ANNEXURE "A"

GUIDELINES FOR ETHICS REVIEW

1. INTRODUCTION

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

1.2 Unisa, having committed itself to safeguarding the rights of 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.

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

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

1.5 Revision of the Guidelines for Ethics Review may be initiated by any Ethics Review Committee in Unisa. 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.

2. RESEARCH REQUIRING ETHICS REVIEW COMMITTEE (ERC) APPROVAL

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

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

3. NATURE OF ETHICS REVIEW COMMITTEES (ERCs)

3.1 ERCs are independent bodies comprising members who have the ability to undertake thorough, competent and timely reviews of research proposals. They must be independent from political, institutional, professional and market pressure.

3.2 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

3.2.1 It is beneficial for the work of the ERCs to maintain active links with the scientific or technical committee, especially because some methodologies or research designs while technically sound, could involve ethical dilemmas. ERCs 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.

4. TERMS OF REFERENCE OF ETHICS REVIEW COMMITTEES

4.1 The main role of ERCs is to promote the conduct of ethical research in Unisa. 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 Unisa.

4.2 There are two categories of ERCs in Unisa, namely the University ERC and the Unit ERCs:

- The University ERC has Unisa-wide jurisdiction and is not attached to or based in a single unit in Unisa. It is a subcommittee of the Senate Research Committee.

- The Unit ERCs are attached to or based in a specific college/institute/centre. There is a minimum of one Unit ERC per college. An example is the Animal ERC referred to in Part 3.

4.3 The Unisa Ethics Review Committee

4.3.1 provides guidance to Unit ERCs.

4.3.2 reviews research protocols and ongoing research that require its action, including complaints from researchers and matters not resolved at Unit level.

4.3.3 provides guidance to researchers on the ethical aspects of their work.

4.3.4 develops mechanisms in consultation with Unit ERCs for the promotion of cooperation between the Unisa ERC and Unit ERCs, and among Unit ERCs.

4.3.5 develops and proposes policies to enhance and facilitate ethical research and ethics review in Unisa, including those which are necessary for building capacity in ethical research and ethics review.

4.3.6 reviews the UNISA Policy on Research Ethics as the need arises.

4.3.7 provides advice to the Executive Director: Research on matters pertinent to research ethics.

4.3.8 reviews research which:

- is elevated to it for action or opinion from Unit ERCs, researchers, research participants or other stakeholders in research, or

- involves several colleges/institutes/centres. Such cases must first have the approval of the pertinent Unit ERCs before review by the Unisa ERC. Where there is inconsistency in the response to the research proposal between the Unit ERC(s) and the Unisa ERC, steps must be taken by either or both ERCs to resolve the issues involved. If the issue cannot be resolved in this way, the Unisa ERC decision takes precedence. Basic ethical principles for research remain the basis for resolving issues.

4.4 Unit Ethics Review Committees

4.4.1 review research proposals and evaluate the ethical aspects of ongoing research within their jurisdiction. Colleges/institutes/centres should seek the approval of the relevant Unit ERC before research contemplated under paragraph 2 above is conducted.

4.4.2 furnish the Research Directorate with information on all research proposals that they review and investigate all information on unethical studies that are reported to them by researchers, participants or peer reviewers while ensuring the confidentiality of the report or information.

4.4.3 elevate to the Unisa ERC proposals and ethical issues in ongoing research that require appropriate action.

4.4.4 provide guidance to researchers and lecturers in the college/institute/centre with regard to specific ethical issues within the domain of the discipline involved.

4.4.5 propose policies to enhance and facilitate the ethical conduct of research including those that are necessary for capacity building in ethical research and ethics review.

4.4.6 develop specific guidelines for specific needs within a college/institute/ centre or for the composition of Unit ERCs for approval by the Unisa ERC.

4.4.7 provide guidance to other Unit ERCs and College Committees when consulted. In particular, the guidance of the Animal ERC of the College of Agriculture and Environmental Sciences should be sought for all research projects involving animals or other living organisms.

4.4.8 review projects proposed by lecturers who require students to do research as part of formative or summative assessment and/or teaching strategy. Sufficient information should be provided by lecturers and clearance obtained before the project may proceed. Class approval for student research projects may be sought in certain circumstances. See paragraph 10.7 below.

4.4.9 ensure that employees and students adhere to the Unisa Policy on Research Ethics in any collaborative or individual research.

