

TUMAINI UNIVERSITY MAKUMIRA

Research Ethics

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Foreword

Among the objectives of Tumaini University Makumira (TUMA) is to equip other fields of teaching, learning and consultancy through relevant research. This research ethics policy guides lecturers, researchers, and students in conducting research studies that consider ethical conducts. Therefore, a TUMA Research Ethics Policy has 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 conflicts of interest as well as conflicts of commitment. The policy has incorporated 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 TUMA 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 TUMA. In addition, any person not affiliated with TUMA who wishes to conduct research with TUMA 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.

Rev. Prof. Joseph W. Parsalaw **Vice Chancellor** Tumaini University Makumira

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Acknowledgement

This Research Ethics Policy (UREP) could not come into being without the contribution from various organizations and persons. Some of the content materials have been adapted from Research Ethics Policy of Tumaini University Dar es Salaam College (TUDARCo) and customized to reflect the specific context and environments prevailing at the Tumaini University Makumira (TUMA).

I thus, feel pleased to acknowledge the contribution of TUDARCo through its Research Ethics Policy. Their contributions include some of the main contents relating to policy statements, the general policy format and layout as well as some of the the annexes.

I also wish to extend my gratitude to the Vice Chancellor, Rev. Prof. Joseph Parsalaw for his esteemed leadership that made it possible for University to possess its own Research Ethics Policy. I also extended my thanks to the immediate DVCAA, Prof. Ismail R. Mbise, Prof. Dr. Faustin Mahali and Dr. Doward Kilasi for their efforts in the preparation and production of the first draft document (2020). It is my hope that this final document will take the University to yet another competitive level of research practices characterized by the scientific research procedures, publication and dissemination of research results that will enhance the profile of the institution, generate funds for the university and sensitize internal as well as external research clientele and the wiser stakeholder community to abide by research ethics and good research practice.

Prof. Godwill D. Mrema

Deputy Vice Chancellor for Academic Affairs

Tumaini University Makumira (TUMA)

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List of Abbreviations

CPP Consultancy Policy and Procedures

DoRP Directorate of Research and Publication

DRP Director of Research and Publication

DVCAA Deputy Vice Chancellor Academic Affairs

FEHS Faculty of Education, Humanities and Science

FoL Faculty of Law

FTh Faculty of Theology

HRM Human Resources Management

ICPE Institute of Continuing and Professional Education

ICTP Information and Communication Technology Policy

IPP Intellectual Property Policy

SCACA Academic and Curriculum Affairs

TTCL Tanzania Telecommunications Company Limited

TUDARCo Tumaini University Dar es Salaam College

TUMA Tumaini University Makumira

UAC University Academic Committee

UDSP Data Security Policy

UREC University Research Ethics Committee

UREP University Research Ethics Policy

Executive Summary

1. Introduction

One of the institutional objectives of the Tumaini University Makumira is raise quality of education through carrying out relevant research. In view of that, the University established the Directorate of Research and Publications (DoRP) to coordinate research, to support departments and faculties in their research dissemination and to be the custodian of the research policy and coordination of its implementation. Also, as part of its ethical obligations, the university, should ensure that university research is of highest possible quality and foreign researchers working in collaboration with TUMA are granted research permits from COSTECH. Emergence of new programmes and other disciplines may necessitate need for consulting other research permit granting bodies. Research ethics is widely accepted as a guide for the conducting responsible research by indicating on the "dos" and the "don'ts" of research as well as educating and monitoring research conduct with a view to ensuring highest possible ethical standards. It is the desire of the University that all researchers be familiar with basic ethical principles and up-to-date on policies and procedures designed to ensure the safety and responsible consideration of research subjects and avoid irresponsible research. Ignorance of policies designed to protect researchers and research subjects will in no way be considered a viable excuse for ethically questionable research projects. It is therefore the duty of researchers to acquaint themselves with relevant knowledge, skills, and policies designed to guarantee honest and responsible research practices.

2. The Establishment of the University Research Ethics Policy (UREP)

Since research is one of the pillars of the University mission, TUMA strategically aims at increasing research activities and quality of research outputs. However, in some cases, research may cause physical or psychological harm to the communities where it is conducted. In order to research with ethical considerations, research ethics policy is vital 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 TUMA Senate, TUMA Senate Committee for Academic and Curriculum Affairs (SCACA), Directorate of Research and Publication (DoRP), and the TUMA Faculty Boards are the participatory organs responsible for making decisions on the scientific and ethical soundness of research activities. However, these organs have specific roles that may somehow be conflicting with the role of University Research Ethics Committee (UREC), which has the power to manage the overall quality of research undertakings with a specific attention to ethical issues.

