POLICY ON RESEARCH ETHICS

CONTENTS

PART 1

GENERAL GUIDELINES FOR ETHICAL RESEARCH

1. PREAMBLE

1.1 This policy is based on the vision of the University of South Africa (UNISA): *Towards the African University shaping futures in the service of humanity.*

1.2 UNISA is committed to

- undertaking and promoting research that aims to benefit the people of South Africa and/or beyond its borders
- being guided by integrity, accountability and rigour in research
- promoting an institutional ethos that is conducive to systematic knowledge development, critical discourse, intellectual curiosity, tolerance and a diversity of views within a framework of academic freedom
- maintaining an environment for researchers in which they are autonomous, yet ethical in their research practice
- enabling researchers to maintain ethically responsible research practice.

1.3 UNISA promotes high standards of scientific work and strives for excellence in research that is open to public scrutiny[1].

1.4 UNISA espouses the constitutional values of human dignity, equality, social justice and fairness.

1.5 UNISA promotes the internationally recognised moral principles of autonomy, beneficence, non-maleficence and justice.

1.6 The UNISA Policy on Research Ethics aims to ensure that:

1.6.1 an ethical and scientific intellectual culture prevails among the university's employees and students and is followed in research practice.

1.6.2 the rights and interests of human participants, institutions communities, animals and the environment are protected. This is particularly important where the information that has been gathered has the potential to invade the privacy and dignity of participants and third parties, and where participants and third parties are vulnerable owing to their youth, disability, gender, age, poverty, disease, ignorance or powerlessness.

1.6.3 all research activities are conducted with scholarly integrity, excellence, social responsibility and ethical behaviour.

1.6.4 the ethical and scientific soundness of research is not compromised.

1 UNISA endorses the internationally accepted Singapore Statement on Research Integrity. http://www.sigaporestatement.org/)

1.7 This policy should be read in conjunction with other relevant UNISA guidelines, policies and relevant legislative frameworks

2. DEFINITIONS AND ABBREVIATIONS

Academic freedom	is the recognition of academics' right to freedom of investigation, thought, expression, publication and dissemination of results, free of institutional intolerance and of internal or external coercion;
Academic dishonesty	is the conduct or omission in any academic endeavour that violates the values associated with academic integrity and includes any act that is designed to give an unfair or undeserved academic advantage. It includes cheating, plagiarism, falsification, fabrication and violation of research ethics;
Academic integrity	is the honest, fair and responsible research and tuition, associated with honesty, truth, equity, respect, responsibility and accountability;
Academic outputs	refer to all works created by employees and students for tuition and/or research purposes;
Collaborative research	is research that involves the cooperation of researchers from different academic institutions, organisations and/or communities;
Copyright	is the specific intellectual property right, which an author acquires in accordance with the Copyright Act, No. 98 of 1978 ("the Act") in respect of a protected work;
Curation	is the selection, preservation, maintenance, collection and archiving of research data and artefacts;
Ethical review	is an objective appraisal of the effect of the proposed research on the wellbeing of potential participants, animals, the environment, institutions, collectivities and communities by an established Ethics Review Committee;
Department	is an operational unit;
Gatekeepers	are persons who by the right of their position of authority are recognised as a channel of access to a research site and/or participants;
Health research	includes, but may not be limited to research that contributes to knowledge of: • biological, clinical, psychological, or social welfare matters including processes relevant to humans • the causes and effects of and responses to disease • effects of the environment on humans • methods to improve health care service delivery • new pharmaceuticals, medicines, interventions and

devices
- new technologies to improve health and health care[2];

Human participant	is generally a living person about whom a researcher obtains data through intervention or interaction with the person or through the use of her/his identifiable information. However, this definition may be extended for the purpose of this policy to protect the rights of deceased persons[3];
Intellectual property	is a patentable invention or any copyrightable subject matter such as a trade mark, a design, a traditional work as defined in the Intellectual Property Amendment Act of 2010 and a trade secret or knowledge of how to do something;
Integrity	is fundamental to all forms of scientific research and is anchored in the values of "truth" and "honesty". Trust by peers and the public in the truth of research is exemplified by the responsible conduct of researchers, trust in their competence and trust in their devotion to do research according to internationally acceptable ethical norms and values;
Interdisciplinary	means drawing from, relating to, or involving two or more fields of study which are usually considered distinct, resulting in an integration of concepts in a coherent synthesis that crosses disciplinary boundaries;
Non-therapeutic research	is research that benefits people other than the research participant. The acquisition of knowledge may be of no immediate benefit to the participant, but he/she may unexpectedly become a direct or indirect beneficiary of such research;
Research	means a systematic investigation aimed at the development of, or contribution to, knowledge;
Researcher	is a permanently appointed UNISA employee and an employee on a contract of less than three years who has been tasked with conducting research as well as a valid, current Academic Associate (excluding an Emeritus Professor) and a postdoctoral fellow;
Student	is any registered UNISA student;
Therapeutic research	means research that benefits the individual research participants by treating or curing their condition;
Vulnerable participants	include children (i.e. those individuals under the age of 18 years), the elderly, pregnant women, people with a cognitive or mental impairment, prisoners or people on parole, students, people living with HIV/AIDS, people in dependent relationships, persons with disabilities, socio-economically disadvantaged people, indigenous people and indigents;
ERC	means the Ethics Review Committee that is representing a specific UNISA business unit or College, either on unit or

2 Definition according to the National Health Act, 61 of 2003
3 Definition according to the Department of Health, Government Gazette, No. 38000 (2014:5)

departmental level;

URERC means the UNISA Research Ethics Review Committee.

3. PURPOSE

The Policy on Research Ethics is not intended to restrict or discourage research at UNISA. On the contrary, this policy aims to:

3.1 inform the researcher of his/her responsibilities in conducting ethical research

3.2 understand and promote adherence to all applicable procedures

3.3 protect the rights of all stakeholders.

4. SCOPE

The definition of research is based on a number of important principles.

4.1 Research is at the most basic level a human activity. This implies that research is never value-neutral or mechanistic. Researchers have preconceptions determined by social, political, cultural and gender influences. These preconceptions influence both their theories and findings.

4.2 Research is a communal activity. Researchers work as part of a national and international community of scholars. This community influences the paradigms within which research is undertaken in and across certain disciplines and/or subjects.

4.3 Acceptable research may be interdisciplinary, discipline-, field- and subject-specific.

4.4 Research is theory-dependent. Research is informed by the dominant theories within certain fields and theories which, in turn, are influenced by the paradigms referred to above.

4.5 The purpose of research is the study of natural, social and metaphysical phenomena in order to improve our understanding of how the world functions as well as to addressing its needs.

4.6 Research involves creative, innovative, systematic and original work that explains phenomena. In addition, research embraces the critical evaluation of such phenomena in both the natural and social sciences.

4.7 Research includes basic, applied, strategic and reflexive research.

5. RIGHTS AND RESPONSIBILITIES OF UNISA IN ENABLING ETHICAL RESEARCH

5.1 UNISA should respect the autonomy and academic freedom of researchers.

5.2 UNISA should create and maintain an enabling environment in which researchers are able to conduct ethical research.

5.3 UNISA should promote the compliance with the Policy on Research Ethics and take appropriate steps when this policy is breached.

5.4 UNISA has the right to monitor research that has been approved by any of its Ethics Review Committees and to require submission of regular reports or other information

regarding the research. The university may impose disciplinary measures or stop research when ethical principles are violated or the integrity of the university is jeopardised.

5.5 As a general rule, all intellectual property resulting from research conducted with UNISA funds or use of its facilities, vests in the university in accordance with UNISA's Intellectual Property Policy.