4.4.10 evaluate ongoing research that they have previously approved.

4.4.11 review research which:

- involves their personnel or students,
- is funded from college/institute/centre funds or the funding of which was acquired through the college/institute/centre, or
- will use college/ institute/centre facilities or will be done on the premises of the college/institute/centre.

4.5 There must be open communication and active cooperation between the Unisa ERC and the Unit ERCs to achieve the highest possible quality of ethical review in Unisa.

4.6 Multi-institutional research

Research involving external bodies (e.g. laboratories/institutions/universities) in

South Africa or in other countries must have the approval of appropriate ERC(s) in Unisa. To facilitate the review process, parallel or simultaneous reviews may be conducted among the ethics committees of the institutions involved. In no case however may the approval by ethics committees of external institutions replace the review and action by the appropriate Unit/Unisa ERC.

5. COMPOSITION OF ETHICS REVIEW COMMITTEES

5.1 Chairpersons of the College Research Committees serve ex officio on the Unisa ERC and Unit ERCs.

5.2 Regular membership of an ERC is between 5 - 11 members. The regular members of ERCs should come from different academic disciplines and sectors. These are

- 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.

5.3 Membership on *ad hoc* basis

5.3.1 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 special expertise or guidance not adequately available in its regular membership, e.g. representatives of special groups or communities and other Unit ERCs. The duration of their membership in the committee must be based on the need of the ERC for their special expertise.

5.3.2 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.

5.3.3 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.

5.3.4 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.

5.4 When a case is elevated to the Unisa ERC, the chairperson of the relevant Unit ERC is invited to sit in the meetings of the Unisa ERC.

5.5 All ERCs at Unisa should strive for balanced representation in terms of gender, race, and discipline.

6. OFFICE BEARERS OF ETHICS COMMITTEES

6.1 Chairperson

The chairperson of the ERC is elected by the members from among themselves and has a term of three years.

6.2 Secretary

The ERC is provided secretarial and administrative assistance, as well as a secure office, by the Unit or Unisa.

7. FUNCTIONS OF OFFICE BEARERS

7.1 Chairperson

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

7.1.2 The chairperson is responsible for:

- ensuring that the records and documents of the committee are secure and, in appropriate cases, kept confidential;
- documenting adequately and in a timely manner all documentation of committee meetings and deliberations;
- the recording of receipts of applications, documents submitted and other transactions of the ERC; and
- reporting annually to the members and the Unisa ERC (in the case of Unit ERC) and to the Unisa Executive Director: Research (in the case of the Unisa ERC) on funds received and disbursed.

7.2 Secretary

The secretariat is responsible for:

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

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

7.2.3 obtaining signature of chairperson;

7.2.4 keeping records and receipts;

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

7.2.6 submitting all research that obtained ethics clearance to the Research Directorate for registration;

7.2.7 signing a confidentiality agreement;

7.2.8 executing other tasks assigned by the chairperson.

8. MEMBERSHIP OF ETHICS REVIEW COMMITTEES

8.1 Appointment

8.1.1 Members of the ERC, including those who do not have appointments as employees of Unisa, are appointed by the Executive Director: Research and have a term of office of three years with possible reappointment.

8.1.2 To ensure continuity in the workings of the ERC, as well as utilise accumulated experience and wisdom, the term of office of regular members of the ERC is rotated. The first ERC membership tenure rotation is broken down as follows:

- No more than 50% of the members serve for two years, the remainder for three years.
- The succeeding members serve the full three-year term.

8.2 Conditions of appointment

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

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

8.2.3 Only members who are not appointed as employees of Unisa may receive honoraria for work on the ERC, and all reimbursements and payments received in relation to their work in the ERC must be recorded.

8.3 Resignation

8.3.1 A member who can no longer serve on the committee must resign in writing. No reason for the resignation need be stated.

8.3.2 A vacancy should be filled as soon as possible. The chairperson of an ERC recommends people to fill vacancies to the Executive Director: Research.

9. MEETINGS

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

9.2 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.

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

9.4 Members must be furnished well ahead of time with all documents which will be deliberated on at the meeting.

9.5 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.

9.6 Voting

9.6.1 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.

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

9.6.3 The chairperson votes only when there is a tie.

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

9.7 Timely decisions

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

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

9.8 Possible decisions

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

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

9.9 Conflict of interest on ethics review committee

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

9.9.2 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.

