



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

[]

(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 lawful collection, access, transfer, use, processing, storage, retention, disclosure, safeguard and destruction of Project Data transferred by the South African National Blood Service ("SANBS") to the Recipient in connection with an approved Health Research project.
- 1.2. This Agreement establishes the respective rights, responsibilities and obligations of the Parties in relation to the Processing of Project Data and is intended to ensure compliance with:
 - 1.2.2 the Protection of Personal Information Act 4 of 2013 ("POPIA");
 - 1.2.3 the National Health Act 61 of 2003;
 - 1.2.4 applicable ethical requirements and HREC approvals; and
 - 1.2.5 all other Applicable Legislation.
- 1.3. This Agreement is of no force or effect unless and until Health Research Ethics Committee (HREC) have approved the Project of which this Agreement forms a part.
- 1.4. The Recipient shall only Process the Project Data for the Processing Purpose approved by SANBS and the HREC and may not use the Project Data for any secondary, unrelated or commercial purpose without the prior written approval of SANBS and the HREC.

2. PARTIES

- 2.1. The Parties to this Agreement are:
 - 2.1.1. [The South African National Blood Service, a non-profit company duly incorporated in accordance with the laws of the Republic of South Africa, with its principal place of business at: 1 Constantia Boulevard, Constantia Kloof, Extension 22, Weltevreden Park, Gauteng, South Africa ("SANBS" or "the Provider"), represented by _____ in capacity as _____
 - 2.1.2. _____, an institution duly incorporated in accordance with the laws of the Republic of South Africa, with its principal place of business at _____ ("the Recipient"), represented by _____ in capacity as _____.
- 2.2. Each Party warrants that:
 - 2.2.1 it has the legal authority and capacity to enter into this Agreement;
 - 2.2.2 the person signing this Agreement on its behalf is duly authorised to do so; and
 - 2.2.3 it shall comply with all Applicable Legislation relating to the Processing of Project Data

3. DEFINITIONS AND INTERPRETATION

- 3.1. In this Agreement, unless the context indicates otherwise, words importing any gender include the other genders, the singular includes the plural and vice versa, and the following words shall bear the meanings assigned to them below:
 - 3.1.1 "Agreement" - means this Agreement and all annexures and amendments thereto;
 - 3.1.2 "Applicable Legislation" - means all laws, regulations, ethical requirements, guidelines, directives and codes applicable to:
 - 3.1.2.2.** the collection, transfer, access, Processing, retention, storage, disclosure, safeguarding or destruction of Project Data;
 - 3.1.2.3.** the conduct of the Project:
 - 3.1.2.3.1.** Health Research; and
 - 3.1.2.3.2.** the rights and protection of Data Subjects,including but not limited to legislation listed in 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 any actual, suspected or reasonably suspected unauthorised access to, acquisition of, disclosure of, loss of, destruction of, corruption of, alteration of or inability to account for Project Data;
- 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 [];
- 3.1.14 "Expiry Date" – means [];
- 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, analyses, models, interpretations, insights or conclusions generated through analysis of the Project Data which create new knowledge or hypotheses not expressly contained in the original Project 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.
- 3.2.** In the event of any conflict between this Agreement and any annexure, the provisions of this Agreement shall prevail unless expressly stated otherwise.

4. AGREEMENT

- 4.1. This Agreement regulates the transfer and Processing of Project Data in connection with the project.
- 4.2. The Provider hereby grants the Recipient a limited, non-exclusive, revocable and non-transferable right to access and Process the Project Data solely for the approved Processing Purpose.
- 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 Project Data and all rights of Data Subjects in terms of POPIA remain fully applicable.
- 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 arising from unlawful Processing and regulatory breaches..

