DATA TRANSFER AGREEMENT FOR DATA COLLECTED OR TO BE COLLECTED FOR RESEARCH PURPOSES

(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, storage and destruction of Data derived retrospectively or prospectively, during the conduct of Health Research or clinical care.

1.2. The purpose of this Agreement is to facilitate the lawful transfer of Project Data between the Parties, and to comply with the Protection of Personal Information Act 4 of 2013 and Applicable Legislation by regulating the Processing of Data

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 AND INTERPRETATION

3.1. In this Agreement, unless the context indicates otherwise, if a word starts with a capital letter, it has the following meaning:

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

3.1.2 "**Applicable Legislation**" - means any legislation applicable to the Processing of Data, 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 E);

3.1.3 "**Appropriate Safeguards**" - means the technical and organizational measures that a reasonable Person would use to safeguard the Data;

3.1.4 "**Benefit/s**" - means, amongst others, the sharing of information; use of Health Research results; royalties; acknowledgement of the Provider as the source of the Data; publication rights; and capacity building;

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

3.1.6 "**Confidential Information**" - means information relating to a Party's business and

3.1.6.1 The Project's results, and/or intellectual and/or other proprietary interests;

3.1.6.2 A Party's trade secrets, including business and strategic plans, financial affairs, licensing agreements, contractual relations, business methods and know-how, technology, computer systems and other technical matters;

3.1.6.3 A Party's trade connections, including the identity of, and its relations with, its customers or clients, financiers, suppliers and providers of services;

3.1.6.4 A Party's know-how relating to the manufacture, development, use or sale of any of its products, including its know-how with regard to its manufacturing techniques, prices, designs, specifications, formulae, systems, processes, materials and marketing;

This applies irrespective of how the information is disclosed, whether orally, visually or in computer language or by inspection or documentation or other objects; or the time

when the information is or has been disclosed, whether before or after the Effective Date.

3.1.7 **"Consent"** - means any voluntary, specific and informed expression of will in terms of which permission is given for the Processing of Personal Information;

3.1.8 "**Custodian**" - means a Person or entity entrusted by the Donor with safeguarding and protecting the Data;

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

3.1.10 "**Data Breach**" – means a situation where there are reasonable grounds to believe that a breach of security in respect of the Data/Project Data 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;

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

3.1.12 "**Donor**" - means a Person who has consented to the use of their Data for Health Research purposes and/or teaching;

3.1.13 "**Effective Date**" – means [insert];

3.1.14 "**Expiry Date**" – means [insert];

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

3.1.16 "**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;

3.1.17. **"Human Participant"** - means a Person about whom a researcher obtains biological specimens or Personal Information through intervention or interaction with that Person;

3.1.18 **"Inferential Data"** - means Data that arises not merely from the cleaning, ordering, or reformatting of the Project Data, or the combination thereof with other Data, but from analysis of the Project Data that generates new knowledge or hypotheses that were not explicitly contained in the Project Data or its combination with other Data; in the event that the Recipient generates Inferential Data, the Recipient grants the Provider a non-exclusive, non-transferable, royalty-free license to use such Inferential Data;

3.1.19 **"Information Regulator"** - means the Information Regulator of South Africa as established by section 39 of POPIA;

3.1.20 "**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 Data to be used for the purpose of Health Research;

3.1.21 "**Intellectual Property Rights"** - means statutory and other proprietary rights resulting from the creation of the human mind or otherwise, including but not limited to all copyright, patents, scientific works, discoveries, rights in inventions, know-how, trade secrets; trademarks and trade names, service marks, design marks, design rights in get-up, database rights, utility models, domain names and all similar rights and, in each case: whether registered or not; including any applications to protect or register such rights; including all renewals and extensions of such rights or applications; whether vested, contingent or future; and wherever existing;

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

3.1.23 **"Person"** - means any natural or juristic person;

3.1.24 **"Personal Information"** - means information relating to an identifiable, living natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to -

