Chapter 13

Research ethical standard policy

Policy on research ethics for research on human beings, animals, environment and culture ensures that the rights and dignity of subjects involved in University research are protected. This policy aims to promote awareness of ethical principles and issues in the conduct of research activities thereby clarifying for researchers their ethical obligations. The core values of the University are based on commitment to the principles and values enshrined in the constitution of South Africa. The University is committed to upholding the highest ethical standards in a research community that is committed to the principles of quality and excellence, accountability, transparency, integrity, respect, diversity and social responsibility, community engagement and Ubuntu.

This policy prescribes the ethical framework for the University community within which all research should be conducted, while being mindful of the goal of developing an enabling environment for all learners and scholars in the pursuit of their studies in accordance with the principles of academic freedom

The policy is designed to support ethical standards at the University of Venda and provide guidelines for seeking approval of the University Research Ethics Committee for research projects. The policy does not replace existing codes of ethics of professional bodies and/or national legislation.

13.1 Scope

The policy on ethics with respect to the use of human, animal, environment, community subjects, shall apply to all University research and class projects. In addition, policy applies to research involving the use of University facilities by outside persons/agencies operating under an agreement with the University.

13.2 Definitions

i. University research project(s)

All research projects carried out by students and staff of the University of Venda or by outside agencies but using University of Venda's facilities.

ii. Class project(s)

A classroom project or research project assigned by the academic as part of the requirements for a qualification.

iii. Principal investigator and research assistant

A principal investigator is a staff member or any other researcher appointed by the University or a person who leads a team of researchers carrying out a research project. He/she could be supervising postgraduate students. This extends to a lecturer supervising a class project/practical.

iv. Research assistant

Students or other persons who are authorised by the principal investigator to carry out a research project.

v. Protocol

The description of the project to be submitted for clearance by the University Research Ethics Committee.

13.3 Human subjects

Research involving human beings as subjects is important for the advancement of knowledge in the sphere of human welfare and University research has made a substantial contribution to the welfare of society. The protection of the rights and dignity of all subjects by a policy statement of ethical standard and procedures is seen as an important aspect of research procedures.

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

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

13.3.1 The University policy on research ethics shall be binding upon all researchers and lecturers and the research projects of concern.

13.3.2 The University research projects referred to in this document are those involving the use of human subjects and these must be approved by the appropriate committees before commencement of the project where they involve -

(a) Personal or physical observation of or contact with a human subject or community.

(b) Eliciting personal information from or about a human subject, including use of personal records of an institution.

(c) Experimental therapeutic or non-therapeutic research on human subjects.

(d) Interviewing and interview procedures.

(e) The use in a new research project of stored confidential data originally collected by any of the preceding methods.

(f) The use of tissues of human origin.

13.3.3 Where class projects are involved, it is incumbent upon lecturers to make student investigators aware of the policy, procedures and ethical guidelines for use of human subjects in academic research. The Committee established to implement this policy has discretion in applying the ethical guidelines where exceptional circumstances or common sense dictate, provided that the basic principles underlying the policy are not compromised.

13.4 Ethical guidelines and information to human subjects

13.4.1 University researchers using human subjects will identify themselves to their subjects, that is, their association with the University.

13.4.2 Information to all subjects to facilitate their giving fully informed consent includes -

- the nature of the research, its purpose and usefulness
- a precise description of the procedures in which the subject will be asked to participate
- the anticipated personal risks, including direct physical, psychological or social learning
- the methods for protection of confidentiality and anonymity which will be observed by the principal investigator and other researchers in respect of the subjects participation as well as the legal limitations to anonymity and confidentiality.

13.4.3 The fact that the subject is free to withdraw from the project at any time, even after giving consent and after the project has commenced.

13.4.4 Where appropriate the subject should be provided with this information -

- the anticipated personal benefits derived from his/her participation
- the anticipated social benefits to the subject from his/her participation
- the extent to which risks in the project have been pre-tested and whether the project in which the subject will participate differs from pre-tested practice
- the anticipated risks to a larger social group or a third party
- the possibility that the data from this research may be stored and used for a different purpose in future without obtaining a new consent from the subject, if this is the case

- whether the results of the project will be available from the principal investigator when they are published
- the name of the person to who comments on the project may be directed.

