DATA SHARING AGREEMENT

Ezintsha
a Division of Wits Health Consortium (Pty) Ltd
31 Princess of Wales Terrace, Parktown, Johannesburg

(hereinafter "**the Data Provider**")

and

Wits Reproductive Health & HIV Institute,
a Division of Wits Health Consortium (Pty) Ltd
31 Princess of Wales Terrace, Parktown, Johannesburg

(hereinafter "**the Data Recipient"**)

WHEREAS:

1. The Data Provider collected certain Data under the following Projects:

1.1 "***A Randomised, Phase 3 Non-inferiority Study of DTG + TAF + FTC Compared With DTG + TDF + FTC and EFV + TDF + FTC in Patients Infected With HIV-1 Starting First-line Antiretroviral Therapy - Extension to 192 Weeks***" which was funded by UNITAD ("Advance Project");

1.2 "***A Randomized, Double-Blind, Multi-Centre, Parallel-Group Phase 3b Study To Demonstrate Non-Inferiority Of Stavudine (20 Mg Twice Daily) Compared With Tenofovir Disoproxil Fumarate (300 Mg Once Daily) When Administered In Combination With Lamivudine And Efavirenz In Anti-Retroviral-Naive Patients Infected With HIV-1***" which was funded by the Bill and Melinda Gates Foundation ("WRHI001 Project"); and

1.3 "***Low-dose ritonavir-boosted darunavir once daily versus ritonavir-boosted lopinavir for participants with less than 50 HIV RNA copies per mL (WRHI 052): a randomised, open-label, phase 3, non-inferiority trial***" which was funded by the South African Medical Research Council ("WRHI 052 Project").

2. The Data Recipient received an Award from the National Institutes of Health for the Project titled "Developing Data Science Solutions to Mitigate the Health Impacts of Climate Change in Africa: the HE2AT Center" ("HE2AT Project").

3. The Data Recipient has requested the Data Provider to transfer certain Data that were collected under the Projects listed in Clause 1, and further described in **Annexure A**, for purposes of the HE2AT Project.

4. The Data Provider will transfer deidentified Data to the Data Recipient, which Data will not be capable of reidentification.

5. The Data Recipient undertakes that the Data will be used for research purposes as envisaged in Article 15(3)(e) and Article 16(4)(f)(ii) of the Protection of Personal Information Act, 4 of 2013 ("POPIA").

6. The Data Provider and Data Recipient hereby record that the privacy of the data subject to which the Data pertains will not be adversely affected as provided for in Article 27(1)(d)(ii) of POPIA.

7. The transfer of the Data will be done in accordance with the terms and conditions of this Data Sharing Agreement (hereinafter referred to as the "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 **15 November 2021**;

1.3 **"Controller"** shall mean the entity that alone or jointly with others determines the purposes and means of the Processing of 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 **"Parties"** shall mean the parties to this Agreement, namely Ezintsha and Wits Reproductive Health & HIV Institute, both divisions of Wits Health Consortium (Pty) Ltd; and the term "Party" shall refer to either of them;

1.6 **"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;

1.7 **"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.

1.8 "**Processor**" means the person who is responsible for processing personal data on behalf of the Data Controller;

1.9 **"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" as per the Project Description attached hereto as **Annexure B**;

1.10 **"Study Data"** shall mean data and results produces in the execution of the Project and more specifically the Project Description attached hereto as **Annexure B**;

1.11 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 Subject to the terms and conditions of this Agreement, Data Provider grants the Data Recipient the nonexclusive right to use the Data solely for purposes of the Project for the duration of this Agreement. This Agreement will terminate on the completion of the Project.

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.

2.4 Data Provider retains ownership of the Data, and retains all rights to distribute the Data to other parties. Data Provider warrants its authority to provide the Data to the Data Recipient.

2.5 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.

2.6 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 stemming from the use of the Data.

