MINISTRY OF HEALTH

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

GUIDELINES ON ETHICS FOR HEALTH RESEARCH IN TANZANIA

THIRD EDITION

2023

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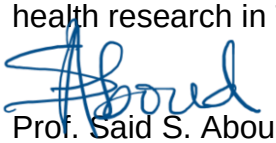
FOREWORD

Health research is extremely important and has a potential value to society for both prevention and treatment of diseases globally. It provides vital information about diseases trends, risk factors, patterns of care, healthcare cost and outcome of the treatments or public health interventions. Health research is essential for individual health improvement and stimulates national economic growth.

Changing diseases patterns, increased population, and emerging and re-emerging health issues to mention a few have led to the increasing demand for conducting research and thus, necessitating revision of the existing guidelines to accommodate the changes and ensure the rights, dignity, safety and protection of research participants in the country.

These guidelines are intended to guide individuals and institutions to conduct research in Tanzania in a scientifically and ethically appropriate manner. They should assist investigators in fulfilling their obligations to plan and conduct research in accordance with sound scientific and ethical principles.

NIMR sincerely appreciates those who have contributed to the revision of the guidelines in one way or another. It is my hope that this version will provide comprehensive information for investigators who are conducting health research in Tanzania,



Prof. Said S. Aboud

DIRECTOR GENERAL

PREFACE TO THE THIRD EDITION

The 3rd Edition of the Guidelines on Ethics for Health Research in Tanzania has been formulated to provide a system in Tanzania that facilitates the carrying out of important research without compromising the rights and welfare of individual research participants. It aims at health research stakeholders conducting research in Tanzania with guidelines to carry out health research in accordance with established and accepted ethical standards and norms.

This revision broadened the guidelines to cover additional aspects of health research to include research in traditional and alternative medicine, handling stored human biological specimens and data sharing amongst others.

Finally, these guidelines would not have been possible without the support from NIMR Management and Researchers, the Medical Research Coordinating Committee (MRCC) and the National Health Research Ethics Committee (NatHREC). This guideline was revised with financial support from the United States President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Centers for Disease Control and Prevention (CDC), this support is highly appreciated.

Dr. Mary T. Mayige

DIRECTOR OF RESEARCH INFORMATION AND REGULATORY AFFAIRS

ABBREVIATIONS AND ACRONYMS

CIOMS	Council for International Organizations of Medical Sciences
COSTECH	Tanzania Commission for Science and Technology
DSMB	Data and Safety Monitoring Board
IBC	Institutional Biosafety Committee
IRB	Institutional Review Boards
IREC	Institutional Research Ethics Committee
MoH	Ministry of Health
MRCC	Medical Research Coordinating Committee
NatHREC	National Health Research Ethics Committee
NBS	National Bureau for Statistics
NEC	National Ethics Committee
NIMR	National Institute for Medical Research
NMRA	National Medicines Regulatory Authority
PO-RALG	President's Office Regional Administration and Local Government
REC	Research Ethics Committee
SOPs	Standard Operating Procedures
TMDA	Tanzania Medicines and Medical Devices Authority
WMA	World Medical Association

CHAPTER 1: **INTRODUCTION**

1.1 Overview

Tanzania has unique health, environmental, social and economic problems that attract both local and international research interests. Health research specifically refers to the scientific investigations carried out for the purpose of contributing to the knowledge of health. It is the means by which scientists discover new knowledge that may lead to the prevention, treatment, or even elimination of certain categories of disease and disability (CIOMS, 2016). To effect this, the National Institute for Medical Research (NIMR), a parastatal organisation under the Ministry of Health (MoH), was established by the Parliament Act No. 23 of 1979 (Cap. 59, R. E. 2002) and became operational in 1980. The Act gives NIMR dual mandates as a health research institution and national regulatory authority of health research undertaken within Tanzania. As a health research institution, NIMR is mandated to carry out medical research designed to alleviate disease among the people of Tanzania. As a regulatory authority, it is mandated to monitor, control, coordinate and promote medical research in Tanzania. The mandates are as follows:

i. To carry out and promote the carrying out of health research designed to alleviate disease among the people of Tanzania;
ii. To carry out and promote the carrying out of medical research into various aspects of local traditional medical practices to facilitate the development and application of herbal medicine;
iii. In co-operation with the Government or any other person or body of persons to promote, or provide facilities for the training of local personnel for carrying out scientific research into medical problems;

iv. To monitor, control, and coordinate medical research carried out within Tanzania, or elsewhere, on behalf of or for the benefit of the Government of Tanzania, and to evaluate the findings of that research;

v. To establish a system of the registration of, and to register, the findings of medical research carried out within Tanzania and promote the practical application of those findings to improve or advance the health and general welfare of the people of Tanzania;

vi. To establish and operate systems of documentation and dissemination of information on any aspect of the medical research carried out by or on behalf of the institute;

vii. Carry out and promote the carrying out of research and investigation into the causes and the ways of controlling and preventing the occurrence in Tanzania of particular diseases or a category of them; and

viii. In cooperation with the Government of Tanzania or any person or body of persons, carry out and promote the carrying out of basic, applied, and operational research designated to provide effective measures for the control of diseases endemic in the Country.

Tanzania has several academic and research institutions that conduct research on a variety of national health research priority areas. Due to the phenomenon of globalisation and given the pace at which medical science and technology is changing, health researchers are constantly exposed to new ethical dilemmas. In some cases, those dilemmas are in direct conflict with their professional ethics. It is the opinion of the National Institute for Medical Research that researchers of today in Tanzania need to be thoroughly guided in the health-related components of human rights and

ethics for them to be able to analyse complex issues raised by the political, socio-economic and cultural changes in the society. The purpose of this guideline is to guide researchers and other stakeholders on how to balance the rights and welfare of individuals and the need of society within the context of health research. Since the 1980's, the number of research projects involving humans as research participants in Tanzania has more than tripled. This increasing quest for knowledge and the search for novel remedies to health, environmental, social and economic challenges is beneficial but could involve exposing research participants to a spectrum of risks. These guidelines provide a national framework for harnessing the benefits of research while ensuring that the rights, interests, values and welfare of research participants are protected.

1.2 Rationale

Ideally, research is conducted for the benefit of society. There is a need for all countries to put in place guidelines and regulations that will safeguard the interests of research participants during research. The need to achieve good standards has prompted many countries to develop guidelines and regulations for safeguarding research participants' interests. Therefore, society and professionals must concentrate on building an ethical framework that will permit research activities to progress but, at the same time, maintain public confidence that individual autonomy is respected.

The research participant's rights and welfare should not be compromised when researchers follow their quest for new knowledge. Developing a system that promotes beneficial research and safeguards against misconduct is imperative.

Tanzania is tackling poverty, illiteracy and diseases, both communicable and non-communicable diseases. Currently, there is an increasing trend of non-communicable diseases such as diabetes, cardiovascular diseases, hypertension, and cancers (Ministry of Health, 2021). In addition, the increasing occurrence and re-occurrence of emerging and re-emerging infectious and non-infectious diseases, and the current digital evolution; triggers the need for more innovative research and hence revision of the guidelines is needed to accommodate the anticipated ethical issues that will need to be addressed.

The purpose of the Guidelines on Ethics for Health Research in Tanzania is to guide researchers and other stakeholders on balancing the rights of individuals and the need of society within the context of health research.

1.3 Scope of Application

The aforementioned general policy and other provisions of these guidelines apply to (1) all research involving humans as research participants in Tanzania conducted in or by public institutions, private, inter-governmental and non-governmental organisations among others, and (2) research conducted in a foreign country on human biological materials and information collected from Tanzania.

1.4 Objectives

The overall objective of these guidelines is to facilitate the conduct of human health research without compromising the dignity, rights and welfare of research participants and society.

Specifically, these guidelines are to:

a. Protect the rights and welfare of research participants;
b. Provide ethical standards and procedures for the conduct of research involving humans as research participants;
c. Ensure that research takes into account social and cultural sensitivities of participating communities; and
d. Ensure ethical principles and guidelines are followed for the use of animals in human health research.

1.5 General Policy Statement

Research and development, including scientific investigations and technological trials involving humans as research participants, shall be conducted for the benefit of communities in Tanzania and beyond without causing unnecessary harm or inconvenience to human research participants and shall not compromise the rights and welfare of the participants.

CHAPTER 2: **REGULATION OF HEALTH RESEARCH IN TANZANIA**

NIMR fulfils its regulatory roles through two principal committees, namely, the Medical Research Coordinating Committee (MRCC) and the National Health Research Ethics Committee (NatHREC), which executes delegated functions of MRCC.

2.1 Medical Research Coordinating Committee

The Medical Research Coordinating Committee (MRCC) is the national health research coordinating and regulatory body for health research in Tanzania. The MRCC is a NIMR Council Committee. Members are drawn from the NIMR Council, including the Chairperson. In addition, NIMR Technical Coordinating Directors are also members of the MRCC.

2.1.1 Functions of the MRCC

The Committee's role is primarily to provide oversight on the review, coordination, monitoring and promotion of health research carried out by the Institute. The Committee also provides oversight on the Implementation of the regulatory function of the Institute to, includes ethical clearance, permission to publish and processing of Material and Data Transfer Agreements (NIMR Council Charter, 2020).

The MRCC has delegated the functions of ethics clearance to its sub-committee, the National Health Research Ethics Committee (NatHREC) established in 2002.

2.2 The National Health Research Ethics Committee

The Director General of NIMR is responsible for appointing National Health Research Ethics Committee (NatHREC) members.

2.2.1 Committee Composition

Members are selected based on their capacity, interest, ethical and scientific knowledge and expertise, as well as their commitment and willingness to volunteer the necessary time and effort for the Committee's work.

The Committee shall consist of not less than nine (9) and up to fifteen (15) members with the relevant qualification and experience to review and evaluate the science, medical and ethical aspects of health research protocols. The Committee shall be composed of members with varying backgrounds to promote a complete and adequate review of health research protocols commonly received by the NatHREC. The committee also consist of religious and community representatives.

2.2.2 Other Health Research Coordinating and Regulatory Bodies

i. **Tanzania Medicines and Medical Devices Authority (TMDA)**
   For clinical trials, clearance shall be obtained from the National Medicines Regulatory Authority (TMDA).

ii. **Tanzania Commission for Science and Technology** (COSTECH)

Research permits are obtained from the National Science Council in Tanzania (COSTECH)if the research involves investigators who are not Tanzanian residents. After obtaining ethical clearance from NIMR, the responsible PI is required to proceed to COSTECH to get further approvals.

Ethics clearance and oversight of research involving humans as research participants in Tanzania are done at national and institutional levels.

For the purpose of this document, the term “REC” refers to both national, zonal and institutional level ethics committees. The terms “REC” and “IRB” will be used interchangeably as they serve the same purpose.

CHAPTER 3: **RESEARCH ETHICS COMMITTEES**

Research Ethics Committees (RECs) are established by institutions that carry out health research and are hence referred to as Institutional Research Ethics Committees or Institutional Review Boards (IRBs). Institutions within Tanzania that regularly host health research activities may apply to NIMR to be mandated to review protocols for ethics clearance. The mandate only applies to research hosted by the Institution.

The RECs have a role of monitoring research activities to ensure compliance. The REC members are appointed by Institutional appointing

authorities. RECs may function at the institutional, zonal, or national levels.

3.1 Establishment of RECs

Institutions that intend to establish an institutional REC shall request, in writing, to the Director General of NIMR. In the communication, the institution shall assure that it will comply with the minimum requirements outlined in these guidelines as follows:

a. A statement of principles governing the institution's discharge of its responsibilities for protecting the rights and welfare of human research participants of research conducted at or sponsored by the institution. This may include an appropriate existing code, declaration, or statement of ethical principles or a statement formulated by the institution itself.
b. Ensuring meeting space availability and sufficient staff and resources to support the IRECs review and record-keeping duties.
c. A list of members identified by name, qualifications, profession, representative capacity, indicators or experience such as board certification, and licenses.
d. Written procedures for monitoring the conduct of studies approved by the IREC.

3.2 Committee membership

The REC must be constituted according to a document that specifies the manner in which members and the Chair will be appointed, reappointed, and replaced. RECs must have members capable of providing a competent and thorough review of research protocols. Membership

typically includes physicians, scientists, laboratory experts, nurses, lawyers, ethicists and other professionals. In addition, the above membership also includes community members or representatives of patients' groups who can represent the cultural and moral values of study participants. When a proposed study involves vulnerable individuals or groups, as may be the case in research involving prisoners or illiterate persons, representatives of relevant advocacy groups should be invited to meetings where such protocols will be reviewed.

Regular rotation of members is desirable for balancing the advantage of experience with that of fresh perspectives. Members of research ethics committees must regularly update their knowledge about the ethical conduct of health-related research. If committees do not have the relevant expertise to adequately review a specific protocol, they must consult external persons with the required skills or certification.
Each member shall undergo at least one basic training in research ethics within one year of appointment and, thereafter, should undergo continued ethics training at least once every two years.

In addition;

i. Each REC shall include at least one member who is not affiliated with the institution and is not part of the immediate family of a person who is affiliated with the institution.
ii. A REC may, at its discretion, invite individuals with competence in particular areas to assist in the review of issues, which require expertise beyond, or in addition to that available in the REC. These individuals do not vote with the REC.

iii. Membership in any REC shall serve for a term of three years. Membership terms are defined within REC Standard Operating Procedures.

iv. REC members must guard against any tendencies of unethical conduct on their part for example, they must protect the confidentiality of research projects, documents and discussions; a REC member shall not appropriate the submitted protocol for his or her own use, and IRB members shall not compel investigators to submit to an unnecessary repetition of review.

v. RECs are responsible for determining whether the research objectives are responsive to the health needs and priorities of the proposed study population, particularly in Tanzania.

vi. The ability to judge the ethical acceptability of various aspects of a research protocol requires a thorough understanding of a community's customs and traditions. The IRB, therefore, must have competent members or consulting persons with such knowledge. For example, it will then be in a position to determine the acceptability of the proposed means of obtaining informed consent and otherwise respecting the rights of prospective research participants and the means to protect the welfare of the research participants. Such persons should be able, for example, to indicate suitable community members to serve as intermediaries between investigators and research participants and to advise on whether material benefits or inducements may be regarded as appropriate in light of a community's gift exchange and other customs and traditions.