5.6 Ethics clearance will not be granted retrospectively.

5.7 Human, animal, plant, molecular and cell research conducted by UNISA employees and students must have ethics clearance from the relevant Ethics Review Committee before it may commence.

5.8 Health, health-related and animal research conducted by UNISA employees and students should receive ethics clearance from an Ethics Review Committee which is registered with the National Health Research Ethics Council to comply with section 73 of the National Health Act 61 of 2003

5.9 Class approval for student research projects should be obtained in certain circumstances.

5.10 UNISA is accountable only for research which has been approved by any of its Ethics Review Committees.

5.11 This policy should be read in conjunction with other relevant UNISA guidelines, procedures, policies and relevant legislative frameworks.

5.12 A register is maintained of all research that has been given ethics clearance.

6. RIGHTS AND RESPONSIBILITIES OF RESEARCHERS AT UNISA

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

6.2 Integrity in research

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

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

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

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

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

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

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

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

6.2.10 Researchers may not commit plagiarism, piracy, falsification or the fabrication of results at any stage of the research. The research findings should be reported accurately and truthfully, and historical records and study material should be preserved and protected.

6.2.11 Plagiarism, falsification, the fabrication of results, and scientific misconduct in general are regarded as serious offences. These will be investigated by the relevant Ethics Review Committee and relevant actions taken.

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

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

6.3 Relationship among researchers

6.3.1 Principal researchers and/or academic supervisors are responsible for the ethical conduct of research by juniors, assistants, students and trainees under their supervision. At the same time juniors, assistants, students and trainees have a responsibility to act ethically and to observe the Policy on Research Ethics.

6.3.2 Juniors, assistants, students and trainees have a right to receive, and principal researchers have a responsibility to provide proper training and guidance on all aspects of research, including ethical conduct. The principal researchers should delegate to juniors, assistants, students and trainees

only those responsibilities that they are reasonably capable of performing based of their education, training or experience, either independently or under supervision.

6.3.3 Researchers should not engage in discriminatory, harmful or exploitative practices, coercion or harassment in the research process. They should not impose their views or beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees or students.

6.3.4 Researchers should not deceive or coerce other researchers, including employees, juniors, assistants, trainees and students into serving as research participants. Employees or students, either as research participants or as research assistants, have the right to end involvement in the research without having to face adverse consequences.

6.3.5 Students working on research as a tuition requirement should not be exploited by advisors or mentors, nor used as cheap labour.

6.3.6 In addition to researchers and students, other individuals such as administrative employees of UNISA who may have access to data or identifying information, as well as private organisations that are contracted to handle research data should be briefed on ethical issues and the Policy on Research Ethics, including the participants' right to privacy and confidentiality.

6.3.7 In the event of a researcher contravening the Policy on Research Ethics it will be investigated by the relevant Ethics Review Committee and the findings reported to UNISA and the research sponsor.

6.4 Data sharing

6.4.1 Researchers should ensure the protection of the interests of co-researchers and participants, including the participants' right to privacy and confidentiality, when sharing data or making it public in any form.

6.4.2 Data may be commonly shared when it does not identify participants is in the form of anonymous abstracted facts or when the right to anonymity has been waivered, if necessary it may be shared even before publication of the study, among researchers and peer reviewers, and may be made available to the public.

6.4.3 As far as possible, and if required by the design of the research, researchers should ensure that relevant findings of the research are taken back to the research participants, institutions or communities in a form and manner that they can understand, and which will not cause harm.

6.5 Reporting and publication of research

6.5.1 Reporting of research findings advances scientific knowledge. Researchers who conduct the study have the right and the duty to publish research findings in scientific journals, books and/or other media. When they agree to delegate this responsibility to other individual(s) or organisation(s) they should do so only if they have received a mutually agreed commitment to publish or disseminate the results within an agreed period, with an agreed content and in an agreed manner and with due recognition of the relevant researchers and UNISA as institution.

6.5.2 Where there is a conflict between the advancement of scientific knowledge and the protection of intellectual property (e.g. by way of patents) researchers should endeavour to explain the importance of publishing research to the inventor once the provisional application has been filed.

6.5.3 If a client/sponsor/funder requires non-publication of research results or requires giving prior approval for the manner and content of reporting, such research proposal may be rejected by the relevant Ethics Review Committee. If the request not to publish is based on strategic or other reasonable grounds, the committee may consider non-publication of results for no more than one year following the completion of research. Input from the relevant college/institute/centre should be sought where there is a request not to publish.

6.5.4 Research results should be reported irrespective of whether they support or contradict the expected outcome(s).

6.5.5 Researchers should disclose in their publications the source(s) of funding and sponsors, if any, unless there is a compelling reason not to do so.

6.5.6 Researchers should in their publications explain the methodology used, and explain how any ethical dilemmas they encountered were resolved.

6.5.7 The following guidelines should be followed for giving authorship credit while reporting the research in any form:

a) Authorship, and its sequence in case of more than one author, should be based on the quantum of contribution made in terms of ideas, conceptualisation, and actual performance of the research, analysis and writing of the report or any publication based on the research. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere.

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

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

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

6.5.8 When results are disseminated through the popular media, researchers should endeavour to ensure that media people comprehend the limitations and implications of research results, and that distortions and misrepresentations in media reporting are minimised.

6.6 Peer review

6.6.1 Sound methodology and scientific validity are the entry points of ethical research. Engaging in research that has fundamental flaws in design and methodology is a waste of human, monetary and other resources. Apart from ethical review, peer (scientific) review is thus an essential part of research. The purpose of peer review is to improve and advance research, and to

facilitate observance of ethics. Researchers should be encouraged to subject their own work to such a process.

6.6.2 Researchers should be encouraged to make themselves available as peer reviewers for research in the fields in which they have adequate knowledge and expertise.

6.6.3 Peer reviewers should be aware of the ethical aspects of research and publication. They have to act objectively, impartially and constructively.

6.6.4 If peer reviewers have any actual or potential conflicts of personal or professional interest with the research under review that could jeopardise their ability to undertake the review in a scientific and ethical manner, they should either disclose the same or decline to review the work concerned. In such situations, their decision should be based on the type and severity of the conflict of interest.

6.6.5 When scientific misconduct or violation of ethics is discovered, the peer reviewer should take appropriate steps to report it to the relevant Ethics Review Committee.

7. INTERNATIONAL COLLABORATIVE RESEARCH

7.1 Before submission of a collaborative research proposal to an Ethics Review Committee, agreement should as far as practically possible be reached between the host research institution and the collaborating institution on all aspects of the research. These include the ownership of intellectual property, management of the research process, data management, the fate of data and research specimens, division of responsibilities, finances, research output, publication strategy, sharing of benefits and burdens, development of infrastructure and research capacity in the host country and an ombudsman to settle disputes.

7.2 Intellectual property rights of parties should be respected and acknowledged before the research commences.

8. RIGHTS AND RESPONSIBILITIES OF FUNDERS, CLIENTS AND SPONSORS

8.1 Researchers should ensure that they have an explicit written research mandate from the client/sponsor/funder in which the conditions, scope and terms of the research are set out clearly (e.g. research problem, expected deliverables, financial commitments and time frames).

8.2 The acceptance of a mandate should be sealed by a legally binding, written contract between the parties. This contract should specify the terms agreed on, including the rights and obligations of the parties involved, and the ownership of intellectual property rights and benefits.

8.3 The position with regard to the dissemination and publication of findings from the research study should be clarified.

8.4 Researchers should recognise the right of the client/sponsor/funder to request information from them at any stage in the course of the research. However, interference that may jeopardise the scientific integrity of the study or the interests of the research participants may oblige UNISA to cancel the cooperation.