- 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. SANBS may suspend, restrict or terminate the transfer or Processing of Project Data immediately upon written notice where the Recipient breaches this Agreement, Applicable Legislation, HREC requirements or the approved protocol, fails to maintain Appropriate Safeguards, where a Data Breach, cybersecurity incident or unauthorised disclosure occurs or is reasonably suspected, or where continued Processing may expose SANBS, Data Subjects or donors to legal, regulatory, ethical or reputational risk. Where reasonably practicable, SANBS shall allow the Recipient a reasonable opportunity to remedy the breach, unless immediate action is required to comply with Applicable Legislation, protect confidentiality or prevent further risk or unauthorised Processing.
- 5.4. SANBS makes no warranty or representation, whether express or implied, regarding the completeness, accuracy, reliability or fitness for purpose of the Project Data, and the Recipient acknowledges that the Project Data is provided "as is" for the approved Processing Purpose only.

6. OBLIGATIONS OF THE RECIPIENT

- 6.1 The Recipient shall only Process the Project Data strictly in accordance with:
- 6.1.1 this Agreement;
 - 6.1.2 the approved research protocol;
 - 6.1.3 HREC approvals and conditions;
 - 6.1.4 Applicable Legislation; and
 - 6.1.5 the approved Processing Purpose.
- 6.2 The Recipient shall implement and maintain appropriate safeguards to ensure the confidentiality, integrity, availability and security of the Project Data at all times.
- 6.3 The Recipient shall not disclose, transfer, sublicense, assign, provide access to, or otherwise make Project Data available to any third party, operator, subcontractor, affiliate or external service provider without the prior written approval of SANBS and the HREC., other than those Parties listed in Annexure A.
- 6.4 Should any de-identified or anonymised Project Data become identifiable, re-identifiable or reasonably capable of re-identification, the Recipient shall:
- 6.4.1 immediately cease further Processing of such Data;
 - 6.4.2 notify SANBS without undue delay;
 - 6.4.3 cooperate fully with SANBS and the HREC; and
 - 6.4.4 implement immediate remedial measures.
- 6.5 The Recipient shall provide the Provider with periodic written progress updates, reports and findings relating to the Project upon reasonable request and in accordance with applicable ethical, scientific and legal requirements. The Recipient shall ensure that all persons with access to Project Data:
- 6.7.1 are subject to written confidentiality obligations;
 - 6.7.2 receive appropriate privacy and security training; and
 - 6.7.3 only access Project Data on a need-to-know basis.

6.7 The Recipient shall use the Project Data solely for the approved Processing Purpose and in accordance with this Agreement, Applicable Legislation, approved protocols and HREC requirements, and shall not use the Project Data for publication, grant applications, commercial purposes or any other unauthorised purpose without SANBS's prior written approval.

RESPONSIBILITIES OF THE HREC

7.1. The HREC shall:

- 7.1.1 Review and approve Health Research proposals and protocols that require the transfer of Project Data;
- 7.1.2 monitor ongoing compliance with approved protocols where required
- 7.1.3 assess ethical, privacy and donor protection risks relating to the Project
- 7.1.4 review and approve any Secondary Use of Project Data; and retain the right to request additional safeguards, amendments or restrictions where necessary.

7.2. HREC approval of the Project does not absolve the Parties from complying with Applicable Legislation or institutional governance requirements.

8. BENEFIT-SHARING

- 8.1. The Parties acknowledge that any benefits arising from the Project or use of Project Data shall be managed in a fair, transparent and ethically appropriate manner.
- 8.2. The Parties shall record any agreed benefit sharing arrangements 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.
- 9.2. The Recipient shall not retain Project Data for longer than is necessary for the approved Processing Purpose unless such retention is required by law, approved by SANBS and the HREC, or required for approved archival or research purposes.

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;
 - breach of POPIA;

- loss of ethical approval;
- unauthorised disclosure;
- 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 Upon termination or expiry of this Agreement, the Recipient agrees to return and/or destroy all Project Data in its possession.

10.6 Any provisions of this Agreement which by their nature are intended to survive termination or expiry, including provisions relating to confidentiality, data protection, intellectual property, publication and publicity, dispute resolution, liability and the destruction or return of Project Data, shall survive 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, archive or continue to Process Project Data following termination without the prior written approval of SANBS and the HREC.

