GUIDELINES

FOR

RESEARCH ETHICS REVIEW

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1. TITLE	GUIDELINES FOR RESEARCH ETHICS REVIEW
2. APPROVING AUTHORITY	SENATE
3. FIELD OF APPLICATION	RESEARCH
4. COMPLIANCE OFFICERS	ALL VUT STAFF AND STUDENTS
5. STATUS OF POLICY	NEW
6. REVIEW DATE	JUNE 2012
7. STAKEHOLDER CONSULTATION	SENATE & FACULTY BOARD, EMC, IF
8. DESIGNATION OF POLICY OWNER	EXECUTIVE DIRECTOR: RESEARCH
9. OTHER POLICY	THIS POLICY TO BE READ IN CONSULTATION WITH THE RESEARCH POLICY

1. POLICY INTENTIONS

VUT values

VUT recognizes injustices in our past and subscribes to the values enshrined in the Constitution of the Republic of South Africa Act, No 108 of 1996:

> *The Republic of South Africa is one, sovereign, democratic state founded*
>
> *on the following values:*
>
> *(a) Human dignity, the achievement of equality and the advancement of human rights and freedoms.*
>
> *(b) Non-racialism and non-sexism.*
>
> *(c) Supremacy of the constitution and the rule of law.*
>
> *(d) Universal adult suffrage, a national common voters roll, regular elections and a multi-party system of democratic government, to ensure accountability, responsiveness and openness.*

2. POLICY AIMS AND OBJECTIVES

2.1 Ethics is an integral part of every research project but more critically, ethics is vital for improving the quality and integrity of research results.

2.2 The research ethics review system in the VUT aims to protect all actual and potential human participants, animals, other living or genetically modified organisms, and contribute to the highest attainable quality of scientific and ethical research.

2.3 VUT, having committed itself to safeguarding the rights of all potential and actual human research participants, animals, other living or genetically modified organisms, undertakes to provide administrative, financial and other forms of support for the ethics review system.

2.4 The research ethics review system gives expression to the standards and values that apply in VUT and to which all VUT researchers commit themselves in their research.

2.5 The VUT Policy on Research Ethics serves as the fundamental guide for ethics review. Other local and international guidelines may be used by the Ethics Review Committees in VUT.

3. INTERNAL POLICY OWNER

3.1 The Executive Director: Research takes ultimate legal responsibility for the proper application of ethics review at VUT. He/she ensures that the Guidelines for Ethics Review are publicly available at the VUT Research Directorate and registers all research that has obtained ethics clearance.

3.2 Revision of the Guidelines for Ethics Review may be initiated by any Ethics Review Committee in VUT. Revision must be done through the broadest and most transparent process possible, and any changes must be disseminated widely. The Executive Director: Research is the officer responsible for revision.

4. BASIC ETHICS CODES OF BEHAVIOUR

Values and principles

The following values and principles should apply to any research programme:

4.1 *The participant as a person*

Respect for the autonomy of the participant, whether patient or volunteer, demands that the participant must be treated as a unique human person within the context of his or her community system. Freedom of choice must be safeguarded.

4.2 *Human Rights*

Respect for the basic rights of the individual as a human being as well as the rights of groups and communities.

4.3 *The ethics of justice, fairness and objectivity*

Research should always respect the dignity of people involved and should never expose them

to intentions and motives not directly attached to the research project, its methodology and objectives.

4.4 *Competence*

Researchers must be professionally and personally qualified. In all circumstances they must be accountable and act in a responsible manner. Professional standards should be upheld in accordance with academic training.

4.5 *Integrity*

Integrity should be promoted by being honest and fair. Researchers must be honest about their own limitations, competence, belief systems, values and needs.

4.6 *Sensitivity*

Sensitivity in research implies balancing scientific interest (the research) with general values and norms affecting the human dignity of the people involved.

4.7 *Confidentiality*

Confidentiality must be respected under all circumstances. Documentation should be safeguarded and viewed as strictly private in terms of the limits set by the research project

4.8 *Demarcation of roles*

There should be mutual understanding of the roles and interests of investigators and participants in research.

4.9 *Communication*

Clear and understandable verbal communication is required, with factual data. Emotional and cultural values should be considered.

Caution

Possible dangers to be taken into consideration

- *The danger of objectification and fragmentation*

Special care must be taken not to treat a participant as a mere object. Research objectives are subordinate to the following principle: to treat human beings with respect.

