**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a division of WITS HEALTH CONSORTIUM (PTY) LTD**

**MATERIAL TRANSFER AGREEMENT FOR MATERIALS**

(hereinafter, “the Agreement”)

**Signature Date -----------------------**

**Protocol Number:** (Insert Details)

**Protocol Title:** ­­­­­­­­­­­­­­­­­(Insert Details)

**Entered into by and between**:

(Hereinafter, “the Provider”)

|  |  |
| --- | --- |
| **Registered Physical address of Provider:**  **Wits Health Consortium (Pty) Ltd**, a wholly owned company of the University of the Witwatersrand, Johannesburg  8 Blackwood Avenue, Parktown  Johannesburg, 2193  **Registered physical and postal address of Principal Investigator:**  **(Insert Details)** | **E:mail: afarrell@witshealth.co.za**  Tel:  Fax:  Cell:  Email: |

**and**

(Hereinafter, “the Recipient”)

|  |  |
| --- | --- |
| **Registered physical and postal address of Recipient:**  **Covance**  **(Insert Details)** | Tel:  Fax:  Cell:  Email: |

**and**

(Hereinafter, the Human Research Ethics Committee)

|  |  |
| --- | --- |
| **Registered physical and postal address of Human Research Ethics Committee:**  University of the Witwatersrand Human Research Ethics Committee (Medical)  Research Office, Senate House  University of the Witwatersrand, 1 Jan Smuts Avenue, Braamfontein, Johannesburg, 2000 | Tel: 011 717 2301  Fax: 011 274 9281  Email: [peter.cleaton-jones@wits.ac.za](mailto:peter.cleaton-jones@wits.ac.za) |

**PREAMBLE**

**WHEREAS**

* 1. the Provider remains the Custodian (as defined below) of the Materials (as defined below); and
  2. the Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials subject to the terms and conditions below; and
  3. each Party undertakes to engage with the other in the utmost good faith and to conduct itself in the highest ethical standards and comply with all applicable legislation, including but not limited to the legislative ban on the sale of or trade in tissues, gametes, blood or blood products; and
  4. the Parties agree to conduct themselves hereunder in compliance with the Human Research Ethics Committee (Medical), University of the Witwatersrand, Johannesburg (“HREC”) protocols on research on human biological materials; and
  5. understanding, therefore, that no Materials can be transferred for purposes of a research project that has not been approved by the HREC.

**NOW THEREFORE, THE PARTIES AGREE AS FOLLOWS**

1. **OBJECTIVE**

The objective of this Agreement is to set out a framework within which the Parties will engage in the transfer, use and other processing of the Materials, and to provide for matters connected therewith.

1. **DEFINITIONS**

|  |  |
| --- | --- |
| * 1. Agreement | * means this Agreement and all annexures thereto |
| * 1. Confidential Information | * means any scientific, commercial or business data relating to the Materials that a Party asserts is confidential and proprietary, or any other information that a Party regards or would reasonably be expected to regard as proprietary and confidential given the nature of the information and the reasonable efforts in the circumstances used to maintain its confidentiality. Confidential Information shall also include the properties, characteristics, content, composition, potential secondary uses and methods of use of the Materials |
| 2.4 Country | * means the Republic of South Africa |
| * 1. Custodian | * means a person or entity entrusted by the Donor with safeguarding and protecting the Materials |

|  |  |
| --- | --- |
| * 1. Data | * means any information, including personal information in any form, derived directly from Human Biological Materials, which will be used for the Project |

