2020

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DATA SHARING POLICY

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ACRONYMS

DRP	Director of Research and Publications
DTA	Data Transfer Agreement
DVC-ARC	Deputy Vice Chancellor, Academic, Research and Consultancy
ICT	Information and Communication Technology
IRB	Institutional Review Board
MTA	Material Transfer Agreement
MUHAS	Muhimbili University of Health and Allied Sciences
NIMR	National Institute of Medical Research

1.0 INTRODUCTION

1.1 Background

Muhimbili University of Health and Allied Sciences is a premier health training institution in the country with core functions of training, research and consultancy. Research being one of the core functions has accrued credits and recognition to the university both nationally and internationally. MUHAS has had more than 100 research projects funded by different partners producing large amounts of research data and outputs.

Research data are a valuable resource, usually requiring significant investment in time and financial resource to be produced. Most of the research data have a significant value beyond usage for the original research objectives; hence several research funders encourage research data sharing policies and mandate researchers to share data and outputs. However, a crucial aspect for creating data that can be shared and with a long-lasting usability is to ensure that the data is well managed. Furthermore, the accompanying documentation has to be user-friendly, clear, and comprehensive. Metadata and documentation have to be produced from the beginning of a research project and enhanced throughout the course of the data life-cycle.

MUHAS currently does not have a research database with all source documents or reports/published papers. Furthermore, the culture for sharing data among researchers needs to be fostered.

This policy is in line with strategies and other existing policies at MUHAS that include MUHAS Corporate Strategic Plan (2020-2025), MUHAS Research Policy and Guidelines (2011), MUHAS Library Policy and Procedures (2013), MUHAS Institutional Repository Policy (2017), MUHAS Information and Communication Technology Policy (2017) and MUHAS Intellectual Policy and Procedures (2011).

1.2 Rationale

As part of the University's commitment to academic excellence, this document outlines key policy issues and procedures for effective data management and sharing. The University shall implement a set of processes and systems to support researchers to achieve the highest standards of research data management and sharing.

1.3 Purpose and Context

In order to maximize the value of research data produced at MUHAS there is a crucial need to foster a culture in which both data generators and data users adopt good research practice, and act with integrity and transparency in managing, using and sharing research data. This policy provides guidance for data sharing which is fundamental to the conduct of high-quality research and promotion of research integrity.

1.4 Scope of the Data Sharing policy

This policy and procedures is applicable to all MUHAS' staff and students, internal and external research collaborators and any other entity seeking to make use of data which has been created by MUHAS entities. This policy and procedures shall be kept under regular review by the Directorate of Research and Publications.

1.5 Policy Objectives and Outcomes

The main objective of this policy is to lay down principles and procedures for MUHAS to share research data and provide appropriate protection for the shared data while safeguarding the intellectual property rights of data generators. The gist is to give guidance on how to implement data sharing process, by considering that the data shared shall be for public use and shall be made available as soon as possible without jeopardizing privacy, confidentiality, proprietary interests and national security. To this end, the specific objectives of this policy are to:

i. Guide MUHAS researchers and external users on data management and sharing processes.
ii. Encourage transparency and accountability among researchers
iii. Encourage multidisciplinary collaborations among staff, students and other stakeholders within MUHAS and beyond

It is expected that the following outcomes will be attained upon full implementation of the policy.

i. The University will implement a set of processes and systems to support researchers to achieve the highest standards of research data management and sharing.
ii. Research data will be managed to the highest standards throughout the research data lifecycle as part of the University's commitment to research excellence.
iii. Sharing of research data will observe the fundamental intellectual property rights and copyrights of researchers as well as safeguard interests of research subjects.

2.0 DEFINITION OF TERMS

Autonomous data: Data that is independently available for use subject to consent but not restricted through intellectual property rights or for any other reason.

Conditional (Restricted) data: Data available on condition, by the study team, which is shared based on the nature of data acquisition

Data Generator: Any MUHAS entity that invested human, time and financial resources to obtain quality data that enables sharing.

Data management: Administrative process involving data acquisition, validation, storage and protection to ensure accessibility, reliability and transparency for its users.

Data Requestor: Any individual, group or organisation that would like to obtain data generated by MUHAS entities.

Data sharing agreement: A formal contract that clearly documents what data are being shared and how the data can be used

Data sharing procedures: Processes set out to facilitate data sharing.

