BREEDIME

CONSORTIUM AGREEMENT

Version 1– 4 June 2023

for a Collaborative Project under Horizon Europe'

Project full title:

BUILDING RESILIENT RESEARCH ETHICS, DIAGNOSTICS AND MEDICINES REGULATORYCAPACITY DURING ROUTINE AND PUBLIC HEALTH EMERGENCY PERIODS

Coordinator:

Karolinska Institutet

THIS CONSORTIUM AGREEMENT (hereinafter "Consortium Agreement") is based upon Regulation (EU) No 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation (2021-2027), laying down its rules for participation and dissemination (hereinafter referred to as "Horizon Europe Regulation"), and on the European Commission's General Model Grant Agreement and its Annexes, and is effective from 1 July 2023, hereinafter referred to as the Effective Date

BETWEEN:

1. **Karolinska Institutet,** Department of Global Public Health, with legal address in SE-171 77 Stockholm, Sweden ("KI" or the "Coordinator"),

2. **NATIONAL INSTITUTE FOR MEDICIAL RESEARCH, TANZANIA**, with legal address in SOKOINE LUTHULI DRIVE OCEAN ROAD 255, DAR ES SALAAM Tanzania, ("NIMR")

3. **THE GOOD SAMARITAN FOUNDATION**, with legal address in P.O BOX 545, Moshi, Tanzania, ("GSF")

4. **MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES** with legal address in UNITED NATIONS ROAD 65001, DAR ES SALAAM Tanzania, ("MUHAS")

5. **ZANZIBAR FOOD AND DRUG AGENCY** with legal address in P.O.BOX 3595, CHANGU ROAD, MOMBASA AREA, ZANZIBAR po box: 3595, ZANZIBAR Tanzania, ("ZFDA")

6. **ZANZIBAR HEALTH RESEARCH INSTITUTE** with legal address in BINGUNI P.O box: 236, ZANZIBAR Tanzania, ("ZAHRI")

7. **THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ANDREWS** with legal address in NORTH STREET 66 COLLEGE GATE, KY16 9AJ, ST ANDREWS United Kingdom, ("USTAN")

8. **RWANDA FOOD AND DRUGS AUTHORITY** with legal address in NYARUTARAMA PLAZA KG 9 AVENUE, P.O box: 1948, KIGALI Rwanda, ("Rwanda FDA")

9. **TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY** with legal address in MABIBO EXTERNAL, OFF- NELSON MANDERA ROAD, NEAR EPZ, P.O box: 77150. DAR ES SALAAM Tanzania, ("TMDA")

hereinafter, jointly or individually, referred to as "Parties" or "Party" relating to the Action entitled "Building Resilient research Ethics, diagnostics and medicines regulatory capacity during routine and public health emergency periods", in short "BREEDIME" hereinafter referred to as "Project".

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Granting Authority **as part of the Research and Innovation Actions supporting the global health EDCTP3 Joint Undertaking.**

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement to be signed by the Beneficiaries and the Granting Authority (hereinafter "Grant Agreement").

The Parties are aware that this Consortium Agreement is based upon the DESCA model consortium

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Horizon Europe Regulation or in the Grant Agreement including its Annexes.

1.2 Additional Definitions

"Consortium Body" means any management body described in Section 6 (Governance Structure) of this Consortium Agreement.

"Consortium Plan" means the description of the Action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the Project Steering Committee.

"Granting Authority" means the body awarding the grant for the Project, in this case the Global Health EDCTP3 Joint Undertaking under Horizon 2020, the European Union's Framework Programme for Research & Innovation.

"Defaulting Party" means a Party which the Project Steering Committee has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.3 of this Consortium Agreement.

"Needed" means:

For the implementation of the Project:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

For Exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

"Starting Date" means the date reported in Article 4 of the Grant Agreement as the starting date of the Action, which is expected to be June 1st, 2023.

"Software" means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

2 Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, Access Rights and dispute resolution.

