NATIONAL INSTITUTE FOR MEDICAL RESEARCH

Established in 1979

RESEARCH POLICY, GUIDELINES AND REGULATIONS

ACRONYMS/ABBREVIATIONS

AJSC	Annual Joint Scientific Conference
DITC	Director of Information Technology and Communication
DRCP	Director of Research Coordination and Promotion
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property
MDGs	Millennium Development Goals
MKUKUTA	Mkakati wa Kukuza Uchumi na Kupunguza Umasikini Tanzania
MoHSW	Ministry of Health and Social Welfare
MRCC	Medical Research Coordinating Committee
MTA	Material Transfer Agreement
NSGRP	National Strategy for Growth and Reduction of Poverty
NIMR	National Institute for Medical Research
TJHR	Tanzania Journal of Health Research
URT	United Republic of Tanzania
WMA	World Medical Assembly

EXECUTIVE SUMMARY

The National Institute for Medical Research (NIMR) was established under the Ministry of Health as a body corporate of the Government of the United Republic of Tanzania by the Act of parliament No. 23 of 1979. The Act gives NIMR dual mandates, as a health research institution and as a national regulatory authority of health research undertaken within Tanzania. As a health research institution, NIMR is mandated to carry out medical research designed to alleviate disease among the people of Tanzania. On the other hand as a regulatory authority it is mandated to monitor, control, coordinate and promote the carrying out of medical research within Tanzania.

This Research Policy, Guidelines and Regulations shall apply to all members of staff, visiting researchers, graduate, undergraduate students and any other person who are involved in health research at NIMR. The policy shall also apply to all NIMR research partners and collaborators.

Health research capacity building and strengthening in NIMR is key for the fulfilment of research and regulatory mandate of the institute. On this realization, NIMR needs to put in place an operational mechanism of conducting research such that there is uniformity in the process as well as progressive advancement of the institute. NIMR shall therefore, make sure that all staff are well aware of the national health research priorities and actively participate in translating and integrating them into research agenda of their respective health research disciplines. NIMR shall also ensure the adoption of a common operational framework in preparation, processing and approval of health research protocols.

Health research funding remains the single most critical bottleneck in research performance. It is appreciated that for sustainability and relevance, the main source of health research funds shall be the Government of the United Republic of Tanzania. Recently with due recognition of the need to invest in research, the government is allocating at least 1% of the annual GDP to research programmes. However, national funding has continued to be extremely low and health research activities have remained largely donor-driven. Therefore, there is a need to ensure that the government decision to substantially increase research funds is reciprocated by enhanced health research at NIMR.

In order to stimulate and motivate research and reward productivity, all funded health research projects should include a budget item on research allowances and other remunerations which must be attractive, comparable and competitive in order to retain quality staff. NIMR shall inculcate and establish a culture that recognizes transparent criteria/indicators to measure research excellence and annually reward health research performance at individual, departmental and directorate/centre. NIMR shall ensure that, health research output constitutes a major criterion in the promotion of scientific staff. Subject to the Intellectual Property Policy, NIMR shall encourage the incorporation of the dissemination of research results in the research proposals. NIMR shall require research projects to contribute at least 15% of the total project research costs to the institutional overheads.

NIMR shall as far as feasible endeavour to manage, coordinate and make attractive health research support environment. Areas that deserve specific attention will include maintenance of health research infrastructure, support of purchase of basic consumables, the provision and continuous improvement of modern information and technology systems and facilitated access to international literature and databases, provision of research administration allowance, provision of support for publication and distribution of the Tanzania Health Research Journal (THRJ) and development and maintenance of data repositories.

NIMR shall ensure that all health research involving human subjects conform to the recommendations as adopted by the 18th World Medical Assembly (WMA), Helsinki, Finland, June 1964, and its amendment by the 59th WMA, Seoul, October 2008. NIMR shall ensure that sponsored project agreements include the terms and conditions for the disposition of tangible properties (e.g. equipment, vehicles reports, theses or dissertations) or intangible properties such as rights in data, copyrights and inventions. Except as otherwise expressly provided, all equipment purchased within a research project shall be the property of NIMR. The laws of Tanzania apply. Policies and procedures governing the disposal of NIMR property (obsolete or otherwise) shall be applied.

CHAPTER 1

INTRODUCTION

1.1 Background

The National Institute for Medical Research (NIMR) is the largest public health research institution in Tanzania. It was established by the Government of the United Republic of Tanzania (URT) through Parliamentary Act No. 23 of 1979 as a parastatal service organization 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.

NIMR was established to perform the following functions: (i) carrying out and promoting the carrying out of medical research designed to alleviate disease among the people of Tanzania; (ii) carrying out and promoting 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) cooperating with the government or any person, or body of persons, in promoting or providing facilities for, the training of local personnel for carrying out scientific research into medical problems; (iv) monitoring, controlling and coordinating 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) establishing 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) establishing 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; (vi) controlling and managing the affairs of Centres vested in the Institute; (vii) assuming responsibility for the control and management of any other Centres that may be established by the Institute or vested in the Institute; and (viii) doing anything necessary to uphold and support the credit of the institute and its research findings to obtain and justify public confidence and facilitate the proper and efficient performance of its functions.

Vision: To be an outstanding institution for advancement of health research excellence in Tanzania and beyond

Mission: To conduct, coordinate, regulate and promote scientifically and ethically sound, high quality health research and deliver evidence-based information that is responsive to the needs of human wellbeing

Core Values

- Integrity
- Accountability
- Unity
- Innovation
- Quality

1.2 Governance and Structure

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 is made up of a Chairman and twelve members. The Council Chairman is appointed by the President of the United Republic of Tanzania (URT), whereas other Council members are appointed by the Minister for Health. The Council operates through three committees, namely 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 Centre Directors at the Centre level. The Coordinating Directorates are: (i) Finance, Human Resource, Planning and Administration; (ii) Research Coordination and Promotion; and (iii) Information Technology and Communication.

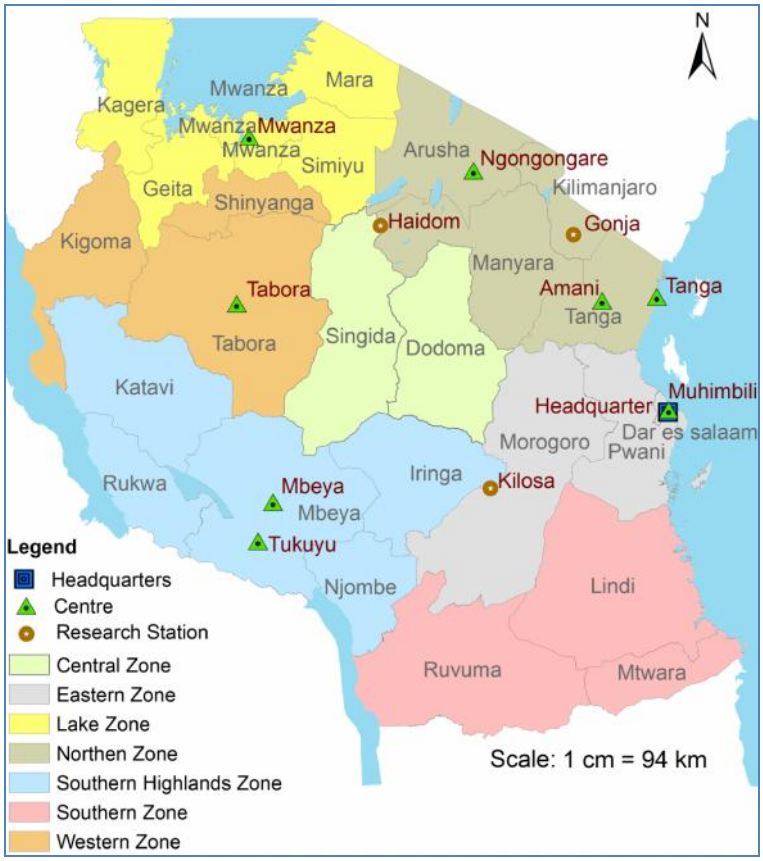

Figure 1: Research Centres and Station of the National Institute for Medical Research

1.3 Research Centres and Research Areas

The NIMR's headquarters are in Dar es Salaam and the Institute has eight centres and five research stations in different regions of Tanzania (as shown in Figure 1).

