

DATA TRANSFER AGREEMENT

Stellenbosch University
acting through its **Department of Obstetrics and Gynaecology**
with administrative address at
Division for Research Development, Krotoa Building, 2nd floor,
Victoria street, Stellenbosch, 7600

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

and

Wits Reproductive Health & HIV Institute,
a Division of Wits Health Consortium (Pty) Ltd
31 Princess of Wales Terrace, Parktown, Johannesburg
(hereinafter "**the Data Recipient**")

WHEREAS:

1. The Data Provider has collected / is in possession of certain Data (as defined below);
2. The Data Recipient has requested the use of the Data for research purposes;
3. The transfer of the Data will be done in accordance with the terms and conditions of this Data Sharing Agreement (hereinafter referred to as the "Agreement").

THEREFORE, THE PARTIES AGREE AS FOLLOWS:

1. DEFINITIONS

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

- 1.1 "**the/this Agreement**" shall mean this Agreement together with any Annexures hereto;
- 1.2 "**Commencement Date**" shall mean the date on which this Agreement commenced, namely **the seventh of September 2022;**
- 1.3 "**Data**" shall mean the Data to be transferred from the Data Provider to the Data Recipient as described and detailed in **Annexure "A";**
- 1.4 "**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).

- 1.5 **"Data Subject"** shall mean the person to whom the Personal Information relates;
- 1.6 **"Operator"** person who processes personal information for the Responsible Party in terms of a contract or mandate, without coming under the direct authority of that party;
- 1.7 **"Parties"** shall mean the parties to this Agreement, namely Stellenbosch University and Wits Health Consortium (Pty) Ltd; and the term **"Party"** shall refer to either of them;
- 1.8 **"Personal Information"** 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;
- 1.9 **"POPIA"** means Protection of Personal Information Act, 4 of 2013, its amendments and Regulations thereto;
- 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 **"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 Information;
- 1.12 **"Results"** shall mean the findings produced as a result of use of the Data;
- 1.13 Words importing the singular shall include the plural and *vice versa*, and words importing the masculine gender shall include females. The head notes to the clauses to this Agreement are inserted for reference purposes only and shall not affect the interpretation of any of the provisions to which they relate.

2. TRANSFER AND USE OF DATA

- 2.1 Subject to the terms and conditions of this Agreement, Data Provider grants the Data Recipient the non-exclusive right to use the Data.
- 2.2 Notwithstanding date of signature, this Agreement will commence on the Commencement Date and continue for an initial period of five (5) years, or as long as the Recipient has possession of the Data if longer.

- 2.3 Either Party may terminate this Agreement by thirty (30) days prior notice of termination in writing should the other Party be in breach, and such breach has not been rectified within 30 (thirty) days notwithstanding written notice.
- 2.4 Upon termination of this Agreement, Data Recipient's rights to use the Data will cease and Data Recipient will discontinue all use of the Data. Data Recipient will return or destroy Data, except Data Recipient shall not be required to destroy any Data which has been created pursuant to automatic archiving and back-up procedures and cannot be reasonably deleted. All other terms hereunder will continue unaffected.
- 2.5 Data Provider retains all rights to distribute the Data to other parties. Data Provider warrants its authority 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. To the best of Data Provider's knowledge the use of the Data will not infringe any intellectual property or other proprietary right. 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 for purposes of its research projects.
- 2.8 The Data Recipient is allowed to transfer the Data to third parties as may be required under its research projects subject to a Data Transfer Agreement being entered into between the Data Recipient and such third party.
- 2.9 If the Data Recipient wish to publish results of its research projects, Data Recipient will furnish Data Provider with a copy of any such manuscript or abstract at least thirty (30) days prior to submitting such publication to the scientific journal or to examiners, to give Data Provider the opportunity of requesting the removal of any proprietary confidential information pertaining to the Data. Data Recipient must comply with Provider's removal requirement to the reasonable satisfaction of Provider prior to submitting such publication. Data Recipient will acknowledge the Data Provider as contributor of the Data.
- 2.10 Legal title to the Data shall remain with the Data Provider if they are the owner, or alternatively with the Data owner, and nothing in this Agreement grants Data Recipient any rights to use the Data or any product(s) or process(es) derived from or with the Data for profit-making or commercial purposes. Except as provided in this Agreement, no express or implied licences or other rights are provided to the Data Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Data Provider, including any altered forms of the Data made by the Data Recipient.