(a) information relating to the race, gender, sex, pregnancy, marital status, nationality, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the Person;

(b) information relating to the education or the medical, financial, criminal or employment history of the Person;

(c) any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the Person;

(d) the biometric information of the Person;

(e) the personal opinions, views or preferences of the Person;

(f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature, or further correspondence that would reveal the contents of the original correspondence;

(g) the views or opinions of another individual about the Person; and

(h) the name of the Person if it appears with other Personal Information relating to the Person or if the disclosure of the name itself would reveal information about the Person;

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

3.1.26 **"Processing"** - means any operation or activity or any set of operations, whether or not by automatic means, concerning Personal Information, including -

(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;

3.1.27 **"Processing Purpose"** - means the purpose for which the Recipient will process the Project Data in terms of this Agreement, as set out in Annexure B;

3.1.28 "**Project**' - means the Health Research project for which the Data will be used;

3.1.29 "**Project Data**" - means the Data transferred 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;

3.1.30 **"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;

3.1.31 **"Secondary Use"** - means other use, or further Processing, of Data for a different purpose, not immediately related to the purpose of the Project;

3.1.32 "**Secure Data Transfer**" - means the transfer of Project Data using industry-standard secure norms;

3.1.33 **"Signature Date"** - means the date of signature of this Agreement by the Party last signing in time;

3.1.34 **"Special Personal Information"** - means Personal Information concerning:

3.1.34.1 the religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information of a Data Subject; or

3.1.34.2 the criminal behaviour of a Data Subject to the extent that such information relates to the alleged commission by a Data Subject of any offence; or

3.1.34.3 any proceedings in respect of any offence allegedly committed by a Data Subject or the disposal of such proceedings;

3.1.35 **"Transfer Date"** - means the date the Project Data is transferred from the Provider to the Recipient;

3.1.36 "**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. This Agreement regulates the Project Data in relation to the project.

4.2. The Provider hereby undertakes to transfer the Project Data to the Recipient on the Transfer Date via Secure Data Transfer for Processing Purposes.

4.3. The Recipient may only process the Project Data in terms of this Agreement, and on condition that the Recipient complies fully with POPIA where POPIA is applicable.

4.4. The Parties agree to conduct themselves hereunder in compliance with Applicable Legislation and to ensure that Appropriate Safeguards are taken regarding the Project Data.

4.5. This Agreement must always be interpreted in a manner that is consistent with POPIA and so that it fulfils the Parties' obligations to comply with Applicable Legislation,

4.6. The rule of construction that this Agreement will be interpreted against the Party responsible for its drafting or preparation will not apply.

4.7. Provider remains Custodian of the Data and the Donor remains the owner of the Data.

4.8. 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.

4.9. Nothing in this Agreement limits or excludes either Party's liability to Data Subjects or to the Information Regulator under this Agreement or POPIA.

4.10. 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.

5. OBLIGATIONS OF THE PROVIDER

5.1. The Provider shall inform the HREC, and the relevant Donor(s) should the Provider be informed that the Data becomes identifiable for any reason whatsoever.

5.2. The Provider must obtain Informed Consent from the Donor(s), and approval from the HREC for any further uses of the Data.

5.3. It is the duty of the Provider to ensure that the legal protection of Data should equal or exceed the legal protection provided under South African law.

6. OBLIGATIONS OF THE RECIPIENT

6.1 The Recipient may only carry out what is approved by the Provider and HREC.

6.2 The Recipient shall protect and keep the Data confidential.

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

6.4 Should the Data 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.

7. RESPONSIBILITIES OF THE HREC

7.1. The responsibilities of the HREC are to:

7.1.1 Review and approve Health Research proposals and protocols that require the transfer of Data;

7.1.2 Review and acknowledge the processes of this Agreement to ensure that it adequately safeguards the Data and the ethical requirements set out herein; and

7.1.3 Review and approve all Secondary Use research of the Data transferred. The HREC will be the last signatory.

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 Recipient before Data is transferred to the Recipient.

