



Agreement ID: DUA24-0995

Agreement Name: Child 1 & Child 2

OUTGOING DATA USE AGREEMENT (the “Agreement”) between President and Fellows of Harvard College, acting on behalf of Global Health and Population - Harvard T.H. Chan School of Public Health [HSPH], hereinafter referred to as “Harvard,” and Wits Health Consortium (Pty) Ltd, South Africa, hereinafter referred to as “Data Recipient.” Harvard and Data Recipient may hereinafter be referred to individually as a “Party,” and collectively as the “Parties.” The effective date of this Agreement shall be the date of execution (the “Effective Date”).

WHEREAS, Harvard shall make Data, as defined below, available to Data Recipient as described herein.

WHEREAS, the research contemplated by this Agreement will further the instructional and research objectives of Harvard in a manner consistent with its status as a non-profit, tax-exempt, educational institution.

NOW, THEREFORE, the Parties hereto agree as follows:

1. **PURPOSE.** Harvard shall provide the Data to Data Recipient at no cost, for the purpose set forth in Exhibit A (the “Purpose”). The Data shall not be used except as authorized under this Agreement. For purposes of this Agreement, a “Data Recipient Researcher” is an individual who (i) is a faculty member, fellow, student, or employee of Data Recipient, and (ii) needs to access the Data for the Purpose. The Data will be made available only to Data Recipient Researchers. The Data shall not be further distributed to others, including without limitation, employees or representatives of Data Recipient other than the Data Recipient Researchers, without Harvard’s prior written consent.

In no circumstances shall the Data be used in connection with the diagnosis or treatment of human subjects.

2. **DATA.** “Data” means the confidential and proprietary information that is described in Exhibit B, to be disclosed by Harvard in accordance with this Agreement.
3. **TERM.** The term of this Agreement commences on the Effective Date, and expires upon the earlier of: (i) 5 years after effective date or (ii) termination under Section 10.
4. **LICENSE TO USE DATA.** Nothing in this Agreement will be construed to confer on Data Recipient any ownership interest, license or other rights as to the Data or any other intellectual property of Harvard except as expressly stated in this Agreement.

Subject to the terms and conditions of this Agreement, Harvard hereby grants to Data Recipient and Data Recipient Researchers the non-exclusive, irrevocable, royalty-free rights: (i) to use the Data and research results derived from the Data for teaching and research, and related scholarly activities, including those listed in the Purpose; (ii) to use the Data in raw and aggregated form, as well as in combination with other data sets; and (iii) subject to Sections 6 and 7, to publish, reproduce or otherwise publicly disclose the research results and other products of the research.

5. **INTELLECTUAL PROPERTY.** Data Recipient or Data Recipient Researcher, as the case may be,



shall own the entire right, title and interest, including all patents, copyrights, and other intellectual property rights, in and to (i) all research results based on, derived from or using the Data, and (ii) all tangible materials, inventions, discoveries, works of authorship, software, information, and data, in each case, conceived or developed by Data Recipient Researchers in the performance of the Purpose.

6. **PUBLICATION.** Data Recipient and Data Recipient Researchers will be free to distribute and publish research results and other products of their research in works such as academic journals, books, online publications, unpublished working papers, reports, information included in presentations for academic seminars and conferences, and other materials derived from, based on or using the Data. Prior to any such public use, Data Recipient Researchers will provide Harvard with a thirty (30) day period in which to review each proposed publication in confidence, provided that the scope and purpose of such review will be limited to the identification of Data or otherwise confidential information contained in the publication which Harvard does not consent to disclose. At the end of the 30-day review period, Data Recipient and/or Data Recipient Researchers will have the right to publish. For the avoidance of doubt, once a work has been reviewed, the content may be further disclosed in substantially the same form on multiple occasions without additional review by Harvard.

Data Recipient agrees to recognize the contribution of Harvard as the source of the Data in all written or oral public disclosures concerning Data Recipient's research using the Data, as appropriate in accordance with scholarly standards.

Data Recipient will provide Harvard with at least one copy of the final versions of all published papers generated under this Agreement.