13.4.5 If the subject is a child or a person under legal disability, full information must be provided to the legal guardian or curator.

13.4.6 Except where the principal investigator justifies an alternative method, the information set out in 1.2 and 1.3 will be presented to the subject in writing as part of the consent. Where the information is justifiably presented verbally, reference shall be made to a printed copy of the information.

13.4.7 Deception of human subjects

13.4.7.1 Where it is necessary for the principal investigator to withhold or to misrepresent significant facts in informing the subject, such deception must be expressly justified in his protocol. Particularly the protocol must demonstrate that-

- the deception is indispensable to the effectiveness of the project
- the deception must extend to all the elements as proposed
- all alternative investigative methods are unsatisfactory
- the deception will not invalidate the informed consent of the subject
- the subject shall be informed of all elements of the programme which were withheld or misrepresented by a member of the research team as soon as possible after participation in the project has been completed.

13.4.7.2 No protocol shall be approved where deception disguises or misinforms the subject of the risks, or in itself creates substantial risks to the subject's esteem and dignity.

13.4.8 Informed consent of human subjects

13.4.8.1. The information and consent forms will contain these elements -

- the name of the University and the principal investigator
- a brief but explicit description of the procedures the subject will personally participate in
- an explanation that the subject is free to withdraw from the project at any time, even after the consent is given and the project commences
- when a foreseeable risk exists, the consent form shall include an acknowledgement by the subject of the risks involved in the research and a waiver by the subject of any claims arising from the research.

13.4.8.2 Remuneration for participation as a subject in a University research project, if any, will depend on the time required of the subject and inconvenience caused, and will not be sufficient to induce the subject to disregard any risk interest in the participation.

13.4.8.3 Where the subject group is a "captive population" such as populations of correctional institutions, provision may be required in the protocol for receiving the consents of the institutional authority and the individual subjects and/or their legal guardians or curators. In respect of this guideline school pupils and students involved in a particular project may be considered as "captive populations".

Provision of informed consent is understood to include consent to publish findings subject to the requirements in receipt of subject confidentiality and anonymity.

13.4.9 Risks and benefits to human subjects

13.4.9.1 It is the responsibility of the principal investigator to demonstrate in the protocol, where appropriate -

- That the direct and indirect risks to human subjects of the proposed research has been carefully analysed, particularly where the subject population displays vulnerability by reason of age or mental capacity that consideration has been given to the risk of damages or offence to third parties who may identify with subject individual or groups for racial, cultural or sexual reasons, and to public sensitivity at large.

- That the principal investigator has explored the risk factor sufficiently in the protocol.
- Whether the benefits to the subject personally and the importance of the knowledge to be gained outweigh the risks inherent in the project.
- Whether risks have been minimised and provision made to remedy any harm.
- Whether the consent of the subject will encompass all foreseeable risk factors.

13.4.9.2 Procedures involving physiological intrusions of clear medical concern will be performed by a medically authorised person. No methodology will be approved which may subject the participants to short or long term change, unless such change is directly beneficial to the subject.

13.4.9.3 The Committee reviewing the protocol will observe caution in approving any methodology, which stimulates negative behaviour, such as anger, aggression or racial antagonism.

13.4.10 Privacy of human subjects

13.4.10.1 The University recognises and supports the freedom of persons and communities to reveal or withhold all information about themselves not already in the public domain, by deliberate and fully informed decision, and with the assurance that subjects' anonymity will be protected and all records of participation in the research project will be kept confidential.

13.4.10.2 The University Research Ethics Committee reviewing the protocol shall examine the proposed use of institutional records in a project. The Committee will consider the potential invasion of the privacy of the individuals whose records are to be used, and the advisability of obtaining consent from those individuals and the institutional authorities.

13.4.10.3 Consideration shall be taken of the privacy of third parties where the subject may be asked to disclose information or opinion about such third parties.

13.4.10.4 Mechanical methods of observation, such as television, camera, microphones and tape recorders may be used only with the consent of subjects and/or their legal guardians.

13.4.10.5 Use of student records will be consistent with the University's policy on privacy of student records.

13.4.10.6 Location of a University research project on a private properly must be disclosed in the protocol and approved in advance by the property owner (shopping centres and commercial businesses are private property).