8.2. The Parties agree to Benefit Sharing as detailed in Annexure D.

9. DURATION OF AGREEMENT

9.1. Notwithstanding the signature date of this Agreement by the Provider and HREC, this Agreement shall come into full force and effect on the Effective Date and shall continue until the Expiry Date or the date upon which the Project Data is no longer necessary for the Processing Purpose, whichever is sooner, subject to clause 10.3.2 below.

10. TERMINATION OF PROJECT

10.1. When the Project terminates, for any reason whatsoever, the Recipient shall provide the Provider and 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 Data.

10.3. Termination of the Project may occur under one or more of the following circumstances:

10.3.1 The Project reaches completion;

10.3.2 The Project cannot be carried out by the Recipient for any one or more of the following reasons:

- The Donors withdraw Consent for use as contemplated hereunder and in such numbers as to render the continuation of the Project impracticable or impossible;
- The Recipient entity dissolves, winds -up or ceases to continue operating for any reason whatsoever;
- The Provider and HREC withdraw approval for the Project in its entirety;
- At any time during the subsistence of this Agreement, a Party may terminate this Agreement for any reason whatsoever, on sixty (60) days written notice to the other Parties; or
- A *force majeure* makes the continuance of the Project impracticable or impossible.

10.4 The Recipient will on termination of the Project, immediately discontinue using the Data for any purpose whatsoever.

10.5 On termination or expiry of this Agreement, the Recipient agrees to return and/or delete all Project Data in its possession.

10.6 Clauses 3, 10, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23 and 27 will survive the termination or expiry of this Agreement.

10.7 Destruction, deletion, return to the Provider or transfer of Data will be undertaken by the Recipient or any other arrangements made with the express approval of the HREC.

10.8 The recipient may not retain the Data without the approval of the HREC.

11. INFORMED CONSENT

11.1 The Provider must obtain Informed Consent from the Donor(s) to provide Data to the Recipient to undertake the Project as contemplated. Informed consent is provided on the Donor questionnaire and entered into the Laboratory Information System (LIS).

11.2 The Provider must confirm to the HREC that Informed Consent for Secondary Use of de-identified Data has been obtained, and, should the need arise for Secondary Use, refer to the SANBS HREC for approval.

11.3 The Provider must inform the Donor(s) of developments or progress made by the Recipient in the Project which is relevant to the Donor(s) Informed Consent.

12. COMPLIANCE WITH HEALTH RESEARCH LAW

12.1 If the Project Data contains 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:

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

12.1.2 It consulted with community representatives, where deemed appropriate by the Health Research Ethics Committee.

13. DATA PRIVACY OBLIGATIONS ON THE PROVIDER AND RECIPIENT

13.1 If the Project Data contains Personal Information, each Party warrants that:

13.1.1 The conditions set out in Chapter 3 of POPIA, and all the measures that give effect to such conditions, will be fully complied with.

13.1.2 The Processing of the Project Data will always be conducted lawfully, in accordance with applicable legislation, and in a reasonable manner that does not infringe on the privacy of the Data Subject. If it is a Responsible Party, it will register its information officer with the Information Regulator if required to do so by the regulations, guidance or directives issued by the Information Regulator.

13.1.3 The Project Data will only be processed where, taking into account the purpose for which it is processed, the Processing is adequate, relevant and not excessive.

13.1.4 The Project Data will only be processed where a ground of justification exists as set out in section 11 of POPIA.

13.1.5 A Personal Information impact assessment, as required by Regulation 4 of the regulations to POPIA, has been completed prior to the transfer of any Project Data.

13.2 If the Project Data contains Special Personal Information, or children's Personal Information, the Parties warrant that, to the extent applicable, they will also comply with Chapter 3 Part B, relating to the Processing of special Project Data contained in POPIA (sections 26–33) or Chapter

3 Part C, relating to the Processing of children's Personal Information contained in POPIA (sections 34–35). For purposes of this Agreement the term 'child' shall bear the meaning assigned to it in POPIA.