|  |  |
| --- | --- |
| * 1. Donor | * means a person who has donated Materials to be used for the Project |
|  |  |
| * 1. Human Biological Materials | * means materials from a human being including but not limited to blood products, Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof |
| * 1. Human Research Ethics Committee (Medical) University of the Witwatersrand, Johannesburg (“HREC”) | * means the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg which is registered with the South African National Health Research Ethics- - Council, whose purpose is to review and, where the proposals meet the ethical standards of the committee, approve all health research protocols |
| * 1. Intellectual Property Rights | * means any creation of the mind and includes inventions, literary and artistic works, symbols, names, images and designs used in commerce, including patent right, copyright, database right, moral right, trademark, service mark, trade secrets, domain name, know-how, utility model, plant breeders’ rights or where relevant, any application for any such right, or other industrial or intellectual property right emanating from the use of the Materials |
| * 1. Informed Consent   2. Materials | * means the process which allows a Donor to consent to participate and determine whether and how their Materials will be utilised in the Project, as approved by the HREC from time to time * means Human Biological Materials and Data provided by the Provider to the Recipient in respect of the Project |
| * 1. Parties | * means the Provider and the Recipient in this Agreement |
| * 1. Project | * means the health research project for which the Materials will be used hereunder as approved by HREC. |
|  |  |
| * 1. Regulatory Requirements   2. Secondary Use | * means all applicable national laws, regulations, code of practices relating to the Use of Human Biological Materials for commercial research providing protection for human subjects in the Country of Origin; * means use of the Materials for health research purposes other than the uses determined in the approved protocol. Secondary uses must be approved by the HREC |
| * 1. Sponsor | * means (Insert Details) |
| * 1. Use | * means collection, storage (including retention period) transfer (including import and export), use and return or disposal of Human Biological Materials including by commercial organizations |

1. **OBLIGATIONS OF THE PROVIDER**
   1. The Provider agrees to transfer to the Recipient the Materials more fully described in **Annexure A**, and in the correct quantity, packaging and by correct mode of transport as more fully described in **Annexure A**.
   2. Should the Provider be informed that the Materials have become identifiable for any reason whatsoever, the Provider is responsible for informing the HREC and the relevant Donor(s) of same and for obtaining approval from the HREC and consent from the Donor(s), where reasonably possible, for any further uses of the Materials.
   3. This Agreement shall have no force or effect unless and until, the HREC has approved the Project *and* this Agreement.
   4. The Provider of the Materials represents and warrants that:
      1. all Materials supplied under this Agreement are or have been procured and supplied to Recipient ethically and in full compliance with any and all Regulatory Requirements;
      2. the Donor has read, understood and signed an HREC approved Informed Consent Form (“ICF”) covering all the services to be provided by Recipient;
      3. it has all the necessary consents, licences and approvals to use the Materials;
      4. all Materials will be supplied to Recipient without any information or data that could result in the Donor being personally identifiable by the Recipient;
      5. all Materials supplied to Recipient may be used to provide data in support of commercial product development;
      6. and there is no financial benefit to the Donor from the commercialization or use of the Materials.
2. **ACKNOWLEDGEMENTS BY AND OBLIGATIONS OF THE RECIPIENT**
   1. The Recipient acknowledges that the Materials have been obtained and/or developed by the Provider, where applicable.
   2. The Recipient acknowledges that the Materials are of health research value.
   3. The Recipient may only carry out research according to the protocol approved by the HREC.
   4. The Recipient acknowledges that the Materials may contain sensitive and confidential information, which information the Recipient undertakes to protect and keep confidential.
   5. Other than those parties stipulated in **Annexure A**, the Recipient may not transfer or otherwise provide the Materials to any Party without the prior written approval of the HREC, Sponsor and the Provider.
   6. Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider without delay.
3. **USE AND PURPOSE OF THE MATERIALS**
   1. The Recipient warrants that the Materials will be used only for the purposes of the Project, as more fully described in **Annexure A**, attached hereto.
   2. The Recipient agrees that the Materials will be located at: ***Covance [PLEASE INSERT DETAILS]****.*
   3. The Recipient shall not, without the written permission of the Provider, use the Materials for any purpose other than that permitted in terms of this Agreement.
4. **DURATION OF AGREEMENT**

Subject to clause 3.3, this Agreement will commence on the date of last signature hereof (the “Effective Date”) and shall continue until the termination of the Project or the termination date (stated below in clause 7).

