students is assured; much standard socio-economic survey and interviewing work where standard protocols re informed consent, voluntary withdrawal and confidentiality are in place. (Sociology and Social Anthropology)

g. Low risk research is research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. The participants in such research are typically adults or children who are unremarkable in terms of their social status, health status and/or development. As such, there is the little potential for discomfort or inconvenience on the part of participants; where such potential does exist, the predicted discomfort or inconvenience would be minor. (Department of General Linguistics).

20.3. 2 Medium risk

Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk.

a. It is highly probable that the participant would experience major discomfort, emotional distress, or a range of negative emotions while participating in the research activity. The participant would be asked to reflect on personal matters that they would not normally share with anyone outside of the research context or they would be asked to reflect on or respond to questions on a topic that is considered sensitive and/or controversial. The potential risk of participation could include emotional distress which could necessitate referral for counselling. The participants in the study would be groups that are considered vulnerable or stigmatised, but this could also include the case where non-vulnerable populations would be rendered vulnerable due to their participation in your research activities.

b. A study of vulnerable social categories, e.g. relationships between children and adults as experienced by both these categories. A study of controversies about school discipline is an example. Some of the knowledge is private and is based on a relation of trust between researcher and participants. (Sociology and Social Anthropology).

c. Dealing with potentially sensitive topics such as HIV, sexuality, rape, violence, but one cannot presume that sensitivity can be generalised across all cultural/social contexts. (Example: researchers in Uganda maintained that stigma re HIV not an issue there compared to SA, so very different context in which to make judgements re potential harm or discomfort.) (Sociology and Social Anthropology)

d. Medium risk research is research in which there is an increased potential for emotional or psychological discomfort, due to either the topic investigated being controversial or connected to social stigma or the

participants themselves being vulnerable. Such research could be harmful to the participant if not managed properly by the researcher. (Department of General Linguistics)

e. One or more of the following apply: the research topic is 'sensitive'.

    i. Information gathered is personal rather than opinion or attitudes, or a combination of both.

    ii. The information needs to be collected with personal identifiers (name, student number, etc).

    iii. The research participants may come from a vulnerable or marginalised group such as those with disabilities, people living with HIV or other chronic disease, the economically or educationally disadvantaged, etc.

20.3.3 **High risk**

Research in which there is a real and foreseeable risk of harm and discomfort to participants and or the research team, and which may lead to serious adverse consequences if these risks are not managed in a responsible manner. High-risk research could also be described as research involving highly sensitive topics and/or the participation of very vulnerable and marginalised individuals/groups.

a. Criminal activities that are linked to names, or ones in which victims of sexual abuse are asked questions about their abuse in ways that provoke flashbacks. (Sociology and Social Anthropology)

b. A study involving vulnerable social categories where exploitation or severe personal loss is involved, e.g. research re sexual abuse, abortion, crime, drugs, witchcraft accusations, etc. The knowledge that is gained in this category of risk often involves intimate or secretive aspects. Information that is provided is often not meant to be published in detail. (Sociology and Social Anthropology)

c. Research with/on political dissidents in a very repressive political environment; research on whistle-blowers. (Sociology and Social Anthropology)

d. A study on bereavement. (Sociology and Social Anthropology)

e. A study on children's access to pornography. (Sociology and Social Anthropology)

f. A study on political refugees.

g. A study on ex-criminals on the Cape Flats.

h. Any study on prisoners.

i. A study on cutting behaviour among adolescent girls, with a waiver of parental consent.

j. A study of bereavement among adolescents in a high school setting.

k. Research involving highly sensitive topics and/or very vulnerable and marginalised individuals or communities.

l. Research involving deception of research participants.

m. Research investigating illegal activities; research involving participants who are illegal immigrants or engaged in illegal activities.

n. Agreeing to participate in the research may well place participants at real risk of harm.

o. Information revealed during the course of the research may place the researcher at risk of breaking the law, e.g. research investigating gang activities and possession of illegal firearms.

p. The research may reveal information that requires action on the part of the researcher that could place the participant or others at risk e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.

