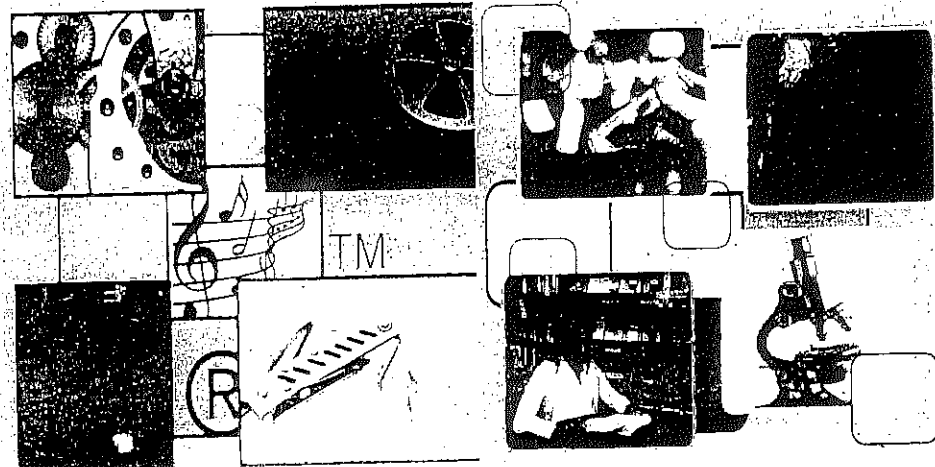




UDSM Research Ethics Policy and Operational Procedures



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Contents

Abbreviations.....	vii
Foreword.....	viii
Executive Summary.....	ix

CHAPTER 1

BACKGROUND AND RATIONALE FOR DEVELOPING RESEARCH

ETHICAL STANDARDS

1.1 Background.....	1
1.2 Rationale.....	1
1.3 Objectives.....	2

CHAPTER 2

THE POLICY ISSUES AND THE STATEMENTS

2.1 Capacity Building in Research Ethics.....	3
2.2 Selection and Conduct of Research.....	3
2.3 Collaborative Research.....	3
2.4 Students Research.....	3
2.5 Honesty and Integrity.....	4
2.6 Environment.....	4
2.7 Biohazard.....	5
2.8 Intellectual Property.....	5
2.9 Disputes Between Co-researchers.....	5
2.10 Disciplinary Action.....	5
2.11 Ethical Behaviour and Code of Conduct for Research.....	6
2.12 Management of Research Data, Materials, Specimen and Records.....	7
2.13 Publication.....	8
2.14 Authorship.....	8
2.15 Citation.....	9
2.16 Acknowledgement of Financial and Other Support.....	10
2.17 Peer Review.....	10
2.18 Redundant Publication.....	11
2.19 Plagiarism.....	12

2.20	Research Misconduct.....	12
2.21	Conflict of Interest and Conflict of Commitment.....	12
2.22	Internet Research.....	12

CHAPTER 3

OPERATIONALIZATION OF THE POLICY

3.1	Implementation Strategy.....	14
3.1.1	Membership to the Research Ethics Committee (REC).....	14
3.1.2	Meetings.....	15
3.2	Sub-Committees of REC.....	15
3.2.1	Biomedical Research Ethics Sub-Committee.....	15
3.2.2	Humanities and Social Sciences Research Ethics Sub-Committee (non-Biomedical).....	16
3.2.3	Animal Research Ethics Sub-Committee.....	16
3.2.4	Internet Research Ethics Sub-Committee.....	17
3.2.5	Natural Sciences and Engineering Research Ethics Sub-Committee.....	17
3.3	Guidelines to Sub-Committees of REC.....	18
3.3.1	Guidelines for Biomedical Research Ethics Review.....	18
3.3.1.1	Research with Human Participants.....	18
3.3.1.2	Application Process.....	18
3.3.1.3	Ethics Review Process.....	19
3.3.1.4	Human Research Ethics Review.....	19
3.3.1.5	Ethics Clearance of Modifications to Approved Projects.....	19
3.3.1.6	Annual Progress Report/Form.....	20
3.3.1.7	Reporting Adverse Events.....	20
3.3.2	Research Involving Animals.....	21
3.3.2.1	Guidelines to Animal Research.....	21
3.3.3	Guidelines for Humanities and Social Sciences Research Ethics Review (non-Biomedical).....	23
3.3.3.1	General.....	23
3.3.3.2	Humanities and Social Sciences Research Review.....	23
3.3.4	Guidelines for Internet Research Review.....	23
3.3.5	Guidelines for Natural Sciences and Engineering Review.....	23

3.4	Sub-committee Meetings.....	24
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CHAPTER 4

CODE OF CONDUCT FOR RESEARCH AND ETHICAL BEHAVIOUR

4.1	Code of Conduct for Research.....	25
4.1.1	Guiding Principle.....	25
4.1.2	Requirements for Observance.....	25
4.2	Breach of the Code.....	26
4.3	Advice and Help.....	26
4.4	Findings of Research Misconduct.....	26
4.5	Dealing with Research Misconduct.....	26
4.6	Disclosure of Conflict of Interest.....	28
4.7	Conflict of Commitment.....	29
4.8	Safety.....	29
4.9	Ethical Behaviour.....	29
4.9.1	Ethical Principles.....	29
4.9.2	Specific Principles (Human Rights).....	30

CHAPTER 5

OPERATIONAL GUIDELINES AND PROCEDURES

5.1	Introduction.....	32
5.2	Research Ethics Guidelines.....	32
5.2.1	Institutional Framework for Research Ethics at UDSM.....	32
5.2.2	Guidelines on the Capacity Building in Research Ethics.....	32
5.2.3	Guidelines on Selection and Conduct of Research.....	33
5.2.4	Guidelines on Collaborative Research.....	33
5.2.5	Guidelines on Student Research.....	33
5.2.6	Guidelines on Environment.....	33
5.2.7	Guidelines on Biohazards.....	34
5.2.8	Guidelines on Dispute Resolution.....	34
5.2.9	Guidelines on Ethical Behavior and Disciplinary Measures.....	35
5.2.10	Guidelines on Management of Research Data.....	35
5.2.11	Guidelines on Publication of Research Data.....	36
5.2.12	Guidelines on Authorship and Citation.....	36
5.2.13	Guidelines on Plagiarism.....	36

5.2.1.4. Guidelines on Conflict of Interests.....	37
5.3. Other Issues.....	37
3.1. Periodical Review of the Guidelines.....	37
3.2. Application of the Guidelines.....	37
References.....	38
APPENDICES.....	40-62

Abbreviations

BREC	Biomedical Research Ethics Committee
COSTECH	Commission for Science and Technology
DVC	Deputy Vice Chancellor
IP	Intellectual Property
IPP	Intellectual Property Policy
MUHAS	Muhimbili University of Health and Allied Sciences
NIMR	National Institute for Medical Research
PhD	Doctor of Philosophy
PI	Principal Investigator
REC	Research Ethics Committee
TANHER	Tanzania National Health Research Forum
TSPCA	Tanzania Society for the Prevention of Cruelty to Animals
UCC	University Computing Centre
UDSM	University of Dar es Salaam
UDSM-REC	University of Dar es Salaam Research Ethics Committee
WWF	World Wildlife Fund

Foreword

The University of Dar es Salaam (UDSM) is an autonomous organization, one of whose institutional objectives is to advance frontiers of knowledge through conducting relevant research. Currently the UDSM does not have a comprehensive institutional ethics policy that would guide the ethical conduct of research. A UDSM Research Ethics Policy has thus been developed to address those needs.

The policy aims at promoting awareness of ethical principles and issues in the conduct of research activities thereby clarifying for researchers their ethical obligations and giving guidelines for dealing with conflict of interest as well as conflict of commitment. The policy has in place a code of conduct for research, which provides guidelines for human, animal, as well as internet research, management of data and records, confidentiality of data, material and specimen transfer, publication and authorship. The code of conduct also gives guidelines on acknowledgement of financial support and how to deal with research misconduct.

The policy is an explicitly stated ethical framework for the University community within which all research shall be conducted. It applies to all members of staff, graduate and undergraduate students who are involved in research on or off the campuses of the UDSM. In addition, any person not affiliated with UDSM who wishes to conduct research with UDSM staff or students will be bound by the same ethics framework. Each member of the University is responsible for implementing this policy in relation to scholarly work with which he/she is associated and to avoid any activity which might be considered to be a violation of this policy.

Prof. Rwekaza S. Mukandala
Vice-Chancellor
University of Dar es Salaam

September, 2010

Executive Summary

1. Introduction

One of the institutional objectives of the University of Dar es Salaam is to advance frontiers of knowledge through carrying out relevant research. In view of that, the University established the Directorate of Research to coordinate research, to support faculties and institutes in their research dissemination and to be the custodian of the University-wide research policy and coordination of its implementation.

In Tanzania, the Commission for Science and Technology (COSTECH) was established as a Government institution that coordinates all research and the only institution that grants research permits to foreign researchers after ascertaining that the research being proposed has been cleared by the relevant institution.

The National Institute for Medical Research, on the other hand, is the national body that offers research clearance for health-related research in Tanzania upon being satisfied with the scientific and ethical integrity of proposals. University researchers collaborate with these institutions in carrying out relevant research studies as a way of alleviating community concerns.

2. Need for Establishing the UDSM Research Ethics Committee

Since research is one of the pillars of the University mission, the University has as its strategic objective, to increase the volume and quality of research outputs. However, in some cases, research may cause physical or psychological harm to the communities where it is conducted. The atrocities committed by the Nazis, the Tuskegee Syphilis Study, the Willowbrook School Study, the Jewish Chronic Disease Hospital, the Milgram Obedience and Tearoom Trade Studies are some of the few examples of violation of the rights of research participants. As a result of these, the international research community observed the need for the rights of research participants to be protected. Thus, the Nuremberg Code, the Declaration of Helsinki and the Belmont Report are some of the international research

community initiatives to ensure that communities' interests are safeguarded and their rights observed and protected through the following basic principles of research ethics:

- a) Respect for autonomy;
- b) Beneficence;
- c) Justice.

The UDSM Senate Research and Publications Committee is the participatory organ responsible for making decisions on the scientific and ethical soundness of research proposals. However, the Committee is composed mainly of the University academic staff, which is contrary to international and national guidelines. Moreover, the University does not have a comprehensive institutional ethics policy that would guide the ethical conduct of research. Based on this background, a UDSM Research Ethics Policy has been developed to address those needs.

3. The University of Dar es Salaam Research Ethics Policy

The policy aims at promoting awareness of ethical principles and issues in the conduct of research activities, thereby clarifying for researchers their ethical obligations. It is an explicitly stated ethical framework for the University community within which all research shall be conducted. The policy applies to all members of staff, as well as graduate and undergraduate students who are involved in research on or off the campuses of the UDSM. In addition, any person not affiliated with UDSM who wishes to conduct research in collaboration with UDSM staff or students will be bound by the same ethics framework. Each member of the University is responsible for implementing this policy in relation to scholarly work with which he/she is associated and to avoid any activity which may be considered to be a violation of this policy.

