**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**

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. 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.
   2. An adaptive phase I/II randomized placebo-controlled trial to determine the safety, immunogenicity, and efficacy of the non-replicating ChadOx1 SARSCoV-2 vaccine in South African adults living without HIV and the safety and immunogenicity in adults living with HIV
   3. Severe Acute Respiratory Syndrome Coronavirus 2 Infection Among Healthcare Workers in South Africa: A Longitudinal Cohort Study
   4. Surveillance of Severe Childhood Illness and Pregnancy Outcomes in Soweto, South Africa
2. The Data Recipient is carrying out research projects under The Climate and Health Directorate titled as follows:

* Individual Participant Data meta-analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa;
* Innovative machine learning and multi-source data analysis towards development of an urban heat-health Early Warning System for African cities;
* HIGH Horizons Population-Level Heat-Health Impacts Study in Greece, Italy, Kenya, South Africa and Sweden.

1. 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 research conducted under the Climate and Health Directorate. The details of the Directorate and Research Projects are set out under Annexure “B-D” attached hereto.
2. 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. Given the nature of our research, we request that postal addresses are not deleted. In accordance with Ethics in Health Research Guidelines(Department of Health, 2015) and the Protection of Personal Information Act No.4 of 2013 (POPIA), these are not considered direct identifiers and are of utmost importance in our research. Due to the potential identifiability of this information, this modified **“Limited Data Set”** will be managed in accordance with our data management policy to protect the identity of the individuals.
3. 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. “**Data”** shall mean the Data to be transferred from the Data Provider to the Data Recipient as described and detailed in **Annexure A**;
  2. “**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”** shall mean the specific study within the Project as more fully described in **Annexure “C-D”** 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 April 2024** for the project “HIGH Horizons Population-Level Heat-Health Impacts Study in Greece, Italy, Kenya, South Africa and Sweden”, whilst the termination date **30 June 2026** will apply for the projects “Individual Participant Data meta-analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa” and “Innovative machine learning and multi-source data analysis towards development of an urban heat-health Early Warning System for African cities”, or the termination will be effective upon completion of the respective Projects, 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 Centre for Sexual Health and HIV/AIDS Research(CeSHHAR), Zimbabwe

2.8.3 IBM Research Africa

2.8.4 Climate and Systems Analysis Group (CSAG)-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 “E”** 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 ethical clearance 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.

## **COMPLIANCE**

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

## **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.

## **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.

## 

## **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.

## **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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_ or Email: \_\_\_\_\_\_\_\_\_\_\_\_\_

## **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](mailto: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](mailto:piet.barnard@uct.ac.za)

## **If to Data Provider Investigator:**

## [Provider legal contact details]

## Attention:

## Address:

## Email:

## **If to Data Provider (Legal):**

## [Provider legal contact details]

## Attention:

## Address:

## Email:

**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 (Representative):**

By: By:

(signature) (signature)

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: Date:

**DATA RECIPIENT (Principal Investigator)**

**DATA PROVIDER:**

By:

(signature)

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

**ANNEXURE A**

**DESCRIPTION OF DATA**

**Data Source 1**

**Project Title: [Full research project title]**

**Funder: [Original research funding details]**.

**Data to be transferred:** [Description of data to be transferred].

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

* **Static Variables (e.g. Unique Identifiers, Date of Birth, Address etc.)**
* **Clinical Variables (Maternal Outcomes, Neonatal, Infant and Child Outcomes, etc.)**
* **Laboratory Variables (Chemistry, Haematology, Histology, etc.)**
* **Other Variables (Study ID, Consent, etc.)**

**Associated metadata/documentation**

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

**Purpose of Data Transfer:**

1. The data will be used to examine extreme heat on pregnant women, infants, and health workers, and test adaptation measures to reduce these impacts. This information will be used to develop locally relevant and risk-stratified Early Warning Systems.