20.4 Submission of the Application

20.4.1 An electronic version of all applications for ethical clearance shall be processed through the HDMS. Protocol to be followed as shown in the manual of the HDMS process20.3.2 Where the nature of the research is such that an expedited process can be followed, the faculty can send a request to the Research office ethics division.

20.4.3 The Research office will attend all FREC meetings for quality assurance.

20.3.4 Should a FREC Chairperson decide to call an extraordinary FREC meeting, , they will alert the Ethics division in the research Office

20.4.5 The documentation will be prepared according to its normal procedures and distribute them, along with the agenda and minutes of the previous meeting, at least three days prior to a FREC meeting.

20.4.6 In order to protect any vested or future rights and interests, confidentiality of all documentation and data contained therein must be assured.

21. FREC MEETINGS AND PROCESSES

21.1 FREC Meetings

21.1.1 FRECs shall normally meet once a term based on the faculty Board Meetings, but where the number of applications warrants, it can meet more often.

21.1.2 The FREC Chairperson may call extraordinary meetings as and when necessary.

21.1.3 Provided that all such decisions are referred to a formal FREC meeting for noting, FRECs may conduct their business electronically in the following circumstances:

(a) Where an expedited process is followed.

(b) Where the FREC Chairperson is satisfied that a matter requires urgent attention.

c) All honours projects must be reviewed at FREC and approval granted with minutes to be noted by UZREC

21.1.4 Decisions must be made in a fair, consistent and transparent manner, preferably by consensus, otherwise by simple majority vote.

21.1.5 A quorum shall be 50% Plus 1 of FREC members.

21.2 The FREC Processes

21.2.1 Prior to making a recommendation, a FREC will review ethical clearance application templates, research proposals, research questionnaires, consent forms, conflict of interest forms and/or any other relevant research documentation.

21.2.2 Ethical clearance for a particular project will not be considered without the completed protocol and the research proposal; but where other documents are not submitted, FREC, if satisfied with the applicant's reasons for not submitting the required documentation, may consider granting provisional clearance pending the submission of particular documentation.

21.2.3 The FREC may:

(a) Recommend to the UZREC that clearance be granted.

(b) Recommend to the UZREC that clearance be granted subject to certain specified conditions.

c) Approve Honours and desktop research and send to UZREC for noting

(d) Decline to make a recommendation to the UZREC and refer the application back to the applicant, with reasons for the decision and suggested amendments on how to meet the requirements of this policy.

21.2.4 All FREC recommendations must be recorded in its minutes and the Chairperson must within two days complete in respect of each application an ethical clearance application cover sheet which records FREC's recommendation to the UZREC and submit the cover sheet and all documentation considered by the FREC to the Research Office.

21.2.5 Where a matter has been referred back and an applicant is unable to agree to the FREC's suggestions, or where an applicant wishes a FREC decision to be reviewed, the matter shall be referred to the UZREC, whose decision shall be final.

21.2.6 Should any member of the FREC disagree with a majority decision, that fact should be recorded and made known to the UZREC; and any dissenting member may provide the UZREC with reasons for such dissent.

21.2.7 If ad hoc members were consulted in the course of making a decision, the FREC should inform the UZREC of that fact.

21.2.8 The Research Office shall record and retain on file all documentation

21.2.9 Submitted to and/or considered by the FREC, and thereafter submit the documents to the UZREC.

22 UZREC MEETINGS AND PROCESSES

22.1 UZREC Meetings

22. 1.1 The purpose and functionality of UZREC is based on research ethics and granting of certificates and withdrawal of certificates and so forth, SENATE is not the appeals body. Any appeals, complains of applicants on UZREC must be directed to NHREC

22.1.2 The UZREC shall normally meet twice a Semester, but may, where the number of applications warrants it, meet more often.

22.1.3 The UZREC Chairperson may call extraordinary meetings as and when necessary.

22.1.4 Provided that all such decisions are referred to a formal UZREC meeting for noting, the UZREC may conduct its business electronically in the following circumstances:

(a) Where an expedited process is followed.