1.3.3 Research areas

Health research conducted by NIMR is guided by National Health Research Priorities and the NIMR Strategic Plan. The research priorities are categorized into: (i) Biomedical Research, (ii) Health Systems and (iii) Social determinants of health

The Institute disseminates research information through different formats and channels including its quarterly published *Tanzania Journal of Health Research (TJHR)*. The Journal, established in 1997, is available on-line since 2007. Others include publications in international peer reviewed journals, newsletters, research summaries, fact sheets, and evidence briefs. Since 1982, the NIMR has been organizing, without failure, an Annual Joint Scientific Conference (AJSC). The AJSC provides a forum for researchers, practitioners, policy makers and the media to share and discuss research results and experiences on issues related to health and suggest potential areas needing further research or new areas for research. This provides an opportunity for the conference participants to think more critically on more innovative research approaches for better results and knowledge sharing.

CHAPTER 2

OBJECTIVES OF THE NIMR RESEARCH POLICY

In line with the National Research Policy, the National Strategy for Growth and Reduction of Poverty (NSGRP) or Mkakati wa Kukuza Uchumi na Kupunguza Umaskini Tanzania (MKUKUTA), Millennium Development Goals (MDGs) and Vision 2025, the NIMR Research Policy aims at inculcating a health research culture among NIMR staff and collaborators by:

2.1 Providing a mechanism of ensuring that research conducted by NIMR:

a. Is in line with national health research priorities;
b. Addresses local, regional and global health problems of public importance;
c. Aims at addressing health research questions identified in different health researches institutionally, nationally and internationally.

2.2 Providing attractive terms and conditions of service for researchers so as to motivate research and reward productivity.

2.3 Strengthening the health research infrastructure in NIMR by placing due emphasis on institutional development and improving logistical and technical support to health research operations.

2.4 Identifying, promoting and developing special talents among NIMR researchers and support staff with a view to developing a critical mass of Research Scientists and support staff in NIMR.

2.5 Encouraging collaborative research between scientists within NIMR and researchers in other Research and Development (R&D) institutions within and outside the country, to promote a multidisciplinary approach.

2.6 Improving the linkage between health research and the application of research results in guiding policy and best practices action in the health sector.

2.7 Encouraging and rewarding individual initiatives in securing research funds.

2.8 Establishing research quality assurance system.

2.9 Facilitating repackaging of research information to ensure dissemination of friendly research findings within and outside NIMR.

CHAPTER 3

RESEARCH POLICY GUIDELINES

3.1 Research Priorities

Tanzania faces challenges of achieving improved health and well-being of its people in the face of severe resource limitations. Because of these challenges NIMR has had to find an acceptable way of identifying priority areas for health research in Tanzania. NIMR, therefore, sets out its research priorities in line with the national development agendas, including Vision 2025, the MDGs and MKUKUTA. NIMR priorities should be addressing health problems that cause or are the major contributors to burden of diseases for which cost-effective interventions are available or need to be made available.

In view of limited resources it is imperative for NIMR to establish priorities. To that end:

a. NIMR centres and stations shall define the relevant national health research priorities as per their specializations which shall come to the Management as centres/stations research agenda.
b. The institute shall fund or support soliciting funds of research programmes and projects that are within the NIMR priorities.
c. NIMR shall encourage research aiming at solving national health problems and advancing knowledge.
d. NIMR shall encourage collaboration within and across all centres and stations as well as national and international institutions.
e. The Directorate responsible for research coordination and promotion shall, from time to time, identify emerging priority areas of national and international interests for health research within NIMR. These will be areas in which health research could contribute to major health gains in the society, leading to improved health, poverty reduction and socio-economic development.
f. NIMR recognizes the freedom of its Scientific and Support staff to initiate and pursue research consistent with NIMR's vision and mission.
g. NIMR shall develop and review health research agenda every five years with the objective of ensuring it is relevant to the existing situation.

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

Health research has to be performed within a clear framework with targets, responsibilities, and outputs. To maximize the use of available scarce resources and avoid duplication, NIMR shall therefore;

a. Strengthen the research regulatory, promotion and coordination infrastructure;
b. Endeavour to establish and maintain environment that facilitate health research planning, monitoring and evaluation;
c. Ensure a critical mass of health research administrators who have qualifications in health research management;
d. Strengthen the capacity for health research planning at all levels;
e. Create a mechanism by which scientific staff can be motivated to conduct high quality health research;

f. Ensure that funding of health research by major donors is coordinated centrally and sanctioned by NIMR;
g. Encourage a multidisciplinary approach to health research.

3.3. Sourcing and Management of Research Funds

It is a matter of fact that for sustainability, relevance and socio-economic development, main source of health research funds should be the Government of the United Republic of Tanzania. The government is allocating at least one per cent (1%) of its Gross Domestic Product (GDP) to research programmes, despite that, national funding has continued to be extremely low and health research activities are still largely donor-driven. Available information indicate that the government funding to research institutions in support of research programmes reached 0.012% of the GDP as of 2003/2004, fiscal year. As a consequence, there are limited Tanzanian research projects and programs addressing the national development agenda. In addition, contribution to research funding by the private sector remains negligible in Tanzania. On this background, there is a need to make use of the Government allocation of 1% GDP. In this respect, NIMR shall:

a. Timely disseminate information to scientific staff about the budget allocated for research by the government of Tanzania.
b. NIMR shall create conducive environment for its researchers to develop research proposals to secure funds from the government.
c. NIMR shall encourage its scientific staff to solicit funds from the development partners and the private sectors to support the central research fund in addressing national health research agenda.
d. NIMR shall maintain a separate budget line for health research funding coordinated and presented by the Directorate responsible for research to MRCC and Governing Council.
e. Provide general information on possible sources and modes of research funding both within and outside the NIMR on regular basis.
f. Establish professorial research chairs in centres and stations
g. Create adjunct position for non-NIMR researchers.

The allocation of Research Funds in transparent manner is important for successful implementation of health research projects. NIMR shall therefore:

a. Ensure that the disbursement of funds follows approved accounting procedures.
b. All health research funds are deposited in NIMR account
c. Ensure that funds are disbursed by instalments as imprests, the management of which will be approved by the relevant NIMR organs.
d. Ensure that funds are disbursed according to the approved budgetary and timely allocation. Re-budgeting among major cost categories will not be allowed unless prior approval is obtained from the funding agency.
e. Require that recipient of research funds timely produces and submit to the relevant authorities, both technical and financial reports.

3.4 Procedures for Approval, Control and Monitoring of Research Process

3.4.1. NIMR has put in place an operational mechanism for research registration and ethical approval that there is uniformity in the process. NIMR shall therefore:

a. Ensure that scientific staffs are well aware of the national health research agenda and align with it when planning for research projects and programs.
b. Give priority to projects which address the national health research agenda when approving research projects and programs for funding.
c. NIMR scientists shall follow a uniform general framework guiding the preparation and approval of health research projects. The framework addresses the following issues/processes:
    i. Initiation of research project
    ii. Formats of research proposal; scrutiny and approval process for research proposal shall focus on quality, relevance, need, soundness and resource requirements (including financial resources). This will clearly spell out the roles and powers of different organs within the NIMR administrative hierarchy
    iii. Planning and budgeting guidelines, including applicable rates for cost estimates (professional fees, daily subsistence allowance, etc.)
    iv. Financial regulations governing financing of research
    v. Procurement of equipment and consumables. These have to be within the relevant national procurement policies and procedures. In principle all equipment procured for research is the property of NIMR
    vi. All research projects shall be registered with the Directorate responsible for research coordination and promotion. Registration of research projects is mandatory, whether internally or externally funded. Standard contracts between the funding agency and NIMR will be entered and copies of such contracts will be deposited in the Directorate responsible for research coordination and promotion. The Directorate shall also receive progress and final project reports. Regulations regarding employment within research projects will be spelt out by the Directorate responsible for research coordination and promotion in collaboration with Directorate of Finance, Human Resources and Planning, and these have to be within approved Human Resource Management Policies in Tanzania
    vii. Format for final research reports shall be provided by the Directorate responsible for research coordination and promotion, and updated from time to time.
d. Enter into a research contract with the non-NIMR researcher(s) when the project has been approved and the source of fund is legally acceptable one. The duration of such contract will be the same as the duration of the project in question.
e. When there is an interest of joint ownership of research results/outputs, the contract shall be between the researcher(s) as one party and joint financiers as the other parties and NIMR's Director General will be the trustee of NIMR researchers for the contract signed.
f. Scrutinize all contractual requirements to be fulfilled as planned after a proposal has been funded. Any proposed change shall be agreed upon by all parties in a fair, participatory, genuine and transparent manner.