3 Entry into force, duration and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

An entity becomes a new Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

Should an entity become a new Party to the Consortium Agreement as an Associated Partner (entity which participate in the action, but without the right to charge costs or claim contributions), the accession of such new Party will be subject to an amendment of the Consortium Agreement to be signed by all Parties. Such accession shall have effect from the date of signature of the amendment to the Consortium Agreement.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect from its Effective Date until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated earlier in accordance with the terms of this Consortium Agreement and the Grant Agreement.

If the Grant Agreement

- is not signed by the Granting Authority or a Beneficiary, or
- the Grant Agreement is terminated, or
- a Party's participation in the Grant Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights, Dissemination and confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Project incurred prior to the date of termination, unless otherwise agreed between the Project Steering Committee and the leaving Party. This includes the obligation to provide all necessary input, deliverables and documents for the period of the leaving Party's participation in the Project.

4 Responsibilities of the Parties

4.1 General principles

4.1.1 Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

4.1.2 Each Party undertakes to notify promptly the Granting Authority and the other Parties, in accordance with the governance structure of the Project, of any significant information, fact, problem or delay likely to affect the Project.

4..1.3 Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks and shall responsibly manage the access of its employees to the EU Funding & Tenders Portal.

4.1.4 Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

4.1.5 Each Party shall ensure that its work on the Project complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Grant Agreement, including those governing health and safety, data protection, and where relevant, the use of human or animal subjects and good clinical practice. In this regard, each Party shall maintain the confidentiality, in accordance with the applicable laws, regulations and guidelines, of all samples and data relating to the use of human subjects, which is created or used in the course of the Project.

4.1.6 Each Party shall secure all necessary approvals from the relevant research ethics committees before undertaking any part of the Project requiring ethics committee approval and shall, if required, obtain properly signed informed consent and acknowledgement forms from any human subjects, or their legal guardians, who they will involve in the Project. Where any part of the Project takes place in a hospital, the Party involved shall first obtain all necessary approvals, indemnities and agreements from that hospital.

4.1.7 When a Party (the "Provider") sends biological material to another Party (the "Recipient") in respect of the Project, a bilateral material transfer agreement (MTA), shall be concluded between such Parties to specify the conditions applying to such transfer of material. The material shall only be used for the purpose of the Project and only for as long as is necessary for that purpose. The Recipient will be entirely responsible for the use of the biological material and the Provider shall have no obligation or liability for the material, except for gross negligence or wilful misconduct. Material provided in the performance of the Project shall remain the property of the Provider. The Recipient shall not be entitled to transfer the material to any third party (including another Party) without the Provider's prior written consent. Each Party is responsible for ensuring that the MTA is adapted to the relevant situation and that it complies with this Consortium Agreement and all applicable rules, laws or regulations.

4.2 Specific responsibilities for Associated Partner(s)

Not applicable.

4.3 Breach

In the event that the Project Steering Committee identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Project Steering Committee, will give formal notice to such Party requiring that such breach will be remedied within thirty (30) calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the Project Steering Committee may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation.

4.4 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities or other Participants) in the Project remains solely responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement. Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement, notably regarding Background and Results.

4.5 Specific responsibilities regarding data protection

Where necessary, the Parties shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* and relevant national data protection law applicable to said Party) within the scope of the performance and administration of the Project and of this Consortium Agreement.

In particular, the Parties shall, where necessary, conclude a separate data processing, data sharing and/or joint controller agreement before any data processing or data sharing takes place.

The Parties agree that any personal data collected or generated pursuant to this Consortium Agreement will be processed fairly and lawfully by the Parties in accordance with the European General Data Protection Regulation. Each Party will ensure that it has in place and observe appropriate technical and organisational measures to ensure the security of the personal data and to guard against unauthorized or unlawful access to or processing of the personal data and against accidental loss or destruction of, or damage to the personal data. The Parties acknowledge that they may each collect personal data under this Consortium Agreement but will not share any personal data (including pseudonymised data) with each other until a separate data protection agreement setting out the obligations and responsibilities of the Parties further to the European General Data Protection Regulation has been signed.

5 Liability towards each other

5.1 No warranties

In respect of any information or materials (including Results and Background) supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the

sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its entities under the same control) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts.

A Party's general aggregate liability towards the other Parties collectively shall be limited to once the Party's share of the total costs of the Project as identified in Annex 2 of the Grant Agreement.