Data sharing: Practice of making scholarly research data available to other investigators or users

Data standards: In this context, data standards are defined as consensual specifications for the representation of data from different sources or settings

Digital Research Data: Information stored using specific machine language systems that can be interpreted by various technologies that includes: experimental, observational, and simulation data; codes, software and algorithms; text; numeric information; images; video; audio; and associated metadata.

Non-digital research data: Data that is represented in a physical way (hard copies).

Readily available data: Data which can be made available for sharing, without any restriction because the nature of data and the risk involved with respect to use is minimal.

Research Data: Factual records (e.g. numerical and textual records, images and sounds, videos etc.) used as primary sources for research, and that are commonly accepted in the research community as necessary to carry out and validate research findings.

Unavailable data: Unavailable data for sharing refers to all kind of data that may not be available to the public for some reasons that include, for example, national security, ethical concerns and strong confidentiality of participants.

3.0 POLICY STATEMENTS AND PROCEDURES

The policy statements are presented in seven thematic policy issues followed by the operational procedures under each policy statement.

3.1 Policy Statement 1: Research Data Management

MUHAS shall create uniform research data management practices for all researchers that include storage, retention, accessibility and disposal of data in accordance, with all legal, statutory, ethical, contractual and funding requirements.

3.1.1 Research Data Management Procedures:

i. The University shall establish a Digital Research Data Repository to facilitate data sharing.
ii. The University shall put in place mechanisms and services for storage, backup, registration, deposit and retention of research data assets that support current and future access to data, during and after completion of research projects.
iii. The University shall provide training to ensure that all researchers are conversant with systems and processes put in place by MUHAS on research data management.
iv. All researchers must ensure that all research data in digital and computer-readable form is stored securely and with adequate metadata, in the University Digital Research Data Repository for ease of access by data requestors.
v. Where research data is stored in another repository, an entry must be made in the University Repository indicating where the Research Data has been stored.
vi. Researchers and research administrators must have a backup strategy to recover data after loss and/or to recover data from a particular time according to best practice for electronic data storage.

vii. Non-digital research Data unsuitable for digitization should be stored securely; labelled, indexed or categorized appropriately for easy identification. The Directorate of Library Services shall provide guidance on processes for storage of non-digital research data.

viii. Unless the terms of research grants or contracts provide otherwise, data generated by research projects are the property of the University.

ix. All research data stored in the University Digital Research Data Repository shall be retained for a minimum period of 10 years from completion of collection of the research data or from publication of the research data (whichever is the latest).

x. Indefinite retention of research data may be considered if the results of the research have resulted in a patent application; the outcome of the research has a high public interest or heritage value or due to any other justifiable reason.

xi. Research data that is due for disposal shall be destroyed in accordance with the MUHAS policy on information retention and disposal.

xii. All researchers, undertaking research have a personal responsibility to manage effectively the data they create.

xiii. The University shall institute a unit dealing with biological data banking facility, fully staffed with Information Communication Technology (ICT) and laboratory personnel. Due to their sensitivity, there may be separate guidelines for sharing biological data, over and above those stipulate in this agreement.

3.2 Policy Statement 2: Classification of shared data

MUHAS shall ensure all data that are generated through research are correctly classified to enable data requestor to make an informed choice.

3.2.1 Classification of shared data procedures:

In order for interested parties to know the category of the available data:

i. The following classification shall hold when considering data sharing: Readily available data, Autonomous data, Conditional (Restricted) data, and Unavailable data.

ii. All research data shall be correctly classified during submission to the Director of Research and Publications (DRP) for deposition into the University Digital Research Data Repository.

iii. Study investigators shall clearly state the category of data in their data sharing plan and provide justification for their categorisation.

iv. Application for amendment of data classification can be submitted to the DRP. Study investigators shall provide justifications for the need of data re-classification.

3.3 Policy Statement 3: Declaration for Data Sharing

The university shall ensure that for each research study, the Principal Investigator makes a declaration on the classification and availability of data for sharing to the research community.

3.3.1 Declaration for Data Sharing Procedures:

i. The DRP will ensure that each proposed research study provides a declaration statement on readiness for sharing of the data generated.

ii. This statement may read as follows: *'The research data generated from this study will be deposited in the University Digital Research Data Repository and made accessible to the research community according to the MUHAS Research Data Sharing Policy and Procedures 2020'.*

iii. Unless the terms of research grants or contracts state otherwise, no research proposal shall be approved by MUHAS review board without including a data sharing declaration.

