

## DATA SHARING AGREEMENT

**Vaccines and Infectious Diseases Analytics Research Unit (VIDA),  
a Division of Wits Health Consortium (Pty) Ltd**  
31 Princess of Wales Terrace, Parktown, Johannesburg, 2193, South Africa

(hereinafter “the Data Provider”)

and

**Wits Reproductive Health and HIV Institute (Wits RHI),  
a Division of Wits Health Consortium (Pty) Ltd**  
31 Princess of Wales Terrace, Parktown, Johannesburg, 2193, South Africa

(hereinafter “the Data Recipient”)

### WHEREAS:

1. The Data Provider collected certain Data (as defined below) under the following projects:
  - 1.1 MATFLU: Influenza Vaccine Trial in HIV Uninfected Pregnant Women (MatfluHIVneg) and HIV Infected Pregnant Women (MatfluHIVpos) (NCT01306669 and NCT01306682). Data from all sites in Africa.
  - 1.2 *“An Adaptive Phase 1/II Randomized Placebo-Controlled Trial to Determine Safety, Immunogenicity, and Efficacy of Non-replicating SARS-CoV-2 Vaccine in South African Adults Living without HIV; and Safety and Immunogenicity in Adults Living with HIV”* funded by the South African Medical Research Council and sponsored by The University of Oxford;
  - 1.3 *“Covid-19 ChAdOx Clinical Trials in RSA”* funded by the Bill and Melinda Gates Foundation;
  - 1.4 Health worker COVID-19 study at CHBH
  - 1.5 Pfizer GBS studies: 28OB, GBS-COP (possible)
2. The Data Recipient is carrying out a project titled “Developing Data Science Solutions to Mitigate the Health Impacts of Climate Change in Africa: the HE2AT Center” (“HE2AT Project”) which is funded by the National Institutes of Health (NIH).
3. The Data Recipient has requested the Data Provider to transfer certain Data that was collected under the Project/s listed in Clause 1 for purposes of the HE2AT Project, the details of which are set out under **Annexure “B”** attached hereto.
4. The Data Provider will transfer a Limited Data Set to the Data Recipient. A **“Limited Data Set”** consists of health information that has had all direct identifiers concerning the subject of the record (and his or her employer, family, and household members) deleted; that is, the information excludes all of the following: names; street addresses (excluding suburb, small area or town); telephone numbers; fax numbers; electronic mail addresses; government insurance

numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full-face photographic images and any comparable images.

5. The transfer of the Data will be done in accordance with the terms and conditions of this Agreement.

## **THEREFORE, THE PARTIES AGREE AS FOLLOWS:**

### **1. DEFINITIONS**

In this Agreement, unless the context otherwise indicates, the following words will have the following meanings:

- 1.1 **"the/this Agreement"** shall mean this Agreement together with any Annexures hereto;
- 1.2 **"Commencement Date"** shall mean the date on which this Agreement commenced, namely **the last date of signature**;
- 1.3 **"Responsible Party"** means a public or private body or any other person which, alone or in conjunction with others, determines the purpose of and means for Processing Personal Data;
- 1.4 **"Data"** shall mean the Data to be transferred from the Data Provider to the Data Recipient as described and detailed in **Annexure "A"**;
- 1.5 **"Data Protection Legislation"** shall mean any data protection or data privacy laws applicable, including but not limited to POPIA, the Electronic Communications and Transactions Act 26 of 2005, the Consumer Protection Act 68 of 2008, and the General Data Protection Regulation (GDPR).
- 1.6 **"Data Subject"** means the person to whom Personal Data relates;
- 1.7 **"Parties"** shall mean the parties to this Agreement, namely VIDA, a Division of Wits Health Consortium (Pty) Ltd and Wits RHI, a Division of Wits Health Consortium (Pty) Ltd; and the term **"Party"** shall refer to either of them;
- 1.8 **"person"** means a natural or juristic person;
- 1.9 **"Personal Data"** means information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person. Key-coded data are considered Personal Data even if the holder of that data does not have access to the key that links the data to the identity of an individual;