3. The University 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 TUMA 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 campus of the University. In addition, any person not affiliated with TUMA who wishes to conduct research in collaboration with TUMA 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 being a violation of this policy.

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

There shall be established University Research Ethics Committee (UREC). The appointment of members to the committee shall be made by the Vice Chancellor. The committee shall be chaired by the Deputy Vice Chancellor for Academic Affairs (DVCAA) while the Director of Research and Publication (DoRP) shall be the Secretary. The UREC shall be responsible to the University Directorate of Research and Publication which shall on the other hand report to University Academic Committee and Senate.

The University Research Ethics Committee shall have a sub-committee in each of the major disciplines. Among them there shall be the following sub-committees:

- (a) Education, Humanities and Science Research Ethics Committee
- (b) Science Research Ethics Committee
- (c) Theology Research Ethics Committee
- (d) Law 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 UREC for ethical clearance.

The committee shall meet four times a year (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 University is an autonomous entity 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, law, business as well as internet research, management of data and records, confidentiality of data, 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 within the principles of openness, trust and free enquiry. The policy gives guidelines for dealing with conflicts of interests as well as conflicts of commitment. It shall be the responsibility of every principal investigator to make sure that he/she is familiar with the provisions of the University Research Ethics Policy and code of conduct for research and undertakes to comply with its requirements.

CHAPTER ONE

BACKGROUND AND RATIONALE FOR DEVELOPING RESEARCH ETHICAL STANDARDS

1.1 Background

One of the institutional objectives of TUMA is to carry out research as a way of advancing learning and teaching and integrating it with consultancy and services. Consequently, the University will collaborate with other national, international and external institutions in research, in order to increase the quality and the volume of research. Effective coordination of research has thus been seen to be important in realizing this mission.

Apart from the expected increase in the volume of research, there is great potential for an increase in diversity, multi-disciplinarity 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

The TUMA Research Ethics Policy is intended to provide a standard or yard-stick for the safeguard of integrity of data arising from research activities at the University. The articulated principles in the document are also expected to support researchers in adhering to best research practice in relation to research studies with a view of ensuring compliance to the needs of the wider-stakeholders involved directly or indirectly in the research undertaking.

Therefore, consistent with the *National Research Integrity Framework of Tanzania*, COSTECH, 2020, all staff and students conducting research with humans must ensure that their projects undergo prior ethics review and clearance through a University Research Ethics Committee (UREC). In addition, any person not affiliated with TUMA, who wishes to conduct research on campus with university staff and students as participants, is bound by the same ethics review requirement. The UREC 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. The UREC has also incorporated other standards to conform to when carrying out experiments on human participants, since this policy has to be inclusive of all disciplines for expansion purposes.

The COSTECH which is a government body mandated to issue research permits, requires confirmation from relevant institutions that the research has been cleared and complies with ethical considerations, especially for research done in collaboration with foreign researchers.

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 TUMA thereby clarifying for researchers their ethical obligations. The specific objectives are:

- (a) To establish a system for research ethical assurance at TUMA
- (b) To establish a code of ethical conduct for research at TUMA

CHAPTER TWO

POLICY ISSUES AND STATEMENTS

2.1 Capacity Building in Research Ethics

The University shall:

- a) Facilitate the ethical conduct of scholarly research by developing and providing capacity building programmes in research ethics for researchers and members of the University Research Ethics Committees.
- b) Inculcate and create awareness of ethical conduct of research in the wider community.

2.2 Selection and Conduct of Research

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

2.3 Collaborative Research

TUMA shall be involved in collaborative research projects with other national and international institutions. Where collaborative research is being conducted:

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

2.4 Students Research

The University shall encourage students to participate in research in order to inculcate the research culture. Where research is to be conducted by students for academic credit:

- a) It shall be the responsibility of the supervisor to inform the student of his/her obligations in respect of the ethical conduct of research.
- b) The supervisor shall ensure that the student understands his/her obligations in accordance with the University Policy.
- c) 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 sign the University Code of Research Conduct (to be included in TUMA Research Manual and Tools).