11. INFORMED CONSENT

11.1 The Provider shall ensure that, where required by Applicable Legislation and ethical requirements, 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 Where Secondary Use of Project Data is contemplated, the Provider shall ensure that such use is ethically approved, that the proposed Processing remains lawful, and that appropriate donor protections remain in place. 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 Where the Project Data contains Personal Information, each Party warrants and undertakes that it shall process such Personal Information strictly in accordance with Applicable Legislation, including POPIA, and shall implement appropriate technical, organisational and security measures to protect the confidentiality, integrity and availability of the Project Data:

- 13.1.1 Each Party shall ensure that Personal Information is processed lawfully, for a legitimate and authorised purpose, and only to the extent necessary for the performance of this Agreement;
 - 13.1.2 Each Party shall take reasonable steps to prevent unauthorised access to, disclosure of, loss of, damage to, or destruction of the Project Data;
 - 13.1.3 The Recipient shall not use, disclose, transfer or process the Project Data for any purpose other than the purpose contemplated in this Agreement without the prior written consent of the Provider; and
 - 13.1.4 Where required by Applicable Legislation, the Parties shall conduct appropriate privacy or impact assessments and maintain records relating to the processing activities contemplated in this Agreement.
- 13.2 If the Project Data contains Special Personal Information, or children's Personal Information, each Party warrants and undertakes that such information shall only be processed strictly in accordance with Applicable Legislation, including sections 26 to 35 of POPIA, and only to the extent necessary for the authorised Processing Purpose contemplated in this Agreement.
- 13.3 If the Project Data contains Personal Information, the Provider warrants and undertakes that:
- 13.3.1. the Project Data has been collected and processed lawfully, fairly and in accordance with Applicable Legislation, including POPIA
 - 13.3.2. a valid lawful basis for the Processing and transfer of the Project Data exists, including consent where required by Applicable Legislation or any other lawful justification recognised under POPIA;
 - 13.3.3. The Project Data was collected for a specific, legitimate and authorised purpose related to the Project and shall not be further processed in a manner incompatible with that purpose;
 - 13.3.4. the Project Data transferred to the Recipient is adequate, relevant and limited to what is reasonably necessary for the authorised Processing Purpose contemplated in this Agreement; 13.3.5 reasonable steps have been taken to ensure that the Project Data is accurate, complete and updated where necessary, having regard to the purpose for which it is processed;
 - 13.3.5. appropriate technical, organisational and security safeguards have been implemented and maintained to protect the confidentiality, integrity and availability of the Project Data against unauthorised access, disclosure, loss, destruction or damage;
 - 13.3.6. records reasonably required by Applicable Legislation relating to the Processing of the Project Data shall be maintained by the Provider;
 - 13.3.7. the Provider shall cooperate with reasonable requests or investigations by the Information Regulator or other competent regulatory authority relating to the Project Data, where required by Applicable Legislation; and
 - 13.3.8 the Provider shall notify the Recipient without undue delay if it becomes aware of any matter which may materially affect the lawful transfer or continued Processing of the Project Data under this Agreement.
- 13.4 If the Project Data contains Personal Information, the Recipient warrants and undertakes that it shall only process and use the Project Data for the purpose contemplated in this Agreement and shall not disclose, transfer or make the Project Data available to any third party without the prior written consent of the Provider, unless required by law.
- 13.5 The Recipient further undertakes to implement and maintain appropriate security and confidentiality measures, including the safeguards set out in Annexure C, to protect the Project Data against unauthorised access, disclosure, loss or damage, to restrict access to authorised personnel only, to promptly notify the Provider of any actual or suspected unauthorised access or disclosure relating to the Project Data, and to return or securely destroy the Project Data upon termination or expiry of this Agreement, unless retention is required by law.

14. DATA BREACHES

- 14.1.1 Each Party shall promptly notify the other Party upon becoming aware of any actual, suspected or reasonably suspected unauthorised access to, disclosure of, loss of, destruction of, or Processing of the Project Data in breach of this Agreement or Applicable Legislation ("Data Breach").
- 14.1.2 The Party experiencing the Data Breach shall, without undue delay: take reasonable steps to contain, investigate, mitigate and remediate the effects of the Data Breach;
 - 14.1.2.1. implement reasonable corrective measures to prevent a recurrence of the Data Breach;
 - 14.1.2.2. provide the other Party with reasonably available information relating to the nature and extent of the Data Breach and the corrective actions taken; and
 - 14.1.2.3. comply with its obligations under Applicable Legislation, including section 22 of POPIA, where Personal Information has been compromised.
- 14.1.3. The Parties shall reasonably cooperate with one another in relation to the investigation, mitigation and management of any Data Breach affecting the Project Data.

