Add logos for other Parties

MRC/UVRI and LSHTM Uganda Research Unit

"Title of study"

DATA SHARING AGREEMENT FOR study Title

This Data Sharing Agreement ("Agreement") dated the date of last signature is made by and between the following consortium members of the study title:

The London School of Hygiene & Tropical Medicine (''LSHTM'') whose administrative offices are located at Keppel Street, London WC1E 7HT, United Kingdom and also operating as a branch office as the Medical Research Council/Uganda Virus Research Institute and London School Of Hygiene And Tropical Medicine Uganda Research Institute ("MRC/UVRI and LSHTM Uganda Research Unit" and ''Data provider''), at Plot 51-59 Nakiwogo Road, P.O. Box 49 Entebbe, Uganda.

and

name and address of second collaborator

and

name and address of third collaborator

and

name and address of fourth collaborator

The consortium members are hereinafter collectively referred to as the "Parties" and each a ''Party'', for the purpose of setting forth the terms and conditions for the sharing of the study data. Each Data Provider shall collectively be known as the ''Data Providers'' and each Data Recipient shall collectively be known as the ''Data Recipients''.

1 BACKGROUND

- Data are the basis for all sound public health actions and the benefits of data-sharing are widely recognized, including scientific and public health benefits.
- The Parties previously entered into a consortium agreement affixed at Annex 2 (the ''Consortium Agreement'') with an effective date of 14 February 2020 for the UPTAKE study (the ''Study'').

- This Agreement covers the transfer of Data from MRC/UVRI AND LSHTM UGANDA RESEARCH UNIT to KAVI-ICR, Busara and IAVI; from KAVI-ICR to LSHTM and the MRC/UVRI AND LSHTM UGANDA RESEARCH UNIT , Busara and IAVI, and between LSHTM and the MRC/UVRI AND LSHTM UGANDA RESEARCH UNIT; and the use of the Data (as defined below) by the recipient consortium members for the non-profit, research and public health purposes, and, more specifically for the Study under the conditions set forth in this Agreement.
- Data will be used for the purpose of generating results of the study title study only (the **''Intended Use''**) for which they have approval to do so by an appropriate institutional review board or independent ethics committee.
- With respect to the Agreement Personal Data, the Parties acknowledge and agree that they shall each be a Joint Data Controller in accordance with the terms of this Agreement. Accordingly, each Party hereby undertakes to comply with the Data Protection Laws in respect of their Processing of such Personal Data as Data Controllers.

2 DEFINITIONS

''Applicable Laws'' shall mean all applicable laws, rules, regulations, codes of conduct, codes of practice, research governance or ethical guidelines, and/or guidance, directions, decisions, determinations, or other requirements issued, from time to time, by any regulatory authority, that may apply to the use, processing, storage, transfer and/or disposal of the Data, including, without limitation and where applicable, the UK GDPR ("UK GDPR") and the Data Protection Act 2018, as amended, replaced or superseded from time to time, together with all applicable Ugandan and add other country data protection laws, and laws concerning confidentiality and privacy, including the Ugandan Data Protection and Privacy Act 2019 and the "Add other country Act".

"**Data**" as used in this Agreement means verified information, numbers and figures collected through the title of study, as more fully described in Annex 1.

"**Data participants**" means the individuals whom Data are related to.

"**Joint Data Controllers**" has the meaning ascribed to that term in, and shall be interpreted in accordance with, the Data Protection Laws, namely where two or more Data Controllers jointly determine the purposes and means of the Processing of Personal Data.

"**Personal Data**" means any subset of data or information that directly or indirectly identifies an individual. This entails data that directly identifies individuals (e.g. name, ID number, phone number, household address or household GPS coordinates) as well as combinations of data that together can reasonably make it possible to identify an individual.

''Pseudonymised Data'' means Data which is Personal Data in origin, but which has had all identifying features removed, and is linked only by a key which is not provided to the Data Recipients.

3 RESPONSIBILITIES WITH RESPECT TO DATA

3.1 The Data Providers (MRC/UVRI AND LSHTM UGANDA RESEARCH UNIT and (other provider)) agree to provide the Data to the Data Recipients (Name receipts if any).

3.2 The Data shared in the context of this Agreement will remain the property of the Data Providers (MRC/UVRI AND LSHTM UGANDA RESEARCH UNIT and (other provider)) who grants a royalty-free license to the Data Recipients (Name receipts if any) for use of the Data for the Study only.