2.5 Honesty and Integrity

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

- a) Researchers maintain the highest standards of honesty and integrity.
- b) Any form of academic dishonesty, including but not limited to the following shall be penalized:
 - i) Falsification of Data
 - ii) Plagiarism
 - iii) Fabrication
 - iv) Not declaring a Conflicts of Interest or Conflicts of Commitment
 - v) Misuse of Research Funds
 - vi) 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. The University shall therefore ensure that:

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

2.7 Intellectual Property

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

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

2.8 Disputes between Co-researchers

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

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

2.9 Disciplinary Action

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

The University shall:

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

2.10 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 University shall therefore ensure that:

- a) Each member of the University endeavours to contribute to the existence of a just and supportive society based on equality and respect for individual differences;
- b) Research environment is free from harassment and discrimination and abuse of, and by supervisory authority.
- c) Services, benefits, opportunities, and facilities offered by the University match their intended purposes and are provided to all personnel in the University with the relevant qualifications. Thus, such provisions shall not be denied wholly or partly on irrelevant or prohibited grounds;
- d) 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;
- e) No member of the University (staff, student) shall unduly interfere with the research of other members of the University or any other related activity of another institution;
- f) Those with supervisory authority (academic or employment) use such authority solely for the purposes explicitly stated or implied in University policies.
- g) All forms of discrimination or sexual harassment in research are not condoned.
- h) Staff and students adhere to the following guiding research ethical principles:
 - i) Respect for human dignity
 - ii) Respect for vulnerable persons
 - iii) Respect for confidentiality and privacy
 - iv) Respect for justice
 - v) Respect for safety of students
 - vi) Respect for existing ethical codes and professional standards
 - vii) Balancing harm and benefits

2.11 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 Intellectual Property (IP) purposes. TUMA shall ensure that:

a) 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;

- b) Material or specimen transfer is specified in the protocol agreement. Where the agreement does not specify, special permission shall be obtained from the University Research Ethics Committee;
- c) All researchers ensure adequate arrangements for back-ups and security of electronic datasets;
- d) Primary data be stored at the faculty or department in which it has been gathered and not by individual researchers;
- e) Data on which any research publication is based be retained for at <u>least ten</u> years after publication.
- f) 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 shall be:
 - i) The data set is retained in the University.
 - ii) The researcher has access to the original data set and may keep copies.
 - iii) 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.
- g) If no publications based on the data set appear within five years, the data may be destroyed;
- h) With respect to data confidentiality, the following shall apply:
 - i) Researchers are entitled to keep data sets confidential before publication.
 - ii) 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.
 - iii) 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.

2.12 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.

TUMA shall require researchers to satisfy themselves that:

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

2.13 Authorship

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

- a) Each author shall have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- b) One or more of the authors, as corresponding author, shall take responsibility for the integrity of the work as a whole.
- c) Credit as an author shall be based only on participation in each of the following aspects of the work:
 - i) Substantial contribution to conceptualisation and design of the research, or acquisition of data, or analysis and interpretation of data;
 - ii) Either drafting the article or commenting critically on the draft;
 - iii) Approving the final version, to the extent that each author is prepared to take joint responsibility for it.
- d) The acquisition of funding, the collection of data, or the general supervision of the research group, shall not, by themselves, justify authorship. Such contributions shall be listed in the acknowledgements;
- e) The order of authorship shall be a joint decision of the authors, decided at an early stage of drafting the paper. Nevertheless:
 - i) 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.
 - ii) 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.

2.14 Citation

It is important in all publications, including such documents as research proposals, 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 University shall require:

- a) Researchers to give due credit to their sources of ideas, quotations or data.
- b) That any of the following are appropriately cited:
 - i) Direct quotations of published material longer quotations may require a release from the copyright holder.
 - ii) The description, summarising, or paraphrasing of any previous work.
 - iii) 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.
 - iv) Ideas that originate from other published or unpublished sources.

2.15 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, mainly in form of funding. Collaboration 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 University shall require that:

- a) Any publication emanating from research supported by the University funding or other resources shall acknowledge receipt of the University support.
- b) 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.
- c) 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.
- d) The author's address for work done while on sabbatical leave should include the University address.
- e) 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.
- f) A research done in a form of a project solicited by the Directorate of Research/Faculty/Department or individual shall follow financial guidelines set in the Consultancy Policy and Procedures (CPP).

2.16 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 ethics. The TUMA shall require the referees to be meticulous about the following:

- a) 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.
- b) No use should be made of any of the ideas or results in the work under review until it has been published.
- c) Care should be taken to avoid a conflicts 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.
- d) 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.

2.17 Redundant Publication

Redundant publication is one that overlaps *substantially* with another publication already published and is thus an unnecessary publication of similar material in different places and is considered to be a special type of plagiarism.

The University shall require that:

- a) 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.
- b) Researchers consider carefully the most effective way to publish a particular research result or set of research results taking into account the TUMA IP Policy. This shall be done with regard to the best way to timely communicate the results and not to maximise the publication count.
- c) 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 (according to latest version of TRMT) 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.

2.18 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. To ensure good practice, the University has put in place Regulations governing academic dishonesty – plagiarism as well as Anti-plagiarism Policy and guidelines. Furthermore TUMA has a Code of conduct, disciplinary code and permissible penalties which every member of the TUMA community as well as strategic partners have to observe and comply. It is the wish of the University that good and ethical practice flourishes in all TUMA activities as is also expected by the most recent TCU (2019) Handbook for Standards and Guidelines for University Education in Tanzania.