15. DATA SUBJECT RIGHTS

- 15.1 Where the Project Data contains Personal Information, shall reasonably cooperate to facilitate Data Subject rights, requests relating to the Project Data.
- 15.2 The Recipient shall promptly notify the Provider of any request, objection or communication received from a Data Subject relating to the Project Data, including requests to access, correct, delete, restrict or object to the Processing of Personal Information, and the Parties shall cooperate in determining the appropriate response and any action required.

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 In the event of any dispute arising from or in connection with this Agreement, the Parties shall first attempt to resolve the dispute amicably and in good faith through consultation between authorised representatives, within thirty days after the date on which the dispute arose (the Dispute Date).
- 19.2 If the dispute is not resolved in terms of 19.1, the dispute will be referred to mediation for a resolution.
- 19.3 If the dispute remains unresolved, either Party may institute proceedings in a court of competent jurisdiction in the Republic of South Africa, unless the Parties agree otherwise in writing.

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.
- 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 Neither Party shall be liable to the other for indirect or consequential damages arising from this Agreement, except where such damages arise from unlawful Processing, breach of confidentiality, a Data Breach, gross negligence, wilful misconduct or non-compliance with Applicable Legislation.
- 21.3 Nothing in this Agreement limits or excludes either Party's liability to Data Subjects, regulatory authorities or third parties under POPIA or Applicable Legislation.

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: [] and []
- 22.3.2 For the Recipient: [] and []

23. CONFIDENTIALITY

Each Party shall keep all Project Data, donor-related information and Confidential Information strictly confidential and shall implement Appropriate Safeguards to protect such information against unauthorised access, disclosure or use. Neither Party shall disclose Confidential Information to any third party except where required by Applicable Legislation or a court order, where disclosure is necessary for the approved Processing Purpose and authorised under this Agreement, or with the prior written approval of the other Party. The Recipient shall ensure that access to Project Data is limited to authorised persons on a need to know basis and subject to confidentiality obligations and shall not publish, disclose or use Project Data or Confidential Information for any purpose other than the approved Processing Purpose without SANBS's prior written approval. The confidentiality obligations contained in this Agreement shall survive termination or expiry of this Agreement.

26. PUBLICATION AND PUBLICITY

- 26.1. The Recipient shall not publish, present, disclose or otherwise make public any Project Data, research findings or outputs derived from the Project Data without SANBS's prior written approval.
- 26.2. The Recipient shall ensure that no publication, presentation or public disclosure directly or indirectly identifies any Data Subject or discloses confidential Project Data.
- 26.3. The Recipient shall not use SANBS's name, logo or branding in any publication, presentation or public communication without SANBS's prior written approval.

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: []

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: [HOD]

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 [], 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

[]

ANNEXURE B

Project and Processing Purpose

[]

ANNEXURE C

Technical and organisational measures to protect Data

The Recipient is to implement appropriate safeguards to ensure the confidentiality, integrity and security of the data, including:

- Storage of data on secure, password-protected institutional systems
- Access limited solely to authorised members of the research team
- Use of encrypted storage and secure transfer protocols where applicable
- Make regular secure backup copies of the data in an environment provided by the institution
- Follow all data management practices and information security procedures established by the institution
- Dispose of any data received from us at the end of this project according to the privacy and ethics standards that apply to the Provider's use of data. |

ANNEXURE D

Benefit Sharing Arrangement between the Recipient and Provider

•).

No financial or commercial benefit-sharing arrangements are provided for under these agreements. |

ANNEXURE E

Relevant legislation

FRM-PRU-006

1101728 REV 1 (25/07/25)

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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

[NA]