8.5 Clients/funders/sponsors should be made aware of the UNISA Policy on Research Ethics. They have the right to receive a copy of the policy and to expect that the

research proposal submitted for funding or sponsorship by researchers and UNISA contains the necessary information on ethical issues and complies with the policy.

8.6 Clients/funders/sponsors should respect the UNISA Policy on Research Ethics and should not expect researchers or UNISA to undertake research or conduct which is in any way contrary to the policy, other related UNISA policies and/or legislative frameworks.

8.7 Where clients/sponsors/funders act, directly or indirectly, as gatekeepers and control access to the participants, researchers should not devolve onto the gatekeepers their responsibility to obtain separate and informed consent from participants and to protect their rights.

Acknowledgements and works consulted

1. National Health Act 61 of 2003 (http://www.acts.co.za/national-health-/national health act 2003)

2. Department of Health, (2004). Regulations Relating to research with Human Participants, Government Gazette, No. 38000, 19 September 2014. (http://www.gov.za/sites/www.gov.za/files/38000 rg10268 gon719.pdf)

3. Intellectual Property Amendments Bill of 2011

4. Protection of Personal Information Act 4 of 2013

5. South African Human Sciences Research Council *Draft Code of Research Ethics* http://www.hsrc.ac.za/about/researchEthics/draftCode.html)

6. Stellenbosch University Policy for Responsible Research Conduct at the University of Stellenbosch, 2013 (http://www.sun.ac.za/research/assets/files/Integrity_and_Ethics/SU%20Research%20Ethics%20policy%20approved%20by%20Council_24%20June%202013.pdf)

7. South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles (Book 1)* (2002)

8. University of Pretoria Code of Ethics for Research (www.ais.up.ac.za/research/docs/code_ethics.pdf)

9. University of Kwazulu-Natal Research Policy V (http://research.ukzn.ac.za/research-ethics/Overview.aspx)

PART 2

GUIDELINES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

1. BASIC PRINCIPLES FOR RESEARCH

1.1 Moral principles

UNISA promotes the following four internationally recognised moral principles of ethics as bases for research:

- autonomy (research should respect the autonomy, rights and dignity of research participants)
- beneficence (research should make a positive contribution towards the welfare of people)
- non-maleficence (research should not cause harm to the research participant(s) in particular or to people in general)
- justice (the benefits and risks of research should be fairly distributed among people)

These principles are not ranked in any order of preference. In disputes a balance between the four principles should be pursued.

1.2 General ethics principles

In addition to, and expanding on, the above moral principles, the following ten general ethics principles should be adhered to by researchers. Again, the ethics principles may not, by themselves, resolve all ethical problems and dilemmas which confront researchers. Researchers may be required to balance the demands made by moral principles of research and to privilege one principle over another, depending on the context and circumstances of the research involved.

1.2.1 Essentiality and relevance

Before undertaking research adequate consideration should be given to existing literature on the subject or to the issue under study, and to all available alternatives. In view of the scarcity of resources in South Africa, it should be clearly demonstrated that the research is in pursuit of knowledge and/or the public good.

1.2.2 Maximisation of public interest and of social justice

Research should be carried out for the benefit of society, and with the motive of maximising public interest and social justice. All efforts should be made to make public in an appropriate manner and form, and at an appropriate time, information on the research undertaken, as well as the results and implications of the completed research.

1.2.3 Competence, ability and commitment to research

Researchers should be both personally and/or professionally qualified for the research that they undertake. A commitment to research in general and to the relevant subject in particular is an essential prerequisite for good and

ethical research.

1.2.4 Respect for and protection of the rights and interests of participants and institutions

Researchers should respect and protect the dignity, privacy and confidentiality[4] of participants and where relevant, institutions. Researchers should ensure that the personal information of participants used for research purposes is adequately protected to prevent possible loss, damage and/or unauthorised access as required by Protection of Personal Information (POPI) Act, No. 4 of 2013. They should never expose such participants and institutions to procedures or risks not directly attached to the research project or its methodology. Research and the pursuit of knowledge should not, in themselves, be regarded as the supreme goal at the expense of the rights of participants and institutions.

1.2.5 Informed and non-coerced consent

Autonomy requires that individuals' participation should be freely given, based on informed consent and for a specific purpose, as required by the POPI Act. Direct or indirect coercion, as well as undue inducement of people in the name of research should be avoided. These act as barriers to autonomous decision making and may result in people consenting against their better judgment to participate in studies that may involve risks.

1.2.6 Respect for cultural differences

Researchers should treat research participants as unique human beings within the context of their community systems, and should respect what could be traditionally sacred and secret. Research should preferably be undertaken with, the members of an identified community or communities rather than merely about such community(ies). In some situations the consent of "gatekeepers" may have to be obtained in addition to that of research participants.

1.2.7 Justice, fairness and objectivity

Criteria for the selection of research participants should be fair, as well as being scientific. Easily accessible individuals or groups should not be inordinately burdened with repeated demands on their time and knowledge by the researcher.

1.2.8 Integrity, transparency and accountability

The conduct of research should be honest, fair and transparent. Researchers should be honest about their own limitations, competence, belief systems, values and needs. The contribution of other researchers or members of the research team should be properly acknowledged. Researchers should not abuse their positions or knowledge for personal power or gain.

1.2.9 Risk minimisation

Researchers should ensure that the actual benefits to be derived by the

[4] That is, the nondisclosure of personal information (e.g. direct quotations or identifiable images) to others. Participants may consent to disclosure, preferably in writing.

participants or society generally from the research clearly outweigh any possible risks, and that participants are subjected only to those risks that are clearly necessary for the conduct of the research. Researchers should ensure that these risks are assessed and that adequate precautions are taken to minimise and mitigate risk in line with the UNISA Research Ethics Risk Assessment Standard Operating Procedure.

1.2.10 Non-exploitation

There should be no exploitation of research participants, researchers (including students and junior members), communities, institutions or vulnerable people. The researchers should ensure that the use of the participants' personal information is done in line with the requirements of the POPI Act (4 of 2013) and should ensure that the information is not used for unlawful and secondary purposes incompatible with the original purpose consented by participants. There should be benefits to the community in which research is conducted. As far as possible, feedback should be given to participants and other relevant stakeholders. When research is carried out with communities they must receive feedback on the results of the research.

2. RELATIONSHIP BETWEEN RESEARCHERS AND PARTICIPANTS

2.1 Participants should be seen as indispensable and worthy partners in research. Researchers should respect and protect the rights and interests of participants at every stage and level of research and acknowledge their contribution.

2.2 The risks and benefits of the research to the prospective participants should be fully weighed and the participants must be informed of them. Research that could lead to unnecessary physical, social and/or psychological harm should not be undertaken. Researchers should identify potential risks to participants and make provision for avoiding them. When risks form part of the conduct of the study, efforts should be made to mitigate the risks and protect the participants.

2.3 All steps should be taken to prevent harm (physical, psychological and/or spiritual) injury or loss of opportunity to participants. In the event of that harm, injury or loss of opportunity should occur, It should be dealt with in accordance with the relevant policy and/or legislative frameworks.

2.4 If during the course of the research it becomes evident that a participant has suffered harm in a way not foreseen by the researcher, this should immediately be reported to the university ERC and the relevant unit ERC for immediate investigation and action. Such action may, for example, include the need to refer the participant for counselling.

2.5 The criteria for selecting research participants should be fair.

2.6 A mutually beneficial agreement should be in place if a community or research setting is used as a continuous and long-term resource for collecting data to be used for curricular research or training.

2.7 The relevant social, cultural and historical background of participants should be taken into consideration in the planning and conduct of research.

