NATIONAL RESEARCH INTEGRITY FRAMEWORK OF TANZANIA

"Reliability, Honest, Respect and accountability"

TANZANIA COMMISSION FOR SCIENCE AND TECHNOLOGY

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FOREWORD

Research is governed by a range of ethical, legal and professional frameworks, obligations and standards. The National Research Integrity Framework, therefore, cuts across all fields of research and it recognizes the different responsibilities of researchers, research institutions, employers, funders and other bodies involved in the research enterprise including the conception of the research, its execution, and evaluation and reporting of research findings. The framework considers high standards of research integrity to be of utmost importance in any research undertaking.

This framework calls for consciousness of ethical practice by researchers, their respective institutions and all other bodies involved in facilitating or implementing research including but not limited to employers, funders, and research permit granting institutions especially in areas such as those of preparation of research proposals, data acquisition, processing, reporting and dissemination.

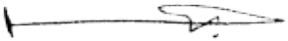
The framework sets out clear standards for each of these stages. It is my view that researchers and institutions involved in research will ensure high standards of integrity throughout the research process.

I welcome efforts to develop this framework as a step towards raising the profile of research governance issues and believe that the implementation of this framework will assist Tanzania to earn an excellent reputation in

research governance.

I request all institutions involved in research to ensure that their research governance systems comply with the guidelines provided in this framework to enable the country to attain the highest standards of ethical standards and good practice in research.

I therefore call upon all stakeholders engaged in conducting or facilitating research to observe the ethical requirements as recommended by the framework and promote the same within their professional networks.



Prof. Makenya Abraham Honoratus Maboko

CHAIRMAN OF THE COMMISSION

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The National Research Integrity Framework is a guiding document developed by the Tanzania Commission for Science and Technology (COSTECH) through a series of consultative processes with researchers from Higher Learning Institutions and Research and Development institutions.

COSTECH wishes to acknowledge the contribution of various stakeholders whose insights and active participation led to the successful development of this Framework. The Framework specifically benefited from expert contribution provided by representatives from University of Dar es Salaam, Sokoine University of Agriculture, Ardhi University, Dar es Salaam Institute of Technology, Ifakara Health Institute, Institute of Social Work, Kilimanjaro Christian Medical University College, Hubert Kairuki Memorial University, Tanzania Fisheries Research Institute, Nelson Mandela African Institute for Science and Technology,

St John's University of Tanzania, Tanzania Industrial Research and Development Organization, National Institute for Medical Research, Tanzania Veterinary Laboratory Agency, Mzumbe University, Geological Survey of Tanzania, Tanzania Wildlife Research Institute, Tanzania Forestry Research Institute, University of Dodoma, Economic and Social Research Foundation, Open University of Tanzania, Muhimbili University of Health and Allied Sciences, Zanzibar Planning Commission, Second Vice President's Office, State University of Zanzibar,

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Dr. Amos Muhunda Nungu

DIRECTOR GENERAL

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ACRONYMS

AR	Appeal Report
CBO	Community Based Organizations
COSTECH	Tanzania Commission for Science and Technology
DoI	Director of Institution
DTA	Data Transfer Agreement
DUA	Data Use Agreement
HLIs	Higher Learning Institutions
IRBs	Institutional review Boards
IP	Intellectual Property
IPMO	Intellectual Property Management Office
IPR	Intellectual Property Rights
M & E	Monitoring and Evaluation
MoU	Memorandum of Understanding
MTA	Material Transfer Agreement
NGOs	Non-Governmental Organizations
R&Ds	Research and Development Institutions
RCAC	Research Conduct Appeal Committee

RCIC	Research Conduct Investigation Committee
RCR	Responsible Conduct of Research
REC	Research Ethics Committee
RM	Research Misconduct
RMAH	Research Misconduct Allegation Handling
SDG	Sustainable Development Goals
Sida	Swedish International Development Cooperation Agency
SJUT	St John's University of Tanzania
SOPs	Standard Operating Procedures
SRC	Swedish Research Council
TDV	Tanzania Development Vision
ToR	Terms of Reference
ToT	Training of Trainers

1. INTRODUCTION

Research plays a very crucial role in the socio-economic development of any society and a nation at large. The government, through the Tanzania Commission for Science and Technology (COSTECH) is committed to enhancing the contribution of research in sustainable socio-economic development and growth of the country.

The country's National Development Vision 2025 commits to building a strong, dynamic, resilient and competitive national economy through investing in research. In the year 2009, the President of United Republic of Tanzania promised to deploy at least 1% of annual Gross Domestic Product to research activities as stipulated in 1999 National Policy on Higher Education.

This commitment cemented the declaration made by African Heads of Summit held in Addis Ababa, Ethiopia in January 2007. Government and development partners have increased research funding over the years. The research contributes to innovations which are of great benefit to the Tanzanian community. Scientific research, for instance, has laid the foundation for the development of new technological and scientific revolutions that have supported socio-economic advances.

Misuse of research techniques and knowledge could result in negative outcomes, such as the misuse of genetic engineering, which could pose a threat to the public's health and safety. This situation implies that if research is unreliable or mismanaged, lives of people, other living organisms and the environment will be affected and money invested in research put to waste.

Due to pressure for funding, need for publications, recognition and the desire to excel in the research career, calls for proper management of research processes to ensure rigour and ethical adherence to avoid malpractices such as fabrication, falsification, plagiarism that seriously deviate from what is commonly accepted within the research community. These standards cannot be achieved without standardized guidelines for good conduct of research and well-established structures such as Research Ethics Committees (RECs) or Institution Review Boards (IRBs). When such mechanisms are well established, institutional RECs/IRBs can advance to a stage of accreditation.

This framework seeks to provide guidance to the introduction and or strengthening research integrity mechanisms. Given its mandate, COSTECH has taken stewardship by providing this guidance in establishing and institutionalizing responsible conduct of research.

All institutions engaged in research activities within Tanzania have the responsibility to develop research integrity mechanisms and equip its researchers with resources to attain the highest standards of professional practices and integrity. The effective functioning of those mechanisms will uphold the quality and objectivity of the research profession and ensure that the resulting evidence is scientifically sound and worth the public's confidence.

The development of the framework was preceded by a survey carried out by COSTECH in 2013 to assess the establishment and functionality of Institutional Review Boards (IRBs) within Research and Development Institutions (R&Ds) in the country, which showed that only few research

institutions had established such mechanisms.

The survey further indicated that ethical review boards/ committees are facing multiple challenges due to inadequate guidance on their operations, limited skills/expertise, weak linkage to mainstream institutional administrative structures and unsystematic operations. This framework is informed by international research ethics standards as well as relevant national policies and guidelines[1].

The National Research Integrity framework adheres to the National Research Policy, Tanzania Development Vision 2025, Sustainable Development Goals (SDG), Five-year Development Plan II, National Science and Technology Policy of 1996, COSTECH Act of 1986(revised) and the National Research Agenda 2015-2020.

The framework cuts across research in all disciplines designed and conducted across public and private research institutions, and it should be adapted and amplified in specific disciplines or research areas as per needs. The framework sets standards for expected ethical conduct in research to maximize the quality and robustness of research. Enforcing responsible conduct of research is an obligation of researchers, research institutions, and funding agencies.

Ethical conduct shall be upheld in all aspects and at all stages, including research idea conception, proposal development, data analysis and drawing conclusions and ultimately reporting and/or publication of the findings. The framework aims to provide a supportive research

[1]Singapore Statement on Research Integrity (2010); the European Code of Conduct for Research Integrity (2010); the Montreal Statement on Research Integrity (2013) and the Amsterdam Statement on Research Integrity (2017).

environment that is underpinned by a culture of integrity, based on good governance, best practices and transparency.

The highlighted relevant research activities by this framework include:

a. Issues pertaining conflicts of interest;
b. Adherence to regulations and compliance to ethical requirements;
c. Adherence to professional standards, ensuring familiarity with up-to-date guidance on best research practice from professional bodies;
d. Clear and well-defined collaboration arrangements among researchers and/or other institutions;
e. Duty of care for participants in, and the subjects of, research;
f. Ensuring the safety of all those associated with the research;
g. Responsibility for proper documentation and data management;
h. Reporting on research methods and procedures;
i. Reporting on and presenting research data and results;
j. Drawing conclusions and making recommendations based on the research;
k. Importance of adhering to scientific standards appropriate processes for research activities; and
l. Proper attribution of the intellectual contribution of others; acknowledgement of the work of others, where appropriate.

2. OBJECTIVES

The overall objective of the framework is to commit all research institutions, higher learning institutions, researchers, research funding agencies and regulatory bodies in Tanzania to the integrity standards in all aspects of research processes originated from basic principles of good research practice.

Specifically, this framework will:

1. Provide guidance on the establishment, strengthening and accreditation of RECs/IRBs within and across disciplines;
2. Foster a culture of responsible research management and oversight within research institutions and associated agencies;
3. Promote awareness and responsible conduct of research among professional bodies and the public;
4. Ensure effective mainstreaming of responsible conduct of research (RCR) and best practices across research based institutions; and
5. Promote timely mechanisms of reporting, recording and handling research misconduct and ethics.

3. RESEARCH MANAGEMENT

3.1. Research Ethical Committees and Institutional Review Boards

Research institutions are required to establish functional and operational Research Ethics Committees/Institutional Review Boards (RECs/IRBs) across various disciplines to ensure that research is carried out in the highest ethical and professional standards. The established REC/IRB will be part of research governance for respective institution and shall apply to all disciplines.

Research and Higher Learning Institutions are responsible for continuous guiding and orienting their researchers to a culture of professional self-bound research regulations, Institutional Policies, and National, Regional and International Regulations.

It is responsibility of RECs/IRBs to stay updated regarding new developments in RCR at national and international standards, adapt and communicate the same to researchers and other institutional authorities handling research issues. RECs/IRBs are responsible for spearheading effective research management practices in respective institutions.

