



Between: -

**NETCELLS herein referred to as: Next Biosciences (Proprietary) Limited and
The Client**

1. Interpretation

1.1 Definitions:

- 1.1.1. "the Act" means the South African National Health Act, 61 of 2003 (as amended);
- 1.1.2. "the/this Agreement" means this Cord Blood and/or Cord Tissue Storage and Related Services Agreement, including the Informed Consent, the Client Registration Form and such terms and conditions on the Next Biosciences website which relate hereto;
- 1.1.3. "Authorised Organisation, Institution or Person" means an organisation, institution or person authorised in terms of the Act and Regulation 183 on Stem Cells Banks to conduct the activities referred to in paragraph 2 of Regulation 183 (which are amended from time to time) or any other internationally accredited establishment;
- 1.1.4. "Autologous" means for use by the Child only;
- 1.1.5. "Age of Majority" means, in terms of the Children's Act, 38 of 2005 (as amended), 18 (eighteen) years of age;
- 1.1.6. "Banking fee" is the fee that covers the Processing and Testing of the Stem Cells as well as the Maternal Blood Test costs.
- 1.1.7. "Child" means the child who is born and from whose umbilical cord the Cord Blood and/or Cord Tissue Stem Cells are collected;
- 1.1.8. "the Client" means the Mother subject to the following:-
1.1.8.1. where the Mother is deceased, the Father of the Child shall automatically be deemed from the date immediately prior to the death of the Mother, to be the Client; or
1.1.8.2. where the Mother and Father of the Child are deceased, the legal guardian of the Child shall automatically be deemed to be the Client with effect from the date immediately prior to the date of the last deceased; or
1.1.8.3. where the Child attains the Age of Majority, the Child shall be deemed to be the Client with effect from the date of attainment;
- 1.1.9. "Client Registration Form" means the Next Biosciences Client Registration Form (CLI-UC-FRM-001) required to be completed by the Client in order to register with Next Biosciences for Cord Blood and/or Cord Tissue Storage.
- 1.1.10. "CMV" means Cytomegalovirus- a herpes type virus.
- 1.1.11. "Collection Kit" means a collection bag with two needles (for Cord Blood), a vial with saline solution (for Cord Tissue), tubes for Maternal Blood collection, sterile cleaning material, a temperature insulating bag, a carrier box provided by Next Biosciences to transport the Cord Blood and/or Cord Tissue and any relevant documentation for the Client which is to be completed and returned to Next Biosciences.
- 1.1.12. "Cord Blood" means the Cord Blood that contains the Haematopoietic Stem Cells and other cells extracted from the umbilical cord and placenta of the Child;
- 1.1.13. "Cord Tissue" means the Cord Tissue that contains the Mesenchymal Stem Cells and other cells contained in the umbilical cord;
- 1.1.14. "Competent Person" means a medical practitioner who by qualification is competent to advise and/or administer a Stem Cell transplant;
- 1.1.15. "Cryopreservation" means cooling of the Stem Cells to a temperature of less than -150°Celsius and maintaining it at this temperature;
- 1.1.16. "Days" means any day other than a Saturday, Sunday or official public holiday in the Republic of South Africa;
- 1.1.17. "Donate" means to give, freely and voluntarily.
- 1.1.18. "Failed" sample means when insufficient cells are present for Processing and Storage.
- 1.1.19. "Father" means the man who:-
1.1.19.1. conceived the Child (biological father); or
1.1.19.2. donated the sperm in respect of the Child (biological father); or
1.1.19.3. the legal guardian of the Child, as the case may be (legal father);
- 1.1.20. "Healthcare Professional" means inter alia, an obstetrician, midwife or nurse;
- 1.1.21. "HLA typing / match" means matching of genetic material to maximize the chances of a successful transplant;
- 1.1.22. "H.I.V." means Human Immunodeficiency Virus 1 and 2 – AIDS-causing virus;
- 1.1.23. "Hepatitis B and C" means Hepatitis B and Hepatitis C viruses that affect the liver causing hepatitis, jaundice and liver dysfunction;
- 1.1.24. "HTLV I and II" means Human T-cell Lymphotropic virus, a type of retrovirus;
- 1.1.25. "Informed Consent" means the Informed Consent agreement that is required to be signed by the Client in terms of statute and which is contained in the documents in the Collection Kit;
- 1.1.26. "Maternal Blood" means the blood to be taken from the birth Mother at birth and to be tested for Transmissible Diseases as required in terms of Regulation 183 of the Act and in terms of the American Association of Blood Banks International Accreditation Standards;
- 1.1.27. "Mother" means the woman who:-
1.1.27.1. gave birth to the Child (birth mother); or
1.1.27.2. donated the egg in respect of the Child (biological mother); or
1.1.27.3. is the legal guardian of the Child (legal mother).
- 1.1.28. "Minimum Storage Limits" - Next Biosciences has set its Storage Limits in line with international best practise on the premise that an Umbilical Cord Blood unit should be suitable to treat a patient 10kg and greater. Samples will be assessed according to the CD45+ (Total Nucleated Cell) count, and the CD34+ (Haematopoietic progenitor cell) count.
- 1.1.29. "Next Biosciences" means Next Biosciences (Proprietary) Limited (Registration No. 2004/026428/07), and its respective shareholders, directors, officers, employees and agents including marketing agents and other representatives. Next Biosciences is a company duly registered and incorporated according to the company laws of the Republic of South Africa;
- 1.1.30. "Parents" means collectively the Mother and the Father, who are jointly and severally liable under this Agreement, for any and all amounts owing in terms hereof;
- 1.1.31. "Processing/Process" means all operations involved in the preparation, isolation, extraction, and cryopreservation of the Stem Cells from the Cord Blood and/or Tissue;
- 1.1.32. "Processing Laboratory" means the laboratory where Cord Blood and/or Cord Tissue is processed and the Stem Cells Cryopreserved and Stored;