2.8 Researchers should not infringe the autonomy of participants by resorting to coercion, undue influence or the promise of unrealistic benefits. Coercion may include taking undue advantage of individuals or abusing their participation in the research. Inducement may include a promise of material or financial gain, services or opportunities. No financial or other inducement should be offered to research

participants, whether children or adults, parents or guardians of children. Reimbursement of expenses (e.g. transport costs, meals) or compensation for the time or effort expended or any opportunity that may be lost is allowed, on condition that all participants are offered similar reimbursement and that such reimbursement is only aimed at recompensing the participants.

2.9 Participants should be informed of the existence of the UNISA Policy on Research Ethics and given details of the Ethics Review Committee. The policy should be made available to them if it can help them make an informed decision regarding their participation. Participants may not be instructed by researchers to participate in research under conditions that can be burdensome, abusive or threatening or that have the potential to risk or abuse the researcher's position. Unfairness or anything that prevents the participant from freely terminating his/her participation is not permissible nor should there be any negative implications should the participant choose to do so.

3. INFORMED CONSENT

3.1 Personal information should be collected in adherence to the Protection of Personal Information Act 4 of 2013.

3.2 The participation of individuals should be based on their freely given, specific and informed consent. Researchers should respect their right at any stage to refuse to participate in particular aspects of the research or to decide to withdraw their previous given consent without demanding reasons or imposing penalties.

3.3 Participants should give their consent in writing and preferably accompanied by their signature. They, in turn, should be given written information containing adequate details of the research, including any risks associated with the study. If participants refuse to provide their consent in writing, consent may be recorded verbally, provided that verbal consent can be linked to the individual providing such verbal consent. For example, where a participant is illiterate, consent should be obtained in the presence of a literate witness who should verify and sign a document stating that informed consent had been given. Where the research is done on-line or electronically, informed consent can be obtained electronically but in a format separate from the on-line research in order to protect the identity of the participant.

3.4 Consent for participation in research is freely given and informed if

3.4.1 it is given without any direct/indirect coercion or inducement.

3.4.2 prospective participants have been informed on the processing and purpose of the intended research.

3.4.3 prospective participants have understood this information and have indicated so as per paragraph 3.3.

3.4.4 the researcher has answered any question(s) about the research and their participation.

3.4.5 it is given before research commences.

3.5 If research is conducted in a foreign country, the relevant standards as set out in the UNISA Research Ethics Policy will take precedence and will apply.

3.6 Non-disclosure of all information

3.6.1 In some situations the methodology or practicalities of a research project may necessitate the concealment of information. This may be due to the possibility that behaviour changes may result or responses be affected when such details are revealed to participants. In such a case the researcher should determine beforehand.

(a) whether the use of such a methodology is justified by its potential scientific, educational or applied benefits

(b) whether alternative procedures which do not require the concealment of information should rather be used

3.6.2 If the use of such methodology is deemed justified by the researcher, there are steps which he/she should take:

(a) When obtaining informed consent a detailed justification for not revealing all necessary information should be provided in the research proposal and methodology. This justification should be subject to scientific and ethical review by the relevant Ethics Review Committee. Only after the committee has given its approval should such research be undertaken.

(b) The participants' right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know the real purpose or objectives for which they are providing information.

(c) Even should both scientific and ethical reviews allow that some of the information about the study need not be revealed, participants should be provided with all other information. In no case, however, should researchers withhold information regarding risks, discomfort, unpleasant emotional experiences, or any such aspect that would be material in making the decision to participate.

(d) Participants should be given the reasons for not providing full information as soon as is possible after completion of the research. Where needed, services such as counselling and referral should be offered.

3.7 Consent where gatekeepers or organisational structures are involved

3.7.1 It is the responsibility of the primary researcher to ensure compliance with the research policy/directives of gatekeepers or organisational structures.

3.7.2 In some situations there may be a need to obtain permission from the “gatekeeper” to access the participants, information and/or research sites. Care should be taken in the following situations:

(a) Permission obtained from the gatekeeper may not be substituted for the need to obtain separate and informed consent from the participants. The rights of participants in such a situation are the same as in all other cases.

(b) In the process of research or data collection, care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardised.

3.8 Vulnerable participants

3.8.1 Researchers should be take particular care of the rights and interests of vulnerable participants.

3.8.2 Research results that can be obtained if carried out on adults should never be carried out on children. Children should participate only when their participation is indispensable to the research. The protection and best interests of children are of prime importance.

3.8.3 Therapeutic research or experimentation on a child under the age of 18 years may be conducted only if it is in the best interests of the child, and if the assent of the child (if he or she is capable of understanding) and the consent of his or her parent or guardian, has been obtained.

3.8.4 Non-therapeutic research or experimentation may only be conducted on a child under the age of 18 years with the consent of the following persons: the Minister responsible for social development, the parent or guardian of the child, and the child if he or she is capable of understanding.

3.9 Where research involves the participation of persons unfamiliar with the language in which the research is to be conducted, the principle researcher must ensure that:

3.9.1 the participant's information statement has been translated into the participant's language

3.9.2 it is his/her responsibility to ensure that the participant understands the information statement he/she has been given

3.9.3 an interpreter is present during discussions with the participants about the project. As a rule the interpreter should be independent, but when the research proposal is of minimal risk, a relevant language-speaking relative or friend of the participant may be acceptable.

4. PRIVACY, ANONYMITY AND CONFIDENTIALITY

4.1 All research participants have the right to privacy to the extent permitted by law or as directed by legal frameworks.

4.2 Privacy includes autonomy over personal information, anonymity and confidentiality, especially if the research deals with stigmatising, sensitive or potentially damaging issues or information. When deciding on what information should be regarded as private and confidential, the perspective of the participant(s) on the matter should be respected.

4.3 All personal information and records provided by participants should remain confidential. It should be made clear during data collection that confidentiality and anonymity will be safeguarded unless waived by the research participant. Whenever it is methodologically feasible, participants should be allowed to respond anonymously or under a pseudonym to protect their identity and privacy.

4.4 All personal information obtained directly or indirectly on or about the participants (e.g. names obtained by researchers from hospital and school records), as well as information obtained in the course of research which may reveal the identity of participants, should remain confidential and anonymous. This guarantee should also be given when researchers ask consent to use data which is not already available within the public domain (e.g. classified data on prisoners held by the Department of Correctional Services).

4.5 In the case of observation (e.g. of a public scene) steps should be taken to ensure that the information will not be used or published in a form in which the individuals could be identified.

4.6 Researchers should maintain privacy, anonymity, and confidentiality of information in collecting, creating, storing, accessing, transferring and disposing of personal records and data under their control, whether these are written, automated or recorded in any other medium, including computer equipment, graphs, drawings, photographs, films or other devices in which visual images are embodied.

4.7 Researchers should preserve research records for a minimum of five years (or as required by policy or legal frameworks) after the submission of the report or the results.

4.8 Researchers should take reasonable technical and operational steps to ensure that research records are stored in such a manner as to protect confidentiality of records and the anonymity of participants.

4.9 Codes or other identifiers should, where possible, be used to break obvious connections between data and individuals/organisations/institutions. Where there is a mixture of information obtained from the public domain and that obtained with the participants' informed consent, there should be no traceable link between the two sets of information.

4.10 Confidentiality and anonymity of participants and their localities should be maintained when reporting to clients/sponsors/funders. Participants should not be identified or made identifiable in the report unless there are clear reasons for doing so. If the researcher or institution needs to identify participants or communities in the report, their informed consent allowing such disclosure should be obtained, preferably in writing.

4.11 Research findings published in the public domain (e.g. theses and articles) which relate to specific participants (e.g. organisations or communities) should protect their privacy. Identifiers which could be traced back to the participants in the study should not be included. However, public interest may outweigh the right to privacy, and may require that participants be named in reports (e.g. when child labour is used by a firm).

