INTELLECTUAL PROPERTY POLICY

Revised 2022

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Acronyms

DRCP	Director of Research Coordination and Promotion
IP	Intellectual Property
MTA	Material Transfer Agreement
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 an Act of Parliament no. 23 of 1979 [Cap. 59, R.E. 2002]. The Act gave NIMR dual mandates, as a medical research institution and as an authority to regulate medical research undertaken within Tanzania. As a medical research institute, NIMR is vested with the statutory mandates 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. The functions of NIMR as enumerated under Section 4 of the Act connects to a number of issues that have a direct and indirect bearing to the issues and perspectives of intellectual property rights. Apart from carrying out research, NIMR's statutory functions include evaluation of medical research findings, establishing a registry of medical research findings, promoting practical application of medical research findings, and dissemination of findings from medical research. Under Section 13 of the Act, NIMR is empowered to own discoveries from medical research and obtaining patents from medical research findings and commercialization thereof.

Therefore, there is a strong statutory basis for NIMR to adopt and operationalize the Intellectual Property (IP) Policy. This Policy shall apply to all members of staff, visiting researchers, graduate and undergraduate students who are involved in medical research at NIMR or elsewhere under the auspices of NIMR. The Policy shall also apply to all NIMR research partners and collaborators.

The objective and structure of this Policy aims at achieving three important goals. First, to promote creativity among researchers at NIMR and in the institutions that collaborate with NIMR by introducing a specific framework through which new knowledge in the field of medical research may be generated, protected, rewarded and shared for the betterment of the livelihood of the people of Tanzania. Secondly, the Policy constitutes an important tool that will assist NIMR in discharging its statutory functions in a better way by responding to the changing global research landscape in which issues of intellectual property rights have taken a centre stage. Thirdly, the Policy provides a requisite platform through which NIMR will be able to collaborate with other research institutions and private entities with a clear institutional position in as far as protection and ownership of medical research findings arising from joint research programs are concerned. In the end, the Policy is a necessary and a critical document for protection of national interests in the field of healthcare and traditional medicinal plants and other related species.

Apart from the national legal perspectives, the Policy is also informed by the regional and international framework that governs the interface between public health and intellectual property rights. In this context, the Policy is cognizant of the role that is played by the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) particularly through the adoption of the Doha Declaration on TRIPs Agreement and Public Health of 2001 which was adopted to limit the strictures of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) by allowing member States to WTO to take requisite measures to protect public health as well as extending the transition period for Least Developed Countries (LDCs) for implementation of the TRIPs obligations. The Policy is also mindful of the many initiatives of the World Health Organization (WHO) such as the Global Strategy on Public Health, Innovation and Intellectual Property.

Medical research capacity building and strengthening in NIMR is key for the fulfilment of the Institute's research and regulatory mandate. 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, ensure that all staff are well aware of the national and institutional Intellectual Property Policy and actively participate in translating and integrating them into a research agenda of their respective disciplines. NIMR shall also ensure the adoption of a common operational framework in preparation, processing and approval of health research protocols.

In order to stimulate and motivate research and reward productivity, all discoveries shall include a 40% share of the net IP revenue that shall be allocated to the Creator. Where there is more than one Creator, the Creators are entitled to a pro rata share, based on contribution, except where there is a prior written agreement between all the Creators to the contrary of the stipulated allocation. Other attractive remunerations, comparable and competitive should be offered in order to retain quality staff.

NIMR shall inculcate and establish a culture that recognizes transparent criteria/indicators to measure research excellence and reward IP at individual, departmental and directorate/centre each year. NIMR shall ensure that, medical 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 research proposals.

NIMR shall as far as feasible, endeavour to manage, coordinate and make attractive health research supportive environment. Areas that deserve specific attention will include maintenance of health research equipment, support 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 Journal of Health Research (TJHR).

Within the above broader policy context, NIMR commits to ensure that all medical research involving human subjects conform to the recommendations which are guiding researchers in medical research involving human subjects as adopted by the 18th World Medical Assembly (WMA), Helsinki, Finland, June 1964, and its amendments by the 59th WMA, Seoul, October 2008 and the 64th WMA, Fortaleza, Brazil, October 2013. NIMR is set to 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.