4. Establishment of the University Research Ethics Committee (REC)

This policy advocates the establishment of a University Research Ethics Committee. Appointment of members to the committee shall be made by the Vice-Chancellor. The committee shall be chaired by the Deputy Vice-Chancellor (Academic) and the Director of Research shall be the Secretary. The REC shall be responsible to the Senate Research and Publications Committee.

The University Research Ethics Committee shall have five sub-committees:

- a) Biomedical Research Ethics Committee
- b) Humanities and Social Sciences Research Ethics Committee
- c) Animal Research Ethics Committee
- d) Internet Research Ethics Committee
- e) Natural Sciences and Engineering Research Ethics Committee

The primary roles of the sub-committees shall be to receive and critically review the scientific and ethical soundness of submitted research proposals and make recommendations to the REC for ethical clearance.

The committee shall meet at least once every three months or as deemed necessary. In appointing members to the committees, gender will be given consideration.

5. The Ethical Behaviour and Conduct for Research

The UDSM is an autonomous community which exists to further the pursuit and dissemination of knowledge and understanding through scholarship and teaching. The code of conduct for research in this policy underscores the need for staff and students to respect the following ethical principles:

- a) Respect for human dignity
- b) Respect for vulnerable persons
- c) Respect for confidentiality and privacy
- d) Respect for justice
- e) Respect for safety of researchers
- f) Respect for existing ethical codes and professional standards
- g) Balancing harm and benefits

The code of conduct provides guidelines for human, animal, as well as internet research, management of data and records, confidentiality of data, material and specimen transfer, publication and authorship. Furthermore, it explicitly provides guidelines on the acknowledgement of financial support and how to deal with research misconduct.

While the University encourages its members to interact with the wider community by undertaking sponsored research, consulting and engaging

in other activities, this policy stresses that such activities must be consistent with the principles of openness, trust and free enquiry. The policy gives guidelines for dealing with conflict of interest as well as conflict of commitment. It shall be the responsibility of every principal investigator to make sure that he/she is familiar with the provisions of the UDSM Research Ethics Policy and code of conduct for research and undertakes to comply with its requirements.

PART I

POLICY ISSUES AND STATEMENTS

CHAPTER 1

BACKGROUND AND RATIONALE FOR DEVELOPING RESEARCH
ETHICAL STANDARDS

1.1 Background

One of the institutional objectives of the University of Dar es Salaam is to carry out research as a way of advancing the frontiers of knowledge. Consequently, the University collaborates with many national and external institutions in research, which in turn has increased the volume of research. Effective coordination of research has thus been seen to be important in order for the University to realize this mission.

Apart from the increase in the general volume of research, there has also been an increase in diversity, multidisciplinary and the number of stakeholders, giving rise to a number of ethical issues such as:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness

1.2 Rationale

Consistent with the National Health Research Ethics Committee Guidelines for Research Involving Human Participants, all staff and students conducting research with humans must ensure that their projects undergo prior ethics review and clearance through an Institutional Ethics Review Committee. In addition, any person not affiliated with UDSM, who wishes to conduct research on campus with UDSM staff and students as participants is bound by the same ethics review requirement. Unfortunately, since its inception, UDSM has not established an Institutional Ethics Review Board. With increasing pressure for establishing such review committees, it is now appropriate that UDSM establishes such a committee that will enhance awareness of the existing national and international ethics guidelines, and

the role of researchers in protecting the rights of the communities where research is conducted.

Ethical consideration in research has expanded considerably, spanning from treatment of human subjects in research to the actual conduct of research itself. For instance, with regard to medical research, prior to World War II, there was little concern with the treatment of human subjects/ participants in research. Thus, there were no formal protections. However, the atrocities committed by the Nazi physicians and administrators led to the Nuremberg Code in 1948, which laid down standards for physicians to conform to when carrying out experiments on human participants.

The Commission for Science and Technology (COSTECH), a government body mandated to issue research permits, requires confirmation from relevant institutions that the research has been cleared and complies with ethical considerations.

1.3 Objectives

The broad objective of this policy is to promote awareness of ethical principles and issues in the conduct of research activities at the University of Dar es Salaam thereby clarifying for researchers their ethical obligations. The specific objectives are:

- i) To establish a system for research ethical assurance at the University of Dar es Salaam.
- ii) To develop a code of ethical conduct for research at the University of Dar es Salaam.

CHAPTER 2

THE POLICY ISSUES AND THE STATEMENTS

2.1 Capacity Building in Research Ethics

The University shall:

- i) Facilitate the ethical conduct of scholarly research by developing and providing capacity building programmes in research ethics for researchers and members of the Research Ethics Committees.
- ii) Create awareness of ethical conduct of research in the wider community.

2.2 Selection and Conduct of Research

- i) The choice of a research topic and the conduct of research shall be the responsibility of an individual researcher in accordance with the University research priority areas.
- ii) Other relevant national and institutional policies, regulations and guidelines shall apply where appropriate.

2.3 Collaborative Research

The University of Dar es Salaam is involved in collaborative research projects with other national and international institutions. Where collaborative research is being conducted:

- i) The Principal Investigator (PI) shall ensure that members of the research team are aware of the contents of this Policy and of other applicable ethical norms governing the conduct of research.
- ii) The Principal Investigator shall take all possible steps to ensure that the provisions of this Policy are complied with by the research team.

2.4 Students Research

The University of Dar es Salaam encourages students to participate in research in order to inculcate the research culture. Where research is to be conducted by students for academic credit:

- i) It shall be the responsibility of the supervisor to inform the student of his/her obligations in respect of the ethical conduct of research.

- ii) The supervisor shall ensure that the student understands his/her obligations in accordance with the University Policy.
- iii) The supervisor shall take all possible measures to ensure that the student's research is conducted in accordance with the provisions of this Policy, and with other applicable ethical norms, and that the student has signed the University Code of Research Conduct.

2.5 Honesty and Integrity

Honesty and integrity are critical in ensuring sustainable and quality research; therefore the UDSM shall ensure that:

- i) Researchers maintain the highest standards of honesty and integrity.
- ii) Any form of academic dishonesty, including but not limited to the following shall be penalized:
 - a) Falsification of Data
 - b) Plagiarism
 - c) Fabrication
 - d) Not declaring a Conflict of Interest or Conflict of Commitment
 - e) Misuse of Research Funds
 - f) Any other form of dishonesty in research that brings the University into disrepute

2.6 Environment

In the course of research, the environment may be affected by the process or applications in the research. UDSM shall ensure that:

- i) All research is conducted in a manner that does not harm the ecosystem.
- ii) The environment is protected for the benefit of present and future generations.
- iii) Research does not harm health and well-being.
- iv) Pollution and ecological degradation are avoided in order to:
 - a) Promote conservation; and
 - b) Secure an ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

2.7 Biohazard

Researchers working in laboratories are at risk of exposure to hazardous biological or chemical materials. The UDSM shall ensure that:

- i) All personnel working in research laboratories at UDSM are protected from possible harm resulting from exposure to hazardous biological or chemical materials.
- ii) All personnel are appropriately trained to work with hazardous biological or chemical materials.
- iii) Appropriate safety measures are established for the use of hazardous material in each laboratory.
- iv) Research conduct complies with relevant national and international regulations with regard to biohazard materials.

2.8 Intellectual Property

Intellectual property is essential in research and academic institutions. The UDSM shall ensure that:

- All researchers abide by the rules and principles as stipulated in the Intellectual Property (IP) Policy of the UDSM.

2.9 Disputes Between Co-researchers

The UDSM encourages team work in research which may sometimes give rise to disputes among the researchers. UDSM shall ensure that:

- All disputes between co-researchers are resolved amicably giving preference to mediation and arbitration.

2.10 Disciplinary Action

In the event of defaulting research ethical standards, disciplinary measures may be necessary in order to maintain high research ethical standards. The UDSM shall:

- Define appropriate penalties such as loss of ethical certification or eligibility for funding or any other penalty which the University deems appropriate.

2.11 Ethical Behaviour and Code of Conduct for Research

The University aims at ensuring an environment of tolerance and respect and believes that the right of individuals to advance their views openly must be upheld throughout the University. The University also believes that the pursuit of knowledge is the pursuit of truth, and should be carried out with honesty and integrity, via safe and responsible methods, bearing in mind fairness and equity for the participants. The UDSM shall ensure that:

- i) Each member of the University endeavours to contribute to the existence of a just and supportive community based on equality and respect for individual differences.
- ii) There is a research environment free from harassment and discrimination and abuse of supervisory authority.
- iii) Services, benefits, opportunities, and facilities offered by the University are compatible with its purposes and are provided to all personnel in the University community with the relevant qualifications. Thus, such provisions shall not be denied wholly or partly on irrelevant or prohibited grounds.
- iv) Academic freedom is exercised in a manner consistent with the scholarly obligation on the basis of teaching and research in honest and ethical quest for knowledge. The academic environment which fosters free debate may from time to time include the presentation or discussion of unpopular opinions or controversial material. Such material shall be dealt with as openly, respectfully and sensitively as possible.
- v) No member of the University community (staff, student) shall unduly interfere with the research of other members of the university or any other related activity of another University.
- vi) Those with supervisory authority (academic or employment) use such authority solely for the purposes explicitly stated or implied in University policies.
- vii) All forms of discrimination or sexual harassment in research are not condoned.
- viii) Staff and students adhere to the following guiding research ethical principles:

- a) Respect for human dignity.
- b) Respect for vulnerable persons.
- c) Respect for confidentiality and privacy.
- d) Respect for justice.
- e) Respect for safety of students.
- f) Respect for existing ethical codes and professional standards.
- g) Balancing harm and benefits.

2.12 Management of Research Data, Materials, Specimen and Records

The University is committed to openness in research but recognises the right for protection of certain data and information for IP purposes. The UDSM shall ensure that:

- i) All researchers arrange for safe storage of all data and specimens on which research is based in accordance with the provisions of the IP policy.
- ii) Material or specimen transfer be specified in the protocol agreement. Where the agreement does not specify, special permission shall be obtained from the UDSM Research Ethics Committee.
- iii) All researchers ensure adequate arrangements for back-ups and security of electronic data sets.
- iv) Primary data be stored in the school or department in which it has been gathered and not by individual researchers.
- v) Data on which any research publication is based be retained for at least ten years after publication.
- vi) If a researcher leaves the University, the University and the researcher are jointly responsible for ensuring that satisfactory arrangements are made for maintenance of the data set. If there is no contractual arrangement to determine what is to be done with the data, then possible arrangements are:
 - a) The data set is retained in the University.
 - b) The researcher has access to the original data set and may keep copies.
 - c) The data set is transferred to the research institution to which the researcher is moving, provided that adequate facilities are available for conservation and storage.

- vii) If no publications based on the data set appear within five years, the data may be destroyed.
- viii) With respect to data confidentiality, the following shall apply:
 - a) Researchers are entitled to keep data sets confidential before publication.
 - b) After publication, when the research is in the public domain, the data should be available to other researchers. It is recognised that there may be technical or cost problems which prevent it from being freely available, but the principle is that there should be an opportunity for checking any data on which the material in the public domain is based.
 - c) In no way do the requirements for data availability override the right to confidentiality and the privacy of individuals who are the subjects of the research.