3.3 Functions of the REC

RECs act as independent reviewers of any proposed study on human research participants, to ensure ethical conduct of research, and that participant's rights and welfare are not violated. Therefore, the major responsibility of RECs is to safeguard the rights, safety, and well-being of research participants. It is essential for IRBs to review the scientific soundness of the research protocols. Because of this, the functions of any REC/IRB in Tanzania shall be to:

i. Maintain ethical standards of practice in research;
ii. Protect research participants and investigators from harm or exploitation; Preserve the research participant's rights and welfare;
iii. Assure society of the protection of the rights and welfare of research participants; and
iv. Ensure adherence to ethical conduct of research protocol approved by the REC/IRB.

3.4 Conflicts of interest on the part of committee members

RECs/IRBs must provide independent ethical opinions. RECs must have mechanisms to ensure the independence of their operations. In particular, they must avoid undue influence and minimise and manage conflicts of interest.

No REC/IRB member may participate in the IRB's initial or continuing review of any project in which a member has a conflict of interest except to provide information as requested by the REC.

RECs must require that their members disclose to the committee any interests they may have that could constitute a conflict of interest or otherwise bias their evaluation of a research protocol. RECs must evaluate each study in light of any disclosed interests and ensure appropriate steps are taken to mitigate possible conflicts of interest. RECs/may receive a fee for reviewing protocols. However, this need not constitute a conflict of interest.

3.5 The Conduct of REC Meetings

i. For effective operations, RECs should hold meetings as frequently as possible as a strategy to facilitate timely ethical clearance.

ii. The REC shall review proposed research at convened meetings at which at least fifty percent (50%) of the members of the IRB are present, including at least one member who represents the interests of the community;

iii. The Chairperson may be given powers to approve minor matters on behalf of the Committee but ensure that the papers are made available to the rest of the members of REC/IRB at the next meeting; and

iv. The committees should have powers to co-opt professional or lay members where necessary.

v. For the research protocol to be approved, it shall receive the approval of a simple majority of those members present at the meeting. The only exception to this procedure shall be in the case of expedited review;

vi. A REC shall require that information given to research participants as part of informed consent complies with the general requirements

for informed consent as prescribed by these guidelines. However, the REC may require that more information be given to the research participants, provided such additional information would meaningfully add to the protection of the rights and the welfare of the research participants;

vii. REC shall generally require documentation of the informed consent process. For certain types of research, however, the REC may need the investigator to administer a comprehension test (or test of understanding) to ensure that prospective research participants have acquired adequate knowledge of the relevant facts and consequences of participation in the study;

viii. The REC shall notify investigators in writing of the outcome of the investigator's research protocol review. Such notice shall be provided to the investigator within 14 days from the date of the REC review of the research protocol. In case the IRB does not approve a research activity, it shall include in its written notification a statement of the reasons for its decision;

ix. REC shall conduct continuing review of research covered by these guidelines at intervals appropriate to the degree of risk, but not less than once a year, and shall have authority to observe or have a third party observe the informed consent process;

x. The REC shall investigate research fraud and take appropriate or recommend to relevant authorities for immediate action where scientific fraud has been suspected or proven;

xi. The REC/IRB shall prepare quarterly and annual progress reports and submit them to NIMR.

3.6 REC Documentation

The institution shall ensure that the REC prepares and maintains adequate documentation of its activities, including the following:

i. Detailed written procedures for the REC.

ii. Copies of all research protocols reviewed, scientific evaluations that accompany the protocols, approved sample consent documents, progress reports submitted by the investigator(s), reports of injuries to research participants, etc.

iii. Minutes of REC/IRB Meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

iv. Records of continuing review activities.

v. Copies of all correspondence between the IREC/IRB and investigator(s).

vi. Statements of significant new findings that were provided to research participants. The records required by these standards shall be retained for at least five (5) years after the completion of the study.

All records shall be accessible for inspection and copying by authorised representatives.

CHAPTER 4: **SCIENTIFIC AND ETHICAL REVIEW**

4.1 Requirements for submission of applications for ethics review and approval

All research protocols submitted for ethics review and approval must, at the least, include the following information:

i. A clear statement of the objectives of the research, the present state of knowledge and a justification for undertaking the research;
ii. A precise description of all proposed procedures and interventions, including the duration of the study;
iii. A statistical analysis plan;
iv. Description of the study population, including the number of study participants to be recruited;
v. The inclusion and exclusion criteria for study participants and procedures for the withdrawal of individual participants;
vi. Complete details of the informed consent process, including the proposed means of obtaining informed consent (or assent in case of minors);
vii. Evidence that the investigators are appropriately qualified and experienced, and have adequate facilities for the safe and efficient conduct of the research;
viii. Provisions that will be made to protect the confidentiality of information/data obtained from research participants;
ix. The study tool (s), e.g., questionnaires, case report forms, videos, flip charts and other data collection tools.

4.2 Scientific Review

Although, in some instances, scientific review precedes ethical review, RECs must always have the opportunity to combine scientific and ethical review to ensure ethical conduct in health research. The ethical review must consider, among other aspects, the scientific rigor of the protocol including the study design, provisions for minimising risk, an appropriate balance of risks in relation to potential individual benefits for participants and the social value of the research; safety of the study site, medical interventions, monitoring safety during the study; and the feasibility of the research. Scientifically unsound research involving humans and animals is unethical because it may expose them to risk or inconvenience for no purpose. Even if there is no risk of injury, involving persons' and researchers' time in unproductive activities wastes valuable resources. The IRB must therefore recognise that the scientific validity of the proposed research is essential for its ethical acceptability. Committees must either conduct a proper scientific review, verify that a competent expert body has determined the research to be scientifically sound, or consult with qualified experts to ensure that the research design and methods are appropriate. If IREC/IRB do not have expertise to judge science or feasibility, they must draw on relevant expertise.

4.3 Types of Review Processes

4.3.1 Ordinary Review Process

Ordinary review is the process involving minimal or more than minimal risk studies. This review follows the normal REC procedures.

4.3.2 Expedited Review Process

Expedited review is a process by which studies that involve no more than minimal risk may be reviewed and approved in a timely manner by an individual REC member or a designated subset of the full Committee. Relevant authorities or RECs may establish procedures for the expedited review of research protocols. These procedures should specify the following:

i. The nature of the applications, amendments, and other considerations that will be eligible for expedited review;
ii. The minimum number of committee members required for expedited review; and
iii. The status of decisions (for example, subject to confirmation by a full IREC/IRB or not).

Relevant authorities or RECs must establish a list of criteria for protocols that qualify for an expedited review process.

4.3.3 Accelerated review of Clinical Trial Protocols

An accelerated review process may be used for a Clinical Trial protocol submitted for ethical approval. In reviewing a clinical trial, reviewers may exercise all of the authorities of the Committee to recommend approval of the submitted protocol. Final approval for protocol is granted in accordance with the standard procedures outlined above. However, applications for accelerated review of clinical trial protocols will be reviewed on a case-by-case basis by the REC, and the applicant may be required to undergo an ordinary review process due to the nature of the trial or else, as determined by the REC.

4.3.4 Protocol Reviews After Approval

The REC shall conduct additional reviews on approved studies as necessary, particularly if there are significant changes in the protocol that require re-consent by participants, affect the safety of participants or other ethical matters that emerge during the study. These further reviews include amendments, progress reports submitted by researchers and possible monitoring of researchers' compliance with approved protocols.

4.4 Externally Sponsored Research

Research may be externally sponsored, meaning that it is sponsored, financed, and sometimes wholly or partly carried out by an external organisation with the collaboration or agreement of the appropriate authorities of the host community. The ethical standards should not be less stringent than they would be for research carried out in the country of the sponsoring organisation. Local committees must be fully empowered to disapprove a study they believe is unethical.

4.5 Multi-centre or Multi-Country Research

Some research projects are designed to be conducted in more than one site in one or more than one country. To ensure that the results are valid, the study must be conducted in a methodologically identical way at each centre. However, committees at individual centres have the authority to adapt the informed consent document provided by the lead institution in the multi-centre trial to make it culturally appropriate.

To avoid lengthy procedures, multi-centre research within the Country should be reviewed by only one REC and other applicable RECs should accept that review. Consultation with the study team should be done to be

informed of the approach they need to take. In cases of multi-centre research, if a local review committee proposes changes to the original protocol that it believes are necessary to protect the research participants, these changes must be reported to the research institution or sponsor responsible for the whole research programme for consideration and possible action. This should ensure that all persons are protected and that the research will be valid across sites.

Ideally, review procedures should be harmonised, which may decrease the time needed for review and, accordingly, speed up the research process. Joint reviews may be organised and requested by the study team or sponsor across country borders or institutions in compliance with guidelines. Joint reviews are based on voluntary cooperation between the relevant national regulatory authorities and ethics committees. In the case of multi-country joint reviews, each country is solely responsible for granting regulatory or ethics approval to the sites within its borders. To harmonize review processes and to maintain sufficient quality of these processes, ethics committees should develop quality indicators for ethical review.

4.6 Exemptions from Review

Some studies may be exempt from review. The following may be exempt from review specified in these guidelines:

i. Research with negligible risk involves using existing collections of data or records that contain only non-identifiable data about human beings.

ii. Use of publicly available unlinked data that does not identify individuals or communities;
iii. Use of existing collections of data or records that contain only non-identifiable data about human beings;
iv. Quality assurance/evaluation activities undertaken in the normal course of conducting the business of the institution, i.e., educational assessments, student feedback surveys, audits of organisational activities and systems, and quality assurance reviews;
v. Emergency use of a test article provided that such emergency use is reported to the REC within five (5) working days. Any subsequent use of the test article at the institution is subject to REC/IRB approval;
vi. Health systems research may be exempted from review if public officials are interviewed in their official capacity on issues that are in the public domain.
vii. If an investigator considers that their research project satisfies the requirements for exemption from ethics review, the investigator shall apply to the REC for the study to be exempted from ethics review. The REC shall review the application to ensure that the proposed research satisfies the requirements for exemption from REC review and will, after that, grant exemption through procedures set by the REC.

4.7 Monitoring

RECs/IRBs should monitor ongoing studies. The researcher must provide relevant information to the committee to permit the monitoring of research records, especially information about any serious adverse events.

Researchers must submit a final report to the Committee containing a summary of the study's key findings, recommendations and conclusions.

4.8 Conduct of Clinical Trials

During the conduct of clinical trials, deviations from the original study might occur, such as changes in the sample size or analysis of the data as described in the protocol. Deviations must be reported to RECs. In the case of permanent deviations, researchers may write an amendment. The REC must decide whether a deviation is accidental or purposeful.

Protocol violations are deviations from the original protocol that significantly affect the rights or interests of research participants and the scientific validity of the data. In the case of protocol violations, RECs should ensure those study participants are informed and provisions are made to protect their safety and welfare. A researcher must submit a protocol to REC for prospective review. This omission is a serious violation of ethical standards and may specify conditions for exemption from review.

Although RECs do not have the authority to impose sanctions on researchers, the Committees may halt the continuation of a previously approved protocol if found to have protocol violations or other misconduct.

Any serious or continuing non-compliance with ethical standards in the conduct of previously approved research projects must be reported to the sponsor and institutional or governmental authorities by study PI and the DSMB.

4.9 Suspension or Termination of Ethics Approval of a Research Project

The IRB shall have the authority to halt, suspend or terminate approval of research that is not being conducted in accordance with the IREC/IRB requirements or that has been associated with unexpected serious harm to research participants or that contravenes these guidelines. The IREC/IRB may suspend research when, for instance:

i. It finds that the investigator has implemented significant changes in the research protocol without the prior approval of the IREC/IRB.
ii. When the investigator has failed to follow specific procedures or requirements articulated by the IREC/IRB in its initial review of the research protocol, or
iii. When there is severe unexpected harm to the research participants, including, but not limited to, serious physical injury or death.

Any suspension or termination of ethics approval shall include a written statement of the reasons for the IREC/IRB's action. It shall be reported promptly to the investigator(s), appropriate institutional officials and the NIMR Director General. Any disciplinary action towards the conduct of a Clinical Trial should be in consultation with the NEC and National Medicines Regulatory Authority (NMRA) which in the country is the Tanzania Medicines and Medical Devices Authority (TMDA).

CHAPTER 5: ETHICAL CONSIDERATIONS IN THE REVIEW OF RESEARCH PROTOCOLS

In order for a research project to be scientifically valid, it should have fulfilled the following criteria:

5.1 Scientific Validity

Validity refers to the degree to which a study or data collection tools accurately reflects and assess the specific concept that the researcher is attempting to measure. Any research project asking valuable questions, if designed or conducted poorly, will yield scientifically unreliable or invalid results. Scientifically unsound research on humans is unethical because it may expose research participants to risks. For research to be ethical, the methods must be scientifically valid and practically feasible, with clear objectives. The design should use acceptable scientific principles, methods and reliable practices; it should have sufficient power to test the objective and offer a plausible data analysis plan.

5.2 Science and Social Value

The main objective of research using humans is the anticipated benefit, which could be in the form of a new intervention to improve the quality of life of a community or generalizable knowledge to benefit the entire scientific world. A research project should demonstrate value regarding new information to be added to the scientific community and probably an improvement in health care provision and general social well-being. There should be foreseeable benefits to the individuals and community where studies will be conducted and the risks, if any, should be minimal.

5.3 Favourable Risk-benefit Ratio

The fulfilment of this requirement must ensure risk reduction to individual research participants and society; however, the risks should be minimal in relation to the benefits to be obtained. The RECs should systematically analyse the risks and benefits of a research project to individual research participants and society and ascertain that the anticipated benefits justify the risks. The risks may include psychological, mental, social, physical and economic harm; on the other hand, the benefits may include medical care and treatment.

5.4 Community Involvement

Where appropriate, there should be a provision for the involvement of the community in the research process right from the inception to the post-research period. The community in this context may be geographical or study population.

Community involvement includes participation in planning, implementation of the research project and dissemination of findings. Community involvement shall not override the rights of individuals to provide voluntary consent for participation in the research project.

5.5 Fair Selection of Research Participants

The selection of research participants should be justified by the scientific hypothesis or research question rather than by the convenience of obtaining research participants. The risks/burdens and benefits of research should be equitably distributed among both disadvantaged and privileged communities. Vulnerable groups should not be targeted for high-risk research and should not be denied potentially beneficial research. Consideration shall be made of the socio-economic factors,

gender, age, and ethnic and racial differences, where applicable. The exclusion of a category of research participants who should have otherwise been included in the study should be justified.