**Data Source 2:**

**[repeat as above for each data set to be shared]**

**ANNEXURE B**

**Directorate profile:** Climate change and health projects at the Climate and Health Directorate, Wits RHI

The Climate and Health Directorate of the Wits Reproductive Health and HIV Institute (Wits RHI) is conducting six projects on climate change and health involving several countries in Africa, including South Africa, Kenya, Zimbabwe, Botswana, Burkina Faso and Côte d’Ivoire. We collaborate with leading Universities in the European Union and United States. WHO is also a key partner on several projects. Our research is mainly supported by grants from the US National Institutes for Health, the European Union Horizons programme and Wellcome Trust. We also work closely with IBM on our data science portfolio of work. All our work is investigator driven.

The main focus our work is on the impacts of extreme heat on pregnant women, infants, and health workers, and adaptation measures to reduce these impacts. We have strategically targeted pregnant women and infants as these are the population groups that are placed at the centre of almost all health programmes in Africa to date. The focus on this population group means that there are well established workforces, monitoring systems, advocacy networks and funding streams that we can leverage. In our work we highlight that the health sector response to the climate crisis needs to do more to take this fact on board, and to shore up the overall resilience of the health systems against extreme heat.

The projects apply rigorous research methods in field conditions to establish the effectiveness of interventions in real-world settings. These interventions are then intended to be implemented at large scale, adapted to specific contexts. Most projects are set in two or more regions of Africa, aiming for relevance across the continent. Together the study sites cover a wide range of climate zones, urban or rural characteristics, and socio-economic levels.

The projects together constitute a coherent body of research, with each covering different aspects of the heat exposures, health outcomes and the populations groups we are studying. Moreover, the projects build on the foundations of each other. These projects include:

1. Individual Participant Data meta-analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa
2. Innovative machine learning and multi-source data analysis towards development of an urban heat-health Early Warning System for African cities
3. HIGH Horizons Population-Level Heat-Health Impacts Study in Greece, Italy, Kenya, South Africa and Sweden

Specifically, we have progressively extended our activities into new regions of Africa, and applied more detailed intervention design techniques, and additional complementary evaluation methods to interrogate our research and programmatic questions. HIGH Horizons, our most recent grant, is an EU Horizons project which will test a novel integrated adaptation-mitigation package of interventions within health facilities in South Africa, Kenya and Zimbabwe. The comprehensive intervention package will be selected based on thermal modelling of the facilities, modelling of carbon emissions with different interventions, and cost-effectiveness modelling around health outcomes. This novel approach brings together the strengths of all of our projects and provides a model for future work on the continent, and for applications for funding from global multilateral climate financing organisations such as the Green Climate Fund and Adaptation Fund.

**ANNEXURE C**

**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 African 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) program1. 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.

1. To develop a collaboration between the HE2AT Center and investigators of each of the studies who contribute participant-level data.

1. To link health outcome data spatially and temporally with weather and other environmental data, as well as with socio-economic and related factors.

1. To utilize classic statistical methods and novel machine learning approaches to understand and quantify the impact of heat exposure on maternal and child health.

1. 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/prospero/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.

**The project is interested in the non-exhaustive list of maternal, foetal, newborn and child variables in the table below:**