A Party's liability shall not be limited under either of the two foregoing paragraphs to the extent such damage was caused by a willful act or gross negligence or to the extent that such limitation is not permitted by law.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

5.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the Project Steering Committee of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the Project Steering Committee.

5.5 Export control

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement due to a restriction resulting from import or export laws and regulations and/or any delay of the granting or extension of the import or export license or any other governmental authorisation, provided that the Party has used its reasonable efforts to fulfil its tasks and to apply for any necessary license or authorisation properly and in time.

Each Party will notify the Project Steering Committee of any such restriction without undue delay. If the consequences of such restriction for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the Project Steering Committee.

6 Governance structure

6.1 General structure

The organisational structure of the consortium shall comprise the following Consortium Bodies:

The **Project Steering Committee** is the decision-making body of the consortium.

The **Project Management Team (PMT)** consisting of members of KI (the overall coordinator), and TMDA (the scientific coordinator) who assists the Coordinator and the Project Steering Committee with the day-to-day management of the Project.

The **Coordinator** is the legal entity acting as the intermediary between the Parties and the Granting Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.

Other Consortium functions may be set up in accordance with Annex 1 of the Grant Agreement.

6.2 Project Steering Committee Members

The Project Steering Committee shall consist of one representative of each Party (hereinafter referred to as "Member").

Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.7 of this Consortium Agreement. If a Member is not duly authorised by his/her institution or company to make the proposed decision on behalf of that Party, the Member shall ensure that he/she duly transfers the information on such decision to the authorised representative for his/her institution or company at the earliest time possible and will inform the Coordinator of such referral.

The Coordinator (KI) shall chair all meetings of the Project Steering Committee, unless decided otherwise by the Project Steering Committee.

TMDA shall co-chair all meetings of the Project Steering Committee, unless decided otherwise by the Project Steering Committee.

The Parties agree to abide by all decisions of the Project Steering Committee.

This does not prevent the Parties from exercising their veto rights, according to Section 6.3.5, or from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Section 11.8 of this Consortium Agreement.

6.3 Operational procedures for the Project Steering Committee:

6.3.1 Representation in meetings

Any Member of the Project Steering Committee:

- should be present or represented at any meeting of the Project Steering Committee;
- may appoint a substitute or a proxy to attend and vote at any meeting; and
- shall participate in a cooperative manner in the meetings.

6.3.2 Preparation and organisation of meetings

6.3.2.1 Convening meetings:
The chairperson shall convene ordinary meetings of the Project Steering Committee at least quarterly and shall also convene extraordinary meetings at any time upon written request of any Member.

6.3.2.2 Notice of a meeting
The chairperson shall give written notice of a meeting, including the agenda, to each Member as soon as possible and no later than 14 calendar days preceding an ordinary meeting and 7 calendar days preceding an extraordinary meeting.

6.3.2.3 Sending the agenda:
The chairperson shall prepare and send each Member an agenda no later than 7 calendar days preceding the meeting, or 3 calendar days before an extraordinary meeting.

6.3.2.4 Adding agenda items:
Any agenda item requiring a decision by the Members must be identified as such on the agenda. Any Member may add an item to the original agenda by written notice to all of the other Members no later than 3 calendar days preceding the meeting and 1 days preceding an extraordinary meeting. During a meeting of the Project Steering Committee the Members present or represented can unanimously agree to add a new item to the original agenda. However, no decision may be taken on this new item if not all Members are present or represented at the meeting.

6.3.2.5 Meetings of the Project Steering Committee may also be held by tele- or videoconference or other telecommunication means.

6.3.2.6 Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.3.6.2.

6.3.3 Decisions without a meeting

Any decision may also be taken without a meeting if

a) the Coordinator circulates to all Members of the Project Steering Committee a suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Party and

b) the decision is agreed by two-thirds of all Parties.

The Coordinator shall inform all the Members of the outcome of the vote.

A veto according to Section 6.3.5 may be submitted up to 15 calendar days after receipt of this information.

The decision will be binding after the Coordinator sends a notification of its acceptance to all Members. The Coordinator will keep records of the votes and make them available to the Parties on request.