3.4.2. 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. Develop and disseminate health research quality guidelines.
b. Ensure that the applications for health research funds are in line with the guidelines
c. Ensure that approval of applications for research funds takes into consideration the relevant health research quality checklist.
d. Reviewing and approving health research proposals and protocols, and ensuring that the research will be in the spirit of promoting health, preventing disease and disability and curing disease.
e. Monitoring approved proposals to ensure compliance with the guiding ethical standards.
f. Ensuring research conforms to generally acceptable ethical and scientific principles, and is based on adequately tested procedures.

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 staffs are the major resources. For NIMR to develop and assimilate the indigenous and foreign technologies it has a duty to identify, nurture and promote special talents among its scientific members of staff. To this end NIMR shall therefore:

a. Ensure that all funded projects have components to facilitate health research capacity building and technology transfer.
b. Facilitate training by encouraging programmes rather than projects.
c. Endeavour to ensure that each research plan demonstrates ways in which capacity building has been or it is being addressed.
d. Make provision for mentoring as an essential component of every research programmes/project.
e. Strengthen and emphasize research training both at undergraduate, postgraduate and on-job training through instituting appropriate specialty courses.
f. Facilitate the writing of fundable project and program proposals.
g. Advocate for increased government funding for undergraduate, postgraduate and on-job training for scientific staff.
h. Updating and expanding researchers' skills continually through strategic international exposure and linkages.

3.6. Collaborative Research

There is a need to facilitate strategic partnerships and collaboration within and between NIMR, the Government, other research institutions and the private sector within and outside the country. Therefore, NIMR shall:

a. Promote collaborative research where there are potential benefits to the institute.
b. Promote external collaboration within and outside Tanzania.
c. Require that a full-time employee of NIMR serve as the Principal or Co-Principal Investigator.
d. Require a valid contract if collaborative research project involves a foreign

researcher in need of biological/chemical materials from the country. The contract should state duration, technical supervision, deliverables with reference to NIMR's Material Transfer Agreement (MTA), Data Transfer Agreement (DTA), rules and regulations, confidentiality with reference to NIMR Intellectual Property (IP) policy, publication rights, other services required from NIMR, payment and payment modalities and reports (especially progressing scientific reports and financial report on funds received), as well as responsibilities and timing for the activities planned. Neither the Institute's Authorities nor the researchers should sign a contract on behalf of the other party without such a party either knowing or expressing consent to accept the consideration and enter into contractual agreement. A breach of any of these agreements/elements may lead to failure of the contract either to be signed by one party or to be implemented successfully, and when it comes to worse, legal penalty may be accompanied.

e. Encourage internal collaborative projects to be multi-disciplinary in nature.
f. Ensure that multi-disciplinary research projects are hosted in centres/stations where the principal researcher belongs.
g. Require that the hosting centres/stations also be the place where the majority of the research activities will be conducted.
h. Require that multi-disciplinary research projects be approved by the centres/stations of the Principal Investigator.
i. Ensure that staff participating in the multi-disciplinary collaborative research project report progress to their own centres/stations, and also report to the hosting centres/stations through the Principal Investigator.
j. Ensure that the collaborating centres/stations agree on sharing administrative costs.
k. 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.
l. Promote equal partnerships in collaborative research.
m. Ensure that updated central records of materials and data shared or transferred out of Tanzania during collaborative research are prepared and maintained
n. Promote Transfer of technology

3.7. Staff Remuneration

In order to motivate research and reward productivity:

a. All funded research projects should include a budget item on research allowance and other remuneration for all investigators and other staff involved in the project/programme.
b. Where daily subsistence (per diem) allowances are paid, these shall be paid at not less than the Government of Tanzania daily subsistence allowance rates.
c. Negotiations for 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 responsible Directorate. This is to provide for the laid down procedures to be followed to ensure that NIMR benefits from the research/consultancy carried out by its staff.

3.8. Research Performance Rewarding

The National Institute for Medical Research 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. Ensure that research outputs constitute a major criterion in the promotion of scientific staff.

3.9. Institutional Administrative Overheads

To create conducive research environment, NIMR requires each research project to contribute 15% of the total project research costs as institutional overheads. If it is a consultancy, then a 30% contribution to the same as for the research item should be effected (as per NIMR Financial Guidelines).

3.10. Sharing of Research Resources

3.10.1 NIMR through the Directorate of Research Coordination and Promotion shall:

a) Require that centres and stations have transparent and on active criteria of making research opportunities known to members of staff and for allocating such opportunities.
b) Encourage sharing of research project resources among all NIMR researchers in order to utilize fully the research resources available.
c) c. Encourage and coordinate sharing of information and information sources of scientific value. Such sources shall include books, journals, electronic information, and sources of such electronic information. d. Set up mechanisms/procedures for utilizing and sharing resources and facilities across centres and stations.
d) Establish mechanisms for assisting researchers to obtain equipment and supplies and to prepare financial reports.
e) Establish a national health research database to enable researchers to access the research inventory and provide data handling facilities.

3.10.2. NIMR staff may not use NIMR resources, including facilities, personnel or equipment, except in a purely incidental way as part of their outside consulting activities or for any other non-NIMR purposes, unless they have a written approval from the Directors/Heads of respective centres/stations

3.11 Research Support Environment

Through the Co-ordinating Directorates and Centre Directors, 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. Provide basic financial management support and training to research coordinators as well as personnel in key research administrative units.
d. Ensure that validated research outputs database will be used for all matters relating to staff research activities.
e. Publicity of NIMR research activities and seek ways to make research findings available to the wider community.
f. Provide support for publication in moral, technical, logistical and/or material support as may be requested by the researchers and allied research staff.
g. 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.

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. Subject to the NIMR intellectual property policy: NIMR shall:

a. Encourage the incorporation of a specific section on dissemination of research results in the research proposals. Different ways of sharing research results at centres/stations include seminars, workshops, annual research meetings/workshops, policy brief meetings, newsletters, media interviews such as radio or television.
b. Require that 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.
c. Ensure that research reports are produced according to the agreed format. Depending on the level of research and the funding agency, research reports may be reviewed at the Directorate/Centre/Station levels.
d. Ensure that all manuscripts prepared for publication are submitted and permission to publish is sought from the Director General prior to the paper submission process takes place. This is to allow the NIMR authorities to be informed of what is contained in the paper and to scrutinize any possible sources of conflict of/competing interests that may be disadvantageous to either NIMR or NIMR staff. The Director General office shall provide feedback to authors within 14 days of submission of the request.
e. Subject all research reports to peer-review before depositing them in the data repository. Require that each centre/station conduct at least one research workshop annually to review research plans, progress and outputs. Annual research workshops shall also include presentations of scientific papers, to which key stakeholders shall be invited.
f. Prepare and submit to policy makers' research summary/evidence (policy) briefs for the purpose of informing policy. Both English and Kiswahili versions of research summaries and evidence briefs must be submitted through the Directorate responsible for Information Technology and Communication.
g. Encourage and support dissemination of research results through regular local and international fora.

h. Encourage and support the inclusion of research findings/publications in accessible institutional electronic databases.
i. Encourage the publication of popular versions of research findings in the local media with the permission of NIMR Director General, including some in Kiswahili.
j. Disseminate research findings through national/international exhibitions in line with National Research Ethics Policy.
k. 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 organized by the institute.

3.13 Ethical Considerations

3.13.1 All research involving human participants should conform to the recommendations guiding biomedical research involving human being according to the Helsinki Declaration, Finland, June 1964, and its amendment by the 59th WMA, Seoul, October 2008 as adopted by the World Medical Assembly (WMA). Recommendations include the following:

a. Research should conform to generally acceptable scientific principles, and should be based on adequately tested procedures.
b. The design of the study should be scientifically formulated.
c. The study should be conducted by scientifically qualified persons and under the supervision of competent persons.
d. The importance of the objectives must be proportional to the inherent risk to the participant.
e. Concern over the interest of the study participant must always prevail over the interests of science and society.
f. Privacy of the individual must be respected.
g. The Researcher should refrain from carrying out the study unless he/she is satisfied that the hazards involved are believed to be predictable and well addressed.
h. In publishing results, the researcher is obliged to preserve the accuracy of the results.
i. Each potential research participant must be adequately informed of the aims, methods, anticipated benefits, and potential hazards.
j. The researcher should obtain participants freely-given informed consent, preferably in writing.
k. The research protocol should always contain a statement of ethical considerations.