13.3 If the Project Data contains Personal Information , the Provider warrants that:

13.3.1 All Project Data has been collected directly from a Data Subject and:

13.3.1.1 with Consent to process the Project Data from the Data Subject or a competent Person if the Data Subject is a child; or

13.3.1.2 that a lawful ground of justification exists in terms of POPIA.

13.3.2 Where, in terms of POPIA, a lawful justification for collection other than Consent was relied upon for the original collection, the Provider shall record this in Annexure A as part of the Project Data.

13.3.2.1 The Project Data:

13.3.2.1.1 was collected for a specific, explicitly defined purpose;

13.3.2.1.2 will only be retained for as long as is necessary;

13.3.2.1.3 will only be processed in a manner that is compatible with the purpose for which it was collected; and

13.3.2.1.4 will be transferred, stored and disposed of in compliance with applicable legislation.

13.3.3 Having regard to the purpose for which the Project Data was collected, reasonable steps will be taken to ensure that the Project Data is complete, accurate, not misleading, and updated where necessary.

13.3.4 Documentation of all Processing operations will be retained, and it will retain written records of its compliance with this Agreement.

13.3.5 All reasonably foreseeable risks to Project Data will be identified and documented, and Appropriate Safeguards will be established, maintained, and regularly audited, and will form part of the mandatory discussions between the Parties' Data protection officers in the regular meetings referred to in clause 14 below.

13.3.6 All reasonable requests made by the Information Regulator in relation to the Project Data will be complied with.

13.3.7 It has carried out reasonable checks on the Recipient's ability to comply with this Agreement, and it will take steps to terminate this Agreement in the event that the Recipient is no longer able to comply with the Appropriate Safeguards and/or any part of POPIA.

13.3.8 It will cooperate with and notify the Recipient about requests and/or notices received from Data Subjects.

13.4 If the Project Data contains Personal Information, the Recipient warrants that:

13.4.1 It will only process the Project Data for Processing Purposes and only further process the Project Data in accordance with what has been expressly agreed to by the Parties and in compliance with the Consent of the Data Subject.

13.4.2 It will not transfer Project Data to any other Person, save where required by law, or where in compliance with section 72 of POPIA, or where agreed to by the Parties and in compliance with the Consent of the Data Subject and POPIA. In the event that Project Data is transferred to a jurisdiction where POPIA does not apply, the Recipient warrants that it will only transfer the Project Data to a jurisdiction with adequate protection as set out in section 72(1)(a) of POPIA.

13.4.3 It will retain a written record of its compliance with this Agreement, including its Processing of the Project Data, and provide such a written record if asked to do so by the Provider. Where in terms of clause 13.4.1 the Recipient relies on sections 15 or 27 or 35 of POPIA to process Data without Consent it must record the basis and justification for such Processing in its written record required by this clause 13.4.3.

13.4.4 It will allow the Provider, on reasonable notice, to audit its compliance with this Agreement and with POPIA.

13.4.5 It will ensure that appropriate technical and organisational measures are taken and that Appropriate Safeguards will be taken in relation to the Project Data as set out in Annexure C.

14. DATA BREACHES

14.1 Where there is a Data Breach, the Parties will, within 72 hours of discovery of the Data Breach:

14.1.1 take reasonable steps to fix the Data Breach;

14.1.2 take action to prevent a similar Data Breach from happening again; and

14.1.3 notify the other Party in writing about the Data Breach and steps taken in relation thereto.

14.2 If the Data Breach relates to Personal Information the Party which suffers the Data Breach will, within 72 hours of the discovery of the Data Breach:

14.2.1 notify the Information Regulator in writing;

14.2.2 comply fully with section 22 of POPIA; and

14.2.3 within 24 hours, convene a meeting of senior Party representatives to determine the reasonable steps to be taken, and to document compliance with this Agreement, POPIA, and other Applicable Legislation.

