

NATIONAL INSTITUTE FOR MEDICAL RESEARCH



HEALTH RESEARCH POLICY AND GUIDELINES

SECOND EDITION

NATIONAL INSTITUTE FOR MEDICAL RESEARCH



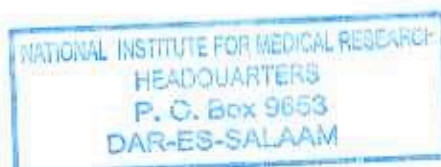
HEALTH RESEARCH POLICY AND GUIDELINES

SECOND EDITION

NATIONAL INSTITUTE FOR MEDICAL RESEARCH
HEADQUARTERS
P. O. Box 9653
DAR-ES-SALAAM

LIST OF ABBREVIATIONS

| | |
|---------|--|
| AJSC | Annual Joint Scientific Conference |
| CCM | Chama Cha Mapinduzi |
| DCS | Director Corporate Services |
| DRCP | Directorate of Research Co-ordination and Promotion |
| DRIRA | Director Research Information and Regulatory Affairs |
| DTA | Data Transfer Agreement |
| GDP | Gross Domestic Product |
| GPA | General Pass Average |
| IPP | Intellectual Property Policy |
| IRBs | Institutional Review Boards |
| KCMUCo | Kilimanjaro Christian Medical University College |
| MoUs | Memorandums of Understandings |
| MRCC | Medical Research Coordinating Committee |
| MTA | Material Transfer Agreement |
| MUHAS | Muhimbili University of Health and Allied Sciences |
| NatHREC | National Health Research Ethics Committee |
| NCDs | Non-Communicable Diseases |
| NHRA | National Health Research Agenda |
| NIMR | National Institute for Medical Research |
| R&D | Research and Development |
| SDGs | Sustainable Development Goals |
| TJHR | Tanzania Journal of Health Research |
| TMDA | Tanzania Medicines and Medical Devices Authority |
| UDSM | University of Dar es Salaam |
| UHC | Universal Health Coverage |
| URT | United Republic of Tanzania |




FOREWORD

As the Chairman of the National Institute for Medical Research (NIMR) Council, I am delighted to provide a foreword in this important document that stipulates several policy issues and their related guidelines to guide smooth implementation of NIMR mandates. NIMR is a parastatal institution under the Ministry of Health in Tanzania mandated for carrying out, coordinating, registering, and monitoring, evaluating, promoting health research in the country and disseminate generated scientific evidence to a wide range of stakeholders for improving health and welfare of Tanzanians.

Effective health research necessitates the establishment of a research agenda, the development of health research capacity, and an understanding of how research as a whole benefits decision makers, practitioners in health and related fields, and society at large. This necessitates sound research mechanisms, as well as transparent internal research administration processes. The Second Edition of the NIMR Research Policy and Guidelines aims to continue providing directives and guidance for conducting effective and sound health research through research regulatory and management practices. The policy addresses issues such as national health research priorities, health research planning, monitoring, evaluation, and administrative capacity building, sourcing and management of research funds, procedures for approval, control, and monitoring of the research process, collaborative research, staff remuneration, research performance rewarding, institutional administrative, sharing of research resources, and research support. This edition drew on the first edition's lessons and experiences, as well as current health research needs.

The purpose of NIMR Health Research Policy and Guidelines is to guide health research operations in Tanzania to achieve quality and reliable results, as well as to foster responsive research conducted by NIMR, individuals, collaborators, and students. The policy stipulates the broad mandates of NIMR in the coordination of health research within NIMR, research and academic institutions and partner organizations within and outside Tanzania to ensure compliance to the research conduct. The policy has expanded areas of traditional medicines, knowledge translations and resource mobilization strategies.

The NIMR, Tanzania's most prestigious public health research institution, will continue to be a centre for excellence in health research and development, attracting both local and international researchers. Furthermore, it will remain a trusted institute for providing critical information about disease trends and risk factors, treatment outcomes or public health interventions, functional abilities, care patterns, and health care costs and utilization in Tanzania. Therefore, this document shall also provide the guidelines to implement the stipulated policy issues as per institutional mandates.


Dr. Andrew Y. Kitua
Chairperson, NIMR Council
November, 2023



PREFACE

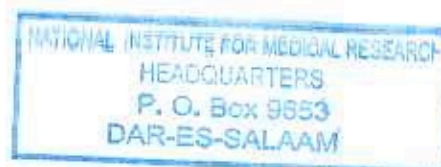
The demand for scientific evidence has increased due to improved awareness among policy and decision-makers of the importance of making informed decisions and avoiding authoritarian approaches. In Africa, and Tanzania in particular, the disease burden is overwhelming the functioning of the health systems due to the increased prevalence of non-communicable diseases amidst the high burden of infectious diseases. Climate change and emerging and re-emerging diseases call for research evidence to inform preparedness and response interventions. The National Institute for Medical Research is mandated to coordinate all health research activities in the country and collate all evidence to inform policy and decision-making at the Ministry of Health. This role can hardly be implemented if there is no up-to-date health research policy and guidelines to guide the whole process.

The second edition of the health research policy and guidelines provides clear directions, including policy issues and guidelines in different areas of coordination, regulation, and dissemination of the research evidence. Enforcement of this policy will fill the “know-do gap” between policy and decision makers that has resulted in a delay in applying the available evidence, knowledge, and best practices or in conducting research of immediate relevance to policy and decision makers. The “know-do gap” has for many years produced difficult scenarios whereby researchers are often frustrated that the innovations they develop do not reach policy, and policymakers are frustrated because they feel they are making policy decisions without all the answers to their questions. The policy statements and their related guidelines will enhance closing the gaps by facilitating the generation and collation of scientific evidence timely from different institutions and organizations carrying out health research in the country. NIMR will therefore be in a position to inform policy and decision-makers on the available and synthesized evidence in particular thematic areas. Different stakeholder forums, symposiums, and conferences coordinated by NIMR will be the avenues for sharing research evidence.

It is my great hope that this health research policy and guidelines will be instrumental in fostering compliance with the carrying out of health research and reporting of generated evidence, as all institutions will be guided and coordinated by NIMR as per mandate according to law of this nation. I wish you happy reading.



Prof Said S. Aboud
NIMR Director General
November, 2023



ACKNOWLEDGEMENT

The development of the Second edition of the Health Research Policy and Guidelines was coordinated by the Directorate of Research Coordination and Promotion (DRCP) through directives and support from the office of the Director General of the National Institute for Medical Research (NIMR). We are grateful to the Director General, Prof. Said S. Aboud, for his vision of initiating review of the health research policy and guidelines that has to date lasted for eight years. He is also thanked for providing a conducive environment to the review committee.

We also thank Dr. George Praygod, Director of Research Coordination and Promotion, for coordinating and advising the review committee throughout the process of developing the NIMR Health Research Policy and Guidelines.

The review committee led by Dr. Elizabeth H. Shayo, Head of Health Systems, Policy, and Translational Research Section, Dr. Sokoine Kivuyo, Dr. Mwanaidi Kafuye, Mr. Emmanuel Makundi, and Dr. Obadia K. Bishoge (Secretary of the committee) are sincerely thanked. They demonstrated the utmost dedication and commitment in developing the second edition of NIMR Health Research Policy and Guidelines.

The development of this Health Research Policy and Guidelines would not have been possible without the active participation of NIMR Directors, Centre managers and health research officers who provided valuable inputs for improvement.



Dr Elizabeth H Shayo

Chairperson of the Health Research Policy and Guidelines Review Committee.



EXECUTIVE SUMMARY

The National Institute for Medical Research (NIMR) was established as a parastatal organization of the Government of the United Republic of Tanzania by the Parliament Act 1979 (CAP. 59 (R.E. 2002)). NIMR is mandated to carry out, coordinate, promote and regulate medical and health related research undertaken to improve human health within Tanzania. It is also mandated to ensure dissemination of findings emanating from different studies in the country to different stakeholders for informing policy and change of practice.

The preparation of the second edition of NIMR Health Research Policy and Guidelines is in line with the Institute's mission which commits to conduct high quality research which is responsive to the needs of the Society. This edition was partly informed by the Sustainable Development Goals (SDGs) (2015-2030), the National Development Vision 2025, the National Five-Year Development Plan (21/22-25/26), the Health Sector Strategic Plan V (2021-2026), the Fifth National Health Research Agenda (2021/22-2025/26), and the NIMR Strategic Plan V (2021/22-2025/26). This Policy acknowledges that health research contributes to improvement in health, social welfare and poverty reduction and thus plays an important role in sustainable development.

The second edition of the NIMR Health Research Policy and Guidelines aims at addressing various health research policy issues that include:

- **National health research priorities.** NIMR shall strive to ensure that all health research activities conducted in Tanzania are in line with identified national priority areas for health research in the country. NIMR shall therefore ensure that existing and prospective researchers are well aware of the national health research priorities that inform the health research agenda and actively engage in translating and integrating priorities in their respective health research disciplines.
- **Health research planning, monitoring, evaluation, and administrative capacity building.** To ensure high quality health research, NIMR shall provide the guideline of strengthening, facilitating, and managing the health research process at individual and institutional levels.
- **Sourcing and management of research funds.** The Policy stipulates that the government will continue to be the major source of funding for NIMR work. However, to complement government efforts, the Institute shall seek external funding from national and international funding bodies to fund its research which is within the national health research priorities.
- **Funding procedures for Health Research Process.** To ensure effective funding consideration for research projects, NIMR has put in place an operational mechanism for research registration, scientific and ethical approval and monitoring of all proposals in the institute and the country at large, to ensure uniformity in the processes.