The University shall therefore require:

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

2.19 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 TUMA community and its strategic stakeholders are expected to fully comply with the University Code of conduct in 2.18 in all their scholarly and related activities.

TUMA shall therefore require:

Staff members and students to refrain from research misconduct.

2.20 Conflicts of Interest and Conflicts 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 University shall:

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

2.21 Internet Research

We are living in the Fourth Industrial Revolution that is characterised by the application of information and communication technologies (ICT) to the industry, also known as the "**Industry 4.0**". Following 3rd Industrial Revolution, the 4th Industrial Revolution has transformed production systems with computer technology expanded by a networks with digital twin on the Internet. Such systems allow communication with other facilities and the output of information about themselves (automation) and "cyber-physical production systems or smart factories, in which production systems, components and people communicate via a network and production is nearly autonomous. Such development would have never been possible without the ICT.

Developments ICT have therefore played a very important role in research in the recent years. With the world 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 more easily. The University has in place the Information and Communication Technology Policy (ICTP) and University Data Security Policy (UDSP) to manage the use and protection of data and information flow on the Internet.

CHAPTER THREE

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 accommodate and undertake the duties of operationalization within the University structures. Towards achieving that, TUMA shall:

- (i) Establish a University (TUMA) Research Ethics Committee (**UREC**) which shall be a subcommittee of the University Postgraduate Studies, Research, Publication and Consultancy & Services Committee (PRC);
- (ii) Establish Research Ethics sub-committees in the following areas:
 - (a) Biomedical and organisms (flora and fauna) research;
 - (b) Research involving human beliefs, human rights, law and entertainment;
 - (c) Research involving education, business and social sciences;
 - (d) Research involving natural sciences and technology
 - (e) Internet research

3.1.1 Membership to the Research Ethics Committee (UREC)

The Vice Chancellor shall appoint members to the UREC who shall be approved by the University Academic Committee (UAC). In the appointment of members to the UREC, gender balance shall be given due weight. Appointments to the committee shall also be in person depending on the interest, experience and expertise in research and ethics matters.

The University Research Ethics Committee (UREC) shall have the following members:

- (a) DVCAA (Chairperson)
- (b) DPRC (Secretary)
- (c) A natural science/biomedical and technology expert, Member
- (d) An environmentalist, Member
- (e) A education/social scientist/business studies expert, Member
- (f) A theology/legal expert, Member
- (h) An expert in information communication technologies, member
- (g) A community representative not associated with the University, member

3.1.2 Meetings

The UREC 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 in all research activities involving the University.

3.2 Sub-Committees of UREC

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

- (i) Education, Business and Social sciences Research Ethics sub-committee;
- (ii) Natural Sciences and Technology Research Ethics sub-committee

- (iii) Human beliefs, Human Rights, Law and Entertainment Research Ethics subcommittee:
- (iv) Biomedical and Organisms (flora and fauna) Research Ethics sub-committee;
- (v) Internet/ICT Research Ethics sub-committee;

The roles and responsibilities of the sub-committees shall be to:

- (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 and, or guide as will be most fit;
- (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 articulated in (ii) above.

The appointment of members to the sub-committees shall be in accordance with the standard operating procedures authorized by the University Academic Committee (UAC).

3.2.1 Education, Business and Social sciences Research Ethics Sub-Committee

There shall be established an Education, Business and Social sciences Research Ethics Sub-Committee. The DVCAA shall appoint members to the sub-committee. Appointment shall be in person depending on interest, experience and expertise on ethics matters. Gender balance shall be given serious consideration. The Sub-committee shall be multidisciplinary including the following members:

- (a) Interim Chairperson Dean, Faculty of Education, Humanities and Science (FEHS)
- (b) Interim Secretary Faculty Coordinator, PRC;
- (c) Three experts in Education, Humanities, and Social Science
- (d) A legal expert
- (e) An expert in business
- (f) Two community representatives not associated with the University
- (g) One graduate student

3.2.2 Natural Sciences and Technology Research Ethics Sub-Committee

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

- (a) Interim Chairperson Dean, FEHS;
- (b) Secretary Faculty Coordinator PRC;
- (c) One Science researcher from the FEHS;
- (d) One Technology expert/researcher;
- (e) Science Technician or laboratory instructor;
- (f) Laboratory Engineer or laboratory instructor;
- (g) A community representative not associated with the University