- *The danger of direct or indirect coercion*

Direct or indirect coercion of people in the name of research must be avoided under all circumstances. Coercion may include the exploitation of vulnerable people; taking undue advantage of a participant, volunteer or any other person; or the misuse of the authority and influence of the research.

5. TYPE OF RESEARCH REQUIRING ETHICS REVIEW COMMITTEE (ERC) APPROVAL

Restriction

Researchers may not undertake research involving humans, animals or other living or genetically modified organisms (the Materials) without the prior approval of the ERC, if the research:

- is done on the premises of VUT or if it uses VUT facilities,
- involves VUT employees or students, in various capacities including collaborative or multi-institutional or multi-country studies, or
- will be funded from VUT funds or if funding for it was acquired through VUT.

Obligation

The Materials shall be used solely for non-commercial research purposes to carry out Research Projects at the VUT's facilities under the direction of the Researcher.

It is expressly understood that the Materials will at all times be used in accordance with applicable laws and regulations.

The Researcher understands that no rights are provided under this Policy to use the Materials for the provision of a commercial service or to use the Materials on behalf of any commercial entity or for use in consulting for a commercial entity under which that entity obtains rights to research results.

6. INDEPENDENT NATURE OF ETHICS REVIEW COMMITTEES (ERC)

6.1 ERC is an independent body comprising members who have the ability to undertake thorough, competent and timely reviews of research proposals. For the purpose of this Policy they must act independent from political, institutional, professional and market pressure.

6.2 The ERC is different from a scientific or technical review committee. While the ERC examines the adherence of the research to ethical principles, the scientific or technical review committee looks at its scientific and technical quality. Membership in committees may overlap but the ethics review must be independent of the scientific review.

6.2.1 It is beneficial for the work of the ERC to maintain active links with the scientific or technical committee, especially because some methodologies or research designs while technically sound, could involve ethical dilemmas. ERC may seek the advice of experts or of the scientific or technical committee when in their view this will help them in the discharge of their functions.

7. INFORMED CONSENT
(the legal and moral justification for research involving human subjects)

7.1 *Informed Patient Consent is essential*

Section 12(2)(c) of the Constitution of South Africa, Act No 108 of 1996, provides that:

> *Everyone has the right to bodily and psychological integrity, which includes the right. not to be subjected to medical or scientific experiments without their informed consent.*

A literal interpretation might mean that only competent persons who are capable of giving consent to clinical research, whether therapeutic or non-therapeutic, interventionist or observational, may be research participants.

The wording used in the South African Constitution is identical to that used in the United Nations Covenant on Civil and Political Rights (1966), which is binding on the states that

are party to it. It may therefore be argued that section 12(2)(c) may be interpreted in a fashion similar to the interpretation given to the Covenant by those states.

7.2 *Form of consent*

In the absence of compelling reasons to the contrary, written information and informed consent forms should be the norm for health research interventions.

7.3 *Requisites of consent*

7.3.1 *Capacity to consent*

Consent must be given by someone who is legally and factually capable of consenting. Where a person, on account of age or physical or mental condition, is incapable of consenting to the proposed research procedure, proxy consent (consent by someone who is legally authorized to act on behalf of the incompetent person) must be procured. With regard to competence to consent and proxy consent, two broad categories of research participants must be distinguished.

7.3.1.1 *Adults*

Provided they are sane and sober, adults have the capacity to give valid consent to clinical interventions. Categories of adults whose competence to consent could be compromised under certain circumstances, are the following:

7.3.1.1.1 The mentally ill or mentally handicapped

Section 60A of the Mental Health Act, No 18 of 1973, provides for consent to clinical interventions (which would include research of a *therapeutic* nature) on institutionalized mentally ill patients. It provides that where a mentally ill patient is incapable of consenting to medical treatment or to an operation, the following persons, in order of precedence, may give written consent to the treatment or operation: a curator, the patient's spouse, a parent, a major child or a brother or sister. In the absence of such persons, or where they cannot be found after reasonable inquiry, the superintendent of the hospital where the patient finds himself or herself may give written consent. The superintendent must be convinced, on reasonable grounds, that the patient's life is in danger or that the patient's health is being seriously threatened by his or her condition, and that the treatment or operation in question is necessary.

Section 60A confirms the viewpoint that the individual mentally ill patient's competence to consent to medical treatment or to an operation depends upon whether, in fact and in the circumstances, the patient has the ability to appreciate the issues involved.