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- 1.1.33 "Stem Cell(s)" means a cell that has the capability of differentiating into a specialized cell of the body and producing a daughter Stem Cell (i.e. capable of self-renewal) that are extracted from the Umbilical Cord Blood and/or Cord Tissue;
- 1.1.34 "Syphilis" means a contagious disease that is characterized by genital ulcers, skins rashes and lesions that can affect all organs of the body;
- 1.1.35. "Storage/Storing/Store" means maintaining the Stem Cells under appropriate controlled conditions, Cryopreserved at less than -150° Celsius;
- 1.1.36. "Storage Period" means any storage period opted and paid for and decided on by the client, as indicated in the Client Registration Form. Notification of expiry of the contract will be sent in terms of the Consumer Protection Act prior to expiry date.
- 1.1.37. "Storage Facility" means the cryopreservation storage tank in which the Stem Cells are stored and the facility in which it is located;
- 1.1.38. "Sub-optimal Limits" - If a sample is shown to have either or both limits below the minimum limit, the sample is deemed to be "sub-optimal". A sub-optimal unit will be stored, but the Client needs to sign a disclaimer acknowledging that they understand that the sample is sub-optimal. The Client has the option NOT to store the sample and will have to sign a disclaimer to destroy the sample. The Client will be refunded the Banking and Storage fee of that sample.
- 1.1.39. "Signature date" means the date of signature of this agreement by the last party to sign;
- 1.1.40. "Testing/Test" means (subject to the context of use of such term):-
 - 1.1.40.1. Maternal Blood Tests performed on the Mother (in the case of the carrier of the Child) using serology and NAT (nucleic acid) testing and tested for Transmissible Diseases ("Maternal Blood Tests"); and/or
 - 1.1.40.2. Laboratory Tests conducted on the Cord Blood and/or Cord Tissue (including flow cytometry tests and sterility tests) ("Cord Blood and/or Cord Tissue Tests");
- 1.1.41 "Transmissible Diseases" means:-
 - 1.1.41.1. H.I.V. -1 and -2 (Human Immunodeficiency Virus);
 - 1.1.41.2. Hepatitis B and Hepatitis C viruses;
 - 1.1.41.3. Human T- lymphotropic viruses I and II;
 - 1.1.41.4. Syphilis; and
 - 1.1.41.5. CMV (Cytomegalovirus).
- 1.1.42. "Venipuncture" means inserting a needle into a peripheral vein of the birth mother drawing a blood sample;
- 1.2. Any reference to an enactment, regulation, rule or by-law is that enactment, regulation, rule or by-law as at the signature date, and as amended from time to time.
- 1.3. All amounts payable in terms of this Agreement are inclusive of VAT (value added tax) unless otherwise indicated.
- 1.4. This Agreement shall be governed by the laws of the Republic of South Africa.

2. Preamble

- 2.1 The Client has requested and consented to the Registration, Banking and Storage of Stem Cells obtained from Cord Blood and/or Cord Tissue collected from the umbilical cord and placenta at the time of the birth of the Child.
- 2.2 The Client intends to store the Stem Cells acquired from the Cord Blood and/or Cord Tissue, for the sole and exclusive benefit of the Child or any such family member that the Client expressly and in writing elects to donate the Stem Cells to, provided that that person is a suitable match. This is at the discretion of the registered treating physician.
- 2.3 The Client authorises Next Biosciences to Process, Test and Store such Stem Cells in terms of this Agreement and the signed Informed Consent.

It is now agreed:

3. Ownership

- 3.1 Subject to the order of any court of competent jurisdiction, and to the terms and conditions of this Agreement, all rights, title and interest in and to the Cord Blood and/or Cord Tissue and Stem Cells derived therefrom shall, vest exclusively with the Client.
- 3.2 All such rights, title and interest shall cede to the Child, at the date at which the Child attains the Age of Majority.

4. Collection of the Maternal Blood and Cord Blood and/or Cord Tissue

The Client undertakes:-

- 4.1 to consult with the relevant Healthcare Professional, and make the necessary arrangements to ensure that the Maternal Blood and Cord Blood and/or Cord Tissue is collected and properly packaged in the Collection Kit, strictly in accordance with the instructions provided therein by Next Biosciences;
- 4.2 to contact Next Biosciences as soon as reasonably possible after the collection of the Cord Blood and/or Cord Tissue, to ensure that a reasonable time is afforded to Next Biosciences to arrange a courier to transport the Cord Blood and/or Cord Tissue to the Next Biosciences laboratory within 48 (forty eight) hours of the collection of the Cord Blood and/or Cord Tissue.
- 4.3 Next Biosciences shall not be held responsible for any compromise to the integrity of the Cord Blood and/or Cord Tissue during such collection.