1.0. Introduction

The National Institute for Medical Research (NIMR) has dual mandates, as a medical research institution and as a regulatory authority of medical research undertaken within Tanzania or elsewhere on behalf of the Government of Tanzania. NIMR derives its regulatory mandate from Section 4 of the National Institute for Medical Research Act No. 23 of 1979 [Cap 59, R.E. 2002]. The mandates of NIMR include:

(i) Monitor, control and coordinate medical research carried out within Tanzania, or elsewhere on behalf of or for the benefit of the Government of Tanzania, and to evaluate the findings of that research;
(ii) Establish a system for the registration of, and to register, the findings of medical research carried out within Tanzania, and promote the practical application of those findings for the purposes of improving or advancing the health and general welfare of the people of Tanzania;
(iii) Establish and operate a system of documentation and dissemination of information on any aspect of the medical research carried out by or on behalf of the Institute; and
(iv) Cooperate with the Government or any person or body of persons within or outside Tanzania and establish in Tanzania a library for reference by medical scientists and a medical museum.

NIMR as a medical research institution is mandated by the government of the United Republic of Tanzania to:

(i) Carry out and promote the carrying out of medical research designed to alleviate disease among the people of Tanzania;
(ii) Carry out and promote the carrying out of research into various aspects of local traditional medical practices for the purpose of facilitating the development and application of herbal medicine; and
(iii) Cooperate with the government or any person, or body of persons to carry out and promote the carrying out of, basic applied and operational research designated to provide effective measures for the control of diseases endemic in Tanzania.

2.0. Rationale of the Policy

This Policy has been adopted by NIMR based on the following rationales:

(i) The statutory mandates of NIMR cut across many aspects and variables that require the attention of the intellectual property policy. Hence, in the absence

of a defined IP policy framework, NIMR may find itself hindered in effectively implementing its statutory functions and duties.

(ii) The changing national policy and legislative set up since the establishment of NIMR in 1979. Since then, a number of policy and regulatory changes have taken place in Tanzania including the adoption of new policies on science and technology, research and development. Also, enactment on new laws on matters of intellectual property rights. All these developments call for institutional realignment in terms of its policy set ups.

(iii) An ever-changing global research landscape in which issues of intellectual property rights have become one of the items in the negotiation with NIMR's collaborating research institutions.

(iv) The need to protect national interest on medical/health related research and align with public health protection and flexibilities in trade related intellectual property system (TRIPS).

(v) This policy is a necessary tool for NIMR in setting up the requisite institutional platform through which it may collaborate with other institutions both public and private in furtherance of medical research for the betterment of public health in Tanzania.

(vi) To serve the common good, it will be necessary to secure protection of NIMR's Intellectual Property (IP), for the Institute and Staff to benefit from their discoveries as well as to encourage commerce and industry to invest their resources in the development and distribution of products and processes for public health use, which will therefore require protection and regulations for Technology Transfer (TT).

NIMR has therefore developed this intellectual property policy and guidelines (herein referred to as "POLICY" for the management of its IP in order to promote, preserve, encourage and aid scientific investigation and research.

Vision and Mission of NIMR

The **vision of NIMR** is:

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

The **mission of NIMR** is:

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

3.0. Scope of Application

(i) This Policy applies to NIMR employees and non-employees (including visiting staff, affiliate and adjunct staff, industrial personnel, herbalists, traditional healers etc.) who participate in health research and other projects at NIMR.

(ii) In terms of the subject matter, the policy covers all aspects of intellectual property that have relevance in health/medical research including, but not limited to, patents, copyrights, industrial designs, trade and service marks, trade secrets, utility model, new plant varieties, indigenous knowledge and geographical indications.

4.0. Policy Issues and Statements

4.1 Ownership of intellectual property

(a) Policy Issues

In the current research and institutional collaboration framework, issue of intellectual property rights have assumed centre stage and have become an integral part to the negotiation and implementation of research projects. Such research can produce useful findings and results of public health interest as well as applications having a broad range of public uses and benefits. Unless these findings are properly protected and ownership is clearly defined, there is a risk that other institutions or unscrupulous persons may take up and protect these research findings and related information and consequently deprive NIMR and the public from benefiting from the findings. NIMR shall therefore manage and protect its intellectual property rights (IP). Determination of ownership will take consideration of the following:-

(b) Policy Statement on Ownership of IP

(i) Except by an express undertaking exempting ownership, all intellectual property (including, but not restricted to instruments that store potential IP information such as laboratory notebooks, cell lines and other tangible health research products, literary works and all other written documents, examinations etc., in hard copy or electronic form) shall be owned by NIMR in cases where if Institute's resources were used; if the findings are generated from a commissioned undertaking; or if it is created pursuant to a research project funded through corporate, government or other external sponsors administered by NIMR.