2.13 Publication

Subject to the provisions of the IP Policy, the University encourages the widest dissemination of research results by appropriate publication. Pressure to publish is a modern fact of academic life with a strong bearing on the career and standing of the researcher. It is important that this pressure does not lead to ethical problems. The UDSM shall require researchers to satisfy themselves that:

- i) They have given full credit to the work of others, whether by citation, acknowledgement or co-authorship.
- ii) They are prepared to take responsibility for all aspects of collaborative work.
- iii) The work that they are submitting for publication is original and worthy of publication.

2.14 Authorship

Based on the Copyright Laws of Tanzania, the UDSM IP Policy and part of the Vancouver Protocol:

- i) Each author shall have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

- ii) One or more of the authors, as corresponding author, shall take responsibility for the integrity of the work as a whole.
- iii) Credit as an author shall be based only on participation in each of the following aspects of the work:
 - a) Substantial contribution to conceptualisation and design of the research, or acquisition of data, or analysis and interpretation of data.
 - b) Either drafting the article or commenting critically on the draft.
 - c) Approving the final version, to the extent that each author is prepared to take joint responsibility for it.
- iv) The acquisition of funding, the collection of data, or the general supervision of the research group, shall not, by themselves, justify authorship. Such contributions should be listed in the acknowledgements.
- v) The order of authorship shall be a joint decision of the authors, decided at an early stage of drafting the paper. Nevertheless:
 - a) In most fields of research, the first author is recognised as having made the most significant contribution. This is the preferred style unless the conventions of the field of research require another ordering.
 - b) In joint publications of a graduate student and his/her supervisor, the graduate student shall be first author unless the supervisor's contribution goes well beyond material on which the graduate student has worked.

2.15 Citation

It is important in all publications, including such documents as research proposals, to cite all sources properly. Citations serve two purposes: to direct the reader to further information; and to give due credit to the source of ideas, quotations, or data. The UDSM shall require:

- i) Researchers to give due credit to their sources of ideas, quotations or data.
- ii) That any of the following are appropriately cited:
 - a) Direct quotations of published material - longer quotations may require a release from the copyright holder.

- b) The description, summarising, or paraphrasing of any previous work.
- c) Use of previously published data, presented in any form, such as graphs, calculations, or tables. Use of such data also requires permission in the form of clearance from the holder of the copyright.
- d) Ideas that originate from other published or unpublished sources.

2.16 Acknowledgement of Financial and Other Support

The University gives a substantial amount of support to research, indirectly by paying the salaries of researchers, and providing an infrastructure for research, and directly by grants or awards. Outside bodies provide substantial direct research support. Collaborations between researchers may lead to indirect support for a research publication from several different institutions. It is important that all such support is appropriately acknowledged. The UDSM shall require that:

- i) Any publication emanating from research supported by University funding or other resources shall acknowledge receipt of the University support.
- ii) The author's address be the University address for work done entirely while an author is at the University. This applies even if a paper is published after the author has left the University.
- iii) If the work is done at more than one institution, then the addresses of each institution should be used as the author's address, either as alternate addresses, or with the main address being that of the institution at which most work is done and a footnote for the addresses of other institutions.
- iv) The author's address for work done while on sabbatical leave should include the University address.
- v) Direct support for research in the form of grants is acknowledged at the end of the paper in the form required by the grant-giving body.

2.17 Peer Review

The world of academic publishing is dependent on the willingness of researchers to give freely their time to referee papers submitted to journals and to recommend on their publication. The University encourages its

members to participate in this process. Such refereeing is done under conditions of confidentiality and is privileged. The UDSM shall require the referees to be meticulous about the following:

- i) Undertake to complete their work expeditiously. If they cannot complete the review in a reasonable time, they should ask the editor to select another referee.
- ii) No use should be made of any of the ideas or results in the work under review until it has been published.
- iii) Care should be taken to avoid a conflict of interest. If the referee is following a very similar line in his/her own work, the work under review should in no circumstances be held up. If the referee is in any doubt of his/her impartiality, the work should be returned to the editor with the request that another referee be found.
- iv) It is acceptable to consult a colleague for technical advice, provided that there is agreement that this is done on the same basis of confidentiality as is required of the referee. Such consultation should be disclosed to the editor.

2.18 Redundant Publication

Redundant publication is the unnecessary publication of similar material in different places. The UDSM shall require that:

- i) Researchers do not publish the same, or substantially the same, article in different places. This does not prevent the later reprinting of an article for a different readership or in an edited compilation by agreement with the editor(s) or publisher(s) involved.
- ii) Researchers consider carefully the most effective way to publish a particular research result or set of research results taking into account the UDSM IP Policy. This shall be done with regard to the best way to communicate the results and not to maximise the publication count.
- iii) Researchers do not release research results that have not been peer reviewed to the media. Research results should be published in a peer-reviewed journal before being released to the media, except in cases of very important results, and with the concurrence of the editor of the journal in which they are to be published.

2.19 Plagiarism

It is a common practice for researchers to read widely in order to find out what others have done or are doing in their areas of study. In the course of doing so, some researchers may use the ideas and work of others whether published or unpublished without acknowledgement. This amounts to plagiarism. The UDSM shall require:

- Researchers to avoid uncredited use of the ideas and work of others, whether this is in published work or in unpublished documents. As such, they must continually be alert to the possibility that they may be unconsciously using the ideas of others and be careful to give full credit to the source.

2.20 Research Misconduct

Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It should, however, be noted that research misconduct does not include honest error or difference of opinion. The UDSM shall require:

- Staff members and students to refrain from research misconduct.

2.21 Conflict of Interest and Conflict of Commitment

The University encourages its members to interact with the wider community, by undertaking sponsored research, consulting, and engaging in other activities which may benefit the University, the public, or the individual. Such activities must be consistent with the principles of openness, trust, and free enquiry. The UDSM shall:

- i) Require that each member of the University has a commitment to act in the best interests of the University.
- ii) Require that members do not allow external activities or financial interests to interfere with that commitment.

2.22 Internet Research

Developments in the Information and Communication Technology have, in the recent years, played a very important role in research. With the globe

being connected by the internet, the flow of information from one centre to another through superhighways has enabled researchers to search, access and download data easily. The UDSM shall:

- Put in place effective measures including a Code of Conduct on the use and protection of data and information from the Internet.

CHAPTER 3

OPERATIONALIZATION OF THE POLICY

3.1 Implementation Strategy

Effective implementation of the Research Ethics Policy requires a well-defined system of institutional structures that will undertake the duties of operationalization within the UDSM structures. Towards achieving that, the UDSM shall:

- i) Establish a Research Ethics Committee (REC) which shall be a sub-committee of the UDSM Senate Research and Publications Committee.
- ii) Establish sub-committees in the following areas:
 - a) Biomedical research
 - b) Animal experimentation
 - c) Research involving the rights of human subjects other than biomedical research
 - e) Internet research
 - f) Natural Sciences and Engineering

3.1.1 Membership to the Research Ethics Committee (REC)

The Vice-Chancellor shall appoint members to the REC and these shall be approved by the University Senate. In appointing members to the REC, gender balance shall be given due weight. Appointments to the committee shall be in person depending on the interest, experience and expertise in ethics. The REC shall have the following members:

- a) Deputy Vice-Chancellor (Academic) - Chairperson
- b) Director of Research - Secretary
- c) A medical practitioner
- d) A biologist
- e) An environmentalist
- f) A social scientist
- g) A legal expert
- h) An Engineer
- i) A community representative not associated with the University

3.1.2 Meetings

The REC shall meet at least once every three months, or as deemed necessary to review and scrutinize protocols and to ensure that scientific and ethical standards are adhered to.

3.2 Sub-Committees of REC

The University shall establish specialist research ethics sub-committees of the UDSM REC. Five specialist sub-committees shall be established, namely:

- a) Biomedical Research Ethics Sub-Committee
- b) Humanities and Social Sciences Research Ethics Sub-Committee
- c) Animal Research Ethics Sub-Committee
- d) Internet Research Ethics Sub-Committee
- e) Natural Sciences and Engineering Research ethics Sub-Committee

The sub-committees shall:

- i) Review research proposals taking into account academic freedom and its responsibilities, while providing accountability and quality assurance to scholars and society in general.
- ii) Effect ethics certification of research proposals.
- iii) Treat research-related documents in the strictest confidence. Any requests for review of such documents outside the respective committees shall be forwarded to the appropriate committee chair for authorization.

Appointment of members to the sub-committees shall be in accordance with standard operating procedures authorized by the University Senate.

3.2.1 Biomedical Research Ethics Sub-Committee

There shall be established a Biomedical Research Ethics Sub-Committee appointed by the Deputy Vice-Chancellor (Academic). The sub-committee shall consist of health professionals, scientists, non-scientists and a community representative. The following members shall constitute the Biomedical Research Ethics Sub-Committee:

- a) Chairperson - Dean, School of Medicine, MUHAS
- b) Secretary - Director of Research

- c) A Representative from the nursing profession
- d) A pharmacologist
- e) A social scientist
- f) A legal expert
- g) A lay member to represent the views of the community

3.2.2 Humanities and Social Sciences Research Ethics Sub-Committee (non-Biomedical)

There shall be established a Humanities and Social Sciences Research Ethics Sub-Committee. The Deputy Vice-Chancellor (Academic) shall appoint members to the sub-committee. Appointment shall be in person depending on interest, experience and expertise on ethics. Gender balance shall be given serious consideration. The sub-committee shall be multidisciplinary including the following members:

- a) Chairperson - Principal, College of Arts and Social Sciences
- b) Secretary - Director of Research
- c) Two social scientists
- d) A behavioural scientist
- e) A health practitioner
- f) A legal expert
- g) Two community representatives not associated with the University
- h) One graduate student

3.2.3 Animal Research Ethics Sub-Committee

There shall be established an Animal Research Ethics Sub-Committee appointed by the Deputy Vice-Chancellor (Academic). The Sub-Committee shall be multidisciplinary and shall include the following members:

- a) Chairperson - Principal, College of Natural and Applied Sciences
- b) Secretary - Director of Research
- c) Two animal researchers
- d) Two non-animal researchers
- e) Animal health technician or laboratory instructor
- f) Laboratory animal veterinarian
- g) A community representative

3.2.4 Internet Research Ethics Sub-Committee

There shall be established an Internet Research Ethics Sub-Committee that:

- i) Recognizes both ethically-pertinent similarities and differences between traditional human subject research and research into online behaviour.
- ii) Articulates values and guidelines for Internet research that are genuinely global in their validity, while acknowledging important cultural and national differences in values that may require specific ethical codes and guidelines for distinctive cultural groups.

