CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)/AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

DATA USE AGREEMENT

This data use agreement ("Agreement") is between the following parties:

Data Provider ("Provider"):

CENTERS FOR DISEASE CONTROL AND PREVENTION

Data Recipient ("Recipient"):

THE UNIVERSITY OF CAPE TOWN, a university established in terms of the Higher Education Act, 1997, and the statute of the University of Cape Town, as published and gazetted on 24 January 2020 in Government Gazette No 41, 42967 and amended under Government Gazette No 45954, Government Notice No 1793 of 25 February 2022.

These parties will collectively be considered the "Parties," or individually, a, "Party". This Agreement will be effective as of the latest date signed below ("Effective Date") by the Provider and Recipient.

PURPOSE AND BACKGROUND

This Agreement establishes the terms and conditions under which the Provider will provide, and Recipient will receive and use, the data covered under this Agreement. This Agreement ensures adherence to guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity. Use and disclosure of the data must be consistent with this Agreement and with applicable law.

The Parties agree that the Recipient will use the data being shared for the purpose(s) of:

Project Title: *"The HEat and HEalth African Transdisciplinary Center (HE2AT Center): Developing data science solutions to mitigate the health impacts of climate change in Africa" (see Appendix "B")*
Study title: *"Individual Participant Data meta-analysis to quantify the impact of high ambient temperatures on maternal and child health in Africa"*

COVERED DATA

This section will provide information about the data being shared per this Agreement.

The Parties acknowledge that Covered Data are limited to those data specified in the Appendix A, which identifies the complete set of data items to which the Recipient will have access to under this Agreement.

The Parties are permitted to transmit, access, receive, share and/or use any part of the Covered Data listed below as specified in the agreed purpose and uses, as set out herein:

BAN Study (Breastfeeding, Antiretrovirals and Nutrition)

Where CDC/ATSDR is the Recipient, the Parties acknowledge that in a public health emergency (PHE) or if an event is significantly likely to become a PHE, as provided in 42 U.S.C. §247d, certain data in the custody and control of CDC/ATSDR may be necessary to respond to the PHE. In that event, CDC/ATSDR may use the Covered Data, consistent with CDC/ATSDR's authorities under applicable federal law. CDC agrees that any such use will be on a need-to-know basis, will be a minimum amount necessary to support a coordinated federal response, and will protect individual privacy and confidential business or financial information to the fullest extent allowed by federal law. CDC further agrees that it will notify Provider of the need to use the Covered Data as soon as practicable prior to use of the data for this purpose and, where practicable and appropriate, will work collaboratively with Provider throughout the response to ensure appropriate coordination and access to developed analyses and reports.

AGREEMENT ADMINISTRATION

Unless otherwise designated and agreed upon by Parties, the Recipient will act as the "Data Custodian" of the Covered Data once the data are transmitted. As Data Custodian, the Recipient is responsible for ensuring that the Covered Data are kept secured and that access to and use of the Covered Data is consistent with this Agreement and applicable law.

Where required by law, Recipient will ensure that the authorized users within Recipient's organization are deemed authorized to access the Covered Data will receive appropriate security training and be aware of the terms of this Agreement.

The Recipient designates the following individual(s) as the primary Data Custodian(s) point of contact:

Christopher Jack,
Position: Deputy Director
Climate System Analysis Group, University of Cape Town
Department: Enviromental and Geographical Science
Institution: University of Cape Town
Email: cjack@csag.uct.ac.za
Address: Environmental & Geographical Science Bldg, South Ln, Rondebosch, Cape Town, 7700
Tel: (+27) 21 650 2784

Unless otherwise designated and agreed upon by Parties, the Provider will act as the "Data Administrator" of the Covered Data being transmitted. As Data Administrator, the Provider is responsible for the Covered Data being transmitted to the Recipient and/or granting appropriate access to authorized users for the Recipient.

To the extent allowed by law, the Provider will ensure that the Covered Data may be transmitted to Recipient's organization consistent with the purposes set forth under this Agreement.

The Provider designates the following individual(s) as the primary Data Administrator(s) point of contact:

Athena P. Kourtis, MD, PhD, MPH
Chief, HIV Research Branch
Division of HIV Prevention, NCHHSTP
Centers for Disease Control and Prevention
Tel 770 488 5216, apk3@cdc.govl

Processes for Communication

All notices or any other communication provided for herein shall be provided in writing through the following means:

- To the above identified Data Administrator/Custodian by registered or certified mail, return receipt requested; by receipted hand delivery; by courier or other similar and reliable carrier.

- To the above identified Data Administrator/Custodian by email.

Effective Date, Term of Data Use, and Termination Date

The term of this Agreement shall be until 30 June 2026 , commencing from the date of the final signature. The Agreement may be renewed upon mutual written consent of the Parties.