(ii) To achieve the above objective, researchers and other persons participating in various research projects shall be under obligation to assign intellectual property rights that may arise from the project to NIMR.

(iii) Ownership of any IP that is made, discovered or created in the course of health research funded by a sponsor pursuant to a grant or research agreement, or which is subject to materials transfer agreement, confidential disclosure agreement or other legal obligation affecting ownership, will be governed by the terms stipulated in the relevant agreement and/or memorandum of understanding (MoU) made prior to execution of the grant.

(iv) The texts of all student theses and dissertations arising from research works in NIMR, and works derived from such works, are considered "Exempted Scholarly works". The student will own copyright in the scholarly work subject to royalty free license to NIMR to reproduce and publish.

4.2 Policy Issues and Statement on Commercialization and Dissemination

(a) Policy Issues

In terms of Section 4(1)(f) of the Act, NIMR is under the statutory obligation to develop system of documentation and dissemination of information on all aspects of medical research carried out by the Institute or on its behalf. On the other hand, NIMR is under statutory obligation to protect and register the findings from medical research and ensure practical application of the medical research findings.

The above two obligations require a defined institutional framework for commercialization and dissemination of research outputs and other intellectual property assets at NIMR, which is balanced and mindful of the broader public interest. NIMR encourages and supports the right of Creators to decide if and when to publish their research results.

(b) Policy Statement

In view of the context of the issues involved in commercialization and dissemination, NIMR undertakes to:

(i) Take measures to protect, and in appropriate cases, enter into production and commercialization agreements with other institutions, public or private in order to facilitate practical application of medical research findings for the broader benefits of the public;

(ii) Support initiatives of other institutions aimed at transforming medical research findings into usable products and services for the public good;

(iii) Promote the widest possible distribution of scientific and public benefits and facilitate the development of IP, both to meet its social obligations as a health and medical research institution and to meet its obligations to disseminate the benefits of research funded by public funds and contracts;

(iv) Subject to reasonable delays to preserve patent or other Intellectual Property Rights (IPR), not to limit or restrict NIMR staff, visiting researchers and students to publish results of their research. Unless otherwise justified, the delays in publication required by NIMR or third parties in sponsored research agreements, as a rule, shall not exceed NINETY (90) days from initial disclosure of the IP to NIMR or the sponsor;

(v) Provide an organization structure and procedures through which documents, publications, inventions and discoveries made in the course of its health research and other activities may be made readily available to the public through channels of commerce;

(vi) Establish standards for assessing and determining the rights and obligations of institutional creators of IP (e.g., inventors, innovators, developers and authors) and their sponsors with respect to inventions, discoveries and works created in NIMR;

(vii) Ensure that both IP and other products of research are made available to the public through and efficient and timely process of technology transfer;

(viii) Encourage, assist and provide beneficial rewards to NIMR and its members who transfer the institutional IP to the public domain through commercial channels under this Policy;

(ix) Ensure compliance with applicable laws and regulations and enable NIMR to secure sponsored research funding at all levels of health research; and

(x) Ensure that NIMR is aware of the different IP systems in place in the countries where the acquisition of IP right is sought.

5.0. Various Policy Responsibilities

For the effective implementation of the Policy, it is pertinent that roles and responsibilities of the various participants and those who are covered by the Policy be properly defined and delineated.

5.1 Responsibilities of NIMR

The obligations of NIMR will include:

(a) To educate its staff regarding the issues of intellectual property and other tangible research property by emphasizing on their central role within the broader policy context and implementation;

(b) To provide support as it deems necessary or desirable to obtain legal protection of the various intellectual property related assets, facilitate the beneficial

transfer of such IP assets to public use and develop mechanisms within the institutional IP Office for the licensing and management of technologies;

(c) To provide legal support as it deems necessary and desirable to defend and protect the interests of NIMR and creators of IP against third party claims or unauthorized use, share royalties, equity or other income derived for IP with the creators;

(d) To timely report to research sponsors as may be required by research and licensing agreements, and applicable laws and regulations, on ownership interests with regards to intellectual property rights arising out of research undertakings. In case NIMR is not interested in pursuing intellectual property protection from a particular research project or output, it may, in writing, allow the individual researcher to claim ownership while retaining its worldwide loyalty-free licence to use the said intellectual property right;

(e) To establish a framework for resolution of disputes that arises between and among NIMR staff, sponsors, and other collaborating partners regarding IP;

(f) To develop and adopt Guidelines for the implementation of the Policy; and

(g) To do any other function or activity that it deems necessary for the realization of the goals and objectives of this Policy.