15. DATA SUBJECT RIGHTS

15.1 Where the Project Data contains Personal Information, the Parties agree that they will facilitate Data Subject access rights, as provided for in sections 23 to 25 of POPIA.

15.2 Where the Project Data contains Personal Information , the Recipient confirms that should a Data Subject:

15.2.1 communicate their objection to the Recipient Processing their Personal Information ; or

15.2.2 request the Recipient to confirm whether it holds Personal Information about them, the purpose of Processing such information, a record or description of the Personal Information held, or which third parties have or have had access to it; or

15.2.3 request the Recipient to rectify, correct or delete their Personal Information, or cease Processing their Personal Information; or

15.2.4 seek to exercise any other rights the Data may have;

15.2.5 the Recipient shall immediately and without undue delay forward such communication to the Provider and, collectively, the Parties shall within 5 (five) business days determine the appropriate steps to be taken.

16. OBLIGATIONS OF THE PROVIDER AND THE RECIPIENT

16.1 Except to the extent set out in this Agreement, the Provider gives no warranty that the Project Data:

16.1.1 has any particular characteristics or qualities; or

16.1.2 is fit for the purpose for which it is being transferred.

16.2 Both Parties agree that Appropriate Safeguards will be taken to protect the Project Data and to ensure that the Project Data is not lost, damaged or unlawfully accessed.

16.3 While both Parties undertake to do everything possible to ensure a positive outcome in relation to the Project generally, they cannot guarantee any specific result, and both Parties agree to participate in the transfer of the Project Data at their own risk.

16.4 In the event that either Party is no longer authorised to retain the Project Data or parts thereof, such Party will return or delete all instances of the Project Data under its control and notify the other Party.

17. LICENCE TO USE DATA

17.1 The Provider hereby grants to the Recipient a non-exclusive, non-transferable licence to use the Project Data for the Processing Purpose, for the duration of this Agreement, and the Recipient hereby accepts the grant of the licence on the terms and conditions contained in this Agreement.

17.2 The Recipient undertakes to ensure that only staff members, contractors, agents and/or relevant Persons who are required as part of their function to access the Project Data will have access thereto, and that those employees will be fully conversant with the terms of this Agreement and the requirements of POPIA.

17.3 In the event that an unauthorised Person(s) comes into possession of a copy of or gains access to the Project Data from the Recipient, the Recipient undertakes to comply with the steps listed in clause 14 above, and:

17.3.1 As soon as possible, and within 72 hours, will take reasonable steps to retrieve the Project Data and all copies that the unauthorised Person(s) might have made, and to take all further reasonable steps to prevent further unlawful distribution of the Project Data; and

17.3.2 Advise the Provider in writing of the steps taken in terms of 17.3.1.

18. DATA OWNERSHIP

18.1 The Provider retains ownership of all original Project Data files and any copies thereof made by the Recipient.

18.2 The Provider will also be the owner of all new files generated by the Recipient that contain the Project Data in whole or in part, whether in its original, processed, cleaned, re-ordered, or reformatted form, and all copies made thereof by the Recipient. For clarity, this does not include Inferential Data, which is provided for under clauses 18.5 and 18.6.

18.3 The Recipient may only make copies of the files contemplated in clauses 18.1 and 18.2 above if required for purposes of the Project and, if the Project Data contains Personal Information subject to clause 13.4 above.

18.4 The Project Data files are transferred on a non-exclusive basis.

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

18.5.1 Ownership of Inferential Data files generated by a single Party shall reside solely with that Party.

18.5.2 Should Inferential Data files be produced through the combined skill and effort of both Parties, such files shall be co-owned by both Parties and shared equally. Further, both Parties commit to engaging in good faith negotiations to outline the terms governing the

use, licensing, and potential commercialisation of such files, aiming to secure fair advantages and recognition for both Parties.

18.6 Ownership of Inferential Data files generated by either Party or both Parties for a purpose other than the Processing Purpose shall reside solely with the Provider.