3.2.3 Human beliefs, Human Rights, Law and Entertainment Research Ethics Sub-Committee

There shall be established a Human Belief, Human Rights, Law and Entertainment Research Ethics Sub-Committee. The DVCAA shall appoint members to the sub-committee. Appointment shall be in person depending on interest, experience and expertise on ethical issues. Gender balance shall be given serious consideration. The Sub-committee shall be multidisciplinary including the following members:

- (a) Interim Chairperson Dean, Faculty of Theology (FTh)
- (b) Secretary Faculty Coordinator, PRC
- (c) Three members from Biblical, Pastoral and Systematic/Church History Departments
- (d) A legal expert
- (e) An expert in Entertainment sub-sector
- (f) One community representatives not associated with the University
- (g) One graduate student

3.2.4 Biomedical and Organisms (flora and fauna) Research Ethics Sub-Committee

There shall be established a Biomedical and Organisms (flora and fauna) Research Ethics Sub-Committee. The DVCAA 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) Interim Chairperson- Dean, Faculty of Law
- (b) Secretary Faculty Coordinator, PRC
- (c) An environmental expert;
- (d) An ecologist expert;
- (e) A legal expert;
- (f) A representative from nursing profession
- (g) One graduate student

3.2.5 Internet/ICT Research Ethics Sub-Committee

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

- (i) Recognizes both ethically-pertinent similarities and differences between traditional human subject research and research into online machine 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/ICT Research Ethics Sub-Committee shall comprise the following members appointed by the DVCAA:

(a) Chairperson- Dean, Faculty of Education, Humanities and Science (FEHS)

- (b) Secretary–Faculty Coordinator, PRC
- (c) Head of ICT Department
- (d) A trusted expert in online management systems from outside the University
- (e) A legal Expert
- (f) An expert in telephone business from TCCRA
- (g) One graduate student

3.3 Guidelines for Sub-Committees of UREC

3.3.1 General Guidelinea

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.

3.3.2 Research involving human subjects and related organisms

Research involving human subjects and related organisms requires ethical clearance from Research Ethics Sub-Committees of respective disciplines approved by the University UREC. Application is to be made on the appropriate application form (Ethical Clearance Form). Guidelines for Education, Business and Social sciences Research are similar to those applicable in Human Beliefs, Human Rights, Law and Entertainment Research because in all cases they involve Guidelines for Biomedical and Organisms (flora and fauna) Research Ethics Review

All biomedical experiments involving human subjects shall require *prior ethical clearance*. Application must be made through the appropriate Form to the Biomedical and Organisms (flora and fauna) Research Ethics Committee (*Appendix-1*)

3.3.2.1 Research with Human Participants

- Consistent with Research Ethics Policy of the Tumaini University Makumira (TUMA) 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 relevant 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 TUMA who wishes to conduct research on campus with TUMA students and/or staff as participants is bound by the same ethics review requirements.
- Ethical clearance is not given to a wholesome 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 relevant Ethics Committee prior to commencement of the study.

3.3.2.2 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.

3.3.2.3 Ethics Review Process

- The intent of the ethics review process is to ensure that all research involving human participants at TUMA is consistent with the relevant University Research Ethics Policy and the National Guidelines on Research Involving Human Subjects.
- The Review 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 shall 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.

3.3.2.4 Human Research Ethics Review

• Projects referred to the Biomedical and Organisms (flora and fauna) Research Ethics sub-committee (BOREC) include those that involve the recruitment of vulnerable persons, e.g., institutionalized elderly people and those with procedures that pose more than minimal (physiological, psychological or other) risk to participants.

3.3.2.5 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, e.g., 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.

- Request for Clearance of Modifications (Appendix-2) 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.

3.3.2.6 Annual Progress Report/Form

- As a condition of ethics clearance, researchers are required to update appropriate Research Ethics Committee for human 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-3) 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 on 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.

3.3.2.7 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-4**).
- 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.

Based on its strategic plan and research endeavours TUMA aspires to be research intensive institution supporting responsible use of animals (abundantly rich at its close environment) in research for the purpose of obtaining knowledge that potentially benefits 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-5*.

3.3.2.8 Animal Research Ethics Review

(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-6*) and **Export Form** (*Appendix-7*) 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 e.g., the World Wildlife Fund (WWF) as well as national organizations e.g., 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-8. It is the responsibility of the investigator to obtain all necessary permits for work with wildlife.

3.3.3 Guidelines for RE Subcommittees

3.3.3.1 Education, Business and Social Sciences Research Ethics Review

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.

Research involving this category of disciplines shall require ethical clearance from the Education, Business and Social Sciences Research Ethics Committee. Application is to be made on the appropriate application Form. Guidelines for research review in this category are similar in many ways to those applicable in biomedical, Organisms (flora and fauna) research as well the Education, Business and Social Sciences Research Ethics Committee because in both cases they involve human subjects.