5.6 Independent Assessment

An Independent Ethics Committee must review each research project before its commencement. These Committees should be accredited by a competent institution recognised by the government to comply with organisational and functional regulations regarding ethical and scientific aspects when reviewing research protocols.

CHAPTER 6: **INFORMED CONSENT**

The purpose of informed consent is to ensure that individual's control whether or not they wish to enrol in the study and participate only when the research project is consistent with their values, interests and preferences. To provide informed consent, individuals must precisely be informed of the purpose, methods, risks, benefits and alternatives to research, understand the information and make a voluntary decision whether or not to participate. It should be remembered that informed consent constitutes the principle of autonomy and must be carried free of persuasion, manipulation, and coercion.

6.1 The informed Consent Processes

Informed consent is a process that requires providing relevant information to a potential participant, ensuring that the person has adequately understood the material facts and has decided or refused to participate without having been subjected to coercion, undue influence, or deception. Informed consent is based on the principle that individuals capable of giving informed consent have a right to choose freely whether to or not to participate in research. Informed consent protects the individual's freedom of choice and respects the individual's autonomy.

Consent is not just a form or a signature/fingerprint but a process of information exchange between the researcher and research participants during the whole research process. The information provided should be adequate, and clearly understood by the research participants.

6.2 General Requirements for the Informed Consent Process

The investigator shall not involve an individual as a research participant unless the investigator has obtained informed consent from the individual or the individual's authorised representative. For example, a community leader may not consent to the participation of community members in research without the individual research participant's informed consent.

An investigator shall seek such consent only after ascertaining that the prospective research participant understands the relevant facts and the consequences of participation. For certain types of research, the REC may require the investigator to administer a comprehension test (or test of understanding) to ensure that prospective research participants have acquired an adequate understanding of the relevant facts and the consequences of participation. Seeking consent shall be carried out under circumstances that provide the prospective research participant or the representative sufficient opportunity to consider whether or not to participate and minimise the possibility of coercion or undue influence. The information given to the research participant or the representative, whether it is conveyed orally, in writing, or another delivery mechanism, shall be in a language and form understandable to the participant or the representative. No informed consent, whether oral or written, shall include any ambiguous and/or sophisticated language through which the research participant or representative is: (1) made to waive or appear to waive any of the research participant's rights, or (2) appears to release the investigator, the sponsor, the institution, or its agents from liability.

The investigator shall ensure that there is initial monitoring at the start of the study and continued adequacy of the informed consent process and

renewal of informed consent if there are significant changes in the conditions or procedures of the research project or if new information becomes available that could affect the research participant's willingness to continue in the research project.

6.3 Elements of an Informed Consent Form

The elements which must be included in the information provided to each research participant for the consent to be valid include the following:

i. A statement that this is a research study; an explanation of the study; an estimate of the duration of the study and the research participant's participation in that study; a description of the procedures to be followed in the study, and the identification of any procedures, including the use of medication or devices, that are experimental when applicable.
ii. A description of any reasonably foreseeable risks or discomforts the study participant may experience.
iii. A description of the benefits to the study participants or to others that may reasonably be expected to result from the study.
iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the study participant.
v. A statement describing the extent, if any, to which privacy and confidentiality of the study participants will be maintained.
vi. For research involving more than minimal risk, a statement as to whether any compensation and any medical treatments are available if injury occurs and, if they are, what they consist of and where further information may be obtained.

vii. Identification by name and contact details of the individual(s) who should be contacted for answers to questions about the research project and the study participants' rights and the name of the individual(s) to contact in case of a research-related injury to the study participant. The designated individuals must be able to communicate with the study participant in the language of the participant or must have the capability and authority to promptly secure the services of an interpreter to assist in responding to the participant's questions.

viii. A statement that participation is voluntary, that refusal to participate will not result in a penalty or a loss of benefits to which the study participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

ix. A statement of the extent of the investigator's responsibility, where applicable, to provide medical services to the study participant.

x. A statement of the nature, form and extent of compensation for study participation, e.g., reimbursement for transport, time and meals.

xi. A brief description of the research project sponsors and the investigators' institutional affiliation.

xii. A statement that study participants will get feedback on findings and progress of the study and that any new information that affects the study or data that has clinical relevance to the participants will be made available to the participants or their health care providers.

xiii. Where necessary, for example, illiterate, mentally incapacitated or physically disabled study participants, the provision for a witness at appropriate stages of the informed consent process should be ensured.

xiv. A statement that the study has been approved by a recognised Tanzanian-based REC.

xv. Any of the following elements shall be provided to the study participant when appropriate based on the nature and conduct of the study:

a. A statement that a particular treatment or procedure under study may involve risk to the study participant or to the embryo or foetus if the participant becomes pregnant, and that the risk is currently unforeseeable.

b. An explanation of circumstances under which the investigator may terminate the study participant's participation, whether or not the participant consents to such termination.

c. An explanation of any additional costs to the study participant that may result from his or her participation in the study.

d. A statement explaining the consequences of a study participant's decision to withdraw from the study. Participants may withdraw at any time without further notice. However, participants should be provided with a description of the procedures to be followed to give notice of their withdrawal.

e. A statement that significant new findings made during the course of the study, whether by the study's investigators or others that may relate to the study participant's willingness to continue his or her participation, shall be provided to the participant in a timely manner.

f. The approximate number of individuals participating in the study.

g. Whether when and how any of the products or interventions proven by the study to be safe and effective will be made available to the study participants at the end of the study and whether they will be expected to pay for them.

h. With regard to research involving the collection of biological/genetic materials, an explanation should be provided on how specimens will be managed at the end of the study. If the samples are stored for future use, separate consent should be obtained. See **section 20.1** on acquisition, storage and future use of biological samples.

6.4 Documentation of Informed Consent

The study participant may imply consent by voluntary actions: express consent verbally or sign (written consent form).

Except as provided in the waiver of informed consent **section 6.6 below**, informed consent shall be documented by the use of a written informed consent form approved by a REC and signed by the study participant or the participant's representative and the person obtaining the consent. A copy shall be given to the study participant or the participant's representative signing the form.

The consent form shall contain all the elements listed in **section 6.3 above.** This form may be read to the study participant or the representative. The study participant or the participant's representative must be given sufficient time to read the consent form before the participant or the participant's representative signs the form or places his or her thumbprint on the form indicating that he or she has read and understands and agrees to participate in the study.

6.5 Verbal Consent

Verbal or oral consent process is where the researcher and participant have a conversation to give information and obtain consent. Usually, oral consent is used when it is not possible to get written consent. The verbal consent may be deemed appropriate and applied under the following situations where;

i. Study deemed to be of minimal risk
ii. There are cultural or political concerns with signing contract-like documents.
iii. The researcher and or participants could be put at risk by existence of a paper record.
iv. Study is conducted remotely via video conferencing software, telephone etc.
v. It may not be feasible in large information-taking settings, e.g., some focus group discussions (FGDs). However, documentation of verbal consent for participants in FGDs must be written down to include the names of participants who consented verbally and those that did not.

For verbal consent, the following guidelines apply:

1. The procedures used to seek consent must be described within the ethics application.
2. Verbal consent must still contain all of the elements required for informed consent.
3. A verbal consent script should be prepared and submitted for review and approval before its implementation.
4. Where possible, a copy of this script, or a parallel information sheet, should be provided to the participant.

5. The researcher must document that oral consent was provided. This can be done via written field notes, audio or video recording or other available means.

For protocols involving verbal consent, the following minimum information must be communicated to the participant:

1. Introduction- who is the caller/interviewer, affiliation, organisation
2. A statement that the study involves research
3. Study purpose
4. What the participant will be asked to do - as well as the amount of time the participant will spend (include any follow-ups that you plan to do)
5. Any compensation and any information you will need to collect to make that payment (mailing address, email address, etc.)
6. The voluntary nature of participation in the study
7. Any risks or benefits associated with participating (leave this out if there are none)
8. That you are taking notes or recording the data.
9. Whether the information collected will remain confidential or if you plan to keep identifiers with the research data (if the address is collected, will that be kept separate from the survey responses).
10. Provide contact information for the researcher and/or the IRB.
11. Ask if the participant has any questions that you can answer.
12. Ask explicitly- do you agree to participate in this study? And record the response.
13. Depending on the nature of the study and the participant pool, the researcher may offer other pertinent information to ensure that

participants are fully informed about the study and any risks or benefits from participating in it.

RECs shall determine whether the investigator's protocol to obtain verbal informed consent is appropriate or not.

6.6 Waiver of Informed Consent and/or Documentation of Informed Consent

For research that is no more than minimal risk, the REC may approve to request to waive some or all of the required elements of informed consent under specific circumstances. Waivers of informed consent are primarily requested for projects involving the secondary analysis of existing data.

To waive in total or to alter informed consent elements, the REC must determine that:

i. The study could not practicably be carried out without the waiver or alteration (whenever appropriate the study participants will be provided with additional pertinent information after participation);
ii. In situations where deception needs to be applied to achieve the objectives of the study;
iii. The only record linking the study participant and the study would be the consent document and the principal risk to the research participant would be potential harm resulting from a breach of confidentiality;
iv. The study participant presents in an emergency situation and informed consent cannot be reasonably obtained from the individual or his/her representative.

If a waiver of written informed consent is granted by the REC, then each study participant should be asked whether he or she wishes to have documentation that links him or her with the study; and the participant's wishes shall govern. In situations in which the participant prefers not to execute a written informed consent form, the investigator must obtain oral informed consent and document that it has been obtained.

6.7 Assent

Assent is agreement by an individual not competent to give legally valid informed consent (e.g., child or cognitively impaired person) to participate in the study. Children and adolescents who are legally minors cannot give legally valid informed consent, but they may be able to give assent. To give assent means that the child or adolescent is meaningfully engaged in the research study discussion in accordance with his or her capacities. Assent must be considered as a process and is not merely the absence of dissent. Furthermore, the researcher must involve the child or adolescent in the actual decision-making process and use age-appropriate information. It is particularly important to inform the child or adolescent and obtain assent as described above, preferably in writing for children who are literate.

Specific protections to safeguard children and adolescents' rights and welfare in the study are necessary. Before undertaking research studies involving children and adolescents, the researcher and the RECs must ensure that:

i. If a parent or a legally authorized representative of the child or adolescent has given permission.
ii. If the agreement (assent) of the child or adolescent has been obtained in keeping with the child's or adolescent's capacity, after

having been provided with adequate information about the study tailored to the child's or adolescent's level of maturity.

iii. If children reach the legal age of maturity during the study period, their consent to continued participation should be obtained.

Children or adolescents required to assent are from the age of 10 years to 17 years who can read and write as well as understand the description of the study. Assent should be sought in addition to parental consent.

In general, the refusal of a child or adolescent to participate or continue in the study must be respected unless; in exceptional circumstances where participation is considered the best medical option. For research interventions or procedures that have the potential to benefit children or adolescents, the risks must be minimized and outweighed by the prospect of potential individual benefit.

For research interventions or procedures that have no potential individual benefits for participants, two conditions apply:

i. Interventions and procedures should be studied in adults first, when these interventions and procedures target conditions that affect adults as well as children and adolescents, unless the necessary data cannot be obtained without participation of children or adolescents.

ii. The risks must be minimized.

6.8 Research in Adults Incapable of Giving Informed Consent

Specific protections to safeguard the rights and welfare of incapacitated persons in research studies are necessary.

Before undertaking research with adults who are not capable of giving informed consent, the researcher and the REC must ensure that:

1. A legally authorized representative of the person who is incapable of giving informed consent has given permission and this permission takes account of the participant's previously formed preferences and values (if any).
2. The assent of the participant has been obtained to the extent of that person's capacity, after having been provided with adequate information about the study at the level of the participant's capacity for understanding this information.
3. If participants become capable of giving informed consent during the study, their consent to continued participation must be obtained. In general, a potential participant's refusal to enrol in the study must be respected, unless in exceptional circumstances where study participation is considered the best available medical option for an individual who is incapable of giving informed consent.

6.9 Consenting Secondary Use of Materials or Data

Secondary use means use in research of materials or data originally collected for other purposes. Biological materials collected for diagnostic or therapeutic purposes are usually stored for future use, e.g., pathology samples. In these circumstances, provisions of informed consent is provided in **section 6.10** below.

6.10 Databases, registries and repositories

Databases, registries (data banks) and repositories (tissue banks) may be created for research, diagnostic or clinical purposes. They constitute a valuable research resource and allow researchers to pursue questions that were not anticipated at the time of collection of either data or material.

Ordinarily informed consent for stored diagnostic or therapeutic samples has not anticipated to include research purposes. Also, researchers may have banked surplus samples in a tissue bank. The importance of stored biological material as a research resource cannot be overstated. The dilemma is whether unanticipated research usage necessitates fresh informed consent and, if so, what should be done when a donor is no longer available.

In the absence of broad consent to future use of material or data, including images, for research purposes, the following is recommended:

i. The nature of the previously obtained consent should be determined to ascertain whether subsequent usage was envisaged and whether it falls within the scope of the current protocol. If so, new consent is not required.
ii. If the scope of the current protocol is different, then new consent may be required.
iii. If samples are anonymous and the results of research would not place any individual, family or community at social, psychological, legal or economic risk of harm, then new consent is not required.

iv. If the link to identifiers exists but is not provided to the research team and the results of research will not place any individual, family or community at social, psychological, legal or economic risk of harm, then new consent is not required.

v. The person who holds the code or link should sign an explicit written agreement not to release the identifiers to the research team. This agreement should accompany the submission to the REC.

vi. If the samples can be linked to identifiers, the REC must decide on a case-by-case basis whether expedited or full review is necessary.

CHAPTER 7: **GENETICS AND GENOMICS RESEARCH**

7.1 Genetic Research

Genetic research refers to the study of genes (human DNA), heredity and variation as well as how they affect inheritance of traits and conditions between generations of people, especially regarding human health and disease.

From an ethical perspective, genetic research has both positive and negative implications. While its purpose may be to shed increasing light on causes of diseases, and how to prevent or combat them, participants in such research may experience negative effects like stigmatisation, unfair discrimination and so on. Furthermore, genetic information is not specific to one individual but reveals much about that person's relatives and others with a shared ancestry.

When assessing the ethics of proposed genetic research, RECs must pay particular attention to multiple considerations, including the proposed social value of the research; consent, privacy, confidentiality as well as the potential effect of the research on families, communities and other groups. The protocol must include a plan that outlines how information revealed by the genetic research will be managed. This plan must be explained to potential participants. Plans to share findings with participants must include opportunities for participants to choose whether they wish to receive the information personally, and whether the information may be shared with biological relatives. Genetic counselling must be available if findings will be disclosed to participants.

