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....31..... Day of .Jun..... , .2020…

Between

Muhimbili University of Health and Allied Sciences ....of P.O Box 65001, Dar es Salaam.

(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 nonprofit organizations or government agencies) who wish to replicate the RECIPIENT Investigator's scientific research).

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

ARTICLE IV

COSTS AND PAYMENT ARRANGEMENTS

The DATA shall be provided at no cost.

ARTICLE V

WARRANTIES

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

ARTICLE VI

LEGAL TITLE TO DATA TRANSFERRED AND BENEFIT SHARING

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

ARTICLE VII

PERMITS, LICENCES AND APPROVALS

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

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

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

ARTICLE VIII

NON-EXCLUSIVE LICENSE

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

ARTICLE IX

AMENDMENTS

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

ARTICLE X

TERMINATION

Termination of this Agreement is accomplished:

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

ARTICLE XI

APPLICABLE LAW, SEVERABILITY

The Parties recognize and agree that this Agreement is a contract and not an International agreement, that

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

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

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

ARTICLE XII

NOTICE

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

ARTICLE XIII

NONAPPLICABILITY OF THIS AGREEMENT TO EXISTING OR FUTURE AGREEMENTS

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

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

SIGNATURE PAGE

FOR RECIPIENT:

RECIPIENT's Authorized Signatory

_____
Signature

_____
Printed Name and Title

Mailing Address for MATERIAL:

Tel: _____Fax_____

Email:_____

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

_____
Signature

_____
Printed Name and Title

Mailing Address for Notices:

Tel:_____Fax_____

Email:_____

FOR PROVIDER:

PROVIDER's Authorized Signatory

_____
Signature

Dr. Nahya Salim, Director of Research and Publications
Printed Name and Title

Mailing Address for MATERIAL:

Muhimbili University of Health and Allied Sciences. P.O.Box 65001, Dar es salaam. Tanzania

Tel: +255713250074 Fax_____

Email: nahya.salim@gmail.com

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

_____
Signature

Dr. Lulu Chirande, Pediatric Hematologist & Oncologist
Printed Name and Title

Mailing Address for Notices:

Muhimbili University of Health and Allied Sciences. P.O.Box 65001, Dar es salaam. Tanzania

Tel: +255717193263 Fax_____

Email: l2chirande@yahoo.com

CERTIFICATION
Authorized Official**: CHAIR MRCC.**

_____
Signature

31 / December / 2020
Date

_____
Printed Name and Title:

Mailing Address:

Tel: _____

Fax:_____

Email:_____

Annex I

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

No 1. De-identified baby and parent demography data

No 2. De-identified sickle cell disease screening results (POCT and IEF/HPLC)

No 3. De-identified stake holders FGD/Key informant interview data on NBS

No 4. Facility staffing and resources for SCD services

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

SickleInAfrica proposal for Clinical and Implementation Research in Newborn Screening for Sickle Cell Disease Using Dried Blood Spots for Point of Care Tests.

A Research protocol Approved by Tanzania Authorities:

☐ Yes Certificate Number:.....

☐ No

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

☐ Yes Number:.....

☐ No

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

Name: Lulu Chirande

Signature:_____ Date.31 /.December / .2020

_____

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.31 /.December / .2020

_____

Seal Stamp