(b) Where the UZREC Chairperson is satisfied that a matter requires urgent attention.

22.1.5 Decisions must be made in a fair, consistent and transparent manner, preferably by consensus, otherwise by simple majority vote.

22.1.6 A quorum shall be 60% of UZREC members.

22.2 The UZREC Processes

22.2.1 Once a month, on a stipulated date, Research Office staff shall coordinate all applications received from FRECs and consult with the UZREC Chairperson on whether or not an extraordinary UZREC meeting is warranted.

22.2.2 Should a FREC Chairperson decide to call a UZREC meeting, the Research Office staff shall prepare a provisional agenda before submitting the material to the Registrar's Division for processing.

22.2.3 Prior to deciding a matter, the UZREC will review ethical clearance application templates, research proposals, research questionnaires, consent forms, conflict of interest forms and/or any other relevant research documentation.

22.2.4 Ethical clearance for a particular project will normally not be considered without the completed protocol, the research proposal and a FREC recommendation.

22.4.5 The UZREC may:

(a) Grant ethical clearance.

(b) Grant ethical clearance subject to certain specified conditions.

(c) Decline to grant ethical clearance and refer the application back to the applicant, with reasons for the decision and suggested amendments on how to meet the requirements of this policy.

(d) Request principal Investigators to make representations to the UZREC in order to provide information which may assist the Committee in making an informed decision about the proposed research protocol.

(e) Require a project to be monitored in a specific manner.

(f) Specify specific methods of reporting progress.

22.4.6 All UZREC decisions must be recorded in its minutes.

22.4.7 Research Office staff must within five days of a UZREC decision:

(a) Communicate in writing with unsuccessful applicants and, where applicable the supervisor, as well as the Chairperson of the relevant FREC, should inform them of the UZREC decision, the reasons for that decision and their recourse to appeal.

(b) Prepare an ethical clearance certificate in respect of each successful application for the UZREC Chairperson's signature.

(c) The Research Office shall forward the signed ethical clearance certificates to the applicants and, where applicable, supervisors.

22.4.8 Principal investigators have the right to re-apply for ethics approval in instances where applications have been refused, withdrawn or suspended.

22.4.9 UZREC approval constitutes ethical approval as required by regulators, funding agencies or sponsors.

22.4.10 The Research Office shall retain on file all documentation submitted to and/or considered by the UZREC, as well as records of all UZREC decisions.

22.3 Review of UZREC Decisions

22.3.1 The UZREC shall refer a matter to ~~Senate~~ NHREC where:

(a) The Principal Investigator refuses to adjust the research protocol as suggested by the UZREC, and the Principal Investigator wishes the decision to be reviewed.

(b) Where disputes or objections are not satisfactorily resolved within the UZREC. SENATE will be duly notified of all such matters.

22.3.2 SENATE's decisions shall normally constitute final resolution of any matter referred to it in terms of this policy on misconduct. However, in an exceptional instance, SENATE may wish to refer a matter to a regulatory authority. Any other matter on ethical clearance certification and decision made by UZREC is binding and can only be over ruled by NHREC.

23 EXPEDITED ETHICAL CLEARANCE PROCESS

23.1 Introduction

23.1.1 An expedited ethical clearance process may be followed in the following instances:

(a) Where the research involves desktop, library work or laboratory work only.

(b) Where some data collection activity will take place, but the research raises minimal levels of ethical concern AND ethical clearance is urgently required.

(c) In exceptional cases, where it is in the public interest to expedite the process.

d) Where risk level is Low or medium

23.1.2 Expedited review may not be followed where the research involves human health and/or animals, children and/or vulnerable people.

23.2 Process

23.2.1 Applications shall be submitted to the Research Office and shall be recorded in the usual manner.

23.2.2 Research Office staff shall assess whether or not the application process could be expedited and if in doubt, they shall request a ruling from the FREC Chairperson or UZREC Chairperson.