5. Transportation of the Cord Blood and/or Cord Tissue Unit

- 5.1 Once the Cord Blood and/or Cord Tissue has been collected, the Client will contact Next Biosciences telephonically to arrange for the courier.
- 5.2 The courier shall transport the Cord Blood and/or Cord Tissue to the Next Biosciences laboratory.
- 5.3 Next Biosciences shall not be held responsible for any compromise to the integrity of the Cord Blood and/or Cord Tissue during such transportation, which is beyond its control.

6. Processing of the Cord Blood and/or Cord Tissue Unit

- 6.1 Next Biosciences undertakes to Process the Cord Blood and/or Cord Tissue and Store the Stem Cells. Next Biosciences reserves the right to refuse to Process and Store the Cord Blood and/or Cord Tissue in the following circumstances:-
 - 6.1.1 the requisite Next Biosciences Storage Agreement and Informed Consent have not been completed, have been incorrectly and/or inadequately filled out or have not been signed, and/or;

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- 6.1.2. the requisite Maternal Health Questionnaire and Birth Identification Form have not been completed, have been incorrectly completed or any information falsely represented and/or inadequately filled out or have not been signed, and/or;
- 6.1.3. if the Cord Blood and/or Cord Tissue cannot be conclusively traced back to the original donor through no fault of Next Biosciences, and/or;
- 6.1.4. if it is suspected that the Cord Blood and/or Cord Tissue has been compromised by contact with bodily fluids from any other person through no fault of Next Biosciences, and/or;
- 6.1.5. the registration fee has not been paid, and/or;
- 6.1.6. the requisite Maternal Blood Tests, have not been complied with, or as a consequence of Testing, the presence of Transmissible Diseases is detected, and/or;
- 6.1.7. the Cord Blood and/or Cord Tissue has been contaminated for any reason; and/or
- 6.1.8. less than 40ml of the Cord Blood is received and after preliminary Testing thereof, is deemed to be sub-optimal;
- 6.1.9. less than 10 cm of the umbilical Cord Tissue is received for storage;
- 6.1.10. once processed, the number and/or viability of the Cord Blood and the viability of the Cord Tissue Stem Cells falls below the minimal requirements for storage as defined by Next Biosciences.

- 8.2.1. continue storing the Stem Cells, in which case Next Biosciences shall invoice the Client for the Storage thereof at its then current rates, which will be market related; or
- 8.2.2. terminate this Agreement in accordance with Clause 14.3.
- 8.3. The Client (or Child obtaining the Age of Majority), in consultation with the Competent Person, may elect to retrieve the Stem Cells from Storage in accordance with Clause 9, as and when deemed necessary.
- 8.4. Next Biosciences shall be entitled to transfer the stored Stem Cells to an Authorised Organisation, Institution or Person in South Africa, internationally or relocate its own storage facility at any time after furnishing the Client with written notice thereof.
- 8.5. In the unlikely event that Next Biosciences ceases to continue trading for any reason, Next Biosciences has contracted its obligations in terms hereof out to an independent Authorised Organisation, Institution or Person, who will ensure the ongoing storage of the Stem Cells in terms of this Agreement.

7. Notification

- 7.1. Once the Cord Blood and/or Cord Tissue Tests have been taken and/or the Stem Cells Cryopreserved and Stored, Next Biosciences shall notify the Client in writing whether:-
 - 7.1.1. the Cord Blood and/or CordTissue Stem Cells are suitable for Storage, in which case they will be stored in terms of this Agreement, or;
 - 7.1.2. the Cord Blood and/or CordTissue Stem Cells are sub-optimal, in which case the Client has the option to elect to:-
 - 7.1.2.1. continue Storage of the Stem Cells, or;
 - 7.1.2.2. destroy the Stem Cells, or;
 - 7.1.2.3. donate them for internal research and/or validation purposes;
 - 7.1.3. the Cord Blood and/or Cord Tissue Stem Cells are deemed as "failed", the Cord Blood and/or CordTissue Stem Cells will be discarded;
 - 7.1.4. In Clause 7.1.2, the Client's express written authorisation therefore will be obtained and the Client will be required to sign the necessary disclaimer;
 - 7.1.5. The Cord Blood Stem Cells are contaminated by a bacteria or fungus during the birth;
 - 7.1.6. In the event that one parent is listed as the preferred contact person, Next Biosciences shall fulfill its responsibility in terms of notification by contacting only that parent. Next Biosciences reserves the right to contact the other parent at its own discretion.

8. Storage of the Stem Cells

- 8.1. Next Biosciences shall Store the Stem Cells according to set requirements as contained in Next Biosciences Cord Blood and/or Cord Tissue Specification Sheets for the Storage Period.
- 8.2. Next Biosciences undertakes to contact the Client 40 (forty) to 60 (sixty) days prior to the expiration of the Storage Period, and the Client will have the option to elect to:-