7.2 Genomics Research

Genomics research refers to the study of all of a person's genes (the genome) and how they interact with each other and with the person's environment. Genomics research permits investigation into diseases at a population level to take into account not only genetic, but also environmental factors.

Collection and storage of data and human biological materials should balance the need for adequate participant safeguards with optimal advancement of such research in line with the stated goal expressed above.

Special or additional protection for participants' interests may be necessary (e.g., in instances where identifiable samples or data are collected) where findings in genetic studies may pose social, psychological, legal or economic risks for a participant, his family or his community. In such cases data and/or biological material should be de-identified after collection or can be collected without identification of the donor.

DIFFERENT TYPES OF CONSENTING APPROACHES USED IN SECONDARY USE OF MATERIALS/DATA AND GENETICS AND GENOMICS RESEARCH:

i. **Narrow (restrictive) consent:** the donor permits use of the biological specimen for single use only; no storage of leftover specimen; and no sharing of data or specimen. This necessitates new consent if further use is desirable.

ii. **Tiered consent:** the donor provides consent for the primary study and chooses whether to permit storage for future use, sample and data sharing**.**

iii. **Broad consent:** the donor permits use of the specimen for current study, for storage and possible future related research purposes. The nature of the further usage should be described as fully as possible and should stipulate that further prior ethics review of the new study may be necessary. Permission may be sought to re-contact the person if intended future use is outside the scope of the current consent.

iv. **Blanket Consent:** RECs and investigators should be aware that 'blanket' or unrestricted consent is not permitted for the reason that it becomes difficult to implement and sustain fundamental ethical principles especially that of respect for persons.

CHAPTER 8: **USE OF HUMAN CELL LINES IN RESEARCH**

This section refers to both primary human cell lines and commercially available cell lines. Research studies involving human cell lines falls within the definition of “research involving humans”. As such, it is subject to review by a REC. Current guidance is intended to protect the privacy of the donor (the “participant”) from whose tissue the cell line was derived and to respect the terms they consented to, if any, for the use of their human biological materials. Research studies involving the creation of a cell line and re-use of an existing de-identified cell line requires REC review.

Biosafety and ethical issues may arise from use of commercially available cell lines depending on the nature of the planned research study. For example, if cells are to be infected, biosafety and hence also ethical issues, arise for researchers rather than participants. If cells will undergo genetic modification, there may also be ethical implications. Review by the RECs should ensure that biosafety and ethical standards are maintained.

CHAPTER 9: **TRADITIONAL AND ALTERNATIVE MEDICINES RESEARCH**

In line with the constitutional guarantees for cultural and language rights, indigenous cultures and traditional values of all communities must be respected. Participants in research studies involving traditional medical systems and beliefs must be accorded the same respect and protection as any other human research participants. The context of the research study, interaction or intervention is important for determining whether, how and when to incorporate traditional values and their cultural expression in research.

The United Republic of Tanzania Traditional and Alternative Medicines Act no 23 of 2002 defines “traditional medicine” as a total combination of knowledge and practice, whether applicable or not, used in diagnosing, preventing or eliminating a physical, mental or social disease and which may rely exclusively on past experience and observation handed down from one generation to another orally or in writing. It further defines herbal medicines" as plant-derived material or preparations with the therapeutic or other human benefits, which contain either raw or processed ingredients from one or more plants; in some traditions material of in organic or animal origin may also be present; and “alternative medicine" as the total sum of knowledge and practice used in diagnostic, prevention and elimination of physical, mental and social imbalance relying exclusively on various established alternative medicine system of respective disciplines.

RECs should pay attention to indications that intellectual property may be intended to be acquired by non-Tanzanians and should advise that appropriate advice be sought. Intellectual property in indigenous flora, fauna and medicines is a particularly sensitive matter and not easily regulated.

International and domestic legislation, policies and regulatory guidelines applicable in these departments must be taken into account when conducting research on traditional medicinal plants, traditional medical practices, indigenous knowledge and genetic materials, to ensure compliance.

Prior ethics review of the proposed research is required to ensure that norms and standards for health research in Tanzania are being upheld. Toxicology tests must be performed on substances to be used on or ingested by participants; and equivalent rigour must apply to such research studies. Researchers should furnish proof of safety of the substances to the RECs. The practice of requiring a randomised controlled trial may not be appropriate in all circumstances for indigenous treatments and interventions.

However, RECs must consider methodology carefully and make decisions on a case-by-case basis.

CHAPTER 10: **RESEARCH USING ONLINE AND DIGITAL TOOLS**

Online and digital tools provide a relatively new platform for health-related research. They present several opportunities, but also raise ethical issues, especially in the informed consent process. Ambiguity in the determination of risk arises from the minimal interaction between the researcher and the participant. In Internet research, there is little means of gauging participant characteristics (e.g., age), and how participants are responding to the study. In addition, there are issues that are associated with data and personal privacy, and access that are inherent in most online activities. While ethical standards have yet to be established for Internet-based research studies, researchers shall be mindful of these issues, and consider current best practices to safeguard the rights of participants and protect them from harm.

Researchers utilizing online and digital tools shall be guided by the following questions to ensure that respondents' right to privacy and confidentiality is upheld:

i. How will participants be recruited?
ii. How can the requirements for informed consent be fulfilled?
iii. Are the individuals identifiable or anonymous? (Note that "online identity," even if a pseudonym, may already be attached to an individual's real identity)
iv. Is the online behaviour "public" or do respondents have reasonable expectations of privacy?
v. Did individuals know or expect that records were being kept (versus ephemeral or impermanent data)?

If individuals have reasonable expectations of privacy and impermanence of their online activities, then researchers may need to take specific measures to inform the respondents and obtain their consent to use their data for research, with the attendant protections to their rights to privacy.

Soliciting the participation of minors shall be done with extreme care, given that the researcher is unable to verify the age of the respondent, and shall include strategies for checking and ensuring parental consent. Internet or online based research studies involving minors should be limited to minimal risk research.

Researchers and RECs shall ensure that research on the Internet or online based only involves minimal risk or includes mechanisms that address more than minimal risk. Moreover, data collection via the Internet or online based shall be justified versus other means.

Additional safeguards for maintaining privacy and confidentiality of information shall be used (e.g., pseudonyms, modified quotes to prevent immediate retrieval through search engines, encryption, separation of data files for identifiers and responses).

CHAPTER 11: **ARTIFICIAL INTELLIGENCE**

Artificial intelligence (AI) is the theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages. AI-based systems can be purely software-based, acting in the virtual world (e.g., voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g., advanced robots, autonomous cars, drones or Internet of Things applications).

Machine learning is the term used for AIs which are capable of learning or, in the case of robots, adapting to their environment. The use of AI technologies has given rise to ethical challenges.

Apart from regular considerations the review of AI related protocols by RECs should further scrutinize:

i. Essentiality and appropriateness of the system;
ii. Alternates available and opportunity/cost comparison;
iii. Qualifications of researchers/developers;
iv. Possible Technology malfunctions / glitches / failures and the redressal mechanisms;
v. Stakeholder responsibility and accountability to various aspects of AI technology malfunction / injury;
vi. Opportunity to constantly upgrade AI technology with additional data and technology and its influence on participants;
vii. Quality check of the AI technology;

viii. Participants ‘right-to-be-forgotten’ This refers to an individual's ability to request that a search engine remove links to information about them from search results; and

ix. Conformity to data storage and sharing policies.

CHAPTER 12: **DUAL-USE RESEARCH OF CONCERN AND GAIN OF FUNCTION RESEARCH**

i. Dual Use Research of Concern

Dual-use research of concern describes research that is intended to provide a clear benefit, but which could easily be misapplied to do harm. It may be misused to pose a threat to public health and/or national security. An example is research into viruses. Scientists may create modified versions of dangerous viruses in laboratories to study how they behave in humans and animals, and ultimately how to fight them. While this is a necessary step in biological research, the modified viruses also pose safety concerns and have the potential to cause great harm if not controlled correctly or used to intentionally infect people or animals.

ii. Gain of Function Research

The term “gain of function” refers to any genetic mutation in an organism that confers a new or enhanced ability. Scientists can induce such changes to organisms through experimentation though such changes often occur naturally. Gain-of-function (GOF) research involves experimentation that aims or is expected to increase the transmissibility and/or virulence of pathogens. Such research, when conducted by responsible scientists, usually aims to improve understanding of disease-causing agents, their interaction with human hosts, and/or their potential to cause pandemics.

Despite these important potential benefits, dual use research of concern and gain of function research can pose risks regarding biosecurity and biosafety. With the aim to control and safeguard against intentional misuse these types of research studies are currently not permitted in Tanzania.

CHAPTER 13: **RIGHTS AND WELFARE OF RESEARCH PARTICIPANTS**

13.1 Research Ethics Principles

It is essential that health research is conducted in order to develop new knowledge for the better care of mankind. However, health research may be associated with risks and the possibility of exploitation of the individual participants or the community in which the study is to be carried out. The increase of likely hood of exploitation especially in low and lower middle-income countries is mainly due to poverty, ill health and lack of resources. Thus, in the field of health research selection of research study participants must take into account whether the study is carried out among healthy participants, patients, children, women, etc. The research protocol must describe the social contexts of a proposed research population, e.g. country or community that create conditions for possible exploitation or increased vulnerability among potential study participants, and strategies that will be taken to overcome these conditions and protect the dignity, safety and welfare of the participants. In order to protect the rights and welfare of human research participants, studies should be conducted in accordance with the four basic research ethics principles, namely: respect for persons, beneficence, non-maleficence and justice.

These four (4) principles are briefly described as follows:

a. **Respect for persons** incorporates at least two fundamental ethical considerations, namely: respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.
b. **Beneficence** refers to the ethical obligation to maximize benefits and to minimize harms. This principle gives rise to norms requiring that the risks of harm by research be reasonable in light of the expected benefits, that the study design is sound, and that the investigators are competent both to conduct the study and to safeguard the welfare of the study participants.
c. **Non-maleficence** (to do no harm) proscribes the deliberate infliction of harm, or evil on study participants.
d. **Justice** refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving humans as study participants the principle refers primarily to distributive justice, which requires the fair and equitable distribution of both the burdens and the benefits of participation in research studies.

These ethics principles may be expressed differently and given different moral weight in different settings, and their application may lead to different decisions or courses of action in those particular settings.

Health research must be scientifically sound and should at all times conform to scientific principles and evidence based scientific knowledge. In order to conduct research in a scientifically acceptable manners research protocols should have the following provisions:

i. Be scientifically appropriate;
ii. The outcomes of the research should benefit the population from which the study participants are drawn;
iii. Have justification for the selected population;
iv. Address particular needs of the proposed study population;
v. Health research must be supported by a well thought out protocol detailing the experimental procedures where applicable, which, before implementation, must have been submitted to qualified independent reviewers for consideration, comments and guidance;
vi. The quality of researchers in health research must be qualified and competent to carry out the proposed study. At no time should health research be left in the hands of incompetent persons. While, in recent years, a multi-disciplinary approach to health research has been given emphasis, in dealing with patients, attention must be directed at ensuring that health research involving patients rests in the hands of qualified and competent personnel;
vii. The risk-benefit of the proposed study must be considered, and be established that the benefits of the research findings outweigh the associated risks, the research must:
    a. Establish safeguards for the protection of study participants from potential harm.

b. Be carefully monitored and whenever there are observable risks to study participants, researchers should immediately discontinue such experiments.

viii. The privacy and integrity of study participants must always be observed, and at all times, precaution must be taken to preserve and respect the privacy of individual participants;

ix. The right to information entails that study participants must be provided with the necessary information related to the study in which they are going to participate. The information must include reason for the study, procedures, techniques, advantages, disadvantages and the right of study participants to decline participation or discontinue from the study without consequences. The right to information is essential and fundamental in establishing trust between researchers and study participants;

x. Accuracy of the results must be maintained and should reflect what was done and what was observed. Fictitious and fabricated results should not be accepted for publication under any circumstances;

xi. Matters related to handling of research outputs must be clearly detailed. The communities where the study was carried out have the right to information on the research outputs. This must be prepared, repackaged and given in a simple language that the community understands;

xii. Capacity building must be given emphasis so that the research must bring and leave behind improvement in the way of life in terms of capacity buildings;

xiii. What happens after the research has come to an end is becoming a major subject for discussion and there should be clear plans on what will happen when the study comes to an end;

xiv. As health research may carry physical, mental, and/ or psychological risks, health research protocols must therefore, detail the ethical issues and the strategies to counter or minimize effects.

Researchers are being directed to familiarize themselves with these principles and apply them. Further details on the basic principles of health research are provided in the Declaration of Helsinki World Medical Association (2001).

13.2 Rights and Welfare of Human Research Participants and the Communities

Research should be conducted in a manner that does not violate the rights and welfare of human study participants and should aim at improving the well-being of participants and their communities. This can be attained through:

i. Provision of health care beyond research related care;
ii. Optimization of collateral benefits to the research communities;
iii. Provision of good client care during study investigations and procedures;
iv. Taking measures to ensure easy access by the community to the test drug or device, if proven beneficial.

The rights of the research study participants include, but are not limited to, the rights to:

i. Participate in ethically acceptable and approved research;

ii. Be respected, including the right of their autonomy, culture, beliefs and values;
iii. Information about the research study (it is important to ensure that information is communicated in understandable and legally accepted language, format and in a conducive environment at all stages of the research);
iv. Protection against research related injuries, harm, exploitation, and any other forms of abuse related to the research;
v. Privacy and confidentiality of their participation, during and after the research study;
vi. Decide whether to participate in the research or not, or withdraw at any time without penalty (Voluntary participation);
vii. The standard of health care that is available nationally;
viii. Compensation for research study related injuries and costs;
ix. The ability to report any abuse of one's rights and welfare to the Principal Investigator, REC, regulatory authorities or any other relevant legal authority.

CHAPTER 14: **PROTECTION FOR VULNERABLE PARTIPANTS AND SPECIAL GROUPS IN RESEARCH**

Vulnerable participants are those categories of people who are relatively (or absolutely) incapable of protecting their own interests. Such groups may have insufficient power, intelligence, education, resources, strength, or other requisite attributes to protect their own interests. Classes of individuals conventionally considered vulnerable are those with limited capacity or freedom to consent or decline consent. These include; children, mature and emancipated minors, street children, prisoners, the homeless, substance abusers, handicapped (mentally and physically), armed forces, and pregnant women. In some cases, willingness to volunteer to participate in research is unduly influenced by expectation of benefits associated with their participation, or fear of retaliation from interested senior members of the hierarchy in case of refusal to participate.