3. COMPENSATION

- 3.1 The Parties agree that the Data Recipient will compensate the Data Provider an amount of R 250 000 (Two hundred and fifty thousand Rand) (including VAT) ("Contract Price") as payment for the costs involved in the transfer of the Data from the Data Provider to the Data Recipient.
- 3.2 Payment will be effected by the Data Recipient upon signature of this Agreement and within 30 (thirty) days after receipt of a valid invoice from the Data Provider into the following account of the Data Provider:
- | | |
|-----------------|--------------------------|
| Account Name: | US Debiteure |
| Account Type: | Business Current Account |
| Account Number: | 072247959 |
| Bank: | Standard Bank |
| Branch: | Stellenbosch |
| Branch Code: | 050610 |
| Reference: | Contract number S008248 |

4. **COMPLIANCE**

Each Party will comply with all applicable Data Protection Legislation governing the Processing of Personal Information in relation to the performance of its obligations under this Agreement. The Data Recipient hereby acknowledges its obligation to comply with the substantive provisions of Data Protection Legislation, and that violation of the provisions pertaining to applicable Data Protection Legislation may subject it to the applicable legal penalties.

5. **RIGHTS OF 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 Information. If 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. Should the Data Provider receive 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 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 Data Protection Legislation.

6. **SUBJECT WITHDRAWAL**

Data Provider acknowledges that Data Subjects may withdraw their informed consent to the Processing of Personal Information 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 Information.

7. CROSS-BORDER DATA TRANSFERS

If it is necessary for the Data Recipient to transfer Personal Information across national borders to the other Party, Data Recipient agrees to ensure the lawful export of Personal Information.

8. SAFEGUARDS

8.1 Data Recipient will maintain a comprehensive privacy and security program designed to ensure that the 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 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 the Data or any other unauthorized or unlawful use, access, alteration, loss, or disclosure of the Data (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.

8.4 Notwithstanding the above, the Data Provider will transfer the Data as deidentified without any keys or other information to assist the Data Recipient in linking the Data to identifiable Data Subjects.

9. SECURITY BREACH

9.1 Data Recipient shall notify Data Provider within twenty-four (24) hours of discovery of a potential or actual Security Breach. Upon 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 Data Protection Legislation.

9.2 In addition to any method of notice described in this Agreement, notice to Data Provider of any Security Breach shall also be reported to Cornelia Malherbe (Director: Research Contracts); Telephone: +27 21 808 3546 or Email: [cvdm2@sun.ac.za](mailto:cvd2m2@sun.ac.za) and to Alfred Farrell (Chief Executive Officer) Telephone: +27 11 274 9200 or Email: ceo@witshealth.co.za.

10. PERSONNEL OBLIGATIONS

The Parties shall ensure that their respective personnel engaged in the Processing of Data are informed of the confidential nature of the 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 Data is limited to those personnel who perform services in accordance with the Agreement.

11. RECORDS / DATA PROCESSING REGISTER

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

12. GOVERNMENT INSPECTIONS

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

13. 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:

Wits Health Consortium (Pty) Ltd

31 Princess of Wales Terrace

Parktown

Johannesburg

2193

For Attention: Alfred Farrell (CEO) / Violet Parker (Contracts Manager)

Email: ceo@witshealth.co.za

With a copy to: Professor Matthew Chersich

Hillbrow Health Precinct

22 Esselen Street

Hillbrow

Johannesburg

2001

For Attention: Matthew Chersich

Email: mchersich@wrhi.ac.za

If to Data Provider:

*Stellenbosch University
Division for Research Development
Krotoa building, 2nd floor
Cnr of Victoria and Ryneveld street
Stellenbosch
7600*

*For Attention: Cornelia Malherbe (Director: Research Contracts) / Alwerf Brand
(Legal Advisor)*

Email: contracts@sun.ac.za

*With a copy to: Professor Hein Odendaal
Department of Obstetrics and Gynaecology
Faculty of Medicine and Health Science
Stellenbosch University
PO Box 241
8000 Cape Town*

For Attention: Prof Hein Odendaal

Email: hjo@sun.ac.za

14. GENERAL

- 14.1 In no event shall Data Provider be liable for any use by the Data Recipient of Data or Results or for any loss, claim, damage, or liability, of any kind or nature, that may arise from or in connection with this Agreement or Data Recipient's use, handling, or storage of Data. Data Recipient agrees to indemnify and hold harmless Data Provider, its trustees, officers, employees, students, volunteers and agents from all liability, loss, or damage they may suffer as a result of claims, demands, costs or judgments against Data Provider arising out of the use, handling or storage of Data by Data Recipient.
- 14.2 If a dispute arises between the Parties relating to this Agreement, the Parties will meet and attempt to resolve the dispute in good faith. In the event the dispute is not resolved through negotiation within ten (10) days after said meeting, the Parties will submit to confidential, non-binding mediation before a mutually acceptable mediator. Each Party will designate at least one person with full authority to resolve the dispute that will attend and participate in the mediation. If the dispute remains unresolved after mediation, then each Party will be free to pursue any available remedy in law.
- 14.3 Neither Party shall assign or transfer any interest in this Agreement without prior written approval of the other Party.

