Registration No. 2000/026390/08

MATERIALS TRANSFER AGREEMENT FOR HUMAN BIOLOGICAL MATERIAL
(hereinafter referred to as "this Agreement")

Entered into and between

THE SOUTH AFRICAN NATIONAL BLOOD SERVICE
(hereinafter referred to as "the Provider ")

And

[The Recipient Institution]
(hereinafter referred to as "the Recipient ")

THE PARTIES AGREE AS FOLLOWS

1. OBJECTIVE

1.1. The objective of this Agreement is to set out a framework within which the Parties will engage in the transfer, use, other Processing and destruction of the Materials (as defined in clause 3).

1.2. The purpose of this Agreement is to facilitate the lawful transfer of Materials between the Parties and to comply with the provisions of the National Health Act 61, 2003 and Applicable Legislation.

2. PARTIES

2.1. The Parties to this Agreement are:

2.1.1. [Insert the full legal name, registered address, and name of] a natural person who is duly authorised to represent the Provider and sign this Agreement.

2.1.2. [Insert the full legal name, registered address, and name of] a natural person who is duly authorised to represent the Recipient and sign this Agreement.

3. DEFINITIONS

3.1. "**Agreement**" - means this Agreement and all annexures and amendments thereto;

3.2. **"Applicable Legislation"**- means any legislation applicable to Materials, including, but not limited to the National Health Act 61 of 2003, Protection of Personal Information Act 4 of 2013 (POPIA), and other relevant legislation and regulations (see Annexure C);

3.3. "**Benefit/s**" - means, amongst others, the sharing of information; use of Research Results; royalties; acknowledgement of the Provider as the source of the Materials; publication rights; transfer of technology or Materials; and capacity building;

3.4. "**Benefit Sharing**" - means the process or act of sharing in the Benefits that derive from the Project in a manner that is fair and equitable, as set out in clause 8 and Annexure B below;

3.5. "**Biorepository / Biobank**" – means an institution or unit thereof that Safeguards an organised collection of Human Biological Material and associated Data from different individuals, groups, communities or institutions which are usually kept for an unlimited period of time, for the purposes of Health Research;

3.6. "**Custodian**" - means a Person or entity entrusted by the Donor with safeguarding and protecting the Materials;

3.7. "**Data**" - means any information, including Personal Information in any form derived directly or indirectly during the conduct of research or clinical care, irrespective of the format in which such Data is presented;

3.8. "**Data / Material Breach**" – means a situation where there are reasonable grounds to believe that a breach of security in respect of the Data / Materials has occurred, negligently, intentionally or otherwise which leads to the access, destruction, loss, alteration, unauthorized

disclosure of, or access acquisition by any unauthorised Person to, Personal Information or Materials;

3.9. **"Data Subject"** - means the Person to whom the Personal Information relates;

3.10. "**Donor**" - means a Person who has donated Materials to be used for Health Research purposes and/or teaching;

3.11. **"Health Research"** - means any research which contributes to knowledge, including but not limited to the biological, clinical, psychological or social processes in human beings;

3.12. "**Human Biological Material**" - means Material/s from a human being including, blood, blood products, human pathogenic micro-organisms, Deoxyribonucleic Acid (DNA), mtDNA, Ribonucleic Acid (RNA), cultured cells, progenitor stem cells, tissues and growth factors, and any modifications or derivatives thereof;

3.13. "**Health Research Ethics Committee**" or "**HREC**" - means a Health Research Ethics Committee of the Provider which is registered with the South African National Health Research Ethics Council;

3.14. **"Inferential Data"** - means Data that arises not merely from the cleaning, ordering, or reformatting of the Data, or the combination thereof with other Data, but from analysis of the Materials that generates new knowledge or hypotheses that were not explicitly contained in the Data or its combination with other Data;

3.15. "**Informed Consent**" - means a formal agreement signed by a Person with legal capacity to do so, being either a Donor or a representative of a Donor who has given assent, to give permission for their Materials to be used for the purpose of Health Research;

3.16. "**Intellectual Property Rights"** - means statutory and other proprietary rights resulting from the creation of the human mind or otherwise;

3.17. "**Material/s**" - means Human Biological Material and Data;

3.18. "**Party/ies**" - means the Provider and the Recipient;

3.19. **"Person"** - means any natural or juristic person;

3.20. **"Personal Information"** - means information relating to an identifiable, living natural person, and where it is applicable, an identifiable, existing juristic Person, as defined in POPIA;

3.21. **"POPIA"** - means the Protection of Personal Information Act 4 of 2013, as amended from time to time;

3.22. **"Processing"** - means any operation or activity or any set of operations, whether or not by automatic means, concerning Materials, including, but not limited to -

(a) the collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation or use;

(b) dissemination using transmission, distribution or making available in any other form; or