2.7 The Data Recipient is hereby authorised to transfer the Data to the following Collaborators for purposes of the Project:

2.7.1 2.7.1 University of Peleforo Gon Coulibaly

2.7.2 CeSSHAR, Zimbabwe

2.7.3 IBM Research Africa

2.7.4 University of Cape Town

and subject to the Data Recipient and the Collaborators entering into a Data Transfer Agreement on the same terms as provided for herein.

2.8 The Data Recipient undertakes not to attempt to identify the Data Subject to whom the Data relates.

2.9 The Data Recipient acknowledges its obligation to comply with the substantive provisions of POPIA and that violation of the provisions pertaining to POPIA may subject it to the applicable legal penalties, including those provided under POPIA.

2.10 If any publications emanate from the use of the Data, the Data Recipient undertakes not to publish the data in an identifiable form.

3. CONTROLLER STATUS

3.1 To the extent that any Study Data or samples contain Personal Data when collected for purposes of this Agreement, Data Provider is the Controller of Personal Data. Data Recipient is neither a controller nor a processor of Personal Data.

3.2 Further, nothing in this Agreement is intended to affect Data Provider's Processing of Personal Data of subjects unrelated to this Agreement. Data Provider will not provide Data Recipient any patient identifiable information, nor will it provide any encryption key that could be used to re-identify the patient from any Study data provided to Data Recipient.

4. COMPLIANCE

Each party will comply with all applicable Regulations governing the Processing of Personal data in relation to the performance of its obligations under this Agreement, including without limitation laws, regulations and rules related to the privacy of personal information including POPI as well as the Regulations thereto.

5. RIGHTS OF SUBJECTS

The parties agree that, as between them, Data Provider is best able to manage requests from 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 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 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 Study, the ability to amend, restrict, or delete data disclosed to Data Recipient may be limited, in accordance with applicable Regulations.

6. SUBJECT WITHDRAWAL

Data Recipient acknowledges that 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 subject's Personal Data.

7. CROSS-BORDER DATA TRANSFERS

In the event that it is necessary for the Data Recipient to transfer Personal Data across national borders to the other party, Data Provider agrees to ensure the lawful export of Personal Data to the Data Recipient, which may be outlined in a separate agreement governing such transfer.

8. SAFEGUARDS

8.1 Data Recipient will maintain a comprehensive privacy and security program designed to ensure that Personal Data will be used only in accordance with this Agreement or as required by applicable Regulations, including the appointment of a Data Protection Officer. Data Recipient will apply adequate, commercially reasonable technical, physical, and administrative safeguards to protect the Personal Data.

8.2 Such safeguards shall be appropriate to the nature of the information to prevent any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to Personal Data or any other unauthorized or unlawful use, access, alteration, loss, or disclosure of Personal Data relating to this Agreement (collectively, "Security Breach"). Data Recipient will also implement appropriate internal policies, procedures, or protocols to minimize the risk of occurrence of a Security Breach.

8.3 Once the Data has been transferred to the Data Recipient, the Data Recipient shall, in line with all applicable legislation and regulations, maintain a comprehensive privacy and security program to ensure the safekeeping and integrity of the Data.

9. SECURITY BREACH

9.1 Data Recipient shall notify Data Provider within twenty-four (24) hours of discovery of a potential or actual Security Breach. In the course of notification, Data Recipient will provide feasible, sufficient information for Data Provider to assess the Security Breach. Data Provider will determine, in consultation with Data Recipient, if notification to data subjects and/or government authorities is required by applicable Regulations. Where Data Provider determines that notification is required by applicable Regulations, Data Recipient shall be responsible for all costs and expenses associated with the provision of such notifications. Data

Recipient will also take immediate steps to consult with Data Provider in good faith in the development of remediation efforts to rectify or mitigate the Security Breach.

9.2 Data Recipient will undertake remediation efforts at its sole expense or will reimburse Data Provider for Data Provider's reasonable expenses incurred in connection with Data Provider-performed remediation efforts. In addition to any method of notice described in this Agreement, notice to Data Provider of any Security Breach shall also be reported to Godspower Akpomiemie; Telephone: +27 11 084 4972 or Email: gakpomiemie@ezintsha.org and to Alfred Farrell (Chief Executive Officer of the Data Provider) Telephone: +27 11 274 9200 or Email: ceo@witshealth.co.za.