9. Retrievals for Transplant (Preparation, Transfer and Shipment)

- 9.1. Should the Client wish to retrieve the stored Stem Cells, the Client shall provide Next Biosciences with a minimum of 30 (thirty) day's written notice of the intended transplant date.
- 9.2. The notice in terms of Clause 9.1 shall include details and contact numbers of the Competent Person and Authorised Organization, Institution or Person receiving the Stored Stem Cells and any such other information as may be required by Next Biosciences to transfer the Stem Cells in a manner that ensures their integrity.
- 9.3. In the case of Cord Blood, the Stem Cells are ready for use and will be transported in their frozen state to the place of transplant. The transplant centre may however require the Stem Cells to be washed and if this service is requested to be carried out by Next Biosciences, there will be an additional charge for this service. The Stem Cells will then be transported in a non-frozen state to the place of transplant. In the event of additional technology being offered, these services will be charged for;
- 9.4. In the case of Cord Tissue, additional laboratory work is required to thaw the cord tissue and isolate the Stem Cells from the Wharton's Jelly. Depending on the treatment required, the Mesenchymal Stem Cells will require additional expansion and other laboratory work in order to prepare the therapeutic required. This service is not currently provided by Next Biosciences and the cost of this additional laboratory work will be for the Client's own account. It must be noted that not all umbilical cords yield stem cells that can be cultured, due to patient biological variability.
- 9.5. The Client shall provide Next Biosciences with a signed authorisation within 7 (seven) days of the intended transplant date, by the transplant physician for release of the Stem Cells by Next Biosciences.
- 9.6. Next Biosciences undertakes to release the Stem Cells timeously and to ensure timeous delivery to the transplant centre.
- 9.7. Provided that the Stem Cells are used for transplant, there will be no cost for retrieval, however the cost of transport, testing and all related treatment costs of the Stem Cells will be for the Client's own account.
- 9.8. If the Stem Cells are retrieved at any time prior to the paid-up Storage Period, the Client will be refunded the proportionate amount of unutilised Storage fees.
- 9.9. If the Stem Cells are retrieved and used by the Child or related sibling in a transplant during the first year of Storage, a full refund of the Banking & Storage Fee will be given to the Client.



10. Terms and Conditions of Payment

- 10.1 The total cost of this service is set out in the Client Registration Form and which is to be paid by the Client as follows:-
- 10.1.1 the Registration Fee shall be payable by the Client to Next Biosciences upon registration and prior to the delivery of the Next Biosciences Collection Kit;
- 10.1.2 the Banking & Storage Fee shall be due and payable once the Client has received notification (meaning confirmation of Storage by Next Biosciences together with issue of the Cord Blood and/ or Cord Tissue Test results certificate) of the Storage of the Stem Cells.
- 10.2 Included in the Registration Fee in Clause 10.1.1 above, is the normal cost of a courier. Any additional or special courier charges (public holidays, outlying areas, express delivery) shall be pre-authorized and separately invoiced to the Client.
- 10.3 Included in the Banking & Storage Fee in Clause 10.1.2 above, is the cost for the testing of Maternal Blood. Should the Maternal Blood not be collected at birth and couriered with the Cord Blood and/or Tissue or should there be insufficient blood and additional Maternal Blood is required, the costs of withdrawing the Maternal Blood and couriering it (separately from the Cord Blood and/or Tissue) to the Next Biosciences laboratory, will be for the Client's own account.
- 10.4 The Client may select to pay the Banking and Storage Fee in accordance with a monthly payment plan as indicated in the Client Registration Form. In this case, a compulsory debit order authorisation form needs to be signed and should this be returned by the bank for any reason whatsoever, the Client will be liable to pay a debit order rejection fee of R100 (one hundred Rand). By signing this Agreement the Client confirms that the Parents have the necessary funds and cash flow to service the monthly repayments and that this repayment commitment cannot be deemed to be a reckless extension of the Parent's financial obligations.
- 10.5 All overdue amounts shall bear interest at a rate equivalent to the aggregate of the publicly quoted prime overdraft lending rate charged by the Standard Bank of South Africa plus 2% (two percent).
- 10.6 The Client acknowledges that the failure to effect payment of any fee or cost timeously may result in the termination of this Agreement by Next Biosciences in terms of Clause 14.3, after written notice to the Client.

11. Warranties

- 11.1 The Client acknowledges that Next Biosciences has not made and does not make any representations or warranties to the Client, whether express or implied, of any kind or nature, including, without limitation of the foregoing, with respect to:-
- 11.1.1 the suitability of the Cord Blood and/or CordTissue or Stem Cells derived therefrom for the future treatment of any disease, illness, injury or any other medical affliction;
- 11.1.2 the successful treatment of any disease, illness, injury or any other medical affliction through Stem Cell transplantation;

- 11.1.3 the advantages of transplanting Stem Cells derived from Cord Blood and/or CordTissue over other types of treatment using Stem Cells derived elsewhere.

12. Limitation of Liability

- 12.1 Notwithstanding anything that may be construed to the contrary in terms of Clause 13, the maximum amount of any and all liability which Next Biosciences (and its respective shareholders, directors, officers, employees and agents, including marketing agents and other representatives) may incur to the Client in terms of this Agreement, or in respect of any and all actions or omissions of Next Biosciences under any and all circumstances shall be the total amount paid by the Client to Next Biosciences as set out hereunder.
- 12.2 The Client further acknowledges that Next Biosciences shall not be held responsible for the actions of any other party, which includes, but is not limited to: physicians, nurses, midwives, the birthing hospital or medical facility, hospital or medical facility staff, the couriers and transporters of the Cord Blood and/or CordTissue and Stem Cells.
- 12.3 Next Biosciences shall not be liable to the Client or any other third party for any direct, indirect special, punitive, consequential or incidental damages or losses.
- 12.4 Next Biosciences shall not be held liable for any loss or damage to the Cord Blood and/or CordTissue or Stem Cells derived therefrom which may be caused by any event beyond its control and/or which is considered to be a force majeure event.