3.4 Policy Statement 4: Research Data Standards

Studies shall adopt appropriate data standards to support high quality research and data-sharing.

3.4.1 Research Data Standards Procedures:

i. All data to be shared must not contain any variables that will allow identification of the study subjects.

ii. The Principal Investigator shall provide a comprehensive documentation (for example, metadata, descriptors, schema) so that others can understand and use the dataset and to prevent misuse, misinterpretation, or confusion. These include, for example description of the experimental design, and terminology or vocabulary standards used for a possibility to reuse data.

iii. The Principal Investigator shall communicate with the DRP on how codes will be shared, annotated, acknowledgements and standard citing of data source.

iv. The Principle Investigator shall declare in advance whether there is other data necessary to complement the requested data (for example, qualitative data or service data, etc.).

v. Research data for sharing shall include variable code catalogue of raw data through the DRP and/or in Institution Repository.

3.5 Policy Statement 5: Governance of Data Sharing

The university shall ensure that the processes for data acquisition are straightforward, transparent, and justified.

3.5.1 Governance of data sharing procedures:

The Data requestor shall:

i. Channel an application to the DRP's office stating the title of the study and the description of the data requested for.
ii. Provide a brief study plan outlining the intended purpose for the requested research data
iii. Provide a brief description indicating the new use of the requested data or the added value that it provides to ongoing research
iv. Have the right to appeal in writing to the University Scientific Committee in case of rejected request for research data. The decision of the University Scientific Committee will be final.
v. Adhere to all terms of the data sharing agreement as stipulated in section 3.7 of this document

The DRP's office shall:

i. Verify that the requested data is ready for sharing subject to exclusivity period specified within this document in section 3.6.
ii. Assess the requestor's application to ensure it meets the minimum criteria for data sharing request and in the case the application is considered unsatisfactory- it will be formally referred to the requestor for revision or substantive additional information
iii. Notify the principle investigator of the study regarding request for data sharing if the application is considered satisfactory. A copy of the application will also be provided to the PI for data sharing consideration.
iv. Notify the co-author of the study or the head of the respective principle investigator's department of the data sharing request in the event that the principle investigator is unavailable.

v. Serve a reminder and take other measures in line with this policy in the event that the specified response time lapses without justified principle investigator's response.
vi. Respond to the data requestor depending on response received from the principle investigator regarding approval or rejection of the data sharing request.
vii. Provide annual reports of the number of formal requests; the number (%) of formal requests that were accepted; the number (%) of accepted requests that were formally referred back to the requester for revision or substantive additional information; the number (%) that were declined; and the number (%) that appealed.
viii. Provide reports of data breaches resulting from data sharing

The principle investigator shall:

i. Submit research data with appropriate standards (see section 3.3) to the Directorate of Research and Publication for deposition in the Data Repository upon completion of data collection
ii. Respond to the notification regarding data sharing application from the DRP's office within two weeks from its receipt
iii. Provide the DRP's office with a brief outline of the risks related to the sensitivity of the requested data and information on any anticipated conflict of interest that may arise from the current data sharing application.
iv. Provide the DRP's office a statement with justification regarding objections to sharing of their data. In the absence of this statement, it will be considered that the principle investigators have no objections to sharing of their data.

3.6 Policy Statement 6: Period of Exclusive Data Use

The University shall safeguard the academic and scientific interest of data generators prior to making data accessible for sharing through a defined period of exclusive use of data.

3.6.1 Period of Exclusive Data Use Procedures:

i. Data generators are entitled to a reasonable but limited period of exclusive use of their data before sharing.
ii. The period of exclusivity shall be a maximum of five (5) years from the last data collection point for research with on-going data collection

iii. If data is requested within the five-year exclusivity period, sharing can only occur if the principle investigator approves the request. This will be governed by procedures stipulated in section 3.4.

3.7 Policy Statement 7: Data Sharing Agreement

The university shall ensure that all data transfers within the research community are accompanied by a legally binding agreement.