- **Health research training and capacity building.** The policy stipulates that research training and capacity building should be integrated in research conducted at NIMR to help sustain the Institute's research efforts. This will among other things include identification, nurturing and promotion of talents among scientific and support staff to enhance their career development.
- **Collaborative research.** To improve health research outcomes, NIMR shall provide ways to facilitate strategic partnerships and collaboration within NIMR, the Government, other research institutions and the private sector within and outside the country.
- **Staff remuneration.** To increase research performance, NIMR shall strive to provide attractive remuneration to help recruit and retain highly-trained competent scientific and support staff.
- **Research performance rewarding.** The Policy provides performance criteria to measure research excellence among the research staff and centres in order to reward the ones who perform well.
- **Institutional administration.** To ensure effective institutional administration, the policy sets the requirement of each research project to contribute 15% of the total project research costs as institutional overheads as stipulated in the NIMR overhead policy and procedures for sponsored projects.
- **Sharing of research resources.** To encourage more connection and collaboration between researchers, NIMR shall set the guidance of sharing and allocation of research opportunities to research staff at all centres and stations.
- **Research support environment.** Emphasises the provision of a good and conducive environment that supports effective and efficient carrying out of research and dissemination of results among the research staff.
- **Dissemination of research results.** Provides the guidelines on how research results/findings may be disseminated or shared among research peers, sponsors, stakeholders and the larger community through publications, seminars, and conferences.
- **Research Regulation.** Emphasises that all health research involving human, and animals conducted in Tanzania should comply with Guidelines on Ethics for Health Research in Tanzania. Quality assurance, compliance and guidelines & tools development have been well stipulated in this section of research regulation. Furthermore, it emphasises the need for establishment of various committees which are specific for regulating research ethics committees (RECs accreditation committee) and bio-hazardous research studies (biosafety committee). This section also emphasises the need of establishing forums for discussing ethical issues such as Chairpersons forum for research ethics committees in Tanzania
- **Traditional and alternative medicine.** NIMR shall carry out and promote the carrying out of research into various aspects of local traditional medical practices for the purpose of facilitating the development and application of herbal medicines for improving human health.
- **Intellectual property rights.** Research Policy provides for intellectual property rights that involve parties such as NIMR staff, partners and collaborators to claim and obtain to protect the work from misuse as stipulated in the NIMR IP policy.



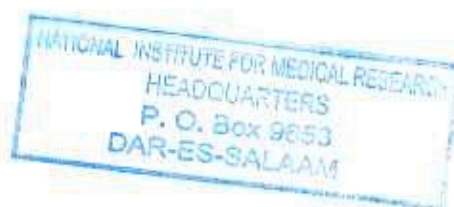
- **Use and disposal of research project resources.** NIMR shall ensure the effective and efficient management and disposal of the resources used in research projects.
- **Impact of research.** The policy insists on establishment of the follow up mechanism to evaluate research impact and agenda in solving societal problems.
- **Research culture.** NIMR shall contribute towards fostering and enhancement of health research culture within and outside the institute through training, promoting, and encouraging research teamwork among NIMR research staff and other collaborating institutions.
- **Data repository and control.** NIMR shall establish and secure a data repository system for all health studies conducted within the Country.
- **The use of up-to-date research approaches in line with the advancement of technology.** Encourages the application of advanced methods in research such as artificial intelligence, mathematical modelling to be updated with world trends in research to ensure the use of the information and technologies in its research activities.
- **Application and review of the health research policy.** This Health Research Policy shall apply to all members of staff, visiting researchers, students, interns, adjunct research fellows, NIMR research partners and collaborators, and any other person who is involved in medical and health related research with NIMR. Moreover, the NIMR Research Policy shall be subject to review after every five years, preceded with midline review.

The guidelines for the implementation of the policy are presented in Chapter four. The guidelines are categorised into three areas that are (1) Research coordination and promotion, (2) Research regulation and (3) Research dissemination, communication and publication. Some of the specific instruments for the implementation of the Health Research Policy are presented in Annexes. These instruments shall be reviewed regularly to accommodate the operating environment. Moreover, from time to time more guidelines or instruments will be prepared to implement the policy needs whenever necessary.

NIMR is confident that this second edition of Health Research Policy and Guidelines will address the conduct of research activities aimed to improve human health in line with the NIMR vision and mission to help achieve sustainable development in the country.

Process in the development of the second edition of the Health Research Policy and Guidelines

- i) The technical committee members convened a planning meeting to discuss and agree on key issues and format of report.
- ii) During the meeting they reviewed key NIMR institutional policies and other documents. They also reviewed documents from other institutions such as MUHAS, UDSM, COSTECH and KCMUCo.
- iii) They consulted key stakeholders to solicit inputs: Director General (DG), Director of Research Co-ordination and Promotion (DRCP), Director of

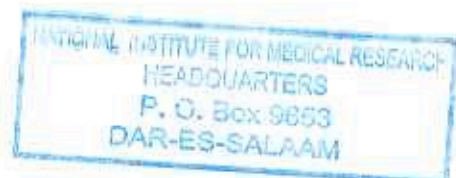


- Information and Regulatory Affairs (DRIRA), Centre Managers, Heads of Sections, Scientific Officers, Legal Officer, and Planning Officer.
- iv) They conducted a working session to incorporate suggested inputs and submitted the draft document to NIMR management.



TABLE OF CONTENTS

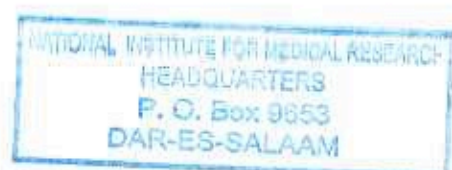
| | |
|--|----|
| LIST OF ABBREVIATIONS..... | 2 |
| FOREWORD..... | 3 |
| ACKNOWLEDGEMENT..... | 5 |
| EXECUTIVE SUMMARY..... | 6 |
| CHAPTER 1..... | 13 |
| INTRODUCTION..... | 13 |
| 1.1 Background..... | 13 |
| 1.2 Rationale for developing second edition of the Health Research Policy and Guidelines..... | 14 |
| CHAPTER 2..... | 16 |
| OBJECTIVES OF THE NIMR HEALTH RESEARCH POLICY..... | 16 |
| 2.1 Core Values..... | 16 |
| CHAPTER 3..... | 18 |
| HEALTH RESEARCH POLICY..... | 18 |
| 3.1 National Health Research Priorities..... | 18 |
| 3.2 Health Research Planning, Monitoring, Evaluation and Administrative Capacity Building..... | 18 |
| 3.3 Sourcing and Management of Research Funds..... | 19 |
| 3.4 Funding procedures for Health Research Projects..... | 19 |
| 3.5 Health Research Training and Capacity Building..... | 20 |
| 3.6 Collaborative Research..... | 20 |
| 3.7 Staff Remuneration..... | 20 |
| 3.8 Research Performance Rewarding..... | 21 |
| 3.9 Institutional Administrative..... | 21 |



| | |
|--|----|
| 3.10 Sharing of Research Resources..... | 21 |
| 3.11 Research Support Environment..... | 22 |
| 3.12 Dissemination of Research Results..... | 22 |
| 3.13 Research Regulation..... | 22 |
| 3.14 Traditional and alternative medicine..... | 23 |
| 3.15 Intellectual Property Rights..... | 24 |
| 3.16 Use and Disposal of Research Project Resources..... | 24 |
| 3.17 Impact of research..... | 24 |
| 3.18 Research culture..... | 24 |
| 3.19 Data repository and control..... | 24 |
| 3.20 The use of up-to-date research approaches in line with the advancement of technology..... | 25 |
| 3.21 Application and Review of the Research Policy..... | 25 |
| CHAPTER 4..... | 26 |
| GUIDELINES FOR IMPLEMENTING THE RESEARCH POLICY..... | 26 |
| 4.1. RESEARCH COORDINATION AND PROMOTION..... | 26 |
| 4.1.1 Managing Research..... | 29 |
| 4.1.2 Research Quality Management..... | 31 |
| 4.1.3 Research supporting environment..... | 31 |
| 4.1.4 Research process tools/instruments..... | 32 |
| 4.2. RESEARCH REGULATION..... | 32 |
| 4.2.1 Research registration, review, approval, quality assurance, compliance and guidelines..... | 32 |
| 4.2.2 Collaborative research..... | 33 |
| 4.2.3 National Health Research Biosafety Committee (NHRBC)..... | 33 |
| 4.3 RESEARCH DISSEMINATION, COMMUNICATION AND PUBLICATION..... | 34 |



| | |
|--|----|
| 4.3.1 Dissemination of Research Results | 34 |
| 4.3.2 Knowledge Translation | 35 |
| 4.3.3 Rights of participants to results of research | 36 |
| 4.3.5 Right of clinicians on accessibility of research results | 37 |
| 4.3.6 Disposal or continued storage of identifiable results | 37 |
| 4.3.7 Publication | 37 |
| 4.3.7 Permission to publish | 37 |
| 4.3.8 Ownership of research data | 37 |
| 4.3.9 Communicating research findings through the public media | 38 |
| 4.3.10 Journal and the Media | 39 |
| 4.3.11 Ethics in Journal Publication | 40 |
| 4.4 POLICY MONITORING AND EVALUATION | 40 |
| 5 POLICY STATUS | 41 |
| 6 STAKEHOLDERS CONSULTED | 41 |
| 7 DETAILS OF APPROVAL | 41 |
| 8 ENDORSEMENT DETAILS | 41 |
| 9 RELATED LEGISLATIONS | 41 |
| 10 RELATED POLICIES AND OTHER DOCUMENTS AND GUIDELINES | 41 |
| 11 EFFECTIVE DATE FOR THE POLICY | 41 |
| 12 NEXT REVIEW DATE | 42 |
| 13 POLICY OWNER | 42 |
| 14 POLICY AUTHOR | 42 |
| 15 CONTACT PERSON | 42 |



CHAPTER 1

INTRODUCTION

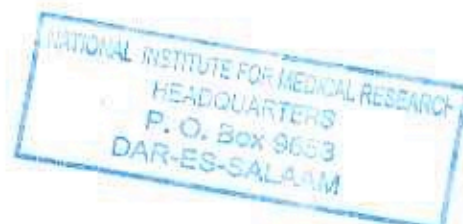
1.1 Background

The National Institute for Medical Research (NIMR) is the public health research institution in Tanzania. It was established by the Government of the United Republic of Tanzania (URT) through Parliamentary Act 1979 (CAP. 59 (R.E. 2002) as a parastatal service organisation under the Ministry of Health. The establishment of NIMR was in recognition by the government of the need to generate scientific information required in the development of better methods and techniques of enhancing disease management, prevention, and control in the country.