The Internet Research Ethics Sub-Committee shall comprise the following members appointed by the Deputy Vice-Chancellor (Academic):

- a) Chairperson - Dean, School of Informatics and Communication Technologies
- b) Secretary - Director of Research
- c) Two system administrators
- d) A representative from the Department of Computer Science
- e) A representative from UCC Ltd
- f) A representative from TTCL

3.2.5 Natural Sciences and Engineering Research Ethics Sub-Committee

There shall be established a Natural Sciences and Engineering Research Ethics Sub-Committee appointed by the Deputy Vice-Chancellor (Academic). The committee shall be multidisciplinary and include the following members:

- a) Chairperson - Deputy Principal (Academic), College of Engineering and Technology
- b) Secretary - Director of Research
- c) One science researcher
- d) One engineering researcher
- e) Science technician or laboratory instructor
- f) Engineering laboratory technician or laboratory instructor
- g) A community representative

3.3 Guidelines to Sub-Committees of REC

3.3.1 Guidelines for Biomedical Research Ethics Review

- All biomedical experiments involving human subjects require prior ethical clearance. Application must be made through the appropriate form to the Biomedical Research Ethics Committee (Appendix 1).

3.3.1.1 Research with Human Participants

- Consistent with Research Ethics Policy of the University of Dar es Salaam, all staff, undergraduate and graduate students conducting research with human participants on or off campus, must ensure that their projects undergo prior ethics review and clearance through the Humanities and Social Sciences Research Ethics Sub-Committee. This requirement applies to all funded and unfunded research regardless of whether the procedures used are invasive or non-invasive in nature. It also applies to research conducted by undergraduate or graduate students for thesis or course purposes.
- The ethics review application extends to data gathering activities involving human participants conducted for purposes of programme evaluation, quality assurance and quality improvement. Any person not affiliated with UDSM who wishes to conduct research on campus with UDSM students and/or staff as participants is bound by the same ethics review requirements.
- Ethical clearance is not given to a research programme. Each individual study or project involving human participants must undergo ethics review. If a grant award covers multiple studies, then each study must have a corresponding application form and undergo ethics review and clearance. For a grant account to be opened for research that will involve human participants, an ethics clearance application needs to be submitted to the Human Research Ethics Committee prior to commencement of the study.

3.3.1.2 Application Process

- The application process begins with the completion and submission of two signed application forms. In addition, two hard copies of all

attachments (e.g., recruitment material, information letter, consent form, feedback letter) must be submitted simultaneously with the hard copies of the application.

3.3.1.3 Ethics Review Process

- The intent of the ethics review process is to ensure that all research involving human participants at UDSM is consistent with the UDSM Policy and the National Guidelines on Research Involving Human Subjects.
- The process:
 - i) Offers a level of assurance to the research participants, the researchers and the University that the proposed procedures are consistent with the research ethics guidelines, that the rights and welfare of the participants will be protected and that the participants will be involved in a consent process which is fully informed and voluntary.
 - ii) Ensures adequate provisions for protection of individuals' privacy as well as confidentiality of information they provide.
 - iii) Makes certain that known and anticipated risks associated with the procedures will be adequately communicated and addressed prior to participation, and are deemed to be outweighed by potential benefits from conducting the research.
- Procedures used to recruit participants should be examined to ensure that participation is voluntary and free of explicit or implicit coercion and that the participants are able to withdraw their consent at any time without fear of reprisal.

3.3.1.4 Human Research Ethics Review

- Projects referred to the Biomedical Research Ethics Committee (BREC) include those that involve the recruitment of vulnerable persons, eg institutionalized elderly people and those with procedures that pose more than minimal (physiological, psychological or other) risk to participants.

3.3.1.5 Ethics Clearance of Modifications to Approved Projects

- As a condition of ethics clearance, researchers must conduct their

projects according to the details they have provided in the application form and for which ethics clearance has been granted.

- Where modifications are required to be made to a project that already has received ethics clearance, eg a change of the design, increase or decrease in sample size, change of procedures, change of materials being used, etc, it is the responsibility of the PI to notify the Human Research Ethics Committee of any proposed modification(s) to a protocol and to seek prior ethics clearance of these modifications.
- A Request for Clearance of Modifications (Appendix ii) must be used for this purpose.
- The chairperson or any designated person will decide if the proposed modifications can be included under the original project or if they are sufficiently substantive to require submission of another application.

3.3.1.6 Annual Progress Report/Form

- As a condition of ethics clearance, researchers are required to update the Human Research Ethics Committee on projects where recruitment of participants and collection of data is expected to continue beyond one year of the full ethics clearance date. This update process is to be done using the Annual Report Form (Appendix iii) in which the PI provides an update on details related to the project such as numbers of participants who are currently enrolled or who have already participated in the project as well as details on the occurrence of any adverse/negative events.
- The PI is expected to complete the form and return it to the Committee by the date specified in the form. Failure to complete and return the Annual Progress Report may result in suspension of ethics clearance.
- The process is repeated each year up to a period of four years from the original ethics clearance date, while the study is continuing or until the PI indicates that the project has been completed.
- Upon notification that the study has been completed, the Committee will close the file and store it.

3.3.1.7 Reporting Adverse Events

- Researchers have an obligation to report to the Human Research Ethics Committee, any occurrence of an adverse event(s) associated with a

project that has ethics clearance. This report must be filed within 24 hours of the event using the Adverse Event Reporting Form (Appendix iv).

- The chairperson, in consultation with other Committee members, will offer recommendations and advice to the researcher on a course of action to be followed and will monitor the situation until it is resolved as appropriate.
- In a case where the Committee deems the risk to future participants to be substantial, a project may be suspended temporarily or indefinitely. This decision may be reached in consultation with the researcher(s).
- Researchers must provide an annual summary of all adverse events which have occurred during the previous twelve months of the project.

3.3.2 Research Involving Animals

The University of Dar es Salaam is a research intensive institution which supports the responsible use of animals in research for the purpose of obtaining knowledge for potential benefit to humans and animals. The use of animals for scientific, technical education and training is also supported when no acceptable alternatives exist. Instructions to investigators submitting animal use research proposals are provided in Appendix v.

3.3.2.1 Guidelines to Animal Research

i) Ethics Review

- a) All research and teaching involving use of live, non-human vertebrate animals must be reviewed and granted ethics approval by the Animal Research Ethics Committee before the work can begin.
- b) All proposals shall undergo rigorous review and scrutiny to ensure that the study is scientifically sound and the procedures are ethical.
- c) The species to be used during the study shall be appropriate for the study and expected research outputs.
- d) Only the minimum number of animals necessary for the study will be used.
- e) Appropriate procedures, anaesthesia and analgesia shall be used to alleviate pain and discomfort both during and after the study.

- f) Only proposals that receive prior ethics approval may proceed and only according to approved procedures.
 - g) All teaching protocols shall undergo review to determine educational merit.
 - h) Any changes to the approved protocols shall receive prior ethics approval.
 - i) All projects shall produce annual progress reports for review and approval for continuation.
 - j) Animal housing facilities shall be monitored through regular inspection to ensure compliance with the guidelines.
- ii) *Import and Export of Animals for Research*
- The contribution of animals in research may at times require importation or exportation of the animals for the following reasons:
- a) Lack of availability of animal species needed for a particular research.
 - b) Comparative research.
 - c) Research in different environments.
 - d) Expertise.
 - e) Facilities.

In any case, research animals for export and import must be fit and free from disease. During transportation they must be handled with care. It is important that there should be a clear MoU between the collaborating institutions. It is the responsibility of the researcher to ensure that all conditions in the Import Form (Appendix vi) and Export Form (Appendix vii) are met.

iii) *Animal Research Field Studies*

Wildlife e.g. monkeys, gorillas and others have provided important information on physiological functions, in the treatment of diseases, behaviour, etc. International organizations eg the World Wildlife Fund (WWF) as well as national organizations eg Tanzania Society for the Prevention of Cruelty to Animals (TSPCA), are keen on how animals are handled. Cruelty against animals is highly discouraged.

Animals, like human beings, may be harmed by research physically or psychologically. Good care improves the welfare of the animals and consequently will yield better, dependable and reproducible results than those for animals that are poorly captured, kept or made to suffer from diseases. Details of the procedures that should be executed in the field are provided in Appendix viii. It is the responsibility of the investigator to obtain all necessary permits for work with wildlife.

3.3.3 *Guidelines for Humanities and Social Sciences Research Ethics Review (non-Biomedical)*

3.3.3.1 *General*

Flawed research has continued to be conducted by prominent researchers, approved by well-constituted institutional review boards and research outputs published in internationally recognized journals despite the numerous international instruments for protecting the rights of research subjects. Research may cause physical and psychological harm that may not be fully perceived and tends to be neglected by researchers. The inclusion of social scientists has proved to be useful in the understanding of diseases and health and should be encouraged.

3.3.3.2 *Humanities and Social Sciences Research Review*

Research involving human subjects requires ethical clearance from the Humanities and Social Sciences Research Ethics Committee. Application is to be made on the appropriate application form. Guidelines to humanities and social sciences research are similar to those applicable in biomedical research because in both cases they involve human subjects.

3.3.4 *Guidelines for Internet Research Review*

The Code of Conduct on the Use of Internet shall provide clear guidelines on the Internet Research Review.

3.3.5 *Guidelines for Natural Sciences and Engineering Review*

Consistent with the University of Dar es Salaam's Research Ethics Policy, all staff, undergraduate and graduate students conducting research within natural sciences and engineering on or off campus must ensure that their

projects undergo prior ethics review and clearance through the Natural sciences and Engineering subcommittee. This requirement applies to all grant-funded and unfunded research regardless of whether the procedures used are invasive or non-invasive in nature. It applies to research conducted by undergraduate or graduate students for thesis or course purposes.

In addition, the application of ethics review extends to data gathering activities for purposes of programme evaluation, quality assurance and quality improvement. Any person not affiliated with UDSM who wishes to conduct research on campus with UDSM students and/or staff as participants is bound by the same ethics review requirements.

3.4 Sub-committee Meetings

All sub-committees of REC shall meet regularly to review protocols.

CHAPTER 4

CODE OF CONDUCT FOR RESEARCH AND ETHICAL BEHAVIOUR

4.1 Code of Conduct for Research

4.1.1 Guiding Principle

Specifically, staff and students should respect the following guiding ethical principles:

4.1.2 Requirements for Observance

This code applies to all individuals participating in research under the auspices of the University of Dar es Salaam. This includes:

- Academic staff
- Staff providing technical or administrative support to research activity
- Staff employed through research grants or contracts administered by the University
- Staff of research centres and units
- Graduate or undergraduate students participating in research
- Any other individual, such as honorary appointees and visiting researchers making use of any University resources

All researchers working on campus must complete a research consent form stating that they are familiar with the code and undertake to observe it. Contracts of affiliation between the University and independent research institutes should ensure that the independent institute adheres to a comparable code of ethics.

Where appropriate, the code specifies formal procedures and regulations. Nevertheless, it recognises that in ethical questions, it is not possible to legislate for every eventuality. The overriding principle is an expectation of all researchers that they are to act with integrity in the interest of the University and to be scrupulous in conducting their affairs.