This includes establishing or strengthening institutional scientific review mechanisms/forums, research registration, establish progress reporting mechanisms and frequency. RECs/IRBs can also provide oversight in research management practices at institutional level in several aspects as stipulated in **Annex 1.**

For proper institutionalization, it is emphasized that the RECs/IRBs be part of the institutional administrative structures

3.2. Research Practices and Procedures

Research Institutions should adhere to established research practices as accepted nationally and internationally in their respective discipline. This should include employing appropriate research methods, basing conclusions on critical analysis of the evidence and reporting and interpretations of findings. Research design and practice must be considered carefully before the research is undertaken to ensure that:

- Research approval is obtained from appropriate RECs/IRBs, regulatory agencies and relevant governing agencies prior to commencement of the research. It is primary obligation of research institutions, researchers and/or related agencies to secure ethical clearance approval for compliances with research ethics and integrity policies set out by the appropriate regulatory body; and

- To safeguard national interests and protect humans, animals and environment while undertaking research, RECs/IRBs will review, approve and recommend for approval, research proposals that have met scientific merit, ethical and professional standards. The institutional RECs/IRBs are expected to provide recommendations on proposals that would need approval from a nationally overseeing ethics body where available. In principle, all research influences the life of human beings (as individuals or communities), animals and environment in varying degrees, hence their protection is fundamental.

3.3. Research Publication and Dissemination Practices

Publication or dissemination of research findings is a universal obligation of researchers and respective institutions. Failure to do so constitute wastage of resources invested in research. Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research.

All potential authors of a publication must be included in the published list of authors. Inclusion as authors should be based on the creativity and significant intellectual contribution of researcher to the research i.e., his/her involvement in conceptual and research design, his/her execution of research, or analysis and interpretation of research data.

Researcher(s) should not solely be named as an author on the basis of being the supervisor of the researcher or student undertaking the research, or the leader of the research group, where a creative and significant contribution has not been made to the research.

The work and contribution of all contributors (researchers) should be acknowledged appropriately and each author should take responsibility of the publication. The sequence of authors should be agreed upon by all authors and may follow national and/or international standards.

Publication of peer reviewed research articles, technical reports and any other publishable materials should:

- Avoid republication of the same material that has already been published;
- Avoid academic fraud;

- Publish accurate and correct information or findings only to avoid data manipulation;
- Report positive and negative findings where applicable;
- Adhere to any restrictions relating to confidentiality, privacy, intellectual property or culturally sensitive information;
- Avoid plagiarism by recognizing and acknowledging relevant works of other authors through citation;
- Seek permission before republishing material owned by other researchers or institutions;
- Acknowledge all financial sources/communities that supported the research; and
- Research participants should be provided with an opportunity to access an appropriate summary of the research findings.

It is an obligation of researchers and institutions to ensure that research conducted under their auspices is disseminated in timely, appropriate and productive manner. Dissemination strategy should be inbuilt in the study protocols/proposals and budgeted for. Dissemination, where applicable, should be close to the data source as much as possible.

This could be local communities, local authorities and service delivery or production points. For research with implications to national policies, strategies or guidelines, dissemination with relevant authorities is expected. All disseminated research findings should be done in an open, honest and transparent manner.

3.4. Research Mentorship and Coaching

Research institutions should promote and encourage mentorship among researchers, that is, through effective mentoring and supervision of researchers and research trainees. They should also encourage open exchange of ideas between peers, and respect for freedom of expression and inquiry in order to maintain a climate in which responsible and ethical behaviour in research is expected. Research institutions should internally develop innovative, transparent and sustainable motivation arrangements to promote mentorship and coaching in research skills at all levels of career development.

3.5. Research Governance and Accountability Mechanisms

All research institutions and related agencies should have in place a Research Governance Framework through which researches will be assessed for quality, safety, privacy, risk management, financial management and ethical acceptability. The framework should provide for discipline-specific tools, standards, guidance or clear mechanisms to gauge compliance and/or quality assurance for creating and maintaining a culture of good research conduct. Institutions should also provide training where possible to enable researchers to meet their obligations. For overall compliance assurance, the following tools and/or capacities can be useful:

- All research institutions and related agencies should develop professional-specific institutional SOPs to govern quality assurance, safety, privacy/confidentially in research reviews, risk management, financial management and ethical compliance;
- The framework/SOPs should specify the personnel, roles,

responsibilities and accountabilities of all those who play part in research;

- The research governance framework should demand compliance with Tanzanian laws, regulations, guidelines and codes of practice governing the conduct of research in specific field/profession;
- Each institution must ensure the availability of the documents that help guide good research governance, conduct and management;
- Ensure that SOPs or tools developed match the current level of knowledge at national and international standard of research integrity;
- Establish and promote awareness on research transparency mechanisms to research community and users of research products;
- Establish feedback loops and complaint management machinery with resources (e.g. tools, timeframes and skills-mix) for addressing pertinent concerns by researchers, research subjects and communities; and
- Establish monitoring and/or inspections mechanisms for on-going research projects to ensure compliances based on their registration and approved criteria.

3.6. Managing Conflict of Interests

Research Institutions should formulate conflict of interest guidelines and/or SOPs and sensitize their compliance among researchers. There must be a mechanism to assess the conflict of interest and lay down verdicts/resolutions based on regulations. The use of developed conflict

of interest guidelines should be made mandatory. Researchers should declare or disclose actual or potential conflicts of interest, including financial and other personal, professional and institutional conflicts that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities. All actual or potential conflicts of interest must be handled in accordance with institutional Conflicts of Interest Guidelines. Guidance for Conflicts of Interest development is annexed to this framework (Annex 2).

3.7. Handling Research Collaboration and Cooperation Projects

From time to time institutions may find themselves engaging in collaborative research programme or projects, be it with local or international organizations. In collaborative research projects between research institutions, an agreement should be reached on the expected standards of conduct and management of the research project/ programme.

Mutual cooperation between research institutions and/or researchers should base on clear written research agreements or Memorandum of Understanding that set forth management of activities and outputs. The agreement should preferably include a dully-signed contract by the relevant authorized personnel within the respective institutions.

The contract should cover communication arrangements, access to research facilities, management of research resources (materials, personnel, finances), outputs, dissemination plans, capacity building, intellectual property, confidentiality, sharing of commercial returns (where relevant), responsibility for ethical clearance and safety; and project reporting mechanisms. The agreement will include the procedure

for dealing with any suspected deviations from the agreed standards. The agreement should clearly protect and safeguard Tanzania national interest in all undertakings.

3.8. Management of Materials, Data and Intellectual Property Rights

Research institutions and/or researchers should clarify at the outset of a research project about the ownership and confidentiality of data and samples created in the course of the research, and the results of the research where applicable. Collaborative agreements should be in place to achieve this.

Data collection methods and analysis should be documented in a manner that will facilitate replication by independent researchers and audit or verification of aspects of the research process. Therefore, all data/samples involved should be maintained and archived according to Tanzanian policies, regulations and related institutional policies. Research funders may also require research data and outputs to be made available using open access routes, such as data repositories.

All participating research institutions and/or researchers must sign a non-disclosure/confidentiality form before the commencement of any research activities. Institutional Intellectual Property policies should provide guidance on management of IPR issues **(Annex 3)**. For researchers wishing to send or receive research sample materials and/or data overseas, for either analysis or other research purposes, they should sign a Material or Data Transfer Agreement Form **(Annex 4).**

However, research data and records should be stored while consideration is given to:

- Issues pertaining to safety and security of the research data and records;
- Durability of the data storage using appropriate method while discouraging the storage of data on computer hard drives;
- Issues pertaining to data privacy and confidentiality;
- Ethical approvals and requirements in data storage;
- Data indexing and cataloguing; and
- Research institution's policies on data storage and retention.

Moreover, research data should be made available to peers who wish to repeat or elaborate on the study, subject to requirements for privacy, confidentiality and intellectual property.

4. PROMOTING AND MAINSTREAMING RESPONSIBLE CONDUCT OF RESEARCH

In the implementation of this framework, each research institution will be responsible to promote Responsible Conduct of Research (RCR). The RCR is defined as the practice of scientific investigation, which adheres to principles of integrity. It involves awareness and application of professional norms and ethical standards, pertaining to the performance of all activities related to scientific research.

Furthermore, RCR sets forth general principles governing the conduct of research and the requirements that address the developmental needs arising from the rapid growth of research knowledge; the increasing sophistication of research tools and approaches; the increasing complexity of research ecosystem including funding, laws, rules, and regulations that govern the behaviour of not just researchers but also research institutions that engage in research.

The influx of research trainees with diverse backgrounds among the various proliferating research institutions and the ever increasing demand for collaborative research programs needs to be managed in manner that will promote high standards.

In this context, the RCR requires that research institutions and their researchers uphold the highest level of integrity, reliability in performing research, objectivity based on robust methodologies and professional standards of a given discipline, impartiality and independence from socio-economic or financial interests. They should also be honest in reporting and communicating research findings, respect of participants

and the subjects of research; fairness in providing references and giving credits and/or recognitions to other research workers; and responsibility for future research generations. They are also required to be accountable for the conduct of research from its commencement to the end of the research project.

Therefore, research institutions should promote or raise awareness of RCR and mainstream it in their policies, regulations and frameworks in such matters as:

1. Plagiarism, falsification, manipulation;
2. Responsible authorship and allocation of credit;
3. Collaborative research and Intellectual Property issues;
4. Conflict of interest management;
5. Data acquisition, management, sharing and ownership;
6. Environment and laboratory safety;
7. Use of human subjects, animals and plants in research;
8. Peer review mechanisms;
9. Responsibility to scientific community ;
10. Reporting of Research Misconduct;
11. Responding to Suspected Misconduct; and
12. Timely reporting of both positive and negative results.

4.1. Ownership and Institutionalization of Responsible Conduct of Research

All research institutions and related agencies are obliged to build the capacity of researchers on issues pertaining to regulations governing their areas of research expertise and provide supportive research tools for good research conduct. To promote ownership and sustainability, RCR shall be embedded in key institutional documents such as internal policies, code of conduct, strategic plans, annual plans, and charters. The top management of the respective institutions should take charge of this, with technical support of COSTECH. Where RECs/IRBs are already established they could take a major role in facilitating the process. Institutions shall also develop innovative strategies for further mainstreaming of RCR mechanisms through integration into academic programme, on-job training activities such as, mentorship, coaching, induction programme as well as short and long-term capacity building programme.