7. **CONFIDENTIALITY.** Data Recipient (i) will use reasonable care to protect the security of the Data, (ii) will limit access to the Data to authorized recipients as provided in Section 1; and (iii) will not at any time during or after the term of this Agreement disclose Data to persons other than Data Recipient Researchers without first obtaining Harvard's prior written consent, except as otherwise required by law in which case Data Recipient shall, unless prohibited by law, notify Harvard prior to such disclosure. Data Recipient will report promptly to Harvard any disclosure of the Data not authorized by this Agreement of which it becomes aware.

Notwithstanding the foregoing, in no event is information Data if it (a) was lawfully in the possession of Data Recipient or Data Recipient Researchers before receipt from Harvard under this Agreement; (b) is or becomes publicly available other than as a result of a breach of this Agreement by Data Recipient or Data Recipient Researchers; (c) is received by Data Recipient or Data Recipient Researchers from a third party having an apparent bona fide right to disclose the information to Data Recipient; or (d) is independently developed by Data Recipient or Data Recipient Researchers without use of the Data.

Harvard may be identified as the source of the Data. Furthermore, each Party may disclose both the existence and purpose of the relationship that is the subject of this Agreement, including the existence of this Agreement.

The Data shall be provided to Data Recipient by means of electronic files, access to which shall be encrypted, or otherwise transmitted securely by Harvard (e.g., secure file sharing system, such as Accellion or an encrypted IronKey secure flash drive).

8. **REPRESENTATIONS AND WARRANTIES.** ALL DATA ARE PROVIDED "AS IS." HARVARD MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED,



REGARDING THE DATA'S ACCURACY, COMPLETENESS OR USE. 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.

9. **USE OF NAME.** Except as expressly provided in this Agreement, neither Party shall use or register the other Party's name (alone or as part of another name) or any logos, seals, insignia or other words, symbols or devices that identify the other Party, including any school, unit, division or affiliate ("Names") for any marketing, publicity, or promotional purposes in connection with this Agreement or the Purpose, except with the prior written approval of, and in accordance with restrictions required by the Party whose Name is to be used. The foregoing notwithstanding, the Parties agree that each Party may make factual statements regarding the existence and purpose of the relationship that is the subject of this Agreement, without written permission from the other Party. In any such statements, the relationship of the Parties shall be accurately and appropriately described.
10. **TERMINATION.** This Agreement shall expire as of the date described in Section 3, unless extended by agreement of the Parties or terminated earlier under this Section. Either Party may terminate this Agreement for any reason by providing thirty (30) days prior written notice to the other Party. Harvard may terminate this Agreement immediately if the Data Recipient is determined to be in breach of this Agreement.

Upon the earliest to occur – either termination or expiration of this Agreement – Harvard may instruct Data Recipient in writing to either destroy or return the Data to Harvard within a reasonable time limit, but not more than thirty (30) days from the date of notification. Notwithstanding the foregoing, Data Recipient may retain one copy of the Data to the extent necessary to comply with the records retention requirements under any law or regulation and for the purposes of research integrity and verification.

11. **LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, PUNITIVE, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING LOST REVENUES OR PROFITS, ARISING FROM BREACH OF THE TERMS IN THIS AGREEMENT, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR ANY OTHER CAUSE.

Data Recipient assumes all liability for claims by third parties which may arise from its use, storage or disposal of the Data.

12. **GOVERNING LAW.** This Agreement will be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any action, suit or other proceeding arising under or relating to this Agreement (a "Suit") shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and the Parties hereby consent to the sole jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Each Party agrees not to raise any objection at any time to the venue of any Suit in any of the specified courts, irrevocably waives any claim that Suit has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to any Suit, that such court does not have any jurisdiction over such Party.
13. **COMPLIANCE WITH LAW.** Harvard and Data Recipient will perform under this Agreement in compliance with all requirements of all laws, rules, regulations, and professional standards



applicable to the transfer of the Data and the performance of research for the Purpose. The Parties shall cooperate with each other to facilitate compliance with these laws, regulations and standards.