According to the Act mentioned above, NIMR is mandated to: (i) carry out and promote the carrying out of medical research designed to alleviate disease among the people of Tanzania; (ii) carry out and promote the carrying out of research into various aspects of local traditional medical practices for the purpose of facilitating the development and application of herbal medicine; (iii) cooperate with the government or any person, in promoting or providing facilities for, the training of local personnel for carrying out scientific research into medical problems; (iv) 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 evaluating the findings of that research; (iv) establish a system of the registration of, and registering the findings of medical research carried out within Tanzania, and promoting the practical application of those findings for the purpose of improving or advancing the health and general welfare of the people of Tanzania; (v) establish and operating systems of documentation and dissemination of information on any aspect of the medical research carried out by or on behalf of the institute. Therefore, development and revising health research policy over time ensures inclusion of new changes and smooth running and implementation of the mandates.

The legislation that established NIMR vested its governance oversight in the Institute's Council. The Governing Council is responsible for the performance of the functions and management of the affairs of the institute. The Council operates through four committees: Appointments and Disciplinary Committee, Finance and Planning Committee, Audit Committee, and Medical Research Coordination Committee (MRCC). The Director General, also appointed by the President of the URT, is the Chief Executive Officer and leads the management team composed of Coordinating Directors at the headquarters and managers at the Centre level. The Coordinating Directorates, according to the new organogram of 2022 are the Directorate of (i) Corporate Services (ii) Research Coordination and Promotion; and (iii) Research Information and Regulatory Affairs.

It is important to note that since its inception, NIMR has expanded in terms of increased human resources and infrastructures that has led to the establishment of new centres and stations. To-date, NIMR has seven research Centers and seven stations with the



coordination from NIMR headquarters. The management of these centres and stations required revising the policy to cater their needs and changes.

The NIMR structures and management monitor the achievement of the vision and mission that are well guided by the health research policy and guidelines.

Vision: To be a leading institution for advancement of high-quality health research and innovations.

Mission: To conduct, regulate, coordinate and promote health research that are responsive to the needs and wellbeing of Tanzanians.

To effectively implement the stipulated mandates, NIMR has over years relied on the National Health Policy that outlines the importance of conducting operational research, health surveys and in identifying national health research priorities. It also took initiatives to develop national health research priorities that guided the carrying out of health research for the nation. However, since 2014/2015 NIMR decided to develop its first health research policy with the aim of ensuring inclusiveness of all-important policy issues as per its mandates. The document included the guidelines stipulating strategies on conducting health research, and important actions for implementation of policy issues.

The 2014/2015 health research policy focused on key areas as reflected in the National Health Research Priority List (2013-2018) that were categorised into: (i) Biomedical Research, (ii) Health Systems and (iii) Socio-cultural issues. The 2nd edition of the health research policy therefore is in line with the current research priorities as outlined in the 2021/2022 - 2025/2026 National health Research Agenda with the following areas: i) Community Health Systems, ii). Non-Communicable Diseases (NCDs), iii). Reproductive, Maternal, New-born, Child, and Adolescent Health, iv). Communicable Diseases, v). Social and Environmental Determinants of Health, vi. Health System Strengthening including Universal Health Coverage (UHC), vii). Emerging and Re-emerging Diseases and viii) Traditional and Alternative Medicine.

The second edition of the health research policy accommodates the changes related to the NIMR functions and the current priority research areas with improved ways of ensuring utilization of the generated evidence to the fullest. This ensures that the scientific and technological knowledge generated by the Institute is responsive to the socio-economic needs of the country.

1.2 Rationale for developing second edition of the Health Research Policy and Guidelines

The revised NIMR research policy and guidelines (2015) was the first edition that has lasted for eight years. A number of changes and developments at the institutional, national, and international levels have occurred since 2015, necessitating a review of the policy. There has also been an increase in the number and variety of health research activities conducted in Tanzania by NIMR staff, local and international institutions including new areas such as emerging or re-emerging diseases. As it was observed in

COVID19 era, the absence of these areas in the policy made it difficult to implement research activities.

The revised health research policy has also accounted for research provisions in the Sustainable Development Goals (SDGs) agenda, the National Development Vision 2025, the National Five-Year Development Plan 2021/22 - 2025/26, Chama Cha Mapinduzi (CCM) leading Party Manifesto 2020-2025, the Health Sector Strategic Plan Five July 2021 - June 2026, the Fifth National Health Research Agenda 2021 - 2026, and the NIMR Strategic Plan VI 2021 - 2026. Furthermore, the revised policy addresses regional and international integration health research and development issues, as well as current opportunities and challenges in health research and development.

The revised policy also has focused on addressing the following issues that were either absent or inadequately captured in the previous policy and guidelines:

- 1) Increased number of NIMR centres and stations and the revision of the institutional organogram where the function of registering, review, approval and monitoring of health research in the country has moved to the newly established Research Information and Regulatory Affairs Directorate, which replaced the Directorate of Information, Technology and Communication (DITC).
- 2) The need for NIMR to conduct more research in district and regional hospitals in collaboration with the respective regional and district health teams.
- 3) The need to have robust mechanisms for soliciting research funding in relation to national research priorities.
- 4) Put more emphasis on research and development of traditional and alternative medicine that was not stipulated in the first edition.
- 5) Strengthening, upgrading, and modernising laboratory services and clinical trial facilities to keep in pace with current developments in the world as this was not stipulated in the first edition.
- 6) Put more emphasis on dissemination of health research findings, through AJSC, monthly seminars, symposia and meetings involving decision and policy makers.
- 7) Institutional capacity strengthening through recruitment of high-quality research officers in accordance with the new NIMR Schemes of Services 2022 criteria.
- 8) NIMR Centers and stations to develop annual publication plans to enable tracking of the research output over time.
- 9) Inclusion of statements related to the special ethnic groups, use of visual materials and bio banking as part of ethics regulation.
- 10) Introduction of Adjunct Research Fellow positions at NIMR
- 11) Additional aspects on Data transfer criteria
- 12) Development of short training courses for researchers, knowledge translation, and establishment of consultancy and grants management unit.
- 13) Other changes include removing the word 'regulations' from the previous policy documents (Research Policy, Guidelines, and Regulations). The team has added the missing sections such as foreword and acknowledgement, and have included specific chapter for research policy demarcating with guidelines for implementing the policy.
- 14) Promoting capacity building in research
- 15) Enhancing equity in research partnerships.

CHAPTER 2

OBJECTIVES OF THE NIMR HEALTH RESEARCH POLICY

In line with the National Research and Development Policy, Sustainable Development Goals 2030, National Development Vision 2025, the National Five-Year Development Plan (21/22-25/26), the Health Sector Strategic Plan V (2021-2026) and the Fifth National Health Research Agenda (2021/22-2025/26), the purpose of the Health Research Policy is to provide guidance to all parties involved in health research within and outside NIMR in order to achieve NIMR goals, mission and vision specifically in carrying out, regulating, coordinating, disseminating and promoting health research in Tanzania as described in details below;

1. To provide guidance in the generation of credible evidence to inform health and related policy and decision making, and change of practices.
2. To set mechanisms for institutional capacity strengthening and attraction of external research funds to complement government funding.
3. To set a framework of research coordination aimed at preventing duplication of efforts and ensuring efficient use of resources at NIMR.
4. Set procedures for developing and prioritising the health research agenda.
5. Lay down processes and procedures for conducting ethical and responsible medical and health research in the country.
6. To set mechanisms for increasing uptake and use of health research findings, data sharing and promoting knowledge translation.

2.1 Core Values

The Institute operates under the following overall principles counted as core values as per NIMR strategic plan that facilitate smooth implementation of the policy.

1) Integrity

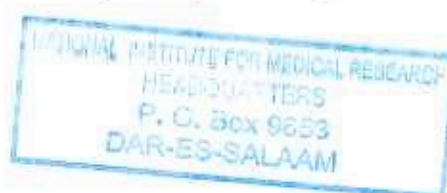
We uphold ethically sound and moral standards in our conduct reflected by honesty, sincerity, truthfulness, and confidentiality in executing our duties.

2) Inclusiveness

We believe in the broad stakeholders' participation, engagement, teamwork, and partnerships needed to harness multiple intellectual potentials, complementarities, skills and experiences in the course of discharging our research work objectives.