Except as otherwise expressly provided herein, this Agreement may be amended only by the mutual written consent of the signatory as the authorized representatives of each Party. Amendments to this Agreement must be requested in writing through the means above and must be signed by all Parties to be effective.

Either Party may terminate this Agreement at any time by giving thirty (30) days' advance written notice.

CONFIDENTIALITY, SECURITY, AND LEGAL REQUIREMENTS

The Parties will establish appropriate administrative, technical, procedural, and physical safeguards to assure the confidentiality and security of Covered Data. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by applicable law for the type of data provided under this Agreement.

Recipient agrees to the following:

> **Confidentiality:** Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable, Recipient agrees to maintain the confidentiality of the Covered Data to the fullest extent required by applicable law. Recipient further agrees to not disclose such Covered Data, including but not limited to names and other identifying information of persons who are the subject of such Covered Data, either during the term of this Agreement or longer, except as consistent with this Agreement or as may be allowed or required by applicable law.

Where CDC/ATSDR is the Recipient, CDC/ATSDR will protect the privacy and confidentiality of the Covered Data consistent, where applicable, with the following federal laws: the Privacy Act of 1974; to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Freedom of Information Act (FOIA). Where other more specific federal laws apply to the Covered Data; CDC/ATSDR as Recipient will comply with those laws, as well. CDC/ATSDR will seek to assert relevant exemptions to disclosure available under federal law, most critically, where applicable, for personal and/or private information, the disclosure of which would constitute an invasion of privacy; trade secret and commercial or financial information that is private and confidential; or information exempted from release by federal statute.

Except as may be provided for in this Agreement, Recipient shall not use the information from Covered Data to link to other data nor establish contact with any potentially identified person or his/her family nor establish contact with the persons represented in the data without prior written approval from the Provider.

Where required by law and/or where practicable, Recipient agrees to notify Provider before releasing Covered Data to a third party pursuant to a judicial, governmental, or other request under law, to allow Provider the opportunity to state any objection to the disclosure of the Covered Data.

Security: Recipient will use all reasonable administrative, technical, and physical measures to safeguard Covered Data once transmitted, and to protect Covered Data from unauthorized access, disclosure, use, or modification. This includes setting permissions to access or edit data commensurate with the level of sensitivity of the data. Should there be a data breach and unauthorized disclosure of Covered Data, consistent with applicable legal requirements, Recipient notify appropriate response teams and Provider of the incident.

Transfer: Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, transmission of the Covered Data from the Provider to Recipient shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents. The Parties may coordinate to implement methods to achieve these outcomes consistent with procedures already in place for similar data exchanges. If encrypted identifiable information is transferred electronically through means such as the Internet, then said transmissions will be consistent with the rules and standards promulgated by applicable legal requirements regarding the electronic transmission of identifiable information.

Storage: Covered Data will be maintained and stored in compliance with the Recipient's security policies and procedures and consistent with applicable law. Where Covered Data are identifiable or potentially identifiable or are privileged, sensitive or confidential, such records and data shall be secured in an encrypted, password-protected electronic folder with access restricted to project personnel for purposes as set forth in this Agreement.

Access: Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, Recipient and its authorized users shall access Covered Data on secured devices only.

Recipient may provide Covered Data access to appropriate employees, contractors, and other authorized users. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized access to the Covered Data.

Data Maintenance, Deletion or Storage Requirements after Termination

Unless explicitly stated otherwise in the Agreement, ownership of Covered Data shall remain with the Provider. However, the Parties agree that the Covered Data provided under this Agreement and in the custody and control of the Recipient is subject to the laws applicable to the Recipient.

Accordingly, the Recipient agrees to maintain, store, protect, archive and/or dispose of Covered Data in accordance with applicable law. Obligations under law to maintain and secure Covered Data will survive termination of this Agreement. At a minimum, the Provider agrees that an archival copy of the Covered Data may be retained by Recipient to comply with relevant records retention requirements and/or for the purposes of research integrity and verification.

When CDC and/or ATSDR act as Recipient, as federal agencies, the disposition of records in their custody and control is governed by the Federal Records Act and may only be accomplished in accordance with schedules for destruction as provided under law.

APPLICABLE LEGAL AUTHORITIES

Applicable federal and/or state/jurisdiction or local laws that govern the collection, use, disclosure, and maintenance of the Covered Data may be cited as standard authorities related to the Covered Data, which includes project-specific authorities and regulations. Parties acknowledge that CDC and ATSDR, as federal agencies, are not subject to the application of state or local laws or regulations or the internal policies and/or procedures of the other party, except where consistent with federal law.

This Agreement is governed by applicable federal law.