5.2 Responsibilities of the Creators of Intellectual Property

The obligations of the creators of IP will include:

(a) To abide and observe all the terms and dictates of the Policy;

(b) To timely and fully disclose to the DRCP office all research activities, research results, inventions, discoveries and other related works that have bearing on intellectual property to which NIMR have stake as described in the Policy;

(c) To cooperate and provide such assistance as may be necessary throughout the technology transfer process to protect and effectuate transfer of the IP, including assignment or transfer of the IP to NIMR, if necessary;

(d) To abide by all commitments made in license, sponsored research and other agreements, and laws related to public and private funded research; and

(e) To promptly disclose all potential conflicts of interest to the appropriate Committee.

6.0. Operationalization of the Policy

In order to realize the objectives of the Policy, certain institutional organs/units must be established within NIMR. The roles, functions, and set up of such units must also be

defined. Towards this direction, NIMR undertakes to establish a framework of intellectual property management with defined functions.

(a) Management of Intellectual Property and other Allied Matters

(i) NIMR may designate an IP Management unit, to support the Institution through the DRCP in managing and commercializing its IP in a form that will most effectively promote its development and use for economic and social benefit.

(ii) There shall be a Committee known as the Intellectual Property Management Committee (IPMC) whose members shall be appointed by the Director General of NIMR to provide oversight of NIMR's intellectual property matters and of the implementation of this policy;

(iii) The composition of the IPMC shall include: The Director of Research Coordination as Chairperson, Head of Legal Unit, Director of Finance, Human Resources and Planning, Director of Information Technology and Communication, Head of Department of Innovations, Commercialization and Technology Transfer and other co-opted member from outside NIMR who is knowledgeable or an expert on matters of intellectual property rights;

(iv) The Committee shall report to the DG; and

(v) The Committee shall pay particular attention and be informed in its undertakings by the statutory mandates of NIMR in line with its technology transfer mission, budget, resolution of disputes and the benefit sharing from income generated from IP related transactions.

(b) Functions of the Intellectual Property Management Committee (IPMC)

(i) Develop mechanism and initiatives for the implementation and monitoring of this Policy;

(ii) Advise DG and staff of NIMR on all matters relating to intellectual property promotion, protection, and implementation of the Policy;

(iii) Review requests for the interpretation of the Policy and make written recommendations regarding such requests;

(iv) Review annually the financial situation related to IP and Technology transfer with particular attention on expenditure and IP income. Provide advice to the DG regarding disputes between creators and NIMR; and

(v) Review and where applicable advise or recommend to the DG adjustment of plans for the division of IP income.

(c) The designated IP Management Unit shall support the DRCP in the following functions:

(i) Outreach/awareness to Creators;
(ii) Relationship management with Creators;
(iii) IP management;
(iv) Assist with Technology marketing and IP contract negotiation; and
(v) Any other related duties assigned as seen fit by the DRCP.

7.0. Benefit Sharing Framework

In order to motivate researchers to carry out more research for the good of the public in Tanzania, it is pertinent that outputs from research are not only protected but when opportunities present are also commercialized so as to provide economic benefits to researchers and NIMR.
Towards this endeavour, NIMR undertakes to:

(a) Where applicable sharing of income for IP will be based on the net value arrived at after deducting all applicable operation and overheads costs which have been incurred by NIMR. This includes all costs incurred by the Institute in the course of protection and maintenance of the intellectual property. Joint creators or inventors will mutually agree on the formula to be used for sharing any accrued income.

(b) Subject to other approved framework that may be agreed upon, any accrued income to NIMRs will be shared with respective Centres/ Stations/collaborating institutions. Apart from the commercialization model that involves direct licence or assignment agreements, NIMR may also negotiate arrangements in the framework of spin-offs and start-ups companies under which NIMR may acquire designated equity interest in the company which may have the appropriate production and commercialization capabilities in a particular market.

8.0. Dispute Resolution

(a) All disputed issues related to IP or the interpretation of this Policy, shall be amicably resolved through the existing institutional set up within NIMR.

(b) Any person who has a complaint relation to any matter addressed under this Policy, shall report the complaint to DRCP who shall refer to the IPMC for technical review and guidance.

(c) Any dispute that cannot be resolved by IPMC will be referred to the Director General. The DG may refer disputed issues to the Governing Council for its recommendations and advice.

(d) Without prejudice to other attendant laws of Tanzania, the decision of the Governing Council shall be deemed as final and conclusive.

