**DATA TRANSFER AGREEMENT**

***Insert Name***

*Insert Address*

(hereinafter “**the Data Provider / Recipient**”)

and

***Insert Division*,**

**a Division of Wits Health Consortium (Pty) Ltd**

31 Princess of Wales Terrace, Parktown, Johannesburg

(hereinafter “**the Data Provider / Recipient”**)

**WHEREAS:**

1. The Data Recipient and the Data Provider entered into a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“the Main Agreement”) for the project entitled “*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”* respectively signed by the parties on the \_\_ and \_\_ of \_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_ (“the Project”) funded by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“the Funder”);
2. In terms of the Main Agreement, the Data will be transferred by the Data Provider to the Data Recipient;
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 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**;

1.3 **“Controller”** shall mean the entity that alone or jointly with others determines the purposes and means of the Processing of Personal Data;

1.4 “**Data”** shall mean the Data to be transferred from the Data Provider to the Data Recipient as described and detailed in **Annexure A**;

1.5 **“Parties"** shall mean the parties to this Agreement, namely \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and Wits Health Consortium (Pty) Ltd; and the term “Party” shall refer to either of them;

1.6 **“Personal Data”** means information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person. Key‑coded data are considered Personal Data even if the holder of that data does not have access to the key that links the data to the identity of an individual;

1.7 “**POPIA**” means Protection of Personal Information Act, 4 of 2013, its amendments and Regulations thereto;

1.8 **“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.

1.9 “**Processor**” means the person who is responsible for processing personal data on behalf of the Data Controller;

1.10 **"the Project"** shall mean the project entitled *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* as per the Protocol / Project Description attached hereto as **Annexure B**;

1.11 **“Results”** shall mean data and results produces in the execution of the Project and more specifically the Protocol / Project Description attached hereto as **Annexure B;**

1.12 Words importing the singular shall include the plural and *vice versa*, and words importing the masculine gender shall include females. The head notes to the clauses to this Agreement are inserted for reference purposes only and shall not affect the interpretation of any of the provisions to which they relate.

**2. TRANSFER AND USE OF DATA**

2.1 Subject to the terms and conditions of this Agreement, Data Provider grants the Data Recipient the nonexclusive right to use the Data (including Results) solely for purposes of the Project for the duration of this Agreement. This Agreement will terminate on the termination of the Main Agreement and/or completion of the Project.

2.2 Notwithstanding the abovementioned, either Party may cancel this Agreement with \_\_\_\_ (\_\_) 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 (and Results).

## 2.3 Unless the Main Agreement determines otherwise, 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.

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

## 2.5 The Data Provider will transfer the Data (including Results) as is without any warranties, express or implied, including without limitation, any warranty of fitness for a particular purpose. This Agreement does not grant any rights, license or other proprietary interest to the Data Recipient in the Data save as provided for in this Agreement.

2.6 Data Recipient will use the Data only for purposes of the Project. If the Data Recipient seeks to use Data for other purposes, the Data Recipient will obtain written consent from Data Provider, either by an amendment to this Agreement or a new agreement, before such use. The Data Recipient will report to the Data Provider on the result of the Project as determined in the Main Agreement.

2.7 The Data Recipient is not authorised to transfer the Data to any third-party without the prior written consent of the Data Provider.

2.8 The Results will be owned by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in accordance with the terms of the Main Agreement.

## **3.** **CONTROLLER STATUS**

## 3.1 To the extent that any Results or samples contain Personal Data when collected for purposes of this Agreement, Data Provider is the Controller of Personal Data and Data Recipient is the Processor.

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

## **COMPLIANCE**

Each party will comply with all applicable Regulations governing the Processing of Personal data in relation to the performance of its obligations under this Agreement. The Data Recipient hereby acknowledges its obligation to comply with the substantive provisions of the POPIA and that violation of the provisions pertaining to POPIA may subject it to the applicable legal penalties, including those provided under POPIA.

## **RIGHTS OF SUBJECTS**

## The parties agree that, as between them, Data Provider is best able to manage requests from subjects for access, amendment, transfer, restriction, or deletion of Personal Data. In the ordinary course, Data Recipient does not process sufficient information to link Results to an identified individual who makes a request for access, amendment, transfer, or deletion of Personal Data. In the event that the Data Recipient receives a request from a subject for such access, amendment, transfer, restriction, or deletion, the Data Recipient shall forward the request to Data Provider. In the event that the Data Provider receives a request from a subject that affects the data disclosed to the Data Recipient or the Data Recipient’s ability to use or process such data, Data Provider shall promptly, and no later than five (5) business days notify Data Recipient. Data Provider acknowledges that in order to maintain the integrity of results from the Study, the ability to amend, restrict, or delete data disclosed to Data Recipient may be limited, in accordance with applicable Regulations.

## **SUBJECT WITHDRAWAL**

## Data Provider acknowledges that subjects may withdraw their informed consent to the Processing of Personal Data at any time. Data Provider shall promptly notify Data Recipient of any such withdrawal upon which the Data Recipient will immediately discontinue use of the subject’s Personal Data.

## **CROSS-BORDER DATA TRANSFERS**

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

## **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 (including Results) 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.

## 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:  [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_](mailto:Betiel.Haile@roche.com) and to Alfred Farrell (Chief Executive Officer of the Data Provider) Telephone: +27 11 274 9200 or Email: [ceo@witshealth.co.za](mailto:ceo@witshealth.co.za).

## **10**. **PERSONNEL OBLIGATIONS**

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

## **11**. **RECORDS / DATA PROCESSING REGISTER**

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

## **12**. **GOVERNMENT INSPECTIONS**

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

## **13**. **DATA PROTECTION IMPACT ASSESSMENT**

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

**15.** **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**:

## *Insert address*

## With a copy to:

## *Insert address*

## **If to Data Provider:**

## *Insert address*

## If to Investigator:

## *Insert details if applicable*

**16.** **GENERAL**

16.1 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.

16.2 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.

16.3 Notwithstanding anything states in this Agreement, in the event of any discrepancy between the terms and conditions of this Agreement and the Main Agreement, especially, the terms and conditions of the Main Agreement will apply.

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

**DATA PROVIDER: DATA RECIPIENT:**

By: By:

(signature) (signature)

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

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

Date: Date: \_\_\_\_\_\_

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Principal Investigator

|  |
| --- |
|  |

Date:

**ANNEXURE A**

**DESCRIPTION OF DATA**

**Project Title:**

**Funder:**

**Data to be transferred:**

**Purpose of Data Transfer:**