3.7.1 Data sharing agreement procedures:

i. The DRP shall ensure that a data-sharing agreement template (Appendix: A) is available and used by MUHAS stakeholders.
ii. The DRP shall ensure that data sharing agreement clearly show what type of data are being shared and how will be used.
iii. The Data sharing agreement shall clearly indicate when the provider will give the data to the receiver and how long the receiver will be able to use the data.
iv. The agreement shall indicate how data will be transferred from provider to the recipient (i.e. physically or electronically).
v. The agreement shall indicate who will cover the financial costs of data sharing process (receiver, provider or both)
vi. The DRP shall ensure that a data-sharing agreement is issued and signed by appropriate authorities before data are released.
vii. Data-sharing agreements must prohibit any attempt to (i) identify study participants from the released data or otherwise breach confidentiality, (ii) make unapproved contact with study participants.
viii. The agreement should reflect roles and responsibilities of each partner, recognition (authorship and acknowledgement) and other benefits according to the specific contributions of the individuals and organizations involved.

4.0 POLICY STATUS

This is a new MUHAS Data Sharing Policy.

5.0 KEY STAKEHOLDERS

A: The stakeholders who were consulted during formulation of this policy include the following:

i. Vice Chancellor, Deputy Vice Chancellors
ii. Deans and Directors
iii. Students and Staff
iv. Principal Investigators (PIs)

B: The main stakeholders of this policy are:

i. All MUHAS staff and students
ii. Other Researchers
iii. All partners funding research at MUHAS
iv. Deans and Directors
v. Heads of Departments and Administrative units

6.0 APPROVAL DETAILS

The policy was approved by the University Council at its 57th meeting held on on7th August 2020 and come into force immediately thereafter.

7.0 ENDORSEMENT DETAILS

The University Council approved the policy at its 57th meeting held on 7th August 2020.

8.0 RELATED LEGISLATION

MUHAS Charter of Incorporation, February 2007;

9.0 RELATED POLICIES

i. MUHAS Intellectual Property Policy (2011)
ii. MUHAS Research Policy (2011)
iii. MUHAS Institutional Repository policy (2017)
iv. MUHAS Information Communication Technology Policy (2017)
v. MUHAS Gender Policy (2013)
vi. MUHAS Human Resources Training and Development Policy (2012)
vii. MUHAS HIV/AIDS Policy (2008)
viii. MUHAS Library Policy and Procedures (2013)

10.0 RELATED DOCUMENTS

i. MUHAS Cooperate Strategic Plan (2013/14 – 2017/18)
ii. MUHAS Charter (2007)
iii. DRP Strategic Plans (2013/14 – 201718)
iv. MUHAS Student Bylaws (2013)
v. MUHAS Annual Reports

11.0 EFFECTIVE DATE FOR THE POLICY

Unless otherwise determined by the approving body, the policy shall become effective from the date it is approved by the University Council.

12.0 NEXT REVIEW DATE

The MUHAS Research Data Sharing Policy and Procedures will be reviewed after every three years or when deemed necessary to assess the effectiveness of its implementation and determine policy areas that need to be revised. The periodic review will ensure the policy is in line with the University, national and international changes that might have taken place.

13.0 POLICY OWNER

The University Council shall own the MUHAS Research Data Sharing Policy and Procedures.

14.0 POLICY AUTHOR

The Directorate of Research and Publications of the University.

15.0 CONTACT PERSON

The contact person for issues related to the Research Data Sharing Policy and Procedures shall be:

Director of Research and Publications,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65001,
United Nations Road, Dar es Salaam, Tanzania.

16.0 APPENDIX A: DATA SHARING AGREEMENT TEMPLATE

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DATA SHARING AGREEMENT

THIS DATA SHARING AGREEMENT FOR

(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 ***"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 health and allied sciences 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 generated 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 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:**

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 described below:

a) Description of Information to be transferred under this Agreement

_____

_____

_____

b) Title of study _____

c) Was research protocol approved by Tanzania Authorities? 1. Yes 2. No

If yes, mention place and certificate number _____

d) Mode of data transfer (Circle selected option) 1. Electronic 2. Physical

Obligation of the RECIPIENT

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

1. 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.

2. 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.
3. The RECIPIENT shall use the DATA for teaching or academic research purposes only.
4. 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.
5. The RECIPIENT shall acknowledge the source of the DATA in any publications reporting use of it.
6. 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.
7. 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.
8. The RECIPIENT shall be liable for damages which may arise from RECIPIENT's use, storage and disposal of the DATA.