Each research institution and related agencies should provide an appropriate research governance framework through which researches will be assessed for quality, safety, privacy, risk management, financial management and ethical acceptability.

Institutions are therefore expected to:

- Develop institutional SOPs to govern quality assurance, safety, privacy, risk management, financial management and ethical compliance;
- Specify the roles, responsibilities and accountabilities of all those who play part in research in the SOPs;
- Demand compliance with laws, regulations, guidelines and

codes of practice governing the conduct of research in Tanzania;

- Ensure the availability of the documents that help guide good research governance, conduct and management; and
- Mainstream RCR activities in institutional plans and budgets.

4.2. Responsible Conduct of Research Advocacy

Research institutions should promote awareness of all guidelines, policies, legislation and procedures relating to good conduct of research through induction and formal or on-job trainings for all research staff, including research trainees. Among other things, training should cover research methods, ethics and/or code of conduct, confidentiality, intellectual property, data storage and records retention, as well as regulation and governance. Institutions may also make arrangements for joint induction and training with other research institutions and stakeholders.

5. RESEARCH MISCONDUCT

Research misconduct includes practices that seriously deviate from those that are commonly accepted within the research community such as fabrication, plagiarism, falsification for proposing, conducting, reporting, reviewing research that has been committed intentionally knowingly or recklessly and that has been proven by preponderance of the evidence.

In dealing with research misconduct all research institutions must have written policies and/or procedures for dealing with allegations of research misconduct and appoint a designated person (other than the head of the institution) to whom allegations of research misconduct must be directed.

When an allegation of research misconduct arises, investigations should be undertaken as per the stipulated procedures for dealing with alleged Research Misconduct in **Annex 5.** The procedures set out in this Framework should be interpreted in a way that allows for procedural fairness, objectivity and timeliness. Each situation must be assessed based on its own particular facts to determine how to respond to an allegation resolution/disposition.

Policies and/or procedures should describe how to receive, handle and report disciplines-specific complaints and allegations. The policy should recognize both minor and serious misconduct and describe how to warrant formal allegation, investigation, and denial or admission. If proven, such misconduct would be expected to lead to disciplinary action by the institution in accordance with its instruments of employment.

Depending on the circumstances, aspects of research misconduct may be dealt with under other national policies/regulations in addition to or

instead of this Framework. Moreover, the funders should be notified when an allegation of misconduct is evidenced after an initial investigation is conducted. The research Institution's whistle blowing policy **(Annex 6)** should also be applied to complaints of misconduct in research, and is designed to assist and protect people who report malpractice and impropriety of all kinds within the institution.

6. SUPPORT AND MONITORING IMPLEMENTATION OF THE FRAMEWORK

Government ministries and through COSTECH shall provide conducive environment for nurturing Responsible Conduct of Research. Institutions shall maintain and update documentation of RCR activities. It is expected that COSTECH, research conducting and or supporting institutions shall allocate resources for implementation of RCR mechanisms.

The institutions shall also ensure functional system for managing research integrity information, continuously identify and document weaknesses and achievements as well as promote information sharing for the purpose of escalating RCR.

6.1. Monitoring at Institutional Level

Research institutions (research coordinating units) are responsible for monitoring the implementation of the framework. Monitoring of the implementation of the framework should be integrated in institutional routine reporting systems.

6.2. Sytem Support and Monitoring by COSTECH

The performance of this framework will be monitored or assessed periodically through a systematic collection of data based on specific indicators so as to assess the extent of progress and achievements.

COSTECH shall from time to time conduct follow up performance on the implementation of the framework. The framework will be reviewed based on the feedback from monitoring (e.g. modify inputs and activities to

ensure that the framework achieves its intended goals).

COSTECH is responsible for profiling all research institutions and the registration/ recording of all scientific research activities. In additions, it will provide a list of instruments/ guidelines that will support the implementation of this framework.

6.3. Systems Support by Government Ministries

All research approved at national level is implemented at sub-national levels including regional, district, wards, village or hamlet levels. The Ministry responsible for Local Government Administrations and other sectoral ministries shall provide supportive environment and establish mechanisms for monitoring responsible conduct of research.

REFERENCES

1. A European Code of Conduct for Research Integrity: http://static.uni-graz.at/fileadmin/forschen/dokumente/diverses/A_European_Code_of_Conduct_for_Research_Integrity.pdf
2. Australian Code for the Responsible Conduct of Research http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf
3. International Ethical Guidelines for Biomedical Research Involving Human Subjects: Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)https://cioms.ch/
4. Montreal Statement on Research Integrity in Cross Boundary Research Collaborations 2013) https://wcrif.org/montreal-statement/file
5. Research Priorities for Tanzania 2015-2020; Tanzania Commission for Science and Technology http://www.costech.or.tz
6. Singapore Statement on Research Integrity: http://singaporestatement.org/statement.html
7. Singapore Statement on Research Integrity www.singaporestatement.org
8. Sustainable Development Goals (SDG) https://sustainabledevelopment.un.org/
9. United Republic of Tanzania (1996), National Science and Technology Policy for Tanzania, Ministry of Science, Technology and Higher Education
10. United Republic of Tanzania (2000) Tanzania Development Vision 2025, Dar es Salaam: Planning Commission www.mipango.go.tz

11. United Republic of Tanzania (2016), National Five Year Development Plan II 2016/17-2020/21, Nurturing Industrialization for Economic Transformation and Human Development. Ministry of Finance and Planning

ANNEXES

Annex # 1 A Guideline for Establishing Research Ethics Committee/ Institution Review Boards (RECs/IRBs)

Annex #2: Conflict of Interest Guideline

Annex # 3: A Guideline for Development of Institutional Intellectual Property Policy for R&D Institutions

Annex # 4: A Guidelines for Data Transfer or Use and Material Transfer Agreements

Annex # 5: A Guideline for Preparation of Research Misconduct and Allegations Handling Procedures Guideline

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Annex 1: A Guideline for Establishing Research Ethics Committee/ Institution Review Boards (RECs/IRBs)

1. OBJECTIVE OF THIS GUIDE

This document intends to provide general guidance to development of institutional Research Ethics' Committees (RECs/IRBs) in Tanzanian research institutions. While it is undeniably known that some institutions already have in-built mechanisms for assessing research proposals, we recognize ranges in standards for doing so with some institutions having well-established mechanisms within their research framework.

Others rely on peers or forward their proposals to national bodies directly, and to the extreme end some research institutions do not have any elaborate means of ensuring that research conducted within institutional auspices are cleared for ethical content pertaining to protection of human beings, animals involved in research and safeguarding of the environment. This guide provides minimum standards at institutional levels to help researchers and research coordination offices to form RECs/IRBs or potentially strengthen existing ones.

Type of research conducted in different institutions vary widely depending on academic disciplines, professional levels or perhaps institutional and individual interests, so we expect that this guide will encourage institution heads to establish RECs/IRBs and make it easier for them to own and embed it within their administrative structures, plans, budgets and monitoring frameworks for proper functioning and sustainability.

Ethical standards evolve from time to time with increasing knowledge

and experiences from research practices, so is expected for RECs/IRBs shall develop in-built mechanisms for self-revisions and improvements whenever deemed necessary.

2. THE ROLE OF RECs/IRBs

The core function of REC is to review research proposal for overall quality while keeping a close eye to ethical issues of the proposal at hand. This is important for safeguarding the dignity, rights, safety, and well-being of all research participants (humans and animals) and whether the environment exposed to research is also protected.

With respect to engaging human participants in research, the overriding principle is 'respect for the dignity of persons'. While research goals and objective can be well stated, it should not, for what-so- ever reasons be permitted to rise above protecting the health and well-being of research participants as individuals, sub populations or communities exposed.

The RECs/IRBs should also ensure that the principle of justice is taken care in the proposal; that is the benefits accruing from the research distributed fairly among all sub groups/ populations; considering such factors as age, age, gender, economic status, ethnic diversity, and people with special needs considerations (equity principle). The proposed research shall indicate mechanisms through which unnecessary pain and discomfort to animals involved in research (if any) is minimized and justified.

Use, processing and disposal of any biological materials or harmful substances such as toxic materials, pharmaceuticals should be accompanied by scientific procedures for managing such materials such that human dignity, animal safety and the environment exposed to research operations/site are protected. Plans for keeping the effects to minimal and acceptable standards shall be thoroughly scrutinized. In

such cases referral of proposals beyond the REC should be expected, if need be.

In their operations, RECs/IRBs shall stay free from political, institutional, and market influences. RECs/IRBs are responsible for establishing mechanisms through which all research proposals are thoroughly examined for ethics before a research permit is granted. In some cases, research proposal can be forwarded to other bodies/committees beyond the institution for expert opinion.

In such cases, the RECs/IRBs shall make a follow up to ensure the ethical ground is cleared. The committees shall also ensure that plans for securing relevant approval from administrative and regulatory agencies are clearly stated in the proposal and that national legal framework is observed. RECs/IRBs shall determine the frequency of following up on-going research projects for ethical compliance. As a matter of principle, any alterations in the study content or plan shall be re-examined for ethics.

3. CRITERIA FOR ESTABLISHING RESEARCH ETHICS COMMITTEES

Management of research institutions is responsible for appointing members or REC and establish a fully functional body. RECs/IRBs should be formed in such a way that it permits highest possible standards for reviewing research proposals for ethics. Its composition should not only be multi- disciplinary and multi-sectorial but should also balance scientific expertise (e.g. methodological skills), age and gender distribution, and should have a non-technical representation member representing community interests.

Clear documentation of candidacy requirements, procedures for identifying or recruiting REC members, duration and terms of service should be stated as well as duties and responsibility of each type of members. Membership requirements should be established that include the Following:

4.1 MEMBERSHIP REQUIREMENTS

i. Clear procedures for identifying or recruiting potential EC members should be defined in the SOPs for RECs/IRBs. Member recruitment shall consider: Appointment of REC members shall be done at institutional managerial level in consultation with experts, relevant boards and may involve peer institutions;

ii. Determine type of members, establish procedure for selecting/ appointing members and number of persons. It recommended that RECs/IRBs should have 7-15 members;

iii. Efforts should be directed to minimize conflicts of interest at selection and managing the ones that may emerge in future; and

iv. Members' integrity – mechanisms for maximizing transparency and confidentiality of review processes. This may be enhanced by rotation and turnaround of members to allow inflow of new ideas and optimize accountability.