3.3.3.2 Humanities Beliefs, Human Rights, Law and Entertainment Ethics Review

Research involving this group and category of disciplines shall require ethical clearance from the Humanities Beliefs, Human Rights, Law and Entertainment Ethics Committee. Application is to be made on the appropriate application Form. Guidelines for research review in this category are similar in many ways to those applicable in biomedical, Organisms (flora and fauna) research because in both cases they involve human subjects.

3.3.3.3 Guidelines for Natural Sciences and Technology Ethics Review

Consistent with the TUMA 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 TUMA who wishes to conduct research on campus with TUMA students and/or staff as participants is bound by the same ethics review requirements.

3.3.3.4 Guidelines for Biomedical, Organisms (flora and fauna) Ethics Review

The Code of Conduct on Biomedical and Organisms research shall be consulted to provide guidance and guidelines regarding Research Review. All biomedical experiments involving human subjects shall require *prior ethical clearance*, thus application must be made using the appropriate Form to the Biomedical and Organisms (flora and fauna) Subcommittee for Research review

3.3.3.5 Guidelines for Internet Ethics Review

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

3.4 Sub-committee Meetings

All sub-committees of the **UREC** shall meet regularly as per need to review protocols and directed by the REC and other relevant higher University organs.

CHAPTER FOUR

CODE OF CONDUCT FOR RESEARCH AND ETHICAL BEHAVIOUR

4.1 Code of Conduct for Research

4.1.1 Guiding Principles

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 TUMA. This includes:

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

All researchers working on campus must <u>complete a research consent form</u> 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 shall 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 academic disciplines Sub-research Ethics Committees, namely:

- (a) Education, Humanities, and Science Research Ethics Committee.
- (b) Law Research Ethics Committee.
- (c) Theology Research Ethics Committee.

4.4 Findings of Research Misconduct

In order to establish beyond reasonable doubt research misconduct has occurred 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 whistle-blower in deciding how to proceed. It is important, therefore, to emphasize that the University is committed to the following principles:

- (a) Any allegation of research misconduct must be dealt with expeditiously. If such misconduct is established there is an absolute responsibility to expose it.
- (b) A finding that research misconduct has occurred will be dealt with openly, and all steps to correct its effects will be taken.
- (c) The rights of any researcher accused of misconduct must be protected.
- (d) 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 counselling to determine whether the concerns fall within the definition of research misconduct.

The consequences of research misconduct are very severe; thus there are several stages in the process for investigating it:

- (i) Facts concerning an individual believe to have committed research misconduct should be reported to the DVCAA.
- (ii) The DVCAA 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:

- 1. 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.
- 2. Conduct an investigation to establish the facts.
- 3. Report to the DVCAA <u>within three weeks</u> of establishment of the committee. This should either be a final report or a motivation to extend the investigation for a limited period.
- 4. The final report shall recommend:
 - a) Whether there is a *prima facie* case for disciplinary action.
 - b) 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 DVCAA 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 Conflicts of Interest

- (a) 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.
- (b) In the academic environment, there are many opportunities for conflicts of interest to occur. Not all can be covered by formal procedures.
- (c) 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.
- (d) If a member of the University has any reason to believe that some activity constitutes, or has the possibility of constituting a conflicts of interest, it is required that a disclosure statement be lodged to the DPRC.
- (e) The disclosure statement should include:

A statement of the nature of the conflict has:

- 1. A proposal from the staff member of how the conflicts of interest is to be managed.
- 2. A procedure for the management or elimination of the conflict agreed with the Vice Chancellor, Dean, and Head of Department or as is appropriate may demand varying levels of oversight, and may include prohibition of the activity.
- (f) To assist members of the University in the process of disclosure there shall be a disclosure Form providing a check-list to help establish the nature of the conflicts. Failure to disclose the existence of a conflicts 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-5.

4.7 Conflicts of Commitment

- (a) 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.
- (b) 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.
- (c) In undertaking external activities, members of the University should take into account the possibility of conflicts 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 and Health Authority Act* (OSHA).

4.9 Ethical Behaviour

4.9.1 Ethical Principles

The TUMA 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 Human Rights Violation

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, demeanour compromise a reasonable person at whom such advances, requests or conduct were directed, and as further elaborated in the TUMA 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.

REFERENCES

University of Helsinki: Research Integrity and Research Ethics, file:///C:/Users/MacBook/Downloads/RDM_Advanced_research_ethics_2021.pdf

National Research Integrity Framework of Tanzania, COSTECH, 2020

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 Forms

General Information

As afore-stated in **3.3.1**, the University Research Ethics Committee (**UREC**) serves initially the following five broad areas:

- (i) Biomedical and organisms (flora and fauna) research;
- (ii) Research involving human beliefs, human rights, law and entertainment;
- (iii)Research involving education, business and social sciences;
- (iv)Research involving natural sciences and technology;
- (v) Internet research

Contact Information

All researchers are advised to contact the Director, PRC for further clarification.