- 1.10 **“Processing”** (or its conjugates) shall mean any operation or set of operations, which is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.
- 1.11 **“Operator”** means a person who processes Personal Data for a Responsible Party in terms of a contract or mandate, without coming under the direct authority of that party;
- 1.12 **"the Project / HE2AT Project"** shall mean the project entitled “Developing Data Science Solutions to Mitigate the Health Impacts of Climate Change in Africa: the HE2AT Center” funded by the National Institutes of Health;
- 1.13 **“Study Data”** shall mean data and results produced in the execution of the Study;
- 1.14 **“POPIA”** shall mean the South African Protection of Personal Information Act 4 of 2013 and regulations as amended from time to time;
- 1.15 Words importing the singular shall include the plural and *vice versa*, and words importing the masculine gender shall include females. The head notes to the clauses to this Agreement are inserted for reference purposes only and shall not affect the interpretation of any of the provisions to which they relate.

## **2. TRANSFER AND USE OF DATA**

- 2.1 This Agreement shall commence on the Commencement Date and will terminate on **30 June 2026** or upon completion of the Project whichever event occurs first.
- 2.2 Notwithstanding the abovementioned, either Party may cancel this Agreement with 30 (thirty) days’ prior written notice. On termination of this Agreement, the Data Recipient will immediately discontinue use of the Data and will return all copies of same to the Data Provider or alternatively, and on the Data Provider’s written instruction, destroy all copies of the Data. The Data Provider however acknowledges that in order to maintain the integrity of results from the Project, the ability to amend, restrict, or delete Data disclosed to Data Recipient may be limited, in accordance with applicable regulations.
- 2.3 Subject to the terms and conditions of this Agreement, Data Provider grants the Data Recipient the non-exclusive right to use the Data solely for purposes of the Study and/or HE2AT Project, for the duration of this Agreement.
- 2.4 Each Party shall pay its own costs incurred in the performance of this Agreement. Any given expense or cost can only be committed in writing by the Party responsible for the cost in question. In no case can one Party commit an expense on behalf of another Party, without prior written consent.

- 2.5 Data Provider retains ownership of the Data and retains all rights to distribute the Data to other third parties. Data Provider warrants its authority and that it has obtained the necessary consent required to provide the Data to the Data Recipient.
- 2.6 The Data Provider will transfer the Data as is without any warranties, express or implied, including without limitation, any warranty of fitness for a particular purpose. This Agreement does not grant any rights, license or other proprietary interest to the Data Recipient in the Data save as provided for in this Agreement.
- 2.7 Data Recipient will use the Data only for purposes of the Project. If the Data Recipient seeks to use Data for other purposes, the Data Recipient will obtain written consent from Data Provider, either by an amendment to this Agreement or a new agreement, before such use. The Data Recipient will report to the Data Provider on the results of the Project or Study stemming from the use of the Data.
- 2.8 The Data Recipient is hereby authorised to transfer the Data to the following third parties listed below (“Collaborators”) for purposes of the Project:
- 2.8.1 University of Peleforo Gon Coulibaly, Côte d'Ivoire
  - 2.8.2 CeSHHAR, Zimbabwe
  - 2.8.3 IBM Research Africa
  - 2.8.4 University of Cape Town
- and subject to the Data Recipient and the relevant Collaborator/s entering into a Data Transfer Agreement on the same terms as provided for herein.
- 2.9 The Data Recipient undertakes not to attempt to identify the Data Subject to whom the Data relates.
- 2.10 The Parties acknowledge their obligation(s) to comply with Data Protection Legislation and that violation of the Data Protection Legislation may subject them to applicable legal penalties.
- 2.11 If any publications emanate from the use of the Data, the Data Recipient undertakes not to publish the Data in an identifiable form.
- 2.12 Under NIH grant funding policy, Study Data resulting from analysis of the Data will, where no personally identifiable data is included, be made openly available through open data access platforms to support further research.
- 2.13 Publications emanating from the use of the Data will follow the HE2AT Centre authorship policy included in **Annexure “C”** attached hereto. The HE2AT Centre Authorship Policy may be updated from time to time, which updates will be shared between the Parties to this Agreement.