4.2 Terms of Appointment

This should cover issues such as membership duration of service, qualifications, disqualifications, resignation procedures, re-appointment/ renewal and replacement

4.3 Conditions of Appointment

Conditions for appointment shall be clearly indicate decision on whether to release members professional profiles open, level of accessibility,

members' cost recovery ceilings for REC related activities, confidentiality and any other mechanisms geared to enhancing confidence over REC's operations. The pros and cons of each option shall be carefully considered and communicated to candidates. Both scientific and support staff shall sign a confidentiality agreement and declare conflict of interest from the outset.

4.4 Rec Offices

It is recommended that REC establishes a physical office/desk where contacts can be made and for easy access of information and clarification of ethical issues, despite the fact that many communications shall also be electronic. The office shall have its mail address, email, and fax. In the wake of booming use modern forms of communications through social media such as blogs, twitter, Facebook, even WhatsApp, RECs/IRBs may choose to utilize them productively.

While these can enhance between REC and its potential clients e.g. updates on REC meetings, guidelines and capacity building opportunities; utmost precautionary measures should be taken to avoid breaching of confidentially requirements needed for specific aspects of REC operations. Administrative support staff identified through clear procedures and accorded ToR for their operations and respective remuneration system.

4.5 Quorum Requirements

RECs/IRBs shall determine quorum requirements needed for making decision over research permit applications. There is a need to consider such as absolute number of members (e.g. percentage, proportion);

necessary skills-mix and representation of different sub-groups per each sitting. The minimum requirement is that for each sitting at least one member should be from the non-scientists category and at least one more member who is not employed by respective institution.

4.6 Independent Reviewers

RECs/IRBs should determine a standing list of reviewers, with criteria for selection for different type of research applications based on required expertise for different research fields. A database for reviewers also called consultants will be established and updated from time to time. Terms of service, guidelines for review process and expenses compensation plan for them shall be determined before appointment and written agreement for review process to be signed upon consensus.

It is important that reviewers are knowledgeable in proposed research area but equally important they should have an established record of integrity in scientific and general conduct in professional matters. They shall sign conflict of interest declaration in special forms designed for the purpose. Independent reviewers will be identified from different research institutions, professional associations or knowledgeable experts from relevant technical authorities

5. INSTITUTIONALIZING REC SYSTEM

All research institutions shall put out maximum efforts and resources to ensure establishing a properly resourced, functional and competent RECs/IRBs. Although established under the auspices and featured in administrative structures, RECs/IRBs shall be independent bodies, multi-disciplinary, multi-sectorial, and pluralistic in nature depending on the type of institution.

Relations, cooperation and communication lines with other bodies within and beyond institution shall be established at early stages during the course of creating RECs/IRBs to avoid confusion of roles, responsibilities and potential conflict of interest. The necessary resources, monitoring needs and accountability lines shall be considered from the outset while allowing rooms for improvement in the future. The minimum levels of expertise required, members terms and conditions, capacity building plans, proposal referral mechanisms/consultations shall be featured in RECs/IRBs terms of reference (ToR).

6. RECEIVING AND PROCESSING APPLICATIONS FOR ETHICAL CLEARANCE

6.1 Setting Application procedures

Responsibility for submitting a research proposal to REC lies with the lead researcher who is the principle investigator of the study, since has overall responsibility for scientific quality, ethical and stay answerable to overall content.

6.1.1 Conditions for receiving or registering research applications with REC

The procedures for receiving application should be clearly stated in SOPs of REC. The following are some of the basics that can guide applicants:

a. The name and or title of REC member who will receive applications;
b. Application template or standard forms for submitting applications;
c. Recommended channel for routine submissions (e.g. email) and format e.g. MS word;
d. Proper submission of supporting documents with the application;
e. Use of appropriate language (as recommended) and number of copies;
f. Feedback to applicants in relation standard time for accomplishing review process;
g. Name and addresses of contact person for follow up with comments;
h. Expected time for review process and feedback mechanisms to applicants;

i. Approximate time lapse between application receipt and contact to applicants for supplementary information;

j. Fee structure, mode of payment and submitting a proof of payment; and

k. Applicable procedure for proposal amendment, submissions and supporting tools.

6.1.2 Documentation requirements for supporting research applications

RECs/IRBs should be clear on their own requirements for documents to be submitted for application of an ethical clearance for research. While these could vary depending on the nature of research institution or other specific details of the research calls; the following are typically required:

a. Completed application and signed by the lead Investigator/researcher (s);

b. Full proposal completed in all sections with supporting documents (annexes);

c. 'Lay' summary of the application with no technical jargons. It can also be in a form of flow chart representing key milestones or simplified theory of change;

d. Description of ethical issues pertaining to the research, and how they shall be tackled;

e. Tools required for operationalizing the research & how they shall be applied;

f. Safety issues pertaining to use of instruments, materials and research data;

g. Investigators CVs- up to date and signed;

h. Research context- Criteria for identifying research participants, research environment and relevant protection measures;

i. Information to be provided to research subjects (in a familiar language), which may include tools and use of local translators, if needed;

j. Procedures for informed consent by participants or (securing approval from caretakers or authorities);

k. Compensation plans for research participants (if any), usually symbolic for appreciating the latter's participation in research. It is given to persons, groups, authorities or communities if applicable (e.g. access to services, expenses incurred to participate in research) ;

l. Description for indemnity and or insurance coverage for participants if applicable; and

m. A history of rejection of the same research protocol, reasons for rejection and measures taken henceforth to address the concerns. (Withholding such information should be regarded as a misconduct and managed with misconduct guidelines).

7. REVIEW OF RESEARCH PROTOCOLS

Protocols shall be reviewed in accordance with the SOPs established by the RECs/IRBs, in a timely and professional manner to maintain trust to the REC and reviewers. Names, titles and institutional affiliation of actual reviewers for each proposal will be kept confidential. However the SOPs can be known to the researchers (e.g. the proposal shall be reviewed by multiple experts, approximate time for receiving feedback, etc).

8. MANAGING REC MEETINGS

REC shall conduct their meetings as provided in the SOPs and announced in institutional media from to time when the meeting dates are approaching. Meetings should be based on institutional arrangements and requirements. The following considerations may apply:

a. Frequency of standard meetings depends on workload/ turnover of proposals;

b. Considerations of sufficient time for REC members to review the results and recommendations from independent reviewers/ consultants;

c. Standard procedures/tools for documentation of approval process;

d. Possibility, criteria and procedures for inviting investigators to REC meeting for clarification or additional information. Applicants' sponsor may also be contacted; and

e. Requirements for reaching out to independents reviews for clarification.

9. ELEMENTS OR CRITERIA FOR REVIEWING PROPOSALS

There are variations regarding the criteria for reviewing and grading performance of proposals. In most cases, the energy is directed towards the scientific/ technical quality, feasibility, ethical considerations, supporting documentation, resource needs/versus budget and qualifications of the applicant team. The following could be minimum consideration for proposal grading for scientific design of the study/scientific quality:

i. Examines the relationship between study objectives, relevance of proposed methodologies, study sample/participants and expected outcomes;

ii. Include justification for chosen research sites and participants ;Characteristics or participants, selection criteria, requirements for representativeness, criteria for inclusion and exclusion of sites and participants;

iii. Justification for assigning control and intervention arms (for trials);

iv. Justifiable use of specific method and tools for data acquisition, processing and progress monitoring ;

v. Justification of risks to study participants/subjects weighed against benefits to individuals, groups or communities;

vi. Ethical consideration – information to be provided to research participants/and or relevant authorities responsible for research site, tools for acquiring consent, protecting participants anonymity/ confidentiality, conditions for participants' withdrawal or termination of part or entire project as managing emergencies. It includes care, protection and continuous support to participants. Issues of care, protection and continuous support to participants during the course of research and minimizing negative effects arising from project withdrawal shall also be covered;

vii. Project monitoring, for lessons, risks, modification, or termination decisions by study team or expert boards/authorities;

viii. Dissemination plans to scientific, non-scientist audiences including policy makers and communities depending on the type of study; and

ix. Types of reviews and criteria for subjecting assigning proposals for each type.

10. EXPEDITED REVIEWS

RECs/IRBs should determine conditions and terms for conducting expedited reviews. The REC chair, or designated reviewer, may review on behalf of the full committee, and give expedited approval to particular study protocol. This is possible for studies which involve no more than minimal risk that is where the risk to harm participants is very low.

Expedited review also means that specific types of proposals are reviewed as they come, that is they do not have to wait for the regular sittings of RECs/IRBs. Research protocols that involve subjecting human to special conditions with possible effect to their health or wellbeing; or a study that involves collection or use of biological or toxic substances should not qualify for expedited review. Expedited reviews can consider factors such as:

a. The nature of study (risks involved), and whether is new submission or amendment;
b. Change's to be done in the proposal from previous submission (major or minor);
c. Quorum requirement(s); and
d. Degree of decision making -status of decisions (e.g., subject to confirmation by full REC or not).

11. DECISION MAKING PROCESS

During the course of making a decision over specific proposals REC member (s) should consider:

a. Declare conflict of Interest and leave the panel before discussion of the proposal starts. This should be done in writing before the session starts ;

b. Sufficient time has been provided to review each proposal and reviewers have submitted their reports;

c. Quorum requirements have been met as per SOPs of the REC;

d. All relevant documents have been submitted alongside the review report;

e. Pre- defined approach for decision making approved as per SOPs (e.g. voting, where consensus in not easily established);

f. Where conditional approval has been stated, a clear list of changes to be made and recommendations should be written; and

g. In case of rejection, clear explanations should be provided.

12. COMMUNICATING REC DECISIONS

Decisions made by RECs/IRBs need to be communicated in timely and appropriate manner maintain its reputation. This should be done in writing and address such matters as:

a. Research/study title as written in the application;

b. Other key identifiers of the protocol such as name of the applicant, research site, draft number, date submitted; name & date of REC sitting for that proposal, suggested changes, clear statement of final decision by REC and any other details deemed appropriate by REC;

c. When the proposal has been accepted, REC shall communicate with the researcher(s) on need to confirm receipt acceptance of the study and operate within specified conditions, notify the REC when protocol amendments have been introduced, reporting of unforeseen circumstances affecting the study, termination of the study, progress reporting and study termination before or at completion; and

d. The written letter to investigators should be signed and or stamped by the chair or designated person identified prior to commencement or review process.