10. **PERSONNEL OBLIGATIONS**

The parties shall ensure that their respective personnel engaged in the Processing of Personal Data are informed of the confidential nature of the Personal Data, have received appropriate training on their responsibilities, and have executed written confidentiality agreements or are otherwise subject to professional obligations of confidentiality. The parties shall ensure that access to Personal Data is limited to those personnel who perform services in accordance with the Agreement.

11. **RECORDS / DATA PROCESSING REGISTER**

Data Recipient shall maintain a written record of all Processing activities that are carried out under this Agreement. Such record shall contain, at a minimum, (i) the name and contact details of any processors; (ii) the name and contact details of the processors' data protection officers; (iii) the categories of Processing that are carried out; (iv) transfers to third countries or international organizations and documentation of the suitable safeguards that are employed; and (v) a general description of the administrative, technical, and physical security measures that have been taken to safeguard the Personal Data. Data Provider shall provide Data Recipient with a copy of such records upon request.

12. **GOVERNMENT INSPECTIONS**

Data Recipient agrees to promptly, and in no case later than five (5) business days, notify Data Recipient of any inspection or audit by a government authority concerning compliance with applicable Regulations governing the Processing of Personal Data to the extent related to this Agreement.

13. **DATA PROTECTION IMPACT ASSESSMENT**

Data Recipient shall develop and maintain a data protection impact assessment regarding the Processing of Personal Data under this Agreement. Data Provider shall cooperate with and assist Data Recipient in the development of the data protection impact assessment and/or with prior consultations with government authorities that may be required.

14. NOTICES

Notices under this Agreement will be given by personal delivery, certified mail, or recognized overnight courier service to the person designated below:

If to Data Recipient Principal Investigator:
Prof. Matthew Chersich
Wits Reproductive Health and HIV Institute, a Division of Wits Health Consortium (Pty) Ltd
Faculty of Health Sciences, University of the Witwatersrand

If to Data Provider Investigator:
Professor WD Francois Venter
Ezintsha, a division of Wits Health Consortium (Pty) Ltd
Building C, Sunnyside Office Park, 32 Princess of Wales Terrace, Parktown 2193
Faculty of Health Sciences, University of the Witwatersrand

With copies to:
Wits Health Consortium (Pty) Ltd, 31 Princess of Wales Terrace, Parktown, 2193
vparker@witshealth.co.za

Godspower Akpomiemie (gakpomiemie@ezintsha.org)
Ezintsha, a division of Wits Health Consortium (Pty) Ltd
Building C, Sunnyside Office Park, 32 Princess of Wales Terrace, Parktown 2193
Faculty of Health Sciences, University of the Witwatersrand

15. GENERAL

15.1 In no event shall Data Provider be liable for any use by the Data Recipient of Data or Results or for any loss, claim, damage, or liability, of any kind or nature, that may arise from or in connection with this Agreement or Data Recipient's use, handling, or storage of Data. Data Recipient agrees to indemnify and hold harmless Data Provider, its trustees, officers, employees, students, volunteers and agents from all liability, loss, or damage they may suffer as a result of claims, demands, costs or judgments against Data Provider arising out of the use, handling or storage of Data by Data Recipient.

15.2 This Agreement does not constitute, grant nor confer any license under any patents or other proprietary interests of one party to the other, except as explicitly stated in this Agreement.

15.3 This Agreement may be amended by written agreement between the Parties.

DATA PROVIDER: **DATA RECIPIENT:**

By: _____ By: _____

(signature)

Name: Jéan du Randt

Title: Chief Financial Officer

Date: 17 October 2023

(signature)

Name: _____

Title: _____

Date: _____

WITS HEALTH CONSORTIUM (PTY) LTD:

By: _____

(signature)

Name: _____

Title: _____

Date: _____

ANNEXURE A

DESCRIPTION OF DATA

Data Source 1

Project Title: A Randomised, Phase 3 Non-inferiority Study of DTG + TAF + FTC Compared With DTG + TDF + FTC and EFV + TDF + FTC in Patients Infected With HIV-1 Starting First-line Antiretroviral Therapy - Extension to 192 Weeks. ADVANCE ClinicalTrials.gov number, NCT03122262

Funder: U.S. Agency for International Development, Unitaid, and the South African Medical Research Council. Investigational drugs were donated by Gilead Sciences and ViiV Healthcare.