Identification of what needs to be reviewed:

- All research involving organisms, viz. human subjects conducted by a University-affiliated faculty, students or staff, at TUMA or elsewhere, requires review and approval by the UREC 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:
- (ii) The collection of information through any interaction or intervention with a living individual including animals.
- (iii) The secondary use of data previously collected from human subjects.
- (iv) Identifiable private information about an individual.
- (v) Human remains, cadavers (corpses), human organs, tissues and biological fluids, embryos or foetuses.

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 at times be exempted from review requirements. The researcher is responsible for consulting with the UREC to clarify what types of research must be reviewed and what exceptions may thus exist.

Note: 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 normally not intended for publication or presentation outside the classroom.
- The review of such applications may be delegated to the UREC departmental or faculty representative and do not normally have to go to the regular **UREC** review.
- 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 minimum risk, or involve minors or other vulnerable populations, **must** be reviewed by the UREC.
- Thesis (+dissertation) and postdoctoral research must undergo regular UREC 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 ongoing approval expires. If a renewal request is not received before the approval elapses the project is considered to no longer be 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* should be used to notify the UREC 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 UREC before they can be implemented.
- This form should also be used to notify the UREC of administrative changes such as the addition of co-investigators or new funding sources and titles.

Adverse Events

- Investigators must also inform the UREC 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
 UREC. 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 **DRPC**. For **course-based projects** as already described, submit the original plus **two** copies of the application Form to the DRPC who will arrange and distribute them for review.

NB: Please take note of the following points before you submit your ethics application Forms, in order to ensure that your application is properly filled out. Incomplete applications Forms can cause delays in turn-around time:

- 1. All applications must be signed by the applicant who is the <u>Principal Investigator</u>, and if a student, by the <u>supervisor</u> 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 TUMA. 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 the **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 the relevant 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 adverts (including information that is sent to the 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 UREC

application Form. 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 (e.g., 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 e.g., 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 relieving 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 letter-head. 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 above the age of **13** must also provide written consent.

Consent Form Examples

The **UREC** 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 TUMA 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. ca Supervisors: 1 st	andidate, 2 nd
Contact Information: Tel: Email:	
Purpose of the research:	
What is involved on participating?	
Consent: I wish to be identified in the reportYES	SNO
I have read the above information and I agree	to participate in this study
Participant's Name:	Researcher's name:
Participant's Signature:	Researcher's signature:
Date:	

This is to invite you to participate in a study entitled											
Your participation in the study will entail an oral interview, lasting approximately on e hour, to be conducted by											
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 opinion 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											
You may contact me; if you have any questions or concerns.											
I agree to be tape-recordedYESNO											
I agree that the tape may be used as described aboveYESNO											
Participant's nameResearcher's name											
Participant's signature:Researcher's signature											
Date											

Application for Ethics Clearance for Human Subject Research

Project Title:
Principal Investigator: Department:
Phone: Email:
Mailing Address (if different from Department):
Status: Staff () Postdoctoral Fellow () other (specify) ()
Type of Research: Staff Research
Thesis () Dissertation () Independent Study Project () Course Assignment (specify course name) () other () (specify)
Supervisor (for student PIs): 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 TUMA Principal Investigator's Signature: Date:
Faculty Supervisor 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 TUMA and I agree to provide all necessary supervision to the student.
Faculty 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 (e.g. thesis, demonstration, 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

- (a) 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.
- (b) 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.
- (c) 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

- (a) 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.
- (b) Comment on any other potential ethical concerns that may arise during the course of the research.

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 **UREC**. 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/ongoing approval expires.

LIDEC File Number:

	ALC THE NUMBER
Pr	oject Title:
Pr	incipal Investigator:
De	epartment/Phone/Email:
Fa	culty Supervisor (for student PI):
1.	Were there any significant changes made to this research project that have any ethical implications?YesNo. If yes, describe these changes and append any relevant documents that have been revised.
2.	Are there any ethical concerns that arose during the course of this research? Yes No If yes, please describe.
3.	Have any subjects experienced any adverse events in connection with this research project? Yes No If yes, please describe.
4.	This is a request for renewal of ethics approval.
5.	This project is no longer active and ethics approval is no longer required.
6.	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.
Pr	incipal Investigator's name:Signature:
Fa	culty Supervisor's name: Signature
	Date

For Administrative Use (tick)						
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 UREC Chair or designate: Date:						
Approval Period: From to						