Characteristics that constitute vulnerability with reference to communities include one or more of the following:

i. Limited economic empowerment;
ii. Inadequate protection of human rights;
iii. Discrimination on the basis of health status;
iv. Inadequate understanding of scientific research;
v. Limited availability of health care and treatment options;
vi. Limited ability in the community to provide informed consent.

Research among vulnerable groups requires additional attention to ensure their protection. Where factors relating to vulnerability are an

aspect of the research study, researchers should specify how that particular vulnerability would be addressed. In particular, RECs must ensure that:

i. Selection of the particular communities is justified by the research goals;
ii. Research study is relevant to needs and priorities of the community in which it is to be conducted;
iii. Research study is beneficial to that community;
iv. The community can access products of the research;
v. Where appropriate, feedback of results should be provided to the community;
vi. Study participants must be fully aware that they are participating in the research and should provide informed consent.
vii. Special attention should be paid to the content, language of the consent document, procedures for obtaining informed consent, monitoring of the process and testing comprehension.

14.1 Research Involving Children

Research involving greater than minimal risk but presenting the prospect of direct benefit to the child may be conducted only if:

i. The risk is justified by the anticipated benefit to the child;
ii. The relation of the anticipated benefit to the risk is at least as favourable to the research study participants (children) as that presented by available alternative approaches;
iii. Adequate provision has been made for the solicitation of the child's assent and their parents'/guardians' informed consent

Research that involves greater than minimal risk and entails no prospect of direct benefit to the individual child participant but is likely to yield generalizable knowledge about the child's disorder or condition may not be conducted unless:

i. The risk represents a minor increase over minimal risk;
ii. The intervention or procedure presents experiences that are commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
iii. The intervention or procedure is likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of that disorder or condition;
iv. Adequate provisions have been made for the solicitation of the child's assent and their parents'/guardians' informed consent.
v. Children should only participate in (clinical) research studies when their participation is indispensable and where participation is not contrary to the child's best interest.
vi. The child's assent takes precedence over the parent's or guardian's consent.

For all research involving children, there must be no financial or other inducements to participate for the parent, guardian or child, although reimbursements and a token for the child after completion of the study may be acceptable.

14.2 Mature and Emancipated Minors

14.2.1 Mature Minors

Mature minors are individuals 14-17 years of age who are able to demonstrate the ability and capacity to manage his/her own affairs and to live wholly or partially independent of his parents or guardian. This is someone who has not reached adulthood (as defined by country law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care).

14.2.2 Emancipated Minors

Refer to a person before attaining the age of majority (18 years) is free from control by their parents or guardians, and the parents or guardian are free from the responsibility for their child and empowered by law to make autonomous decisions.

Mature and emancipated minors may independently provide informed consent to participate in research if:

i. In view of the REC, the research is not objectionable to parents or guardians (established with evidence from the community);
ii. The research protocol includes clear justification for targeting mature and emancipated minors as participants; and a clear justification for not involving parents or guardians in the consent process.

14.3 Prisoners

A prisoner is a person deprived from liberty and kept under involuntary restraints, confinement, or custody. Prisoners are vulnerable to abuse by

research because their freedom for consent can easily be undermined. These could affect their ability to make a voluntary decision regarding their participation in research.

Research with prisoners can be conducted only if;

i. it offers a distinctly favourable benefit to risk ratio, not because the prisoners are a convenient source of participants,
ii. it improves the well-being of prisoners while taking the great care to protect their health, well-being and human rights.

The REC must review the prisoner's research and find if it complies with the following requirements:

i. The study satisfies the criteria for permissible research
ii. The REC members have no association with the prison(s) involved other than their status as members of the REC reviewing the proposed research study;
iii. Where possible, a prisoner or an ex-prisoner should be co-opted to the REC in reviewing the proposed research study.
iv. The risks involved in the research study are commensurate with risks that will be accepted by non- prisoner volunteers.
v. Procedure for selection of participant in the prison are fair to all prisoners
vi. There is adequate assurance that a prisoner's participation or refusal to participate will not be considered in decisions regarding his or her release or further detention and each prisoner is clearly informed in advance that his or her participation in the research study will have no effect on his or her release.
vii. Any possible advantages accruing to the prisoner through his or her participation in the research study, when compared to the

general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such magnitude that the prisoner's ability to weigh the risks of the research against the value of these advantages in the prison environment is impaired.

Research involving prisoners may not be approved unless:

i. The proposed research has the intent and a reasonable probability of improving the health and well-being of the study participants; and
ii. Appropriate knowledgeable persons in penology, medicine, and ethics have been consulted in the course of reviewing the research protocol.

14.4 Homeless persons

Homeless is the condition of lacking stable, safe and adequate housing. This category includes street children, adults staying on the street, refugees and internally displaced persons. To the extent that these and other classes of people have attributes resembling those classes identified as vulnerable, the need for special protection of their rights and welfare shall be considered.

Researchers must strive to ensure that the physical, social and psychological well-being of homeless research study participants is not adversely affected by their participation. In conducting research with people who are homeless, researchers should be guided by the following principles.

i. Must be conducted with respect to human rights, welfare and dignity of study participants;

ii. The research study must be conducted a non-judgemental way for example person appearance, strategies for making money or personal habits;
iii. The rights of people who are homeless to privacy and security must be respected at times.

14.5 Persons Living with Disabilities

Persons living with disabilities and challenges (mental and physical) require special attention because they are prone to being socially marginalized. Therefore, their dignity, rights and well-being in research must be respected. Careful consideration should be made where proxy consent is to be used, and where the use of signed consent forms is not feasible, alternative viable methods should be employed.

Persons living with disabilities should not be unfairly excluded from participating in research. Researchers should make efforts to address communication, disability and comprehension constraints.

For research studies specifically addressing disability issues, a representative of the potential participants should be co-opted into the REC. If the REC routinely reviews research protocols on disabilities, it is advisable for such REC to have a member or a person who is conversant with and committed for the enhancement of the well-being of disabled persons.

Persons with mental health conditions including psychiatric, cognitive or developmental conditions and substance abuse related disorders at times

may be hospitalized or institutionalized. This situation may further compromise their ability to make voluntary decisions to participate in a research project. Therefore, scrutiny should be given to:

i. Sufficient justification for inclusion;
ii. Have appropriate evaluation procedures for ascertaining study participants' ability to give informed consent. If such study participants are deemed unable to understand and to make an informed decision, then an appropriate proxy should be identified;
iii. Have an informed consent process that is free from coercion;
iv. Be of no more than minimal risk; or if minimal risk is involved, the risk is outweighed by the anticipated benefits of the research study to the participants.

Research shall not be conducted if:

i. The purpose of the research is not relevant to the particular health needs of persons living with disabilities;
ii. Alternative interventions exist which are at least as advantageous to the individual participant as that under the proposed study.

14.6 Pregnant Women and Foetuses

Additional safeguards are necessary in reviewing activities relating to research studies involving foetuses and pregnant women in order to assure that they conform to appropriate ethical standards and relate to important societal values. Research studies relating to pregnant women or foetuses may be undertaken under the following conditions:

i. The risk to the foetus is minimal and is the least possible risk for achieving the objectives of the research study, except where the purpose of the research study is to meet the health needs of the mother and the foetus, and the foreseeable benefits outweigh the potential risks;
ii. No procedural changes that could cause greater than minimal risk to the foetus or to the pregnant woman may be introduced into the procedure for termination of the pregnancy, solely in the interest of the research study.
iii. No inducements, whether financial or any other form, may be offered to terminate the pregnancy for the purposes of the research study.
iv. Appropriate studies on animals and non-pregnant individuals have been completed;
v. The purpose of the proposed research is to meet the health needs of the mother and the foetus will be placed at risk to the minimum extent necessary to meet these needs or the risk to the foetus is minimal;
vi. Mother and the father are both legally competent and have been fully informed of the possible impact on the foetus and have given their informed consent to proceed. However, the father's consent shall not be required if:
    a) the purpose of the research is primarily to meet the health needs of the mother;
    b) The father's identity and/ or where abouts are unknown;
    c) The father is not available;
    d) The pregnancy resulted from rape or incest.

14.7 Terminally ill Patients

A terminal illness is an illness or condition which cannot be cured and is likely to lead to someone's death. The dire state of terminally ill patients may affect their ability to make voluntary decisions regarding their participation in research studies.

Any REC reviewing a research protocol involving terminally ill patients as study participants must meet the following additional requirements:

i. The research can only be conducted to terminally ill patients; if the research objectives of the study cannot be addressed using another non-vulnerable group;
ii. The risk-benefit ratio should be favourable to the patients.

14.8 Armed Forces

Armed forces involved in research may be under constraints because of the conditions of their military service and these constraints could affect their ability to make a voluntary decision regarding their participation in research. Any REC reviewing proposed research protocol on participants from armed forces must meet the following additional requirements:

i. Majority of the REC members shall have no association with the potential participants involved other than their status as members of the REC reviewing the proposed research study protocol;
ii. The REC should enlist a member of the armed forces to be part of the review team for the protocol.

Research studies involving soldiers on command shall conform to the following requirements:

i. Any possible advantages accruing to participants through their participation in the research study (when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings) are not of such magnitude so that it might impair participants ability to weigh the risks of the study against the value of these advantages in the military environment;

ii. The risks involved in the research study are commensurate with the risks that would be accepted by non-armed force volunteer participants;

iii. Procedures for the selection of study participants from within the military are fair to all military personnel and insulated from arbitrary intervention by military authorities or by other members of the armed forces;

iv. The information conveyed to the participants is presented in language that is understandable to them;

v. There is adequate assurance that a participant's participation or refusal to participate in the study will not be considered in decisions regarding his or her promotion, pay, or any other career opportunities.

14.9 The Elderly

1) When considering inclusion of elderly patients in health research, special care must be exercised when involving elderly people who have stayed long in the hospital or residential homes because of their vulnerability to suggestions and dependence to others.
2) Research with potential benefits to individual and others in the same category should be discussed in the presence of an independent but

caring observer (such as a Senior Nurse); and the observer should be satisfied that the investigator properly explained the aims, procedures, benefit and risks, if any, to the patient and that the elderly person understood the intended research activities and agreed.

14.10 Student Participation in Research

Research studies involving students can be conducted as long as:

i. The tutor involved in the tuition of the student should not be involved in the recruitment and other negotiations on the terms and research conditions;
ii. The informed consent should clearly state that the students may wish at any stage of the research study to withdraw without any undue consequences;
iii. An impression should not be created that acceptance to participate in the study will benefit the student in the passing of their examinations;
iv. An impression should not be created that non-acceptance will result in discrimination and consequences on the student's studies; and
v. There should not be any form of coercion, pressure or financial inducement other than that proposed as reimbursements for participants.

CHAPTER 15: **STANDARD OF CARE DURING CLINICAL RESEARCH**

15.1 Standard of Care for Research Participants

A care package for research participants of a diagnostic, therapeutic, or preventive intervention project should be stated before initiation of a project. Care and treatment for research study participants should be provided with the ideal aim of providing the best-established effective intervention.

The duration and sustainability of care and treatment for the participants after the study should be negotiated before initiation of the study. The negotiation should be between REC, study PI and Sponsor. Sponsors are encouraged, but not obliged, to provide care for concurrent illnesses not associated with the research study. Investigators should provide relevant follow up procedures for participants for an appropriate period of time after the trial.

15.2 Standard of Care for Research Participants in Control Groups

Research participants in a control group of a research project of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention or as otherwise determined. Sponsors are encouraged, but not obliged, to provide care for concurrent illnesses not associated with the research project. Only in certain circumstances, would it be acceptable to use an alternative comparator such as a placebo or no treatment.

Placebo-controlled trials may be conducted provided that:

i. Based on the knowledge available at the commencement of the trial, the new drug or device to be tested does not confer any significant benefit compared to the placebo, and a proven prophylactic, diagnostic or therapeutic method or established effective intervention does not exist;
ii. Withholding an established effective intervention would expose the participants to at most temporary discomfort or delay in relief of symptoms;
iii. Use of an established effective intervention as comparator would not yield scientifically reliable results and the use of a placebo would not add any significant risk or irreversible harm to the research participants;
iv. Once the intervention being studied has been demonstrated to be superior, the Sponsor(s) shall promptly offer to study participants in the placebo arm the intervention treatment free of charge. However, Sponsors shall not be obliged to provide lifelong care and treatment for chronic and relapsing illnesses;
v. Withholding an established effective intervention would expose the study participants to at most temporary discomfort or delay in relief of symptoms;
vi. Use of an established effective intervention as comparator would not yield scientifically reliable results and the use of a placebo would not add any significant risk or irreversible harm to the participants;
vii. Once the intervention being studied has been demonstrated to be superior, the Sponsor(s) shall promptly offer to study participants in the placebo arm the intervention treatment free of charge. However, Sponsors shall not be obliged to provide lifelong care and treatment for chronic and relapsing illnesses.

15.3 Care for Research Related Injuries

The sponsor should provide care until complete cure or stabilization of a research related injury. The study participants shall be entitled to the highest attainable standard of care within and outside the country for the research related injury. Research participants shall not be required to waive their legal rights for redress in courts of law.

15.4 Referral of Research Participants

The Investigator shall undertake to refer all study participants whose conditions may not be managed adequately within the expertise and licensure of the medical professionals at the study site, and/or where facilities or supplies at the study site do not allow adequate handling of the condition. The referral process should be adequately documented, and all referral guidelines should be adhered to as stipulated in national guidelines on referral. Study participants should always be informed of all options available for management of their conditions including those outside the country.

15.5 Ancillary Care

Health researchers may be confronted with the need, sometimes dire and/or urgent, of participants for additional health care that does not form part of the research objective. Belsky and Richardson, 2004 define ancillary care as “health care required by participants, which is not necessary for the validity of the scientific design, for the safety of the participant, nor for redressing a participant’s injury”. The health care needed is therefore unrelated to the research aim(s). An example is the

detection of tuberculosis in a patient, who is participating in a clinical drug trial for new HIV drugs. Another example was participants in a vivax malaria treatment trial, participants received treatment for a number of non-malarial health conditions, including viral illness, worms, anaemia, bronchitis, ulcers, dengue, diarrhoea, herpes, pneumonia, typhoid, and urinary tract infections (Pratt et al., 2013).