4.2 Breach of the Code

Failure to observe the requirements of the code may be grounds for disciplinary action under the conditions of service applying to the University staff or under the student disciplinary code as appropriate.

4.3 Advice and Help

Advice and help in interpreting the code may be obtained from the chairpersons of the five Research Ethics Committees, namely:

- a) Biomedical Research Ethics Committee.
- b) Animal Research Ethics Committee.
- c) Humanities and Social Sciences Research Ethics Committee.
- d) Internet Research Ethics Committee.
- e) Natural Sciences and Engineering Research Ethics Committee.

4.4 Findings of Research Misconduct

In order to establish beyond reasonable doubt research misconduct there must be evidence that:

- a) There is significant departure from accepted practices of the relevant research community.
- b) The misconduct must have been committed intentionally, or knowingly or recklessly.
- c) The allegation must be proven by a preponderance of evidence.

Therefore, research misconduct, as so defined, is a serious disciplinary offence. It is classified as misconduct under the conditions of service applying to the University staff and under the student disciplinary code. In cases where an investigation leads to a recommendation for disciplinary action, this will be taken under the provisions of whichever of these codes is applicable.

4.5 Dealing with Research Misconduct

Research misconduct is rare. Most researchers operate according to the highest standards, and, as a consequence, there is generally a high level of trust between them. Individuals are naturally reluctant to entertain any

suspicion about the activities of a colleague. A serious case of research misconduct may lead to the end of a research career, and may reflect badly on colleagues and on the University. If suspicion arises, it can lead to considerable agony of mind on the part of a potential whistleblower in deciding how to proceed. It is important, therefore, to emphasize that the University is committed to the following principles:

- Any allegation of research misconduct must be dealt with expeditiously. If such misconduct is established there is an absolute responsibility to expose it.
- A finding that research misconduct has occurred will be dealt with openly, and all steps to correct its effects will be taken.
- The rights of any researcher accused of misconduct must be protected.
- The rights of any individual reporting suspicions of such misconduct in good faith must also be protected.

An individual who suspects that research misconduct may have occurred is strongly encouraged to discuss the problem in confidence with the chairperson of the appropriate Committee who will confidentially provide counseling to determine whether the concerns fall within the definition of research misconduct.

The consequences of research misconduct are so severe, hence there are several stages in the process for investigating it:

- Should an individual believe that research misconduct may have occurred the facts should be reported to the Deputy Vice Chancellor (Academic).
- The Deputy Vice-Chancellor (Academic) shall, without delay, appoint a committee of investigation to establish the facts of the matter and to recommend whether there is a prima facie case to be answered. The committee shall:
 - a) Inform, in confidence, those directly affected by the investigation of its nature. This will include the appropriate line manager, or supervisor of the individual involved.
 - b) Conduct an investigation to establish the facts.

- c) Report to the Deputy Vice Chancellor (Academic) within three weeks of establishment of the committee. This should either be a final report or a motivation to extend the investigation for a limited period.
- d) The final report shall recommend:
 - i) Whether there is a prima facie case for disciplinary action.
 - ii) What immediate action, if any, must be taken to rectify any irregularity. Full details of such action shall be made available to all interested parties inside and outside the University, either immediately, or, if necessary, after completion of a disciplinary case.
 - iii) On receiving the report, the Deputy Vice Chancellor (Academic) will, without delay, take appropriate action, based on the recommendations of the committee, referring the matter for disciplinary action if necessary.
 - iv) After the completion of any disciplinary case, a full report of the facts of the case and the actions that have been taken to rectify the situation will be made public.
 - v) All steps will be taken to protect the interest of the individual reporting the misconduct.

4.6 Disclosure of Conflict of Interest

- A conflict of interest occurs when a member of the University has an opportunity, whether real, potential, or perceived, to place his or her personal interests, or the interests of external organisations, ahead of the interests of the University.
- In the academic environment, there are many opportunities for conflicts of interest to occur. Not all can be covered by formal procedures.
- All members of the University are expected to conduct their affairs in such a way that they can stand close scrutiny and are in accordance with scrupulous ethical standards. In case of doubt, advice should be sought before proceeding.
- If a member of the University has any reason to believe that some activity constitutes, or has the possibility of constituting a conflict of interest, it is required that a disclosure statement be lodged in the Directorate of Research
- The disclosure statement should include:

- i) A statement of the nature of the conflict.
- ii) A proposal from the staff member of how the conflict of interest is to be managed.
- iii) A procedure for the management or elimination of the conflict agreed with the College Principal, Head of School, Dean or as is appropriate. This procedure may demand varying levels of oversight, and may include prohibition of the activity.
- To assist members of the University in the process for disclosure there is disclosure form providing a check list to help establish the nature of the conflict. Failure to disclose the existence of a conflict of interest may constitute dishonesty in terms of the University's disciplinary code and may lead to disciplinary action. The emphasis is on self-regulation. Details are provided in Appendix ix.

4.7 Conflict of Commitment

- A conflict of commitment takes place when the commitment of a member of the University to external activities affects his/her ability to meet his/her University commitments.
- Generally, University researchers have commitments to their teaching, research programmes, research supervision, consultancies and their administrative duties. It is expected that these commitments will be fully met, not just in the formal requirements of the University policies and practices, but also in the spirit of the University vision of excellence.
- In undertaking external activities, members of the University should take into account the possibility of conflict of commitment and should abide by the University policy governing private remunerative work.

4.8 Safety

- The University, in common with all other organisations in Tanzania, is subject to the provisions of the Occupational Safety Act.

4.9 Ethical Behaviour

4.9.1 Ethical Principles

The University of Dar es Salaam is an autonomous community which exists to further the pursuit and dissemination of knowledge and understanding

through scholarship and teaching. The University aims at ensuring an environment of tolerance and respect and believes that the right of individuals to advance their views openly must be upheld throughout the University. The realization of these intentions requires respect for the following specific principles:

4.9.2 Specific Principles (Human Rights)

Without limiting the generality of Section 4.1.1, the following shall be taken as violations of this Policy, and may also be in contravention of the Bill of Rights:

- a) Discrimination is defined as any action or behaviour that results in adverse or preferential treatment related to those grounds prohibited under the Bill of Rights.
- b) Harassment is defined as engaging in a course of vexatious comment or conduct that is known, or ought reasonably to be known, to be unwelcome.
- c) Sexual Harassment is defined as unwelcome advances, requests for sexual favours, or other physical conduct of a sexual nature by way of words, acts, gestures or comments that would embarrass, humiliate, intimidate, demean or compromise a reasonable person at whom such advances, requests or conduct were directed, and as further elaborated in the UDSM Anti-Sexual Harassment Policy.
- d) A 'poisoned environment' (or one that is intimidating, hostile or offensive) can be created based on any of the prohibited grounds under the Bill of Rights; and can be described as comment or conduct that is contrary to the aims of maintaining a supportive, respectful and tolerant environment.

PART II: OPERATIONAL GUIDELINES

CHAPTER 5

OPERATIONAL GUIDELINES AND PROCEDURES

5.1 Introduction

These Guidelines are made pursuant to the adoption of the UDSM Research Ethics Policy. The guidelines highlights the main action points and responsibilities of the relevant organs contemplated under the Policy. The guidelines aim at facilitating the smooth operation and realization of the vision envisaged under the UDSM Research Ethics Policy. The guidelines are not meant to be substitutes to the provisions of the Policy, rather are intended to amplify and contextualize the provisions of the Policy.

5.2 Research Ethics Guidelines**5.2.1 Institutional Framework for Research Ethics at UDSM**

5.2.1.1 The Research Ethics Committee (REC) established under Article 4 of the UDSM Research Ethics Policy shall be the highest decision making organ in the review exercise of research proposals for examination of scientific and ethical compliance.

5.2.1.2 The Research Ethics Sub-committees in Biomedical, Humanities and Social Sciences, Animal, Internet, and Natural Sciences and Engineering shall assist the REC in discharging its role effectively.

5.2.1.3 Unless there are special circumstances or an overlook of the material fact(s) in the review exercise, the decision of REC shall be final on matters pertaining to research clearance.

5.2.1.4 An aggrieved party may appeal against the decision of REC under Article 2.1.3 above in writing by showing the facts which were overlooked or the special circumstances.

5.2.2 Guidelines on the Capacity Building in Research Ethics

5.2.2.1 It shall be the duty of REC in liaison with the Research Ethics subcommittees to devise a program for capacity building among members of the UDSM and the collaborative partners.

5.2.2.2 Such programs shall identify targeted groups and the potential source of funding.

5.2.2.3 REC may liaise with the Directorate of Research for the acquisition of the funds to facilitate the building of capacity in research ethics.

5.2.3 Guidelines on Selection and Conduct of Research

5.2.3.1 Whereas the selection of research topic and the overall conduct of research is the responsibility of the investigator, the underlying goal for selection shall be aimed at improving the welfare of human beings.

5.2.3.2 In the case where a research involves human subjects, it shall be conducted under the principles of respecting the voluntary wishes of the subjects under the study and protecting their privacy and right to health.

5.2.4 Guidelines on Collaborative Research

5.2.4.1 Unless it is otherwise expressly agreed by the parties, in the case of collaborative research between members of UDSM and other external parties where the primary research location is in Tanzania, the provision of the UDSM Research Ethics Policy shall be applicable.

5.2.4.2 In the case of conflict between the provisions of the UDSM Research Ethics Policy and the policy of collaborating institution(s), the consensus shall be arrived at by involving REC and responsible organ of the collaborating institution(s).

5.2.5 Guidelines on Student Research

5.2.5.1 Students who are conducting research as part of their studies at UDSM, either as full time, part-time, or visiting students, are bound to observe the provisions of the UDSM Research Ethics Policy.

5.2.5.2 Under special arrangements to be approved by REC, visiting students/researchers may be exempted from certain provisions of the UDSM Research Ethics Policy, in particular where there are special arrangement between UDSM and the institution of the visiting students/researchers.

5.2.6 Guidelines on Environment

5.2.6.1 In the case where REC have reason to believe that given the nature of a particular research, there is a danger to environment, special

care shall be exercised in making sure that a thorough Environmental Impact Assessment (EIA) is carried out and presented for examination before REC before a research clearance is granted.

5.2.6.2 The criterion for EIA issued and applied by the National Environmental Management Council (NEMC) shall apply *mutatis mutandis*.

5.2.6.3 In order to effectively discharge its duties regarding environmental protection, REC shall regularly liaise with appropriate national organs that deal with environmental issues.

5.2.7 Guidelines on Protection against Biohazards

5.2.7.1 In order to establish the safest possible research environment at UDSM, REC shall liaise with Insurance Companies to ascertain the possibility for the UDSM to provide insurance covers against biohazards to researchers in certain specified types of research.

5.2.7.2 The decision on which types of research should be covered by insurance shall be made by the UDSM Senate Research and Publications Committee, taking into account the nature of research, the extent of risk involved, and the potential social and economic value returns from the research output.

5.2.7.3 Where appropriate, REC shall oblige research funding agencies to provide for insurance cover to researchers of UDSM who are involved in a particular research against biohazards prior to commencement of the research.