3) Excellence

We seek to execute our duties professionally, by allowing creativity and innovativeness while continuing to strive for improving and strengthening the organizational (Institute's) performance.



4) Accountability

We are collectively and individually responsible, with accountability in our work and behaviours as we discharge our day-to-day duties and responsibilities.

5) Transparency

We conduct our activities with a high level of openness.

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CHAPTER 3

HEALTH RESEARCH POLICY

3.1 National Health Research Priorities

Tanzania faces challenges in achieving improved health and well-being of her people due to resource limitations. This has necessitated NIMR to find an acceptable way of identifying national priority areas for health research implementation in Tanzania. NIMR, therefore, sets out national health research priorities in line with the national development agendas, including Vision 2025, the Sustainable Development Goals (SDGs) 2030s, Ministry of Health Strategic Plans, and Chama Cha Mapinduzi (CCM) leading Party Manifesto. Current priority areas (2021-2026) include i) Community Health Systems, ii) Non-Communicable Diseases (NCDs), iii) Reproductive, Maternal, New-born, Child and Adolescent Health, iv) Communicable Diseases, v) Social and Environmental Determinants of Health, vi) Health System Strengthening and Health Care Financing, vii) Emerging and Re-emerging Diseases and viii) Traditional and Alternative Medicine. To that end, NIMR shall:

- a. Coordinate activities related to the national health research agenda. The Institute shall be responsible for identifying and engaging stakeholders in developing the National health research agenda and setting priorities.
- b. Coordinate all health research carried out in the country and ensure their compliance with the national research priorities for the interest of the Nation
- c. Conduct research in collaboration with other research institutions which aligns with the national health research priorities in Tanzania.
- d. Identify from time-to-time emerging priority areas of national and international interests for health research in Tanzania and beyond. Recognize the freedom of its scientific staff to initiate and pursue research activities consistent with NIMR's vision and mission.
- e. Develop new health research priority areas every five years with the objective of ensuring relevance to the existing situation in the country.
- f. Ensure carrying out of midterm and endline evaluation during implementation of this health research policy after every two and a half and five years respectively.
- g. Ensure high quality health research activities are carried out in the country.
- h. Facilitate Coordination of National Policy Forum for dissemination of research evidence to inform policy and decision making in the country

3.2 Health Research Planning, Monitoring, Evaluation and Administrative Capacity Building

In order to inform policy, practice and programme, health research of high quality has to be planned and implemented within a clear framework for monitoring and evaluation. To maximise the use of available scarce resources and avoid duplication, NIMR shall therefore;

- a) Strengthen the research regulatory, promotion and coordination infrastructure.
- b) Strive to establish and maintain an environment that promotes health research planning, monitoring and evaluation.

3.3 Sourcing and Management of Research Funds

To respond to the national health research priorities, the Government of the United Republic of Tanzania should be the main source of health research funds. The National Research and Development policy of 2010 states that the government should allocate at least 1% of the Gross Domestic Product (GDP) annually to research and development activities. The available information indicates that the government funding to research institutions in support of research programmes reached 0.52% of the GDP as of 2021/2022 fiscal year. The national budget has continued to be extremely low, making health research activities remain largely donor-driven. To ensure continuity in receiving Government and donor funds, NIMR shall:

- a. Timely disseminate information to scientific staff about the budget allocated for research by the government of Tanzania.
- b. Create a conducive environment for its researchers to develop research proposals to secure funds from the government in line with the national research agenda.
- c. Enable scientific staff to solicit funds from the development partners and the private sectors to support the central research fund in addressing the national health research agenda.
- d. Provide general information on possible sources and modes of research funding both within and outside the NIMR on a regular basis.
- e. Implement research activities funded by the Government of Tanzania, non-state actors, development partners (bilateral and multilateral), private sectors and others shall adhere to the established financial regulations.
- f. Establish and operationalize Research Consultancy and Grants Management Unit.
- g. Promote Adjunct Research Fellow (ARF) positions for non-NIMR researchers and the retired scientists who are known to have good image, and can attract funds from different sources and have networks with different partners across the world.

3.4 Funding procedures for Health Research Projects

In the aspects of funding research projects, NIMR has put in place an operational mechanism for research registration, scientific and ethical approval and monitoring of all proposals in the institute and the country at large, to ensure uniformity in the processes. NIMR shall therefore:

- a. Ensure that scientific staff at NIMR, academic and other organizations carrying out health research in the country are well aware of the National Health Research Agenda (NHRA) and align with it when planning for research projects and programs.
- b. Give priority to projects which address the NHRA when approving research projects and programs for national funding.



- c. Ensure that NIMR researchers follow a uniform general framework guiding the preparation and approval of health research projects. Management of health research has to ensure that the research is well planned so as to provide reliable research output(s). In this regard, NIMR shall:
 - a) Coordinate all data, evidence and provision of technical services for the benefit of the institute and nation.
 - b) Develop and disseminate health research quality guidelines.
 - c) Review and approve health research proposals and protocols based on scientific and ethical standards.
 - d) Monitor approved proposals to ensure compliance with the guiding ethical requirements.

3.5 Health Research Training and Capacity Building

Health research training represents one of the most significant areas of national investment in research and development, and research staff members are the major resources. For NIMR to develop and assimilate the indigenous and foreign technologies it has a duty to:

- a. Ensure career development of research staff by promoting research programmes with funded projects that include capacity building and technology transfer.
- b. Make provision for mentoring as an essential component of every research project or program.
- c. Establish a training unit with a training needs database (updated annually) for promoting career development of scientific officers and support staff within NIMR.

3.6 Collaborative Research

NIMR shall

- a) Facilitate strategic partnerships and collaboration within and between NIMR, the Government, and other research institutions.
- b) Engage in contractual agreements with other institutions or individuals inside or outside Tanzania in implementing research activities.
- c) Approve a valid Material Transfer Agreement (MTA) and Data Sharing and Transfer Agreement (DSTA) if a collaborative research project involves a foreign researcher in need of biological materials and associated data and information from the country.
- d) For any data/material transfer between research institutions / partners within the country, the DTA and MTA form should be completed and signed by the two parties and approved by NIMR.

3.7 Staff Remuneration

In order to motivate research and promote productivity, NIMR shall insure that:

- a. All funded research projects include a budget item on research allowance and other remuneration for all investigators and other staff involved in the project/programme as agreed by the granters.
- b. Where daily subsistence (per diem) allowances are paid, these shall be paid not less than the Government of Tanzania daily subsistence allowance rates. Unless the granters state otherwise.
- c. In addition to subsistence allowances, scientific staff should be rewarded by professional fees as motivation for professional technical services they provide, and this will be negotiated equally between investigators in partnership countries and sponsors.
- d. Negotiations for an official contract of the research or consultancy to be done in the name of NIMR, or with a mention of NIMR as a trustee, should be done through the office of the Director General.

3.8 Research Performance Rewarding

The NIMR shall:

- a) Establish transparent criteria/indicators to measure research excellence.
- b) Evaluate research performance of individuals, centres/stations, and multi-disciplinary research teams on an annual basis.
- c) Reward research performance at individual centres/stations and research teams each year
- d) Establish awards for different levels of research officers (juniors vs seniors; males vs female) for outstanding performance in health research in the country.
- e) Ensure that research outputs constitute a major criterion in the promotion of scientific staff and using of evidence for informing policy and decision making.

3.9 Institutional Administrative

In order to create a conducive research environment, NIMR requires each research project to contribute a certain percent of the total project research costs as institutional overheads. Distribution of the overhead shall be guided by the Institutional overhead guideline (see revised overhead guideline, 2023). If it is a consultancy, then a certain contribution to the same as for the research item should be effected (as per NIMR Financial Guidelines).

3.10 Sharing of Research Resources

NIMR shall:

- a. Ensure that centres and stations have transparent and objective criteria of making research opportunities known to members of staff and for allocating such opportunities.
- b. Establish a national health research database to enable researchers to access the research inventory and provide data handling facilities.



3.11 Research Support Environment

NIMR shall:

- a) Provide research support services that include the provision and continuous improvement of modern management information systems and facilitate access to international literature and databases.
- b) Work towards the creation of a stable and conducive internal research environment. This shall include the provision of research administration allowance and maintenance of equipment and support for purchase of basic consumables.
- c) Obtain membership to international peer reviewed journals to enable researchers publish in high impact factor.

3.12 Dissemination of Research Results

Dissemination of research results may entail sharing research findings with research peers, sponsors, stakeholders and the larger community through publications, seminars, and conferences (See Annex....). NIMR shall:

- a. Require that all research proposals include at least one local seminar/workshop to ensure local ownership of research findings by the study community. For large research projects, local conferences/symposia shall be organized.
- b. Require all Principal Investigators seeking ethical clearance at NIMR to include plans for publications and development of a policy brief to inform policy and practise in Tanzania.
- c. Ensure that all manuscripts prepared for publication are submitted and permission to publish from the NIMR Director General prior to the paper submission process takes place.
- d. Subject all research reports and others documents that need to be shared outside NIMR or depositing them in the data repository to peer reviewed.
- e. Develop dissemination channels for the evidence generated in the country.
- f. Disseminate research findings through national/international exhibitions in line with National Research Ethics Policy.
- g. Provide moral, financial, technical, and logistical support to enhance publication of findings as may be requested by the researchers and allied research staff.