3.13.2. The statement of ethical considerations should include the following:

a. The risk to the study participant.
b. The anticipated benefits to the study participants and others.
c. The importance of the knowledge that may reasonably be expected to be obtained.
d. The informed consent process to be employed. This should include what the participation of the research participants will entail, including any possible risks. The provisions to protect the privacy of study participants must be observed.

e. The additional safeguards for study participant likely to be vulnerable to coercion or undue influence including foetuses, pregnant women, children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.
f. Compensation for research-induced injury, time and inconvenience.

3.13.3. All research involving human participants in Tanzania shall require Ethical Clearance by the Medical Research Coordinating Committee (MRCC), regardless of whether the research is cleared by other institutions within or outside the country, if the research:

a) Is sponsored by United Republic of Tanzania or
b) Is conducted by or under the direction of an employee of NIMR, or using any property or facility of NIMR, or
c) Involves the use of the NIMR's name to identify or contact study participants or prospective participants, or
d) Involves human participants within NIMR.

3.13.4. Research on Animals

a) All research, research training, experimentation, biological testing, and related protocols involving live, vertebrate animals conducted in NIMR, or at another institution as a consequence of sub-granting or subcontracting, shall comply with internationally acceptable standards on humane care and use of laboratory animals.
b) NIMR will make reasonable effort 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.
c) 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.
d) 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.
e) 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.
f) 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.

3.14. Bio-hazardous Agents

a. The appropriate NIMR committee will be designated to review the institution's training/teaching projects, research activities and facilities involving the acquisition, use, storage and disposal of bio-hazardous agents.
b. NIMR shall endeavour to provide appropriate training in the safe handling and management of biological and chemical hazard agents used in research studies.

c. Research proposals involving use of bio-hazardous agents shall include a section on handling of bio-hazardous materials.
d. NIMR shall ensure that products of hazardous chemicals and reagents as well as expired materials are appropriately disposed according to the local and international guidelines. Each laboratory/Centre/Station working with such materials shall develop and maintained updated standard operating procedures for disposal of chemical and biological hazardous materials.
e. NIMR shall ensure that its facilities and staff refrain from producing and maintaining biological materials which can be used as warfare or terror agents.

3.15. Intellectual Property Rights

All participating researchers must sign the NIMR Intellectual Property Policy Agreement form before the commencement of any research activities. For researchers wishing to send research samples/data abroad, either for analysis or other research purposes, should sign the Tanzania Material or Data Transfer Agreement Form.

3.16. Use and Disposal of Research Project Resources

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 he title to all equipment purchased for the project or programme. 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 a feedback/follow up mechanism to foster continued refinement of the research impact in solving societal problems.
b. Utilize the feedback mechanism to foster continued refinement of the research agenda.

3.18. Research culture

The National Institute for Medical Research shall:

a. Instil a research culture through training of scientific staff in respective research specialty.
b. Contribute towards fostering and enhancement of research culture both within and outside NIMR.

c. Promote and encourage research teamwork among NIMR staff and other institutions.
d. Educate NIMR staff on the research policy and procedures.
e. Attract young students from high learning institutions with interest and potentials to join the research career.

3.19. 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. It shall also apply to all NIMR research partners and collaborators.
b) The NIMR Research Policy shall be subject to review every five years.
c) 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 is necessary in order to kick-start the streaming of research management. The strategies and some of core operational procedures are presented in chapter 4.0.

CHAPTER 4

STRATEGY FOR IMPLEMENTING THE RESEARCH POLICY GUIDELINES

The National Institute for Medical Research aims to provide a research policy implementation strategy that will promote a comprehensive and high standard of professional conduct of its researchers, and a culture of research practice that is ethical, competent, transparent, safe and accountable.

4.1 Principal strategy

The principal strategy in carrying out the NIMR's research policy lies in the strengthening of the directorate in charge of research, followed by the consolidation of the research administrative infrastructure. The roles, duties, and responsibilities of the directorate will have to reflect its obligations in implementing this policy. The following actions are necessary for the successful implementation of the research policy:

a. Enhancement of the capacity of the directorate to manage, administer and coordinate research. This will need trained human resources, establishment of a more effective structure, equipment and some initiation funds. The directorate will have the responsibility of coordinating internal and external linkages on all matters related to research.
b. 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.
    i. Hands-on work on NIMR policies to ensure that research interests are safeguarded.
    ii. Establishment of a close working cooperation with other relevant offices to implement the NIMR Strategic Plan.
    iii. 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.
c. 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. Standardizing internal research administrative mechanisms
iii. Ensuring that research funds from public, private and external sources are secured.
iv. Actively assisting in the dialogue between researchers and research clients.
v. Ensuring and supporting marketing of research results where appropriate.
vi. Acting and serving as a custodian of research outputs on behalf of NIMR by keeping a register of all R&D activities and acquisition of patents.

vii. Publishing of regular Tanzania Health Research Journal and Research Annual Reports on the status of research activity within NIMR.

4.2 Managing Research

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

a. Identify possible sources of research resources – national and international – and strategies for mobilizing/accessing the same;
b. Ensure that pertinent information relating to specific research opportunities is passed on to relevant NIMR organ;
c. Make widely and continuously available general information on possible sources and modes of research funding on regular basis. This information shall be available in hard and web based e-format. A mechanism shall be put in place to make sure that e-format is only accessible by NIMR staff;
d. Hold regular research resources mobilization workshops in which new opportunities for research funding shall be presented and discussed;
e. Assist the liaison process with research donors where such donors have been identified through the directorate;
f. Set up liaison relationships with other national stakeholders to form pressure/lobbying groups to contend for an increased share of research funding from government, the private sector and the international donor community;
g. Collaborate closely with potential researchers in preparing research proposals for submission to potential donors;
h. Compiling relevant reports of various research projects for onward transmission to the donors;
i. Proposing specific operational modalities in line with the NIMR Research Policy for the various research funding sources for approval;
j. 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 utilized for the purpose;
k. 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 multi-disciplinary research teams; and
l. Annually compile the NIMR Annual Research Report that shall summarize annual activities performed under all research grants in a standard format to be approved by the NIMR Management.

4.3 Dissemination of Research Results

a) Sustain and continuously update NIMR research activity database. In this respect, selected information shall be published on regular basis onto a NIMR research web page;
b) 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: (i) Sustain compilation and organization of printing hard copies of the project on annual basis; and (ii) Produce brochures to market institutional research services

4.4 Research Quality Management

The directorate responsible for research coordination 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
f. Facilities and access to information resources
g. Proportion of staff according to NIMR staff Regulations
h. Proportion of staff directly doing research
i. Time duration of research degrees
j. Indicators that measure society perceptions on the research that NIMR staff do
k. Number of clients continuously using NIMR research services
l. Number of local/international research assignments that NIMR wins in a competitive environment
m. Collaboration with regional and international institution – establishment of active research networks
n. Subsequent availability of funds for the research following completion and dissemination of a phase of the research.

The directorate for research coordination and promotion shall recommend to the NIMR Management on what benchmarks of these indicators should be for NIMR.

4.5 Research process tools/instruments

In order to standardize and harmonize research process within NIMR, the Directorate responsible for research shall provide clear guidelines in form of guiding documents. These guiding documents shall be reviewed regularly to accommodate developments in the operating environment. The directorate responsible for research within NIMR 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.

CHAPTER 5

RESEARCH COMMUNICATION AND PUBLICATION GUIDELINES

5.1 Background

These guidelines are developed for the fact that all investigators have responsibilities to share possible benefits of research results with research participants, practitioners and policy makers.

5.1.1 Rights of participants to results of research

i. In studies that involved sustained co-operation on the part of participants, it is good practice to make arrangements to inform them of the outcome of the research, in broad terms, and to combine this with a letter of thanks
ii. The benefits of research are to be made available to the research population and the local communities from which they were drawn, and adequate reports of the research must be made publicly accessible within the reasonable period of time.
iii. All research participants should be informed of the outcome (s) of the research in which they were involved.
iv. Where communities are researched, they should be told the results of the study – such as on disease prevalence within their communities. 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.

5.1.2 Right of clinicians on accessibility of research results

Information that emerges in the course of research and is likely to assist the diagnosis or treatment of the participating patient should be made available without delay to the clinician having overall responsibility for the patient's care.

5.1.3 Disposal or continued storage of identifiable results

When the research is complete, the need for continued security and confidentiality remain. Storage of documents should be arranges as short or long term archiving within NIMR or in a secured archiving facility where NIMR staff who was responsible for the study should have access.