ETHICS REVIEW - ADVERSE EVENT REPORTING FORM

Pr Pr De	rincipal Investigator:epartment/Phone/Email:	
1.	Describe the adverse event that occurred i	in conjunction with this research project:
2.	How many subjects have experienced the	
3.	Was this adverse event a potential risk that or was this an unforeseen event?	t was disclosed to the subject in the consent form,
4.	Will it be necessary to revise the consent of the reduce the risk of the occurrence of the revisions.	form or make any changes to the project in order his adverse event? If yes, append the relevant
Pr	rincipal Investigator's Name:	Signature:
	Date:	
Fa	aculty Supervisor's Name:	Signature:
Da	ate:	
F	For Administrative Use Only	
Г	Date Reviewed:	
N	Name of UREC Chair or designate:	Signature:
C	Comments:	

Disclosure Form - Conflicts of Interest

Any staff member of the University, including staff employed in posts funded by outside bodies, is required to disclose to the Vice Chancellor, DVCAA, Dean of Faculty, or other appropriate line manager, any actual or perceived conflicts 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 conflicts of interest may lead to disciplinary action.

Name of staff member making disclosure	
Staff ID number	
Faculty	
Name of staff member to whom disclosure is being	
made	

Check list

Circle "Yes" or "No" for every question. Benefits marked with an asterisk 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?	Yes	No
(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.)		
* Discounts or concessions or other financial benefits from a company		
or individual that is awarded a contract?	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 Note that answer to any of the above is "Yes" then: Outline the nature of the conflict. Describe the sense in which the situation is of benefit to the University and the Research programme. Propose a mechanism for the management of the conflict.	Perception of nepotism Will any close member of your family be employed from funds under your	Yes	No
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 Note the answer to any of the above is "Yes" then: Outline the nature of the conflict. Describe the sense in which the situation is of benefit to the University and the Research programme. Propose a mechanism for the management of the conflict.	control?		
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	approval organ.		

Certification

I certify that I have disclosed everything relevant to the University Vice Chancellor/ DVCAA/ Dean of Faculty. I undertake to act according to the above management plan. Name of Researcher: Signature of Researcher..... Date: I have applied my mind to the situation described above and will monitor compliance with the Management Plan. Name of Vice Chancellor/DVCAA/Dean of Faculty: Appendix-6 **Animal Importation Form: Guidelines** Typical simple but necessary ethical issues for consideration during transport of animals 1. □ Yes \square No. 2. Is transport of live animals necessary and, if so, what method and precautions will be used? 3. What is the type of container to be used? 4. What shelter/bedding will be provided? 5. How many animals per container? 6. Will food and/or water be provided? Give details. 7. What precautions will be taken to protect animals from temperature extremes?

8. What is the maximum length of time that animals will be held in this way?

Animal Export Form: Guidelines

Typical	simple	but	necessary	ethica	l issues	tor	consid	leratio	on c	luring	transport	of	anımalı	S
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	Guidelines on Field Handling of Animals - Form
	Appendix-8
8.	What is the maximum length of time that animals will be held in this way?
7.	What precautions will be taken to protect animals from temperature extremes?
6.	Will food and/or water be provided? Give details.
5.	How many animals per container?
4.	What shelter/bedding will be provided?
3.	What is the type of container to be used?
2.	Is transport of live animals necessary and, if so, what method and precautions will be used?
1.	□ Yes □ No,

For All Work Involving Wildlife or Studies in the Field /Countryside

For All Work involving whome or Studies in the Field /Countryside:		
27. Does this research involve intentional killing, injuring or taking of animals?		
Yes □ No □		
28. Does this research involve the possession or control of live or dead animals, their parts or		
derivatives?		
Yes □ No □		
29. Does this research involve damage to, destruction of, or obstruction of access to any structure		
or place used by a scheduled animal for shelter or protection?		
Yes □ No □		
30. Does this research involve disturbance of animals occupying such a structure or place?		
Yes □ No □		
31. Does this research involve selling, offering for sale, possessing or transporting for the purpose		
of sale live or dead animals, their parts or derivatives?		
Yes □ No □		
33. Ethical Approval from Other Bodies		
Does this research require the approval of an external body?		
Yes □ No □		
If 'Yes', please state which body		

34. Has ethical approval already been obtained from that body?		
Yes □ Please append documentary evidence to this form		
No D		
If 'No', please state why not:		
Please not that any such approvals must be obtained and documented before the project begins.		
35. What is the funding source?		
Internal		
External (specify)		
APPLICANT SIGNATURE		
I hereby request ethical approval for the research as described above.		
Please inform the UREC Secretary if the conditions described in this Form change after the the Committee has approved your research.		
Signatures: Applicant:		
Date:		
Project Supervisor (if applicable):		
Date:		