DATA SHARING AGREEMENT

Methods for Improving Reproductive Health in Africa (MIRA) Study

Alexandra Minnis of RTI International provided with permission from MIRA Principal Investigator

(PI) Dr. Nancy Padian

MIRA was led by PI Padian when she was a professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco

(hereinafter "the Data Provider")

and

WITS HEALTH CONSORTIUM (PTY) LTD

Registration Number: 1997/15443/07
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 Methods for Improving Reproductive Health in Africa (MIRA) Study.
 Study title in Clinical Trials Registry: The Latex Diaphragm to Prevent HIV Acquisition
 Among Women: A Female-Controlled, Physical Barrier of the Cervix

MIRA assessed the effect of provision of latex diaphragm, lubricant gel, and condoms (intervention), compared with condoms alone (control) on HIV seroincidence in women in South Africa and Zimbabwe. The open-label, multi-site randomized, controlled trial was conducted with 4,948 HIV-negative, sexually active women recruited from clinics and community-based organisations, who were followed up quarterly for 12–24 months (median 21 months). All participants received an HIV prevention package consisting of pre-test and post-test counselling about HIV and sexually transmitted infections, testing, treatment of curable sexually transmitted infections, and intensive risk-reduction counselling. The primary outcome was incident HIV infection. This study is registered with ClinicalTrials.gov, number NCT00121459.

Primary results publication: <u>Diaphragm and Iubricant gel for prevention of HIV acquisition in</u> southern African women: a randomised controlled trial - PMC (nih.gov)

- 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 "Individual Participant Data meta-

analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa" ("the Study") within 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; 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. Given the nature of our research, we request that street addresses are not deleted.
- **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;
- "Commencement Date" shall mean the date on which this Agreement commenced, namely 11 June, 2024;
- 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:
- "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;

- "Parties" shall mean the parties to this Agreement, namely Wits Health Consortium (Pty) Ltd and MIRA Study via Alexandra Minnis of RTI International; and the term "Party" shall refer to either of them;
- 1.8 "person" means a natural or juristic person;
- "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;
- "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" shall mean the specific study within the Project as more fully described in Annexure "B" attached hereto;
- 1.14 "Study Data" shall mean data and results produced in the execution of the Study;
- 1.15 **"POPIA"** shall mean the South African Protection of Personal Information Act 4 of 2013 and regulations as amended from time to time;
- 1.16 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. RESPONSIBLE PARTY STATUS

- 3.1 For purposes of this Agreement, the Data Recipient is the Responsible Party and the Data Provider is neither the Responsible Party nor an operator.
- 3.2 Further, nothing in this Agreement is intended to affect Data Provider's Processing of Personal Data of Data Subjects unrelated to this Agreement. Data Provider will not provide any encryption key that could be used to re-identify the patient from any Data provided to Data Recipient.

4. <u>COMPLIANCE</u>

Each Party will comply with Data Protection Legislation in relation to the performance of its obligations under this Agreement.

5. 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.

6. 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.

7. CROSS-BORDER DATA TRANSFERS

- 7.1 In the event that it is necessary for the Data Recipient to transfer Personal Data across national borders to authorised Collaborator/s or other authorized third parties (as may be agreed between the Parties), the Party providing the Data will ensure the lawful export of the Personal Data and shall enter into a separate agreement governing such transfer on terms no less stringent than the terms set out herein.
- 7.2 In the event that the Data is transferred to a jurisdiction where POPIA does not apply, the respective Party transferring the Data undertakes that the Data will only be transferred to a jurisdiction with adequate protection as set out under Section 72 (1) of POPIA.

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. <u>SECURITY BREACH</u>

- 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 Alexandra Minnis; Telephone: +1 (604) 841-3558 or Email: aminnis@rti.org.