18.7 If the Project Data or the Inferential Data contemplated in this clause are Personal Information ownership in such Data is limited by the rights of Data Subjects in terms of POPIA.

19. DISPUTE RESOLUTION

19.1 Should a dispute arise between the Parties in connection with this Agreement, the Parties must, within 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.

19.2 If the Parties are unable to resolve the dispute in terms of 20.1 within thirty (30) days from the Dispute Date the dispute will be referred to the company executives of the respective Parties for resolution. Senior management will endeavour to resolve the dispute to the best of their abilities. Their determination will be final and binding and will be carried into effect by the Parties.

19.3 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.

20. INTELLECTUAL PROPERTY

20.1 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.

20.2 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 14.3 and 14.4.

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

20.3.1 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 outlined in this Agreement.

20.3.2 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.

20.4 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.

21. INDEMNITY AND LIMITATION OF LIABILITY

21.1 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.

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

22. RELATIONSHIP MANAGEMENT

22.1. Both Parties will appoint a Data protection officer for the purposes of ensuring compliance with this Agreement and POPIA, where applicable, and to generally manage the relationship between the Parties and the Processing of Data.

22.2. The Data protection officers and any Persons who the Data protection officers may deem necessary will meet as often as may be necessary but no less than once every 3 (three) months, to consider the Processing of Data and general compliance with POPIA where appropriate, and to audit the Appropriate Safeguards to ensure that they are maintained.

22.3. The Data protection officers will be:

22.3.1 For the Provider: [insert name] and [insert contact details]

22.3.2 For the Recipient: [insert name] and [insert contact details]

23. CONFIDENTIALITY

23.1. The Recipient shall keep the identity of the Donor Data secure and confidential at all times.

23.2. The Provider and the Recipient shall treat all information relating to the nature and process of the Health Research in whatever form as confidential.

24. PERMITTED USES OF DATA BEING REQUESTED:

24.1. Provider shall prepare and furnish to Recipients Data sets

24.2. Recipients will use Appropriate Safeguards to prevent the use or disclosure of Data not permitted by this Agreement.

24.3. Recipients will use Data to conduct statistical Data analysis in accordance with approved protocols and Consent documents.

24.4. Recipients shall manage Data in collaboration with Providers and according to SOPs and quality control procedures that are required for acceptance of a study Dataset

24.5. Recipients may not use the Data for publications or grant application purposes without prior approval from the Provider

25. PROTECTION OF DATA:

25.1. The Recipients acknowledge that they have adequate means to protect Data and that they will use all reasonable security means to process and protect Data.

26. PUBLICATION AND PUBLICITY

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

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

26.2.1. unless that Party obtains the written Consent of the other Parties, or unless South African legislation provides otherwise; and

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

26.3. 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.

27. GENERAL

27.1. This Agreement will in all respects be governed by and construed under the laws of the Republic of South Africa.

27.2. This Agreement does not establish any principal-agent or similar relationship between the Parties, and nothing in this Agreement shall be interpreted as allowing either Party to represent or act in the name or for the account of the other Party. The Parties shall in all respects act as independent contractors.

27.3. This document constitutes the sole record of the agreement between the Parties with regard to the subject matter hereof.

27.4. No addition to, variation or consensual cancellation of this Agreement will be of any force or effect unless in writing and signed by or on behalf of all Parties to this Agreement.

27.5. No Party will be entitled to cede, assign or otherwise transfer all or any of its rights, interest or obligations under and in terms of this Agreement, except with the prior written Consent of the other Party.

27.6. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement.

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

28. DOMICILIA

28.1. 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]

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

Attention:

Physical:

Postal:

Tel:

Email:

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

28.4. 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.

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

Project Data to be transferred

[insert]

ANNEXURE B

Project and Processing Purpose

[insert]

ANNEXURE C

Technical and organisational measures to protect Data

[insert]

ANNEXURE D

Benefit Sharing Arrangement between the Recipient and Provider

[insert]

ANNEXURE E

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]