9.0. Reports to Governing Council

(a) In order to fully implement the Policy and for the proper oversight, issues of intellectual property rights and the implementation of this Policy, shall be reported by the Director General to the Governing Council on quarterly basis and shall always form part of the Annual Report of the Director General to the Governing Council.

(b) Among others, the report may include details on: the awareness programmes undertaken to staff, number of IP rights acquired, commercialization report, and any recommendations from the IPMC.

10.0. Review and Amendment of the Guidelines

(a) This Policy shall be reviewed after every five (5) years. Provided there are necessitating circumstances for an interim review, such review may be done at any time.

(b) Any recommendation to the amendment of the Policy shall be brought to the attention of IPMC who shall, in writing, advise the Director General, who may present the recommendations to the Governing Board for the requisite approval.

Annex I

GLOSSARY

Assignment: Total transfer of rights and title in real, personal or IP in writing with the result that the assignee is vested with rights of ownership. Other IP may be assigned to NIMR, or to other parties pursuant to a Research or License Agreement.

Commercialization: Any form of utilisation of IP intended to generate value, which may be in the form of a marketable product, process or service, commercial returns, or other benefits to society. **Commercialize** is similarly defined.

Commercial Venture: A start-up company, partnership, joint venture, corporation or any other enterprise entity that has obtained a license to transact technology in exchange for equity in the enterprise entity.

Company: Means a corporation or a business enterprise incorporated under the relevant laws of any country

Conception: Creation in the Inventor's mind of a new and useful way to solve a problem; the act of visualizing an invention, compete in all essential detail conception occurs when a solution is formulated, not when a problem is recognized. Conception is the unequivocal mental discovery of an invention.

Confidentiality Agreement: Separate agreement between disclosing and recipient parties, or a term in a Research Contract or License Agreement. When information is disclosed by a company to NIMR employee, he/she is personally bound not to release the information unless expressly permitted by the company. When information disclosed by NIMR employee to a company, the company is prevented from using the information without permission, and to protect the patentability of any invention, or trade value of other technology, disclosed by NIMR Inventor or Creator to the company.

Confidential Disclosure: Sharing of proprietary information (such as the description of an invention), which is protected against unauthorized disclosure by a Confidentiality Agreement between the disclosing and receiving parties.

Conflict of Interest: Two or more goals are advanced simultaneously, placing them in potential competition with each other. Productive interchange between NIMR, its research staff, or other employees and the non-scientific world may sometimes engender Conflicts of Interest, in which legitimate but disparate goals of the institution

or of an individual employee may present difficult choices. If conflicts of interest cannot be avoided, they may be minimized, and NIMR policies and procedures for the disclosure and management of conflicts of Interest will apply.

Contract: A legally binding mutual agreement between two or more parties in which an exchange of value occurs, and which obligates each party to certain duties covering this exchange. Those signing such an agreement must be authorized to bind the entity that they represent.

Copyright: Refers to the creative works protected as artistic or literally works as defined under the Copyright and Neighbouring Rights Act, Cap. 218 [R.E. 2002].

Creator. Any person to whom this Policy is applicable, who creates, conceives, reduces to practice, authors, or otherwise makes a substantive intellectual contribution to the creation of IP and who meets the definition of 'inventor', 'author' or 'breeder' as generally implied in the IP laws of Tanzania.

Disclosure: A formal process through which the proprietary or potentially proprietary information is shared by the provider to the receiver.

Equity or Equity Shares: Shares of common or preferred stock, warrants, options, convertible instruments, units of a limited partnership, or any other instrument conveying ownership interest in a Commercial Venture.

Intellectual Property (IP). All outputs of creative endeavour in any field at the Institution for which legal rights may be obtained or enforced pursuant to the law. IP may include:

(a) literary works, including publications in respect of Research results, and associated materials, including drafts, data sets and laboratory notebooks;
(b) teaching and learning materials;
(c) other original literary, dramatic, musical or artistic works, sound recordings, films; broadcasts, and typographical arrangements, multimedia works, photographs drawings, and other works created with the aid of Institution resources or facilities;
(d) databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material;
(e) patentable and non-patentable technical information;
(f) designs including layout designs (topographies) of integrated circuits;
(g) plant varieties and related information;
(h) trade secrets;
(i) know-how, information and data associated with the above; and
(j) any other Institution-commissioned works not included above.

Intellectual Property Right (IPR): Is a legal right granted to owner (s) of the IP, to give moral and economic rights of creators in their creations and the rights of the public in access to those creations; and to promote creativity and the dissemination and application of its results for economic and social development.