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 this 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 Operators; (ii) the name and contact details of the Operators' data protection officers; (iii) the categories of Processing that are carried out; (iv) transfers to other 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 Recipient shall provide Data Provider 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 Provider 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:

Attention: Matthew Francis Chersich (Research Professor)

Climate and Health Directorate, Wits RHI

22 Esselen Street, Hillbrow, Johannesburg 2100

Email: mchersich@wrhi.ac.za

If to Data Recipient (Legal):

Attention: Alfred Farrell (CEO)

Wits Health Consortium (Pty) Ltd, 31 Princess of Wales Terrace, Parktown,

Johannesburg, 2193

Email: ceo@witshealth.co.za

If to Data Provider Investigator:

If to Data Provider (Legal):

Attention: Alexandra Minnis

RTI International Email: aminnis@rti.org

15. **GENERAL**

- 15.1 In no event shall Data Provider be liable for any use by the Data Recipient of Data or Study Data 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.
- 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.

15.4 This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

DATA PROVIDER:	DATA RECIPIENT:
Digitally signed by Alexandra Alexandra Minnis Minnis	
By:	Ву:
(signature)	(signature)
Name: Alexandra Minnis	Name: Jéan du Randt
Title: Director, Women's Global Health Imperat	ive <u>Title: Chief Financial Officer</u>
Date: February 14, 2024	Date: 3 July 2024

ANNEXURE A

DESCRIPTION OF DATA

Data Source 1

The variable list below is indicative. A decision about the final set of variables to be transferred will be made through discussion with the Data Provider and Data Recipient.

Project Title: Methods for Improving Reproductive Health in Africa (MIRA) Study

Funder: Bill & Melinda Gates Foundation (number 21082).

Data to be transferred: [Description of data to be transferred]. Please see Data Dictionary for description of data provided.

Individual participant data for a limited set of variables from the original dataset/s relating to:

1. Cross-sectional time invariant variables

Variable cate- gory	Variable name (examples)	Definition
	Location of study follow-up	The place where the follow-up assessment or examination was conducted.
	Location of participant	The location where the participant resides or lives.
	Household address	The specific address of the household where the participant resides or lives.
	Housing type	The type of housing or accommodation in which the participant lives, such as apartment, house, or informal housing.
	No. of people in household	The number of people who reside or live in the same household as the participant.
	Air conditioning access	Whether the participant has access to air conditioning in their living quarters or not.
Demographics and socio-eco-	Socio-economic status indices	Measures of the economic and social standing of the participant or their household.
nomic status	Personal income	The amount of money the participant earns from their personal work or business
	Household income	The total amount of money earned by all members of the household, including the participant.
	Race	The ethnic or racial identity of the participant.
	Substance use	The use of drugs or alcohol by the participant.
	Smoking or alcohol use	The frequency and amount of tobacco or alcohol use by the participant
	Employment status	Whether the participant is currently employed or not.
	Education (highest level achieved)	The highest level of education completed by the participant.
	Marital status	The current marital status of the participant.

Variable cate- gory	Variable name (examples)	Definition
	Religion	The religious affiliation of the participant.
	Loss to follow-up	Whether the participant was lost to follow-up during the study period or not.
	Date of interview/examina-	The date when the interview, examination, or
	tion/special investigations	special investigation was conducted.

2. Repeated measure variables

Variable cate- gory	Variable name (examples)	Definition
Anthropometry	Height	The height of the participant, usually measured in centimeters or feet and inches.
	Weight	The weight of the participant, usually measured in kilograms or pounds.
	Other measures of obesity	Other measures of obesity, such as body mass index (BMI), waist circumference, or body fat percentage
	Ischemic heart disease	A history of heart disease caused by reduced blood flow to the heart muscle.
	Stroke	A history of stroke or cerebrovascular accident.
Previous medi-	Heart failure	A history of heart failure or a weakened heart.
cal history	Chronic lung or renal disease	A history of chronic lung or renal disease, such as chronic obstructive pulmonary disease (COPD) or chronic kidney disease (CKD).
	Chronic medication	A list of chronic medications that the participant is taking for their medical conditions.
Physical examination	Systolic blood pressure	The pressure in the arteries when the heart beats and pushes blood out, usually measured in millimeters of mercury (mmHg).
	Diastolic blood pressure	The pressure in the arteries when the heart is resting between beats, usually measured in millimeters of mercury (mmHg).
	Heart rate	Heart rate: The number of times the heart beats per minute, usually measured by feeling the pulse or using an electrocardiogram (ECG).
	Body temperature	The temperature of the body, usually measured in degrees Celsius or Fahrenheit using a thermometer.
	Respiratory rate	The number of breaths a person takes per minute, usually measured by counting breaths.
	Signs of dehydration	Physical signs of dehydration, such as dry mouth, thirst, decreased urine output, or sunken eyes.
	Systems(cardiovascular, respiratory, abdominal, skin, neurological, general)	(cardiovascular, respiratory, abdominal, skin, neurological, general): Assessment of different systems in the body, including the cardiovascular system, respiratory system, abdominal organs, skin, nervous system, and general appearance.
Adverse events	Metabolism and nutrition disorders	Disorders related to the body's metabolism or nutrition, such as diabetes, obesity, or malnutrition.