10. PROCEDURE FOR ETHICS REVIEW

10.1 Submissions required for ethics review

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.

10.2 **The application for review form** must contain the following information:

(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 jeopardise his/her ability to undertake the research in a scientific and ethical manner.

10.3 **The proposal summary sheet** must contain the following information:

(i) Title of the 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 Unisa must be included.

(iv) Names and addresses of all sponsor(s) or funder(s)

(iv) Abstract of the proposal in nontechnical language

(v) Research objectives

(vi) Anticipated outcomes

(vii) Inclusion or exclusion criteria (if applicable)

(ix) Withdrawal or discontinuation criteria (if applicable)

(x) Methodology or research design

(xi) Activity plan or time line

(xii) Safety procedures and criteria (if applicable)

(xiii) Description of procedure of reporting to ERC

(xiv) 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

(xv) Description of the risks of the procedures which participants may/will suffer (e.g. no risk, discomfort, pain, stigmatisation, negative labelling/other potential risks) as well as the level of risk. See paragraph 10.10 below.

10.4 **The proposal-related documents** must include the following:

(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 provided to participants (if applicable)

(v) Description for arrangement for indemnity (if applicable)

(vi) Description of any financial costs 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 Unisa 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)

10.5 Steps for reviewing proposals

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

10.5.2 They then write their decision on the appropriate page of the Assessment Form/Checklist. 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/Checklist.

10.5.3 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.

10.5.4 The members' views are discussed at the meeting and a decision reached in accordance with paragraph 9 above.

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

10.5.6 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.

10.5.7 Research which involves external institutions as well as the participation of employees or students from Unisa must be reviewed and acted on by the Unit ERC(s) to which the employees or students belong.

10.6 Expedited review

10.6.1 Expedited review is possible for proposals that pose no significant risks or need only minor revisions after previous conditional approval.

10.6.2 The chairperson may nominate two or more members to review the proposal. If it is a resubmission, previous reviewers should be nominated. The reviewers examine the proposal and documents.

10.6.3 The chairperson circulates the reviewers' decision and comments to the rest of the members for 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.

10.6.4 The chairperson then communicates the decision to the researchers.

10.7 Class approval

10.7.1 Projects that vary in detail but conform to the same general pattern may be given class approval by the Unit ERC to avoid repetitive submissions. This is appropriate for training and research projects to be carried out by students, especially where these pose no risk of distress or injury to participants.

10.7.2 If research is to be undertaken according to class approval previously obtained, a letter stating this should be sent to the Unit ERC for its records.

10.8 Ongoing review

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

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

(i) Report of any adverse event[1] 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 two weeks 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.

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.

[1] 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.

10.8.3 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 for the premature termination, including an explanation of measures taken to protect the participants against any adverse effects of the premature termination.

10.9 Review fees

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

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

10.10 Vulnerability and risks

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

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

10.10.3 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

10.10.4 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).

11. ASSESSMENT FORM/CHECKLIST

11.1 Code number

11.2 Title of research proposal

11.3 Proponent(s)

11.4 College or Institute

11.5 Sponsor or funder

	No	N/A	Yes
(i) Demonstrated that potential benefit outweighs potential harm			
(ii) Justification for risk			
(iii) Protective measures for vulnerable participants			

(iv) Informed consent form in language familiar to participant

(v) Information in consent form clear and comprehensible to participant

(vi) 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 or harm attributable to study occurs
- statement that participant can withdraw any time without obligation to explain

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

(x) Security of data storage

(ix) Information and consultation with participants on findings or results

(xi) Participants' access to products developed by study

(xii) Sharing of benefits from products developed by study

(xiii) Reporting to ERC after approval

(xiv) Qualifications of investigators and staff

(xv) Disclosure of conflict of interest

(xvi) Benefit to local community

(xvii) Benefit to larger society

(xviii) Community participation

(xix) Possible adverse impact on the community

(xx) Manner of sharing or disseminating findings or results

(xxi) Prior informed consent

Acknowledgement and works consulted

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

    - the Declaration of Helsinki,
    - 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* (2002)
    - The Philippine Council for Health Research, National Ethics Committee *National Guidelines for Biomedical/Behavioural Research* (2000)

2. 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.

3. 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. Items 7, 9, 10 and 11 were adapted from

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

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

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

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