Invention: has a meaning ascribed to it under the Patents (Registration) Act, Cap. 217 [R.E. 2002]. Invention means a solution to a specific problem in the field of technology and may relate to a product or process.

Inventor: Any person to whom this Policy is applicable, who individually or jointly with others makes an Invention and who meets the criteria for inventorship under the Patents (Registration) Act, Cap. 217 [R.E. 2002].

IP Policy: Intellectual Property Policy for NIMR.

IPMC Committee: The body within the Institution, which is responsible for overseeing the drafting, implementation, monitoring and evolution of the Policy, and for providing strategic oversight.

Material Transfer Agreement: Is a contract, which covers the transfer of proprietary tangible property, often-biological materials. May cover materials coming into NIMR from any source or vice versa. Negotiated terms of such agreements may cover the use of the original materials, materials produced by replication of the original sample and modifications of the original materials. Points of contention in negotiations include preservation of publication rights, preservation of ownership, disposition of liability arising from hazardous materials and ownership of new inventions arising from the use of the materials.

Patent: A Patent is a grant, which gives the owner of an invention, covered by the Patent the right to exclude all others from making, using, selling or importing the invention in the country.

Publication: As related to Inventions and Patents, a Publication is a public Enabling Disclosure of an Invention and may be verbal or printed. Printed Publications include abstracts, student theses and in certain instances, grant proposals, whether funded or unfunded. A public Enabling Disclosure is a non-privileged, non-confidential communication. Publication usually limits the potential Patent and then only if an application is filed before the expiration of one-year from Publication.

Research Contract or Agreement: A separate agreement to fund and conduct research, which may or may not be related to licensed technology.

Royalties: Royalties are compensation for rights in IP and are usually expressed as a percentage of revenue received by the licensee from sales of a product.

NIMR's Resources: All tangible resources made available by NIMR to an inventor or creator including: salary and allowances, office, time, laboratory and equipment; computer hardware, software and support. Supplies and utilities; funding for research and teaching activities, travel and other funding or reimbursements.

Tangible Property: Tangible Property is anything having a physical embodiment (e.g., cell-lines, compositions of matter) whether or not patentable or copyrightable.

Trademark: A trade or service mark consists of a word, symbol, phrase or design, or combination of these, and exists for the exclusive use of the holder in identifying the source of a product or service. Marks are identified by the symbols® or SM. Marks have no necessary relation to Invention or discovery. Unlike Patents and Copyrights, marks can exist for an indefinite time.

Trade Secret: Trade Secrets comprise confidential data, information or compilations used in research, business, commerce or industry. The information may include confidential scientific and technical data and business, commercial or financial information not publicly known which is useful in an enterprise and that confers competitive advantage on one hanging a right to use such information. The secrecy of the information must be maintained to conserve its Trade Secret status. Trade Secret information may be disclosed or shared under the terms of a Confidentiality Agreement. Confidential information may be created I sponsored research projects; the sponsor will generally require NIMR and the Creator to preserve the secrecy of the information. Trade Secrets may be vital to the practice of patented Inventions and other innovations. Trade Secrets information may have considerable value by itself or in conjunction with other forms of IP.

Annex II

GUIDELINES OF THE POLICY

These Guidelines are made in order to provide for specific action points that are required for the implementation of the Policy.

1.0. Administration, Protection and Dissemination of Intellectual Property

(a) **Administration of NIMR Intellectual Property:** The day-to-day administration of IP will be done by the DRCP. The goal of the DRCP is to promote the transfer of NIMR technology for public use and benefit while generating income to support further health-related research. DRCP have the following additional roles:

i) To administer a wide range of IP developed through either public or donor funds, industrially funded research, or other forms of financing;

ii) To evaluate, obtain proprietary protection for, and assists in the commercial development of selected technology.

iii) Properly negotiate with external collaborators on how issues of intellectual property will be handled in collaborative research agreements.

iv) Prepare a budget for carrying out various activities relating to the implementation of this Policy.

(b) **Disclosure:** The obligation to disclose is mandatory to all persons covered under this Policy. New findings on medical research shall be disclosed to the Director General in writing at the earliest possible time. The creators will consult DRCP with respect to their duties to disclose inventions and the manner and timeliness with which such disclosure should be made the Director General.