6.3.4 Voting rules and quorum

6.3.4.1 The Project Steering Committee shall not deliberate and decide validly in meetings unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached, the chairperson of the Project Steering Committee shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members is present or represented.

6.3.4.2 Each Member of the Project Steering Committee present or represented in the meeting shall have one vote.

6.3.4.3 A Party that the Project Steering Committee has declared according to Section 4.3 to be a Defaulting Party may not vote.

6.3.4.4 Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast, except in the following cases which require the unanimous vote of the Parties:
- Section 6.2.2.2 (i) Entry of a new Party to the Consortium and approval of the settlement on the conditions of the accession of such a new Party
- Section 6.2.2.2 (i) Termination of a Defaulting Party's participation in the Consortium and measures relating thereto.

6.3.5 Veto rights

6.3.5.1 A Party that can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of the Project Steering Committee may exercise a veto with respect to the corresponding decision or relevant part of the decision. Such veto shall be reasonably and duly justified.

6.3.5.2 When the decision is foreseen on the original agenda, a Party may only veto such a decision during the meeting.

6.3.5.3 When a decision has been taken on a new item added to the agenda before or during the meeting, a Party may veto such decision during the meeting or within 15 calendar days after receipt of the draft minutes of the meeting.

6.3.5.4 When a decision has been taken without a meeting a Party may veto such decision within 15 calendar days after receipt of the written notice by the chairperson of the outcome of the vote.

6.3.5.5 In case of exercise of veto, the Parties shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all Parties.

6.3.5.6 A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

6.3.5.7 A Party requesting to leave the consortium may not veto decisions relating thereto.

6.3.6 Minutes of meetings

6.3.6.1 The chairperson shall produce written minutes of each meeting which shall be the formal record of all decisions taken. The chairperson shall send draft minutes to all Members within 10 calendar days of the meeting.

6.3.6.2 The minutes shall be considered as accepted if, within 15 calendar days from receipt, no Party has sent an objection to the chairperson with respect to the accuracy of the draft minutes by written notice.

6.3.6.3 The chairperson shall send the accepted minutes electronically to all the Members, and to the Coordinator, who shall retain copies of them.

6.3.7 Decisions of the Project Steering Committee

The Project Steering Committee, shall have the role described in Annex 1 of the Grant Agreement and shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein.

The following decisions shall be taken by the Project Steering Committee:

Content, finances and intellectual property rights

- Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Granting Authority
- Changes to the Consortium Plan
- Modifications or withdrawal of Background in Attachment 1 (Background Included)
- Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section **Error! Reference source not found.**)
- Additions to Attachment 4 (Identified entities under the same control)
- Approve the content and timing of press releases and abstracts to scientific meetings and congresses by the Consortium upon the suggestion of the Communication Team
- Approve the joint areas of cooperation between the Consortium and other European and international initiatives and regulatory bodies
- Prepare the content and timing of joint publications by the Consortium or proposed by the Granting Authority in respect of the procedures of the Grant Agreement.

Evolution of the consortium

- Entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal
- Proposal to the Granting Authority for a change of the Coordinator
- Proposal to the Granting Authority for suspension of all or part of the Project
- Proposal to the Granting Authority for termination of the Project

Breach, defaulting party status and litigation

- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party

- Termination of a Defaulting Party's participation in the consortium and measures relating thereto

Appointments

On the basis of the Grant Agreement, the appointment, if necessary, of:

- External Expert Advisory Board Members, upon a proposal by the Coordinator

In the case of abolished tasks as a result of a decision of the Project Steering Committee, Members shall rearrange the tasks of the Parties concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

6.4 Coordinator

6.4.1 The Coordinator shall be the intermediary between the Parties and the Granting Authority and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

6.4.2 In particular, the Coordinator shall be responsible for:

a) monitoring compliance by the Parties with their obligations
b) keeping the address list of Members and other contact persons updated and available
c) collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certification) and specific requested documents to the Granting Authority
d) preparing the meetings, proposing decisions and preparing the agenda of Project Steering Committee meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings
e) transmitting promptly documents and information connected with the Project to any other Party concerned
f) administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 7.2
g) providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims

If one or more of the Parties is late in submission of any Project deliverable, the Coordinator may nevertheless submit the other Parties' Project deliverables and all other documents required by the Grant Agreement to the Granting Authority in time.