23.2.3 Where an expedited process is appropriate, Research Office staff will forward electronic versions of the application to the FREC.

23.2.4 Where the nature of the research is such that an expedited process can be followed, the Research Office staff shall immediately distribute the electronic version to the relevant FREC and allow a 5-day period to make recommendations.

23.2.5 The FREC may deal with the matter electronically, and in such an instance the recommendation to submit the application to the UZREC requires the approval of a simple majority of FREC members entitled to vote.

23.2.6 Should a FREC member object to a matter being expedited, the Chairperson shall record that objection and the reasons therefore and thereafter may?

(a) Hold the matter over and place it on the agenda of the next FREC meeting.

(b) Submit the matter to the UZREC for a decision.

23.2.7 Normal approval principles set out in this Policy, especially in Clauses 6 and 7 above, shall apply.

23.2.8 Upon the required majority having been attained, the FREC Chairperson shall within two days complete an ethical clearance application cover sheet and submit it and any additional documentation considered by the FREC to the Research Office.

23.2.9 The Research Office shall record and retain on file all documentation submitted to and/or considered by the FREC, and thereafter submit the documents, together with the ethical clearance application cover sheet to the UZREC.

23.2.10 The UZREC may deal with the matter electronically, and any decision requires the approval of 60% of FREC members entitled to vote.

23.2.11 Upon the required majority having been attained, the UZREC Chairperson shall notify the Research Office staff of the decision and cause the ethical clearance certificate to be processed in the normal manner.

23.2.12 All FREC and UZREC decisions made electronically shall be placed on the agenda of the committee meeting following that decision and formally noted in the minutes of that meeting.

24 MONITORING AND REPORTING

24.1 Monitoring

24.1.1 UZREC does have a post- approval passive monitoring system of using (annually written reports by the principal investigator about the progress of the research involving human participants, and problems or challenges met when undertaking the study.

24.1.2 Principal investigators and supervisors shall in the first instance be responsible for monitoring compliance with research ethics obligations

24.1.3 Generally as well as any specific obligations that the UZREC may impose in a particular instance.

24.1.4 Principal Investigators shall keep full records of all steps taken to comply with ethical obligations. In particular, monitoring of projects involving animals shall include keeping records of acquisition, breeding, health, care, housing, use and disposal of animals.

24.1.5 The UZREC may specify additional monitoring requirement and/or specific methods of monitoring a research project, the nature and the frequency of such monitoring being dependent upon the risk factors related to the research.

24.1.6 The UZREC will require the principal investigator to do random monitoring of ethical compliance in high-risk research and submit a report to the committee after data has been collected.

24.1.7 The UZREC retains the right to monitor or investigate any research project falling within this policy at any time, and to inspect any facility, equipment or process associated with such research.

24.1.8 Inspections may occur on notice or randomly, and in the presence of a person involved in the research, preferably the Principal Investigator. Only in most exceptional and urgent instances shall inspections be conducted without a researcher being present; and in such instances the inspector shall inform the Principal Investigator, failing which another person involved in the research, immediately upon completion of the investigation or, if where attempts to contact them have been unsuccessful, within a reasonable period.

24.1.9 Duration of the certificates is on accordance with NHREC guidelines of 1-year. The committee issues 1-year ethical clearance certificate, upon the certification reaches its expiry date, the researcher is required to submit annual progress report stating all activities carried out during data collection. Researchers are allowed to request an extension via recertification process if more time is required for continuity on data collection.

24.2 Reporting

24.2.1 For monitoring purposes, the UZREC will require Principal Investigators to send an annual report demonstrating clear compliance to ethical issues pertinent to their research and specifically on any conditions that the UZREC may have imposed when granting the initial ethical clearance certificate.

24.2.2 At the end of each project, the Principal Investigator shall provide a close-out report, which shall form the basis of any ethical compliance certificate that might be required. No higher degree shall be awarded without such a report and ethical compliance certificate; and the University may withhold further funding to a researcher pending the submission of such a report.