13.4.10.7 A University researcher given access to a government or community institution or agency has a responsibility not to make public exposure of the conditions or practices with which the researcher disagrees without first reporting them to the responsible authority and giving reasonable time for an investigation to be made and a decision reached.

13.4.11 Anonymity of subjects and confidentiality of data

13.4.11.1 The subjects' anonymity shall be strictly protected and all data collection will remain absolutely confidential. Where the subjects have given written consent, information may be disclosed only with the strict limits of the terms of the consent.

13.4.11.2 Measures shall be taken to preserve the anonymity of the research subject, both in the published results of the project and in the records retained by the principal investigator.

13.4.11.3 Where confidential data are to be stored for possible re-use the method of recording and storing data must be strictly designed to confer anonymity on the subject.

13.4.11.4 All research assistants and persons having access to confidential data must be briefed by the principal investigator on the duty to observe the rules of anonymity and confidentiality set by the Health, Safety and Research Ethics Committee.

13.4.11.5 In a situation where a researcher acquires information on illegal activities or information relevant to a criminal investigation, such a researcher may be called as a witness in court proceedings and can be compelled to make full disclosure of such information received. Principal investigators should appraise all researchers associated with the project of the legal implication in this connection.

13.5 Animal research ethics

University staff, intending to make any use whatsoever of animals in their work, whether in research or for teaching purposes, are required to apply to the Research Ethics Committee for ethical clearance by submitting an application on the appropriate form. A sub panel of experts will be formed to review the protocol. The term "Animals" in this framework policy refers to all animals having the power of sense perception or sensation.

The use of animals in scientific research can only be justified if the benefits to both humans and animals outweigh the potential harm to the animal subject. All research and teaching involving animals must be approved by the Research Ethics Committee before the research commences, so that a formal evaluation of the potential harm/benefit equation can be undertaken.

"Justification for causing psychological or physical distress, illness or pain to animals should not be based on any explicit or implicit assumption that non-human animals experience these conditions in qualitatively different ways to humans." (Medical Research Council guidelines)

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

- Replacement of so-called "sentient" animals wherever possible, with "non-sentient" research models or systems to eliminate the use of animals that can experience unpleasant sensations.
- Reduction of the numbers of animals in experiments by design strategies that facilitate use of the smallest number that will allow valid information to be obtained from the study.
- Refinement of animal sourcing, animal care practices and experimental procedures to eliminate physical and psychological distress within limitation imposed by the objectives of the research.

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

13.6 Humanities and social sciences research and community engagement ethics (non-biomedical)

Research involving human subjects in the collection or sourcing of information and is non-invasive, requires ethical clearance from the University Research Ethics Committee.

This includes the use of communities and cultural areas. Ethical clearance is mandatory before seeking permission from local authorities or traditional leadership. The same principles described under human subjects apply. Application is to be made on the appropriate application form.

13.7 Research involving environment and bio-safety

Projects involving hazardous biological or chemical materials will be reviewed by a subpanel consisting of the experts in biosafety, in addition to the usual ethical review. The University's Health and Safety Committee may be consulted as well. The subpanel will also review research involving environmental matters and genetically modified organisms.

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

All research involving genetically modified organisms or research that poses a risk to the natural environment or the researcher and supporting staff, must be submitted to the Committee for review and approval. This includes -

- all research involving recombinant DNA techniques or genetically modified organisms
- research involving organisms that are pathogenic to humans and/or animals
- research involving radiation
- research which may potentially cause harm to the natural environment.
- Bio-hazardous research involving humans or animals will be reviewed by the applicable panel, unless specifically referred to this committee, after the initial review.

The researcher is ultimately responsible to apply for ethics approval for a given project and should make this decision after discussion with peers, the head of the department, which will refer the matter to the chairperson of this committee for a decision, if necessary. Researchers are also responsible for registering the use of bio-hazardous materials in compliance with the relevant act as per regulations. The evidence of registration should be filed at the Research and Innovation Office.

13.8 The researcher – client/sponsor relationship

It is recognised that the researcher has the right to receive an explicit research mandate from the sponsor/client. These conditions apply -

- There shall be no interference from sponsors or clients that may jeopardise the scientific integrity of the study or prejudice the interests, health or dignity of the subject.
- Information that may reveal the identity of the human subjects may not be supplied to the sponsors/client unless this was in the original proposal and was part of the informed consent given by the subjects.