6.4.3 If the Coordinator fails in its coordination tasks, the Project Steering Committee may propose to the Granting Authority to change the Coordinator.

6.4.4 The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

6.4.5 The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

7 Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

The financial contribution of the Granting Authority to the Project shall be distributed by the Coordinator according to:

- the Consortium Plan
- the approval of reports by the Granting Authority, and
- the provisions of payment in Section 7.2.

A Beneficiary shall be funded only for its tasks carried out in accordance with the Consortium Plan.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Beneficiary shall be solely responsible for justifying its costs (and those of its Affiliated Entities, if any) with respect to the Project towards the Granting Authority. Neither the Coordinator nor any of the other Beneficiaries shall be in any way liable or responsible for such justification of costs towards the Granting Authority.

7.1.3 Funding Principles

A Beneficiary that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its units/actual duly justified eligible costs only.

A Beneficiary that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

7.1.4 Excess payments

A Beneficiary has received excess payment

a) if the payment received from the Coordinator exceeds the amount declared or

b) if a Beneficiary has received payments but, within the last year of the Project, its real Project costs fall significantly behind the costs it would be entitled to according to the Consortium Plan.

In case a Beneficiary has received excess payment, the Beneficiary has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within thirty (30) days upon request for return of excess payment from the Coordinator, the Beneficiary is in substantial breach of the Consortium Agreement.

Amounts which are not refunded by a breaching Beneficiary and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Beneficiaries pro rata according to their share of total costs of the Project as identified in the Consortium Budget, until recovery from the breaching Beneficiary is possible. The Project Steering Committee decides on any legal actions to be taken against the breaching Beneficiary according to Section 6.3.7.

7.1.5 Revenue

In case a Beneficiary earns any revenue that is deductible from the total funding as set out in the Consortium Plan, the deduction is only directed toward the Beneficiary earning such revenue. The other Parties' financial share of the budget shall not be affected by one Beneficiary's revenue. In case the relevant revenue is more than the allocated share of the Beneficiary as set out in the Consortium Plan, the Beneficiary shall reimburse the funding reduction suffered by other Beneficiaries.

7.1.6 Financial Consequences of the termination of the participation of a Beneficiary

A Beneficiary leaving the consortium shall refund to the Coordinator any payments it has received except the amount of contribution accepted by the Granting Authority or another contributor.

In addition, a Beneficiary declared to be a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Beneficiaries in order to perform the leaving Beneficiary's task and necessary additional efforts to fulfil them as a consequence of the Beneficiary leaving the consortium. The Project Steering Committee should agree on a procedure regarding additional costs which are not covered by the Defaulting Party or the Mutual Insurance Mechanism.

7.2 Payments

7.2.1 Payment responsibilities

Payments to Beneficiaries are the exclusive task of the Coordinator. In particular, the Coordinator shall:

- notify the Beneficiary concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references
- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts
- undertake to keep the Granting Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Article 22 of the Grant Agreement, no Beneficiary shall before the end of the Project receive more than its allocated share of the maximum grant amount less the amounts retained by the Granting Authority for the Mutual Insurance Mechanism and for the final payment.

7.2.2 Payment schedule

The transfer of the initial pre-financing, the additional pre-financings (if any) and interim payments to Parties will be handled in accordance with Article 22.1. and Article 7 of the Grant Agreement following this payment schedule:

Funding of costs included in the Consortium Plan will be paid by the Coordinator to the Parties after receipt of payments from the Granting Authority in separate instalments as agreed below:

- A 60% of the pre-financing received from the Granting Authority will be paid to the

Grant Agreement. The Coordinator shall not use the remaining part of each Party's pre-financing share for any other purposes than further instalments for the respective Parties as described below.

- The remaining pre-financing (40%) will be paid to Parties in Month 10 of the project, upon the Project Steering Committee approval of a 9-month progress report, including estimated effort and costs incurred during the first 9 months of the project.

- The interim payment will be paid to Parties after receipt from the Granting Authority without undue delay and in conformity with the provisions of the Grant Agreement.