24.2.3 UZREC may stipulate a different reporting cycle depending upon the nature of the risk factors related to the project.

24.3 Reporting of adverse events

24.3.1 Study site visits will be conducted to promote active monitoring. The Chair will appoint two members of UZREC to conduct active monitoring and site visits when the need arises and report back to the committee following the SoPs for guidance.

24.3.2 Principal investigators shall report immediately to the UZREC Chairperson any breach or threat of a breach of ethical obligations and/or anything that could materially affect ethical compliance and warrant a review of the protocols, including, but not limited to:

(a) Proposed changes to the protocol serious/adverse to

(b) Unforeseen events that may affect ongoing acceptability of the project.

(c) The project being halted prematurely.

(d) Whether any activity has constituted a serious breach of ethics.

24.3.2 In such instances, the project must be halted immediately and appropriate remedial action must be taken.

24.3.3 A full report must be submitted to the UZREC Chairperson within five days of discovery of the ethical breach of threat of a breach.

24.4 Complaints

24.4.1 All citizens have the right and responsibility to report unethical or questionable research activities and accordingly, anyone has the right to forward complaints regarding research ethics to the UZREC, which shall investigate the complaint and take appropriate action.

24.4.2 If the response from the UZREC is not satisfactory, then the appropriate regulatory authority may be approached.

24.4.3 Whistle-blowers have the right to anonymity.

24.4.4 Researchers have the right to fair and impartial investigation, as stipulated in this policy, with recourse to appeal.

24.5 Review

24.5.1 Following any monitoring or investigation activity, or a report of any nature, the UZREC shall review the matter and may amend the ethical clearance certificate in which event the initial certificate is revoked and replaced by the new certificate.

24.5.2 The UZREC may, based on the review, determine that the project continues, be suspended, requires modification or be terminated.

24.5.3 Recommendations made subsequent to review, may include random inspections of research sites, data, consent forms, records of interviews, and prior consent forms.

24.5.4 On receipt of the initial notification and the subsequent report of an adverse event, the UZREC Chairperson shall notify all members of the UZREC and take appropriate action, which shall include requesting an emergency meeting of the UZREC or establishing an ad hoc subcommittee to review and revise the scope of the research protocol.

25 Compliance Reporting

25.1 The UZREC shall report to the NHREC as required. Such reports will ordinarily include information related to the membership and composition of the UZREC; the number of meetings held; confirmation of participation of members; the number of protocols presented to the UZREC and the number approved and not approved; monitoring and compliance activities and the complaints procedure and number of complaints received, including outcomes.

26. Indemnity

26.1 The University accepts legal liability for bona fide decisions and advice given by members of its ethics committees and staff who administer this policy and indemnifies them from any liability relating to the bona fide discharge of their duties.

27. POPI Act, Data Storage and Retention and Confidentiality

27.1 On 1 July 2021, the Protection of Personal Information Act (POPIA or the Act), No. 4 of 2013, came into effect. The Act will have implications for all research activities that involve the collection, processing, and storage of personal information. POPIA provides for the development of Codes of Conduct to guide the interpretation of the Act with respect to a particular sector or class of information in terms of Section 57 of POPIA for the sector to which it applies. POPIA regulates the processing of personal information for research purposes, and the flow of data across South Africa's borders to ensure that any limitations on the right to privacy are justified and aimed at protecting other important rights and interests.

27.1.1 Wherever possible, original data must be retained in the department or research entity in which they were generated. Individual researchers should hold copies of the data for their own use. However, retention solely by the individual researcher provides little protection to the researcher or the University in the event of an allegation of falsification of data. When data is obtained from limited access databases, or via a contractual arrangement, the location of the original data must

be identified, or key information regarding the database from which it was collected and this must be retained by the researcher or research unit. In all cases, prior to the publication of research findings Location of Data Form must be completed.

27.1.2 Data related to publications must be available for discussion with other researchers for as long as interest and discussion persists following publication.

27.1.3 Data (including electronic data) collected in the course of implementing and administering this policy must be recorded and stored in a durable and appropriately-referenced format.