3.3 The Data Providers represent and warrant that they have the authority to submit the Data to the Data Recipients and that it has obtained all informed consents that are necessary and appropriate to enable the sharing of the data with the Data Recipients for the Intended Use.

3.4 The Data Providers confirm that: (i) all Data have been collected in accordance with any applicable national laws, including data protection legislation aimed at protecting the confidentiality of identifiable persons; and (ii) all Data will be provided as Pseudonymised Data by using high standards and techniques to avoid possible re-identification of Data Participants as required by applicable regulations in the country of collection.

3.5 Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing, the Parties shall take appropriate technical and organizational security measures to ensure the confidentiality and security of the Data from any unauthorised or accidental use, access, disclosure, damage, loss or destruction.

3.6 Each Party will ensure that access to the Data is restricted to those staff, students or consultants who have a need to know for the Intended Use, who shall use the Data in accordance with good research practice, and with due skill and care. Each Party shall ensure that all persons authorised by it to process the Data, before they have access to the Data, have received appropriate training in relation to data protection and have committed themselves to keep the Data confidential (at least to the same standard of confidentiality as is required by this Agreement) or are under an appropriate statutory obligation of confidentiality.

3.7 Each Party shall comply fully with all Applicable Laws relation to the use, processing, storage, sharing, transfer and/or disposal of the Data and of any Confidential Information under this Agreement.

4 CONDITIONS OF ACCESS AND USE OF DATA

4.1 The Data shall not be used for any purpose other than the Intended Use. Special permission from the Data Providers shall be sought for other uses with no obligation for the Data Providers to grant access.

4.2 The Data shall be used in compliance with all applicable statutes, regulations and ethical requirements.

4.3 The Parties agree that ownership of the Data will remain with the Data Providers.

4.4 The Parties agree that the Data may be used alone or in combination with other data to carry out analyses.

4.5 The Data Providers agree that the Data Recipients shall be entitled to use, compile, aggregate, evaluate and analyse the Data.

4.6 The Parties shall not use, disclose, release, show, sell, rent, lease, loan, or otherwise grant access to the Data or the Confidential Information to any Third Party, except as expressly permitted by this Agreement pursuant to Clause 3 or otherwise required by law. The Parties shall not use the Data and the Confidential Information for work on human subjects, including diagnostic testing, unless as expressly provided by the Project, nor for commercial or for-profit purposes.

5 RESULTS

The Results (as defined by the Consortium Agreement) of the analyses conducted by the Data Recipients shall be owned in accordance with section (8 of the Consortium Agreement – reference accordingly). Where Results are owned by a Data Recipient or jointly between Data Recipients, a royalty-free, non-exclusive, non-transferrable licence shall hereby be granted to the Data Provider to use the Results for academic teaching and non-commercial research purposes (including, for the avoidance of doubt, collaborative research with third parties).

6 PUBLICATIONS AND CONFIDENTIAL INFORMATION

6.1 Publication terms shall comply with clauses (add as appropriate) of the Consortium Agreement with the following additional terms as set out in this clause 6.

6.2 The Data Recipients and Data Provider will aim to co-author any publications arising from this Agreement. For publications arising from use of the Data not authored by the Provider Institution, the Recipient Scientist will acknowledge the Provider Institution as the source of the Data and will

provide the Provider Institution with a copy of any publications describing work carried out using the Data.

6.3 Any publications by Data Recipients based on analysis of the Data will duly acknowledge the Data Providers. Manuscripts for publication will be submitted to a peer-reviewed journal with open access. Authorship shall be in accordance with normal academic practice and will comply with the International Committee of Medical Journal Editors.

6.4 The Data Providers may include on their website and in its communication materials a reference citation to any publication by the data providers pertaining to their analysis of the Data.

6.5 All terms relating to the disclosure and use of Confidential Information (as defined within the Consortium Agreement) shall comply with clause (add as appropriate) of the Consortium Agreement.

7 TERM, AMENDMENT AND TERMINATION

7.1 This Agreement commences from the last date of its signature and will continue into force for five years and may be renewed for a further term by mutual agreement of the Parties in writing.

7.2 The terms of this Agreement can be changed only by a written modification of the Agreement by duly authorised signatories of the Parties or by the Parties adopting a new agreement in place of this Agreement.

7.3 A Party's participation in this Agreement shall be terminated with immediate effect if they withdraw from the Consortium or have their participation in the Consortium terminated.