Interim progress reports can be requested by the Coordinator during the project period if necessary.

For the payment of the balance (final payment); the provisions of the Grant Agreement will be followed.

Funding for costs accepted by the Granting Authority will be paid by the Coordinator to the Party concerned.

The Coordinator is entitled to withhold any payments due to a Party identified by the Project Steering Committee to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Beneficiary which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Granting Authority. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Granting Authority.

7.3 Reporting

The periodic reports, final report and certificates on the financial statements which need to be submitted to the Commission in accordance with Article 21 of the Grant Agreement shall be submitted by each Party to the Coordinator within thirty (30) days after the end of each respective reporting period. Each Party shall be solely liable for its financial data. No other Party, including the Coordinator or their representatives acting within the scope of this Consortium Agreement may change these data without express written permission of the relevant Party.

If one or more of the Parties is late in the submission of its financial statement according to the deadlines set for that purpose by the Funding Authority, the Coordinator may submit the financial report without the financial statement(s) of such Party/Parties. In such case, the Coordinator shall indicate in the financial report that the concerned Party/Parties is/are late in submitting the requested data. The Party or Parties that were late in submitting their financial statements shall be solely responsible for the possible consequences of this lateness omission.

8 Results

8.1 Ownership of Results

Results are owned by the Party and/or the researchers of the Party that generate them according to each Party's applicable laws and internal policies on intellectual property. If the researchers of a Party are entitled to claim rights to the Results pursuant to applicable laws, the Party concerned must ensure that its researchers comply with the Party's obligations under the Grant Agreement and this Consortium Agreement

8.2 Joint ownership

Joint ownership is governed by Grant Agreement Article 16.4 and its Annex 5, Section Ownership of results, with the following additions:

In case of joint ownership, each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).

Unless otherwise agreed, each of the joint owners shall be entitled to otherwise Exploit the jointly owned Results and to grant non-exclusive licenses to third parties (without any right to sub-license), if the other joint owners are given: (a) at least forty-five (45) calendar days advance notice; and (b) fair and reasonable compensation.

The joint owners shall agree on all protection measures and the division of related cost in advance.

8.3 Transfer of Results

8.3.1 Each Party may transfer ownership of its own Results, including its share in jointly owned Results, following the procedures of the Grant Agreement Article 16.4 and its Annex 5, Section Transfer and licensing of results, sub-section "Transfer of ownership".

8.3.2 Each Party may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) of this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to such a transfer to listed third parties according to the Grant Agreement Article 16.4 and its Annex 5, Section Transfer of licensing of results, sub-section "Transfer of ownership", 3rd paragraph.

8.3.3 The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties under the Consortium Agreement and the Grant Agreement will not be affected by such transfer. Any addition to Attachment (3) after signature of this Consortium Agreement requires a decision of the Project Steering Committee.

8.3.4 The Parties recognise that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give at least forty-five (45) calendar days prior notice for the transfer as foreseen in the Grant Agreement.

8.3.5 The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.4 Dissemination

8.4.1 Subject to the terms in the Grant Agreement and this Consortium Agreement, the Parties shall endeavour to disseminate Results produced under this Agreement by means of scientific publications, presentations at symposia, etc. All dissemination activities shall be subject to established academic standards and custom and shall be carried out in respect of the limitations set out in Sections 8 and 10. For the avoidance of doubt, the confidentiality obligations set out in Section 10 apply to all dissemination activities described in this Section 8.4 as far as Confidential Information is involved.

8.4.2 Dissemination of own (including jointly owned) Results

8.4.2.1. During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination, subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least forty-five (45) calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement by written notice to the Coordinator and to the Party or Parties proposing the dissemination within thirty (30) calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted. For the avoidance of doubt, submissions of abstracts to scientific meetings and congresses will be excluded from the forty-five (45) days prior written notice, provided that they do not disclose details of research or Confidential Information of the other Parties, and provided that the submission can be retracted if objections by other Parties occur. Notice of such abstracts

shall be sent to other Parties at least 15 calendar days prior to the submission. If no objection is made within 7 calendar days, the publication is permitted.