Section 60A, however, does not cater for consent to the medical treatment of, or an operation on, a mentally ill patient who is not institutionalized, but is in private care and has neither a curator nor relatives to consent on his or her behalf. Under these circumstances, an application should be made to the High Court for the appointment of a curator.

Should a mentally ill or mentally incapacitated patient be incapable of consenting to *therapeutic* research, proxy consent is permissible only where the proposed research pertains, directly or indirectly, to the mental illness or mental defect from which the patient suffers. In addition, the consent of the patient should be obtained, provided that the patient is mentally able to comprehend the issues involved.

Non-therapeutic research on incapacitated persons would not be permissible, with the following exception: proxy consent may be obtained for:

i. Observation research of a non-therapeutic and non-invasive nature, as there is no risk and no interference with the integrity of the incapacitated person, provided that the research entails no more than negligible distress or discomfort to the incapacitated person involved;
ii. Observation research of a non-therapeutic and invasive nature, provided that normally no more than negligible risk is foreseeable or known from routine medical practice, and that distress and discomfort are negligible.

In addition to the above, the following requirements must be met in non-therapeutic research:

i. the research pertains, directly or indirectly, to the mental illness or mental defect from which the person suffers;
ii. the consent of the person is sought. An objection by the incapacitated person is decisive;
iii. research involving incapacitated persons significantly benefits persons of the same category as the research participant;
iv. the same scientific results cannot be obtained by other methods, or by research on persons who do not belong to this category.

8. TERMS OF REFERENCE OF ETHICS REVIEW COMMITTEE (ERC)

8.1 *Status of ERC*

The ERC has independent status at VUT and is not attached to or based in a single department or unit in VUT. It is a subcommittee of the Senate Research Committee. The independant nature of the ERC is of crucial importance in the proper regulation of research.

8.2 *Main roles of Ethics Review Committee (ERC)*

The main role of ERC is to promote the conduct of ethical research in VUT. In particular they contribute to safeguarding the dignity, rights, safety, and wellbeing of all actual or potential research participants and communities, as well as animals, while taking into account the interests and needs of researchers and the integrity of VUT. Reviews research protocols and ongoing research that require its action.

In particular, the ERC is responsible to

- Provide guidance to researchers on the ethical aspects of their work.
- Develop and propose policies to enhance and facilitate ethical research and ethics review in VUT, including those which are necessary for building capacity in ethical research and ethics review.
- Review the VUT Policy on Research Ethics as the need arises.
- Provide advice to the Executive Director: Research on matters pertinent to research ethics.
- Review research which:
  Involves Faculties, Institutes, Centers and Technology stations. Basic ethical principles for research remain the basis for resolving issues.

8.3 *Objectives of ERC*

The objectives of the ERC are the following:

i. To maintain ethical standards of practice in research;
ii. To protect research participants and investigators from harm or exploitation;
iii. To reserve the research participant's rights, which take preference over society's rights;
iv. To provide reassurance to society that this is being done.

v. In promoting these objectives, ERC should remember that research benefits society and that

they should take care not to hinder it without good cause. Investigators should be assisted to achieve a high standard of research ethics, if necessary by being provided with basic training in research ethics. ERC also protect investigators from unjustified criticism. International guidelines on human research indicate that an ERC should consider that:

- The objectives of research are directed to a justifiable advancement in knowledge

  compatible with prevailing community interests and priorities;
- Interventions are justifiable in terms of these objectives.

9. COMPOSITION OF ETHICS REVIEW COMMITTEE

9.1 Chairpersons of the Faculty Research Committee serve ex officio on the VUT ERC.

9.2 Regular membership of the ERC is between 5 – 11 members. The regular members of ERC should come from different academic disciplines and sectors. The membership may comprise:

- Scientists or researchers
- Person(s) with competence in law
- Person(s) with competence in research ethics
- Lay person(s) including representatives of interest groups such as groups for consumer rights, animal welfare, indigenous peoples' rights and environmentalists.

9.3 Membership on *ad hoc* basis

9.3.1 In addition to the regular members, members may be appointed on an ad hoc basis by the Executive Director: Research to provide the ERC with impetus and special expertise or guidance not adequately available in its regular membership, e.g. representatives of special groups or communities. The duration of their membership in the committee must be based on the need of the ERC for their special expertise.

9.3.2 The ERC must exert efforts to include a representative of the population which will be studied. If this is not possible, the ERC must invite persons who are knowledgeable about the culture, history, social dynamics and vulnerabilities of this population and who can speak on their behalf.