27.1.4 Data management should comply with relevant privacy protection laws and regulations.

27.1.5 Data must be held for an appropriate period to allow access for reference and monitoring purposes and for data that is published, for as long as interest and discussion persists following publication.

27.1.6 Without derogating from the provisions of the above clause, the minimum period for retention of all research ethics data shall be five years from the date of the granting of an ethical clearance certificate or the date of granting an ethical compliance certificate, whichever is the later date; while for research involving animals or human health, the period for retention shall be fifteen years. (Must check with NHREC).

27.2 Confidentiality issues

27.2.1 Confidentiality agreements will be developed to protect intellectual property rights (see UNIZULU Intellectual Property Policy) belonging to the University, or to pass on obligations of confidence to others in relation to confidential information received by the University. Where such agreements limit free publication and discussion, limitations and restrictions must be explicitly agreed.

27.2.2 Under the Protection of Personal Information Act, 04 of 2013 (“POPIA”), researchers have a general legal duty to protect information they process. They must ensure the security and protection of any personal information processed through the research and provide a compliant and consistent approach to data protection. The information collected via interviews must be for research purposes only. No personal information such as opinions, views and academic background may be linked to the respondents' identity or shared with anyone for marketing purposes or otherwise.

27.2.3 Copies of all confidentiality agreements relating to research falling within the ambit of this policy should be lodged with the Research Office as soon as they have been concluded. Should any reason exist why this cannot be done, the researcher shall inform the Deputy Vice- Chancellor, Research and Innovation who shall then attempt to resolve the issue in a manner that protects the interests involved.

27.2.4 Where confidentiality provisions apply (for example, where the researchers or the University have given undertakings to third parties, such as the subjects of the research), it is desirable for data to be kept in a way that reference to them by third parties can occur without breaching such confidentiality.

27.2.5 The researcher is responsible for enquiring into whether confidentiality agreements apply and the Head of Department or the research entity is responsible for informing researchers of their obligations with respect to these provisions.

27.2.6 Researchers are responsible for ensuring appropriate security of any confidential material, including that held in electronic media. Where computing systems are accessible through networks, particular attention to security of confidential data is required. Security and confidentiality must be assured in a way that copes with multiple researchers and the departure of individual researchers.

27.7.7 The provisions of this clause apply equally to members of committees responsible for research and research administrators, with the necessary changes.

28 PROCEDURES FOR DEALING WITH ALLEGATIONS OF RESEARCH MISCONDUCT

28.1 Introduction

28.1.1 The UZREC and a mentor/supervisor, a head of department, a Dean, the DVC Research & Innovation are empowered to institute disciplinary steps, via the normal institutional channels, against researchers who violate ethics guidelines.

28.1.2 Any research involving risk to animals, humans or the environment, that is conducted by persons to whom this policy is applicable without prior ethical clearance approval will be regarded as a transgression of research ethics and the UZREC may act against such transgressions, within the scope of the university disciplinary policies and procedures.

28.1.3 The UZREC may appoint standing or ad hoc subcommittees to investigate ethical transgressions that fall under its jurisdiction.

28.1.4 The UZREC has a responsibility to take all necessary steps to ensure that all persons who disclose such information are protected from any reprisals as a result of disclosing misconduct.

28.2 Definition of Research Misconduct

28.2.1 "Misconduct" or "scientific / academic misconduct" is taken here to mean misrepresentation, fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research and for recording research activity in curricula vitae or similar documents. It includes the misleading ascription or credit of authorship including the listing of authors without their permission, attributing work to others who have not in fact contributed to the research, and the lack of appropriate acknowledgement of work primarily produced by a research student/trainee or associate. It does not include honest errors or honest differences in interpretation or judgments of data.

28.2.2 Examples of research misconduct include, but are not limited to, the following:

(a) *Misappropriation.* A researcher or reviewer shall not intentionally or recklessly

- Engage in plagiarism, as understood and defined in the University's Plagiarism Policy.
- Make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

This section should be read in conjunction with the University's Plagiarism Policy as well as applicable staff and/or student disciplinary codes.