7.4 Any Party (the ''Withdrawing Party'') may withdraw its participation from this Agreement upon three (3) months prior written notice to the others. Withdrawal by the Withdrawing Party will only take place after discussions between the Project Management Group (as defined in the Consortium Agreement). Such discussions to occur within one (1) month of submission by the Withdrawing Party of notice to withdraw, after which the Parties will confirm to the Withdrawing Party the official date of withdrawal ("Date of Withdrawal").

7.5 In the event of Withdrawal, the Withdrawing Party shall grant to the other Parties a non-exclusive, royalty free license to use its Results for the purpose of carrying out the Study.

7.6 This Agreement may be terminated by mutual agreement following discussions between the Parties at any time for any reason upon 30 days' written notice.

7.7 In the case of any termination or expiration of this Agreement, the Data Recipients shall immediately discontinue all use of the Data and, at the Data Provider's discretion and at the Data Recipient's own cost, either (i) securely and permanently destroy or erase the Data, such that it cannot be recovered or reconstructed (and must certify that it has complied in full with this requirement); or (ii) return all of the Data without keeping copies of such Data, subject to compliance with their obligations under the Consortium Agreement or Study Protocol.

8 USE OF NAME OR LOGO

Without the Data Recipients' prior written approval, the Data Providers shall not, in any statement of an advertising or promotional nature, refer to this Agreement or its relationship with the Data Recipients. In no case shall the Data Providers use the name or emblem of the Data Recipients, or any abbreviation thereof, in relation to its business or otherwise.

9 CONFLICT OF TERMS

In the event of any conflict arising between the terms of this Agreement and the Consortium Agreement, to the extent the inconsistency relates to data protection matters, this Agreement shall prevail.

10 DISPUTE RESOLUTION

Any dispute relating to the interpretation or application of this Agreement will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, with the rules of the International Chamber of Commerce. The Parties will accept the arbitral decision as final.

11 PRIVILEGES AND IMMUNITIES OF THE DATA PROVIDERS.

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by MRC/UVRI and LSHTM Uganda Research Unit or by the (other provider) under national and international law and/or as submitting MRC/UVRI and LSHTM Uganda Research Unit, or (other provider), or to any national court jurisdiction.

12 GOVERNING LAW

This Agreement shall be governed by English Law, and the English Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Agreement.

On behalf of all Parties, the undersigned individuals hereby attest that they are authorized to enter into this Agreement and agrees to all the terms specified herein.

[Signatures on following page]

For and on behalf of The MRC/UVRI and LSHTM Uganda Research Unit	**For and on behalf of (other provider)**
Signature:	Signature:
Name:	Name:
Title:	Title:
Date:	Date:

Add logos for other Parties

MRC/UVRI and LSHTM Uganda Research Unit

For and on behalf of **(Name recipient)**	**For and on behalf of** (Name other receipts if any)
Signature:	Signature:
Name:	Name:
Title:	Title:
Date:	Date:

Annex 1 - Data

Subject matter of processing	(Title of study)
Duration of processing	Electronic data will be kept on the secured servers. Data will be kept for at least ten years from the end date of the (name of study).
Nature of processing	Data collection: Data will be collected through questionnaires, records reviews, and recording of participatory workshops. Storage and archiving: All consent forms will be stored in safe cabinets at MRC/UVRI and LSHTM Uganda/(other recipient), separate from other participant documents and only accessible by the local study coordinator. Paper forms and audio data will be stored in lockable cabins at MRC/UVRI and LSHTM Uganda/(other recipient). Transfer: Files, themselves encrypted (e.g., with 7-Zip software), will only be sent via Filr sharing system or SharePoint. Paper forms and documents containing participant information will not be transferred via internal or external surface mail. Data will always be transferred in anonymised formats. Analysis: analysis of data will follow the guidelines for data analyses agreed by all partners.
Purpose of processing	Generating results of the (name of study)
Type of Personal Data	1. Patient characteristics 2. Quantitative data: -- Socio-demographic data - list other data - Data from exit interviews: 3. Qualitative data: - list kind of data

Categories of Data Subject	*Study participants in three categories:* 1. emancipated minors aged 15-17 years and women aged 18-24 years that are sexually active and have had more than one sex partner in the last six months 2. Women aged 18-45 years who have had two or more sexual partners in the last month and have received money or goods in exchange for sexual services in the last six months, or those who self-identify as FSW 3. Healthcare workers working at research sites

Annex 2 – Consortium Agreement

UPTAKE Consortium Agreement_signature