(c) **Sponsored Programs:** The following practice shall be followed with regards to sponsored research programs:

i) The terms in the Sponsored Agreement shall be negotiated and agreed upon by making sure that NIMR's and broader national interests are protected.

ii) Irrespective of the source of funding, inventions or discoveries and copyrightable works developed should be promptly disclosed to the Director General.

iii) Invention reporting to the Government will be done to the extent practicable, within the set timelines as may be prescribed by Government regulations, of receipt of disclosure form the creator.

(d) **Other Programmes:** All forms of intellectual property assets developed either under the NIMR programs, as a work-for-hire or with the use of the NIMR resources, shall also be disclosed to the Director General.

(e) **Form and Content of Disclosure:**

(i) The creator(s) are required to make disclosure to the Director General in writing, on a special prescribed form designed as *NIMR Form-1*.

(ii) The disclosure shall be full and complete, with sufficient details to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purposes, operation, biological and technical characteristics of the invention.

(iii) The creator(s) should also disclose any publication or submission for publication, sale or offer for sale, or public use of the invention.

(iv) The creator (s) also has/have the responsibility to update the Director General in a timely manner of any developments involving publication, sale or use of which they become aware after the initial disclosure.

(f) **Premature disclosure:**

(i) The release of information of a potential invention to the public, shall be made after consultation with Director General.

(ii) The premature disclosure may relate to disclosures in the form of abstracts, poster sessions, shelved theses or even presentations, prescribing an invention to an open audience, even if given by a person who is not the inventor or creator.

2.0. Determination of Intellectual Property Rights (IPR)

The determination of whether a particular research finding qualifies for an application for intellectual property protection shall follow the following steps:

(a) Prompt disclosure to the NIMR Director General.

(b) Submission of a written report of the relevant research findings to the Secretary of the IPMC.

(c) Upon receipt of the report, IPMC shall within 14 days convene a meeting in which a presentation will be made by the researcher on the key findings and demonstration on how the findings differ from the knowledge already known and the specific benefits that the findings may bring to the society.

(d) After the meeting, IPMC shall, within 7 days, compile a report indicating its recommendations to the DG regarding whether protection should be sought or otherwise.

(e) The DG is not bound by the recommendations of IPMC and may direct the IPMC to further evaluate or solicit additional information from the researcher.

(f) Researchers shall have the right to appeal against the findings of the IPMC in case where the Committee recommends that the findings are not meritorious for IP protection.

(g) Once the decision is made concerning the protection of the research finding through the intellectual property rights system, IPMC shall ascertain the expertise required for drafting of the application and the cost involved.

3.0. Evaluation of IP for Protection and Commercial Development

(a) The IPMC office will evaluate potential inventions and other disclosed potential intellectual property and suggest the appropriate form of IP protection, if any, which should be considered and the potential for technology transfer through licensing. Costs associated with obtaining protection of IP and maintaining the registered and granted patents will be incurred by NIMR.

(b) Copyright: The DRCP will review copyrightable materials which are disclosed by the authors. When necessary, DRCP may advise and consult with creator (s) to help ensure that proper notices are affixed to the property

and that deposition to the Copyright Society of Tanzania (COSOTA) is made on a timely manner.

(c) The copyright warning notice must be clearly marked on all print copies of materials, and a similar notice shall be displayed on thee-learning platform and e-mails for all electronic copies. Any variations of this copyright warning notice must be approved in advance by the Director General.

(d) Patents: The IPMC will review invention disclosures and will consult with the inventor (s) and others as necessary to investigate the patentability and commercial potential of inventions. The DRCP, upon the advice by IPMC, will also assist the Director General in determining whether a patent application should be filed or otherwise.

(e) Other types of protection: The IPMC will review inventions that meet all other forms of protection such as industrial design, trade secret or as the case may be and make recommendations to NIMR accordingly.

4.0. Commercial Development

NIMR, through the IPMC and the creator(s), share mutual responsibility for disclosing inventions and other licensable IP and cooperate to make the IP available commercially.

(a) Responsibilities of the creator(s) are to:

i) Disclose inventions, discoveries and other new IP to Director General through the IPMC in a through and timely manner as stated above.

ii) Abide by all commitments made in license, sponsored research and other agreements and comply with all laws and regulations related to government and private funded research.

iii) Provide such assistance as may be necessary throughout the technology transfer process to realize the goals and objectives set forth in these guidelines.

iv) Properly consider, disclose and manage any possible conflicts of interest arising from agreements to commercialize IP. If multiple agreements exist, for example, when a company funds NIMR research and also has a consulting arrangement with the creator, there may be conflicts created with respect to IP Management. The

creator should work with IPMC through the DRCP's office to resolve such conflicts.