13. Assignment

Next Biosciences may:-

- 13.1 transfer the location of the Processing Laboratory, and/or;
- 13.2 transfer the Storage Facility, and/or;
- 13.3 cede and assign any and all of its rights and obligations under this Agreement to an Authorised Organisation, Institution or Person after prior written notice is furnished to the Client on condition that the Client is given full details of the Authorised Organisation, Institution or Person in advance.

The Client may:-

- 13.4 after giving prior written notice to Next Biosciences, transfer to one or more persons his or her rights under this Agreement at any time, in particular upon the Client's death or disablement. No transfer shall take effect until such time as the transferee or successor consents, in writing, to the transfer and thus agrees to be bound by this Agreement. Should the Client be deceased or disabled and should there be no transferee or successor to the Client's rights, Next Biosciences may, in its entire discretion, recognise the authority of any other person to represent the Client.

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14. Termination

- 14.1 Next Biosciences reserves the right to terminate this Agreement in the following circumstances:-
- 14.1.1 failure of the Client to provide the Cord Blood and/or Cord Tissue, and/or the Maternal Bloods and/or the information that Next Biosciences requires for the performance of its services or compliance with the relevant law, regulations or accreditation;
 - 14.1.2 receipt of the results of the Maternal Blood Tests, and according to Next Biosciences' internal quality and accreditation requirements or the relevant government regulations or statute, indicating that the Cord Blood and/or Cord Tissue is not appropriate for Storage;
 - 14.1.3 should Next Biosciences be unable to extract any Stem Cells from the Cord Blood, or should the Cord Blood yield insufficient Stem Cells according to Next Biosciences internal quality and accreditation requirements, then no Storage shall take place, and accordingly, the Client shall not incur any liability in regard to the Banking & Storage Fee; in the event that any payment due has not been received within 30 (thirty) days after the date of written notification to the Client to effect payment;
 - 14.1.4 in the event of the Client not responding to Next Biosciences within 6 (six) months after the expiration date of the Storage Period, despite Next Biosciences having notified the Client at least twice, within 6 (six) months prior to the date of expiration and once within the 6 (six) months after expiration.
- 14.2 The Client may terminate this Agreement at any time upon written notice to Next Biosciences. In this instance the Client will be refunded the proportionate unutilised portion of the Registration, Banking and Storage fee.
- 14.3 On termination, the Client can elect that stored Stem Cells are:
- 14.3.1 Transferred to an alternative storage location at the client's cost (once all outstanding fees have been paid, including the withdrawal fee); or
 - 14.3.2 Destroyed; or
 - 14.3.3 Donated for internal research and/or validation purposes.
- 14.4 Notwithstanding the foregoing, this Agreement will be terminated on withdrawal by the Client of all his/her stored Stem Cells for transplant and any unutilised Storage fees will be refunded.
- 14.5 The ownership of the biological material stored vests entirely with the Client. The Client may therefore request that the stored material be released for burial. All aspects of the South African National Health Act 2003 (as amended) or any superseding law must be adhered to at all times during release of the material.

15. Maintenance and Protection of Client Information

- 15.1 The Client undertakes to provide Next Biosciences with complete and accurate contact information of the Client and the Child, in writing, as is required by Next Biosciences. The Client also agrees to provide any other information that may be required by Next Biosciences for the Testing of the Cord Blood and/or Cord Tissue, Maternal Blood, performance of its services, compliance with the laws, regulations, permits and certifications, as well as for the proper identification of the Client and the Child.

- 15.2 If any information that the Client has provided to Next Biosciences changes or is no longer valid, the Client acknowledges that it is his/her/their responsibility to advise Next Biosciences promptly, and in writing, of all such changes or invalidity.
- 15.3 Next Biosciences shall use all reasonable endeavours to keep confidential all information relating to the Client and/or Child. Personal information will only be held in Next Bioscience's hard copy files in a locked location and on our secure electronic database and back-up files.
- 15.4 Information or any test results will only be released to the Client and/or Child's Healthcare Professional and/or Competent Person for their internal confidential records or otherwise as requested by the Client and/or Child in writing. Information may also be released for the purposes of performing Next Biosciences' obligations under this Agreement. None of the information held on Next Biosciences' database will otherwise be disclosed or released to any third parties other than those required by law.
- 15.5 By signing this Agreement, the Client consents to Next Biosciences holding the Client and/or Child's personal data for the purposes of performing Next Biosciences' obligations under this Agreement.
- 15.6 It is the responsibility of the parents to notify Next Biosciences if their Child is diagnosed with any genetic or serious medical condition that may affect the use of the Stem Cells in the future.
- 15.7 Next Biosciences may, from time to time, send out electronic information by email or SMS to the Client, to update the Client on developments regarding Next Biosciences and the Stem Cell industry in general. The Client may at any time opt out from receiving this communication by written notification.

16. Domicilium and Notices

- 16.1 The parties choose as their domicilium citandi et executandi their respective addresses set out on the Next Biosciences website (in respect of Next Biosciences) and the Informed Consent (in respect of the Client).