(c) merging, linking, as well as restriction, degradation, erasure or destruction of information;

3.23. **"Processing Purpose"** - means the purpose for which the Recipient will process the Materials in terms of this Agreement, as set out in Annexure A;

3.24. "**Project**' - means the Health Research Project for which the Materials will be used;

3.25. "**Project Data**" - means the Data transferred with the Materials from the Provider to the Recipient as set out in Annexure A, as well as any data actually transferred from the Provider to the Recipient as part of the Project;

3.26. "**Protocol**" - means approved research Protocol, which is a document that describes the background, rationale, objective(s), design, methodology, statistical considerations and organization of a research study;

3.27. "**Research Results**" - means all products of the research, whether tangible or intangible;

3.28. "**Safeguards**" - means the technical and organizational measures that a Person would normally use to safeguard the Materials according to prevailing industry standards;

3.29. "**Secondary Use**" - means the use, or further Processing, of the Materials for Health Research purposes other than the uses determined in the approved Protocol;

3.30. "**Termination Report** " - means a report prepared by the Recipient and submitted to the Provider on termination or completion of the Project as contemplated in clause 10.

4. AGREEMENT

4.1. The Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials from the Provider as described in Annexure A.

4.2. The Parties agree to conduct themselves hereunder in compliance with Applicable Legislation.

4.3. The Provider remains the custodian of the Materials. Each Party undertakes to engage with the other in the utmost good faith and to conduct itself with 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.

4.4. This Agreement is subject to the suspensive condition that, and is of no force or effect unless and until, HREC approves the Project of which this Agreement forms a part, and HREC, by its signature below, indicates its approval of this Agreement.

5. OBLIGATIONS OF THE PROVIDER

5.1. The Provider must obtain the necessary permits and authorisations for the export of Materials.

5.2. The Provider shall inform the HREC and the relevant Donor(s) should the Provider be informed that the Materials have become identifiable for any reason whatsoever.

5.3. The Provider must obtain Informed Consent or assent from the Donor(s), where reasonably possible, and approval from the HREC, for any further uses of the Materials.

6. OBLIGATIONS OF THE RECIPIENT

6.1. The Recipient may only carry out research according to the Protocol approved by the HREC.

6.2. The Recipient shall protect and keep the Materials and Data confidential.

6.3. The Recipient may not without the prior approval of the HREC transfer or otherwise provide the Materials and/or Data to any party, other than those Parties listed in Annexure A.

6.4. Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider without delay.

6.5. The Recipient shall deliver feedback to the Provider on the development and progress made with regard to the Project by supplying the Provider with updated information where relevant and in terms of applicable ethical and legal requirements.

6.6. The Recipient agrees that the Materials will be located at:

(Entity details and location of Materials)

7. RESPONSIBILITY OF THE HREC

7.1. The responsibilities of the HREC are to:

7.1.1. Review, and where appropriate in its discretion approve research proposals and Protocols that require the transfer of Materials;

7.1.2. Review and where appropriate in its discretion grant approval of this Agreement to ensure that it adequately Safeguards the Materials and the ethical requirements set out herein; and

7.1.3. Review and where appropriate in its discretion approve all Secondary Use research of the Materials transferred.

7.2. This Agreement is subject to the suspensive condition that it is of no force or effect unless and until the HREC has approved the Health Research of which this Agreement forms a part.

8. BENEFIT-SHARING

8.1. Benefit Sharing is a requirement of this Agreement. The sharing of Benefits should be discussed and negotiated between the Provider and the Recipient before Materials are transferred to the Recipient.

8.2. The Parties agree to Benefit Sharing as may be detailed in Annexure B.

8.3. in the event that the Recipient generates Inferential Data, the Recipient grants the Provider a non-exclusive, non-transferable, royalty-free licence to use such Inferential Data; all academic publications and press releases that report on the Project must acknowledge that the Materials were provided by the Provider.

8.4. If the Materials include Personal Information, all academic publications and press releases that report on the Project must:

8.4.1. ensure that no Data Subject is identified or identifiable from the publication unless the Data Subject's express consent has been obtained for such publication;

8.4.2. take action to prevent discrimination, stigma or harm to any community identified in the publication; and

8.4.3. acknowledge the Data Subjects (anonymously) and, where relevant, the Data Subjects' community.

8.5. If the Materials were generated from biospecimens, either directly or indirectly, or associated with biospecimens, each party warrants that it did not and will not provide any reward in money or kind to the Data Subjects, whether directly or indirectly, excluding Health Research Ethics Committee approved compensation for:

8.5.1. expenses incurred; and

8.5.2. time, inconvenience, and risk.

9. DURATION OF AGREEMENT

9.1. This Agreement will commence and become effective upon the HREC approval of the Protocol and signed by both Parties and shall continue until the Project is terminated or is completed.