4.12 Participants' consent should be sought where data identifying them are to be shared with individuals or organisations who are not part of the research team.

4.13 The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers at UNISA, UNISA administrative employees, and all persons (from or outside UNISA) not directly associated with the research who may possibly have access to the information.

5. COLLABORATIVE RESEARCH INVOLVING HUMAN PARTICIPANTS

5.1 In national and international collaborative research the parties are host institutions, collaborating institutions, researchers from both institutions, research participants and/or communities.

5.2 There should be clear justification for the need for and benefit of collaborative research.

5.3 Research involving human participants must not commence without ethics approval by the Ethics Review Committees of all collaborating institutions. This requirement may be waivered under certain conditions by an Ethics Review Committee.

5.4 Research cannot commence without informed consent from participants and/or communities.

5.5 There may be no exploitation of institutions, researchers, research participants or communities.

5.6 Institutions and researchers should assist indigenous communities and traditional societies to protect their knowledge and resources, and should respect that which is traditionally sacred and secret.

5.7 Researchers involved in international collaborative research should have some understanding of, and be sensitive to, the social, economic and political conditions in which the research is carried out. This will alert them to the need to protect research participants who are, for example, subject to deprivations through poverty.

Acknowledgements and works consulted

1. Belmont Report (1978) (http://www.hhs.gpv/ohrp/humansubjects/guidance/belmont.htm)

2. Intellectual Property Amendments Bill of 2010

3. Protection of Personal Information Act 4 of 2013

4. South African Human Sciences Research Council *Draft Code of Research Ethics* http://www.hsrc.ac.za/about/researchEthics/draftCode.html)

5. Stellenbosch University Framework Policy for the Assurance and Promotion of Ethically Accountable Research (http://www0.sun.ac.za/research/assets/files/Policy_Documents/Framework%20Policy_for_the_Assurance_and_promotion_of_Ethically_Accountable_Research_at_SU.doc)

6. South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles (Book 1)* (2002)

7. University of Pretoria Code of Ethics for Research (www.ais.up.ac.za/**research**/docs/**code_ethics**.pdf)

8. University of Johannesburg Research Policy and Strategy (http://www.uj.ac.za/EN/Research/Research%20Information/Pages/ResearchPolicies.aspx)

9. University of Kwazulu-Natal Research Policy V (http://research.ukzn.ac.za/research-ethics/Overview.aspx)

PART 3

GUIDELINES FOR ANIMAL, PLANT, ~~AND~~ MOLECULAR AND CELL RESEARCH

1. PREAMBLE

UNISA's commitment to ethical research applies to all aspects of the use and care of, and the interaction with, animals for research purposes in the field of medicine, biology, agriculture, nature conservation, animal health and other disciplines within UNISA and in collaboration with other institutions. UNISA abides by the South African National Standards document (SANAS) where animal research is concerned. UNISA's commitment to ethical research also includes research on plants as well as molecular and cell research which may include research on genetically modified organisms.

2. DEFINITIONS

Animal	means any live non-human vertebrate, such as fish, amphibians, reptiles, birds and mammals including domestic animals, purpose-bred animals, livestock, wildlife and cephalopods like octopus and squid. The definition includes eggs, foetuses and embryos and higher invertebrates such as advanced members of the Cephalopoda and Decapoda;
Animal welfare	refers to an animal's quality of life based on an assessment of its physical and psychological state as an indication of how the animal is coping with the ongoing situation as well as a judgment about how the animal feels;
Animal wellbeing	refers to an animal's present state with regard to all aspects of its environment, both internal and external. It implies a positive mental state, improved physiological and biological functioning, positive experiences and freedom from any adverse condition;
Death as an end-point	is the deliberate and intended measure used to evaluate biological or chemical processes, responses or effects. In such cases the animal will not be killed humanely but death will be allowed to occur in the course of a scientific activity;
Distress	indicates the state of an animal which is not able to completely adapt to stress and that results in abnormal physiological and/or behavioural responses. Distress can be chronic or acute and may result in pathological conditions;
Ethics	applies to considerations whether actions are regarded as good or bad, right or wrong. Ethical considerations are applied in the evaluation of what should or should not be done when animals are proposed for use, or are used, for scientific and teaching purposes.
Euthanasia	is the humane killing of an animal consistent with veterinary recommendations and practice. Euthanasia is applied when the animal's pain and distress are so acute that it is judged necessary;

Genetically modified organism	means an organism, the genes or genetic material of which have been modified in a way that does not occur naturally through mating, through a natural recombination or both. 'Genetic modification' has a corresponding meaning" (Genetically Modified Organisms Act 15 of 1997);
Humane killing	is the killing of an animal with minimal pain and distress;
Livestock	is animals that are used in agriculture and aquaculture;
Pain	means an unpleasant sensory and/or emotional experience associated with actual or potential tissue damage. It may provoke protective actions and result in avoidance and distress and may modify behaviour;
Wildlife	refers to free-living animals of native, non-indigenous or feral species including captive-bred animals and those captured from free-living populations.

3. USE OF ANIMALS IN RESEARCH

3.1 General principles for the care and use of animals in research

3.1.1 All vertebrate animals are protected in South Africa by the Animal Protection Act 71 of 1962, and the use of animals for research has to adhere to this Act Therefore, these guidelines emphasise the responsibilities of researchers to

a) ensure that the use of animals is justified,

b) ensure that optimal standards in terms of animal health, care and welfare are observed,

c) only use animals when alternative techniques and research methods for a certain project do not exist,

d) use only the number of animals absolutely required by the study, and

e) refine methods and procedures to minimise or avoid pain or distress in animals used in research projects.

3.1.2 The guidelines require that researchers adhere to the "3 R" principles of Replacement, Reduction and Refinement when planning and conducting research studies involving animals. An Animal Ethics Review Committee (ERC) should determine for each research project using animals whether the rules of these guidelines are adhered to before approving such projects. See paragraphs 3.4, 3.5 and 3.6 below on the "3 R" principles.

3.1.3 These guidelines apply to all live non-human vertebrates and higher-order invertebrates, i.e. fish, amphibians, reptiles, birds and mammals including domestic animals, purpose-bred animals, livestock and wildlife as well as cephalopods such as octopus and squid. Early stages of development, such as embryonic, foetal and larval forms are also included. As different species develop differently, the experience of pain and distress in those developmental stages varies. Decisions with regard to the welfare of animals and their developmental stages should therefore be made for each case individually based on specific knowledge and evidence of the animal's neurobiological development.

3.1.4 Researchers must be committed to the welfare of the animals they use and must respect the contribution those animals make to research.

3.1.5 Researchers must ensure that procedures which cause hunger, thirst, injury, disease, discomfort, fear, distress, deprivation or pain to the animals involved in the studies are limited to the absolute minimum. The elimination or reduction such conditions experienced by an animal will be achieved by the application of the '3 R' principles. See paragraphs 3.4, 3.5 and 3.6 below.

3.2 Justification

3.2.1 The use of animals for research purposes must be justified by assuring that the outcomes of the studies will essentially contribute to

a) the understanding of humans and/or animals,

b) the maintenance and improvement of human and/or animal health or welfare,

c) the improvement of animal management or production,

d) the understanding, maintenance or improvement of the natural environment,

e) ensuring that the potential benefits outweigh the potential harm to the animals used.

3.2.2 Approval for each research project involving animals must be based on considerations whether the project is justified and whether the potential benefits outweigh the potential harmful effects on the welfare of the animals being used.

3.2.3 Researchers must submit written proposals to the Animal ERC for all projects involving animals. These proposals must address the expected value of knowledge to be gained, justification for the project and an ethical analysis regarding the animal welfare aspects under consideration of the "3 R" principles.