17. Disputes

- 17.1 In the event of any dispute, disagreement or claim arising between the Next Biosciences and the Client concerning this agreement, the parties shall attempt to resolve the dispute by way of negotiation. This entails that one party invites the other party, in writing, to a meeting to attempt to resolve the dispute within 14 (fourteen) days from date of the invitation.
- 17.2 Failing such a resolution, the dispute, if arbitrable in law, shall be finally resolved in accordance with the Rules of the Arbitration Foundation of Southern Africa (AFSA) by an arbitrator or arbitrators appointed by the Foundation.
- 17.3 The provisions of this clause shall not preclude either the Client or Next Biosciences from access to an appropriate court of law for interim relief in respect of urgent matters by way of an interdict, or mandamus pending finalisation of this dispute resolution process.



18. Entire Agreement

18.1 This Agreement, the appendices, all references to terms and conditions contained on the Next Biosciences website and the explanatory terms as contained in the information booklet within the Collection Kit, constitute the entire Agreement between the parties and no warranties, representations or guarantees not contained or recorded herein shall be of any force or effect.

19. Variation and Cancellation

19.1 No agreement varying, adding to, deleting from or cancelling this Agreement shall be effective unless reduced to writing and signed by or on behalf of the parties.

20. Indulgences

20.1 No indulgence granted by a party shall constitute a waiver of any of that party's rights under this Agreement.

Signed

Signed by Parents

Chief Executive Officer
Next Biosciences (PTY) LTD

.....
Mother

.....
Father

.....
Date

Client No.:

Next Biosciences (Pty) Limited
Registration No.: 2004/026428/07
Galaxy Building
International Business Gateway
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Midrand, 1685, Johannesburg
PO Box 1664, Parklands 2121

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www.nextbio.co.za



Mother's Particulars

Full Names

ID Number

I am the Mother of the unborn child ("my Child") whose Cord Blood and/or Cord Tissue is to be collected at the time of its birth.

I am entitled and duly authorized to sign this document on behalf of my Child.

I authorize Next Biosciences to Receive, Process and Test the Cord Blood and/or Cord Tissue from the placenta and umbilical cord and to Cryopreserve and Store the Stem Cells contained therein (collectively, "Cord Blood and/or Cord Tissue") in accordance with the accompanying Cord Blood / Tissue Storage and Related Services Agreement.

Should the mother be unable to sign due to medical reasons, the father of the unborn child may sign consent.

1. What are Stem Cells?

Stem Cells are the earliest cells of a developing embryo that differentiate to form all the cells of the human body. Researchers have found that Stem Cells remain in our bodies to maintain and repair our organs throughout life. Stem Cells are also found in the blood and tissue of the umbilical cord and placenta of newborn babies, which are normally discarded after birth.

Cord Blood contains blood forming Haematopoietic Stem Cells ("HSCs") and the main uses of these are in the treatment of the following groups of disease:

- **Malignancies** (Leukaemia, lymphoma, multiple myeloma, solid tumours);
- **Anaemia** (Fanconi's anaemia, sickle cell disease, Thalassaemia);
- **Bone marrow failures** (Aplastic anaemia, pancytopenia);
- **Immunodeficiency** (SCID, Kostmann syndrome, Wiskott-Aldrich syndrome, lymphoproliferative disorder, ataxia telangiectasia, Di George syndrome);
- **Inborn errors of metabolism** (Adrenoleukodystrophy, Gaucher's disease, Krabbe disease, Niemann-Pick syndrome, Tay-Sachs disease).

Cord Tissue is rich in Mesenchymal Stem Cells ("MSCs"). MSCs are being employed in research environments for a variety of aesthetic and medical conditions that include:

- **Skin regeneration** (wound healing and burns, scar remodeling, pigmentation disorders);
- **Neurology** (nerve regeneration and repair);
- **Orthopaedics** (cartilage, bone repair);
- **Sports injury** (tendon, ligament repair);
- **Cardiology** (heart muscle regeneration);
- **Reconstructive surgery** (fat grafts); and
- Other possible clinical areas.

2. How is the Cord Blood Collected?

- 2.1 A Collection Kit is provided for the collection of the Cord Blood, which is taken to the birth of my Child and handed over to the Healthcare Professional that will perform the collection.
- 2.2 The collection bag is packaged in a sterile manner and needs to be opened on a sterile tray.
- 2.3 After my Child is born (via normal vaginal delivery or Caesarian section) the umbilical cord is clamped and my child is safely handed over.

- 2.4 The Healthcare Professional will clean the umbilical cord with a suitable antiseptic solution to limit contamination but this does not eliminate this risk. Then the needle of the collection bag is inserted into the umbilical vein of the umbilical cord. The bag will fill with Cord Blood. Once the flow of blood stops, the needle will be removed from the vein.
- 2.5 The clamps are closed and a knot will then be tied on the main line of the tubing just above the bag. The Cord Blood bag will be packed into the temperature insulating bag and placed back into the Collection Kit for courier to the laboratory.

3. How is the Cord Tissue Collected?

- 3.1 Cord Tissue is collected after the Cord Blood is collected and the placenta delivered.
- 3.2 The Healthcare Professional will clean the cord with a suitable antiseptic to limit contamination but this does not eliminate the risk of contamination in the final product. A 10-15cm piece of umbilical cord is cut and will be placed inside the tube provided in the Collection Kit to be couriered to the laboratory.