Applicability of HIPAA

As applicable to the Covered Data and the Provider, CDC/ATSDR, as Recipient, is a “public health authority” as defined at 45 C.F.R. §164.501 and as used in 45 C.F.R. §164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). CDC/ATSDR, as a public health authority, is authorized by 45 CFR 164.512(b) to receive Protected Health Information (“PHI”).

REPORTING OF DATA USED IN PUBLICATIONS AND PRESENTATIONS

Notification

Recipient agrees to allow Provider no more than thirty (30) days to review and provide comments for consideration on papers, reports, publications, or presentations that Recipient plans to submit for publication or presentation. If publication needs to occur sooner than 30 days, Recipient agrees to notify Provider, who will expedite review consistent with the need to publish. However, notification shall not act to prevent the publication of information if there is an emergency need to publish

meaningful, real-time information for a public health response. Appropriate privacy protections will be considered prior to any such emergency need to publish.

Attribution

Recipient agrees to factually acknowledge Provider in any paper, publication or presentation using the covered data and shall follow the authorship policy attached hereto as **Annexure "C"**.

Where CDC/ATSDR is the Provider, the citation must read as follows:

"Centers for Disease Control and Prevention/Agency for Toxic Substances and Drug Registry, [Name of data file, year(s)], as compiled from data provided through [Program/Study Name] "

Representation

Recipient agrees to assume full responsibility for the analysis, interpretation of the data, and provide a copy of the report, publication, or presentation to Provider.

Use

Where CDC/ATSDR is the Provider, per mutual agreement between Provider and Recipient, Provider grants full permission and a royalty-free, non-exclusive, irrevocable license to HHS, CDC/ATSDR to use, reproduce, publish, distribute, and exhibit materials arising from this Agreement for use in education, training, and other purposes consistent with CDC/ATSDR's mission.

ADDITIONAL TERMS AND CONDITIONS

- Entire Agreement: This Agreement, including any appendices related to data, specifications, or operations incorporating this Agreement by reference, and as amended from time to time, constitutes the entire agreement and understanding between the Parties and supersedes all prior oral or written agreements and understandings between them with respect to the Covered Data.

- Assignment: No Party may assign or transfer any or all of its rights and/or obligations under this Agreement or any part of it, nor any benefit or interest in or under it, to any third party without the prior written consent of all Parties, which shall not be unreasonably withheld.

- Mutual Representations: Each party to this Agreement represents to the other Party that, at all times during the term and at such other times as may be indicated, it shall comply with, and as applicable, shall require its directors, officers and employees to comply with its duties and obligations pursuant to applicable law and this Agreement, including but not limited to duties and obligations which survive the termination of this Agreement

- Use of Electronic Signatures and Electronic Records: The Parties may elect to establish processes for the use of Electronic Records in the management of and compliance with this Agreement. This may include for the addition of published policies, procedural information, notices, and any other documents arising from or pertaining to this Agreement, including this Agreement itself. Any such process must

include the establishment of a mutually acceptable Electronic Signature process, which complies with federal and state laws.

- Disagreements: Disagreements between the Parties arising under or relating to this Agreement will be resolved by consultation between the Parties and referral of the dispute to appropriate management officials of the Parties whenever possible.

- Public Document: This Agreement may be made publicly available.

- Funding: This Agreement is not an obligation or a commitment of funds, or a basis for the transfer of funds, and does not create an obligation or commitment to transfer data, but rather is a statement of understanding between the Parties concerning the sharing and use of Covered Data. Expenditures by each Party are subject to its budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies."

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

  University of Peleforo Gon Coulibaly, Côte d'Ivoire
  CeSSHAR, Zimbabwe
  IBM Research Africa
  Wits Reproductive Health & HIV Institute, a Division of Wits Health Consortium ("WHC")

  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.

DISCLAIMERS

Disclaimers for Entity Providing the Data

It should be noted that as a Federal agency, CDC/ATSDR cannot agree to indemnification provisions. However, representations or disclaimers on the accuracy of the data may be appropriate.

- Intellectual property rights on material arising from the use of the data will be determined by applicable federal law.
- Interpretations, conclusions, and/or opinions that are reached as a result of analyses of the data are the Recipient's interpretations, conclusions, and/or opinions, and do not constitute the findings, policies, or recommendations of the Provider.

The data provided and covered under this Agreement are provided on an 'as is' basis. Except as expressly set forth herein, the data provider makes no representations, of any kind, either express or implied, with respect to the data set and expressly disclaims any and all representations of any kind with respect thereto, including any representations of data quality or fitness for a particular purpose. Metadata documents have been reviewed for accuracy and completeness. Unless otherwise stated, all data and related materials are considered to satisfy the quality standards

relative to the purpose for which the data were collected. However, neither the author nor any part of the federal government can assure the reliability or suitability of the data for a particular purpose. The act of distribution shall not constitute any such warranty, and no responsibility is assumed for a user's application of t data or related materials.