13. FOLLOW UP OF APPROVED STUDIES

RECs/IRBs have a responsibility of following all studies to which an ethical clearance was sought and granted at the institution. RECs/IRBs shall also follow up implementation of all research conducted by researchers within their institution regardless of where the ethical clearance certificate was granted.

Communications lines should be open and well known to institutional RECs/IRBs, other RECs/IRBs issuing research permits and researchers. Reporting content, frequency and level of details required should be established.

While these should already be provided in the general SOPs for RECs/IRBs, researchers shall be reminded in writing when communicating the results from RECs/IRBs or before commencement of the study. RECs/IRBS should also:

a. Establish quorum requirements for review of progress reports;
b. Procedures for follow up, frequency of reporting depending on complexity, risks. The minimum frequency of follow up/reporting is once a year;
c. Circumstances under which researchers can be prompted for immediate reporting to REC, which includes harm to participants, adverse events, unapproved alteration to risk/benefit ratio;
d. In case of premature termination of the study a comprehensive report on progress to date and reasons for termination shall be produced signed by researcher and submitted to REC; and
e. Upon successful completion, the researcher(s) should submit the copy of technical report and lay summary to all levels of study approval.

14. DOCUMENTATION, REPORTING AND ARCHIVING

SOPs for RECs/IRBs should have clear description of documentation of RECs/IRBs processes, reporting and archiving requirements. Documenter should be identified before REC starts its operations and resources for electronic database established.

Records of research application and decisions made should be kept for a minimum 3 years. REC should also acquire and keep records of ethical clearances for research which was approved by another authority and conducted by researchers within the institution. This is to ensure that RECs/IRBs are informed of all research conducted by researchers working or taking their studies at the institution and to facilitate national coordination mechanisms.

Support from institution management and research coordination directorates/departments is required to facilitate this. Records of REC operations should also be documented and stored. These include such documents as:

a. REC policies, guidelines, SOPs, members CVs, annual reports, financial records (receipts and expenditures);
b. Meeting agendas, decisions, research applications, correspondence regarding research applications, written notifications to researchers;
c. Final report from approved research; and
d. Copy of all approved proposals involving researchers from the institution.

Institutional management and respective REC should determine frequency and modality of reporting REC activities within institutional routines. Institution's management should follow up REC operations to

provide material and resource support. REC activities should be reported to COSTECH at least once a year to facilitate national profiling of research conducted within the country, strength and gaps in REC operations and system support requirements.

Annex 2: Conflict of Interest Guideline

1. INTRODUCTION

Conflicts of interest may arise in such cases like when handling of research/ innovation proposals, fellowship grants, staff recruitment, promotions, however, they do not need to present a problem to an institution if they are openly and effectively managed. Hence, institutions should strive to see that ethical, legal, financial or other conflicts of interest are avoided and that any such conflicts when they arise are managed in a manner that do not affect the efficiency of the organization.

The conflict of interest guideline is an important tool in safeguarding the principle of objectivity as enshrined in the Constitution of the United Republic of Tanzania, which provides for the recognition of equality of persons, respect of human rights, social justice and bans all forms of discriminations, which implies that government agencies must maintain objectivity and impartiality, and must consider the equality of all persons before the law.

2. DEFINITION OF CONFLICT OF INTEREST

Each institution needs to have a clear definition of what entails conflict of interest, which should be widely communicated to staff, students and other relevant stakeholders of the respective institution. The definition should take on board the fact that a conflict of interest occurs when a person's personal interests, whether actual, potential, perceived or alleged conflicts with their responsibility to act in the best interests of the organization.

Personal interests include direct interests as well as those of family, friends, or other organizations; a person may be involved with or have an interest in. These situations present the risk that a person will make a decision based on, or affected by, these influences, rather than in the best interests of the organization and must be managed accordingly.

3. RECOGNIZING CONFLICT OF INTEREST

There should be clear guidelines in place of how conflicts of interests are recognized. It is the responsibility of each individual to recognize situations in which he or she has a conflict of interest, or might reasonably be seen by others to have a conflict, to disclose that conflict.

There can be situations in which the appearance of conflict of interest is present even when no conflict actually exists. Thus, it is important when evaluating a potential conflict of interest to consider how it might be perceived by others.

4. PROCEDURE FOR DISCLOSING CONFLICT OF INTEREST

It is the duty of every staff member of the institution to disclose any conflict of interest or any circumstances that might reasonably give rise to the perception of conflict of interest. Disclosure of conflict of interest should be made at the time the conflict first arises, or it is recognized that a conflict might be perceived, in writing to the responsible officer in the respective directorate. In many situations, it is expected that nothing more than a declaration and a brief written record of that declaration will be required for record purposes.

5. PROCEDURE OF MANAGING CONFLICT OF INTEREST

The procedure of managing conflict of interest including:

a. Institutions will need to establish a Conflict of Interest Committee that shall be responsible for monitoring the compliance and implementation of the guideline and handling cases of misconduct;
b. It is the responsibility of respective Unit / Committee to develop instruments/tools to operationalize the policy;
c. Once an actual, potential or perceived conflict of interest is disclosed, it must be recorded and handled with confidentiality and action must be taken immediately and a decision to resolve it must be made;
d. The nature and extent of the conflict of interest and steps taken to address it must be recorded;
e. If it is noted that a person has failed to disclose a conflict of interest it should be reported to the committee to take necessary actions against the person ; and
f. Someone who has a conflict may not handle the matter in question. The general rule shall be that a person who has a conflict of interest may neither undertake nor participate in resolutions of the matter in which a conflict of interest has been established.

6. AWARENESS AND COMMUNICATION OF THE CONFLICT OF INTERESTGUIDELINE

It is essential that all staff, students and other relevant stakeholders of the respective institutions are well informed about the Conflict of Interest Guideline and its implications in the conduct of their respective roles and responsibilities.

Annex 3: A Guideline for Development of Institutional Intellectual Property Policy

FOREWORD

Intellectual property (IP) plays a crucial role in the knowledge-based economy or generation, particularly in the promotion of research and innovation. A number of knowledge based assets are developed and generated by institutions, mostly universities and research institutions, attract protection of various form of intellectual property rights which enable and create opportunities for the utilization of such knowledge (research outputs) and innovation (technology) in the public for sustainable development and growth of a given society and beyond.

For decades, IP has continued to take a vital function in teaching and research activities performed by Research institutions and Universities (through their R&D activities, universities and research institutions producing results in the form of inventions as well as; teaching activities generate IP, such as teaching materials, theses, software or designs). In that case, appropriate IP policies are essential for research institutions and universities in order to deal with the ownership and management of generated inventions/innovation or research results and; produced teaching/scholarly materials and information.

According to WIPO, an institutional IP policy is a formally-adopted document, which:

i. Clarifies the ownership of and right to use the IP resulting from the institution's own or collaborative R&D activities;
ii. Sets out the rules of the institution on how to accurately identify, evaluate, protect and manage IP for its further development, usually

through some form of commercialization; and

iii. Provides a transparent framework for cooperation with third parties and provides guidelines on the sharing of economic benefits arising from the commercialization of IP.

Therefore, IP policy provides the framework, management and foundation of creativity and innovation for R&D institutions, which commonly serves as the starting point for a system of institutional best practices.

GUIDELINES FOR DEVELOPING AN INSTITUTIONAL IP POLICY

When formulating and developing an institutional IP policy, R&Ds should consider, but not limited to, the followings:

1. INTRODUCTION

Commonly, most introduction part of Institutional IP policies provides the background of the IP issues and policies in relation to the governing national IP policies or laws in existence. Also, this section may introduce related policies including the existing institutional IP policy status (administration and management) of the particular institution in regard to its activities (i.e. research, consultancy and teaching/training).

1.1. Definition

Further, some IP policies include definitions for key terms used in the policy. In some instances, these may be provided at the beginning or in the appendices. However, not all policies include a definition section.

Definition of key terms used is very indispensable, in order to provide the exact meaning that is or will be used within the document in relation to IP issues and management as per the scope of related policy.

Thus, the defined terms must be clearly defined so as to avoid ambiguity and misconceptions to relevant stakeholders. Key terms that can be found in IP policies are such as Intellectual Property/Intellectual Property Rights, Patents, Trademarks, Copyrights, Plant Variety, Industrial Designs, Utility Models, Trade Secrets, Innovation, Commercialization, inventor, confidentiality and so on.

2. OBJECTIVE/ PURPOSE/MISSION/PRINCIPLES/GOALS

It is a custom of some institutions to provide the purpose of their policies. In addition,, the policy of some institutions may include objectives and principles in relation to the activities done by the institutions (including undertakings by the faculties, departments, researchers, students etc.). In this section, some institutions also outline their goals, mission and vision associating with their related policies to fulfil and show the need or significance of having an Institutional IP policy.

3. SCOPE/APPLICATION

The scope of policy may be found in some of policies, whereby this section provides for the scope of application of the policy; as how, to whom and limitation of the policy coverage. This section shows to what extent the policy can be applied and when should be applied, it tries to answer the question as 'To whom does this policy and operational procedures apply'?

4. MANAGEMENT OF IP

Management of intellectual property comprises of numerous issues when addressing intellectual property affairs. In most cases, it involves interactions and collaborations which involve exchange of materials, information as well as access and utilization of equipment.

This may start prior to engaging into any proposed research and development collaborative activities between the intended parties, during and further at advanced stages. This chapter may provide and cover such important issues including:-

4.1. Establishment of Intellectual Property Management Office (IPMO)

IP Policy of research institutions and universities should introduce an office/unit/department, which its main function is to manage the IP assets of the institution. The institution will have to set out IP structure within its organizational framework in order to ensure that IP management office responsibilities are institutionalized and run accordingly.