5.2. Publication and authorship

5.2.1 Introduction

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

Those engaged in research have a moral obligation to share their findings with other investigators, society and policy makers, for mutual benefit of all. There are personal pressures on investigators to publish, and institutions in Tanzania also benefits from the volume and quality of their research outputs.

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; that results have been honestly gathered and reported and that due credit has been given to collaborators. Research results are usually published in scientific journals after peer review. Ethical conduct in publishing is a mutual responsibility of authors and NIMR, of editors and journal publishers.

5.2.2 Authorship

Authorship of a manuscript should be settled as early as possible, the main criterion being **public accountability for content of the paper**. The assignment of the authorship may cause problems. Loose assignment of authorship degrades the value of the efforts put in by those who truly qualify as authors. Those who genuinely deserve authorship should not be deprived of it. Open communication among all the individuals in research is a guarantee of serving the best interests of all. The National Institute for Medical Research endorses the recommendations of the International Committee of Medical Editors which are reproduced below:

5.2.3 Guidelines on authorship

International Committee of Medical Journal Editors

Each author should have participated sufficiently in the work to take public responsibility for the content. This participation must include:

i. Conception and design, or analysis and interpretation of data, or both;
ii. Drafting the manuscript or revising it for critically important intellectual content;
iii. Final approval of the version to be published.

Participation solely in the collection of data does not justify authorship. All elements of an article (i, ii, and iii above) critical to its main conclusions, must be attributable to at least one author. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

A manuscript with corporate (collective) authorship must specify the key person responsible for the article; other contributing to the work should be recognised separately. This means, authorship credit should be based on:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it critically for important intellectual content;
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

When a large, multicentre group has conducted the study, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above.

5.2.1.2. Acknowledgements of intellectual contributions that falls short of authorship
All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include funding institutions, a person who provided purely technical help, writing assistance, critical review of the manuscript, data collection, participation in clinical trial, or a Head of Department/Centre Director who provided only general or logistic support.

5.2.1.3. Corresponding author
A corresponding author is meant to facilitate correspondence between the editor and authors, and work on behalf of all the other authors. She or he may also convey the decision of her/his other co-authors to the editor.

She/he cannot take a unilateral decision to include or drop any co-author. For any such decision, the concurrence of all the other co-authors (excluding the one to be dropped), in writing, before submission of the manuscript for publication is essential and must be reported to the Director responsible for Information Technology and Communication.

As regards inclusion of a new author later, not only all co-authors must agree, the concerned co-author must himself express agreement in writing and submit the request to the Directorate of Information Technology and Communication. The reason for late inclusion should be provided justified by the senior/corresponding author.

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

i. The title of the original project/programme.
ii. The Ethical Approval Certificate (Reference) Number.
iii. The manuscript to be published with names of authors and their respective institutional affiliations and their contribution.

Application form for permission to publish is available as Appendix III

5.4. Clinical studies
Any work involving clinical research should conform to the guidelines issued in the Declaration of Helsinki, and must have received ethical committee approval; details of this should be stated in the manuscript. NIMR supports the registration of trials as an important initiative to improve the reporting of clinical studies. Trial registers that currently meet all of the International Committee of Medical Journal Editors and World Health Organization requirements can be found at http://www.icmje.org/faq.pdf

5.5. Ownership of research data

5.5.1. The National Institute for Medical Research owns the data and holds the original data should the investigator leaves the Institute.

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

5.6. Communicating research findings through the public media

5.5.1. NIMR recognizes the potential pitfalls that face researchers 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. 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 scientists 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 Information Technology and Communication is available to any NIMR member or any affiliated researcher for advice and guidance regarding contact with the public media.

5.7. 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 minimizes 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 minimizing economic chaos, since some articles contain information that has potential to influence financial markets.

NIMR emphasizes the following principles:

- Authors should not publicize 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
- 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.
- Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific conferences or to the abstracts from these conference.

- 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 detail about their study than was presented in the talk, or should consider how giving such detail might diminish the priority journal editors assign to their work (see duplicate publication).

5.8. Secondary Publication

Certain types of articles, such as guidelines produced by governmental agencies and professional organizations, may need to reach the widest possible audience.

Secondary publication for various other reasons, in the same or another language, especially in other countries, is justifiable, and can be beneficial, provided all of the following conditions are met.

(a) The authors have received approval from the editors of both journals; the editor concerned with secondary publication must have a photocopy, reprint, or manuscript of the primary version.

(b) The priority of the primary publication is respected by a publication interval of at least one week (unless specifically negotiated otherwise by both editors).

(c) The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.

(d) The secondary version faithfully reflects the data and interpretations of the primary version.

(e) The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference.

(f) The title of the secondary publication should indicate that it is a secondary publication (complete republication, abridged republication, complete translation, or abridged translation) of a primary publication.

5.9. Conflict of interest

It is the NIMR publication requirement for authors to list conflicts of interest by entity, followed by the type of relationship. The time frame for reporting conflicts related to the submitted work now spans from the initial conception and planning to the present, which makes more sense than a specific number of years. "Conflict of interest exists when an author (or the author's institution) has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties).

Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion. All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Disclosure of such relationships is also important in connection with editorials and review articles, because it can be more difficult to detect bias in these types of publications than in reports of original research.

5.10. Scientific misconduct in publication

NIMR shall not entertain scientific misconduct in publication. Individual involved in scientific misconduct will face disciplinary actions as determined by the Medical Research Coordinating Committee. Scientific misconduct in publication includes but is not necessarily limited to multiple publications; data fabrication; data falsification including deceptive manipulation of images; and plagiarism.

5.10.1. Duplicate Submission and Publication

Authors should not submit the same manuscript, in the same or different languages, simultaneously to more than one journal. The rationale for this standard is the potential for disagreement when two (or more) journals claim the right to publish a manuscript that has been submitted simultaneously to more than one journal, and the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review, edit the same manuscript, and publish the same article.

Duplicate publication is publication of a paper that overlaps substantially with one already published, without clear, visible reference to the previous publication. Readers of medical journals deserve to be able to trust that what they are reading is original unless there is a clear statement that the author and editor are intentionally republishing an article (which might be considered for historic or landmark papers, for example). The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources. Duplicate publication of original research is particularly problematic because it can result in inadvertent double-counting of data or inappropriate weighting of the results of a single study, which distorts the available evidence.

When authors submit a manuscript reporting work that has already been reported in large part in a published article or is contained in or closely related to another paper that has been submitted or accepted for publication elsewhere, the letter of submission should clearly say so and the authors should provide copies of the related material to help the editor decide how to handle the submission. See also Section IV.B.

This recommendation does not prevent a journal from considering a complete report that follows publication of a preliminary report, such as a letter to the editor or an abstract or poster displayed at a scientific meeting. It also does not prevent journals from considering a paper that has been presented at a scientific meeting but was not published in full, or that is being considered for publication in proceedings or similar format. Press reports of scheduled meetings are not usually regarded as breaches of this rule, but they may be if additional data tables or figures enrich such reports. Authors should also consider how dissemination of their findings outside of scientific presentations at meetings may diminish the priority journal editors assign to their work. An exception to this principle may occur when information that has immediate implications for public health needs to be disseminated, but when possible, early distribution of findings before publication should be discussed with and agreed upon by the editor in advance.

Sharing with public media, government agencies, or manufacturers the scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances; reportable diseases; or public health hazards, such as serious adverse effects of drugs, vaccines, other biological products, medical devices. This reporting, whether in print or online, should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance when possible.

5.10.2. Salami Publications

Salami publication meaning a paper that has overlapping data with another paper by the same authors, but not enough overlap to be considered duplicate publication. Literary, salami is a cured sausage, fermented and air dried. Have you ever tried to eat one whole! And that is why many ethical and responsible authors will 'package' data into more palatable portions.

Simultaneous submission of manuscripts to more than one periodical by authors is a serious problem faced by medical journals.

The core notion of plagiarism is theft of intellectual property. http://www.publicationethics.org.uk/flow-charts/cope-flowcharts-optima l.pdf/download

5.11. Ethics in Journal Publication

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

5.11.1. 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 journal (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.

5.11.2. Release of research finding should always be via professional biomedical journals, not non-reviewed "lay" publications, in order to avoid misleading sensationalism

5.11.3. Anonymity of research participants and confidentiality of their details must be maintained. Any proprietary interest in a drug, vaccine, treatment, medical device, diagnostic, or institution must be clearly divulged.

5.11.4. It is a responsibility of the principal investigator/senior author to ensure that no fraudulent publications emanate from the team. Should fraudulent publication occur the responsibility is shared by all the authors.