SIGNATORIES

The undersigned individuals represent that they have competent authority on behalf of their respective agencies to enter into the obligations set out in this Agreement. Signature indicates that an understanding of the terms of this Agreement and an agreement to comply with its terms, to the extent allowed by law.

PROVIDER	**RECIPIENT**
Signature: Athena P. Kourtis, MD Printed Name: Athena Kourtis Title: Chief, HIV Research Branch, Div. of HIV Prevention, NCHHSTP Organization: U.S. Centers for Disease Control and Prevention Date: 3/24/23	Signature: JC Senekal Printed Name: Jessica Senekal Title: Legal Advisor Organization: University of Cape Town Date: 16 March 2023

APPENDIX A: DATA USE AGREEMENT DEFINITIONS

- Terms used, but not otherwise defined, in this agreement shall have the same meaning as those terms in applicable laws and regulations, unless specifically stated otherwise.
- “Agreement” means this data use agreement, as amended from time to time in accordance with the terms and conditions set forth below.
- “Authorized User”, for purposes of this Agreement, means an individual who, as part of directly supporting the Recipient activities, has a need for access to data provided under this Agreement and has been granted appropriate access, which may include executing necessary documentation for such access. Generally, authorized users will be employees, contractors, and/or other agents of the Recipient.
- “Effective date” is the date this agreement becomes valid, either on the date specified or the last date of signature.
- “Data Provider” or “Provider” refers to the party providing the data outlined in this Agreement.
- “Data Recipient” or “Recipient” refers to the party receiving the data outlined in this Agreement.
- “Data Administrator” is the data provider’s individual who is responsible for the data and granting appropriate access to agreement parties.
- “Data Custodian” is the individual from a recipient agreement party responsible for the maintenance and protection of the data for their party.
- “Covered Data” shall mean the data provided to the Recipient by the Provider and any associated records, reports, copies, or databases.
- “Limited data set (LDS)”, to the extent the term is used to define data elements being shared, is consistent with the term as defined in the Privacy Rule at 45 CFR Section 164.514(e).
- "Applicable law" means all laws, statutes and regulations promulgated by all regulatory authorities and all governmental authorities.
- “Project” refers to the specific research or analysis outlined in Appendix B.
- “Results” means all normalized data and results generated in the performance of the Project.
- “Required by law” means as applicable federal laws require.
- “Protected health information (PHI)” is information is considered to be individually identifiable information relating to the past, present, or future health status of an individual that is created, collected, or transmitted, or maintained by a HIPAA-covered entity in relation to the provision of healthcare, payment for healthcare services, or use in healthcare operations.
- “Personally identifiable information (PII)” is any information about an individual maintained by an agency, including (1) any information that can be used to distinguish or trace an individual‘s identity, such as name, social security number, date and place of birth, mother‘s maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.
- “Agreement party” / “parties” or “signatory” refers to the representative for both the data provider and data recipient with the authority to sign this agreement into place.
- “Completed work” refers to any draft or final product of analysis, research, or project findings gleaned from the covered data set.

LIST OF SUPPORTING DOCUMENTS

Appendix B – Project Description

Appendix C – Authorship Policy

APPENDIX B : PROJECT DESCRIPTION

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 HE^{2}AT 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) program[1]. DS-I Africa aims to make optimum use of existing data resources across Africa to address the most pressing health concerns on the continent.

1 https://commonfund.nih.gov/africadata

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

The specific objectives are:

1. To locate, acquire, collate and transform prospectively collected data from cohort studies and randomized trials on maternal and child health in sub-Saharan Africa
2. To develop a collaboration between the HE^{2}AT Center and investigators of each of the studies who contribute participant-level data
3. To link health outcome data spatially and temporally with weather and other environmental data, as well as with socio-economic and related factors
4. To utilize classic statistical methods and novel machine learning approaches to understand and quantify the impact of heat exposure on maternal and child health
5. To document variations in the relationship between heat exposure, and maternal and child health outcomes across different settings, climate zones and population groups in sub-Saharan Africa

Methods: We will systematically locate eligible studies through a mapping review of publication databases, the searching of data repositories, and through communicating with experts in the field. Eligibility is based on study- and individual-level criteria. To be eligible, the study needs to include longitudinal data, have enrolled at least 1000 pregnant women in sub-Saharan Africa in the period January 2000 to June 2022, and have collected data on key maternal and child outcomes. At an individual level, participants need to have been recruited during pregnancy or intrapartum, and have data available on date and location of childbirth (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.

APPENDIX C : Authorship Policy

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
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- 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.