3.3 Responsibilities

3.3.1 Responsibilities of researchers

The adherence of researchers to these guidelines will ensure a transparency which should result in the high quality ethical and scientific screening of proposals and monitoring of research studies. Researchers are responsible for all matters relating to the welfare of the animals they use. They should respect the animals and their demands and should not treat animals as mere objects. Research objectives should be subordinate to the humane treatment of animals. Researchers and teachers have direct and ultimate ethical and legal (according to Animal Protection Act) responsibility for all matters related to the welfare of the animals they use.

a) The responsibility of researchers for the welfare of animals involved in their studies begins with the design of a project and ends with the completion of the project unless unforeseen long-term negative effects result from the experiments. Researchers and teachers have direct

and ultimate ethical and legal (according to Animal Protection Act) responsibility for all matters related to the welfare of the animals they use.Under these circumstances the responsibility of the researcher continues until these issues have been addressed satisfactorily. It is essential when invasive procedures are to be used that a veterinarian is consulted during the protocol design.

b) When applying for approval for a research project, researchers must inform the Animal ERC of any other institutions that will be participating in the project. The norm is to obtain ethical clearance or a letter of approval from all the involved institutions prior to the project commencing.

c) UNISA's Animal ERC needs to be informed in writing if a researcher plans to participate in a research project undertaken at another institution. Ethical clearance or a letter of approval should be sought from both institutions prior to the project commencing.

d) Researchers are requested to keep complete records of all matters related to the animals used during a research project.

e) Researchers must choose a species appropriate for their research purpose.

f) When livestock are used in research projects, standard husbandry procedures that are carried out for research purposes need approval by the Animal ERC. Approval from the department of Agriculture, Forestry and Fisheries may have to be obtained in the form of a section 20 permit. Approval is also required for the use of livestock for the production of any biological products other than food or fibre. Approval is not required for regulatory inspection measures like control of external parasites or disease surveillance carried out by qualified personnel.

g) In their proposals submitted to the Animal ERC for approval, researchers must indicate the category of experiments according to Table 1. The qualifications, experience and specific knowledge of researchers and employees with regard to the performance of experimental procedures on the animals that are used must be stated in detail. Such researchers and employees must be competent in terms of the relevant South African legislation and the Rules for Veterinary and Para-veterinary Professionals as stipulated by the South African Veterinary Council. The qualifications and experience of employees responsible for or involved in the care and husbandry of the animals that are used must also to be addressed clearly in the proposal. A veterinarian must be affiliated to the project so that he/she may be called in during an emergency and is aware of the project and its outcomes.

h) In the case where privately owned animals are used in a research project and where those animals remain under the responsibility of their owners, their employees or other personnel will continue to attend to the day-to-day tasks of treatment, care and welfare. The various responsibilities of the owner and the researcher in this regard must be stated clearly in the proposal. The owner should provide the researcher and Animal Ethics Review Committee with the details of the supervising veterinarian.

i) Researchers are obliged to submit annual progress reports to the Animal Ethics Review Committee. They need to inform the Animal Ethics Review Committee immediately if there are any unexpected adverse effects impacting on the animals resulting from the procedures and advice when a project is completed or discontinued. Annual progress reports should be submitted.

j) Research activities may not be performed before written approval has been granted by the Animal Ethics Review Committee.

k) The acquisition, care and use of animals for research purposes in South Africa must be done in accordance with the relevant South African legislation including the National Environmental Management: Biodiversity Act 101 of 2004, which aims to prevent bio-piracy of indigenous biological resources. The SANS 10386:2008 the use and care of animals for Scientific Purposes is a nationally accepted standard incorporated in certain provincial legislation and by which UNISA also abides.

3.3.2 Responsibilities of the institution

UNISA should ensure through the Animal Ethics Review Committee that all research projects making use of animals adhere to the standards and requirements of these guidelines which include to monitor, inspect and assess the acquisition, transportation, production, housing, care, use and disposal of animals (Refer to section 5 of the SANS). UNISA adheres to the implementation of the SANS: 20386:2008 the use and care of animals for scientific purposes standard, as it is a nationally accepted and recognised standard when doing animal research and has been accepted into certain provincial legislations.

3.4 Replacement

Techniques, models or systems that can replace the use of animals completely or partially must be investigated, developed and used.

3.5 Reduction

3.5.1 Reduction of the number of animals used in research studies means that only the minimum number of animals necessary to obtain valid information or results must be used.

3.5.2 Reducing the number of animals should not be considered if it means that they will suffer disproportionately.

3.5.3 An animal should not be exposed to repeated procedures unless it is essential for the purpose of the project.

3.5.4 The killing of healthy animals should be kept to the absolute minimum number required by the study.

3.6 Refinement

Refinement of animal sourcing, animal care and procedures means to minimise or eliminate physical or psychological distress imposed on the animals by the requirements of the research study.

3.6.1 Animals selected for a research project must be suitable for the specific purpose.

3.6.2 The care of animals should be according to species-specific needs in terms of behavioural and biological requirements.

3.6.3 Animals bred in captivity should be used for projects involving wildlife species where possible.

3.6.4 Researchers must be competent in the procedures their projects require or they must make use of a person competent in the procedures.

3.6.5 Project design must be aimed at the avoidance or minimisation of pain and distress.

3.6.6 Pain and distress in animals must be evaluated on the basis of relevant species-specific knowledge. In principle it must be assumed that animals experience pain and distress in a manner similar to humans and decisions regarding the animals' welfare should be based on this assumption.

3.6.7 Unpredicted pain or distress in animals should be alleviated immediately irrespective of the effect on the project. If alleviation is not possible, the animal should be euthanised without delay.

3.6.8 Any procedure that is carried out under anaesthesia or sedation in a medical or veterinary practice must be carried out using anaesthetics appropriate to the species and the procedure.

3.6.9 Appropriate pain management must be applied.

3.6.10 If the purpose of a procedure inhibits the use of anaesthetic or analgesic drugs to alleviate pain or distress, the procedures must be carried out in such a way as to minimise the degree of pain and distress and the duration thereof to which the animal is exposed.

3.6.11 Death as an end-point, that is, when the death of an animal is a deliberate measure used to evaluate biological or chemical processes, responses or effects, must be avoided as much as possible. If death as an end-point is unavoidable, distress should be minimised by choosing the earliest end-point that is compatible with the scientific objectives of the research study.

3.6.12 The duration time of exposure of animals to procedures for research purposes must be kept to a minimum.

3.7 Wildlife studies

This section refers to free-living vertebrates, native, non-indigenous or feral species including captive-bred animals and those captured from free-living populations. All research projects and scientific studies involving wildlife are subject to Animal ERC approval. In addition to the requirements and responsibilities listed above, the following is applicable to research involving wildlife:

3.7.1 As many wildlife species are protected by national and/or international laws, conservation authorities need to be consulted when these species are involved in the research, and permits must be obtained if required.

3.7.2 Observational studies of free-living animals must be designed in a way that any impact on the animal's wellbeing is minimised.

3.7.3 As field studies may cause disturbances of the environment or habitat and subsequently adversely affect target and non-target species, such disturbances should be minimised.

3.7.4 Studies and research projects must not be repeated unnecessarily. When repeated studies are proposed, the Animal ERC must decide whether the repetition is scientifically justified for the specific research purpose. Animal ERC approval is required every time a study is to be repeated.