5.11.5. The same study results should not be published in more than one peer reviewed journal article unless:

- The results are substantially re-analysed, re-interpreted for a different audience, or translated into a different language; and
- The primary publication is clearly acknowledged and cited; and

- The article is clearly presented as an analysis derived from the previously published primary results or is a translation, is not presented as reporting the primary results, and respects copyright law.

5.12. Bibliography

Davidoff, F. For the CSE Task Force on Authorship (2000) Who's the author? Problems with Biomedical Authorship and some Possible Solutions. Science Editor; 23: 1111-119.

Guidelines on authorships. International Committee of Medical Journal Editors (1983) British Medical Journal (Clinical Research Edition) 291, 722.

Uniform Requirements for Manuscripts Submitted *to Biomedical Journals.* www.download.thelancet.com/flatcontentassets/authors/**icmje**.pdf

World Association of Medical Editors: http:///www.wame.org

Council of Science Editors. http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=1

Appendix 1: MATERIAL TRANSFER AGREEMENT FOR RESEARCHERS/ ORGANIZATIONS

(FOR RESEARCH USE ONLY)

Agreement No.

THIS MATERIAL TRANSFER AGREEMENT FOR Researchers/Organizations (here-in-after referred **to as *the "Agreement"***) is made this..... Day of **..... , ...**

Between ..... of P.O Box .....

(here-in-after referred to as the
"PROVIDER");
and
.....of P.O Box .....
(here-in-after referred to as "a person" or the
"RECIPIENT").

PROVIDER and RECIPIENT may each be referred to as a "Party" or collectively as "Parties" to this
Agreement.

This preamble shall be a definitive part of this Agreement

WHEREAS under this Agreement it is agreed that MATERIALS for medical research may be transferred between Parties to this Agreement only through the conditions stipulated in this Agreement;

WHEREAS under this Agreement it is agreed that the MATERIAL to be transferred pursuant to this
Agreement are only those to be used for academic or research purposes;

WHEREAS it is hereby agreed that no transfer to third parties is allowed, except for academic or research purposes where RECIPIENT has secured the written consent of the PROVIDER;

AND WHEREAS the parties to the Agreement undertake to be bound by any lawful order or instruction, as they will be from time to time obliged to do by the Permit-Issuing Organization.

NOW THEREFORE in consideration of the mutual benefits to be derived and the representations, conditions and promises herein contained,
the **PARTIES HEREBY AGREE AS FOLLOWS:**

ARTICLE I

DEFINITIONS AND RULES OF INTERPRETATIONS

1.1 Definitions

"Agreement" means this "Material Transfer Agreement for Researchers/Organizations" between the Parties.

"Permit-Issuing Organization" means the entities with the legal authority under the law to issue permits and/or to conduct scientific research or to do any activity collateral to that scientific research or matters connected thereto.

"Permit" means all consents, approvals, authorization, notifications, concessions, acknowledgements, licenses, permits or similar items required to be obtained from any recognized Permit-Issuing Organization.

"PROVIDER" means a person or organization providing the original MATERIAL.

"RECIPIENT" means a person or organization to which the original MATERIAL is transferred.

"Medical Research Coordinating Committee" means a committee of the NIMR Council which reviews, monitors and coordinates health research in the United Republic of Tanzania

"The Law" means any applicable laws of the United Republic of Tanzania or the RECIPIENT
country when there is a *lacuna* in the laws of
Tanzania.

"MATERIAL" in this Agreement are those biological/chemical or any research materials which are specified in ***Annex I***, which forms part of this agreement.

1.2 Rules of Interpretation

In this Agreement:

a) The headings are for convenience only and shall not be considered in interpreting this Agreement;

b) The singular includes the plural and vice versa;

c) The obligations on part of the PROVIDER or RECIPIENT shall be interpreted to apply to the conduct and responsibilities of the PROVIDER Investigator or RECIPIENT Investigator, respectively.

ARTICLE II

TRANSFER OF THE MATERIAL

2.1 ***MATERIAL to be transferred***

Subject to the terms and conditions of this Agreement, the PROVIDER agrees to transfer the MATERIAL and the RECIPIENT agrees to receive the MATERIAL as identified in ***Annex I***.

2.2 ***Obligation of the RECIPIENT***

It is hereby agreed that the following conditions to the Agreement shall be binding on the RECIPIENT:

(a) The RECIPIENT agrees to use, store or dispose of the MATERIAL in compliance with all applicable laws, including, in particular but not limited to those relating to research involving the use of human and animal subjects.

(b) The MATERIAL shall remain the property of the PROVIDER and PROVIDER hereby consents to the MATERIAL being made available as a service to the research community.

(c) Subject to the law, the RECIPIENT shall use the MATERIAL for teaching or academic research purposes only.

(d) Except as previously approved by the Permit-Issuing Organization, and with the written consent of the PROVIDER, the RECIPIENT shall not transfer or distribute the MATERIAL to a third party.

(e) The RECIPIENT shall acknowledge the source of the MATERIAL in any publications reporting use of it.

(f) Subject to Article IV of this Agreement, the RECIPIENT shall be liable for damages which may arise from RECIPIENT's use, storage and disposal of the MATERIAL.

(g) The RECIPIENT and the RECIPIENT Investigator shall sign two copies of this Agreement and return one signed copy to the PROVIDER. The PROVIDER shall then forward the MATERIAL.

2.3 ***Obligation of the PROVIDER***

It is hereby agreed that the following conditions to the Agreement shall be binding on the PROVIDER;

(a) The PROVIDER agrees to transfer, store or dispose of the MATERIAL in compliance with all applicable laws.

(b) The PROVIDER shall transfer immediately the MATERIAL upon receipt of one of the two copies duly signed by the RECIPIENT.

(c) Subject to availability, the PROVIDER may agree to make the MATERIAL available under a separate agreement with other scientists (at least those at non-profit organizations or government agencies) who wish to replicate the RECIPIENT Investigator's scientific research.

(d) Subject to Article IV of this agreement, the PROVIDER shall be liable for damages which may arise from PROVIDER's use, storage and disposal of the MATERIAL.

ARTICLE III

COSTS AND PAYMENT ARRANGEMENTS

The MATERIAL shall be provided at no cost and, if requested, the RECIPIENT will pay for shipping costs.

ARTICLE IV

WARRANTIES

Any MATERIAL delivered or transferred pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER and RECIPIENT MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

ARTICLE V

LEGAL TITLE TO MATERIAL TRANSFERRED AND BENEFIT SHARING

Legal title to the MATERIAL transferred shall be unaffected by this Agreement or the transfer of any MATERIAL hereunder. (i) As between the PROVIDER and the RECIPIENT, the PROVIDER shall be the sole owner of all rights and the title to the MATERIAL transferred including existing intellectual property rights. (ii) The PROVIDER and RECIPIENT shall discuss the sharing of benefits arising from use of these MATERIALS in accordance with the contributions of the Parties.

ARTICLE VI

PERMITS, LICENCES AND APPROVALS

Prior to commencement of this Agreement, PROVIDER and RECIPIENT shall, at their own expense:

(a) Make or cause to be made all necessary prerequisite applications for the consents to the Permit-Issuing Organization and shall diligently pursue all such applications and shall use all reasonable efforts to maintain the consents in effect once obtained and;

(b) Give all required notices and allow all required inspections under all consents obtained in connection with that transfer. The information supplied in the applications shall be complete and accurate and shall satisfy the substantive and procedural requirements of the applicable laws of the United Republic of Tanzania or of the other country where the MATERIAL is transferred.

ARTICLE VII

NON-EXCLUSIVE LICENSE

The transfer of the MATERIAL constitutes a nonexclusive license to use the MATERIAL solely for academic and research purposes only. The transfer of MATERIAL does not grant the RECIPIENT any additional rights in the MATERIAL other than specifically set forth in this Agreement.

ARTICLE VIII

AMENDMENTS

This Agreement may be amended by mutual written Agreement of the Parties, which shall enter into force on the date agreed by both Parties.

ARTICLE IX

TERMINATION

Termination of this Agreement is accomplished:

a) Immediately upon mutual written consent of both Parties;
b) Unilaterally by either Party with sixty (60) days' written notice to the other Party; or c) Upon 30 days' written notice of a Party's contravention of law; and
d) As stated in Article X.