(b) Responsibilities of NIMR are to:

(i) Publish or advertise the technology, as it deems appropriate.

(ii) Assist the creator in finding a partner for NIMR or a sponsor for the creator.

(iii) Negotiate and manage agreements to the best advantage of the creator and NIMR, in consistence with the IP Policy and Guidelines.

(iv) Provide legal support as deemed necessary or desirable by NIMR for all technology transfer and other commercialization activities and initiatives.

(v) Prepare legal instruments necessary to realize the technology transfer and commercialization objectives.

(vi) Provide legal and administrative support following such realization as may be needed.

(vii) Manage conflicts of interest, including negotiating agreements, which are consistent with NIMR policy.

5.0. Dissemination of NIMR Intellectual Property

As a public institution which is largely funded by the public funds in its various operations, hence, NIMR is under the obligation to implement this policy with broader public benefit objectives in mind. Therefore, in order to effectuate this public goal, NIMR may do the following:

(a) Keeping Creative Ideas in the Public domain: Whenever desirable and upon advice from the IPMC, NIMR may opt to put in the public domain certain information which is considered to be proprietary after which such information shall be freely accessible by the public. A formal public notice shall be put to inform the public and the world that such information cannot be appropriated by an individual person or a company.

(b) Commercialization: When it has been determined that protection of IP is likely to help commercialize the research results, the IPMC will recommend to the Director General upon satisfied that protection should be sought. In addition,

protection of IP may be obtained or pursued although the exact commercial potential is unknown, for either defensive protection, to preserve opportunities for commercialization in the future, or when required by an outside sponsor.

(c) Publication: These Guidelines are not intended to limit or restrict the right of creators to publish results of their research, subject to reasonable delays to preserve patent or other IP management. Delay of publication required by NIMR or third parties in sponsored research agreements should, as a general rule, not exceed NINETY (90) days from initial disclosure of the IP to the Director General or the sponsor.

(d) Ownership: As a general rule and unless otherwise agreed, in cases resources of NIMR are used in carrying out research, ownership of all resultant IP shall vest to NIMR. However, in case of joint research, the terms of the agreement may provide a different ownership framework. In all such cases, the Director General shall be consulted and approve in advance the terms of the agreement that create a different ownership arrangement.

(e) Limits to online access: NIMR will limit access of material on e-learning sites to the general public and they should only be accessible by authorized personnel.

6.0. Commercial Interactions

For proper discharge of its statutory obligations NIMR may interact with other partners on commercial basis. The form of interaction may include: consulting agreements, research agreements, or licensing agreements or combination of any.

7.0. Interactions Between Companies, Creators and NIMR

Basic principles must be observed in the structuring of interactions among the creator, NIMR and a company as follows:

(a) Publications: The publication of research results must not be hampered by agreements made to commercialize IP. However, a minimal and defined delay to protect IP through patent applications may be necessary. Similarly, creators may be required to observe confidentiality and nondisclosure agreements covering defined company IP.

(b) Educational Mission: The educational mission of NIMR must not be compromised. Trainees (students, fellows, associates) must have access to the best guidance and choice of research opportunities, which the staff member can

provide. They also must have the ability to publish the results of their research and should not be prohibited from continuing work on a project when they leave a laboratory, as a result of an agreement to develop IP.

(c) Scientific Integrity: Any agreement should not compromise or appear to compromise the design, conduct or reporting of research conducted by the creator or NIMR.

(d) Contracts: The terms of any agreement must be in conformance with applicable laws and regulations. The terms of an agreement must not be in conflict with existing licensing or research agreements.

(e) Indemnification: A company/institution will normally be required to indemnify NIMR with respect to general liability, product liability and/or infringement claims related to licensed IP to be used in any product.

8.0. Management of Conflicts of Interest

The possibility of conflict of interest is inherent in the commercial development of IP. Therefore, NIMR shall:

(a) adopt a conflict-of-Interest Management applicable to all its Centres and IPMC will advise the administrative mechanisms to manage such conflicts for staff engaged in research.

(b) have institutional conflicts of interest. Such conflicts will be handled on an *ad hoc* basis and are outside the mandate of the IPMC. In general, the following factors increase the perceived level of risk present in a material conflict of interest:-

(i) Increasing magnitude of personal compensation;

(ii) Increasing number of financial relationships between a creator and a company;

(iii) Increasing commitment of a creator's time to a company;

(iv) Holding of equity in a company;

(v) Involvement of trainees or students; and

(vi) Involvement of patients or other human participants.