9.3.3 If, in the view of the ERC, human populations will be affected by particular agricultural science research, the committee must exert efforts to include a representative of the populations that will be potentially affected. If this is not possible, the ERC must invite persons who are knowledgeable of the culture, history, social dynamics and vulnerabilities of this population and who can speak on their behalf.

9.3.4 Where appropriate, e.g. where animals or plants are involved, ERC membership must include persons who are knowledgeable in appropriate fields, including animal welfare, environmental or ecological principles, and nature conservation laws.

9.4 The ERC at VUT should strive for balanced representation in terms of gender, race, and discipline.

10. OFFICE BEARERS OF ETHICS REVIEW COMMITTEE

10.1 *Chairperson*

The chairperson of the ERC is the Executive Director: Research and the committee is elected for a term of three years.

10.2 *Secretary*

The ERC is provided secretarial and administrative assistance.

11. FUNCTIONS OF OFFICE BEARERS

11.1 *Chairperson*

11.1.1 The chairperson is the presiding officer and overall administrator of the work of the ERC.

11.1.2 The chairperson is responsible for:

i. Ensuring that the records and documents of the committee are secure and, in appropriate cases, kept confidential;
ii. Documenting adequately and in a timely manner all documentation of committee meetings and deliberations;
iii. The recording of receipts of applications, documents submitted and other transactions of the ERC; and
iv. The chairperson will report to CRC bi-annually.

11.2 *Secretary*

The secretariat is responsible for:

11.2.1 preparing communications regarding the listing of each received and approved document, the frequency of continuing review, and other obligations of the investigator or researcher;

11.2.2 stamping approval and expiry date on every page of the consent form;

11.2.3 obtaining signature of chairperson;

11.2.4 keeping records and receipts;

11.2.5 organising and maintaining a registry of research proposals reviewed by the ERC;

11.2.6 submitting all research that obtained ethics clearance to the Research Directory for registration;

11.2.7 signing a confidentiality agreement;

11.2.8 executing other tasks assigned by the chairperson.

12. MEMBERSHIP OF ETHICS REVIEW COMMITTEES

12.1 *Appointment*

12.1.1 Members of the ERC, including those who do not have appointments as employees of VUT, are appointed by the Executive Director: Research and have a term of office of three years with possible reappointment. It is essential that members serve on the Committee as individuals and not as delegates taking instruction from other bodies or reporting to them.

12.1.2 To ensure continuity in the workings of the ERC, as well as utilize accumulated experience and wisdom, the term of office of regular members of the ERC is rotated.

12.1.3 Pending general arrangements for training, new members should be provided with core literature for their induction.

12.2 *Conditions of appointment*

12.2.1 ERC members should be willing to have their names and affiliations made publicly available.

12.2.2 ERC members should sign a confidentiality agreement regarding meetings, deliberations, applications and related matters.

12.2.3 Only members who are not appointed as employees of VUT may receive honoraria for work on the ERC, and all reimbursements and payments received in relations to their work in the ERC committee.

12.3 *Resignation*

12.3.1 A member who can no longer serve on the committee must resign in writing.

12.3.2 A vacancy should be filled within one month after resignation. The chairperson of an ERC recommends people to fill vacancies to the Executive Director: Research.

13. MEETINGS

- The ERC meets every three months or more frequently if the need arises.

- It may decide to meet regularly *"en banc*" or as subcommittees. However, in instances where
  there is disagreement among members regarding action on applications, or whenever the need arises, the chairperson may call for an en banc meeting.

- A simple majority of regular and ad hoc members constitutes a quorum.

- Members must be furnished with all documents 7 days prior to a meeting which will then be deliberated on at the meeting.

- The ERC may decide to divide the members into subcommittees to review research proposals. This is particularly pertinent to ERCs that have a considerable volume of proposals and/or a diversity of research fields to review. Alternatively, it may decide to review the research proposals *en banc*.

- For all the members of the Committee to be given the opportunity to express their views, it is important that meetings be held according to correct procedure.

13.1 *Voting rights*

13.1.1 When a vote is required to arrive at a decision, a simple majority of members present suffices. However, any dissenting opinion must be adequately recorded and kept.

13.1.2 All regular and ad hoc members are entitled to vote. Each member has one vote.

13.1.3 The chairperson has a casting vote when there is a tie.

13.1.4 No member who has not reviewed the application can vote on that application.

13.2 *Timely decisions*

13.2.1 To ensure complete and correctly accomplished applications the ERC must communicate to applicant(s) its action or decision within fourteen days after the meeting where the application was decided on.