8.4.2.2 An objection is justified if

a) the protection of the objecting Party's Results or Background would be adversely affected, or
b) the objecting Party's legitimate interests in relation to its Results or Background would be significantly harmed, or
c) the proposed publication includes Confidential Information of the objecting Party.

The duly justified objection based on the reasons above has to include a precise request for necessary modifications.

8.4.2.3 If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion. In the case of peer-reviewed publications which are subject to specific submission deadlines, the Parties involved will do their best efforts to solve the issue amicable to enable the timely submission of the abstract.

8.4.2.4 The objecting Party can request a publication delay of not more than ninety (90) calendar days from the time it raises such an objection. After ninety (90) calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

8.4.2.5 Authorship on publications will be based on academic standards and custom. In accordance with normal academic practice, all investigators and contributors to a publication will be acknowledged, always in compliance with recognized standards concerning publication and authorship, including the most recent "Recommendations for the Conduct, Reporting, Editing and Publications of Scholarly Work in Medical Journals" developed by the International Committee of Medical Journal Editors (ICMJE).

8.4.3 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

8.4.4 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

8.4.5 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

8.4.6 Open Access

Each Party is responsible for the fulfilment of the requirements in the Grant Agreement regarding Open Access publications involving that Party. If two or more Parties are publishing together they shall agree

9 Access Rights

9.1 Background included

9.1.1 For the avoidance of doubt, all Background used in connection with the Project shall remain the property or under the control of the Party introducing the same. In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

9.1.2 Any Party may add additional Background to Attachment 1 during the Project provided they give written notice to the other Parties. However, approval of the Project Steering Committee is needed should a Party wish to modify or withdraw its Background in Attachment 1.

9.2 General Principles

9.2.1 Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

9.2.2 Any Access Rights granted exclude any rights to sublicense unless expressly stated otherwise.

9.2.3 Access Rights Needed for the performance of the work of a Party under the Project shall be free of any administrative transfer costs.

9.2.4 Access Rights are granted on a non-exclusive basis.

9.2.5 Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

9.2.6 All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place. For the avoidance of doubt, the provisions in Section 4.1.7 shall apply in respect of the specific conditions covering the grant of Access Rights to biological materials for implementation of the Project.

9.2.7 The requesting Party must show that the Access Rights are Needed.

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 1.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results

Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions.

Access Rights to Results for non-commercial/academic research and for teaching activities shall be granted on a royalty-free basis, provided that no Results shall be accessed by or transferred or licensed to any third party without the owning Party's consent.

9.4.2 Subject to third party rights as well as any legal or contractual limitation defined in Attachment 1, Access Rights to Background if Needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be granted on Fair and Reasonable conditions.

9.4.3 A request for Access Rights may be made up to twelve (12) months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

9.5 Access Rights for entities under the same control

Entities under the same control have Access Rights under the conditions of the Grant Agreement Article 16.4 and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for entities under the same control" if they are identified in Attachment 4 (Identified entities under the same control) to this Consortium Agreement.

Such Access Rights must be requested by the entity under the same control from the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's entity under the same control listed in Attachment 4. Access Rights to an entity under the same control shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Entities under the same control which obtain Access Rights in return fulfil all confidentiality obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such entities were Parties.

Access Rights may be refused to entities under the same control if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any entity under the same control are subject to the continuation of the Access Rights of the Party with whom it is under the same control and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an entity under the same control, any Access Rights granted to such former entity under the same control shall lapse.

Further arrangements with entities under the same control may be negotiated in separate agreements.

9.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Grant Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Project Steering Committee to terminate its participation in the consortium.

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation.

It may request Access Rights within the period of time specified in Section **Error! Reference source not found.**.

9.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

9.8 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

Parties' Access Rights to Software do not include any right to receive source code or object code ported to a certain hardware platform or any right to receive respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

10 Non-disclosure of information

10.1 All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

10.2 The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement, for a period of 5 years after the final payment of the Granting Authority:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. The Recipients may keep a copy

to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient complies with the confidentiality obligations herein contained with respect to such copy.

10.3 The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

10.4 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section **Error! Reference source not found.** hereunder.