Researchers should identify ancillary care needs prospectively whenever possible. This does not preclude meeting additional ancillary care needs identified during the course of research studies but planning ahead is generally preferable.

At present, there is a lack of consensus on how ancillary care decisions ought to be made and no guidelines have been developed so far for ancillary care provision in health research. Eventually, it is up to principal investigators and Sponsor to decide in consultation with, for example, RECs/IRBs and host communities of their research.

15.6 Compensation for Research Related injury

Injury related to research participation may be physical, mental, social or psychological, and may be classified as follows:

i. **Definitely:** When the injury is directly caused by participation in the research study;
ii. **Probably:** When the injury is most likely explained by participation in the research study but when no definite proof of causality is evident;
iii. **Possibly:** When explanation for the injury is equally due to participation in the research study or other cause

iv. **Unlikely:** When the injury is more likely explained by another cause other than participation in the research study;

v. **Not related:** When the injury is clearly due to another cause other than participation in the research study. Subject to applicable laws in Tanzania, participants shall be entitled to compensation when the injury is classified as “Definitely” or “Probably” related to their participation in the research study. Sponsors shall ensure that research participants who suffer injury as a result of their participation in the research study are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their next of kin are entitled to compensation.

Research study participants shall not be asked to waive the right to compensation and shall retain the legal rights to seek monetary compensation for research related injuries including settlements out of court, in accordance with applicable laws in Tanzania.

15.7 Compensation for Participation in Research

Research study participants may be reimbursed for lost earnings, travel costs, lunch and other expenses incurred in taking part in a study; they may also receive free medical services. Research participants, particularly those who receive no direct benefit from the research will be compensated for inconvenience and time spent.

Compensation must not be so large as to induce potential participants to consent to participate in the research study against their better judgement (undue inducement). A local research REC must approve reimbursement and compensation for research study participants.

15.8 Incentives

Incentives to research study participants for their participation in research studies shall not be considered a research benefit, but a recruitment incentive, and should not present undue influence on potential research participants.

15.9 Insurance and Indemnity for Research

Indemnity refers to the legal exemption from liability for damages. Insurance is the act, system, or business of insuring life, one's person, etc., against loss or harm arising in specified contingencies, as accident, death, disablement, or the like, in consideration of a payment proportionate to the risk involved.

Insurance issues must be clearly described in all clinical trial protocols, and it shall be the responsibility of RECs to determine the adequacy of the financing and insurance framework in line with institutional and laws of Tanzania.

Sponsors and Investigators shall abide to the Guidelines for Insurance and Indemnity of Clinical Trials in Tanzania (2010) and any updated or revised versions that will be released in the future.

CHAPTER 16: **RESPONSIBILITIES OF INVESTIGATORS, SPONSORS AND HOST INSTITUTIONS**

16.1 The Role of Investigators

The Principal Investigator (PI) holds primary responsibility for managing and ensuring the integrity of the research study from initiation to finalization. They oversee the study's design, conduct, and reporting, while also maintaining collaborative relationships. The PI directs and oversees financial, personnel, and other related aspects of the study, coordinating with sponsors, Research Ethics Committees (RECs), and administrative personnel. In summary, the PI is accountable for the study's management, integrity, and coordination with relevant authorities, ensuring adherence to the country's laws, regulations, and procedures.

Specifically:

i. The investigator must sign the research protocol and shall be responsible for ensuring that it is strictly followed. The investigator shall not implement changes in the research protocol without prior approval of an REC, except when necessary to eliminate an apparent immediate hazard or danger to research study participants. Any change in the research protocol must be in the form of an amendment, appended to the original research protocol and signed by the investigator and where applicable, the sponsor.

ii. For clinical trials the investigator, must promptly investigate all serious adverse events, take appropriate measures to ensure the safety of all research participants, and report these and any other information that is likely to affect the safety of the research participants or the conduct of the research events, to the regulatory,

institutions and sponsor within timelines as stated in standard operating procedures.

iii. If the investigational product is found to be beneficial, the investigator should assist to secure its provision, without charge, to participants in the research study following the conclusion of the study.

iv. In the event of early termination of the research study, the investigator must inform, in writing, the appropriate IRB, NIMR, TMDA, and the research sponsor of the early termination and the underlying reason for such termination.

v. The investigator is responsible for the documentation of all steps in data management to allow step-by-step retrospective assessment of the quality of the data and the performance of the research study.

vi. The investigator shall ensure appropriate and timely feedback on the research process including timely submission of progress reports as required and research findings.

16.2 Role of the Sponsor

The sponsor is responsible for providing all the necessary financial support for initiation and completion of the research study. Specifically, the Sponsor is responsible for:

i. Preparation and approval of a comprehensive final study report that is suitable for regulatory purposes, whether or not the research study has been completed

ii. Provision of special forms for the reporting of any adverse events that occur during the course of the research study, and to monitor

the investigation and management of adverse events until resolution or stabilization.

iii. Providing compensation or indemnity in the event of research-related injuries, disability, or death, in accordance with applicable Tanzanian laws and regulations.

For research involving investigational new drug or device, the sponsor should:

i. Provide to the REC and all other regulatory authorities, a description of the Investigational and comparator drugs/devices;

ii. Provide a dossier (compilation of documents regarding the safety, and efficacy of product);

iii. Ensure that the investigational product and any comparator products are of appropriate quality and are subject to quality assurance procedures. This information must be accurate and adequate to justify the nature, scale, and duration of the clinical trial;

iv. Promptly provide the investigator with any relevant new information that arises during the course of the trial, including information relating to product safety;

v. Be responsible for proper packaging and labelling of the investigational product(s) or medical device. The investigational and comparator products must be labelled in conformity with the research protocol and the labelling must state that the product is for investigational purposes only;

vi. Retain sufficient samples of each batch of the investigational products under study and a record of analyses and characteristics so that, if necessary, an independent laboratory may check the product for quality control or bioequivalence.

16.3 Institutions Hosting Research Projects

Hosting institutions are overall accountable for research projects within their institutions. The institution must work closely with the investigators and monitor implementation of the research activities. Specifically, the host institution shall:

i. Ensure that they have qualified and competent investigators to carry out the research studies at the institution;
ii. Facilitate the smooth implementation of research studies conducted at the institution;
iii. Take appropriate disciplinary action against investigators for non-compliance with these guidelines.

CHAPTER 17: **NON-COMPLIANCE**

Non-compliance is defined as the failure by an investigator (s) to abide by national and international regulations governing the protection of human participants in research including the requirements of the REC.

Non-compliance is categorized as follows:

i. **Serious**: An action that potentially places research study participants to more than minimum risks and involved deliberate disregard the regulations of RECs. Non-compliance may affect participants safety, increase risks to participants, affect the integrity of the data, violate the rights and welfare of study participants, or affect a participants' willingness to continue in a research study. For example (i) Beginning or continuing more than minimal risks research without REC approval; (ii) Serious misuse or non-use of approved consent form; (iii) Not reporting adverse events;(iv) Using data from a minor who did not have parent/Guardian permission to participate in research study; (v) Changing or adding study location (s) and (vi) Pre-testing or piloting research materials or activities without REC approval.

ii. **Continuing noncompliance**: A pattern of non-compliance that indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or involves frequent instances of minor non-

compliance. Continuing non-compliance may also include failure to respond to a request from the REC to resolve an episode of non-compliance or a pattern of minor non-compliance.

Depending on the nature of the non-compliance event, the REC may decide to halt the project to safeguard the study participants. A written document about non- compliance should be submitted to NIMR and TMDA as applicable. The REC or the host institution to respond to the non-compliance within a specified time period and describe the corrective actions that will be taken. NIMR and where applicable TMDA may schedule a visit to confirm the adequacy of corrective actions taken.

In addition, depending on the nature of the non-compliance and other factors that will be considered, NIMR and/or TMDA where applicable may:

- Withhold approval of new studies to be conducted at the institution;
- Direct that no new research participants be added to ongoing studies;
- Terminate ongoing studies when such termination would not harm study participants;
- Stop an institution from carrying out a research study;
- Withdraw the research permits of Investigators involved in repeated non-compliance;
- Disqualify RECs that have failed to take adequate steps to correct the non-compliance

iii. Minor noncompliance: Any noncompliance that is not persistent and does not: 1) adversely affect the rights and welfare of the study participants; 2) increase risks to study participants or others or alter the risk/benefit ratio; 3) compromise the integrity or validity; or 4)

result from the wilful, knowing, or intentional misconduct on the part of the investigator or research staff.

iv. Allegation of Non-Compliance: Allegation of Non-Compliance is defined as an unproved assertion of non-compliance.

v. Unanticipated Problem: Any unanticipated problem related to the research study, whether serious or not, that adversely affects the safety, rights, or welfare of participants or others.

Generally, an unanticipated problem is an event that satisfies all of the following criteria:

1. Related to the research study itself;
2. Unanticipated (unexpected, not described in study documents, or higher frequency/severity);
3. Adversely affects the safety, rights, or welfare of participants or others.

17.1 Protocol deviations and violations

Any change in the stated procedure, activity or any provision of the protocol without prior approval except for the purposes of intervening when a person's life is in danger constitutes a protocol violation or deviation. Violations tend to be more serious than deviations. When any of these occur, the Investigator shall notify the REC and the MRCC. Where the health-related intervention is a drug, TMDA shall also be notified.

The violation or deviation report should contain the following information:

i. Title of the study,
ii. Name of Investigator,
iii. Organizational affiliation,

iv. Date of report,

v. Date(s) when violation occurred,

vi. Brief description of what happened,

vii. Any effect on the study,

viii. Any adverse events arising from the violation,

ix. Management and follow up of violation and steps to avoid recurrence of the violation. Notification should be made to the MRCC, and where applicable the collaborating IREC or any other regulatory bodies by the Investigator within seven (7) days after becoming aware of the event.

CHAPTER 18: **ADVERSE EVENTS**

These guidelines give criteria for prompt reporting of certain categories of adverse events to RECs. When the health-related intervention is a drug, the National Medicines Regulatory Authority shall also be notified.

The Investigator undertakes prime responsibility for monitoring and reporting of adverse events to the regulatory authorities. While the Investigator undertakes to monitor and manage all adverse events during the conduct of the investigation, not all adverse events are reportable to the regulatory bodies.

The requirement to report adverse events to regulatory authorities shall not apply to events that are observed among participants who are in observational studies in which no health-related intervention is being administered.

Severity of an adverse event shall be graded as follows:

a) **Mild:** Includes events that do not interfere with activities of daily living and do not require treatment;
b) **Moderate:** Includes events that have minimal effect on activities of daily living and usually require out-patient treatment;
c) **Severe:** Includes activities that significantly affect activities of daily living and may require inpatient hospitalization;
d) **Life-threatening**: Includes all events that are life threatening and usually require emergency procedures.
e) **Death**:

An adverse event shall be deemed unexpected if:

i. It is previously unobserved or undocumented in humans under the health research intervention (or one substantially similar);
ii. The nature or severity is not consistent with information in the investigators brochure or other safety information known at the time;
iii. The event is observed with higher frequency or severity than previously documented.
iv. Unexpectedness shall not include events that may reasonably be extrapolated from in vitro and animal studies.

The following grading shall be used to define the relation of adverse event to a health-related intervention:

i. **Definitely**: When the event is directly caused by the intervention.
ii. **Probably:** When the event is most likely explained by the research intervention but when definite proof of causality is not evident.
iii. **Possible:** When explanation for the event is equally due to research intervention or other cause.
iv. **Unlikely:** When the event is more likely explained by another cause.
v. **Not related:** When the event is clearly due to another cause.

18.1 Reporting Adverse Events during Research

Events requiring prompt reporting to regulatory bodies include:

i. All serious adverse events (SAE) irrespective of relationship to the health-related intervention;

ii. All unexpected events of greater than moderate severity irrespective of relationship to health-related intervention;
iii. All events associated with protocol violations irrespective of severity and relationship to health-related intervention;
iv. When criteria for stopping or pausing a study as stipulated in the protocol are met;
v. Any event mandated by regulatory authorities;
vi. Any event stipulated in the protocol as reportable to the regulatory bodies.

All serious adverse events must be reported to the local REC as soon as possible and in any case no later than seven (7) days of becoming aware of the event. Thereafter, a detailed report of the SAE should be submitted within eight (8) days.

All other reportable adverse events should be reported to the REC as soon as possible and in any case not later than fifteen (15) days.

Other issues to consider are that the Investigator must clearly outline in the protocol how management of both foreseeable and unforeseeable adverse events will be done. This outline should clearly show:

i. How adverse events will be recognized promptly.
ii. How immediate harm or risk would be managed.
iii. Plans for management of events till recovery/or stabilization.
iv. Reporting procedures, timelines and documentation of events.

18.2 Monitoring of Adverse Events after Close-out of a Study

Certain categories of interventions whose long-term effects are not known or cannot be extrapolated will require extended monitoring for adverse

events. This may include genetically modified substances, gene therapy and DNA-based therapies.

CHAPTER 19: **OVERSIGHT AND MONITORING OF HEALTH RESEARCH**

Monitoring is the process of overseeing the progress of implementation of other health research studies and of ensuring that it is conducted, recorded and reported in accordance with the approved protocol, standard operating procedures (SOPs), and the applicable regulatory requirement(s).

When conducting research studies, each institution is responsible for safeguarding the rights and welfare of human participants and for complying with all applicable regulations. The REC that reviewed and approved the research is primarily responsible for monitoring the ethical conduct of the research procedures. However, the National REC can monitor the proper conduct of the research whenever it deems further oversight is necessary.

Monitoring of health research in Tanzania is done by the RECs, NIMR and TMDA. REC members or persons delegated by the REC are responsible for oversight visits in order to monitor ongoing studies approved by the IRB.

19.1 Compliance Monitoring

19.1.1 Types of Monitoring

i. **Passive monitoring** – The IRB receives information about the research that it approved and uses that information to assess the study's progress.

- Progress reports - PIs should submit progress reports at regular intervals stipulated by the REC. Periodic progress reports enable the REC to determine whether the research study is progressing according to the approved protocol.
- The REC shall establish a follow-up mechanism to monitor the progress of all ethically approved research studies.
- In case of a premature suspension or termination of a research study, the investigator should notify the REC including the reasons for the premature suspension or termination of the research and summary of the research findings.

ii. **Active monitoring** – REC members should physically visit the research site(s) in order to assess the conduct of the studies.