5.2.8 Guidelines on Dispute Resolution

5.2.8.1 In the case of dispute between co-researchers, or researchers and UDSM, or another institution and UDSM, which the parties have failed to settle amicably, an *ad hoc* Dispute Resolution Committee (DRC) of three members shall be constituted by DVC (Academic) within 21 days of reporting.

5.2.8.2 The DRC shall consist of a legal expert, an expert in the relevant field of research from UDSM, and an independent party from outside UDSM.

5.2.8.3 Within 14 days of its, DRC shall set a date for a preliminary meeting to discuss preliminary issues on the basis of the available information.

5.2.8.4 Within 7 days after the preliminary meeting, DRC shall set a date for hearing of the parties and resolving the dispute. Parties may appear in person or submit their arguments in writing.

5.2.8.5 Unless there are exceptional circumstances to justify the contrary, DRC shall endeavor to undertake all reasonable steps to make sure that the matter is resolved within 90 days of its receipt of the dispute.

5.2.8.6 By agreeing to submit their disputes to DRC, parties implicitly agree to waive their rights to further pursue their rights in the subject matter of dispute in courts of law.

5.2.9 Guidelines on Ethical Behavior and Disciplinary Measures

5.2.9.1 UDSM through REC shall ensure that all researchers comply with the highest ethical standards enshrined in the UDSM Research Ethics Policy.

5.2.9.2 In order to effectively administer ethical compliance, REC shall devise a special Checklist of Ethical Compliance Form which researchers will be obliged to fill quarterly or otherwise as deemed fit by REC.

5.2.9.3 A deliberate Non-compliance to the established research ethical standards as enshrined in the UDSM Research Ethics Policy shall attract a severe penalty.

5.2.9.4 Apart from the forms of penalties enumerated under Article 2.10 of the UDSM Research Ethics Policy, other disciplinary measures may include criminal sanctions as per the criminal laws of the Country.

5.2.10 Guidelines on Management of Research Data, Material, Specimen, and Records

5.2.10.1 All recordable research data shall be recorded in the UDSM Research Notebooks and kept and locked in the safe at the departments.

5.2.10.2 The ultimate responsibility of safe custody of research data, specimen, material and other records rests with the Lead/Principal Investigator.

5.2.10.3 Under no circumstances, shall the materials or specimen for research be transferred to another party without leave of the

REC and duly signing of the Material Transfer Agreement (MTA), the sample of which are available at the UDSM Intellectual Property Management Office (IPMO):

- 5.2.10.4 Receipt of data, records, specimen, and material for research by UDSM from another party shall abide to the same procedure enumerated under 5.2.10.3 above.

5.2.11 Guidelines on Publication of Research Data

- 5.2.11.1 Research data shall only be published after consultation with the IPMO which shall examine the IP potentials of the said data and advise accordingly.
- 5.2.11.2 In order NOT to thwart dissemination of otherwise unpatentable data for the public good, the IPMO shall be required to carry its examination expeditiously within reasonable time-frame, not exceeding 90 days.

5.2.12 Guidelines on Authorship and Citation

- 5.2.12.1 It is understood that determination of authorship is a legal process which shall be based on the provisions of the Copyright and Neighbouring Rights Act of 1999 and the provisions of the UDSM Intellectual Property Policy, 2008.
- 5.2.12.2 All researchers are required to give full acknowledgement and citation of the source of information that they use in their research, failure of which shall be regarded to be a research ethical misconduct, punishable within the framework of the UDSM Research Ethics Policy.

5.2.13 Guidelines on Plagiarism

- 5.2.13.1 UDSM shall undertake to launch a special campaign to raise awareness on the risks and consequences of plagiarism to students as well as researchers.
- 5.2.13.2 Supervisors shall promptly report to REC all cases of plagiarism from their supervisee for onward disciplinary actions.
- 5.2.13.3 In all cases where plagiarism is established by evidence, UDSM shall met severe punishment to a guilty party; the penalties may include a written reprimand, dismissal, discontinuation from studies or any other disciplinary measure which the prevailing circumstances may warrant.

5.2.14 Guidelines on Conflict of Interests

- 5.2.14.1 In all cases of conflict of interests in a particular research project, a member of the UDSM who is involved or required to be involved shall notify REC on the existence of such conflict.
- 5.2.14.2 Upon receipt of such notice, REC shall promptly evaluate the facts and make a decision on whether such party should withdraw from such research project or otherwise.

5.3 Other Issues

5.3.1 Periodical Review of the Guidelines

- 5.3.1.1 These Guidelines shall be reviewed after every 3 years in order to ascertain their efficacy and updating in line with the national, regional and international research regulations and best practices.
- 5.3.1.2 The review team shall be constituted by DVC (Academic) and shall include members from academic, research and development institutions.

5.3.2 Application of the Guidelines

- 3.2.1 These guidelines are applicable to members of UDSM and other parties who may carry on research involving UDSM.
- 3.2.2 These Guidelines shall be read together with the UDSM Research Ethics Policy and UDSM Intellectual Property Policy.

I, Prof. R. S. Mukandala, the Vice Chancellor of the University of Dar es Salaam, by virtue of the powers conferred to me by Section 8 of the University of Dar es Salaam Charter, 2007, and Rule 5(3)(b) of the University of Dar es Salaam Rules, 2007, do hereby approve these Guidelines with effect from..... and they shall form part of the UDSM Research Ethics Policy, 2010

Prof. R. S. Mukandala,
Vice Chancellor,
University of Dar es Salaam

References

- About Ethics at CDU, Charles Darwin University http://www.cdu.edu.au/research/ethics/ethics_about.html
- Current Students -Postgraduate Research. The University of New South Wales <http://www.unsw.edu.au/currentStudents/postgradResearch/res/cspgrpolicyproc.html>
- Ethical Behaviour Policy 33. University of Waterloo <http://www.research.uwaterloo.ca/ethics/misconduct/guidelines/policy33.html>
- Ethics Policy: St Edwards University, Course Policies <http://www.stedwards.edu/educ/minus/read1323/gethicteach.html>
- Ethics Review of Research Involving Human Subjects. Simon Fraser University <http://www2.sfu.ca/policies/research/r20-01.htm>
- Guidelines and Policies, University of Waterloo <http://www.research.uwaterloo.ca/ethics/human/guidelines.asp>
- Guidelines on Ethics for Health Research in Tanzania
- Human Research Ethics Committee. Central Queensland University <http://www.cqu.edu.au/ppmanual/committees/humanresearch.pdf>
- http://www.nyu.edu/projects/nissenbaum/projects_ethics.html
- Integrity in Research Administrative Guidelines, University of Waterloo http://www.research.uwaterloo.ca/ethics/misconduct/guidelines/misconduct_guidelines.html 8/26/2004
- International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS, Geneva, 1993, p.11. Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO)
- Joint NHMRC/AV-CC Statement and Guidelines on Research Practice. Australian Vice-Chancellors' Committee [Http://www.avcc.edu.au/news/public_statements/publications/girespra.html](http://www.avcc.edu.au/news/public_statements/publications/girespra.html)
- Laboratory Biohazards Policy for Research Facilities and Personnel. Texas Tech University Health Sciences Centre
- Large Research Grants Scheme: Guidelines for the year 2000 Grants, Australian Research Council, 1999, p.4. Department of Education, Training and Youth Affairs
- McGill University policy on research ethics. McGill Research at Mc Gill <http://www.mcgill.ca/researchoffice/policies/sponsored/policies/ethics>
- National Statement on Ethical Conduct in Research Involving Humans- Preamble National Health and Medical Research Council <http://www.health.gov.au/nhmrc/publications/humans/preamble.htm>

- Office of Research Integrity US Department of Health and Human Services
- On being a scientist - Responsible conduct in research, National Academy Press, Washington DC 1995
- Online Ethics Center for Engineering and Science at Case Western Reserve University
- Policy and procedures on Ethics in Research. The University of North Carolina at Chapel Hill, August 1994
- Regulations governing conflicts of interest in proprietary research. McGill Research at Mc Gill <http://www.mcgill.ca/researchoffice/policies/sponsored/policies/proprietary>
- Report of the Review of the Role and Functioning of Institutional Ethics Committees. A Report to the Minister of Health and Family Services, March 1996, Commonwealth of Australia, Canberra
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, Department of Health, Education and Welfare Publication No (OS) 78-0012, US Government Printing Office Washington, 1978

Links to Professional Conduct Statements

- American Chemical Society
- American Mathematical Society
- Association for Computing Machinery
- Institute for Electrical and Electronic Engineers

APPENDICES

APPENDIX 1: APPLICATION GUIDELINES FOR ETHICS REVIEW (General Information and Completing the Application)

General Information

The University of Dar es Salaam Research Ethics Committee serves all the academic areas including, but not limited to, the following areas: Health Sciences, Anthropology, Economics, Geography, Political Science, Sociology, Management, Law, Engineering, Religious Studies and any other units deemed relevant.

Contact Information

All researchers are advised to contact the Directorate of Research for further clarification.

What Needs to be Reviewed?

- All research involving human subjects conducted by a University-affiliated faculty, students or staff, conducted on campus or elsewhere, requires review and approval by the REC before the research may begin. This includes all funded (granting agencies/ contracts) and non-funded research.
- Research involving human subjects may include, but is not limited to, projects where data are derived from:
 - 1) The collection of information through any interaction or intervention with a living individual.
 - 2) The secondary use of data previously collected from human subjects.
 - 3) Identifiable private information about an individual.
 - 4) Human remains, cadavers, human organs, tissues and biological fluids, embryos or fetuses.

The examples listed are not intended to represent an exhaustive inventory of research requiring review and, conversely, some activities apparently falling into these categories may be exempted from review. The researcher is responsible for consulting with the REC to clarify what types of research must be reviewed and what exceptions may exist. Ethics approval must be received before the research is begun.

Student Research

- Course-based research projects that require students to conduct human subject research must receive ethics review and approval. These projects differ from research in that the intent is for the student to become more knowledgeable about the research process, rather than to contribute to general knowledge.
- The results of the data are not intended for publication or presentation outside the classroom.
- The review of these applications may be delegated to the REC departmental representative and do not normally have to go to the regular REC.
- This review may not be used for projects carried out as part of a faculty member's own research. Course projects that involve more than minimal risk, or involve minors or other vulnerable populations, must be reviewed by the REC.
- Thesis and postdoctoral research must undergo regular REC review.

Continuing Review

- Ethics approvals are only valid for one year and must be renewed on an annual basis. This requires the submission of an Annual Status Report/Request for Renewal form.
- Renewal requests should be made at least one month before the current approval expires. If a renewal request is not received before the approval elapses the project is considered no longer approved.
- No research activities may be conducted under an expired approval.
- Funding agencies' policies require that research funds be frozen when there is no valid ethics approval in place.

Closing a Project

When a project no longer requires ethics approval, a Final Report form should be submitted to properly close the project. This is especially important for funded projects.

Amendments

- The Amendment Form can be used to notify the REC of any revisions or modifications to be made to a currently approved research project.