IPMO may adopt different names such, as found in some policies, Technology Transfer Office, IP Commercialization Office, Innovation Commercialization Office; what matters mostly are the roles and functions of the said office. IP Technical Committee is also established within the IPMO in order to administer IP related matters and approve IP applications. However, some IP policies place administration of IP matters within departments of Research or Academics affairs.

4.2. Responsibilities

Some policies outline the responsibilities of various stakeholders regarding IP. For example, it may indicate what the role of supervisors is towards postgraduate students in making them aware of IP issues and procedures to follow in theses involving IP or commercialization of IP. It may also highlight other leadership roles regarding IP such as the role of the Head of Department or the role of university administration or role of a researcher or collaborative institution.

4.3. Disclosure of Invention/Disclosure Procedure and IP protection

This is among the key part of most of IP policies in Research institutions and universities, whereby it puts a duty to any employee (covered in the policy) to disclose to relevant office/organ (IPMO) any information or knowledge in their possession which has or is foreseen to be of a commercial value and may lead to IP protection.

Commonly, IP policies and related institution regulations outline the procedures that should be followed by researchers (creators and inventors), employees, students, etc. to disclose and register IP for their inventions and creations. It is also up to the decision made by institutions as to what IP or inventions need to be protected, thus some institutions policies may decide some inventions not to be protected (in case of huge funds needed) and may grant the inventor or offer the IP through other available options.

However, issues of IP protection may have a separate clause in some IP Policies, this clause basically lays out the procedure on how to protect the

invention after the disclosure, and also such section may state the rights of inventor and related stakeholders who contributed in the creation of the said IP.

4.4. Ownership of Intellectual Property

IP ownership is one of the issues that need a well-organized approach for the benefits and bona-fide interests of the collaborating parties in order to overcome any clashes and misunderstanding. Generally, institutional IP policies outline various provisions depending on their nature of activities that govern the ownership of IP generated from their institutions.

This chapter may cover details on ownership related to work/research results created within the scope of employment, work for hire, research or teaching materials. As well as , other scholarly works, collaborations, external sponsored works/research, utilization or use of institutions facilities or equipment, researchers/employees, consultancy works, contracts, institutions logos, marks, or designs,and students etc.

4.5. Confidentiality

The policy should reveal the need for confidentiality specifically for type of information of inventions (for example Patents and industrial designs) that need to be kept in confidence prior their exploitation either in commercial aspects or furtherance of R&D.

In addition, Institutional IP policy should outline with emphasis, that prior

to enter into any partnership (agreements or discussions) in regard to the institutions' generated IP, researchers and all employees should be aware and alerted on the duty to confidentiality in conjunction with other related institution's regulations and principles. Thus, procedures and mechanism for the same should be in place.

4.6. Commercialization/Commercial Exploitation of IP

In this part, the commercialization and sometimes the transfer of generated innovation/research output strategy is laid out. Usually, appropriate office such as IPMO and the inventor make decision and may handle the process. However, note that in this process appropriate arrangements must be put in place and discussed well (IP protection of the invention prior disclosure).

Issues of signing agreements and licenses are to be observed as the researchers (creators) may be required to do so; hence appropriate information and advice must be provided to them before embarking into the process. The policy may also clearly express what would happen if the institution decides not to commercialize the IP or in case the creators are not prepared to support the Commercialization of the IP in accordance with the Commercialization Strategy – for example, the institution may revise the Commercialization Strategy or choose not protect and Commercialize the IP.

In a case where the institution fails to commercialize the generated IP, assignment of the IP to the creator/inventor (researcher) may be arranged usually upon request. The policy should encourage transfer of

technology and make sure there is a proper mechanism for monitoring of commercialization arrangements and licenses entered including sufficient marketing strategies for exploitation IP assets are intact.

4.7. Revenue or Royalties Distribution/Benefit-Sharing Arrangements

IP Policies always provides for how the revenue earnings/profits from commercialization will be shared by the affected stakeholders or targeted groups. The policy may specify how proceeds will be divided between the inventor and the institution. The policy may also include a table outlining how the split will occur, can include a share for IPMO, departments, or units, and commonly indicates percentages of who gets what. There is usually no much difference between staff or students regarding how the revenue would be split.

In addition, IP policy may also include (some highly consider this) provisions about how profits will be determined upon retirement, termination or death of the inventor/staff from the institutions. Benefit Sharing or distribution of revenue accumulated from the transfer of technology or commercialization of IPR has continuously been one of vital factors for motivation of innovativeness to most of institutions.

4.8. IP Agreements/Licenses

In some IP Policies, may include types of Agreements and licenses that are frequently used in regard to the Institutional IP policy applicability and all issues of Intellectual Property Management as concerned. Agreements are normally handled by established and recognized office to all stakeholders. Terms and conditions must be stipulated clearly in these agreement documents so that the involved parties to be aware of what is agreed upon; also the responsible office must keep and store the

documents safely.

IP policies may also define types of agreements and licenses that apply in relation to IP issues. Agreements and licenses must be dealt in accordance to the agreed applicable laws and must contain significant clauses accordingly. Typical IP management licenses can be Exclusive Licenses, Non-Exclusive Licenses and Sole Exclusive Licenses.

Some institutions provide the option of creators of IP to place the creation in the public domain; some institutions mention its Open Access Research IP, open source software. It should be noted that, such approaches have procedure as most of the time such actions do affect issues of IP ownership for both creators and institutions. Open Access policies may be done regularly for works that are not commercialized/ sold for proceeds.

5. CONFLICT OF INTEREST

Institutional IP policy may stipulate that there should not be a conflict of interest regarding institution work; and work outside the institution and its implications on IP.

6. SETTLEMENT OF DISPUTES

IP Policy must show procedures that should be followed should there be a dispute regarding IP. It can also indicate the relevant people (posts)/ organization/committee that should be contacted in the event of a dispute.

7. REVIEW

IP policy, just like other guiding instruments of institutions, must be reviewed and modified within such a reasonable period of time/ periodically. The duration may vary depending on institutions goals, improvement, challenges, national and international regulations/vision and strategic plan. Usually policies may be reviewed from 3-5 years.

8. IMPLEMENTATION AND EFFECTIVE DATE

The Policy must be implemented in accordance with the institution's regulations, policies as well as the applicable national laws. Upon approval by the relevant authorized body/person(s), the effect of the Policy will be on the date it is so signed.

9. NOTIFICATION

It is an obligation of the institution to inform all stakeholders likely to be affected by the policy about its existence, implementation and effect. This includes all institution's employees, contracting parties and collaborators in their various forms whereby they will have a duty to observe the policy.

10. OTHER RELEVANT ISSUES/APPENDICES

IP policy may also have such attachments and forms, in the process of managing of IP assets. These forms/agreements or attachments may include (the list is not exhaustive):

i. Non-Disclosure Forms/ Confidentiality forms (Agreement);

ii. Material Transfer Agreement;
iii. Technology Transfer Agreement/Commercialization Agreement;
iv. Licensing Agreement;
v. Service Agreement;
vi. Participation /Collaborative Agreement;
vii. Disclosure of Invention forms; and
viii. Conflict of Interest Forms.

Annex 4: A Guideline for Data Transfer or Use and Material Transfer Agreements

4.1 INTRODUCTION

Data and materials transfers between and within the research institutions are important aspects in research and for social-economic development, hence specific legal agreements should be made before data or material transfer. Despite of their importance for research and national development, most of the research institutions have underestimated them.

In 2015, the government of Tanzania developed the data act with the aim of protecting the rights of provider /recipient of data and material by regulating the collection and processing of information; provide for the rights of individual whose data is collected and obligations of data collectors, processors and controllers; to regulate the use or disclosure of personal information and related matters. Therefore, the following guidelines give an insight to the research institution on how to develop data and material transfer agreements.

4.1.1 Data Transfer or Use

A Data Transfer Agreement (DTA) or a Data Use Agreement (DUA) is a written agreement that is used to govern the transfer of research and innovation data between and within institutions. It describes the data being transferred or shared and addresses the ownership of the data, the permitted uses of the data, publication of results, development of inventions, disposal of the data, and any liability.

For outgoing data transfers, the goal is to ensure that the R&D institutions receive intellectual property rights for the information the institution is sharing with another R&D institution; or that is being transferred to another institution. For incoming data transfers, the goal is to prevent any misunderstandings about the rights to data.

A DTA/DUA is a legal document and therefore it should include a plan for the procedures that will be used to protect the transferred information and list any protective measures that are necessary based on what is contained in the data. Below is the form with the tentative information to be included in the agreement:

DTA/DTU Questions/Form

1. Description of data to be transferred (subject matter format, size)

a. If it is medical data it must not include any identifying information of the individuals who are the subjects of the data and recipient is prohibited from contacting the individuals.

2. Description of the research purpose for data transfer:

a. How was that research funded (grant, industry, donation);
b. The role of researchers' in the research at the new institution (if any); and
c. Limitation on the use of the data transferred.

3. Duration of the transfer:

a. Start date and end date; and

b. Plan for returning the transferred data (if applicable)

- How modifications of the data will be handled (returned with the data to the provider or kept by the recipient).

4. Is the transfer outgoing (transferring data from your institution to another institution) or incoming (transfer of materials from another institution to your institution)?

a. For outgoing transfers:

- Data recipient institution name and contact information;
- Role of your institution in research performed with this data at the receiving institution (if any);
- Additional services that accompany the data (translation, explanation);
- If this data was received by your institutions from DTA, which institution provided the data;
- Are there any restrictions on transfer from that DTA;
- Shipping/handling fees for the transfer (if applicable);
- Limitations (if necessary) on transferring this data to a third party; and
- Notifications/approval from your institution.

b. For incoming transfer:

- Data provider institution name and contact information;
- Will this data be used with other data you have received or expect to receive from another institution; and

- Role of researchers from provider institution (if any)

1. Additional services that the provider institution will be providing in addition to the data (translation, explanation).

5. Will the data be used in research that is related to an invention disclosure or patent application?

a. If so explain how; and

b. The determination of copyright/patent rights will be necessary (may be needed even if there is no plan for a patent right now).