- Approved research studies should be actively monitored to ensure adherence to ethics principles, as considered necessary by the IRB.
- IRB members should use the IRB's oversight checklist in order to ensure appropriate issues are assessed during the visit.
- Should research study exist that has not received ethical clearance, the presence of such research should be proved through a site-visit, witnesses, and appropriate and prompt actions should be taken.

- The number of IRB members needed to conduct an oversight visit depends on the workload of the monitoring team. To maximize objectivity, at least two (2) members of the REC or delegated persons with diverse expertise and drawn from different institutions should make up the monitoring team. A monitoring team may include the community representative in the IRB.

19.2 Types of Oversight Visits

The type and frequency of oversight visits should depend on the level of risk and complexity of the research. The REC/IRB can make the monitoring visit announced or a spot visit (unannounced).

i. **IRB –initiated announced oversight visit**: the IRB informs the PI the date of the visit in advance.

ii. **IRB-initiated unannounced oversight visit**: the IRB does not inform the PI in advance of the visit.

iii. Additional monitoring visits may be made for the following reasons:
    - Response to reports made directly to the IRB or circulating in the community.
    - Increased frequency of SAE reports.
    - Failure to submit progress reports or a final report on time.
    - Reports of suspected research misconduct.
    - Investigators who extend their research study beyond the approved time frame without formal approval from the REC/IRB.

- Investigators that are suspected of having changed their objectives and study design without the REC's approval.
- Any other reason that the REC feels warrants further follow-up.

19.3 Clinical Trial Audits

Audit activities are sample based and may occur during or after a clinical trial is completed, or for cause in response to issues detected by monitoring activities. The auditor would also assess the effectiveness of the monitoring activities and compliance with the processes outlined in the protocol/monitoring plan/SOPs. The National Medicines Regulatory Authority may carry out clinical trial audits according to their procedures.

19.4 Data and Safety Monitoring Board /Data Monitoring Committee

A Data and Safety Monitoring Board (DSMB) or a Data Monitoring Committee (DMC) is an independent group of experts established by the study sponsors to review safety data during a clinical trial. It ensures that the study is conducted, and the data are handled in accordance with the provisions of the research protocol and monitors adverse events and safety data. A DSMB shall be established before the commencement of a clinical trial and its composition submitted to the IRB and the NatHREC for

record purposes. All Phase I, Phase II, and Phase III, including drug efficacy trials, and all clinical trials conducted in Tanzania shall have a safety monitoring plan and DSMB. Other interventional studies, such as community trials, may be required to set up DSMBs on a case-by-case basis. NatHREC shall ensure the establishment of DSMB or committee in all clinical trial to periodically assess the progress of implementation of safety data and the efficacy endpoints, and to recommend to the sponsor and NatHREC whether to continue, modify or terminate a trial. In assessing the DSMB, the NatHREC shall ascertain the following:

i. Composition of the Committee/Board;
ii. Qualification and competence of members of the Board;
iii. Experience in assessing clinical trial;
iv. Affiliation of members;
v. Terms of reference to members; and
vi. Reporting framework

19.4.1 Membership of the DSMB

The following should be considered:

i. Individual's knowledge in the process of conducting the trial, including requirements for research protocol amendments;
ii. Individuals with adequate medical, pharmaceutical, scientific, and/or ethics qualifications and clinical trial experience. The qualifications most appropriate for a specific DSMB will depend on the nature of the clinical trial and of the product under investigation;
iii. At least three members including a clinician with competence in the research field of the trial and a biostatistician;
iv. One of the members shall be a Tanzanian National who is an expert in the field of the trial;

v. For purely clinical trial that involve testing medicinal drugs, plants, food or anything given to a human participant as a research purpose, the Principal Investigator should be a well experienced clinician who has time to execute his/her duties in a trial.

19.4.2 Functions of the DSMB

i. Ensure safety of study participants;
ii. Preserve the integrity and credibility of the trial;
iii. Ensure availability of definitive and reliable results in a timely manner;
iv. Make decisions related to safety, based on the submitted results and adverse event reports and recommend whether the study should continue or not.
v. Report to the sponsor(s) of the trial:
    a. Any concerns over differences in serious adverse events between study arms;
    b. Any serious social harms;
    c. Any concerns about the conduct of the trial;
    d. Any concerns about data integrity;
    e. Whether the study should be terminated or continued based on safety and interim data;
vi. Determine before the commencement of the study, the following:
    a. Mode and time frame for receiving adverse events reports;
    b. Frequency of receiving data;
    c. Frequency of meetings to review the data and adverse event reports at hand. (Where there may be any element of concern, the DSMB may choose to review the data more frequently);

CHAPTER 20: **HANDLING AND ARCHIVING BIOLOGICAL MATERIALS**

Human biological materials include any substance obtained from a human research participant including, but not limited to blood, urine, stool, saliva, hair, nail clippings, skin, and microorganisms and other associated bio-products.

20.1 Acquisitions, Storage and Future Use of Biological Samples

The acquisition, storage and future use of human biological samples from research study participants in Tanzania shall be guided by the following procedures:

i. In case it is anticipated that the collected human biological materials may be used for other research purposes in the future, the informed consent used should include the information to participants about future intended use. The information should be clear that the collected materials will be stored for possible future research studies. Research participants should be informed on measures to protect confidentiality, policies that will govern use of the samples in future research studies. After explaining the need to store the samples, the research study participant should be offered to choose whether their samples should or should not be stored and/or used for future studies. Future research on archived samples will require a new application to the REC.

ii. The host institution in Tanzania should hold the samples in trust on behalf of the research study participants. Research participants should reserve the right to withdraw their samples from storage if the samples are linked. The host institution is entrusted with custodianship over the samples, and shall have the authority to

decide use, transfer, storage and future use of the samples taking into consideration the rights and welfare of the study participants.

iii. Where samples have not been obtained as part of research study (for example as part of routine surveillance, emergency procedures, laboratory quality control, notifiable diseases, routine counselling and testing, etc.), the institution that collected the samples takes custodianship of the samples. Any future research study on such samples is subject to review by a REC.

iv. When it is necessary to transfer samples for storage abroad, the host institution shall negotiate an appropriate contract with the recipient institution. This Contract shall be in the form of a Materials Transfer Agreement (MTA). The specific details of the MTA should include, among others, purpose for the transfer/export, clear arrangements for collaboration and benefit sharing, a framework for accessing and sharing data, and restrictions to third-party transfer, and annual reports to the host institution and the NIMR on the status of the samples.

v. It is required that a Tanzanian scientist must be included as a co-investigator in all future studies using the human biological materials collected from Tanzania.

vi. RECs in Tanzania shall review all research studies on stored human biological samples.

20.2 Procedures for Transfer of Human Biological Materials

Investigators, sponsors and collaborators must ascertain that in-country capacity to perform the required investigations/testing is not sufficient for the investigations before considering transfer of human biological

materials outside the country. The only exception to this is when samples are being transferred for external quality assurance purposes.

Investigators, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for any investigative testing to fulfil the objectives of the proposed research study. All exchanges and transfers (including importation) of materials for research purposes shall require approval from the National REC.

Applications for permission to exchange or transfer human biological materials shall be made to NIMR. The following are the necessary steps for the exchange or transfer of materials for research purposes:

i. The research study that involves the exchange or transfer of human biological material shall first be registered and approved by the REC through the established procedures for research approvals in Tanzania.
ii. The applicant must be a legal resident of Tanzania or be affiliated with a local legally recognized institution in Tanzania.
iii. A request for the exchange or transfer of human biological material shall be made in writing to the Director General of NIMR.
iv. An MTA and any other document related to the exchange or transfer of human biological material shall accompany the request for the exchange or transfer of the material.
v. The MTA after review and approval, is signed by the NIMR Director General. The NIMR DG may delegate in writing the signing of the MTA to a senior NIMR staff member.
vi. After receipt of a signed MTA, the investigator is required to secure an export or import permit from TMDA to finalize the process that

allows the movement of biological samples outside the country or to enter the country.

vii. The investigators shall abide by any other requirements that are to be followed to facilitate the exchange or transfer of human biological material.

20.3 Institutional Biosafety Committees

Institutional Biosafety Committees (IBC) are established by institutions that undertake research on potentially biohazardous substances such as pathogens, radioactive material and applications of biotechnology, especially recombinant DNA techniques and processes. The IBC's function is to minimize potential human and environmental harm that may be associated with conduct of research on or with potentially hazardous substances.

Specifically, IBCs shall ensure the provision of suitable and safe storage and disposal facilities for all materials involved in work with potentially biohazardous substances; ensure that all appropriate technical personnel of the institution have adequate training in biosafety; establish a health-monitoring plan for all high-risk personnel involved in application, use and production of potentially biohazardous substances.

Institutions that meet the criteria to have an institutional biosafety committee are encouraged to form one if there is no other committee with similar functions.

The establishment and functions of an Institutional Biosafety Committee should also align with other national regulations and guidelines

governing potentially biohazardous material, such as the Ministry of Health, the Ministry responsible for Environment and the Prime Minister's Office.

CHAPTER 21: **ETHICAL USE OF ANIMALS IN RESEARCH**

The decision to use animals in research studies requires critical thought, judgment, and analysis. There are many national and international bodies, which guide experiments using animals as animal welfare is considered as “experimentation with responsibilities.”

No responsible researcher wants to use animals or cause them unnecessary suffering if it can be avoided. Animals should be used for research only within an ethical framework. The following principles shall be used in animal research.

i. Respect for animals must underpin all decisions and actions involving their care and use for scientific purposes.
ii. Before the use of animal for scientific purposes is considered, investigators must be satisfied that a case can be made that the proposed use is ethically acceptable in accordance with the law.
iii. The obligation to respect animals and the responsibilities associated with this obligation, apply throughout the life of the animals.

21.1 . Guiding principles of animal welfare

Russell and Burch's “The Principles of Humane Experimental Technique” was first published in 1959 and a special edition was reissued in 1992. Russell and Burch described the guiding principles of animal welfare are called “Three Rs” which are replacement, refinement, and reduction. These guiding principles have been widely accepted by the scientific community. The Three Rs represent a practical method for implementation of the principles when conducting animal research.

i. Replacement alternatives refer to methods which avoid or replace the use of animals. This includes both absolute replacements (i.e. replacing animals by computer models) and relative replacements (i.e. replacing vertebrates, with animals having a lower potential for pain perception, such as some invertebrates).

ii. Reduction alternatives refer to any strategy that will result in fewer animals being used to obtain sufficient data to answer the research question, or in maximizing the information obtained per animal and thus potentially limiting or avoiding the subsequent use of additional animals, without compromising animal welfare.

iii. Refinement alternatives refer to the modification of husbandry or experimental procedures to minimize pain and distress, and to enhance the welfare of an animal used in science from the time it is born until its death.

All national laws governing animals and animal health shall be followed in the conduct of health research studies. Investigators are advised to familiarize themselves with any additional permissions that need to be secured relating to the use of animals in research studies during the development of their research protocols.

CHAPTER 22: **DATA MANAGEMENT AND SHARING**

Large-scale linkage of international clinical datasets could lead to unique insights into disease aetiology and facilitate treatment evaluation and drug development. Hereto, multi-stakeholder consortia are currently designing several disease-specific translational research platforms to enable international health data sharing.

Data sharing as a strategy for ensuring data integrity and promoting geometric growth of knowledge shall be part of the basic agreements in research collaborations. Procedures for how to govern responsible data sharing in research are not all spelled out.

22.1 Ethical Considerations in Data Sharing

i. Request informed consent to share the data: You should communicate openly with your participants to let them know exactly how their data will be used and shared both in the short and long term. Data sharing should always be consistent with the terms of consent signed by the participants.

ii. Protect identities by fully anonymizing the data: Take care to anonymize any data that may otherwise identify study participants. Anonymize your data by removing anything that identifies the study participants, this includes names, addresses, workplaces, occupations, or salaries. Take out unnecessarily precise information: for example, you can replace participants' date of birth with their age.

iii. Generalize the Data: Generalize where you can for example, replace participants' specific area of expertise with more general definitions. Avoid listing the upper or lower ranges of variables: this

will disguise outliers, such as salary range. Pay special attention to relational data where relationships between variables in datasets could reveal identities and where geo-referenced data and spatial references may reveal location.

iv. Keep the original data separate and secure: it is essential to keep a copy of the original data for your own use and make a record of all the information that has been removed in the process of anonymization. Always store this information separately from the final anonymized data files and ensure that it is kept secure. Be transparent about where you've anonymized data e.g., when you remove content and replace it with generalized information, mark this in an obvious way.

v. Control access to your data: For sensitive data, you may only want to make available to third parties who have a legitimate reason and who you are certain will treat the data carefully. It is still possible to deposit your data in a repository but restrict access to it. This might mean that the files are private, but you can share access with others if certain requirements are met. You may also want to set different privacy settings for different components of your data.

22.2 Knowing when Not to Share Data

There are situations where it would not be legal or ethical to share information. These exceptions include:

i. When sharing data conflicts with a need to protect personal identities.

ii. If consent has not been sought or if study participants have withheld their consent, data should not be shared. You should always ensure that you abide by all relevant data legislation.

iii. Data ownership: If you do not own the data you've used in your research, you shouldn't publish them without the owner's written permission. Preferably, the owner of the data should make it available themselves, which you can then cite.

iv. Where data is commercially sensitive or protected by competition laws or market regulation.

v. If your data has been generated while employed by or partnering with a commercial organization, you should seek permission before sharing it. In some instances, there may be commercial or legal reasons why data cannot be made widely available.

vi. Where release of the data poses a security risk, making some research available could pose risks either to individuals or to national security.

Any investigator who considers that the data arising from their research will not be suitable for sharing must provide clear reasons for not making it available upon their application. Note that even if you decide it is not right to share your data publicly, you may be required to make them available to peer reviewers, to support validation of results in your journal article submission. If you ever have any doubts about whether it would be right to share a particular dataset, your REC should guide you.

22.3 Data Sharing and Transfer Agreement

Signing of a Data Sharing and Transfer Agreement (DSTA) is mandatory for all research involving collaborating and foreign institutions.