13.9 Ethical clearance application procedures

13.9.1 The University's Research Ethics Committee

- The University's Research Ethics Committee shall be a subcommittee of the Research and Publications Committee.
- Membership: The Committee shall comprise of these experts –
- Deputy Vice Chancellor: Academic ex officio.
- Director Research and Innovation, ex officio and secretariat.
- Eight researchers elected by Senate and experts in human research, animal research, human and social sciences research, biosafety, legal and human rights, community responsibility, diversity and environmental issues.
- Two external members - one professional from health research and another from the community.
- The Committee members shall elect the chairperson for a three-year term.
- Membership of the Committee shall be for an initial three-year term but a member may be re-appointed.
- The Director of Research and Innovation and the chairperson appoint the subpanels or ad hoc members to deal with a particular protocol.
- The four subpanels are human and clinical trials, social research, animal research and environment and biosafety.

13.9.2 Functions and responsibilities of the Research Ethics Committee

(a) The University's Research Ethics Committee though its subpanels shall review protocols submitted for University research projects and class projects to ensure that the use of human subjects meet the ethical standards of the University where the projects -

- Involve application for external funding or for internal grant administered by the University.
- Is a University research or class project, which is funded internally or does not require funding.
- Involve an application to an institution or organisation to use its members, who are legal minors, as human subjects.

The Research Ethics Committee may approve the protocol of a project or recommend amendments to the protocol in consultation with the principal investigator, where there is a perceived discrepancy between the protocol and the standard guidelines. The Committee may also require a project to be monitored in such manner as deemed appropriate.

(b) The approval of the Research Ethics Committee constitutes the approval of the ethical standard of the University when required by a funding agency or sponsor.

(c) The Research Ethics Committee shall refer the matter to the Research and Publications Committee or Senate where -

(i) The principal investigator is not prepared to alter the research protocol to conform to the ethical guidelines of the University and the principal investigator wishes the decision of the Committee to be reviewed.

(ii) A minority of the Committee wishes to register dissent from the approval given by the Committee, of a protocol.

(d) The Research Ethics Committee shall investigate and attempt to satisfy objections to ethical standards in any ongoing or completed project submitted for review by the Committee. In a case where the dispute cannot be resolved the matter shall be referred to the Research and Publications Committee or Senate.

(e) The Committee shall clarify and interpret the policy procedures and ethical guidelines and, where necessary, may recommend procedural or policy changes to Senate when necessary and will provide appropriate information to staff.

(f) The Director of Research and Innovation will provide secretarial support for this Committee through the administrators. The office will be responsible for preparing agendas for meetings and minutes.

(g) The Directorate shall produce an ethical clearance certificate using the format agreed upon.

13.9.3 Request for ethical review

- The project supervisor shall apply, using the appropriate form for approval of a University research project or class project involving human subjects or the handling and use of animals in research as described -
  - The principal investigator shall submit a protocol to the Research Ethics Committee at least four weeks in advance of the proposed date of the commencement of the project.
  - Where the project involves an application for external funding or for internal grants from the University, the principal investigator shall submit the protocol at least five weeks in advance to the deadline date of submission of application to the sponsor. The designated University authority will process only such applications that have been cleared by the University Research Ethics Committee.
  - Where a University research project or a class project involves application to a University or school board to use pupils as subjects, the principal investigator shall submit the protocol to the Research Ethics Committee at least four weeks in advance of the deadline date for receipt of application by the school board.

13.9.4 Appeals

- Where a decision of the Research Ethics Committee is appealed by the principal investigator or by dissenting member of the Committee, the Committee shall record the reasons for the decision of the Committee under appeal and the written dissent, if any.
- Where any objection to an ongoing or completed University research project is not resolved, the matter may be taken on appeal to the Research Ethics Committee.
- On appeal, the Research Ethics Committee shall invite the principal investigator to support his project but the deliberations of the Committee will be held in camera.
- The Research Ethics Committee may confirm or modify the decision previously taken regarding the matter on appeal.

13.10 Project report

The principal investigator must submit a brief report of every research project granted ethical approval. The report must include this information -

- Title of project, researchers, ethical approval number, brief summary of results, conclusion, whether there were any unforeseen and desirable consequences and if so the steps that were taken to rectify them, whether the results have been published and if so the full reference.