| Variables | Variables essential for study inclusion | Important variables | Desirable variables |
| --- | --- | --- | --- |
| Maternal outcomes | To be eligible, data should be available on at least 2 of the important maternal or neonatal outcome variables | * Gestational age at delivery * Preterm premature rupture of the membranes (PPROM) * Prolonged rupture of membranes (PROM) * Antepartum and postpartum hemorrhage   estimated blood loss   * Hypertensive disorders in pregnancy   + gestational hypertension   + preeclampsia   + preeclampsia with severe features   + eclampsia   + HELLP syndrome   + blood pressure (systolic/diastolic)   + proteinuria * Anaemia in pregnancy   + hemoglobin, mean cellular volume, hematocrit * Adverse events   + serious adverse events (SAEs) * Gestational Diabetes Mellitus (GDM)   + glucose level in pregnancy (hemoglobin A1c)   + Oral Glucose Tolerance Test (OGTT) * Health facility visits   + emergency department visits   + hospital admissions * Maternal mental health   + emotional stress, maternal global severity index (GSI)   + Life Event Scale for Pregnant Women   + Patient Health Questionnaire-9 (PHQ-9) | * Duration of labor * Caesarean section   + emergency   + elective * Abortion   + spontaneous (miscarriage)   + threatened spontaneous   + induced * Oligohydramnios * Placental complications   + placental abruption   + placenta previa   + fetal growth restriction * Sexual and gender-based violence   + intimate partner violence * Maternal mortality (including cause) * Hyperemesis gravidarum * Maternal cardiovascular disease   + ischemic heart disease   + stroke   + heart failure * Cardiac arrest * Renal function   + Glomerular filtration rate (GFR), urea, creatinine * Liver function   + ALAT, ASAT, total bilirubin/conjugated bilirubin, GGT * Maternal peripartum infections   + pyelonephritis   + puerperal sepsis   + chorioamnionitis   + Group B streptococcus   + urinary tract infection/bacteriuria * Infectious disease   + malaria   + dengue   + TB   + Other * Maternal immunization * Maternal caregiving practices * Ectopic pregnancy * HIV status   + newly diagnosed, chronic   + CD4, viral load   + treatment |
| Fetal, neonatal and child outcomes | To be eligible, data should be available on at least 2 of the important maternal or neonatal outcome variables | * Prematurity (see also gestational age at delivery) * Mortality (including cause)   + stillbirth (fresh/macerated)   + neonatal   + perinatal   + child (first two years) * MTCT (mother-to-child transmission of HIV) * APGAR score * Infant growth   + birthweight   + small for gestational age   + infant height (<2 years)   + failure to thrive   + stunting * Admission to neonatal intensive care units or paediatric ward * Intrauterine growth restriction * Ultrasound findings | * Birth   + singleton/multiple * Meconium staining * Infant sex * Infant feeding practices   + exclusive breastfeeding (if yes, duration) * Fetal distress, hypoxia * Infections   + neonatal sepsis   + TORCH (toxoplasmosis, other (syphilis, hepatitis B), rubella, cytomegalovirus, herpes simplex)   + group B streptococcus   + respiratory tract infection (lower/upper/pneumonia)   + diarrhea * Early Child Development (ECD) * Bayley’s score (<2 years) * Neonatal jaundice * serum and/or transcutaneous bilirubin levels Congenital anomaly |
| Other variables | To be eligible, data should be available on:   * Date of delivery of the newborn OR date of maternal outcome * Location, at a minimum: city of delivery, or city of follow-up (data on location of household, birth facility, or study clinic are preferable) | * Maternal age * Gravidity, parity * Study intervention or exposure * Maternal anthropometry   + Maternal weight, height, BMI, MUAC * Date of interviews or examination * Mode of delivery * Facility of delivery location, or catchment area of facility * Location of research site * Type of facility (community health center/hospital) | * Time of delivery * Location   + home address   + rural/urban/peri-urban * Housing type   + apartment, house, informal   + no. of people in household   + air-conditioning access * Socio-economic status or income   + personal income   + household income * Race, ethnicity * Substance use   + Smoking, alcohol, or illicit substances * Employment status * Maternal co-morbidities   + chronic medication * Education (highest level achieved) * Marital status * Birth attendant (skilled/unskilled) * Religion * Lost to follow-up * Temperature in healthcare facility, incubator, crib, room |

**ANNEXURE D**

**Study title:** Innovative machine learning and multi-source data analysis towards development of an urban heat-health Early Warning System for African cities

**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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**The project is interested in the non-exhaustive list of maternal, fetal, newborn and child variables in the table below:**

1. **Cross-sectional time invariant variables**

|  |  |  |
| --- | --- | --- |
| Variable category | Variable name (examples) | Definition |
| Demographics and socio-economic status | 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. |
| Socio-economic status indices | Measures of the economic and social standing of the participant or their household. |
| 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. |
| 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/examination/special investigations | The date when the interview, examination, or special investigation was conducted. |