3.7.5 Capturing, holding, transporting, handling and releasing free-living animals must be in accordance with the following conditions:

a) The relevant permits must be obtained and submitted when applying for ethics clearance.

b) Researchers must be aware that the effects of numerous stressors can be accumulative.

c) Potential sources of stress must be identified and the measures to be taken to minimise them must be addressed in the proposal.

d) Materials and equipment that are used during the capturing, holding, handling and transport of animals must be maintained in good condition and kept clean to avoid injuries to animals or to personnel handling them and to minimise the risk of disease transmission.

e) When wildlife is captured any distress caused to the captured animals and the populations from which they are taken must be minimised.

f) When capturing is applied for, the proposal must include details about the capturing method and about the skills of people involved in the process.

g) Handling, restraining and transportation of captured free-living animals must be appropriate to the species and be done in such a way as to minimise the risk of injury and/or stress-induced disease.

h) The holding time for captured animals must be as short as possible to achieve the envisaged scientific objectives. Holding of an animal must be done in such a way as to minimise stress and the risk of injuries.

i) Animals should be released at the site of capture unless an alternative site is rationalised in the proposal and approved by the Animal Ethics Review Committee.

j) Identification of individual animals must be done by using a method that causes the least distress and interference with the normal functioning of the animal without hindering the research outcome. Identification done for routine husbandry purposes does not require Animal Ethics Review Committee approval.

k) Research on wildlife interaction and behaviour includes interaction between species (e.g. predator-prey), within a species (e.g. competition) and between species and habitat. Ethical considerations regarding these studies are the degree of manipulation required and the effect of the researcher on the interaction. Proposals should address the wellbeing of the animals primarily targeted in the project,

as well as the other species that may be affected adversely by the research.

4. USE OF PLANTS IN RESEARCH

4.1 UNISA supports the following ethical principles when plant research is conducted:

4.1.1 all plant researchers abide by the stipulations of the National Environmental Management: Biodiversity Act 101 of 2004;

4.1.2 the SANBI red list of endangered species in South Africa will be followed to ensure the classification of the plant species in terms of whether they are endangered or not;

4.1.3 indigenous plant species will not be exploited nor will the indigenous knowledge related to the plants;

4.1.4 respect for the environment and or property from which plants or plant material is collected must be upheld.

4.2 Regulations

4.2.1 Where required, permits should always be sought for the transportation of plant material nationally and internationally.

4.2.2 Respect for the habitat should prevail when plant material is collected.

4.2.3 Only the quantity of plant material required to conduct scientific research should be harvested.

4.2.4 Collection of plant material should not endanger the existence of the species.

4.2.5 When agricultural research is done, cognizance should be taken of the above-mentioned points when plants are used for crop purposes.

4.2.6 Experimental designs used in agricultural research should not endanger the environment or persons involved in the research.

4.2.7 Care should be taken to ensure that crop experimentation does not endanger future crops due to toxic residue in the ground caused by a particular experimental design.

4.2.8 The termination of an agricultural trial should be considered in terms of the toxicity of the remaining ground in which the crop or plant trials had been conducted.

4.2.9 Water used in the irrigation of plant trials should not damage the environment or any person, animal or living organism during or after the experiment or trial;

4.2.10 If insects are bred or used during any crop- or plant-related research trials or experiments, all possible measures should be taken to ensure that the environment or any person, animal or living organism is not endangered in any way.

4.2.11 Spraying of crops or any plants should follow strict health and safety procedures.

4.2.12 Plant boxes or any horticultural plant containers should be returned to their original state to ensure that the contamination of any new plant-related experiments is minimized.

4.2.13 All rules, regulations and guidelines that are used to guide plant research in the horticultural centre at UNISA must be upheld at all times.

5. MOLECULAR AND CELL RESEARCH

5.1 UNISA abides by all relevant Acts that regulate molecular and cell research as well as biomedical research in South Africa. Researchers conducting any form of molecular and/or cell research should follow the principles of the Health and Safety Act and all regulations and guidelines.

5.2 Researchers should adhere to the following ethical principles when conducting molecular and cell research:

5.2.1 Laboratories should have particular Standard Operating Procedures (SOPs) for the procedures that will be undertaken in the laboratory.

5.2.2 Laboratories should ideally be accredited with the necessary documentation submitted as proof of accreditation.

5.2.3 Molecular and cell research projects should be registered with the relevant laboratory manager and a laboratory notebook/log book should be kept of all processes in the experiment.

5.2.4 Researchers should adhere to standard operating procedures that apply in the laboratory they are utilising.

5.3 Researchers should adhere to the following ethical principles when conducting genetically modified organism research:

5.3.1 In South Africa, the development, production, use and application of genetically modified organisms including viruses and bacteriophages are regulated by the Genetically Modified Organisms Act 15 of 1997. The Act defines a *genetically modified organism* as ”an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and ’genetic modification’ shall have a corresponding meaning”.

5.3.2 In order to comply with the provisions of the Act, research projects and scientific studies need to adhere to the following conditions:

a) Any institution or laboratory or similar facility where genetically modified organisms will be developed, produced, used or applied, must be registered in terms of the Act.

b) A permit in terms of the Act has to be obtained in the case of importing, exporting, producing, using, applying, releasing and distributing genetically modified organisms.

c) Institutions, laboratories or similar facilities may be authorised for the use of genetically modified organisms in a contained manner or in a trial release.

d) The researcher or supervisor of the study must provide evidence of his/her qualifications and experience in using genetically modified organisms.

e) A research proposal must contain a risk assessment in terms of the possible impact of the programme on humans and/or the environment. In the event of an accident involving genetically modified organisms, a copy of the written notification to the Registrar in terms of the Act must be submitted to the relevant Ethics Review Committee.

f) The liability for any possible damage caused by the use or release of genetically modified organisms should be addressed in the proposal.

g) The public must be adequately notified about the trial release or the release of genetically modified organisms if this forms part of the study.

h) Waste management and disposal procedures must be included in the proposal as part of the study.

5.4 Researchers should adhere to the appropriate guidelines when conducting biomedical experiments. Various categories of biomedical experiments exist that include specific types of research such as:

EXPERIMENTS

Category	Examples and Comments
Category A: Experiments involving no living materials or uses plants, bacteria, protozoa or invertebrate animal species	Biochemical, botanical, bacteriological, microbiological or invertebrate animal studies, tissue cultures, studies on tissues obtained from autopsies or from slaughterhouses, studies on embryonated eggs. Invertebrate animals have nervous systems and respond to noxious stimuli, and therefore must also be treated humanely and animal behaviour studies in the normal environment.
Category B: Experiments on vertebrate animal species that are expected to produce little or no discomfort	Mere holding of animals captive for experimental purposes; simple procedures such as injections of relatively harmless substances and blood sampling, physical examinations, experiments on completely anesthetised animals which do not regain consciousness; food/water deprivation for short periods (a few hours); standard methods of euthanasia that induce rapid unconsciousness, such as anaesthetic overdose or decapitation preceded by sedation of light anaesthesia and restraining animals for feeding of ticks and other blood sucking insect.