- 14.4 No amendment, consent or waiver of terms of this Agreement shall bind either party unless in writing and signed by both Parties. Any such amendment, consent, or waiver shall be effective only in the specific instance and for the specific purpose given.
- 14.5 This Agreement embodies the entire agreement between the parties hereto and no provision of this Agreement may be changed except by the mutual written consent of the Parties hereto.
- 14.6 This Agreement shall be governed by South African Law and the South African Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Agreement.

DATA PROVIDER



Name: ~~Prof Hain Odendaal~~ *NC Gey van Pittius*

Date: ~~8 October 2022~~ Jan 16, 2023

Capacity: ~~Emeritus Professor, parttime researcher~~ *Vice-Dean Research.*

DATA RECIPIENT

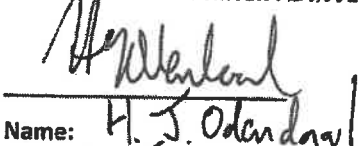


Name: Jean du Randt

Date: 22 December 2022

Capacity: Chief Financial Officer

DATA PROVIDER PRINCIPAL INVESTIGATOR

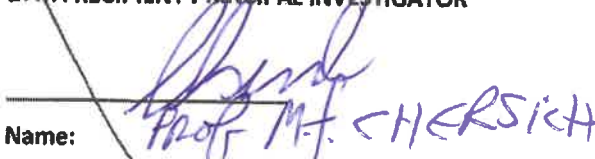


Name: *H. J. Odendaal*

Date: *6 January 2023*

Capacity: *Emeritus Professor, parttime researcher.*

DATA RECIPIENT PRINCIPAL INVESTIGATOR



Name:

Date: *26 JAN 2023*

DESCRIPTION OF DATA

Project Title: The Safe Passage Study

Data to be transferred:

The following variables from the Safe Passage Cohort on all participants. Event data must have full date of event (day, month, year) and a geographical indicator in order to allow linkage to exposure data. Additional variables may be requested.

Characteristics of women and potential confounding or interacting factors

- Project ID [for linking variables in different databases]
- Location of address/suburb [smallest area data available] [for linkage to meteorological data]
- Age of mother at birth
- Body mass index and other maternal anthropometry
- Demographics and socio-economic detail
 - Ethnicity/race
 - Household income [receipt of government assistance]
 - Parity, gravidity
 - Marital status
 - Educational level
 - Alcohol consumption [self-reported. composite score – or consumption categories]
 - Smoking [self-reported. composite score – or consumption categories]
 - Housing quality [if available, preferably household fuel type]

Outcomes

- Dates of all outcomes listed below
- Gestation at birth (preterm birth < 37 weeks of gestation)
- Antepartum or postpartum haemorrhage
- Maternal infection
- Clinical events and emergency admissions in mother [cause of event/admission]
 - Prolonged labour
 - Miscarriages
 - Cardiovascular events
 - Mental health
 - Near-miss complications
 - Admission in intensive care
 - Other obstetric complications
 - Emergency referral of women (cause of referral)
- Clinical outcomes in fetus, newborn, neonate, infancy and childhood
 - Clinical events and emergency admissions
 - Infant measures at birth [birth weight, APGAR score, anthropometry, growth measures, other infant quality measures]
 - Newborn health indicators at 1 month visit -include autonomic, cardiorespiratory, cortical activity assessments.

- Anthropometry of fetus in utero, in newborns and in children
- Infant care practices, including exclusive breastfeeding
- Maternal and child mortality, spontaneous abortion, stillbirth [cause of death]

Purpose of Data Transfer:

Objectives

- Quantify impacts of heat on maternal, perinatal and neonatal health outcomes, including long term impacts beyond the neonatal period
- Characterise groups of pregnant women and neonates at high risk of heat-related conditions and explore the role of modifiers on risks to heat
- Explore variations in impact by factors such as temperature thresholds, cumulative heat exposure and extended heat waves
- To acquire, collate and integrate prospectively collected data from cohort studies and randomized trials on maternal and neonatal health in sub-Saharan Africa
- To develop a collaboration between study groups and the IPD investigators
- To utilize classic statistical and novel machine learning approaches to understand and quantify the impact of heat exposure on pregnant women and children

Project research questions include:

- What are the impacts of extreme hot weather on maternal, perinatal and neonatal health outcomes?
- Is there a threshold above which action can be taken to protect health?
- Do certain maternal characteristics and comorbidities (hypertension, diabetes mellitus (DM), anemia, etc.) increase the risk of adverse maternal outcomes during exposure to extreme heat? (BMI, age, ethnicity, comorbidities, etc.)






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Final Audit Report

2023-01-16

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-  Agreement completed.
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