Variable cate- gory	Variable name (examples)	Definition
3 ,	Nervous system disorders	Disorders of the nervous system, such as Parkinson's disease, multiple sclerosis, or epilepsy.
	Reproductive system and breast disorders	Disorders of the reproductive system or breast, such as infertility, breast cancer, or uterine fibroids.
	Investigations	Results of medical tests or investigations, such as blood tests, imaging studies, or biopsies
	Gastrointestinal disorders	Disorders of the gastrointestinal tract, such as gastroesophageal reflux disease (GERD), inflammatory bowel disease (IBD), or peptic ulcers.
	Infections and infestations	Infections or infestations caused by bacteria, viruses, fungi, or parasites, such as influenza, HIV/AIDS, or malaria.
	Immune system disorders	Disorders of the immune system, such as allergies, autoimmune diseases, or immunodeficiencies.
	Renal and urinary disorders	Disorders of the kidneys or urinary tract, such as kidney failure, urinary tract infec- tions (UTIs), or kidney stones
	Blood and lymphatic system	Disorders of the blood or lymphatic system,
	disorders Musculoskeletal and connective tissue disorders	such as anemia, leukemia, or lymphoma. Disorders of the muscles, bones, joints, or connective tissues, such as arthritis, osteoporosis, or tendonitis.
	Injury, poisoning and procedural complications	Adverse events related to injuries, poisonings, or medical procedures, such as surgical complications, medication errors, or accidental injuries.
	Skin and subcutaneous tissue disorders	Disorders of the skin or subcutaneous tissue, such as acne, eczema, or psoriasis.
	Eye disorders	Disorders of the eye, such as glaucoma, cataracts, or macular degeneration.
	Respiratory, thoracic and mediastinal disorders	Disorders of the respiratory system, such as asthma, chronic obstructive pulmonary disease (COPD), or pneumonia.
	Psychiatric disorders	Mental or behavioral disorders, such as depression, anxiety, or schizophrenia.
	Vascular disorders	Disorders of the blood vessels, such as hypertension, peripheral artery disease (PAD), or deep vein thrombosis (DVT).
	Ear and labyrinth disorders	Disorders of the ear or labyrinth, such as hearing loss, tinnitus, or vertigo.
	Neoplasms benign, malignant and unspecified	Neoplasms benign, malignant and unspecified: Tumors or abnormal growths, either cancerous or non-cancerous.

Variable cate- gory	Variable name (examples)	Definition
	Pregnancy, puerperium and perinatal conditions	Refers to medical conditions related to pregnancy, childbirth, and the postpartum period, as well as conditions affecting the newborn infant. This category includes a wide range of conditions, such as gestational diabetes, preeclampsia, preterm labor, fetal distress, birth defects, and neonatal jaundice. These conditions are of particular interest to researchers and healthcare providers who are studying maternal and child health and working to improve outcomes for mothers and infants.
	General disorders and administration site conditions	Adverse events related to general disorders, such as fever, fatigue, pain, or administration site reactions, such as injection site pain, swelling, or redness.
	Hepatobiliary disorders	Adverse events related to the liver, gallblad- der, or bile ducts, such as hepatitis, liver fail- ure, or cholecystitis
	Congenital, familial and genetic disorders	Adverse events related to inherited or genetic conditions, such as Down syndrome, cystic fibrosis, or sickle cell anemia.
	Social circumstances	Adverse events related to social or environmental factors, such as poverty, homelessness, or lack of social support.
	Endocrine disorders	Adverse events related to the endocrine system, such as diabetes, thyroid disease, or adrenal insufficiency
	Cardiac disorders	Adverse events related to the heart, such as arrhythmias, myocardial infarction, or angina.
	Surgical and medical procedures	Adverse events related to surgical or medical procedures, such as infections, bleeding, or complications from anesthesia
	Basophils	Basophils are a type of white blood cell that works closely with your immune system to defend your body from allergens, pathogens and parasites. Basophils release enzymes to improve blood flow and prevent blood clots.
Haematology	CD4 cell %	In addition to using a test to count the number of CD4 cells, doctors sometimes measure the proportion of all white blood cells that are CD4 cells. This is called a CD4 cell percentage.
	CD4 cell count	CD4 cells, also known as T cells, are white blood cells that fight infection and play an important role in your immune system. A CD4 count is used to check the health of the immune system in people infected with HIV