Category C:	
Experiments that involve some minor stress or pain (short duration pain) to animal species	Exposure of blood vessels or immolation of chronic catheters with anaesthesia; behavioural experiments on awake animals that involve short-term stressful vertebrate restraint; immunisation employing Freund's adjuvant; noxious stimuli from which escape is possible, surgical procedures under anaesthesia that may result in some minor post-operational discomfort. Category C procedures incur additional concern in proportion to the degree and duration of unavoidable stress or discomfort.
Category D:	
Experiments that involve significant but unavoidable stress or pain to vertebrate species.	Deliberate induction of behavioural stress in order to test its effect; major surgical procedures under anaesthesia that result in significant post-operational discomfort; induction of an anatomical or physiological deficit that will result in pain or distress; application of noxious stimuli from which escape is impossible; prolonged periods (up to several hours or more) of physical restraint; maternal deprivation with substitution of punitive surrogates; induction of aggressive behaviour leading to self-mutilation or intra-species aggression; procedures that produce pain in which anaesthetics are not used, such as toxicity testing with death as an end-point; production of radiation sickness; certain injections, and stress and shock research that would result in pain, approaching the pain tolerance threshold, i.e. the point at which intense emotional reactions occur. Category D experiments present explicit responsibility and the investigator has to explore alternative designs to ensure that animal distress is minimised or eliminated. Freund's adjuvant causes moderate to severe pain and inflammation and is considered to be a category D procedure.
Category E:	
Procedures that involve severe pain near, at, or above the pain tolerance threshold of unanaesthetised conscious animals	Use of muscle relaxants or paralytic drugs such as succinyl choline or other inflicting curariform drugs used alone for surgical restraint without the use of anaesthetics; severe burn or trauma infliction on unanaesthetised animals; attempts to induce psychotic-like behaviour; killing by use of microwave ovens designed for domestic kitchens or by strychnine; inescapable severe stress or terminal stress. Category E experiments are considered highly questionable or unacceptable irrespective of the significance of anticipated results. Many of these procedures are specifically prohibited in the national policies of some countries (e.g. the USA) and their use therefore may result in the withdrawal of funds and/or registration.

PART 4

GUIDELINES FOR COMMUNITY ENGAGED RESEARCH

1. PREAMBLE

1.1 Community engagement within academia is understood as the scholarly activity of partnering and engaging with communities to exchange mutually beneficial knowledge and resources to the benefit of all. It recognises that academics will share the privileged domain of “knowledge production” with community members. It blends more traditional forms of knowledge production with “lived experience”.

1.2 It is recognised that community engaged research such as community-based participatory research (CBPR) and participatory action research (PAR) are not methods of conducting research but are rather an orientation to research. Community engaged research can involve quantitative, qualitative, or combined data gathering methods depending on the issues under investigation. This orientation emphasises ownership, participation, access, control and possession by non-academic researchers/communities as values in the process of creating knowledge and change.

1.3 Community engaged research combines knowledge with action and social change.

1.4 Decisions arise from community context and the research foci of the research collaborations and partnerships. Often the collaborative enquiry is a precursor to an intervention or planned activity.

1.5 Although most of the scientific research methods used in PAR are not dissimilar from those used in other approaches, researchers may not be aware of the methods they will need to use until the research begins. Community-engaged researchers can often not anticipate the specific questions they will need to ask and methods they will use before becoming involved with the community of interest as these questions and methods may only be formulated after their entry into the community.

2. ABBREVIATIONS

CBPR	Community-based Participatory Research
CER	Community Engaged Research
PAR	Participatory Action Research

3. PURPOSE

3.1 Researchers need to demonstrate how they foresee the community participating in the identification of the specific issues to be researched.

3.2 Researchers must demonstrate how they will enable community members to contribute their resources to the research, such as local and indigenous knowledges and other pragmatic contributions. In this regard intellectual property rights will have to be negotiated and safeguarded.

3.3 Training community members needs to be considered with the aim of empowering them to participate in the research.

4. SCOPE

4.1 The cyclical nature of PAR might require researchers to seek ethical approval for each cycle of the research process if the enterprise is rated as being of moderate or high risk. In low risk interventions, the researcher must undertake in the initial application to ensure that all methods that are chosen will adhere to ethical standards and guidelines. It is understood that the committee cannot evaluate the scientific validity and ethical merit of a protocol that has not yet described its methods.

4.2 Integrity in CER expressed in the researchers' commitment to adhere to the recognised principles of community-engaged research and in honest and ethical conduct and dissemination of findings in the generation of knowledge.

5. FAIR SUBJECT SELECTION

5.1 Researchers must consider how the selection of certain research participants will aid them in achieving their research goals. It is recognised in community research that some stakeholders may drop out and others may join the project. The same ethical considerations must apply to all participants who form part of the collaborative research enterprise.

5.2 A concerted effort must be made by researchers to consider how the research participants will benefit from the research. They could also consider how the outcomes of the research could have wider applicability.

5.3 Beneficiaries should be directly involved in the research. Researchers need to carefully consider how and at what stages in the cycle the beneficiaries should be involved.

5.4 Barriers must be removed to enable participation by community members. Researchers should consider aspects such as flexibility in scheduling; the need by some participants for childcare; the cost of transport to research sites; etc.

5.5 A researcher must not discriminate in the selection and recruitment of actual or prospective participants by including or excluding them on the grounds of race, age, sex, disability or religious or spiritual beliefs except where these criteria is essential to the purpose of the research.

6. FAVOURABLE RISK-BENEFIT RATIO

6.1 Community-based research is specifically value driven in that in the process of doing research, it can focus on the emancipation of a wide range of exploited or oppressed groups.

6.2 The risks to the participants need to be proportionate to the possible benefits to individual participants or to the community in general.

6.3 The researcher needs to demonstrate how he/she will go about sensitising themselves to the culture and politics of the community.

6.4 Power plays itself out in community politics and research might have political consequences which will have to be mitigated by the researcher. The researcher needs to consider these risks.

7. INFORMED CONSENT

7.1 Informed consent in community-based research must include the provision of complete information about objectives, risks, and adverse effects on participants.

7.2 Informed consent must indicate the roles and responsibilities of participants and community stakeholders in the project.

7.3 Researchers must provide a fair and just representation of the research. They must caution against the overestimation of the benefits for the community and participants and should caution against formulation being biased to induce a positive answer.

7.4 Agreements must be made regarding the interpretation and ownership of data, authorship and the dissemination of findings and financial accountability.

7.5 The blurring of participant and researcher roles will necessitate special precautions for the protection of confidentiality.

7.6 Procedures should be put in place to ensure that the information provided is understood by participants, communities and stakeholders.

7.7 Researchers should place more emphasis on the information exchange and negotiation process between researchers and potential participants and these should be formalised in an informed consent form.

7.8 Potential research participants should be given the opportunity to discuss their decision with their families or peers.

7.9 Alternative ways to record consent if individuals do not want to sign a consent form but are willing to participate in the proposed research, should be sought. These can include using digital recordings of oral consent or signing a register.

7.10 In cases where the participants refuse or are afraid to sign a consent form or to be recorded, the researcher must keep a written record that participants have been informed, understood and accepted participation in the research but that they declined to sign.

7.11 In some cases, it might be important to obtain consent from respected, traditional or elected community leaders.

8. COMMUNITY INVOLVEMENT IN THE RESEARCH

8.1 Permission for research must be obtained from state authorities where needed but should not be confused with involvement of community bodies.

8.2 A ‘functional’ community body such as a community advisory board or a community committee should be involved in each research project. This can be an existing body or one created for the specific purpose of the project. At the minimum, the community should be consulted during the planning stage of the research, should be consulted on an *ad hoc* basis while the research is being done, and should be informed in a structured manner at the end of the research about the results.

8.3 Researchers must negotiate the method and particulars (i.e. authorship and co-authorship) of the release/dissemination of data (i.e. scientific journals or popular publications) with the community researchers. Researchers must consider the potential repercussions to the community if data (sensitive or not) is released prematurely or in an insensitive or any other manner.

8.4 Community participation needs to be ensured and it is important to be realistic about time and resource constraints.

8.5 UNISA should be careful not to "overuse" a well-engaged community by doing research in that community too frequently. The Community Engagement and Outreach Directorate (DCEO) will keep track of the communities where research and other projects are being conducted.

8.6 Where UNISA is providing an intervention as an outcome of any cycle of the research process as sole provider, it should be aware that the community may not feel able to refuse or criticise the results of the research and must guard against this risk.

Acknowledgements and Works Consulted

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