- Intentionally omit reference to the relevant published work of others for the purpose of inferring personal discovery of new information.

(b) *Interference.* A researcher or reviewer shall not intentionally and without authorization take or seize or materially damage any research-related property of another, including, but not limited to the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.

(c) *Misrepresentation.* A researcher or reviewer shall not with intent to deceive, or in reckless disregard for the truth:

- State or present a material or significant falsehood.

- Omit a fact so that what is stated or presented as a whole state or presents a material or significant falsehood.

28.3 Protection of interested parties

28.3.1 Deans and Heads of Department should advise on integrity in research. Their tasks include giving confidential advice to staff and to research students/trainees about what constitutes research misconduct, the rights and responsibilities of a potential complainant, and the procedures for dealing with allegations of research misconduct within the University which are clearly stated in the whistle blowing policy that is available to all staff and students. The whistle blowing policy can be found in the Registrar's office.

28.3.2 The whistle blowing policy covers all concerns raised in good faith, in connection with:

- Failure to comply with any statutory and/or other legal obligations/ requirements;
- Financial or non-financial mismanagement, fraud and corruption, blackmail, miscarriage of justice including money laundering and bribery;
- Any risk or potential risk to the environment, or to the health and safety of any individual;
- Improper conduct or unethical behaviour; or
- Concealment of any of the above.

28.3.3 Care should be taken when dealing with allegations of research misconduct. When an allegation is made, all interested parties must be protected and the matter must be dealt with in a sensitive and speedy matter. These interested parties include:

- The person bringing the allegation.
- The person against whom the allegation is made.
- Staff, students and trainees working with persons making an allegation, or with persons against whom an allegation is made.
- Journals and other media reporting research subject to suspected, alleged, or demonstrated research misconduct.
- Funding bodies supporting persons or research involved.

28.4 The investigation

Procedures involving the investigation of misconduct or serious misconduct shall form:

28.4.1 Academic teaching and research staff, be dealt with in accordance with the current UNIZULU Academic Staff Agreement.

28.4.2 Other general staff, be dealt with in accordance with UNIZULU Human Resources Guidelines on Handling Unsatisfactory Job Performance and Unsatisfactory Job-Related Behaviour: General Staff.

28.4.3 Students, be dealt with in accordance with the Statute and the Regulations for Student Conduct and Discipline in the University Prospectus

28.5 The Reporting Procedure

28.5.1 The person to whom a report is made will notify the Deputy Vice Chancellor or the Dean who will then get an individual or individuals to look into the allegations, depending on the seriousness of the report, who in turn will then make a decision as to whether there is a *prima facie* case to respond to the concern raised.

28.5.2 An investigation may be recommended by the Responsible person and, depending on the nature and materiality of the matter, it can be dealt with by way of an internal investigation, interviews or independent enquiry.

28.5.3 In dealing with the matter, the Responsible Person may consult with the Deputy Vice Chancellor or an appointed member of the executive management team of UNIZULU, as the DVC deems appropriate

28.5.4 If, in the course of the investigation of any report in terms of the Whistle Blowing Policy, the Responsible Person is of the opinion that the matter is of a grievance or disciplinary nature, the appropriate procedures as referred to in paragraph 3.2 of the Whistle Blowing policy will be invoked

28.5.5 The decision of the Responsible Person as to whether there is a *prima facie* case to respond to and, if so, what the nature of the investigation will be or whether the matter should be dealt with as envisaged in paragraph 7.4 of the Whistle Blowing policy, will be communicated to the Reporter in such manner as the Responsible Person deems appropriate.

29. IMPLEMENTATION AND OVERSIGHT RESPONSIBILITIES

29.1 The project owner of this Policy is the Deputy Vice-Chancellor, Research and Innovation, who shall ensure that the policy provisions are implemented and that it is presented for revision and review at the appropriate time.