Variable cate- gory	Variable name (examples)	Definition
3.7		(human immunodeficiency virus). HIV attacks and destroys CD4 cells.
	Monocytes	Monocytes are a type of white blood cell (leukocytes) that reside in your blood and tissues to find and destroy germs (viruses, bacteria, fungi and protozoa) and eliminate infected cells. Monocytes call on other white blood cells to help treat injury and prevent infection.
	Neutrophils	Neutrophils help your immune system fight infections and heal injuries. Neutrophils are the most common type of white blood cell in your body. An absolute neutrophil count identifies whether your body has enough neutrophils or if your count is above or below a healthy range.
	Platelet count	A platelet count is a test that measures the number of platelets in your blood. Platelets are cells that help your blood clot. Too few platelets can be a sign of cancer, infections or other health problems. Too many platelets put you at risk for blood clots or stroke. There are tens of thousands of platelets in a single drop of blood.
	RBC(Red Blood Count)	A red blood cell (RBC) count measures the number of red blood cells, also known as erythrocytes, in your blood. Red blood cells carry oxygen from your lungs to every cell in your body. Your cells need oxygen to grow, reproduce, and stay healthy. An RBC count that is higher or lower than normal is often the first sign of an illness. So the test may allow you to get treatment even before you have symptoms.
	RDW (Red Cell Distribution Width)	A red cell distribution width (RDW) test measures the differences in the volume and size of your red blood cells (erythrocytes). Red blood cells carry oxygen from your lungs to every cell in your body. Your cells need oxygen to grow, make new cells, and stay healthy.
	WBC (White Blood Count)	A white blood count measures the number of white cells in your blood. White blood cells are part of the immune system. They help your body fight off infections and other diseases. When you get sick, your body makes more white blood cells to fight the

Variable cate- gory	Variable name (examples)	Definition
3*1		bacteria, viruses, or other foreign substances causing your illness.
	Haematocrit	measures the proportion of red blood cells in your blood. Red blood cells carry oxygen throughout your body. Having too few or too many red blood cells can be a sign of certain diseases. The hematocrit test, also known as a packed-cell volume (PCV) test, is a simple blood test.
	Alanine aminotransferase (ALT)	An alanine transaminase (ALT) blood test measures the amount of ALT in your blood. ALT levels in your blood can increase when your liver is damaged, so healthcare providers often use an ALT blood test to help assess the health of your liver.
Liver function	Aspartate aminotransferase (AST) tes	The aspartate aminotransferase (AST) test is a blood test that checks for liver damage. Your doctor might order this test to find out if you have liver disease and to monitor your treatment.
	Total bilirubin and conjugated bilirubin	Unconjugated: This is the bilirubin once it reaches the liver and undergoes a chemical change. It moves to the intestines before being removed through your stool. Conjugated This is the bilirubin once it reaches the liver and undergoes a chemical change. It moves to the intestines before being removed through your stool.
	Gamma-glutamyl Transferase (GGT) Test	A gamma-glutamyl transferase (GGT) test measures the amount of GGT in the blood. GGT is an enzyme found throughout the body, but it is mostly found in the liver. When the liver is damaged, GGT may leak into the bloodstream. High levels of GGT in the blood may be a sign of liver disease or damage to the bile ducts. Bile ducts are tubes that carry bile in and out of the liver. Bile is a fluid made by the liver. It is important for digestion.
Renal function	GFR or Creatinine clearance	A measure of the kidney function, either by estimating the glomerular filtration rate (GFR) or by measuring the creatinine clearance. GFR is a calculated value based on blood creatinine levels, age, sex, and race, while creatinine clearance is a measure of how much blood is cleared of creatinine by the kidneys in a given period of time. Both measures are used to assess the severity of