Data to be transferred: Laboratory and clinical data from baseline and follow-up visits.

Purpose of Data Transfer: The data will be used to investigate the urban heat island effect in Johannesburg, South Africa, using multiple data sources from satellites on the natural (e.g., vegetation) and the built environment, combined with weather, air pollution, and health outcome data from clinical trials and cohorts in Johannesburg. Based on these analyses we will identify linkages between environmental exposures and health outcomes across different risk groups.
This information then informs the design of an Early Warning System that can warn people when an extreme heat event is forecast. Risk strata will be generated in the Early Warning System, based on the risk profiles of specific risk groups as defined by the analysis, and as determined by a machine learning algorithm which takes into account forecasted weather conditions, characteristics such as age, geolocation and other factors that drive risk.

Data Source 2

Project Title: A Randomized, Double-Blind, Multi-Centre, Parallel-Group Phase 3b Study To Demonstrate Non-Inferiority Of Stavudine (20 Mg Twice Daily) Compared With Tenofovir Disoproxil Fumarate (300 Mg Once Daily) When Administered In Combination With Lamivudine And Efavirenz In Anti Retroviral-Naive Patients Infected With HIV-1 (WRHI 001)

Funder: Bill and Melinda Gates Foundation, PEPFAR

Data to be transferred: Laboratory and clinical data from baseline and follow-up visits

Purpose of Data Transfer: The data will be used to investigate the urban heat island effect in Johannesburg, South Africa, using multiple data sources from satellites on the natural (e.g., vegetation) and the built environment, combined with weather, air pollution, and health outcome data from clinical trials and cohorts in Johannesburg. Based on these analyses we will identify linkages between environmental exposures and health outcomes across different risk groups.
This information then informs the design of an Early Warning System that can warn people when an extreme heat event is forecast. Risk strata will be generated in the Early Warning System, based on the risk profiles of specific risk groups as defined by the analysis, and as determined by a machine learning algorithm which takes into account forecasted weather conditions, characteristics such as age, geolocation and other factors that drive risk.

Data Source 3

Project Title: Low-dose ritonavir-boosted darunavir once daily versus ritonavir-boosted lopinavir for participants with less than 50 HIV RNA copies per mL (WRHI 052): a randomised, open-label, phase 3, non-inferiority trial

Funder: South African Medical Research Council, United States Agency for International Development, and US National Institute of Allergy and Infectious Diseases.

Data to be transferred: Laboratory and clinical data from baseline and follow-up visits

Purpose of Data Transfer: The data will be used to investigate the urban heat island effect in Johannesburg, South Africa, using multiple data sources from satellites on the natural (e.g., vegetation) and the built environment, combined with weather, air pollution, and health outcome data from clinical trials and cohorts in Johannesburg. Based on these analyses we will identify linkages between environmental exposures and health outcomes across different risk groups.
This information then informs the design of an Early Warning System that can warn people when an extreme heat event is forecast. Risk strata will be generated in the Early Warning System, based on the risk profiles of specific risk groups as defined by the analysis, and as determined by a machine learning algorithm which takes into account forecasted weather conditions, characteristics such as age, geolocation and other factors that drive risk.

Lab and Clinical Data will include the following variables:

1. Socio-demographics:
    a. age, socio-economic category, employment, occupation, type of dwelling
2. Place of recruitment
3. Clinic name
4. Laboratory test
    a. HIV: CD4 and viral load
    b. Haematology: RBC; white cell count and differential breakdown; haematocrit; platelet count; Mean cell volume
    c. Renal function tests
    d. Liver function tests
5. Clinical outcomes
    a. Adverse health outcomes
    b. Serious adverse events