13.2.2 Applications with incomplete or incorrect documents must be returned no later than fourteen days after receipt of the application. Inadequacies in the application must be clearly identified in the communication to researchers.

13.3 *Possible decisions*

The ERC can make any of the following decisions on applications:

- Approved
- Require modifications
- Request further information or clarification, or
- Rejected with reasons

13.4 *Reports*

ERC committee should submit a regular report, at least annually, to the EMC. In addition to a list of members, number of meetings and any other obviously relevant matters it should include a list of the titles of projects approved. The reports shall be available for inspection by the public. The only exception to public inspection may be to protect commercial interests. However, company names and product trade names may be included with the consent of the company. A full record of such commercial research must, however, be kept by the committee secretariat.

13.5 *Conflict of interest on Ethics Review Committee*

13.5.1 Only members without conflict of interest with the research under review may participate in the deliberations and vote.

13.5.2 There is conflict of interest when a reviewer has an interest relative to a specific application for review and such interest can compromise his/her ability to make a free and independent evaluation. Conflicts of interest may arise, for instance, when the reviewer has financial ties to the project.

13.6 *The Chairperson*

The Chairperson shall decide whether the interest disqualifies the member from the discussion. Where the Chairperson has an interest, the Deputy Chairperson should take his or her place. Anyone with a conflict of interests may not take part in the discussion or decision-making and this should be recorded in the minutes of the meeting. Members with a conflict of interest should recuse themselves when that protocol is discussed.

14. PROCEDURE AND REQUIREMENTS FOR ETHICS REVIEW

14.1 *Submissions*

Two copies each in English of the following must be submitted to the ERC:

i. Complete research proposal. The proposal which is submitted for scientific or technical review must be the same as that submitted for ethics review.
ii. Completed application for review form.
iii. Proposal summary sheet.
iv. Documents related to the proposal.

14.2 *The application for review form:*

i. Researchers' names, affiliations, addresses and contact numbers.
ii. Organisation(s) or institution(s) involved in the study.
iii. Sponsors or funders.
iv. Other pertinent information such a conflict of interests. There is conflict of interest when the researcher has an interest in the research that may jeopardize his/her ability to undertake the research in a scientific and ethical manner.

14.3 *The proposal summary sheet:*

i. Title of the proposed proposal.
ii. List and definitions of acronyms and abbreviations.
iii. Name(s) of principal investigator(s)/researcher(s). If this is a student, a letter of confirmation
from VUT must be included.

iv. Names and addresses of all sponsor(s) or funder(s).
v. Abstract of the proposal in nontechnical language
vi. Research objectives
vii. Inclusion or exclusion criteria (if applicable)
viii. Withdrawal or discontinuation criteria (if applicable)
ix. Methodology or research design
x. Activity plan or time line

xi. Safety procedures and criteria (if applicable)
xii. Description of procedure of reporting to ERC
xiii. Description of how participants will be informed of the findings or results and consulted on potential or actual benefits of such findings or results to them and others
xiv. Description of the risks of the procedures which participants may/will suffer (e.g. no risk, discomfort, pain, stigmatization, negative labelling/other potential risks) as well as the level of risk. See paragraph 14.10 below.
xv. The type of participants.
xvi. Place where research is to be undertaken.

14.4 *The proposal-related documents:*

i. Participant information sheet (if applicable)
ii. Description of the process for obtaining informed consent
iii. Informed consent form in English and in the language of the potential participants. The language should be understandable to a lay person.
iv. Description and/or amounts of compensation including reimbursements, gifts or services to be provide to participants (if applicable)
v. Description for arrangement for indemnity (if applicable)
vi. Description of any financial cost to participants (if applicable)
vii. Description of provision of insurance coverage to participants (if applicable)
viii. Description of steps to be undertaken in case of adverse event or when injury or harm is experienced by the participants attributable to their participation in the study.
ix. Statement agreeing to comply with ethical principles set out in the VUT Policy on Research Ethics.
x. Disclosure of any previous ethics review action by other ethics review bodies (if applicable)
xi. Research instruments such as questionnaires, interview guides and similar documents
xii. Research budget
xiii. Project agreement (e.g. MOA)
xiv. CVs of principal investigators
xv. Letter(s) of permission from relevant bodies (if applicable)

14.5 *Steps for reviewing proposals*

14.5.1 After members have reviewed the proposal and related documents they make a summary of the proposal and documents using the Assessment Form.