ARTICLE X

APPLICABLE LAW, SEVERABILITY

The Parties recognize and agree that this Agreement is a contract and not an International agreement, that International Law is not applicable to this Agreement, and that International Law does not govern the interpretation of the provisions of this Agreement. Any dispute arising under this Agreement which is not disposed of by agreement between the Investigators shall be submitted jointly to the Authorized signatories of this Agreement. A joint decision of the Authorized signatories or their designees shall be the disposition of such dispute. If the Parties cannot reach a joint decision, either Party may terminate this Agreement immediately.

The Parties hereby consent to the jurisdiction of the Courts of the United Republic of Tanzania for any action, suit or proceeding arising out of or relating to this letter agreement brought against the United Republic of Tanzania or NIMR, and to the jurisdiction of the courts of the RECIPIENT Government for any action brought against the RECIPIENT Government or any of its agencies.

This Agreement is effective when signed by all Parties and counter signed by the Chair of the Medical Research Coordinating Committee (MRCC) for the Government of United Republic of Tanzania. The Authorized Officials executing this Agreement certify that they are the legal representatives of their respective organizations, authorized to sign on behalf of their respective organizations for the purpose of binding the said organizations to the terms of this Agreement, for the transfer specified above.

ARTICLE XI

NOTICE

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

ARTICLE XII

NONAPPLICABILITY OF THIS AGREEMENT TO EXISTING OR FUTURE AGREEMENTS

The terms of this Agreement are not intended to and do not affect any other existing or future agreements between the Parties.

IN WITNESS WHEREOF the **PARTIES** hereto have signed this Agreement in the presence of the witnesses and at the places and on the dates set opposite their respective signatures.

SIGNATURE PAGE

FOR RECIPIENT:
RECIPIENT's Authorized Signatory

_____
Signature

_____
Printed Name and Title

Mailing Address for MATERIAL:
Tel: _____ Fax:_____

Email: _____

RECIPIENT's Authorized Investigator: I acknowledge and understand the terms to this Agreement.

_____
Signature

_____
Printed Name and Title

Mailing Address for Notices:
Tel: _____ Fax:_____

Email: _____

FOR PROVIDER:

PROVIDER's Authorized Signatory

_____
Signature

Printed Name and Title

Mailing Address for MATERIAL:

Tel: _____ Fax:_____

Email: _____

PROVIDER's Authorized Investigator: I acknowledge and understand the terms to this Agreement.

_____
Signature

Printed Name and Title

Mailing Address for Notices:

Tel: _____ Fax:_____

Email: _____

CERTIFICATION
Authorized Official**: CHAIR MRCC.**

_____
Signature

..... /...../ .....
Date

_____

Printed Name and Title:
Mailing Address:

Tel:_____ Fax: _____
Email:_____

Annex I
Description of Information to be transferred under this Agreement: (**MTA**)

Was the MATERIAL described above collected under (Study Title):

A Research protocol Approved by Tanzania Authorities: Yes
Certificate Number:..... No

Research protocol related Grant or Contact from RECIPIENT`s Government or Organization
Yes Number:.....
No

Provider Investigator : I declare that the above mentioned type(s) and number of samples(s) are only the one to be transferred herein.

Name:

Signature: Date...../...../ .....

Seal Stamp

Authorized Official: CHAIR MRCC: **I approve ONLY _____ type(s) Of sample(s) mentioned here above to be transferred from Tanzania.**

Name:_

Signature: Date..... /..... / .....

Seal Stamp _____

Appendix II: DATA TRANSFER AGREEMENT FOR RESEARCHERS/ORGANIZATIONS

(FOR RESEARCH USE ONLY)

THIS DATA TRANSFER AGREEMENT FOR Researchers/Organizations (here-in-after **referred to as *the "Agreement")*** is made this..... Day of ..... , ...

Between

.....of P.O Box .....

(here-in-after referred to as the
"PROVIDER");
and

.....of P.O Box .....

(here-in-after referred to as "a person" or the
"RECIPIENT").

PROVIDER and RECIPIENT may each be referred to as a "Party" or collectively as "Parties" to this Agreement.

This preamble shall be a definitive part of this Agreement

WHEREAS under this Agreement it is agreed that DATA of medical research may be transferred between Parties to this Agreement only through the conditions stipulated in this Agreement;

WHEREAS the PROVIDER retains all ownership rights on DATA procured from the study;

WHEREAS under this Agreement it is agreed that the DATA to be transferred pursuant to this
Agreement are only those to be used for academic or research purposes;

WHEREAS it is hereby agreed that no transfer to third parties is allowed, except for academic or research purposes where RECIPIENT has secured the written consent of the PROVIDER;

WHEREAS it is hereby agreed that the RECIPIENT shall cooperate with the PROVIDER to facilitate capacity building in DATA management and analysis;

AND WHEREAS the parties to the Agreement undertake to be bound by any lawful order or instruction, as they will be from time to time be obliged to do by the Permit-Issuing Organization.

NOW THEREFORE in consideration of the mutual benefits to be derived and the representations, conditions and promises herein contained,
the **PARTIES HEREBY AGREE AS FOLLOWS:**

ARTICLE I

DEFINITIONS AND RULES OF INTERPRETATION

1.1 Definitions

"Agreement" means this "DATA Transfer Agreement for Researchers/Organizations" between the Parties.

"DATA" in this context refers to facts, observations, or any information generated and documented (numerical, descriptive or visual) as specified in *Annex I*, which forms part of this agreement.

"Medical Research Coordinating Committee" means a committee of the NIMR Council which reviews, monitors and coordinates health research in the United Republic of Tanzania.

"Permit-Issuing Organization" means the entities with the legal authority under the law to issue permits and/or to conduct scientific research or to do any activity collateral to that scientific research or matters connected thereto.

"Permit" means all consents, approvals, authorization, notifications, concessions, acknowledgements, licenses, permits or similar items required to be obtained from any Permit-Issuing Organization.

"PROVIDER" means a person or organization providing the original DATA.

"RECIPIENT" means a person or organization to which the original DATA is transferred.

"The Law" means any applicable laws of the United Republic of Tanzania or the RECIPIENT country when there is a *lacuna* in the laws of Tanzania.

CONFIDENTIAL MATTER means information that is PROVIDER's proprietary and confidential information. Such CONFIDENTIAL MATTER shall not include any item of information, data, that: (a) is within the public domain prior to the time of the disclosure by the PROVIDER to the Receiving Party or thereafter becomes within the public domain other than as a result of disclosure by the RECIPIENT or any of its representatives in violation of this Agreement; (b) was, on or before the date of disclosure in the possession of the RECIPIENT; (c) is acquired by the RECIPIENT from a third party not under an obligation of confidentiality; (d) is hereafter independently developed by the RECIPIENT, without reference to the information received from the PROVIDER; or (e) the PROVIDER expressly authorizes the RECIPIENT to disclose.

1.2 Rules of Interpretation

In this Agreement:

a) The headings are for convenience only and shall not be considered in interpreting this Agreement;

b) The singular includes the plural and vice versa;

c) The obligations on part of the PROVIDER or RECIPIENT shall be interpreted to apply to the conduct and responsibilities of the PROVIDER Investigator or RECIPIENT Investigator, respectively.

ARTICLE II

GUIDING PRINCIPLES FOR DATA TRANSFER AGREEMENTS

1. This Agreement shall be linked to a project that has received ethical clearance from the MRCC under the National Institute for Medical Research. The need to transfer DATA shall be stipulated in an approved proposal or subsequent amendment. Any proposal that has received clearance from a local Institutional Review Board (IRB) will require the Agreement to be processed through the National Institute for Medical Research.

2. Signing of this Agreement shall be mandatory for all research involving foreign researchers, and this shall be declared in a research application for a research permit.

3. This Agreement shall also be mandatory for local researchers collaborating with foreigners, before sending/transferring DATA for research. This Agreement applies also to local researchers when using DATA from communities.

4. Make or cause to be made all necessary prerequisite applications for the consents to the Permit-Issuing Organization and shall diligently pursue all such applications and shall use all reasonable efforts to maintain the consents in effect once obtained and;

5. In the case of this Agreement involving a foreign counterpart, before signing the Implementing Letter of Agreement (ILA), the concerned research institutions in the PROVIDER country, in this case, the United Republic of Tanzania, should access information from the *National Research Registry* formed under the Tanzania Commission for Science and Technology (COSTECH) Act No 7 of 1986, (and amended in 2000), 3rd Schedule, to determine whether the foreign researcher had obtained a research permit.

ARTICLE III

TRANSFER OF THE DATA

3.1 ***DATA to be transferred***

Subject to the terms and conditions of this Agreement, the PROVIDER agrees to transfer the DATA and the RECIPIENT agrees to receive the DATA as identified in ***Annex I***.