- 2.14 The Data Recipient will retain a copy of the Data for a period of 5 years after the termination of the over-arching NIH grant agreement (current Project End Date 30 June 2026) for the purposes of concluding and correcting any analysis and publications resulting from the Data. Any retention of Data after this 5 year period will be negotiated with the Data Provider.
- 2.15 By signing this Agreement, the Data Provider confirms that it has the authority to transfer the Data and consent to provide the Data to the Recipient for use for the duration of this Agreement and as provided for in Clause 2.14.

### **3. RIGHTS OF DATA SUBJECTS**

The Parties agree that, as between them, Data Provider is best able to manage requests from Data Subjects for access, amendment, transfer, restriction, or deletion of Personal Data. In the ordinary course, Data Recipient does not process sufficient information to link Data to an identified individual who makes a request for access, amendment, transfer, or deletion of Personal Data. In the event that the Data Recipient receives a request from a Data Subject for such access, amendment, transfer, restriction, or deletion, the Data Recipient shall forward the request to Data Provider. In the event that the Data Provider receives a request from a Data Subject that affects the Data disclosed to the Data Recipient or the Data Recipient's ability to use or process such Data, Data Provider shall promptly, and no later than five (5) business days notify Data Recipient. Data Provider acknowledges that in order to maintain the integrity of results from the Project, the ability to amend, restrict, or delete Data disclosed to Data Recipient may be limited, in accordance with applicable regulations.


### **4. DATA SUBJECT WITHDRAWAL**

Data Recipient acknowledges that Data Subjects may withdraw their informed consent to the Processing of Personal Data at any time. Data Provider shall promptly notify Data Recipient of any such withdrawal upon which the Data Recipient will immediately discontinue use of the Data Subject's Personal Data.

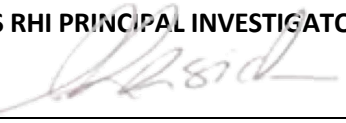
### **5. DISPUTES**

All disputes will be referred to the Chief Executive Officer of Wits Health Consortium (Pty) Ltd, with both Dr Matthew Chersich ([mchersich@wrhi.ac.za](mailto:mchersich@wrhi.ac.za)), Craig Parker ([cparker@wrhi.ac.za](mailto:cparker@wrhi.ac.za)) and Catherine Hill ([catherine.hill@wits-vida.org](mailto:catherine.hill@wits-vida.org)) in copy.

#### **WITS HEALTH CONSORTIUM (PTY) LTD:**

By:  \_\_\_\_\_  
(signature)  
Name: Jéan du Randt  
Title: Chief Financial Officer  
Date: 02 May 2024

**WITS RHI PRINCIPAL INVESTIGATOR:**

By: \_\_\_\_\_


(signature)

Name: Matthew Chersich

Title: Research Professor

Date: 06 May 2024

**VIDA PRINCIPAL INVESTIGATOR:**

By: \_\_\_\_\_

(signature)

Name: Prof Ziyaad Dangor

Title: Research Director

Date: 06 May 2025

**DESCRIPTION OF DATA**

**Data Source 1**

**Project Title:** MATFLU: Influenza Vaccine Trial in HIV Uninfected Pregnant Women (MatfluHIVneg) and HIV Infected Pregnant Women (MatfluHIVpos) (NCT01306669 and NCT01306682).

**Funder:** Bill and Melinda Gates Foundation, Grant number OPP1002747 and HREC approval number 101106 (2011).

**Data to be transferred:** Geographical data, data code book, informed consent forms (templates), HREC Approvals

**Purpose of Data Transfer:** The data will be used to quantify the current and future impacts of heat exposure on maternal and child health in sub-Saharan Africa.