10. TERMINATION OR COMPLETION OF PROJECT

10.1. When the Project terminates, for any reason whatsoever, the Recipient shall provide the Provider and the HREC with a Termination Report.

10.2. The Termination Report will include, *inter alia*, reasons for termination, the status of the Project as of termination and the current status of the Materials.

10.3. Clauses 4, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, will survive the termination or completion of this Agreement.

11. DISPUTE RESOLUTION

11.1. Should a dispute arise between the Parties in connection with this Agreement, the Parties must, within a period of fourteen (14) days after the date on which the dispute arose (the

Dispute Date) meet to discuss the dispute and endeavour to resolve the dispute amicably, by mutual agreement.

11.2. If the Parties are unable to resolve the dispute in terms of 11.1 within thirty (30) days from the Dispute Date the dispute will be referred to the senior management of the respective Parties for resolution. Senior management will use their best endeavours to resolve the dispute and their determination will be final and binding and will be carried into effect by the Parties.

11.3. If senior management of the respective Parties are unable to resolve the dispute within a period of thirty (30) days after it has been referred to them, either Party may institute action in accordance with South African laws, in a South African court, unless the Parties agree to resolve such dispute by arbitration in terms of a separate arbitration agreement.

12. INTELLECTUAL PROPERTY

12.1. Each Party retains sole ownership and all rights, title, and interest, worldwide, in its Intellectual Property that existed prior to the effective date of this Agreement, unless expressly agreed otherwise within this Agreement.

12.2. The Provider retains all rights, title, and interest, worldwide, in the Intellectual Property pertaining to the Project Data in any form, including but not limited to its original, processed, cleaned, reordered, or reformatted versions. For clarity, this does not include Inferential Data, which is provided for under clauses 12.3 and 12.4.

12.3. Provided that Inferential Data is generated in terms of this Agreement:

12.3.1. Any Party that independently generates Inferential Data, as defined herein, shall exclusively own the Intellectual Property Rights to such Inferential Data. This includes the right to use, license, or otherwise exploit the Inferential Data, subject to any obligations or limitations set forth in this Agreement.

12.3.2. Should Inferential Data be generated from the combined skill and effort of both Parties, the Intellectual Property Rights associated with such Inferential Data will be jointly owned. Both Parties shall have equal rights, title, and interest in the Intellectual Property stemming from the jointly generated Inferential Data. Further, both Parties commit to engaging in good faith negotiations to outline the terms governing the use, licensing, and potential commercialisation of this Intellectual Property, aiming to secure fair advantages and recognition for both Parties.

12.4. Should Inferential Data be generated by either Party or both Parties for a purpose other than the Processing Purpose, the Provider shall exclusively own the Intellectual Property Rights to such Inferential Data.

13. CONFIDENTIALITY

13.1. The Recipient shall keep the identity of the Donor(s) and the Materials secure and confidential at all times.

13.2. Confidentiality includes, but is not limited to the properties, characteristics, content, composition, potential Secondary Uses, and methods of use of the Materials.

13.3. The Provider and the Recipient shall treat all information relating to the nature, process and results, and/or intellectual and/or other proprietary interests of the research in whatever form, confidential.

14. PUBLICATIONS & PUBLICITY

14.1. All communication between the Parties regarding the Project and/or Project Data will be regarded as Confidential Information.

14.2. A Party will refrain from making public any results of the Project:

14.2.1. unless that Party obtains the written consent of the other Parties, or unless South African legislation provides otherwise;

14.2.2. and subject to compliance with the Intellectual Property from Publicly Funded Research and Development Act 51 of 2008.

14.3. The Recipient shall not include in any presentations or manuscripts derived from the Data any case studies that describe the characteristics of individual participants, or any combination of Data elements that might allow for identification or the deduction of a study participant's identity.

15. COMPLIANCE WITH HEALTH RESEARCH LAW

15.1. If the Materials contain Data that the Provider collected from human participants as part of Health Research, or that the Provider generated from biospecimens collected from human participants as part of Health Research, irrespective of whether such Data falls within the ambit of POPIA, the Provider warrants that it complied with all the requirements of the National Health Act 61 of 2003 and the regulations made in terms thereof, in particular that:

15.1.1. It obtained approval for such Health Research from a registered Health Research Ethics Committee; and

15.1.2. It consulted with community representatives, where deemed appropriate by such Health Research Ethics Committee.

16. DATA PRIVACY OBLIGATIONS ON THE PROVIDER AND THE RECIPIENT

16.1. If the Materials contain Personal Information, each Party warrants that the conditions set out in Chapter 3 of POPIA, and all the measures that give effect to such conditions, will be fully complied with.