- Significant changes that have ethical implications must be reviewed and approved by the REC before they can be implemented.
- This form should also be used to notify the REC of administrative changes such as the addition of co-investigators or new funding sources and titles.

Adverse Events

- Investigators must also inform the REC of any serious adverse events experienced by subjects.
- Any serious or unexpected adverse events experienced by a subject in conjunction with the research, which affect the risk-benefit ratio of the project, must be reported to the REC. Such events are not limited to physical harm but can include social, emotional or economic harm.
- Reasonable judgment should be used to determine what constitutes a serious event.

Completing the Application Form

- Submit the original plus THREE copies of the application form to the Director of Research. For course-based projects as already described, submit the original plus TWO copies of the application form to the Director of Research who will arrange and distribute it for review.
- Please take note of the following points before you submit your ethics application, in order to ensure that your application is properly filled out. Incomplete applications cause delays in turn-around time:
 - 1) All applications must be signed by the applicant who is the Principal Investigator, and if a student, by the supervisor as well. The Principal Investigator's signature affirms that he/she will conduct the project in accordance with the policies and procedures governing the ethical conduct of research involving human subjects at UDSM. The supervisor's signature affirms that he/she has read and approved the project, that it has received the appropriate academic approval and that he/she is responsible for providing the necessary supervision to the student. Applications with missing signatures will be returned.
 - 2) It is important to list your co-investigators if they want to be able to use this ethics approval for their own. If investigators change, an amendment form should be filled out.

- 3) All funding sources for this project (grants or contracts) must be listed as well as the exact project title of the grant/contract. This is very important since accounts cannot be opened if the project title on the ethics certificate doesn't match that of the grant /contract and there is no explicit reference made to the appropriate funding source. It should be indicated who the holder of the award is, if it isn't the applicant. An amendment form should be filled out to report any changes or additions to titles or funding sources to a currently approved project.
- 4) Be sure to attach, as applicable, all documents such as recruitment ads (including information that is sent to third parties such as when requesting access to a school or another organization), letters of invitation, oral scripts, consent forms, information letters and interview guides.
- 5) Informed consent should be thought of as a process rather than a form. The purpose of "informed consent" is to make certain that research subjects are truly volunteers, and that they know what they are getting into before volunteering. A good, clearly written, informative form is essential to informed consent, but there is more to it than that. Consent forms do not replace a thoughtful discussion with the participants. What are subjects going to be told about the research before they even see the consent form? That information can increase understanding greatly, so researchers need to think carefully about what information they are going to provide and how it can best be given to the potential subject. How and when subjects will be asked to consent is also an important part of the process.

Depending on the complexity of the material and the abilities of the subjects, it might be necessary to ask questions about the subject in order to be sure that the information is understood. When children are involved, how will you explain to them what is required of them so that they understand? How will you determine if they really want to participate or not? The process of obtaining informed consent must be thoughtfully detailed in the REC application. The potential subjects need to know what the purpose, risks, benefits and alternatives are before participating.

- The consent form documents the consent process and the length and detail will depend on the research and the participants involved and what information is required to enable them to give informed consent. The following information is the minimum required in a consent form:
 - a) The researcher's name, department and university, and contact information.
 - b) Student researchers should be identified as such and the supervisor's name and contact information must be indicated.
 - c) A brief description of the research project and its purpose.
 - d) Description of what the subject will be asked to do (eg be interviewed, fill out a questionnaire, be a focus group participant), the location, frequency/number of procedures, and time involved.
 - e) Indicate if the subjects will be audio-taped or video-taped and what the disposition of the tapes will be; if the tapes will be used outside of the research group eg in classrooms or at conferences etc. This must be explicitly stated.
 - f) How and to what degree confidentiality will be maintained, including how their data will be kept secure and who will have access to it.
 - g) If applicable, description of any potential benefits and foreseeable discomforts and/or potential risks to the subject (such as emotional stress and reliving instances of family violence, economic harm, or an employee revealing bad working conditions) and how they will be managed.
 - h) A statement that indicates that subjects are under no obligation to participate, they may withdraw at any time, they may refuse to answer certain questions; when treatment or services are involved, include a statement indicating that a decision not to participate will not affect the availability of services offered or if a student, that their academic standing will not be affected.
 - i) A description of any compensation for the subjects.
 - j) Subjects must be informed if their data will be saved or used for other purposes not described in the consent and a description of these other uses must be provided.
 - k) A separate approval line should be provided for the following: permission to audio/video-tape or photograph, permission to be identified, permission to use direct quotes without attribution.

- l) Any other information particular to your project necessary for the subject to be able to make an informed decision.
 - m) A copy of the consent form should be left with the participant.
- Consent forms should normally be printed on departmental letterhead. The language in the information letters, consent forms or oral scripts must be tailored to the population being addressed. This sometimes requires different forms for different groups of people within the same project (e.g. children and parents).
 - Written consent is normally required, unless otherwise justified. If written consent will not be obtained, you must still provide a copy of the script that will be used to obtain verbal consent from the subjects. There should be a signature line for the subject and one for the researcher. Witness signatures are not required in most circumstances.
 - Written consent must be obtained from a parent when the subject is under the age of 18 as well as assent from the child. The oral script used to invite the children's participation, written at their level of understanding, must be provided. Children over the age of 13 must also provide written consent.

Consent Form Examples

The REC does not prescribe a particular format or wording for a consent form and while it needs to contain all of the elements above, it should be written in a style appropriate to the research and participants involved. The following are examples of how a form can be written but should not be used as a template.

Research Ethics Policy Undertaking

I, hereby acknowledge that I am familiar with the provisions of the University of Dares Salaam Code of Conduct for Research and undertake to comply with its requirements.

.....
 Signature _____ Date _____
 Staff/Student ID Number:

Research Consent Form

Title of Research:

Researcher: Ph.D. candidate, (Pol. Sc.) Supervisor:

Contact Information:

Tel:

Email:

Purpose of the research:

What is involved in participating:

Consent:

a) I wish to be identified in the report ☐ YES ☐ NO

b) I have read the above information and I agree to participate in this study

Signature: Researcher's signature:

Name: Date:

This is to invite you to participate in a study entitled which is being conducted by....., in the Deptment of at the University of Dar es Salaam with funding from the..... The purpose of this research is to investigate

Your participation in the study will entail an oral interview, lasting approximately one hour, to be conducted by a member of research team, which will be tape-recorded in its entirety.

In this interview you will be asked to provide demographic data about yourself (e.g. residential history, ethnicity, occupation, education and language background); to read lists of words; to compare the pronunciation of pairs of words and to talk about any opinions on current issues.

Your participation is voluntary and you may choose not to participate or withdraw at any time or refuse to answer any question you don't want to. You will receive T.shs. in compensation for your time.

Your name will never be revealed in written or oral presentations and no record will be kept of your name. Portions of the interview may be played in linguistic classes or conference presentations for demonstration purposes connected with linguistic analysis.

The tapes will only be accessible to members of the research team and will be kept by..... under locked conditions.

You may contact..... at Tel.....; Email..... if you have any questions or concerns.

I agree to be tape-recorded ☐ YES ☐ NO

I agree that the tape may be used as described above: ☐ YES ☐ NO

Participant's signature _____ Researcher's signature _____

Participant's name _____ Date _____

APPENDIX ii: APPLICATION FOR ETHICS CLEARANCE FOR HUMAN SUBJECT RESEARCH

Project Title:.....

Principal Investigator:.....

Department:.....

Phone :..... Fax:..... Email:.....

Mailing Address (if different from Department):.....

Status: Staff () Postdoctoral Fellow () Other (specify) ()

Ph.D. Student () Master's Student () Undergraduate ()

Type of Research: Staff Research.....

Thesis () Dissertation () Independent Study Project ()

Course Assignment (specify course name) () Other () (specify)

Supervisor (for student Pls):.....Email:.....

Co-Investigator(s) (list name/status/affiliation):
.....
.....

List all funding sources for this project and project titles (if different from the above). Indicate the Principal Investigator of the award if not yourself.

Awarded:

Pending:

Principal Investigator's Statement:

I will ensure that this project is conducted in accordance with the policies and procedures governing the ethical conduct of research involving human subjects at the University of Dar es Salaam.

Principal Investigator's Signature:

Date:.....

College/School/Institute Supervisor's Statement:

I have read and approved this project and affirm that it has received the appropriate academic approval. I will ensure that the student investigator is aware of the applicable policies and procedures governing the ethical conduct of human subject research at UDSM and I agree to provide all necessary supervision to the student.

College/School/Institute Supervisor's Signature:.....

Date:.....

1. Purpose of the Research

Describe the proposed project and its objectives, including the research questions to be investigated (one page maximum). What is the expected value or benefits of the research? How do you anticipate disseminating the results (eg thesis, presentations, internet, film, publications)?

2. Recruitment of Subjects/Location of Research

Describe the subject population and how and from where they will be recruited. If applicable, attach a copy of any advertisement, letter, flier, brochure or oral script used to solicit potential subjects (including information sent to third parties). Describe the setting in which the research will take place. Describe any compensation subjects may receive for participating.

3. Other Approvals

When doing research with various distinct groups of subjects (e.g. school children, cultural groups, institutionalized people), organizational/ community/governmental permission is sometimes needed. If applicable, how will this be obtained? Include copies of any documentation to be sent.

4. Methodology/Procedures

Provide a sequential description of the methods and procedures to be followed to obtain data. Describe all methods that will be used (e.g. fieldwork, surveys, interviews, focus groups, standardized testing, video/ audio taping). Attach copies of questionnaires or draft interview guides, as appropriate.

5. Risks

- Describe any known or foreseeable risks, if any, that the subjects or others may experience during or as a result of the research. Risks may be psychological, physical, emotional, social, legal, economic, or political.
- In light of the above assessment of potential risks, indicate whether you view the risks as acceptable given the value or benefits of the research.
- Outline the steps that may be taken to reduce or eliminate these risks. If deception is used, justify the use of the deception and indicate how subjects will be debriefed or justify why they will not be debriefed.

6. Privacy and Confidentiality

Describe the degree to which the anonymity of subjects and the confidentiality of data will be assured and the specific methods to be used for this, both during the research and in the release of findings. This includes the use of data coding systems, how and where data will be stored, who will have access to it, what will happen to the data after the study is finished, and the potential use of the data by others. Indicate if there are any conditions under which privacy or confidentiality cannot be guaranteed (e.g. focus groups), or, if confidentiality is not an issue in this research, explain why.

7. Informed Consent Process

Describe the oral and/or written procedures that will be followed to obtain informed consent from the subject. Attach all consent documents, including information sheets and scripts for oral consents. If written consent will not be obtained, justification must be provided.

8. Other Concerns

- Indicate if the subjects are a captive population (e.g. prisoners, residents in a center) or are in any kind of conflict of interest relationship with the researcher such as being students, clients, patients or family members. If so, explain how you will ensure that the subjects do not feel pressured to participate or perceive that they may be penalized for choosing not to participate.
- Comment on any other potential ethical concerns that may arise during the course of the research.