1. **TERMINATION OF PROJECT**
   1. Termination of the Project will occur under one or more of the following circumstances:

7.1.1 the Project reaches completion;

7.1.2 the Project cannot be carried out by the Recipient for any reason whatsoever, including but not limited to the following

7.1.3 the Donors withdraw consent for use as contemplated hereunder and in such numbers as to render continuation of the Project impracticable or impossible;

7.1.4 the Recipient entity dissolves, winds-up or ceases to continue operating for any reason whatsoever;

7.1.5 the HREC withdraws approval for the Project in its entirety;

7.1.6 either Party terminates the Agreement on reasonable notice; and

7.1.7 a force majeure event makes continuance of the Project impracticable or impossible.

* 1. On termination, the Recipient will immediately discontinue using the Materials for any purpose whatsoever.
  2. Destruction, return to the Provider or transfer of Materials will be undertaken, or any other arrangements made, with the express approval of the HREC.

1. **INFORMED CONSENT**
   1. The Provider has obtained Informed Consent from the Donor(s) to provide Materials to the Recipient to undertake the Project as contemplated. In the event of Secondary Use of the Materials, the Donor(s) have consented thereto insofar as the Secondary Uses have been approved by the HREC.
   2. Provider shall upon request by Recipient, provide a copy of the relevant de-identified ICF template to Recipient under separate cover.
   3. In the event of a withdrawal of, or a material variation to the Donor’s Informed Consent, service requirements, working document or other approval, the Provider shall immediately notify the Recipient entities of such changes.
   4. Where relevant, the Provider shall provide an updated approved ICF template following any amendment to the Project.
   5. The Provider shall ensure the Materials are de-identified, encrypted or ‘coded’, to protect the identity and confidentiality of the Donor. Full date of birth will only be collected if medically relevant to the Project.
   6. The Donor(s) have been informed that, where reasonably possible, the Provider will inform them of developments or progress made by the Recipient in the Project and which is relevant to the Donor(s)’ Informed Consent.
   7. The Donor(s) have been informed and have accepted that on termination of this Agreement, the Materials will be returned to the Provider or destroyed, or any other arrangements made, as determined by the Provider and HREC.
   8. The Donor(s) are aware that all Materials and associated data are de-identified.
   9. Should the Recipient wish to conduct studies or use the Material for any other purpose than that approved by the HREC, the Provider must be notified in writing and HREC approval must first be obtained.
2. **DISPUTE SETTLEMENT**
   1. All disputes between the Parties will be determined in accordance with the provisions of this clause 9.
   2. The Parties shall use reasonable endeavours to solve any disputes that will arise in connection with this Agreement by mutual agreement. Any disputes between the Parties arising under, or relating to, this Agreement shall be first presented to the senior management of the respective Parties for resolution, who will attempt to resolve the matter amicably and promptly. If the Parties are unable to resolve the dispute within a period of thirty (30) days after it has been referred to them, the Parties agree to resolve such dispute in accordance with clause 9.3.
   3. South African law shall apply to this Agreement and all disputes arising out of, or in connection with, this Agreement, shall be finally settled under the rules of arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said rules.
3. **INTELLECTUAL PROPERTY**

All data and results whether patentable or not – including but not limited to Intellectual Property Rights - which arise in connection with this Agreement (hereinafter called “Results”) will become the sole property of the Sponsor of the clinical trial (insert protocol number). The Sponsor shall be free to use the Results in any form whatsoever.

1. **CONFIDENTIALITY**

11.1 Each Party agrees to keep the Materials secure and confidential at all times. All information relating to the nature and processes of the Project in whatever, form, must also be treated as confidential. The identity of the Donor(s) must be protected and kept confidential at all times by both Parties.

11.2 Each Party agrees not to disclose any information pertaining to the Materials and Results to any third party except the Sponsor. The Recipient will also ensure that the Recipient’s scientists who are assigned to the Project and all other persons allowed to access the Materials comply with this clause.