14.5.2 They then write their decision on the appropriate page of the Assessment Form. If the decision is “disapproved” they must write the reasons for the disapproval. If the decision is “modify” the items for revision must be clearly indicated in the Assessment Form.

14.5.3 Reviewers should as far as possible provide researchers with suggestions for meeting the ethical requirements for the research, especially if the research is deemed to be significantly beneficial to society or has strong social justice merits. However, the justice merit of the research cannot on its own be used to approve an ethically defective proposal.

14.5.4 VUT recognizes the rights and freedom to have access to research findings and information and always acknowledge the individual; however the individual and other institutions' rights will be protected according to the SA Constitution.

14.5.5 The members' views are discussed at the meeting and a decision reached in accordance with paragraph 11 above.

14.5.6 Any member can request the chairperson to invite the investigators and/or funders to elaborate or explain certain aspects of the proposal.

14.5.7 The chairperson must communicate the decision of the ERC to the applicant in writing. This must include a clear explanation if the decision is negative or if revisions are required.

14.5.8 Research which involves external institutions as well as the participation of employees or students from VUT must be reviewed by the ERC.

14.6 *Expedited review*

14.6.1 One or more of the following serves as conditions for the Committee to expedite Research Ethics:

- Minimal risk
- No vulnerable population
- Informed consent
- Using existing data or commonly available public data
- Information is recorded so that subjects are not mentioned
- No extraction of blood or human experimental procedures
- Minor revisions after previous conditional approval

14.6.2 The chairperson and Deputy Vice-Chancellor: Academic & Research will review the proposal. If it is a resubmission, previous reviewers should be nominated. The reviewers examine the proposal and documents.

14.6.3 The chairperson circulates the reviewers' decision and comments to the rest of the members of their decision. If a consensus cannot be reached or a member expresses some concerns, the proposal must be given a full review. An en banc meeting of the ERC may be required.

14.6.4 The chairperson then communicates the decision to the researchers.

14.7 *Ongoing review*

14.7.1 The ERC evaluates ongoing research that it has previously approved.

14.7.2 Principal investigators must submit in writing the following to the ERC:

i. Report of any adverse event (that is, harm or injury suffered by participants that is attributable to the research such as physical harm, psychological or emotional stress, financial loss and social ostracism or stigma) including a detailed description of the event, measures taken to address it and the outcomes. This report must be submitted as soon as possible, but not later than fourteen days after occurrence of the event.

ii. Report of any ethical problems encountered including a description of how these were addressed. This report must be submitted every two months after commencement of the research.

iii. Any changes in the research design including methodology.

iv. A terminal report describing the actual procedures for taking informed consent and any other ethics-related procedures, including the steps taken to ensure that participants are informed of the findings and consulted on how the findings can benefit them or others.

v. For long-term research and highly sensitive research the ERC can require a progress report on a regular basis for renewal of approval.
vi. Relevant to (iii), any envisaged change in the study design or methodology that has potential or actual ethical repercussions must first be approved by the ERC.

14.7.3 It is the duty of researchers to inform the ERC in writing as soon as possible in the case of premature termination of the study. The information should include an explanation of the premature termination, including an explanation of measures taken to protect the participants against any adverse effects of the premature termination.

14.8 *Review fees*

14.8.1 A standard review fee, the amount to be set by the VUT ERC, may be charged for exclusively external research of all research which is externally funded. The fee is payable upon submission of the proposal for review.

14.8.2 Monies thus collected may be spent on the operation of the ERC.

14.9 *Vulnerability and risks*

14.9.1 It is the duty of reviewers to identify whether or not the research will involve vulnerable persons of groups and to ensure that adequate protective measures are provided for.

14.9.2 Special attention should be given to evaluating the risks of participants in relation to benefits.

14.9.3 Research can be classified on the basis of the degree of risk:

'Category 1' Research involving negligible or minimal risk

'Category 2' Research involving greater than minimal risk but presenting the prospect of direct benefit to participants

'Category 3' Research involving a minor increase in minimum risk and presenting no prospect of direct benefit to participants

'Category 4' Research that does not fit the above categories

14.9.4 While all research involving human subjects should be approved by an ERC and subjected to scrutiny, research involving reviews of administrative records which contain names of people may require a lower level of scrutiny, while research involving solely aggregated data and literature reviews needs the lowest scrutiny (if any).