3.2 ***Obligation of the RECIPIENT***

It is hereby agreed that the following conditions to the Agreement shall be binding on the RECIPIENT:

(a) The RECIPIENT agrees to use, store or dispose of the DATA in compliance with all applicable laws including those relating to research involving the use of human and animal subjects.

(b) The DATA shall remain the property of the PROVIDER and PROVIDER hereby consents to the DATA being made available as a service to the research community.

(c) The RECIPIENT shall use the DATA for teaching or academic research purposes only.

(d) Except as previously approved by the Permit-Issuing Organization, and with the written consent of the PROVIDER, the RECIPIENT shall not transfer or distribute the DATA to a third party.

(e) The RECIPIENT shall acknowledge the source of the DATA in any publications reporting use of it.

(f) Subject to Article V of this Agreement, the RECIPIENT shall be liable for damages which may arise from RECIPIENT's use, storage and disposal of the DATA.

(g) The RECIPIENT and the RECIPIENT Investigator shall sign two copies of this Agreement and return one signed copy to the PROVIDER. The PROVIDER shall then transfer the DATA.

(h) The RECIPIENT shall provide the PROVIDER with a manuscript of any proposed publication or presentation resulting from the study using the DATA at least thirty (30) days prior to submission thereof for publication or presentation. The PROVIDER reserves the right to review any such manuscript and to require the removal of CONFIDENTIAL MATTER in order to protect its proprietary rights and interests. PROVIDER shall notify RECIPIENT in writing within a thirty (30) day period concerning the removal of CONFIDENTIAL MATTER and to suggest editorial modifications in the manuscript.

3.3 *Obligation of the PROVIDER*

It is hereby agreed that the following conditions to the Agreement shall be binding on the PROVIDER;

(a) The PROVIDER agrees to transfer, store or dispose of the DATA in compliance with all applicable laws

(b) The PROVIDER shall transfer immediately the DATA upon receipt of one of the two copies duly signed by the RECIPIENT.

(c) Subject to availability, the PROVIDER may agree to make the DATA available under a separate agreement with other scientists (at least those at non-profit organizations or government agencies) who wish to replicate the RECIPIENT Investigator's scientific research).

(d) Subject to Article V of this agreement, the PROVIDER shall be liable all liabilities for damages which may arise from PROVIDER's use, storage and disposal of the DATA.

ARTICLE IV

COSTS AND PAYMENT ARRANGEMENTS

The DATA shall be provided at no cost.

ARTICLE V

WARRANTIES

Any DATA transferred pursuant to this Agreement is understood to be experimental in nature. The PROVIDER and RECIPIENT MAKE NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

ARTICLE VI

LEGAL TITLE TO DATA TRANSFERRED AND BENEFIT SHARING

Legal title to the DATA transferred shall be unaffected by this Agreement or the transfer of any Material hereunder. (i). As between the PROVIDER and the RECIPIENT, the PROVIDER shall be the sole owner of all rights and the title to the DATA transferred including existing intellectual property rights. (ii). The PROVIDER and RECIPIENT shall discuss the sharing of benefits arising from use of the DATA in accordance with the contributions of the Parties.

ARTICLE VII

PERMITS, LICENCES AND APPROVALS

Prior to commencement of this Agreement, PROVIDER and RECIPIENT shall, at their own expense:

(a) Make or cause to be made all necessary prerequisite applications for the consents to the Permit-Issuing Organization and shall diligently pursue all such applications and shall use all reasonable efforts to maintain the consents in effect once obtained and;

(b) Give all required notices and allow all required inspections under all consents obtained in connection with that transfer. The information supplied in the applications shall be complete and accurate and shall satisfy the substantive and procedural requirements of the applicable laws of the United Republic of Tanzania or of the other country where the DATA is transferred.

ARTICLE VIII

NON-EXCLUSIVE LICENSE

The transfer of the DATA constitutes a nonexclusive license to use the DATA solely for academic and research purposes only. The transfer of DATA does not grant the RECIPIENT any additional rights in the DATA other than specifically set forth in this Agreement.

ARTICLE IX

AMENDMENTS

This Agreement may be amended by mutual written Agreement of the Parties, which shall enter into force on the date agreed by both Parties.

ARTICLE X

TERMINATION

Termination of this Agreement is accomplished:

a) Immediately upon mutual written consent of both Parties;
b) Unilaterally by either Party with sixty (60) days' written notice to the other Party; or c) Upon 30 days' written notice of a Party's contravention of law; and
d) As stated in Article XI

ARTICLE XI

APPLICABLE LAW, SEVERABILITY

The Parties recognize and agree that this Agreement is a contract and not an International agreement, that International Law is not applicable to this Agreement, and that International Law does not govern the interpretation of the provisions of this Agreement. Any dispute arising under this Agreement which is not disposed of by agreement between the Investigators shall be submitted jointly to the Authorized signatories of this Agreement. A joint decision of the Authorized signatories or their designees shall be the disposition of such dispute. If the Parties cannot reach a joint decision, either Party may terminate this Agreement immediately.

The Parties hereby consent to the jurisdiction of the Courts of the United Republic of Tanzania for any action, suit or proceeding arising out of or relating to this letter agreement brought against the United Republic of Tanzania or NIMR; and to the jurisdiction of the courts of the RECIPIENT Government for any action brought against the RECIPIENT Government or any of its agencies.

This Agreement is effective when signed by all Parties and countersigned by the Chair of the Medical Research Coordinating Committee (MRCC) for the Government of United Republic of Tanzania. The Authorized Officials executing this Agreement certify that they are the legal representatives of their respective organizations, authorized to sign on behalf of their respective organizations for the purpose of binding the said organizations to the terms of this Agreement, for the transfer specified above.

ARTICLE XII

NOTICE

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

ARTICLE XIII

NONAPPLICABILITY OF THIS AGREEMENT TO EXISTING OR FUTURE AGREEMENTS

The terms of this Agreement are not intended to and do not affect any other existing or future agreements between the Parties.

IN WITNESS WHEREOF the **PARTIES** hereto have signed this Agreement in the presence of the witnesses and at the places and on the dates set opposite their respective signatures.

SIGNATURE PAGE

FOR RECIPIENT:

RECIPIENT's Authorized Signatory

_____ _
Signature

Printed Name and Title

Mailing Address for MATERIAL:

Tel: _____Fax_____

Email:_____

RECIPIENT's Authorized Investigator: I acknowledge and understand the terms to this Agreement.

_____
Signature

Printed Name and Title

Mailing Address for Notices:

Tel:_____Fax_____

Email:_____

FOR PROVIDER:

PROVIDER's Authorized Signatory

_ _
Signature

Printed Name and Title

Mailing Address for MATERIAL:

Tel: _____Fax_____

Email:_____

PROVIDER's Authorized Investigator: I acknowledge and understand the terms to this Agreement.

_
Signature

Printed Name and Title

Mailing Address for Notices:

Tel:_____Fax_____

Email:_____

CERTIFICATION
Authorized Official**: CHAIR MRCC.**

..... Signature

..... /..... /
Date

_____

Printed Name and Title:

Mailing Address:

Tel: _____

Email:_____

Fax:_____

Annex I

Description of Information to be transferred under this Agreement: (**DTA**)

A Research protocol Approved by Tanzania Authorities: Yes
Certificate Number:..... No

Research protocol related Grant or Contact from RECIPIENT`s Government or Organization

Yes Number:.....
No

Provider Investigator : I declare that the above mentioned type(s) and format of Dataset are only the one to be transferred herein.

Name:_____

Signature:_____ Date..... /...../ .....

Seal Stamp

Authorised Official: CHAIR, MRCC: I approve ONLY Dataset type (s) and format of mentioned here above to be transferred from Tanzania

Name:_____

Signature:_____ Date..... /...../ .....

_____
Seal Stamp

Appendix III: APPLICATION FORM FOR PERMISSION TO PUBLISH

1. **Title of the manuscript**:

   _____
   _____
   _____
   _____

2. **Name of the corresponding/senior author:**

   _____

3. **Institutional affiliation and address:**

   _____
   _____

4. **Names of authors, institutional affiliation and contribution**

Name	Institutional Affiliation	Contribution

5. **Type of manuscript:**

   (a) Original research
   (b) Traditional review
   (c) Systematic review
   (d) Meta-analysis

6. **Title of the original and registered and project/programme**

   _____
   _____
   _____

7. **Ethical approval certificate Number:** _____

NB: Application for permission to publish must be accompanied by a covering letter in the respective headed letter