APPENDIX iii: ETHICS REVIEW - ANNUAL STATUS REPORT/RENEWAL REQUEST/ FINAL REPORT

Continuing review of human subjects research requires at a minimum, the submission of an annual status report to the REC. This form must be completed to request renewal of ethics approval. If a renewal is not received before the expiry date, the project is considered no longer approved and no further research activity may be conducted. When a project has been completed, this form can also be used as a Final Report, which is required to properly close a file. To avoid expired approvals and, in the case of funded projects, the freezing of funds, this form should be returned at least one month before the current approval expires.

REC File Number:

Project Title:

Principal Investigator:

Department/Phone/Email:

College/School/Institute Supervisor (for student PI):

- Were there any significant changes made to this research project that have any ethical implications? ☐ Yes ☐ No. If yes, describe these changes and append any relevant documents that have been revised.
- Are there any ethical concerns that arose during the course of this research? Yes ☐ No ☐ If yes, please describe.
.....
.....
- Have any subjects experienced any adverse events in connection with this research project? Yes ☐ No ☐ If yes, please describe.
.....
- ☐ This is a request for renewal of ethics approval.
- ☐ This project is no longer active and ethics approval is no longer required.
- List all current funding sources for this project and the corresponding project titles if not exactly the same as the project title above. Indicate the Principal Investigator of the award if not yourself.

Principal Investigator's Signature: _____ Date: _____

College/School/Institute Supervisor's Signature: _____
Date: _____

For Administrative Use

☐ The closing report of this terminated project has been reviewed and accepted☐ The continuing review for this project has been reviewed, and approved☐ Expedited Review ☐ Full Review

Signature of REC Chair or designate: _____

Date: _____

Approval Period: From _____ to _____

APPENDIX IV: ETHICS REVIEW - ADVERSE EVENT REPORTING FORM

REC File Number: _____

Project Title: _____

Principal Investigator: _____

Department/Phone/Email: _____

College/School/Institute Supervisor (for student PI): _____

1. Describe the adverse event that occurred in conjunction with this research project.
2. How many subjects have experienced the adverse event?
3. Was this adverse event a potential risk that was disclosed to the subject in the consent form, or was this an unforeseen event?
4. Will it be necessary to revise the consent form or make any changes to the project in order to reduce the risk of the occurrence of this adverse event? If yes, append the relevant revisions.

Principal Investigator's Signature: _____

Date: _____

College/School/Institute Supervisor's Signature: _____

Date: _____ (for student PI)

For Administrative Use

Date Reviewed: _____

Signature of REC Chair or designate: _____

Comments: _____

APPENDIX V: INSTRUCTIONS TO INVESTIGATORS SUBMITTING ANIMAL USE RESEARCH PROPOSALS FOR PROJECTS REVIEW

In accordance with the University of Dar es Salaam Research Ethics Policy, all research projects involving the use of animals must be peer reviewed for scientific merit. In cases where project funding comes from non-peer reviewed sources such as internal departmental funds or industry, it is the Principal Investigator's responsibility to provide the Animal Research Committee with appropriate peer review. Documentation must come from two qualified individuals outside the PI's unit or department.

In cases where the project funding comes from a small foundation or an industrial source where peer-review for scientific merit has been conducted, documentation regarding the dates of review, the composition of the scientific panel and a brief description of the review process should be provided.

Definition of Conflict of Interest

Reviewers must declare a conflict of interest when they:

- Are from the same immediate institution or company as the applicant, and who interact with the applicant in the course of their duties at the institution or company.
- Have collaborated, published or been a co-applicant with the applicant, within the last five years.
- Have been a student or supervisor of the applicant within the last ten years.
- Are a close personal friend or relative of the applicant.
- Have had long-standing scientific or personal differences with the applicant.
- Are in a position to gain or lose financially from the outcome of the application (eg hold stock in the company of an industry partner or a competitor) or for some other reason feel that they cannot provide an objective review of the application.

ANIMAL USE PROTOCOL REVIEW QUESTIONNAIRE

Project Title: _____

Investigator: _____ Unit/Department: _____

FOR THE PROJECT INDICATED ABOVE, PLEASE COMMENT ON THE FOLLOWING
(Attach additional pages if necessary)

Scientific Merit: _____

Justification for Animal Use: _____

Experimental Design: _____

Sample Size: _____

Sufficient information supplied: _____

Additional Comments: _____

Reviewer's Name (please print) _____ Signature: _____

Date: _____

Title: _____ Affiliation: _____

I certify that I have no affiliation with the funding source for this project:
Yes _____ No _____

APPENDIX VI: IMPORT FORM

Import No:

Please complete this form 6 weeks prior to preferred delivery date.
Answer all questions in sections 1, 2, & 3. (PLEASE TYPE)

1) GENERAL INFORMATION

- a) Proposal number:
- b) Department:..... Institution:.....
- c) Contacts:
- Postal address:.....
- Tel:..... Email:.....
- (d) Request date:..... Account No:

PLEASE ATTACH THE APPROVED PROPOSAL OR AMENDMENT FORM LISTING THE TRANSGENIC OR KNOCKOUT ANIMALS BEING IMPORTED OR HAVE THE CHAIR OF THE FACILITY ANIMAL CARE COMMITTEE SIGN APPROVAL BELOW:

Chairperson:.....

No animals will be accepted by the University of Dar es Salaam or affiliated institutions without the approval of a University of Dar es Salaam Veterinarian. Please attach a recent health report (serology, bacteriology, & parasitology).

2) SENDING INSTITUTION

- a) Institution name and location:.....
- b) Name of Investigator who owns the animals:.....
- c) Facility Veterinarian:
- Tel: Email:.....

3) ANIMAL INFORMATION

Species	Sex	Background Strain	Genotype with transgenic knocking or knockout designation	N	Age
	M				
	F				
	M				
	F				

Are any animals being shipped in breeding pairs? Yes () No ()

How will the animals be used? Acute study () Breeding colony ()

Will transplantable tumor or cell lines be used?

Where will the animals be housed?.....

Building and room location of where you want animals?.....

For Official Use Only

Health status check completed..... Date:.....

Additional testing: Bacteriology () Parasitology () Serology ()

Others (specify).....

Animal Research Centre's comments:.....

Facility Supervisor's comments:.....

Shipping information:

Arrival date:.....Waybill

Billing Boxes.....

A i r

Freight:.....Brokerage:.....

Administration Fees.....

Request Number:.....

APPENDIX VII: EXPORT FORM

Export Number.....

Please complete this form 2 weeks prior to shipment date.

Answer all the questions in Sections 1, 2, & 3. [PLEASE TYPE]

1. GENERAL INFORMATION

a) Protocol number:

b) Department:

c) Contacts:

Postal address:

Tel:

Email:

d) Request date: Account No:

IMPORTANT

No animals will be shipped out of the University of Dar es Salaam without approval of the Health Status Report (serology, bacteriology, parasitology reports from the animal colony) by the receiving institution's veterinarian.

2. RECEIVING INSTITUTION

a) Principal Investigator:

Postal address:

b) Institution Name: Tel:

c) Facility Veterinarian: Email:

d) Shipping Address:

3. ANIMAL INFORMATION:

Species	Sex	Background Strain	Genotype with transgenic knocking or knockout designation	N	Age
	M				
	F				
	M				
	F				

- i) Are any animals being shipped in breeding pairs? Yes () No ()
- ii) How will the animals be used? Acute study () Breeding colony ()
- iii) Will transplantable tumor or cell lines be used?
- iv) Where will animals be housed?
- v) Building and room location of where you want the animals?

For Official Use Only

Health status check completed by: Date:

Additional testing: Bacteriology () Parasitology () Serology ()

Others (specify):

Animal Research Centre's comments:

Facility Supervisor's comments:

Shipping Information:

Arrival date: Waybill:

Billing Boxes:

Air Freight:

Brokerage:

Administration Fees:

Request Number:

APPENDIX VIII: FIELD STUDIES

1. INTRODUCTION

This form provides a detailed description of the procedures executed in the field. It must be attached to the Animal Use Proposal.

2. INFORMATION REQUIRED

Provide all relevant details:

2.1 Method of capture/restraint, duration of captivity, potential injury/mortality, monitoring frequency:

2.2 Transportation and/or housing of animals in the field:

2.3 Special handling required:

2.4 Capture of non-target species, potential injury/mortality:

2.5 Will captured animals be released at or near the capture site?
YES () NO ()

If not, specify if they will be relocated to other locations and/or populations.

2.6 Describe any potential ecological disruption this study may cause:

2.7 Other pertinent information:

Signature: _____

Date: _____

NOTE: It is the responsibility of the investigator to obtain all the necessary permits for work with the wildlife. Copies of these permits must be supplied when they are obtained.

APPENDIX IX: DISCLOSURE FORM - CONFLICT OF INTEREST

Any staff member of the University, including staff employed in posts funded by outside bodies, is required to disclose to the College Principal, Head of School, or other appropriate line manager, any actual or perceived conflict of interest that may arise in the course of his or her work. Such disclosure may be made on this form or as an equivalent written submission. After completion, the disclosure must be lodged in the Research Office. Failure to disclose a conflict of interest may lead to disciplinary action.

Name of staff member making disclosure	
Staff ID number	
College/School/Institute	
Name of staff member to whom disclosure is being made	

Check list

Circle "Yes" or "No" for every question. Benefits marked with an asterik are prohibited.

Financial Interest

Do you or a close member of your family have any financial interest in or affiliation with an institution, company, or individual that:

Funds or sponsors your research?	Yes	No
May benefit directly or indirectly from access to or use of University resources?	Yes	No
May benefit directly or indirectly from the purchase of major equipment by the University for this project?	Yes	No
May benefit directly or indirectly by inappropriate delays or controls on the dissemination of the results of the research?	Yes	No

Will you or a close member of your family receive any of the following?

* Discounts or concessions or other financial benefits from a company or individual with which an order is placed? (The award of air miles associated with the purchase of air tickets and other travel expenses is permitted and does not require disclosure, provided that mechanisms are in place to ensure that itineraries and fares are appropriate to the travel requirements. The normal mechanism would be a counter-signature on the order by the line manager.)	Yes	No
* Discounts or concessions or other financial benefits from a company or individual that is awarded a contract?	Yes	No

Perception of Nepotism

Will any close member of your family be employed from funds under your control?	Yes	No
---	-----	----

Clinical Trials

Does the research involve a clinical trial sponsored by an individual, company, or organization that has a significant financial interest in the results of the trial?	Yes	No
--	-----	----

If the answer to any of the above is "Yes" then:

1. Outline the nature of the conflict.
2. Describe the sense in which the situation is of benefit to the University and the research programme.
3. Propose a mechanism for the management of the conflict.

.....

Agreed Procedure for the Management of the Conflict

To be completed by the College Principal or Dean of School or other appropriate approval organ.

.....

Certification

I certify that I have disclosed everything relevant to the College Principal/Dean of School. I undertake to act according to the above management plan

Signature of Researcher..... Date:.....

I have applied my mind to the situation described above and will monitor compliance with the Management Plan.

Signature of College Principal/Dean of School:.....
 Date:.....