3.13 Research Regulation

NIMR shall ensure that:

- All health research proposals are registered, scientifically and ethically reviewed, approved and monitored according to the guidelines on Ethics for Health Research in Tanzania, 3rd Edition. National Institute for Medical Research, Tanzania. 2023: ISBN 978-9976-5568-1-0 and SOPs.
- Establishing the National Research Ethics Information Management System (NREIMS) for registering and managing approved research proposals

- MRCC shall ensure Zonal and Institutional Health Research Ethics Committees (Z/IREC) are established and nurtured as per NIMR Act amendment 1997 requirements.
- MRCC shall establish a sub-committee responsible for accrediting health Research Ethics Committees in Tanzania.
- Establishment of frameworks / guidelines and tools for the REC accreditation sub-committee.
- Specific guidelines and tools for ethics regulations shall be in place and reviewed over time as per needs.
- Research targeting special minorities and use of visual materials shall be monitored by NIMR (refer specific guidelines).
- Strengthening mechanisms for health research regulation to ensure that all approved researches are monitored.
- The costs of monitoring approved researches must be attributed by 1% of the total budget of respective proposals
- All research on laboratory animals must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) responsible for overseeing the institution's animal programme, facilities, and procedures.
- The IACUC shall inspect, at least once every 12 months, all of the institutions' animal facilities, compile facility inspection reports and present the reports for discussion at a meeting of MRCC.
- Monitoring the use of all biohazardous and select agents in health research in Tanzania
- Facilitating coordination among the regulatory agencies and authorities such as RECs, TMDA, COSTECH, PO-RALG towards streamlining research regulation in the country.

3.14 Traditional and alternative medicine

Traditional and alternative medicines contribute approximately 45% to the provision of health services and have been instrumental in addressing Tanzanians' various health challenges. To advance research and development in traditional and alternative medicine, NIMR shall:

- a. Carry out and promote the carrying out of research into various aspects of local traditional medical practices for the purpose of facilitating the development and application of herbal medicines for improving human health.
- b. Identify and recognise useful traditional and alternative medicine products and practices that can be improved and integrated in the health care services delivery.
- c. Continue development of the factory for herbal medicines production in-line to support research and development in this field as well as integration of traditional medicine in the healthcare delivery system.



3.15 Intellectual Property Rights

- NIMR requires that researchers participating in the projects/research which have potential for creating IP for commercialization to sign IP Disclosure Agreement (See Annex...).
- Researchers wishing to send research samples/data abroad, either for analysis or other research purposes, should sign the Tanzania Material and / or Data Transfer Agreement Form.
- Benefit sharing on IP in parties involved should be stated (see the IP guideline).

3.16 Use and Disposal of Research Project Resources

NIMR shall ensure that: -

- a) Sponsored project agreements must always include the terms and conditions for the disposal of tangible property (e.g., equipment, vehicles, reports, theses or dissertations) or intangible properties such as rights to data, copyrights, and inventions. Except as otherwise expressly provided, all equipment purchased within a research project is the property of NIMR. National laws, policies and procedures governing the disposal of property (obsolete or otherwise) should be applied.
- b) During the life of a project, all equipment or goods purchased with research funds will not be sold, ceded, exchanged, or otherwise disposed of without the prior approval of NIMR.
- c) On completion or termination of a project/programme, NIMR will retain the title to all equipment purchased for the project or programme.
- d) The centre/station/researcher that had these resources should be given priority in the disposal of research resources when the project is completed.

3.17 Impact of research

For research that has direct impact on the society, NIMR shall:

- a. Establish and utilize a feedback/follow up mechanism to foster, scale up and continue refinement of the research impact in solving societal problems.

3.18 Research culture

The NIMR shall:

- a) Contribute towards fostering and enhancement of research culture both within and outside NIMR.

3.19 Data repository and control

Data repositories are significant in the successful and secure sharing of study data because they give a stable, long-term home for the data, improve archiving security and quality through ongoing data curation, and promote data discoverability through the application. To achieve this, NIMR shall:

- a. Establish a data repository system for all health studies conducted within the Country.
- b. Ensure that the system is secure.

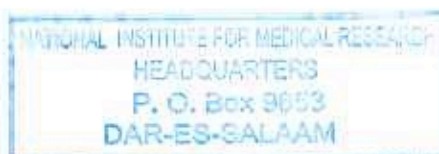
3.20 The use of up-to-date research approaches in line with the advancement of technology

NIMR shall

- Encourage researchers to apply advanced methods in research such as artificial intelligence, mathematical modelling to be updated with world trends in research to ensure the use of the information and technologies in its research activities.
- Ensure its scientists are updated on new methods/approaches in research to enhance competitiveness in grant application.

3.21 Application and Review of the Research Policy

- a) The research policy shall apply to all members of staff who are involved in research at NIMR.
- b) It shall also apply to all NIMR research partners and collaborators and all researchers who want to conduct health and medical research in Tanzania.
- c) The NIMR Research Policy shall be subject to review every five years, preceded with midline review.
- d) The policy statements are to guide the general conduct of research involving NIMR staff as well as NIMR research partners and collaborators. It is necessary for the specific policy intentions to be operationalised by relevant offices within NIMR. A general set of operational procedures and guidelines is necessary in order to kick-start the streaming of research management. The guidelines with some of core operational procedures are presented in Chapter 4.
- e) NIMR from time to time will prepare relevant guidelines and will be required to effectively implement this policy.



CHAPTER 4

GUIDELINES FOR IMPLEMENTING THE RESEARCH POLICY

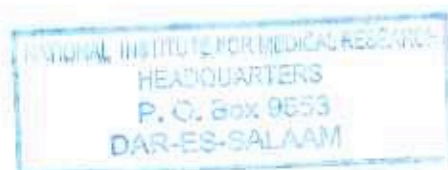
This chapter provides guidelines on how to implement the health research policy (Chapter 3 above). The principal strategy in implementing NIMR's research policy lies in the strengthening of the directorate in charge of research, facilitated by a well-planned research administrative infrastructure. The roles, duties, and responsibilities of the directorate shall reflect its obligations in implementing this policy. This chapter is divided into three guidelines that are:

- i. Research coordination and promotion
- ii. Research regulation
- iii. Research dissemination, communication and publication

4.1. RESEARCH COORDINATION AND PROMOTION

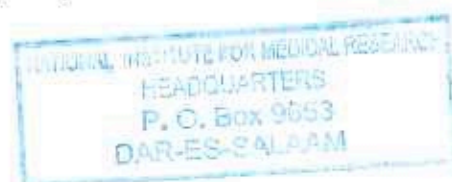
The following actions are necessary for the successful coordination and Promotion of health research activities in Tanzania. As per NIMR's mandates, the Directorate of Research Coordination and Promotion will be responsible to coordinate and promote the carrying out of health research at NIMR and in the country at large. The following should be done:

- a) Enhancement of the capacity of the directorates to manage, administer and coordinate research. This will need trained human resources, establishment of a more effective structure, equipment, and funds.
- b) The directorate will have the responsibility of coordinating internal and external linkages on all matters related to research through:
 - Mapping of all institutions carrying out health research in the country in order to draw a landscape and identify specific areas of research Creating linkages and networks with identified institutions in order to create communication channels for updating on the status of their projects in line with policy makers and other stakeholders' demands.
 - Acting and serving as a custodian of all health research outputs on behalf of the government of Tanzania by keeping a register and repository database of all research and development (R&D) data and acquisition of patents.
 - Develop quality assurance indicators to monitor the quality of health research carried out by all institutions including the human resource and infrastructural capacity(refer to the guidelines)
- c) During implementation activities of 5-Year National Health Research Agenda NIMR shall ensure;
 - Inclusion of all institutions in the process of development of agenda
 - Implementation of agenda, all institutions should use the identified priority areas



- Higher learning institutions should encourage students at Masters and PhD levels to use identified areas of national research agenda in conducting health research
 - All institutions undertaking health research in the country should be aware of midline (every 2 and half years) and end line evaluation (once every 5-years) of implementation of agenda reflecting their activities
- d) Conducting National Policy Forum Meeting in Tanzania. This event will be coordinated by NIMR and will involve all institutions undertaking health research in Tanzania and to be conducted once in every six months where key findings with policy implications will be shared. The Minister of Health according to law is ultimately the policy spokesperson on all matters of health research for the Government of Tanzania.
- e) Document the number and level of laboratory, and clinical trial facilities for health research in the country.
- f) Manage Knowledge Translation Activities at National Level by;
- Establishing a national hub on knowledge translation to bridge the gap between research findings and policy/decision making in Tanzania.
 - Liaising with Tanzania Commission for Universities (TCU) to ensure that Higher Learning Institutions introduce and strengthen Knowledge Translation courses through training at Masters and PhD levels to improve Tanzania Competitiveness in this area in the East and Southern African regions. This will ensure availability of critical mass of human resources in Knowledge Translation.
 - Building capacity of Knowledge Translation in Tanzania through training by sending qualified Tanzanians to training at Masters and PhD levels at centres of excellence abroad.
- g) Within NIMR, the Directorate responsible for research coordination and promotion shall coordinate the process of implementation of the policy through setting up of internal administrative links with other relevant departments at the same centre/station level (horizontal linkages) as well as between Centres and the Stations (vertical linkages). The Directorate shall focus on the following specific actions with respect to establishing horizontal linkages.
- Hands-on work on NIMR policies to ensure that research interests are safeguarded.
 - Establishment of a close working cooperation with other relevant offices to implement the NIMR Strategic Plan.
 - Clear description of excellence in research and coordination of the process of identification and rewarding of excellence as guided by the Human Resources Management Policy.
 - Health Research Planning, Monitoring, Evaluation and Administrative Capacity Building
 - Recruit and retain Ensure a critical mass of health research administrators who have qualifications in health research management.