17. DATA AND/OR MATERIALS BREACH AND DATA SUBJECT RIGHTS

17.1. Where there is a Data and/or Materials breach, the Parties will, within 72 hours of discovery of the breach:

17.1.1. take reasonable steps to fix the Data and/or Materials breach;

17.1.2. take action to prevent a similar Data and/or Materials breach from happening again; and

17.1.3. notify the other Party in writing about the Data and/or Materials Breach and steps taken in relation thereto.

17.2. If the Data and/or Materials breach relates to Personal Information, or the Project Data contains Personal Information the Party/ies undertake to comply with the provisions of POPIA.

18. INDEMNITY

18.1. 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.

18.2. The Provider will not be liable to the Recipient for any claims or damages arising from the Recipient's use of the Materials.

18.3. Each Party indemnifies and holds harmless the other Party from all liability, losses, claims and expenses, including legal costs, arising from or connected with any unlawful conduct it is responsible for.

18.4. In no event will any Party be liable to the other for loss of profits, or for direct, indirect, incidental, special or consequential damages arising out of this Agreement.

19. DOMICILIA AND NOTICES

19.1. The Provider chooses as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention: South African National Blood Service

Physical: 1 Constantia Boulevard, Constantia Kloof Extension 22, Weltevreden Park 1715, South Africa

Tel: 011 761 9000

Email: [As specified by SANBS in this Agreement]

19.2. The Recipient chooses as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention:

Physical:

Tel:

Email:

19.3. Either Party may amend its *domicilium citandi et executandi* by means of written notice to the other Party.

19.4. Notwithstanding anything to the contrary contained or implied in this Agreement, a written notice or communication actually received by one of the Parties from another shall be adequate written notice or communication to such Party.

20. GENERAL

20.1. This Agreement embodies the entire agreement between the Parties and no provision hereof may be altered or amended without the written mutual consent of the Parties

20.2. No 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.

20.3. No 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.

20.4. No Party will be bound by any representation, express or implied term, warranty, promise or the like, and no amendment to this contract will be of any force and effect, unless reduced to writing and signed by the Parties.

20.5. No extension of time or indulgence by any Party will be deemed in any way to affect, prejudice or derogate from the right 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.

20.6. The rule that an agreement will be interpreted against the Party that drafted it shall not apply to this Agreement.

20.7. 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 this Agreement shall be carried out as nearly as possible in accordance with its original terms and intent.

20.8. The Recipient receives only the rights as set out in this Agreement and these rights are not exclusive to the Recipient.

20.9. HREC shall have the right to audit or monitor compliance from time to time.

21. AUTHORITY

21.1. Each Party signing this Agreement on behalf of a Party hereto, hereby warrants in his or her official capacity that he or she is duly authorised by such Party to do so.

22. COUNTERPART SIGNING OF THIS AGREEMENT

22.1. The Parties agree that this Agreement may be signed at different times and in different places and in copy provided the content of this Agreement and signatures are exact replicas(counterparts) of the originals when put together.

22.2. The signed agreements when put together shall constitute a legally binding agreement between the Parties.

THUS DONE AND SIGNED on behalf of the **PARTIES** by their duly authorised representatives, in the presence of the undersigned witnesses, at the places appearing in the appropriate spaces below, on the dates as specified.

Duly authorised and on behalf of The South African National Blood Service, the Provider
Full name:
Tel:
Designation:
Signature:
Signed at _____on this the_____ day of_____ 20__.

Duly authorised and on behalf of the [Recipient Institution], the Recipient
Full name:
Tel:
Designation:
Signature:
Signed at_____ on this the _____day of _____20__.

The Human Research Ethics Committee (HREC) by its signature hereto and below acknowledges that its Processes have been complied with.
Full name:
Tel:
Designation:
Signature:
Signed at_____ on this the _____day of _____20__.

ANNEXURE A - Scope of Materials and Practical implementation

To be completed by the Provider and /or the Recipient

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

_____

_____

Description of Health Research Project under which the Materials will be used on transfer:

_____

_____

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

_____

_____

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

_____

Quantity of Materials required to be transferred:

_____

Preferred method of transfer of Materials:

_____

Period within which Materials will be transferred:

_____

Frequency of exporting of Materials:

_____

Process of destruction of Materials:

_____

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

_____

Other:

_____

_____

_____

_____

ANNEXURE B

Benefit Sharing Arrangement between the Recipient and the Provider

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

ANNEXURE C

Relevant legislation

In addition to the legislation specified in this Agreement, consider the following legislation as and where applicable

SOUTH AFRICA

1. The Intellectual Property from Publicly Funded Research and Development Act 51 of 2008
2. The Exchange Control Regulations in terms of the Currency and Exchanges Act 9 of 1933
3. The Electronic Communications and Transactions Act 25 of 2002, the Regulation of Interception of Communications and Provision of Communication Related Information Act 70 of 2002
4. The Cybercrimes Act 19 of 2020

OTHER

[insert]