**Data Source 2:**

**Project Title:** An Adaptive Phase 1/II Randomized Placebo-Controlled Trial to Determine Safety, Immunogenicity, and Efficacy of Non-replicating SARS-CoV-2 Vaccine in South African Adults Living without HIV; and Safety and Immunogenicity in Adults Living with HIV

**Funder:** SAMRC and Oxford University

**Data to be transferred:** Geographical data, data code book, informed consent forms (templates), HREC Approvals

**Purpose of Data Transfer:** The data will be used to quantify the current and future impacts of heat exposure on maternal and child health in sub-Saharan Africa.

**Data Source 3:**

**Project Title:** Covid-19 ChAdOx Clinical Trials in RSA

**Funder:** Oxford University, through the Bill and Melinda Gates Foundation

**Data to be transferred:** Geographical data, data code book, informed consent forms (templates), HREC Approvals

**Purpose of Data Transfer:** The data will be used to quantify the current and future impacts of heat exposure on maternal and child health in sub-Saharan Africa.

**Data Source 4:**

**Project Title:** GBS V98-28OBTP, HREC Ref 140203 (2014)

**Funder:** Novartis

**Data to be transferred:** Geographical data, data code book, informed consent forms (templates), HREC Approvals

**Purpose of Data Transfer:** The data will be used to quantify the current and future impacts of heat exposure on maternal and child health in sub-Saharan Africa.



**Study title:** Individual Participant Data meta-analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa

**Study rationale:** Global temperatures have already increased by 1.1°C since the industrial revolution and are projected to rise by a further 1-2 degrees over the coming decades. Africa is the continent hardest hit by climate change and temperatures are rising at twice the global rate in many parts of the continent.

The harmful impacts of extreme heat on health are well recognised, affecting a range of population groups, including pregnant women and children. There remain, however, major gaps in evidence on the size of temperature impacts, and which outcomes are most affected. Gaps in evidence are especially large in Africa. A study drawing together the rich data collected in trials and cohorts across the continent could provide the information needed to develop solutions to this rapidly escalating public health problem.

An Individual Participant Data (IPD) meta-analysis entails systematically locating, appraising, transforming, and analysing participant-level data from multiple studies which have a common outcome of interest. Unlike classic systematic reviews which use aggregated study-level data extracted from a publication, an IPD involves analyses of raw participant-level data from multiple studies. This approach can overcome many of the biases of classic systematic reviews, and the challenges in understanding heterogeneity and methodological diversity across published studies.

Analysing pooled participant-level data from multiple settings and time periods also holds several notable advantages over analyses of individual databases from a single location and time, most especially through increasing statistical power and generalisability.

The IPD forms parts of the HE2AT Center (Heat and Health AAfrican Transdisciplinary Center) which consists of partners from South Africa (Universities of Cape Town and Witwatersrand, and IBM-Research Africa), Côte d'Ivoire (University of Peleforo Gon Coulibaly), Zimbabwe (CeSHHAR), and the United States (Universities of Michigan and Washington). The Center is funded through the United States NIH Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) program<sup>1</sup>. DS-I Africa aims to make optimum use of existing data resources across Africa to address the most pressing health concerns on the continent.

**Study objectives:** The overall objective of the study is to use innovative data science approaches to quantify the current and future impacts of heat exposure on maternal and child health in sub-Saharan Africa.

The specific objectives are:

1. To locate, acquire, collate and transform prospectively collected data from cohort studies and randomized trials on maternal and child health in sub-Saharan Africa.
2. To develop a collaboration between the HE2AT Center and investigators of each of the studies who contribute participant-level data.

3. To link health outcome data spatially and temporally with weather and other environmental data, as well as with socio-economic and related factors.
4. To utilize classic statistical methods and novel machine learning approaches to understand and quantify the impact of heat exposure on maternal and child health.
5. To document variations in the relationship between heat exposure, and maternal and child health outcomes across different settings, climate zones and population groups in sub-Saharan Africa.