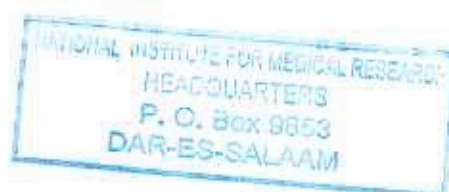
- Strengthen institutional capacity through recruitment of high-quality research officers in accordance with NIMR Schemes of Services and provide on-job training.
 - Strengthen the capacity for health research planning at all levels.
 - Create a mechanism by which scientific staff can be motivated to conduct high quality health research.
 - Ensure that all research planning activities and their implementation involve all stakeholders under the coordination of NIMR.
 - Encourage a multidisciplinary approach in the implementation of health research activities.
 - Strengthen partnership and enhance equity among researchers in carrying out research.
- h) A strong focus shall be established by the Directorate on the following specific actions with respect to establishing vertical linkages.
- i. Involving NIMR researchers and other stakeholders in evolving the research agenda.
 - ii. Actively facilitating the dialogue between researchers, policy and decision makers on emanating research evidence from the field.
 - iii. Standardising internal research administrative mechanisms.
 - iv. Develop short term training courses targeting researchers and health management teams at regional and district levels in order to build capacity in writing proposals, generating, analysis, knowledge synthesis and use of evidence for decision and policy making, and change of practice.
 - v. NIMR Centers to collaborate closely with regional, zonal and referral hospitals in identifying major problems in need of scientific evidence for service delivery improvement.
 - vi. NIMR should seek access to health facilities data collected in the routine health information system to monitor disease trends and advise the Ministry of Health accordingly.
 - vii. Ensuring that research funds from public, private, and external sources are secured.
 - viii. Ensuring and supporting marketing of research results where appropriate.
 - ix. Publishing of regular Tanzania Health Research Journal and Research Annual Reports on the status of research activity within NIMR.
 - x. Sensitise all NIMR staff and stakeholders to carry out research that aims at solving national health problems and advancing new knowledge.
 - xi. Encourage collaboration within and across all centres and stations as well as national and international institutions.
 - xii. In the collaborative projects, NIMR shall serve as the Principal or Co-Principal Investigators according to the skills and experience in the prospective project.
 - xiii. Ensure that through the office of Director General existing Memorandums of Understanding (MoUs) between NIMR and other institutions in Tanzania and other countries are reviewed every five years.



4.1.1 Managing Research

Management of Research will be enhanced at all levels at NIMR in order to address the following issues.

- i. Identify possible sources of research resources at national and international levels and develop strategies for mobilising/accessing them.
- ii. Ensure that pertinent information relating to specific research opportunities is passed on to relevant NIMR organs.
- iii. Develop a framework for coordination of research conducted by different institutions in the country.
- iv. Develop a framework for assessing the capacity of the institutions carrying out health research in the country in terms of structures and human resources and approve or disapprove the role of conducting research in such institutions.
- v. Make widely and continuously available general information on possible sources and modes of research funding on a regular basis. This information shall be available in hard and web-based e-format which will be only accessible by NIMR staff.
- vi. Capacitate consultancy and grants management unit in terms of human and financial resources, infrastructure and other tools to facilitate its functions. The Unit shall be responsible for searching, lobbying and strengthen partnership within and outside the country for attracting research funds and technical experts (refer to the guidelines).
- vii. Hold regular research resources mobilisation workshops in which new opportunities for research funding shall be presented and discussed.
- viii. Convene a meeting involving bilateral, multilateral agencies, embassies and other stakeholders to discuss national health research agenda and NIMR strategic plans with the aim of identifying research areas for funding at least once in every two years.
- ix. In collaboration with other research and development institutions in Tanzania, advocating and lobbying for an increased share of national financial resources allocated for research that at least ONE percent of the GDP shall form the target benchmarks as stipulated in the National Research and Development Policy 2010 under COSTECH. This may need contacting and holding meetings with Members of Parliament on Research and Development and Budget Committees so as to increase budget allocation from current levels.
- x. Initiate linkage between Traditional medicine research Centre and traditional healers in collection of information in indigenous knowledge as per existing guidelines.
- xi. Ensuring that a research budget sufficient to carry out planned priority research is submitted to the government including other sources; and that adequate funds are allocated for such research activities and are effectively utilised for the purpose.
- xii. Exploit fully the potential for multi-disciplinary research projects and initiate the formation of such teams which once formed, shall be left to operate under the approved modalities of multidisciplinary research teams; and



- xiii. Annually compile the NIMR Annual Research Report that shall summarise annual activities performed under all research grants in a standard format to be approved by the NIMR Management.
- xiv. NIMR shall ensure that products of hazardous chemicals and reagents as well as expired materials are appropriately disposed of according to the local and international guidelines. Each laboratory/Centre/Station working with such materials shall develop and maintain updated standard operating procedures for disposal of chemical and biological hazardous materials.
- xv. NIMR shall ensure that its facilities and staff refrain from producing and maintaining biological materials which can be used as warfare or terror agents.
- xvi. Establish a research consultancy bureau which shall promote and monitor consultancy services within the Institute.
- xvii. Establish research groups across NIMR Centres and Stations to aid in identification and response to national and international calls for research applications.
- xviii. Establish mechanisms for institutional coordination of research grant writing and submission to optimize use of institutional research capacity in soliciting funding and avoid duplication of efforts between research groups.
- xix. Ensure that multi-disciplinary research projects are hosted in centres/stations where the principal researcher belongs.
- xx. Ensure that staff participating in the multi-disciplinary collaborative research projects report progress to their own centres/stations, and subsequently Centres/Stations report progress to the Directorate of Research Coordination and Promotion.
- xxi. Ensure that the collaborating centres/stations share administrative costs according to NIMR Overhead Policy.
- xxii. Ensure that the collaborating centres/stations agree on allocation of equipment to be acquired in the project and be clear on modalities for transferring them to centres/stations at the end of the project or program.
- xxiii. Promote equal partnerships in collaborative research.
- xxiv. Promote, Develop and Transfer of Technology.
- xxv. Ensure that the collaborating institutions make provisions for administrative costs; and require that the respective legal officers vet all collaborative research agreements.
- xxvi. Encourage sharing of research project resources among all NIMR researchers in order to fully utilise the research resources available.
- xxvii. Encourage and coordinate sharing of information of scientific value and its sources. Such sources shall include books, journals, electronic information, and sources of such electronic information.
- xxviii. Establish mechanisms for ensuring timely availability of equipment and supplies to researchers for the smooth implementation of project activities.
- xxix. Set up a mechanism for sharing financial benefits and resources to individual researchers and institution at large as per contribution

4.1.2 Research Quality Management

NIMR shall develop and institute a process of monitoring and reporting on the following research quality indicators at NIMR on regular basis:

- a) Research planning.
- b) Research training.
- c) Research degree completion rates
- d) Research publications per scientific staff
- e) Peer reviewed research reports, policy briefs and annual reports.
- f) Facilities and access to information resources
- g) Proportion of staff according to NIMR staff Regulations
- h) Proportion of staff directly doing research
- i) Indicators that measure society perceptions on the research that NIMR staff do.
- j) Number of clients continuously using NIMR research services.
- k) Number of local/international research assignments that NIMR wins in a competitive environment.
- l) Collaboration with regional and international institutions – establishment of active research networks.
- m) Subsequent availability of funds for the research following completion and dissemination of a phase of the research.
- n) Number of traditional medicine products with active ingredients in improving human health approved.
- o) Seek to inculcate research culture among junior research scientists, undergraduate and postgraduate students through internship/fellowship and providing opportunities to work with senior NIMR staff or attend meetings/workshops organised by the institute.
- p) Instil a research culture through training of scientific staff in respective research specialty.
- q) Promote and encourage research teamwork among NIMR staff and other institutions.
- r) Educate NIMR staff on the research policy and procedures.

4.1.3 Research supporting environment

- a. Provide basic financial management support and training to research coordinators as well as personnel in key research administrative units.
- b. Publicise its research activities and seek ways to make research findings available to the wider community.
- c. Provide moral, financial, technical, and logistical support to enhance publication of findings as may be requested by the researchers and allied research staff.
- d. Establish effective mechanisms for assisting researchers to obtain equipment and supplies and the preparation of financial reports through in-house training on research project reporting.
- e. Set aside at least five percent of Institutional overhead to facilitate publications and grants writing skill workshops.



- f. Purchase all necessary and up to date software for data management and analysis such as Stata, NVIVO, SPSS, and ENDNOTE.
- g. Establish the Internal Scientific Committee responsible for reviewing proposals to be submitted for funders at different places (MOH, development partners and other internal and external funders).

4.1.4 Research process tools/instruments

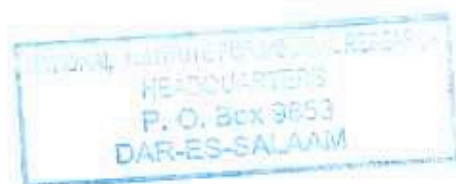
In order to standardise and harmonise the research process within NIMR, specific guidelines to effect the stipulated roles should be accessible (see appendix...). These guiding documents shall be reviewed regularly to accommodate developments in the operating environment. DRCP shall be the custodian of the Research Policy on behalf of NIMR and shall therefore bear the responsibility of ensuring that it continuously meets both the internal and external stakeholders' expectations.