10.5 The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care

10.6 Each Recipient shall promptly inform the relevant Disclosing Party by written notice of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7 If any Recipient becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

11 Miscellaneous

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and:

- Attachment 1 (Background included)
- Attachment 2 (Accession document)
- Attachment 3 (List of third parties for simplified transfer according to Section **Error! Reference source not found.**)
- Attachment 4 (Identified entities under the same control)

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Formal and written notices

Any notice to be given under this Consortium Agreement shall in writing and addressed to the recipients as listed in the most current address list kept by the Coordinator.

Any change of persons or contact details shall be immediately communicated to the Coordinator by written notice. The address list shall be accessible to all Parties.

Formal notices:

If it is required in this Consortium Agreement (Sections 4.3, 9.7 , and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery with acknowledgement of receipt.

Written notice:

Where written notice is required by this Consortium Agreement, this is fulfilled also by other means of communication such as e-mail with acknowledgement of receipt.

11.4 Assignment and amendments

Except as set out in Section 8.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in 6.3.7 require a separate written agreement to be signed between all Parties.

11.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

11.6 Language

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

11.8 Settlement of disputes

The Parties shall endeavour to settle their disputes amicably.

All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled by the courts of Brussels.

12 Signatures

AS WITNESS:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

KAROLINSKA INSTITUTET

Date:

Signature _____

Name Björn Kull

Title Head of Grants Office

Signature _____

Name Marie Hasselberg, Professor

Title Head of Department of Global Public Health

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name Eleni Aklillu, Professor

Title Principal Investigator

Department of Global Public Health

NATIONAL INSTITUTE FOR MEDICIAL RESEARCH, TANZANIA,

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

THE GOOD SAMARITAN FOUNDATION

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

ZANZIBAR FOOD AND DRUG AGENCY

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

ZANZIBAR HEALTH RESEARCH INSTITUTE

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ANDREWS

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

RWANDA FOOD AND DRUGS AUTHORITY

Date:

Signature _____

Name

Title

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name

Title Principal Investigator

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

Date: 9/June/2023

Signature _____

Name ADAM M. FIMBO

Title DIRECTOR GENERAL

I acknowledge that I have read and agree to be bound by the above terms and conditions, and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____

Name ADAM M. FIMBO

Title Principal Investigator

Attachment 1: Background included

According to the Grant Agreement (Article 16.1) Background is defined as "data, know-how or information (...) that is (...) needed to implement the Action or exploit the results". Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the Project. This is the purpose of this attachment.

PARTY 1

As to KAROLINSKA INSTITUTET it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of KAROLINSKA INSTITUTET is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 2

As to NATIONAL INSTITUTE FOR MEDICIAL RESEARCH, TANZANIA, it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of NATIONAL INSTITUTE FOR MEDICIAL RESEARCH, TANZANIA, is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 3

As to THE GOOD SAMARITAN FOUNDATION it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of THE GOOD SAMARITAN FOUNDATION is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 4

As to MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 5

As to ZANZIBAR FOOD AND DRUG AGENCY it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of ZANZIBAR FOOD AND DRUG AGENCY is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement,

Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 6

As to ZANZIBAR HEALTH RESEARCH INSTITUTE it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of ZANZIBAR HEALTH RESEARCH INSTITUTE is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 7

As to THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ANDREWS it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ANDREWS is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 8

As to RWANDA FOOD AND DRUGS AUTHORITY it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of RWANDA FOOD AND DRUGS AUTHORITY is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

PARTY 9

As to TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY it is agreed between the parties that, to the best of their knowledge, no data, know-how or information of TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

This represents the status at the time of signature of this Consortium Agreement.

Attachment 2: Accession document

ACCESSION **of a new Party to BREEDIME Consortium Agreement, version [..., YYYY-MM-DD]**

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Grant Agreement]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE Grant Agreement]

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

[INSERT NAME OF THE COORDINATOR]

Signature(s)

Name(s)

Title(s)

Attachment 3: List of third parties for simplified transfer according to Section 8.3.2.

No Third Parties have been identified by the Parties.

Attachment 4: Identified entities under the same control according to Section 9.5

No Affiliated Entities have been identified by the Parties.