In summary the following should be included in the agreement:

i. Parties entered into agreement;

ii. Scope of the agreement;

iii. Terms and conditions;

iv. Intellectual Property (Rights to ownership);

v. Publication of results;

vi. Reports and notification;

vii. Expiring date and Termination of the Agreement;

viii. Charges / Payment;

ix. Assignment and sub-contracting (Signed informed consent form);

x. Liability and Indemnity;

xi. Unforeseeable Circumstance (Force majeure);

xii. Applicable law and jurisdiction;

xiii. Any attachments; and

xiv. Signatures.

4.1.2 MATERIAL TRANSFER AGREEMENT

A Material Transfer Agreement (MTA) is an agreement entered by the parties to govern the provision or receipt of tangible research material. The specific form of agreement depends upon the nature of the material, the intended use, and type of the institution and it includes the consideration of any intellectual property interests associated with the material.

The MTAs can be transferred between academic or research institutions, or from academia to another type of provider e.g. a company, laboratory, or agency; or transfers from these providers to academia or research institution. Each of these transfer calls for different terms and conditions.

The MTA should detail the rights, obligations, and restrictions agreed upon between the parties with respect to materials and any derivatives. Depending on the type of MTA (incoming or outgoing), the institutions are recommended to develop appropriate agreement which covers at least the following issues:

i. Identities of the transferor or and transferee ;
ii. Purpose of the transfer and use of the materials ;
iii. Nature of the materials (live or dead) to be transferred; export of materials will only be permitted when there is no local capacity to conduct such analysis;
iv. Definitions of terms used;
v. Terms and condition of the agreement;
vi. How material will be transferred;
vii. Recipient's use of the material;
viii. Ownership of the original material and modifications;

ix. Recipient's ability to transfer the material, modifications, and derivatives to third parties;

x. Rights to inventions resulting from the use of the materials (IPR);

xi. Rights to publish results obtained through the use of the materials;

xii. Reporting and confidentiality obligations;

xiii. Declaration of recipients on how to handle the material after analysis i.e Store/destroy/return the material to provider;

xiv. Whether materials collected was under a research study or routine system and if any third party constraints may exist;

xv. The Recipient will at all time, retain the right to use an Invention for non-commercial research purpose upon written permission by the provider ;

xvi. Results obtained from the materials should be reported to the Provider;

xvii. Informed consent form which allows the proposed use or transfer of the material;

xviii. IPR and patent issues should be stipulated in the agreement;

xix. Before signing permission for export provide aliquot or backup material samples that will be retained by the provider, where necessary/applicable;

xx. If the study has received either ethical clearance, permits, license or approvals from accredited institution;

xxi. Who will cover costs, payment and warrant of the materials to be transferred;

xxii. How termination will be done; and

xxiii. The law to be used in case of dispute.

Annex 5: A Guideline for Preparation of Research Misconduct &Allegations Handling Procedures

1. INTRODUCTION

Research misconduct includes practices that seriously deviate from those that are commonly accepted within the research community such as fabrication, falsification, or plagiarism for proposing, conducting, reporting and reviewing research that has been committed intentionally, knowingly or recklessly and that has been proven by a preponderance of the evidence.

Therefore, any allegation of research misconduct, irrespective of discipline, is an offence and as presented in the National research integrity framework, the research misconduct allegation has to be handled in appropriate manner. In this regards all research institutions are recommended to prepare their guideline /policy for handling research misconduct allegations.

This document specifies key procedures for research institutions to develop the guideline for handling Research Misconduct allegations for their research related activities.

1.2. Objective:

To enhance the minimum requirement structure/ guide that the research institutions in Tanzania could follow during the preparation of institutional Research Misconduct Allegation Handling (RMAH) guideline

1.3 Scope

This document outlines the key steps for preparation of the guideline for handling formal allegation of research misconduct. It provide minimum requirement for preparation of the Research handling misconduct allegation guideline. However, based on the nature of research institutions and nature of research related activities, the proposed structure may be improved to suit the institutional status. It has been designed to allow the institutions which do not have RMAH guideline to develop it easily.

1.4 Content of the guideline

The guideline in minimum should have the following contents:

i. Introduction;
ii. Procedures for appointing responsible person to deal with RMAH;
iii. Procedures for initial receiving allegations of RMAH;
iv. Investigation management ;
v. Allegation Evaluation;
vi. Formal investigation;
vii. Reporting; and
viii. Disciplinary Procedures.

The document has to explain the background of Research Misconduct Allegation and its handling procedures, purpose, objective, significance and scope of the guideline.

2. PROCEDURES FOR APPOINTING RESPONSIBLE PERSON TO DEAL WITH RMAH

In this section the developed guideline has to specify the procedure for appointing a person responsible for coordination of handling research misconduct allegation. The appointed Officer will be the one who all allegations of research misconduct should be directed to.

The role, responsibilities and reporting channel of the appointed officer have to be described. It has to explain the process to recruit/appoint/ identify investigatory panel's/committee members and their appropriate professionals and relevant experience (relevant to the subject area and process of investigation).

The appointing authority has to be clearly stated. It has to detail the duty and obligation of all committee and parties participating in process such as respondent, complainant, witness, investigator, decision maker, or those enforcing decisions.

Furthermore, it has to state the obligation of all parties to support an investigation by making available materials and information relevant to that investigation. Moreover it has to state the role and obligation to facilitate an investigation through structural support (where practical) which might include space and resources to assist an investigation.

3. PROCEDURES FOR INITIAL RECEIVING ALLEGATIONS OF RESEARCH MISCONDUCT

The guideline has to describe the procedures for initial steps of receipt and handling of allegations. It has to state to whom or what body an individual should first approach with an allegation.

It has to declare individual officer and offices identified as receiving and that deals with allegations; and introduce Policies/ guidelines that are mostly referred (if any). Among the questions to be answered in initial procedures include:

a. From whom allegations will be accepted;
b. In what form the allegations will be received (orally, written, electronic) or accepted;
c. Whether formal allegations can be filled by researchers or research institutions from within or outside their respective disciplines-specific units or institutions or any other party affected by the practice; and
d. The contact details of the office responsible for RMAH, who is involved and how is handled.

Written allegations must include the following:

a. The three names and contact details of the complainant(s);
b. The three names and contact details of the respondent(s); and
c. Detailed description of the allegations.

4. INVESTIGATION MANAGEMENT

The provision which states that when an allegation is made, the designated person should secretly assess the risk while protecting the interests of all concerned parties, is to be featured.

The document has to clearly explain the procedures that should be structured to ensure that the process is conducted with an appropriate level of confidentiality for party's involved (respondent, complainant, witnesses). Such confidentiality should be maintained provided this does not compromise the investigation of the allegation, health and safety, or the safety of participants in research.

It has to explain the condition for independent investigation and insist on appropriate transparency process and that evidence is disclosed where and/as required. Where possible any disclosure to third parties should be made on a confidential basis. It has to show the appropriate procedures to be followed for the organization and/or its staff to inform third parties of research misconduct allegations while maintaining confidentiality.

It has to consider the provision that could manage/ reduce conflict of interests. It has to ensure the process is accurate, complete, objective, fair, and impartial. The guideline has to describe when it might be appropriate to apply interim steps to protect staff, individuals, animals, the environment and/or research funds. It also has to explain the disciplinary action for any person who will contravene the provision.

5. ALLEGATION EVALUATION

The guideline has to describe procedures which provide detailed steps for gathering of information relevant to the case and to support the fair and sufficient evaluation of allegations. This might include:

5.1 Assessment in preliminary enquiry:

The guideline has to explain step by step procedures for handling misconduct allegations that should be taken after receiving of complain. This might require the designated officer to establish whether or not the allegation falls within the definition of research misconduct and whether an inquiry is warranted.

There should be a provision that require the designated officer to notify respondents, immediately in writing about the filled allegation and the subsequent preliminary enquiry that will be conducted. The nature and detail of the allegation has to be included in written notification and the name of the complainant.

It has to refer the procedure for appointment of officer who needs to be involved in gathering evidence is as in section 2. The procedure for examination, the collection of evidence to support or rebuttal of the allegation, while avoiding the conflicting evidence from parties with real or perceived conflicts of interest has to be provided in the guideline.

The need and the right of the complainant and respondent to be advised by independent advice and/or represented by any person they choose

have to be stated in the guideline. The guideline has to clearly state the process in transparent manner for example, to provide a copy of the draft report of preliminary enquiry to incorporate his/her comment(s) into the report within the limited time to respondent and the complainant shall respond to those comments in writing within the stated period.

The guideline has to describe the need for the head of committee to finalize the preliminary enquiry report once all comments have been incorporated. The time of conducting preliminary inquiry and preparing a draft report has to be clearly stated. The procedure for handling the outcome of investigation should be explained.

5.2 Inquiry stage

The guideline has to explain detailed assessment of enquiry stages of allegation in order to determine if research misconduct was committed. This assessment should be based on an established proof. There should be a description which explains how investigation committee is formulated as referred to section 2 and how the evidence is obtained. It has to provide a procedure for investigations of allegations and it has to show the obligation of any part to provide cooperation during the filing of evidence.

The level of investigation should be defined and elaborated such as:

Intent: The investigation should evaluate the evidence to assess the level of intent with which the act was committed and determine if that level meets the minimum threshold for a finding of research misconduct.

Burden of Proof: The process should determine the evidence and investigation that aim to find burden of proof for a finding of research misconduct.

The guideline has to clearly define procedure for investigation, time frames and actions in each phase and to reach decisions based on sufficient and competent evidence.

The guideline should clearly state the disciplinary actions that might be taken if evidence and proof on the conduction of allegation is concluded. As well, clearly show the mechanism used if evidence proved that misconduct allegation has not been conducted. The guideline has to show reporting procedures for each phase.

There should be a written report that states what evidence was reviewed, summarizes relevant interviews and includes the conclusion of the Assessment Panel as to what actions should be taken. The guideline has to provide the provision for respondents to be given reasonable opportunity to comments. The enquiry report has to be prepared.

Name and position of the respondent, description of allegation of research misconduct, the basis for recommending that, alleged action warranted an investigation need to be stated. There should be a provision that, explained the need for respondent and complainant to be informed in writing of the outcomes.