14. **NOTICES.** Any notice under this Agreement, excluding the actual provision of Data, may be delivered in person, or sent by fax, by electronic mail, by registered or certified mail, postage prepaid, or by recognized delivery service, to the appropriate addresses listed in Exhibit C or to the most recent contact information provided by the recipient (by means of notice complying with this paragraph), and such notice shall be deemed to have been given when so delivered, sent by fax or electronic mail, or mailed.
15. **INDEPENDENT CONTRACTOR.** The Parties are independent contractors and neither Party shall be deemed to be an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind on behalf of the other Party, or to take any action which shall be binding on the other Party.
16. **ASSIGNMENT.** This Agreement and all rights and obligations hereunder shall not be assigned, whether through merger or consolidation, by operation of law, or otherwise, without the written consent of the other Party, and any attempt to assign without such consent shall be void.
17. **MODIFICATION AND WAIVER.** No modification or waiver of any provision of this Agreement or any Exhibit shall be valid unless in writing, and executed by duly-authorized representatives of both Parties. A valid waiver of a breach of any provision of this Agreement shall not be deemed a waiver of any subsequent breach, nor shall it impair any underlying rights or remedies. A failure by one of the Parties to assert its rights hereunder shall not be deemed a waiver of such rights.
18. **SEVERABILITY.** If any provision of this Agreement is or becomes invalid, is ruled invalid by any court of competent jurisdiction, or is deemed unenforceable, it is the intention of the Parties that the remainder of this Agreement shall not be affected unless the invalid provision materially affects the rights of the Parties.
19. **COUNTERPARTS.** This Agreement may be executed in two or more counterparts, and by facsimile or electronic transmission, each of which will be deemed to be an original, but all of which together shall constitute one and the same instrument.
20. **ENTIRE AGREEMENT.** Unless otherwise specified, this Agreement and its Exhibits embody the entire understanding between Data Recipient and Harvard for the Purpose, and any prior or contemporaneous representations, either oral or written, are hereby superseded.

[SIGNATURES ON FOLLOWING PAGE]



IN WITNESS WHEREOF, Harvard and Data Recipient have executed this Agreement as of the date last signed below.

PRESIDENT AND FELLOWS OF HARVARD COLLEGE

By: Michelle Cherubin Joseph

Name: Michelle Cherubin Joseph

Title: Associate Director of Research Administration [Authorized Signatory]

Date: 21 January 2025

Read and Acknowledged: Christopher Duggan

Name: Christopher Duggan

Title: Professor in the Department of Nutrition

Date: January 17, 2025

DATA RECIPIENT

By: Wits Planetary Health Research

Name: Prof Matthew Chersich

Title: Division Director

[Authorized Signatory]

Date: 17 January 2025



EXHIBIT A

PURPOSE

We are requesting help with this Data Transfer Agreement to be able to share data from two older studies, "Trial of Vitamins Among Children of HIV-infected Women" (also known as Child 1), and "A Trial of Zinc and Micronutrients in Tanzanian Children" (also known as Child 2), with colleagues from WITS in South Africa, who are conducting the HEAT Project.

The HEAT Project is an Individual Participant Data (IPD) meta-analysis to quantify the impacts of heat exposure on maternal and child health in sub-Saharan Africa (protocol attached). Child 1 and Child 2 were identified with other studies through a systematic mapping of all cohorts/trials that included pregnant women in sub-Saharan Africa over the past 20 years. The researchers asked PIs of Child 1 and Child 2 to contribute data from these two studies.



EXHIBIT B

DESCRIPTION OF DATA/DATA PARAMETERS

Data shared might include: 1) essential variables such as study IDs, date of delivery of newborn OR date of maternal outcomes, and location of city of delivery or city of follow-up; 2) maternal outcomes; 3) fetal, neonatal, and child outcomes; and 4) other variables such as maternal age, date of interview, mode and facility of delivery, location of research site, maternal HIV status, gravidity, parity, and maternal anthropometry. We will also share study protocols, relevant codebooks, do-files, and other documentation for data processing.



**EXHIBIT C
NOTICES**

HARVARD CONTACTS		DATA RECIPIENT CONTACTS	
	<u>Administrative Contact</u>		<u>Administrative Contact</u>
Name: Address:	Elisabetta Ferrero	Name: Address:	Elizabeth Frederick
Telephone: Email:	eferrero@hsph.harvard.edu	Telephone: Email:	+27-82-852-8853 Elizabeth.Frederick@witsphr.org
	<u>Harvard Researcher</u>		<u>Researcher</u>
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	<u>Authorized Official</u>		<u>Authorized Official</u>
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