**Methods:** We will systematically locate eligible studies through a mapping review of publication databases, the searching of data repositories, and through communicating with experts in the field. Eligibility is based on study- and individual-level criteria. To be eligible, the study needs to include longitudinal data, have enrolled or plan to enrol at least 1000 pregnant women in sub-Saharan Africa, have collected data on key maternal and child outcomes and be identified in publications between January 2012 and June 2022 or through other means such as trial registries or suggestions from other researchers. At an individual level, participants need to have been recruited during pregnancy or intrapartum, and have data available on date and location of childbirth. For studies with no date of childbirth, data should be available on date and location of diagnosis of an adverse maternal health outcome, or end of pregnancy in cases of maternal deaths or abortion. Location information may include facility of birth, or city of the study, for example. The datasets from individual studies will be harmonised through the recoding of raw individual participant data into a common set of variables. Various traditional statistical models such as time-series analysis, time-to event analysis and generalised additive models, as well as novel machine learning approaches will be used to quantify associations between high ambient temperatures, and adverse maternal and child outcomes. Data analysis occurs in several stages. Firstly, each study will be analysed individually. Then, data from the individual studies are aggregated to provide a pooled estimate of effect. If heterogeneity between studies is high, then aggregation across studies may not be done, or may only be done in particular groups of studies that share common characteristics.

**Ethical and legal considerations:** The study has received ethics approval from the Human Research Ethics Committee of the University of the Witwatersrand, South Africa (Ref. No. 220605). There is minimal risk to individual study participants. Participant privacy will be protected as far as possible through the removal of participant identifiers before data transfer, data encryption, and security measures such as limiting the personal who have access to data, and data storage in secure, password-protected servers. Informed consent procedures for the original studies will be assessed to determine whether specific consent had been given for data reanalysis. If not, waivers of informed consent for the IPD analysis will be requested from the Human Research Ethics Committee at the University of Witwatersrand. Data sharing across countries can involve legal considerations depending on legislation in particular countries.

**PROSPERO registration:** PROSPERO 2022 CRD42022346068 Available from: [https://www.crd.york.ac.uk/prosperto/display\\_record.php?ID=CRD42022346068](https://www.crd.york.ac.uk/prosperto/display_record.php?ID=CRD42022346068)

**Funding acknowledgement:** The study is funded by the Fogarty International Center and National Institute of Environmental Health Sciences (NIEHS) and OD/Office of Strategic Coordination (OSC) of the National Institutes of Health under Award Number U54 TW 012083.

## Authorship guidelines for studies who contribute data

Study Principal Investigators, Site Principal Investigators, and additional contributing study members will be invited to be part of the authorship group for any publications that include use of the data from their study.

The authorship guidelines adhere to the ICMJE criteria for authorship, which include:

- 1 Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- 2 Drafting the work or revising it critically for important intellectual content; AND
- 3 Final approval of the version to be published; AND
- 4 Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The authorship guidelines and study acknowledgements are based on an appreciation of the substantial contribution made by Principal Investigators in providing data from their study, and in recognition of the work involved in conducting the study.

We will include one author per included study (usually study PI), but additional country-PI will be included for multi-country studies. The listed authors of the studies which are contributing data will be named in alphabetical order by surname, from positions 4<sup>th</sup> author to second-last author. As such, authorships 1-3 and last authorship will be reserved for those who contributed most to the work, and as per ICMJE.

Some journals may place a restriction on the number of authors that may be listed and require that additional authors beyond that number should be included as part of the '*HEAT Center study Group*'. In this situation, the HEAT Center Steering Committee will have the right to make a decision on final authorship, taking into consideration the studies which contributed most participants to the IPD.

The study group will be published in an Appendix where journals will allow this, or otherwise be listed in the acknowledgement section. Here, listing will be done by role in the study and/or by Study/site. Any additional contributors from a study, who adhere to ICMJE criteria will be listed as part of the '*HEAT Center study Group*' in an Appendix where journals will allow this, or otherwise be listed in the acknowledgement section.

The name of the funder of the contributing study and of other Principal Investigators will be included in the acknowledgements, as relevant.

Study Principal Investigators can be given access to the harmonized database in cases where they intend to conduct a secondary analysis, and are encouraged to submit a concept note of the proposed research question and analysis, should they wish to lead the analysis and/or writing of the paper. All concept notes will be reviewed by the HEAT Center Steering Committee who will make a decision based on the Publication Policy Standard Operating Procedures of the Center.