The possible outcomes/actions have to be clearly stated in the guideline such as:

a. No case is established: the respondent and complainant should be

informed;

b. No case is established but malicious intent is suspected: the respondent should be informed and relevant action should be taken in respect of the complainant; and
c. Minor concern: panel to recommend actions for resolution of the concern. Necessary parties to be informed. If major concern: Proceed to investigation.

6. FORMAL INVESTIGATION

An investigation is a formal examination and evaluation of relevant facts to determine whether or not misconduct has taken place.

The purpose of the Investigation is to develop a factual record by exploring the allegation(s) in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent and the actions that should be taken. The Investigation has to also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations.

Guideline has to refer on the formulation of the Investigation Committee and appointment of Chair in section 2. It should design and insist on the declaration of conflict of interest with either panel with regards to respondents or complainants, and they should have the necessary expertise to examine the evidence, interview witnesses and conduct the investigation.

The guideline should describe the process that allow collection of many relevant information as reasonably possible considering the importance of gathering oral or written information from the main actors (respondent, complainants, witnesses). This may require rapid action to secure information, including information from those against whom the allegations are made.

The Guideline should have a provision, that allow interviews to be conducted with the complainant and the respondent, and any other individuals involved in making the allegation and other individuals who might have information regarding key aspects of the allegations. Provisions should be included to allow the temporary suspension of the individual(s) implicated in the allegation or otherwise restrict their activities while the investigation is being conducted.

It has to also clearly define the procedure for investigations and timeframes. Actions in each phase should be designed to reach decisions based on sufficient and competent evidence. Guideline should consider incorporating the following concepts:

6.1 Investigative phases

It has to discuss receipt and initial evaluation of allegation, screening inquiry and detailed investigation. The guideline should have a provision that, respondent should be advised in detail and the complainant, be given written notice of the process in order to prepare their defence.

Where possible, the investigation should include examination of all relevant documentation, including, but not limited to relevant research data, laboratory notebooks, computer files, other materials, proposals, publications, correspondence and memorandum.

6.2 Adjudicative phase

The guideline has to describe how adjudicative has been reached and the actions and/or sanctions are proportionate to the offence, consistent between cases, proportionate against individuals no matter what their country of origin or employer is. This phase should include provisions for adjudication/formal disciplinary hearing.

6.3 Investigation results/outcomes

The guideline has to state who will submit investigation report to the office of research integrity as per section 2 and provide its copies to both the complainant and the respondent. If the allegation has not been proven beyond reasonable doubt, the guideline has to state the action that might be taken. Respondent and complainant shall be informed in writings if no further action will be taken.

The guideline has to state if the allegation is proven beyond reasonable doubt, the action that might be taken, and that respondent and complainant shall be informed in writings. The guideline has to indicate the time frame for logged appeals pursuant. The allegation verdict shall be documented in the file of the respondent.

6.4 Right of appeal

The guideline should provide the conditions and the right of appeal against the decision and/or sanctions made by the investigation to the respondent. The timeframe for appeal period has to be clearly stated (e.g. 14-20 days) of receiving notification of the final outcome of the investigation. The guideline has to provide the direction for selection of appeal Committee.

Appeals (criteria, such as the submission of new evidence or significant procedural errors, should be specified by which the individual qualifies for an appeal hearing). The criteria for filing and examination of appeal must be made in writing.

The provision that indicate the necessity of preparing appeal report (AR) has to be in the document. AR should state how the appeal was conducted; describe from whom relevant information was obtained; state the findings of the Appeals Board; and explain the basis for those findings.

6.5 Final decision of the appeal

The guideline has to state how the appeal result will be handled, based on the appeal report, whether to endorse, amend or overturn the recommendations of the Investigation Committee and/or resultant sanctions imposed on the respondent.

It has to show the procedure for notification of the respondent (in writing) on the recommendations of the Appeals Board and provide a copy of the appeal report and evidence considered by the appeals board (appointment of appeal board in section2). Consider informing other interested parties, including of the outcome of the investigation

7. REPORTING

The guideline has to provide the reporting structure for evaluation and appeal of allegation. This report should be provided to all relevant parties defined or identified in the collaborative agreement. It has to specifying to whom the report should be made available. The following has to be considered in the report:

a. State how the investigation was conducted and describe how and from whom information was obtained (including the full verbatim reports of interviews);
b. State the findings and explain the basis of the findings;
c. Contain an accurate agreed summary of the views of the respondent;
d. Contain a description of any further actions (sanctions, disciplinary action, legal proceedings etc.) recommended by the committee;
e. General timeframes for the completion of stages of reports and receipt of responses to reports; and
f. Identify to whom reports will be provided; and which organizations (institutions, funding bodies, societies, journals) is provided.

8 DISCIPLINARY PROCEDURES

When an allegation of research misconduct has been formally substantiated, the guideline has to explain disciplinary actions that may be taken. Also has to state who is making such appropriate administrative actions against the individual(s).

The number of sanctions that has been imposed by research institutions and number of sanctions and disciplinary actions has to be elaborated. For example; Sanctions may apply separately or combined actions that may be implemented include:

8.1 Research sanctions may include but are not limited to:

a. Withdrawal of all pending or published abstracts and papers emanating from the research where research misconduct was found;
b. Removal of the responsible person(s) from the particular project;
c. Restricting or prohibiting future grant submissions and/or reviewing grant proposals for agencies; and
d. Special monitoring of future research publication.

8.2 Disciplinary Actions by Employee related disciplinary actions may include:

a. Final written warning;
b. Suspension, Demotion; and
c. Salary reduction.

If the research misconduct is so serious that the above sanctions are insufficient, it has to be clearly stated and its disciplinary action determined. For example, where the research in question is funded by an external agency, the funding body may also impose sanctions (e.g. termination of funding, debarment from further applications for a stated period) as they see fit.

The guideline has to provide processes for dealing with Research Misconduct Allegations related to research funds

If the allegation relates to research funds applied to or awarded by the research funding agencies with their own policy (procedures or regulations) for dealing with the possible reported misconduct in research funds, research institution(s) may choose to adopt that policy as a framework under which the research funds misconduct inquiry will be completed. However, the processes may start as the case of other misconduct allegation.

Investigation should only begin when the specific requirements of the policy of the external funding body have been considered and suitable procedures agreed on. An infringement or a breach of the standards or any other adopted policy may result in disciplinary action.

In case the research institution chooses to adopt the policies of the external funding body, it should be stated in individual funding contracts so that all parties are aware.

Annex 6: A Guideline for Development of Institutional Whistle Blowing Policy and Procedures

PREFACE

The whistle blowing policy in the Higher Learning Institutions, Research and Development Institutions is one of keys documents for observing and following ethical and professional standards in the institutions. Establishment of the policy is highly recommended on handling a potential or raised misconduct for internal and external stakeholders, in safe channels and high confidentiality.

The policy should act in accordance with the Staff Regulations which require staff members and other stakeholders working for the institutions to report in writing any reasonable suspicion of illegal activities to the designated officers directly. In other words, the whistle blowing arrangement serves as a detection mechanism to bring cases to the attention of institution, the duty to report concerns.

When formulating and developing an institutional whistle blowing policy, Research & Development institutions should consider, but not limited to, the followings:

1. INTRODUCTION

It should describe what it is all about (background information), aim or goals and a brief procedures or steps for internal staff and other relevant stakeholders during reporting misconducts.

High confidentiality and protection of whistle blowers and personal information, procedures of reporting and investigation are described and emphasized. It should promote and develop a culture of openness, accountability and integrity in an institution.

2. OBJECTIVE OF THE POLICY

It should clearly describe objectives and goal of the policy. Specifically the policy should ensure all employees feel supported in speaking up in confidence and reporting matters they suspect may involve improper, unethical or inappropriate conduct within the institution; encourage all improper, unethical or inappropriate behaviour to be identified and challenged at all levels of the organization; provide clear procedures for reporting and handling such concern(s); proactively prevent and deter misconduct which could impact the financial performance and damage the institution`s reputation; provide assurance that all disclosures will be handled seriously, treated as confidential and managed without fear of reprisal of any form; and help promote and develop a culture of openness, accountability and integrity.

3. SCOPE AND APPLICATION OF THE POLICY

The policy should indicate its scope and application for internal staff and external relevant stakeholders to report any perceived act of impropriety or misconducts, including but not limited to, all forms of financial malpractices or impropriety such as fraud, corruption, bribery, theft and concealment.

As well, failure to comply with legal obligations, statutes, and regulatory directives; actions detrimental to health and safety or the work environment; unethical behaviour that undermines universal and core ethical values such as integrity, respect, honesty, accountability and fairness; and sexual or physical abuse of staff, customers, prospective staff, service providers and other relevant stakeholders.

4. POLICY STATEMENT

The policy statement should emphasize promotion and development of a culture of fairness, honesty, openness, decency, integrity, respects, accountability and ethical behaviour by fostering and maintaining an environment where employees and other stakeholders can act appropriately, without fear of reprisal.

5. ROLES AND RESPONSIBILITIES

The policy should clearly state the roles and responsibilities of whistle blowers, suspect, designated officer(s), and human resource officers in the whistle blowing process.

6. WHISTLE BLOWING PROCEDURE

The policy should describe the procedures for internal and external whistle blowers. It should provide format and media of reporting such as institution's website, suggestion box located at the office and or by posting through the postal address or orally directly to the complaining desk.

The whistle blowing procedures should involve steps in reporting misconducts and investigation of the reported misconduct for internal and external whistle blowers. It should explain the steps of investigation and reporting to the appropriate authority for further actions and whistle-blowers.

7. TIME LIMIT FOR INVESTIGATION

It should be prompt and fair, and set specified time frame of handling reported misconducts. However, it should be noted that a specified time frame for the conclusion of investigation depends on the nature of potential concerns.

8. ROLES OF THE MANAGEMENTOF THE INSTITUTION

The policy should indicate that the management is one of the key players in raising awareness and promoting the Whistle blowing Policy and Procedures.

9. PROTECTION AND COMPENSATION FOR WHISTLEBLOWER

In the policy, protection of whistle blowers and confidentiality of process should be of high level to convince whistle blowers to disclose their names.

10. STAFF DECLARATION

The policy should provide a declaration form for whistleblowers to fill such as name, staff number, company/location, signature and date of reporting a misconduct. It should be in separate page to return to designated officer.

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