14.10 *The researcher and the sponsor/clients of research*

14.10.1 Research that is undertaken on behalf of sponsors or clients is subject to the usual conventions of contract research. These conventions include the following:

- The researcher has the right to receive an explicit research mandate from the sponsor/client in which the conditions and terms of the research or service (research problems, time framework, etc.) are set out clearly.
- After acceptance of the commission, an explicit agreement or contract between the researcher(s) and client/sponsor should be drawn up.
- The researcher accepts that the sponsor or client has the right to request information on the execution of the research or service from the researcher at any stage in the course of the research. However, interference by sponsors or clients that may jeopardize the scientific integrity of the study or prejudice the interest of the participants in the research is unacceptable.

14.10.2 Information that may reveal the identity of individual participants in the research will not be supplied to the sponsors or clients of the research, except with the written permission of such participants.

14.10.3 If the client or sponsor requests confidentiality in the reporting of research results, the researcher should consider the request in the light of all the principles contained in the research code. The researcher should negotiate the possibility of publication of findings in scientific journals with the sponsors or clients of the research even if such publication should occur after a period of embargo. In certain cases the researcher might even determine that the confidentiality of the findings is essential to protect the interest of the participants in the research.

14.10.4 The Vaal University of Technology will not conduct research on behalf of secret organisations or organisation which cannot account for the application of a particular outcome of research.

15. INTERNATIONAL COLLABORATIVE RESEARCH

15.1 *Concerns*

As globalisation increases, so does collaborative research. Concerns have been expressed about the ethics of this, particularly of clinical research in developing countries and the

application of standards of one country in another. Coupled to this are the intellectual property rights (IPR) of indigenous peoples.

15.2 *Ethics principles*

In international collaborative research, as in any other research, the four principles of ethics apply. These are autonomy, beneficence, non-malfeasance, and justice.

15.3 *Collaborators*

Those taking part in international collaborative research are host country institutions, collaborating country institutions, researchers from both, research participants and their communities. Before submission of a collaborative research proposal to ERC, there shall be clear agreements on all aspects of the research. These include intellectual property sharing, management of the research process, division of responsibilities, finances, spreading of benefits and burdens, and any other appropriate aspects.

15.4 *Principles*

15.4.1 Commencement of research

i. No research shall be undertaken until ERC of all collaborating institutions have given ethics approval to the research.

- Before granting ethics approval, such an ERC shall consider whether the study findings can, and will, be incorporated into the local healthcare system.

ii. No research shall be undertaken after ethics approval of a protocol by an ERC until there is proper informed consent from participants, their families and communities according to local customers. This consent shall:

- Be obtained in a manner that can be understood by the participants;
- Include full disclosure of the aims and methods of the study, benefits and risks, confidentiality methods and commercial implications;
- Be in written or taped form.

15.4.2 *Exploitation*

i. There shall be no exploitation of one institution by another, nor of any investigator, research participant or community.
ii. Intellectual property rights of institutions, investigators, participants and communities shall be respected, shared and acknowledged according to clear agreements before commencement of research.
iii. There shall be equitable compensation of institutions, investigators, participants and communities. This shall be beyond pure financial compensation.
iv. Institutions and investigators have a moral obligation to assist indigenous peoples, traditional s societies and local communities to protect their knowledge and resources.
v. Institutions and investigators have a moral obligation to respect what is sacred and secret by tradition.
vi. No research shall be performed in a host country without local research collaboration in the design and conduct of that research.

15.4.3 *Justification*

i. There must be clear justification of why research is done in a particular country, a particular institution, with a particular investigator, with a particular participant and in a particular community.
ii. Unless there are compelling and acceptable reasons, no research shall be done in a host country that could just as easily be done in a collaborating country.
iii. There must be clear potential benefit to the community being researched.
iv. Those who are involved in international research should have some understanding of, and be sensitive to, the social, economic, and political milieu in which the research is taking place. This will include protection for research participants who are subject to systematic deprivations through poverty and other threats to freedom.

15.4.4 *Benefits to host country*

i. No research shall commence without agreement between the host research institution and the collaborating institution. In this agreement the development of infrastructure and research capacity in the host country should be addressed.
ii. Coercion and inducement of research participants is unacceptable.

iii. There should be benefit – other than pure financial gain – to a host country community in
which research is undertaken, such as access to the best proven prophylactic, diagnostic and
therapeutic methods identified by the study.
iv. There must be a clear and fair system of compensation for research injury with clear lines of
responsibility and guidelines on how to obtain this.
v. Research findings should be translated into components of accessible care in the community
being researched.
vi. Participants should be provided with care or treatment they would not normally obtain.
vii. Care must be taken to ensure that existing disparities are not more deeply entrenched by
inappropriate deflection of local human or material resources away from the healthcare system
towards the research project.