29.2 The various FRECs and the UZREC shall in the first instance oversee compliance in respect of the matters that fall within their jurisdictions.

29.3 SENATE has overarching oversight responsibility.

29.4 Ethical compliance management rests with the Office of the Deputy Vice-Chancellor, Research and Innovation and the Research Office.

30 POLICY REVIEW

30.1 Council shall review the policy on a three-yearly cycle.

30.2 On recommendation of the UZREC, Senate may review and amend Section B and any annexures of a policy at any time, in which event the amendments take effect on the date of the Senate approval.

30.3 The policy owner may review and amend any annexures that contain or illustrate forms or documents for effective administration and/or management at any time.

30.4 Nothing in this clause shall prevent Council from reviewing this policy at any time prior to the stipulated three-year cycle, in which event a new cycle shall commence from the date of such review.

31 ACKNOWLEDGEMENTS AND REFERENCES

31.1 In drafting this policy substantial reliance was placed on Research Ethics Policies of the University of Fort Hare and the Mangosuthu University of Technology. Permission to use some of their material verbatim is acknowledged and appreciated.

31.2 The following documents were consulted in the drafting of both the original Fort Hare document and this document:

31.2.1 Human Sciences Research Council Research Ethics Committee Terms of Reference.

31,2.2 University of Fort Hare Research Ethics Policy.

31.2.3 University of Pretoria Terms of Reference and Standard Operating Procedures.

31.2.4 Stellenbosch University Health Research Ethics Committees Standard Operating Procedures and Guidelines.

31.2.5 The Belmont Report.

31.2.6 Inter Academy Council Responsible Conduct in the Global Research Enterprise: A Policy Report (2012)

31.2.7 Guidelines on Ethics for Medical Research, SA Medical Research Council (1993).

31.2.8 Handbook for the use of Animals in Neuroscience Research, Society

31.2.9 for Neuroscience (USA).

31.2.10 SANS10386:200X ISBN 0-626- Edition 1, 2002.

31.2.11 The South African Department of Health (2015) Ethics in health research: Principles, structures, and processes for National Health Research Ethics Council (NHREC)

31.2.12 South African good clinical practice guidelines (2006)

31.2.13 www.research.uwa.edu.au/staff

31. 3 General Reference Work Included

31.3.1 Cameroon Bioethics Initiative. CAMBIN ethical review committee standard operating procedures, 2008.

31.3.2 Canadian Council for Animal Care. Guidelines on animal use protocol

Review 1997. Downloaded on 06/05/2002.

31.3.4 House of Lords Session 2001- 02. Select Committee on Animals in Scientific Procedures, Volume I Report.

31.3.5 Remfry J. Ethical Aspects of Animal Experimentation. In: Tuffery AA, ed. Laboratory Animals: An Introduction for New Experimenters. New York: John Wiley & Sons, 1987.

31.3.6 South African Medical Research Council. Guide to Ethical Considerations in Medical Research. Parowvallei, Cape Town: South Africa Medical Research Council, 1979.

31.3.7 South African Medical Research Council. Ethical Considerations in Medical Research. Parowvallei, Cape Town: South African Medical Research Council, 1987.

31.3.8 South African Medical Research Council. Guidelines on Ethics for Medical Research. Parowvallei, Cape Town: South African Medical Research Council, 1993.

31.3.9 Stellenbosch University (SU) - https://www.eng.sun.ac.za/media/sites/7/Determining-the-Level-of-Risk.pdf

31.3.10 World Medical Association declaration of Helsinki. Ethical principles for medical research involving human subjects. Adopted by the 15th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 59th WMA General Assembly, Seoul.

31.3.11 University of Cape Town (UCT) Guideline for Risk-Based Ethical Review of Research (Human Participants)
http://www.researchsupport.uct.ac.za/sites/default/files/image_tool/images/362/integrity/UCT%20Ethics%20risk%20guideline%20for%20RECs_11Feb2021.pdf

31.3.12 The University of Western Australia's Research website

The UZREC is acknowledged for their comments given during the review of this policy.