4. Collection Risks and Consent

- 4.1 I will request that my Healthcare Professional collects the Cord Blood and/or Cord Tissue using the Collection Kit provided by Next Biosciences;
- 4.2 I understand that, under normal circumstances, collection should never interfere with the birthing process and cause me no discomfort or pain;
- 4.3 I understand that there may be complications at birth that will make it impossible or problematic to collect the Cord Blood and/or Cord Tissue, and for these reasons my Healthcare Professional would be entitled to refuse to collect the Cord Blood and/or Cord Tissue. I will not hold Next Biosciences responsible for my Healthcare Professional's decision not to collect the Cord Blood and/or Cord Tissue at the time of the birth.
- 4.4 I shall have the opportunity to deny or withdraw consent to the procurement procedures without affecting my access to or quality of medical care.

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- 4.5 I understand that there is a risk of bacterial and/or fungal contamination when collecting Cord Blood and/or Cord Tissue. The contaminating bacteria and/or fungus is usually a naturally occurring contaminant of the birthing canal. Next Biosciences tests every cord blood unit for these contaminants.
- 4.6 I understand that the Cord Blood and/or Cord Tissue collected may be insufficient and/or not viable for storage and/or transplantation and/or any other purpose.
- 4.7 I record and agree that I have been fully informed about the procedure for collecting Cord Blood and/or Cord Tissue and hereby consent to allow my Healthcare Professional to collect the Cord Blood and/or Cord Tissue after the birth of my Child and to furnish it to Next Biosciences for Testing, Processing and Storage.

5. Risks Involved in Storage and Use

- 5.1 I understand that there are no assurances that any benefits of storing my Child's Stem Cells will be obtained;
- 5.2 I understand that the transplantation of Cord Blood Stem Cells and/or Cord Tissue is a relatively new procedure that may offer possible future benefits to my Child and other beneficiaries in treating certain diseases;
- 5.3 I understand that my Child's Cord Blood and/or Cord Tissue Stem Cells are stored exclusively for use for my Child or any family member who is an HLA-type match that I, the Mother of the Child or the Child, decides to donate the Stem Cells to;
- 5.4 I understand that Next Biosciences does not do HLA-typing of the Cord Blood prior to storage; and will therefore not be able to suggest donation of my Child's Cord Blood to persons not known to me, as compatibility is not known. Should HLA testing be requested and performed the result will not be placed on a donor registry or donation suggested;
- 5.5 I understand that there are several instances in which the use of my Child's Cord Blood and/or Cord Tissue Stem Cells for herself/himself would not be recommended (for example certain inherited diseases);
- 5.6 I acknowledge that there are alternative sources of Stem Cells such as bone marrow, peripheral (circulating) blood and adipose tissue, that could be accessed from my child or possibly a suitable matching donor, should I decide not store my Child's own Cord Blood and/or Cord Tissue Stem Cells;
- 5.7 Pertaining to Cord Blood Stem Cells only,
 - 5.7.1 I understand that the likelihood of using my Child's Cord Blood Stem Cells is limited and that it is highly likely that they may never be used;
 - 5.7.2 Even though there is a good chance of a suitable match, I understand there are no guarantees that the Cord Blood Stem Cells will be a match for other family members;
 - 5.7.3 I understand that Cord Blood Stem Cells contaminated by bacteria and/or fungus can be stored, but there is no guarantee that the transplanting physician will accept the sample for transplant which will be dependent on the clinical situation at the time. I acknowledge that we do not know what future medicine will bring and perhaps this contamination will not be an issue in the future.
- 5.8 Pertaining to Cord Tissue Stem Cells only,
 - 5.8.1 I understand that there is the likelihood that my Child's Cord Tissue Stem Cells may never be used;
 - 5.8.2 I understand that Cord tissue is processed with antibiotics (specifically including penicillin) and may be exposed to enzymes and other possible allergens during processing, Stem Cell extraction, proliferation and storage. These components are

washed out before therapeutic use, but trace amounts may still be present in the final product. Transplant may be contraindicated based on the recipient's allergy profile. This is based on current known best practice;

- 5.8.3 If the Cord Tissue Stem Cells are required, I understand that the cord tissue will need to be thawed and the Stem Cells extracted. There is no guarantee on the number and viability of the cells that will be extracted as not all cord tissue yields stem cells that can be cultured, due to patient biological variability. I further understand that additional laboratory work will be required to expand the isolated cells to produce sufficient cells for therapy. In this instance blood serum from the Child may be required to culture the cells and consequently a sample of my child's blood will need to be drawn for the process. Depending on the specific treatment required other laboratory work may be additionally required. Next Biosciences doesn't currently offer this service and the cost of this extraction and culture by another laboratory, will be for my own account, and/or that of my Child.

- 5.9 I understand that the Cord Blood and/or Cord Tissue Stem Cell harvests are typically low in volume and could be insufficient (without expansion or supplementation) for a transplant.
- 5.10 I understand that there is a documented and unavoidable cell loss during the Cryopreservation and thawing process, even though Next Biosciences uses internationally accepted methodology, we are therefore not able to determine post thaw cell yield at time of Cryopreservation.
- 5.11 As this science is relatively new, the longest recorded period of viable thawed Stem Cells has been for 23 (twenty three) years (Broxmeyer H.E et al; Hematopoietic stem/progenitor cells, generation of induced pluripotent stem cells and isolation of endothelial progenitors from 21- to 23.5-year cryopreserved cord blood; Blood. 2011 May 5; 117(18): 4773-4777. Pre-published online 2011 March 10. doi : 10.1182/blood-2011-01-330514), and as such, I understand that there are no guarantees that the Cord Blood and/or Cord Tissue can actually be stored indefinitely.