15.4.5 *General*

A clear agreement on the conduct of the collaborative research must be in place before a study begins including data management and research outputs. Before research begins, particular attention should be paid to the following points:

i. The fate of data must be agreed.
ii. The fate of any research specimens must be agreed.
iii. Publication strategy must be agreed.
iv. An ombudsman to settle disputes should be acceptable to all parties.
v. There should be agreement on the nature of all benefits and their distribution.

ASSESSMENT FORM/CHECKLIST

Code number

Title of research proposal

Proponent(s)

Institute or Faculty

Sponsor or funder Yes No N/A

Demonstrated that potential benefit outweighs potential harm

Justification for risk

Protective measures for vulnerable participants

Informed consent form in language familiar to participant

Information in consent form clear and comprehensible to participant

Procedure for taking prior informed consent ensures that potential participants understand the implications of their participation and are able to make an autonomous decision.

Security of data storage

Information and consultation with participants on findings or results

Participants' access to products developed by study

Sharing of benefits from products developed by study

Reporting to ERC after approval

Qualifications of investigators and staff

Disclosure of conflict of interest

Benefit to local community

Benefit to larger society

Community participation

Possible adverse impact on the community

Manner of sharing or disseminating findings or results

Prior informed consent

Consent form

Consent form contains the following basic information:	
- Purposes of research - Expected duration of participation - Participant's actual role in the study - Procedures for selection of participants - Foreseeable risks and discomforts - Procedures or measures in case of adverse event - How privacy of participants will be ensured - Benefits to the participant - Benefits to others - How confidentiality will be maintained - Compensation/gifts/services to participants - Reimbursements	- Indemnity - Insurance - Approximate number of participants - Additional information required by local laws - Names of contact person for research-related inquiry - Statement that participation is voluntary and no penalty or loss of benefit for nonparticipation - Measures that will be taken if injury of harm attributable to study occurs - Statement that participant can withdraw any time without obligation to explain.

AKNOWLEDGEMENT AND WORKS CONSULTED

This Policy has been compiled by Prof CM van der Bank – Executive Dean: Faculty of Human Sciences

1. INTERNATIONAL GUIDELINES.

The ethics review system for research in VUT has been adapted from international guidelines. These include:

- The Declaration of Helsinki, http://www.wma.net/en/30publications/10policies/b3/index.html
- The Council for International Organizations of Medical Sciences (CIOMS),
- International Ethical Guidelines for Biomedical Research Involving Human Subjects,
- World Health Organisation *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000) Geneva
- Belmont Report *Ethical Principles and Guidelines for the Protection of Human Subjects of Research)*
- Nuffield Council on Bioethics *The Ethics of Research related to Healthcare in Developing Countries* (2000)
- The Philippine Council for Health Research, National Ethics Committee *National Guidelines for Biomedical/Behavioral Research* (2000)
- Royal College of Physicians of London.

2. UN DECLARATIONS

It is further based on principles contained in applicable UN declarations such as:

- The Universal Declaration of Human Rights,
- The Convention for Biological Diversity,
- The Declaration on the elimination of Discrimination against Women,
- The Declaration of the Rights of the Child, and
- The Rights and Protection of Indigenous Peoples.
- South African Constitution with its Bill of Rights.
- The Truth and Reconciliation Commission.

3. FERCAP-WHO

It is also based on the Standard Operating Procedures developed by the Forum for Ethics Review Committees – WHO (FERCAP-WHO) for ethics review and with consideration of relevant national legislation and ethical guidelines. See also Alvarez Castillo F *Ethics for social Research in Health*: *the PHSSA Guidelines* Philippine Health Social Science Association Manila (2001);

4. OTHER SOURCES

The contents of paragraphs 7, 9, 10 and 11 were adapted from

- The WHO 2000 *Operational Guidelines for Ethics Committees that Review Biomedical Research*

- University of the Philippines Manila, college of Medicine Research Implementation and Development Office *Research Manual* (2003); and

  Torres C IEC/IRB Review Requirements and Procedures. UP-NIH Forgery International Center Training Program in Bioethics. Quezon City: Philippines (2005)

WMA DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

[add pft copy of declaration] (5pages)