1. The DSTA shall be linked to a research study that has received ethics clearance from the National Institute for Medical Research. The need to transfer data shall be stipulated in an approved protocol or subsequent amendment. Any protocol that has received clearance from a local Institutional Review Board (IRB) will require the Agreement to be processed through the National Institute for Medical Research.
2. In the case of this Agreement, the provider of the data is the Tanzanian institution that has the overall Principal investigator who holds the ethics clearance certificate. All other collaborating institutions are the recipients. The provider maintains ownership of the data and any future use of the data must be done in consultation with the provider institution.
3. If it happens that the provider needs to share the data with an additional institution outside the collaborating institutions the provider shall sign an agreement with that additional institution as well. In the case of sharing data to an additional institution for an on-going study the provider will amend the protocol to add the new institution.
4. The DSTA after review and approval, is signed by the NIMR Director General. The NIMR DG may delegate in writing the signing of the DSTA to a senior NIMR staff member.

CHAPTER 23: **DISSEMINATION OF RESEARCH FINDINGS**

Reporting research findings to participants is an ethical imperative. Dissemination is a default expectation for all research. The World Medical Association's Declaration of Helsinki insists that "all medical research participants should be given the option of being informed about the general outcome and results of the study."

Research study participants have a right to know the outcome of the research. Reporting back to study communities is part of the discipline of transparency that keeps researchers honest and accountable and foster public understanding.

Those engaged in research have a moral obligation to share their findings with other investigators, society and policymakers, for the mutual benefit of all.

23.1 Publication in Peer-reviewed Journals

The publication of an article in a peer-reviewed journal is an essential building block in the development of a coherent and respected network of knowledge. It is a direct reflection of the quality of the work of the authors and the institutions that support them. Peer-reviewed articles support and embody the scientific method.

The ICMJE recommendations titled "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical

Journals", May 2022 are a set of guidelines produced by the International Committee of Medical Journal Editors (ICMJE) for standardising the ethics, preparation and formatting of manuscripts submitted to biomedical journals for publication. NIMR endorses the recommendations of the International Committee of Medical Editors (ICMJE).

Authorship of a manuscript should be settled as early as possible, the main criterion being public accountability for the content of the paper. Open communication among all the individuals in research is a guarantee of serving the best interests of all.

23.2 Ethics for Authorship and Publication

It is a requirement for ethics clearance for researchers in their protocols to include a description on how findings from the study will be disseminated back to the communities that took part.

It shall be the responsibility of the REC to ensure that all submitted protocols provide a description of how publication of research results will be addressed equitably.

23.3 Permission to Publish

Before any manuscript is submitted for publication, permission to publish should be sought from the Director General of the National Institute for Medical Research. Information that is required in the request for permission publish includes:

- The title of the original project/programme

- The Ethical Approval Certificate (Reference) Number
- The manuscript to be published with names of authors and their respective institutional affiliations and their contribution.

CHAPTER 24: **NON-RESEARCH DETERMINATION**

The term Non-Research Determination (NRD) refers to examining whether an activity is a research or non-research. Non-research activities are limited to activities that intend to allow the identification, monitoring and assessment of investigation of potential diseases and health conditions. They also investigate events of public health importance and enabling environments within the health system.
Public health practices are important milestones to ensure the well-being of any community. These practices, however, have resulted into several challenges in their unambiguous classification of either being research or non-research.

The concept of non-research determination to identify the public health practices has been a concern to most investigators due to questions faced during ethics review processes. Research ethics committees have the role to protect the rights and welfare of individuals who participate in public health-related activities. They have the responsibility, among others to determine whether an activity requires ethical clearance or not. Due to this, the establishment of non-research determination guidelines will lessen these challenges because both research and non-research activities may use similar methodologies.

24.1 Types of Non-research Activities

The following are considered to be non-research activities:

24.1.1 Health Intervention Activities

Interventions or activities that aim at bridging the gaps in a particular area or condition. These must comply with the following;

a) Focus on an implementation strategy
b) Outline implementation outcomes
c) Consider context and other factors that influence implementation
d) Identify the target audience and the intended use of results.

24.1.2 Quality Improvement Related Activities

Activities that focus on quality improvement either at the institutional or organizational levels. They include those with:

a) Formal approach to improve performance
b) Aspects that are essential for a well-functioning practice in improving efficiency, patient safety or clinical outcomes
c) Specific focus areas.

24.1.3 Scoping Review

This refers to the review of data available from different sources. For example, routine data, published and unpublished/ grey literature. As part of a preliminary assessment, the harvested data help to determine the size, scope and nature of particular health and related health-related conditions.

24.1.4 Monitoring and Evaluations (M&E)

Monitoring and Evaluation being used to assess the performance of projects, institutions and programmes set up by governments, international organisations, and NGOs. The main goal is to improve current and future management of outputs, outcomes, and impact.

The M&E activities may be considered non-research activities based on the criteria below:

A. Program activities such as:

a) Formative assessment aiming at informing program performance intervention
b) Track and assess results of interventions throughout the life of a program
c) Summative assessments to evaluate proficiency or success after the project or program
d) Facilitate improvement and develop further plans for their implementation based on lessons learnt

B. Surveillance activities

Public health surveillance involves collecting, testing, analysing, and using information or to improve public health promptly. Information and bio-specimens are obtained from a variety of sources. These may include mandatory reporting of certain conditions, routine monitoring, vital records, medical records, medical billing records and clinical specimens. Surveillance activities that qualify as non-research should aim to:

a) Determine the prevalence or incidence of known risk factors associated with a health problem in the context of a domestic or international public health emergency
b) Locate coverage and source of a disease outbreak or identify cases of a disease outbreak
c) Enable timely detection and notification of a disease outbreak to the respective authority for response measures
d) Determine the trend of diseases over time to inform practice and foster early interventions development
e) Determine the quality and performance of the surveillance systems.

24.1.5 Public Health Emergencies of National and International Concern

Some of the activities focusing on diseases or events threatening national and international health security are considered non-research and hence need immediate attention and response as outlined below:

a) Initial assessments should be rapid and produce the information required to start an appropriate response
b) Continuing monitoring of the exposure linked to the occurrence of disease or event to inform the response.

24.1.6 Inception Phase Activities

This may be a preparatory stage where one defines the project scope, schedule and determine its feasibility. The primary goal is to achieve

stakeholders' consensus regarding project objectives, indicators, implementation framework or mobilization of funds.

24.1.7 Utilization of Routine Governance, Administrative and HMIS Data

This will include routine data collected from governance, administration related activities and through the Health Management Information System (HMIS).

24.1.8 Other Activities of Clinical and Public Health Importance

a) Case reports, case narration and verbal autopsy within a specific public health programme or an emergency or an epidemic
b) Educational health program involving data collection activities meant for developing or improving curriculum/materials for training purposes.

24.2 Criteria for Determining Non-research Activities

For activities to be determined non-research the following criteria below have to be considered:

a) If the purpose of the activity is not meant to generate generalizable knowledge beyond borders but may benefit the local community.
b) If the purpose is mainly meant to improve local community health or quality intervention
c) If the activity does not involve collection of materials from humans for research
d) If the activity does not involve human participants receiving medicines, vaccines /diagnostic tests / interventions for research

e) If the activity does not involve the collection of private, sensitive, and personal information such as those causing emotional and/or mental suffering
f) If the activity does not involve materials transfer within or outside Tanzania for research
g) If the activity does not permit data sharing beyond the intended consortium and/or implementing partners.
h) If the activity is not culturally, socially or politically sensitive in the Tanzanian context

24.3 Review Processes for Non-research Activities

Applications will be reviewed to determine whether the activity is non-research or not. The review process will consider scientific validity and ethical issues considering a case-by-case approach.

The relevant authorities and ethics committees must establish procedures for the review of non-research protocols. These procedures should specify the following:

a) Nature of the applications: if new or amendment and other considerations that will be eligible for non-research activities;
b) The minimum of two reviewers will be required for the review; and
c) Based on the reviewers' recommendations, NatHREC will endorse the application.

24.4 Informed Consent for Non-research Activities

Informed consent will not be required in non-research activities. However, in some instances, informed consent may be required.

24.5 Dissemination of Findings from Non-research Activity

Data originating from non-research activities can be disseminated through different communication channels. If the applicant in the course of implementation develops an interest to publish the data originating from approved non-research activities, s/he will have to seek approval from NatHREC.

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APPENDIX 1: GLOSSARY OF TERMS

Adverse event: is an untoward medical occurrence in a participant in a clinical trial administered a pharmaceutical product and that does not necessarily have a causal relationship with the treatment.
and health care.

Anonymous data or specimen: means data or material without any overt identifying information or link to a specific participant or donor.

Assent: is agreement by an individual not competent to give legally valid informed consent (e.g., child or cognitively impaired person) to participate in the research. Children and adolescents who are legally minors cannot give legally valid informed consent, but they may be able to give assent.

Basic Research: is conducted to increase the base knowledge and understanding of the physical, chemical, and functional mechanisms of life processes and disease. It is fundamental and not directed to solving any particular biomedical problem in humans.

Biological specimen: means material from a person including blood and blood products, DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors.

Biomedical research: comprises the study of specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment and rehabilitation of persons; the design of methods, drugs and

devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions; and the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, immunology. Medical research extends to translational research within the field of medicine.

Children: means persons who have not attained the legal age for consent to treatments or procedures involved in health research including clinical trials.

Clinical trial: The World Health Organization (WHO) defines a clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

Compensation: refers to money, in-kind support or any item(s) given to research participants in acknowledgement of their time and effort provided in participating in the research study; or for making up for an undesirable event, loss, suffering or injury as a direct consequence resulting from their participation in the research study.

Confidentiality: is the prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a participant's identity.

Database: means a collection of information including images (data) arranged to facilitate swift search and retrieval. It may be electronic or paper based.

Discomfort: is less serious than harm and can involve body and/or mind. Some examples of discomfort in research are minor side-effects of medication; discomforts related to measuring blood pressure and anxiety induced by an interview.

Ephemeral Data: is data that is not maintained as a matter of course (i.e. it has an expiration) and is only stored for as long as it is valid, at which point it becomes non-accessible (i.e., it self-deletes).

Foetus: means the product of conception from implantation until delivery. A viable foetus means, a foetus after delivery being able to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beats and respiration. A nonviable foetus means a neonate after delivery that although living, is not viable.

Guardian: means an individual who is authorized under applicable local law to consent on behalf of a child to general medical care when general medical care includes participation in research. It also means an individual authorized to consent on behalf of a child to participate in a clinical trial or research.

Harms: in research includes (but are not limited to) physical harms including injury, illness, pain; psychological harms including feelings of worthlessness, distress or fear; devaluation of personal worth including being treated unjustly; social harms including damage to social networks or relationships; economic harms including the imposition of costs on participants and legal harms including discovery and prosecution of criminal conduct.

Health research: contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of the environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health.
Inconvenience: in research examples include filling in a form; participating in a street survey and giving up time to participate in research.

Informed consent: is a process by which an individual voluntarily confirms his or her willingness to participate in a research study, after having been informed of all aspects of the research that are relevant to the individual's decision to participate. Informed consent is documented by means of a written, signed and dated consent form.

Investigational product: An investigational product refers to a preventative (vaccine), therapeutic (drug or biologic), device, diagnostic, or palliative used in a clinical trial. An investigational product may be an unlicensed product or a licensed product when used or assembled (formulated or packaged) differently from the approved form, when used

for an unapproved indication, or when used to gain further information about an approved use.

Investigator: The investigator/researcher means an individual who actually conducts an investigation i.e., under whose immediate discretion the test product, which is to be administered or dispensed to, or used involving, a participant, or in the event of an investigation conducted by a team of individuals, s/he is the responsible leader of that team.

Minimal risk: mean that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or investigations.

Monitoring: is the process of overseeing the progress of implementation of a clinical trial or health research and of ensuring that it is conducted, recorded and reported in accordance with the approved protocol, standard operating procedures (SOPs), and the applicable regulatory requirement(s).

Negligible risk: describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk involves no more than inconvenience.

Neonate: means a new-born who is 28 days and below.

Pregnancy: Pregnancy encompasses the period of time from implantation until delivery. A woman shall be considered to be pregnant if she exhibits any pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Protocol Deviation: accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the participants rights, safety or welfare; and/or on the integrity of the data.

Protocol Violation: accidental or unintentional change to, or non-compliance with the REC approved protocol without prior sponsor and REC approval.

Publicly available data: mean information that is generally accessible or available on request to the public either in print, online, broadcast or film, such as Court judgments, publicly available statistics, publicly available datasets, Registry of births and deaths, Information in newspapers or media releases, Official publications, Information in public archives and Information freely and openly accessible on the internet including public social media.

Randomization: is a process of assigning trial/research participants to treatment or control groups by using an element of chance to determine the assignment in order to reduce bias.

Reimbursement: refers to sum of money given to research participants toward recovery of any expenses that the participant incurred out of pocket as a result of participation in the research study.

Registry: means a collection of information (data) from multiple sources, maintained over time with controlled access through a gatekeeper organizer.

Repository: means a collection, storage and distribution system for human biological materials for research purposes including blood, urine, faeces, bone marrow, cell aspirates, diagnostic specimens, pathology specimens and so on.

Research: is the systematic process of the collection and analysis of data and information, in order to generate new knowledge, to answer a specific question or to test a hypothesis. Its methodology must be sufficiently documented to permit assessment and replication.

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.

Review Ethics Committee: a Review Ethics Committee means a board or other group formally designated by an institution to review biomedical research involving humans as participants, to approve the initiation of and

conduct periodic review of such research. In these guidelines, the term carries the same meaning as Institutional Review Board.

Secondary data: Information gathered from pre-existing sources or databases.

Sponsor: means an individual, company, institution or organization that takes a legal responsibility for initialisation, management and/or financing of the research.

Undue influence: refers to judgment that a payment made to research participants has, or is likely to have, an effect on a participant's decision to participate in research in such a way as to cause the participant to take risks that they would otherwise not take, underestimate or de-emphasize research risks, withhold or misrepresent information that is required in order to assess the participant's eligibility to participate in or assess the merits of their continuing participation in research.

Virtual Repository: means a digitised system that manages distributed bar-coded electronic versions of material, data or images through shared data systems.

Vulnerable participants: are individuals whose capacity and willingness to volunteer in research may be unduly influenced by the expectation(s), whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in the case of refusal to participate (e.g. student, military, subordinate staff, persons with incurable diseases, unemployed, patients

in emergency situations, refugees, minors, impoverished persons and those incapable of giving consent).

APPENDIX 2: LIST OF MAIN CONTRIBUTORS

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