1. **PUBLICITY**

12.1 Neither Party shall use the name of the other Party or its employees in any advertisement, press release or other publicity without prior written approval of the other Party.

12.2 Where relevant, publications will be subject to the underlying clinical trial agreement and applicable laws.

1. **LIABILITY**
   1. The Provider gives no warranty that the Materials are fit for the use and purpose for which they are transferred hereunder, or that they have any particular qualities or characteristics. Notwithstanding the foregoing, the Provider warrants that the Materials have been properly packed, labelled and stored by the Provider in terms of the relevant industry standards.
   2. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other Party, due to or arising from the Use of the Materials by the Recipient, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the Provider.
2. **GENERAL**
   1. This Agreement embodies the entire agreement between the Parties and no provision hereof may be altered or amended without the written mutual consent of both parties.
   2. Neither Party may assign or cede any benefit, obligation or interest it may have in this Agreement to any other person without the prior written consent of the other Party and the approval of the HREC.
   3. Neither Party is regarded as having waived, or is precluded in any way from exercising any right under or arising out of this Agreement by reason of such Party having at any time extended any extension of time for, or having shown any indulgency to, the other Party with reference to any performance of any obligation under this Agreement, or having failed to enforce, or delayed in enforcing any right of action against the other Party.
   4. This Agreement constitutes the sole record of the Agreement between the Parties in regard to the subject matter hereof and replaces any prior Agreement, which may exist between the Parties. No Party will be bound by any representation, express or implied term, warranty, promise or the like not recorded in this Agreement.
   5. Any amendments to this contract are of no force and effect unless reduced to writing and signed by both Parties
   6. No extension of time or indulgence by any Party will be deemed in any way to affect, prejudice or derogate from the rights of the Party in any respect under this Agreement nor will it in any way be regarded as a waiver of any rights hereunder or a novation of this Agreement.
   7. In the event of any one or more of the provisions of this Agreement being held for any reason to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision was not a part of this Agreement, and the Agreement shall be carried out as nearly as possible in accordance with its original terms and intent.
   8. The Recipient receives only the rights as set out in this Agreement and these rights are not exclusive to the Recipient.

**Duly authorised and on behalf of the Provider:**

Full name: Alfred Farrell

Designation: Chief Executive Officer, Wits Health Consortium (Pty) Ltd

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed at ­­­­­­­­­­­­­Johannesburg on this the ­­­­­­­­\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2017

WITNESSES:

|  |  |  |  |
| --- | --- | --- | --- |
| Witness 1: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Witness 2: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Duly authorised and on behalf of the Principal Investigator:**

Full name: Prof Johnny Mahlangu

Designation: Principal Investigator

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed at ­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_ on this the ­­­­­­­­\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2017

WITNESSES:

|  |  |  |  |
| --- | --- | --- | --- |
| Witness 1: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Witness 2: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Duly authorised and on behalf of the Recipient:**

Full name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed at ­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_ on this the ­­­­­­­­\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2017

**Duly authorised and on behalf of the Human Research Ethics Committee:**

Full name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed at ­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_ on this the ­­­­­­­­\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2017

WITNESSES:

|  |  |  |  |
| --- | --- | --- | --- |
| Witness 1: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Witness 2: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Annexure A**

**To be completed by the Provider and/or Recipient**

**The Responsible Party who will obtain the necessary permits and authorisations and arrange appropriate transport for the Materials to be transferred is:**

**(Insert Details)**

**Description of health research project under which the Materials will be used on transfer:**

(Insert Details)

**Specific experimental tests that the Materials will be subjected to on transfer:**

(Insert Details)

**Parties other than the Recipient to whom the Materials might be transferred as required by the Project:**

**Not Applicable**

**Quantity of Materials required to be transferred:**

(Insert Details)

**Preferred method of transfer of Materials:**

(Insert Details)

**Period within which Materials will be transferred:**

(Insert Details)

**How will confidentiality be maintained should Materials be released into the public domain?**

(Insert Details)