1. **Repeated measure variables**

|  |  |  |
| --- | --- | --- |
| Variable category | 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 |
| Previous medical history | 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. |
| Heart failure | A history of heart failure or a weakened heart. |
| 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. |
| 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 infections (UTIs), or kidney stones |
| Blood and lymphatic system disorders | Disorders of the blood or lymphatic system, such as anemia, leukemia, or lymphoma. |
| Musculoskeletal and connective tissue disorders | 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. |
| 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, gallbladder, or bile ducts, such as hepatitis, liver failure, 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 |
| Haematology | 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. |
| 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 (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 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. |
| Liver function | 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. |
| 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 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 |

**ANNEXURE D**

**Study title:** HIGH Horizons Population-Level Heat-Health Impacts Study in Greece, Italy, Kenya,

South Africa and Sweden

**Rationale:** The frequency, intensity, and duration of extreme weather events, including heatwaves, have increased in the past four decades and are projected to continue rising. Accumulating epidemiological evidence shows an increased risk of adverse health outcomes for pregnant women, newborns, and young children associated with exposure to extreme heat and high ambient temperatures. There is also some evidence to suggest that heat exposure during gestation has long-term health consequences for the child. This study forms part of the larger HIGH Horizons project, focussed on the impacts of climate change, and specifically heat, on maternal, neonatal and child health (MNCH). The study will inform the selection of heat-related indicators for monitoring and surveillance purposes, development of meaningful heat thresholds, and the design and implementation of a personalised Early Notification/Warning System.

Importantly, the study is designed to understand the relationships between heat exposure and health outcomes during pregnancy, the postpartum and neonatal periods, as well as early childhood. The study will be conducted in multiple countries, varying in climate zones and socio-economic characteristics, which will increase international representation and generalisability.

Objectives:

Primary:

1. To quantify relationships between ambient temperature exposures and risk of adverse maternal, neonatal, and child health outcomes;
2. To identify the relative temperature threshold(s) above which risk of an adverse outcome is increased;
3. To determine valid and reliable heat indicators for assessing heat-MNCH impacts at population-level;
4. To characterise groups of pregnant women and children at high risk of heat-related conditions;
5. To determine if heat-MNCH associations vary by location, climate, facility, or quality of care, as the data allow.

Secondary:

1. To identify critical windows of susceptibility during gestation or during infancy and childhood;
2. To explore impacts of both acute and cumulative heat exposures.

**Study design:** The study will follow a time-series approach to assess the impacts of high environmental temperature and heat stress on adverse MNCH outcomes. The study is observational (non-interventional), using data from secondary sources only. No primary data will be collected.

**Methods:** Maternal, perinatal and neonatal health data from different registries and cohorts will be used across different settings and population characteristics. Daily time-series of exposures (such as minimum, mean, and maximum temperatures, universal thermal climate index, wet-bulb globe temperature, apparent temperature, and relative humidity) have been constructed from hourly openly available reanalysis data, obtained from the Copernicus Climate Data Store or other relevant data repository for each country. Daily exposures will be linked with MNCH outcomes in time and space, including varying lag structures. We will employ a range of complementary analytical approaches, including time-series regression, time-stratified case-crossover, and time-to-event analyses to model associations between environmental exposures and MNCH outcomes.

**Ethical considerations:** All partners will obtain approval from relevant ethics committees in countries where the data originate and where data analyses will take place. The data will be anonymized, and results will be presented in aggregated format so that individuals will not be identifiable.

**Dissemination:** Outputs from this study will be presented at different international scientific fora for maternal, neonatal and child health as well as climate change. Scientific evidence generated from the project will be published in scientific peer reviewed articles. Additionally, results will be disseminated among local, provincial and national government officials, advocacy groups, and researchers to support policy changes.

**Funding acknowledgments:** Research that will be conducted in this study is supported by the European Union (EU) under the Environmental and Health Call (Award number: 101057843) under the Framework Programme for Research and Innovation (2021-2027). Project partner LSHTM is funded by UKRI Innovate UK (Reference number: 10038478).

**ANNEXURE E**

**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 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.