4.2. RESEARCH REGULATION

The following actions are necessary for the successful regulation of the conduct of health research activities in Tanzania. As per NIMR's mandates, the directorate of research information and regulatory affairs will be responsible for monitoring, controlling and regulating the conduct of health research carried out within Tanzania, or elsewhere, on behalf of or for the benefit of the Government of Tanzania. The following should be done:

4.2.1 Research registration, review, approval, quality assurance, compliance and guidelines

- a) Medical Research Coordinating Committee (MRCC) shall ensure all health research proposals are registered, scientifically and ethically reviewed, approved and monitored according to the guidelines on Ethics for Health Research in Tanzania, 3rd Edition. National Institute for Medical Research, Tanzania. 2023: ISBN 978-9976-5568-1-0 and SOPs.
- b) MRCC shall ensure Zonal and Institutional Health Research Ethics Committees (Z/IREC) are established and nurtured as per NIMR Act amendment 1997 requirements.
- c) Specific guidelines and tools for ethics regulations shall be in place and reviewed over time as per needs.
- d) In enhancing ethical conduct of research, guidelines addressing special ethnic groups, use of visual methods in research and biobanking should be in place.
- e) NIMR shall monitor all health research proposals submitted and approved by local RECs and request on quarterly basis all REC's activities.
- f) MRCC shall establish Forums for Chairpersons of Health Research Ethics Committees in Tanzania
- g) MRCC shall establish a secretariat which will be responsible for overseeing compliance, regulations and quality assurance of health research conducted in Tanzania.



- h) MRCC shall establish a sub-committee responsible for accrediting health Research Ethics Committees in Tanzania.
- i) Development of guidelines and tools for the National RECs accreditation committee
- j) NIMR to ensure capacity building of the secretariat for compliance, regulations and quality assurance as well as for its respective REC accreditation committee
- k) NIMR shall ensure nurturing and continuous training of new RECs in Tanzania
- l) Guiding researchers on scientific and ethical standards required when submitting protocols for ethical clearance (refer SoP)
- m) Establishing the National Research Ethics Information Management System (NREIMS) for registering and managing approved research
- n) Facilitating coordination among the regulatory agencies such as RECs, TMDA, COSTECH, PO-RALG towards streamlining research regulation in the country.
- o) NIMR will make reasonable efforts to ensure that all individuals involved in the care and use of laboratory animals understand the applicable laws and regulations pertaining to animal care and use. NIMR will also monitor and ensure compliance at individual and collective levels.
- p) NIMR and all individuals involved in animal care and use must comply with occupational health and safety procedures for personnel who work in laboratory animal's facilities or have frequent contact with animals.
- q) Personnel actively working with non-human primates must be screened annually for tuberculosis and participate in training specific for the prevention of illness/injury to the species. Also, each nonhuman primate housing area must be equipped with injury/exposure kits.

4.2.2 Collaborative research

NIMR is obliged to:

- a) Ensure that updated central records of materials and data shared or transferred out of Tanzania during collaborative research are prepared and maintained.
- b) For MTA and DTA, a careful assessment should be done on why data should be transferred, type of data and how and when it should be transferred. The assessor and approver of DTA shall be capacitated in assessing the type of data to be transferred. Transferring of data directly from the field to external partners needs to be controlled.
- c) Demand that if research is implemented by different institutions / partners, approval at institute level shall only be necessary in the hosting institute or partner, but shall be reported to the relevant organs in the non-hosting institute or partner for noting.

4.2.3 National Health Research Biosafety Committee (NHRBC)

Bio hazardous agents include recombinant/synthetic DNA (r/sDNA), agents infectious to humans, animals or plants, other genetically altered organisms and agents, and certain

biological toxins / select agents (determination made based upon the LD50 of the toxin in question). Additionally, cells/blood/tissues/organs harvested directly from humans only require NHRBC approval if they are used in the following manner:

- As a recipient or source for r/s DNA experiments / research
- As a recipient/host for or source of a pathogenic and/or genetically modified microorganism in health research
- As a recipient of biological toxins in vitro during the conduct of health research

All health research involving the use of bio hazardous agents prior to ethics clearance must be reviewed and approved by a special committee responsible for the safety of research participants involved in bio hazardous / select agent research known as biosafety committee.

With this regard, NIMR through the MRCC shall ensure:

- a) Establishment of the secretariat for serving day to day functions for Biosafety oversight during the conduct of bio-hazardous / select agents health research in Tanzania
- b) Establishment of the National Health Research Biosafety Committee (NHRBC)
- c) Capacity building for both secretariat and the respective committee of appropriate training in the safe handling and management of biological and chemical hazard agents used in research studies.
- d) Nurturing and continuous training of new Institutional biosafety in Tanzania
- e) Development of guidelines and tools for the National Health Research Biosafety Committee in Tanzania Development of biobank guidelines.
- f) Establishment of the National biobank accreditation system.
- g) The National Health Research Biosafety Committee as well as Institutional biosafety committees shall observe relevant requirements stipulated in the Environmental Management (Biosafety) Regulations, 2009 and Cartagena protocol of biosafety.

4.3 RESEARCH DISSEMINATION, COMMUNICATION AND PUBLICATION

These guidelines are developed in order to enable all investigators to share possible benefits of research results with research participants, practitioners and policy and decision-makers.

4.3.1 Dissemination of Research Results

- a. There will be an Annual Joint Scientific Conference (AJSC) event every year. During this event, scientific officers from NIMR, researchers and other stakeholders in Tanzania and other collaborating Institutions from other countries will be required to disseminate findings on an annual basis.
- b. Each Year- after the AJSC event, there will be a special supplement issue to publish research articles presented at the Conference following the standard review process. The publication will be through NIMR Health Research Journal and NIMR scientific officers will be encouraged to publish in this journal to promote NIMR and Tanzania

- visibility in health research. All research projects should allocate funds for the dissemination of research findings and part of it (at least 20% of the dissemination budget) shall be used to facilitate the Annual Joint Scientific Conference (AJSC).
- c. Sustain and continuously update the NIMR research activity database. In this respect, selected information shall be published on a regular basis onto a NIMR research web page.
 - d. Set up and maintain an accessible electronic research output database that shall contain abstracts and full texts of the research reports and other related publications and should be uploaded into the NIMR websites. Sustain compilation and organisation of printing hard copies of the project reports on an annual basis.
 - (i) Produce brochures to market institutional research services. All new events in the respective quarter shall be published in the NIMR newsletter.
 - (ii) Conduct internal monthly scientific seminars both physical and virtually involving scientists from all Centers.
 - (iii) All NIMR centres and directorates are obliged to participate (showcase) in every international and national health days and other events either through presentations to the relevant workshops/conferences and mass media (TVs, radios, newspapers) based on their respective areas of excellence.
 - e. Communicate research findings through media including mass media such as radio and televisions; and social media such as twitter, LinkedIn, YouTube, Instagram and Facebook.
 - f. Ensure Centres/stations develop annual publication plans according to their research capacities to promote research dissemination and track and monitor outputs.
 - g. Ensure the preparation of the annual report of the published works to the public and ministry responsible.
 - h. The submitted technical research reports from the other institutions should be checked for their quality
 - i. Require that each centre/station conduct at least one research workshop annually to review research plans, progress, and outputs.
 - j. Prepare and submit to decision and policy makers research evidence (policy briefs) to inform policy and practice. English evidence briefs must be submitted through the DRCP office.
 - k. Encourage and support dissemination of research results through regular local and international fora.
 - l. Encourage and support the inclusion of research findings/publications in accessible institutional electronic databases.
 - m. Encourage the publication of popular versions of research findings in the local media with the permission of NIMR Director General, including some in Kiswahili.
 - n. Publicise its research activities and seek ways to make research findings available to the wider community.

4.3.2 Knowledge Translation

NIMR works to create conditions that enable our world-leading research to thrive. However, despite the availability of volumes of research findings in Tanzania, most of the information has not found its way to the consumers, creating a critical information gap.

The causes of such information gap are likely to be due to: (i) Research has been carried out on the respective subject but the evidence have not been pulled together and interpreted in the context of the local problem; (ii) Relevant information is just not reaching the communities, policy, and decision makers at the right time. (iii) Although the information gets to the communities and policy makers, they may not be able to utilize it properly because they lack the necessary background knowledge. Developing and informing policy is a key part of this. Decisions made by policymakers, notably Government and research funders rely on the synthesised evidence and are well packed to inform policy and practice change and to carry further research. It is therefore important for the following to be undertaken.

- a) Train researchers and academicians on how to synthesise, interpret and package research findings into user friendly manner to inform policy and change of practice.
- b) Develop a plan for policy briefs development based on the current priorities in the Ministry of Health.
- c) Develop a forum for convening policy makers and researchers to discuss and update the best ways of responding to priorities and how to use the generated evidence.
- d) Plan for a policy dialogue meeting involving policy and decision makers to discuss evidence at least one per quarter.
- e) Knowledge translation guidelines should be developed in relation to establishment of the section/units in the NIMR Centers, recruitment, training on policy direction to ensure achievement in this area over short, medium term and long term.
- f) In each quarter, key research findings with policy implications should be presented to the Ministry of Health to guide policy and decision making.

4.3.3 Rights of participants to results of research

- i. In studies that involve sustained cooperation on the part of participants, it is important to inform them of the outcome of the research, in broad terms, and indicate a high level of appreciation for their participation.
- ii. The benefits of research are to be made known to the research population and the local communities from which they were drawn and sustained. Complete reports of the research written in a user-friendly language must be made publicly accessible as soon as the project reaches an end.
- iii. The participants have a right to be informed of new findings that may affect their rights, and they have a right to direct access to their original clinical records. Patients have this right except where, in the view of the clinician concerned, disclosure is likely to cause serious harm to their physical or mental health or well-being, in which case proper counselling should be given.