Obligation of the PROVIDER

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

1. The PROVIDER agrees to transfer, store or dispose of the DATA in compliance with all applicable laws
2. The PROVIDER shall transfer immediately the DATA upon receipt of one of the two copies duly signed by the RECIPIENT.
3. 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).

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

Confidentiality

The PROVIDER confirms that there are no ethical or legal obligations that prevent the use and sharing data sets at the indicated access level. Personal data should remain confidential and should not be disclosed verbally or in writing to an unauthorized third party, by accident or otherwise.

Financial costs

In case there are data-sharing expenses, the PROVIDER and the RECIPIENT shall agree on the modalities of meeting the costs.

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.

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

d) This agreement shall come to end on this day ……of ……. (Month) in ……. (Year)

Signatories

The following signatories have read and agree with the Agreement as presented above:

Representative of the PROVIDER

Name _____

Signature _____ Date _____

Representative of RECEPIENT

Name _____

Signature _____ Date _____

17.0 APPENDIX B: NIMR MTA

NIMR MATERIAL TRANSFER AGREEMENT FOR RESEARCHERS / ORGANISATIONS

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

MATERIAL TRANSFER AGREEMENT FOR RESEARCHERS/ORGANIZATIONS

(FOR RESEARCH USE ONLY)

THIS MATERIAL TRANSFER AGREEMENT FOR Researchers / Organizations (here-in-after referred to as *the "**Agreement**")* is made this..... Day of ..... 2…

Between

_____of P.O Box _____ (here-in-after referred to as the *"**PROVIDER**"*);

And

_____of P. Box _____

(here-in-after referred to as "a person" *"**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.

AR TICLE 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
Date: _____

Mailing Address for MATERIAL:

_____
_____

Tel: _____ Fax: _____

E-Mail: _____

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

_____

Signature

_____
Printed Name and Title
Date: _____

Mailing Address for Notices:

_____
_____

Tel: _____ Fax: _____

E-Mail: _____

FOR PROVIDER:

PROVIDER's Authorized Signatory

_____

Signature

_____
Printed Name and Title

Date: _____

Mailing Address:

_____
_____

Tel: _____ Fax: _____

E-Mail: _____

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

_____

Signature

_____
Printed Name and Title

Date: _____

Mailing Address for Notices:

_____
_____

Tel: _____ Fax: _____

E-Mail: _____

CERTIFICATION
Authorized Official: **CHAIR MRCC**

_____

Annex I

Description of Chemical/ Biological Materials to be transferred under this Agreement: (MTA)

1 _____

2 _____

3 _____

4 _____

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 are only the one to be transferred herein.

_____ _____ _____ _____

Name **Signature** **Date** **Seal Stamp**

Authorized Official: <u>CHAIR MRCC:</u> I approve ONLY _____type(s) of Sample (s) mentioned here above to be transferred from Tanzania.

_____ _____ _____ _____

Name **Signature** **Date** **Seal Stamp**

18.0 APPENDIX C: NIMR DTA

NIMR DATA TRANSFER AGREEMENT FOR RESEARCHERS AND ORGANISATIONS

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

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 Investigator: I acknowledge

_____

Signature

_____

RECIPIENT's Authorized Signatory and understand the terms to this Agreement.

_____

Signature

_____

Printed Name and Title Printed Name and Title

Mailing Address for MATERIAL: Mailing Address for Notices:

Tel: _____Fax_____ Tel: _____ Fax_____

Email: _____ Email: _____

FOR PROVIDER:

PROVIDER's Authorized Investigator: I acknowledge

_____

Signature

_____

PROVIDER's Authorized Signatory and understand the terms to this Agreement.

_____

Signature

_____

Printed Name and Title Printed Name and Title

Mailing Address for MATERIAL: Mailing Address for Notices:

Tel: _____ Fax_____ Tel:_____ Fax_____

Email: _____ 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: (**DTA)**

Was the DATA 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

- o Yes Number: .....
- o 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 _____

Authorized Official: CHAIR MRCC: **I approve ONLY ___ type (s) and format of Dataset mentioned here above to be transferred from Tanzania.**

Name:

_____

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

Seal Stamp _____

Authorized Official: CHAIR MRCC: **I approve ONLY ___ type (s) and format of Dataset mentioned here above to be transferred from Tanzania.**

Name: _____

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

2020

DATA SHARING POLICY