Variable cate- gory	Variable name (examples)	Definition
3 ,		kidney disease or to monitor the effect of treatments on kidney function.
	Urea	A waste product of protein metabolism that is excreted by the kidneys. Urea levels in the blood can be used to evaluate kidney function, as well as liver function or dehydration.
	Creatinine	Creatinine is a chemical compound left over from energy-producing processes in your muscles. Healthy kidneys filter creatinine out of the blood. Creatinine exits your body as a waste product in urine.
	Urea to creatinine ratio	A waste product of muscle metabolism that is excreted by the kidneys. Creatinine levels in the blood can be used to evaluate kidney function, as well as muscle mass or dietary protein intake.
Lipids	HDL (high-density lipoprotein)	A type of cholesterol that is considered "good" because it helps remove excess cholesterol from the bloodstream and carry it back to the liver for processing. High levels of HDL are associated with a lower risk of heart disease, while low levels are associated with a higher risk
	LDL (low-density lipoprotein)	A type of cholesterol that is considered "bad" because it can build up in the walls of arteries and form plaques that narrow or block blood flow. High levels of LDL are associated with a higher risk of heart disease, while low levels are associated with a lower risk
	Total cholesterol	The total amount of cholesterol in the blood, including both HDL and LDL. High levels of total cholesterol are associated with a higher risk of heart disease, while low levels are associated with a lower risk. Total cholesterol levels are often used in combination with HDL and LDL levels to evaluate cardiovascular risk and guide treatment decisions

Associated metadata/documentation

- codebooks
- do files
- documentation on definitions, components and processing of the data

Purpose of Data Transfer: The data will be used to advance understanding of complex spatially and demographically stratified heat-health interactions in large African cities and to apply this information to develop locally relevant and risk-stratified Early Warning Systems.

ANNEXURE B

Study title: Developing data science solutions to mitigate the health impacts of climate change in Africa: the HE²AT Center

Rationale: The study constitutes one of two Research Projects (RPs) within the NIH-funded HE²AT Center. It specifically addresses the complexity of urban spaces with regard to heat-health impacts and the appropriate responses for some particular vulnerable groups.

Objectives: The overarching goal is to advance understanding of complex spatially and demographically stratified heat-health interactions in large African cities and to apply this information to develop locally relevant and risk-stratified Early Warning Systems (EWS). The aims are three: (1) Map intra-urban heat vulnerability and exposure across urban areas in large African cities (Aim 1); (2) Develop a spatially and demographically stratified heat-health outcome forecast model in order to predict the probability of adverse health outcomes at different temperature thresholds (Aim 2); and (3) Develop an Early Warning System reflective of geospatial and individualized risk patterns (Aim 3) Study design: The RP2 focuses on the conditions in two large cities in two regions of Africa (Johannesburg, South Africa, Southern Africa, and Abidjan, Côte d'Ivoire, West Africa). It adopts a transdisciplinary approach in which multidisciplinary experts will collaborate with communities, local government actors, and policy makers to address heat-related complex and interconnected research gaps. Existing data from longitudinal studies (trials and cohorts) in the two cities that were performed among HIV-infected adults, HIV-uninfected adults and adults in COVID-19 prevention or treatment studies will be reanalysed, together with weather, other environmental and socio-economic and other data. Analysis will deploy a range of machine learning methods to construct an index of intra-urban socio-economic and environmental vulnerability factors. As the solutions developed by the RP2 will address two major concerns for global policymakers (how to warn people about a heatwave in urban settings in low- and middle-income countries, and then to track its impacts), local, national and international policymakers will be engaged at all stages.

Dissemination: Findings will be disseminated at various levels, using several channels, including workshops, policy and research fora, scientific conferences and journal publications, and towards different target groups (including policymakers, communities, specific vulnerable groups).

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ANNEXURE C

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:

- 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 4th 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.