4.3.5 Right of clinicians on accessibility of research results.

Whereas information that emerges during research and is likely to assist the diagnosis or treatment of the participating patients it should be made available without delay to the clinician having overall responsibility for the patient's care.

4.3.6 Disposal or continued storage of identifiable results

The need for continued security and confidentiality remains important even if the study is completed. Storage of documents should be arranged as short- or long-term archiving within NIMR or in a secured archiving facility where NIMR staff who are responsible for the study should have access.

4.3.7 Publication

The publication of an article in a peer-reviewed journal is an essential in the development of a coherent and respected network of knowledge. Peer-reviewed articles support and embody the scientific method. Publishing results reflect the quality of the work of the authors and the institutions that support them (Refer to the publication guidelines for more information).

Essential requirements for publication are that research has been granted ethical approval from the beginning, through an Institutional Research Ethics Committee/National Health Research Ethics Committee (NatHREC) review of the protocol; results have been scientifically and ethically collected. Ethical conduct in publishing is a mutual responsibility of authors and NIMR, of editors and journal publishers (refer to the publication guidelines).

Since publication is an important output for research officers at NIMR, there shall be a development of the publication plans for each research centre to track the research output over time and this shall be monitored under the responsible directorate at Headquarters.

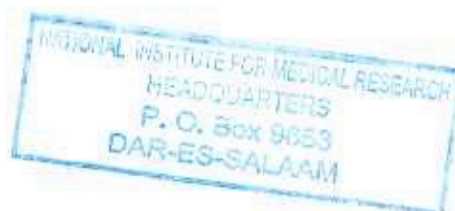
4.3.7 Permission to publish

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 to publish is shown in the Guidelines on Ethics for Health Research in Tanzania of 2023.

The application form for permission to publish is available in Appendix III.

4.3.8 Ownership of research data

- i. The National Institute for Medical Research owns the data and holds the original data even when the investigator leaves the Institute.



- ii. In case of data transfer, the data transfer agreement conditions must be fulfilled (Appendix II).

4.3.9 Communicating research findings through the public media

NIMR recognizes the potential pitfalls that researchers face when they talk to journalists and broadcasters. It also recognizes the need for a free and unfettered press in Tanzania. The popular media play a vital role in communicating research findings to the public and are critical to the wider process of dialogue and engagement. It is important that researchers are aware of how their subject area is covered in the media by addressing these areas:

- What are the main issues and areas of debate that are highlighted?
- Who are the principal actors quoted in the stories?
- Are scientists portrayed as 'divided' over relevant areas of research and their perceived implications?
- Are specific areas of risk highlighted?

Taking advantage of the opportunities offered by editorial coverage in the press, or on television and radio, brings a number of benefits. Public media reach very large audiences. Moreover, the credibility of messages is enhanced by a public perception of editors' impartiality. Television is particularly a powerful medium. The public regards television news especially as one of its most trusted information sources.

The broadcast media offer a cost-effective way of transmitting information. It does not involve costly and time-consuming production or reprographic processes – and dissemination is increasingly achieved by rapid and inexpensive electronic means. Researchers are encouraged to use broadcast media to communicate findings of the research to the general public.

The National Institute for Medical Research maintains responsible cooperation with all public news media in order to communicate scientific information and to cultivate understanding and appreciation of NIMR activities and of clinical research in general.

It is expected that Coordinating and Centre Directors as well as Principal Investigators should cooperate with the media at all times and to the best of their ability. However, all Principal investigators may liaise with the public media ONLY with the permission from the Director General.

Extra care should be taken of the “ingelfinger rule” when reporting research results: clinical research should not be reported in the scientific or lay press prior to publication in an appropriate peer-reviewed journal.

All researchers should observe the following:

- i. All researchers have a professional responsibility to communicate their research to public audiences and to offer appropriate guidance and advice where appropriate.

- ii. Keep up to date with media coverage of general and specific scientific area.
- iii. Attend workshops, seminars and conferences that enable scientists and journalists to meet and discuss relevant issues. Get to know how journalists work and the constraints faced by journalists.
- iv. If the work is at a preliminary stage or has yet to be published in a peer-reviewed journal, this should be made clear during the interviews.
- v. If the findings and conclusions differ from those of other established scientists in the field, make this clear. At the same time, don't talk up the 'novelty' aspect of the work just to appeal to the media.
- vi. Be especially careful when communicating risks or benefits identified in the research. The risk/benefit should always be expressed in a meaningful context that people can understand. The scientific jargons should be avoided.
- vii. Where the research has implications for lifestyle changes or public policy, it should be explained carefully. It is here that the maximum potential for distortion can arise.

The Directorate of Research Information and Regulatory Affairs is available to any NIMR member or any affiliated researcher for advice and guidance regarding contact with the public media.

4.3.10 Journal and the Media

Media reports of scientific research before it has been peer-reviewed and fully vetted may lead to dissemination of inaccurate or premature conclusions, and practitioners need to have research reports available in full detail before they can advise patients about the reports' conclusions.

An embargo system has been established by some journals to assist this balance, and to prevent publication of stories in the general media before publication of the original research in the journal. For the media, the embargo creates a "level playing field," which most reporters and writers appreciate since it minimises the pressure on them to publish stories before competitors when they have not had time to prepare carefully. Consistency in the timing of public release of biomedical information is also important in minimising economic chaos, since some articles contain information that has potential to influence financial markets.

NIMR emphasises the following principles:

- a) Authors should not publicise their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication of the original research in the journal.
- b) In case, the authors believe that their research has clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal; the Director General in liaison with the Chief Medical Officer of the Ministry of Health shall decide whether or not to disseminate information to the media in advance and should be responsible for this decision.



- c) Policies designed to limit pre-publication publicity should not apply to accounts in the media of presentations at scientific conferences or to the abstracts from these conferences.
- d) Researchers who present their work at a scientific conference should feel free to discuss their presentations with public media reporters but should be discouraged from offering more details about their study than was presented in the talk, or should consider how giving such details might diminish the priority journal editors assign to their work (see duplicate publication).

4.3.11 Ethics in Journal Publication

Things to avoid in publication include self-citing, obsolescence, ambiguity, and double publication.

Data reported in the manuscript must be factual, not plagiarised, altered or selective. It should be published in as concise a form as possible, without repetition in several journals (multiple/double publication) or subdivision into multiple small units ("salami" publication). Where others' work is cited, credit must be given through reference to the parent work. Unsubstantiated or exaggerated claims must be avoided.

4.4 POLICY MONITORING AND EVALUATION

For successful implementation of the research and guidelines policy there must be inherent monitoring and evaluation mechanisms. NIMR through DRCP shall establish a mechanism for monitoring and evaluation of the implementation of research and guidelines and Policy.

To achieve effective monitoring and evaluation the Research and Guidelines Committee shall be convening its regular meetings on an annual basis. Deliberations from the Research and Guideline Committee meetings shall be communicated to the respective stakeholders for further actions. Before the end of the implementation of this policy which last for five years, there shall be an evaluation for stock taking on what went well and identify areas for improvement. The output of such evaluation shall inform the review process for the coming policy.

Monitoring and Evaluation shall involve: -

- a. Establishment of mechanisms of accountability for monitoring and evaluating the implementation of the research policy and guideline.
- b. Establishment of a framework that will provide a basis for monitoring and evaluating the research and guideline and policy implementation at all NIMR levels.
- c. Establishment of a sound institutional framework for translating the goals, objectives and strategies outlined in the research policy into actual programmes at all levels, that is, Units/Sections, Centres, Directorates, and stations.



5 POLICY STATUS

This is a revised NIMR Research Policy and Guidelines.

6 STAKEHOLDERS CONSULTED

Stakeholders who were consulted during review are the following: Director General (DG), Director of Research Coordination and Promotion (DRCP), Director of Information and Regulatory Affairs (DRIRA), Centre Managers, Scientific Officers, Legal Officer, Planning Officer and collaborators.

7 DETAILS OF APPROVAL

The policy was approved by NIMR Council at its 141st meeting held on 2nd November 2023.

8 ENDORSEMENT DETAILS

The NIMR Council approved this policy at its 141st meeting held on 2nd November 2023.

9 RELATED LEGISLATIONS

NIMR Act 1979 Amendments 1997.

10 RELATED POLICIES AND OTHER DOCUMENTS AND GUIDELINES

- i. NIMR Research Policy of 2015
- ii. NIMR Intellectual Property Rights Policy of 2023
- iii. Guidelines on Ethics for Health Research in Tanzania of 2023
- iv. NIMR Strategic Plan VI of 2021-2026
- v. National Health Research Agenda of 2021-2026
- vi. Data Transfer Agreement for Researchers and Organisations
- vii. Material Transfer Agreement for Researchers and Organisations
- viii. Application Form for Permission to Publish
- ix. NIMR Overhead Policy of 2023

11 EFFECTIVE DATE FOR THE POLICY

The policy shall become effective from the date it is approved by NIMR Council, unless otherwise determined by the approving body,



12 NEXT REVIEW DATE

NIMR Research Policy and Guidelines will be reviewed after every FIVE years.

13 POLICY OWNER

NIMR Council shall own the NIMR Research Policy and Guidelines.

14 POLICY AUTHOR

The Directorate of Research Coordination and Promotion (DRCP)

15 CONTACT PERSON

Director of Research Coordination and Promotion (DRCP) - NIMR