6. Maternal Blood Testing and Health Questionnaire

- 6.1 Maternal Blood Testing is required for Cord Blood and/or Cord Tissue Stem Cell storage according to the South African National Health Act (61/2003) Regulation on Stem Cell Banks (Reg 183)
- 6.2 I agree to fill out the Maternal Health Questionnaire in the Collection Kit and return the form to Next Biosciences with the Collection Kit. I understand that this part of my medical history will be reviewed by the appropriate Next Biosciences staff.
- 6.3 I agree to provide information related to our family's medical and genetic history, if available.
- 6.4 I understand that I must have a sample of my own blood taken by venipuncture (the usual method for blood tests) within 7 Days prior to delivery or 7 Days after the delivery, in order to be tested for Transmissible Diseases.
- 6.5 I am responsible for and will ensure that I have my blood sample taken by a Healthcare Professional at the hospital or clinic where I am delivering my baby. The blood sample will be taken in the blood tests tubes provided by Next Biosciences in the Collection Kit.
- 6.6 I understand that there is a slight risk of bruising, discomfort, inflammation, or infection at the site of the blood draw.

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- 6.7 My blood will be tested for certain infectious diseases, including:
 - 6.7.1 Human Immunodeficiency Virus (HIV) -1 and -2 (AIDS causing virus);
 - 6.7.2 Hepatitis B and Hepatitis C Viruses (viruses that affect the liver causing hepatitis, jaundice and liver dysfunction);
 - 6.7.3 Syphilis (a contagious disease that is characterized by genital ulcers, skin rashes and lesions that can affect all organs of the body).
 - 6.7.4 Cytomegalovirus (a common herpes type virus that goes unnoticed in healthy individuals but can be life-threatening in immune-compromised patients).
 - 6.7.5 Human T-cell Lymphotropic virus (HTLV I/II) (a sexually transmitted virus that can cause adult T cell leukaemia/lymphoma as well as neurological disorders such as paralysis of lower limbs. It can also be transmitted via blood or body fluid transmission).
- 6.8 Next Biosciences' medical doctors will review the results of the Testing.
- 6.9 I understand that abnormal results will be reported to me. Should my test results be positive for any of the following: HIV, Hepatitis B or C, HTLV I/II or Syphilis, I will have a confirmatory test done i.e. another sample of my blood will be taken and tested. If these confirmatory tests are positive, the Cord Blood Stem Cells and/or the Cord Tissue will be stored in permanent quarantine with other samples of the same infectious disease. I understand that I will be required to sign an Addendum to this Informed Consent should my blood test positive for the above mentioned infectious diseases. The cost of the confirmatory blood tests will be for my own account. CMV positive test results will not preclude the storage of the Cord Blood Stem Cells and/or the Cord Tissue.
- 6.10 I hereby consent to Next Biosciences' disclosure of the results of my blood tests to my Healthcare Professional, to any other Stem Cell storage facility to which I have authorized transfer of the Stem Cells, to the transplantation service in the event the Stem Cells are released for use, and to any government agency to which Next Biosciences may be required to report such results under applicable law and regulations.

7. Testing

- 7.1 **Cord Blood**
I understand that:
 - 7.1.1 Next Biosciences will undertake tests on my Child's Cord Blood to ascertain the nature, number and viability of the Stem Cells to be Cryopreserved;
 - 7.1.2 Prior to the treatment of the intended recipient of the Cord Blood Stem Cells, should the recipient not be the same person from whom the Stem Cells were obtained, the Cord Blood will need to be tested for an HLA-match, which costs are for my account, and/or that of my Child ;
 - 7.1.3 Next Biosciences will not release the Stem Cells until Next Biosciences has received the HLA-typing results (if required) and approval from the recipient's transplant physician and parent(s);
 - 7.1.4 Reference samples of the Cord Blood will be Stored for future testing of HLA-type, and cell count and viability upon thawing. These are small in quantity and do not significantly affect the overall number of Cord Blood Stem Cells stored.
- 7.2 **Cord Tissue**
I understand that:
 - 7.2.1 Viability testing will be carried out on the Cord Tissue prior to storage.

- 7.2.2 Once the cells are required for therapy and have been removed from storage and the Stem Cells isolated from the Cord Tissue, they will be tested for quantity and quality according to the requirements set by the transplanting facility. Due to rapidly changing clinical practice, the test results may not meet their requirements at that time.

8. Preparation of Stem Cells for Transplant

- 8.1 Cord Blood Stem Cells may require washing after thawing, for transplantation. They will be transported in either their thawed or frozen state (to be thawed at the bedside) and infused into the patient's blood stream.
- 8.2 Cord Tissue requires further preparation for transplant. The mesenchymal rich fraction of the Wharton's Jelly is stored and as such the Cord Tissue Stem Cells are not extracted from the cord tissue before storage. When required for transplant, the cord tissue will be transferred to another laboratory for the additional work required. There is an additional cost for this laboratory work which will be for my account, and/or that of my Child.

9. Disclosure of Health Information

- 9.1 Next Biosciences will maintain the confidentiality of my health information that I provide to them concerning myself and my Child.
- 9.2 I do however understand that health care providers may need such information to provide treatment to me and/or my Child and/or matching relative and that government agencies may be entitled to obtain such information under applicable law and regulations.
- 9.3 I authorize Next Biosciences to disclose such information to health care providers that are treating me and/or my Child and/or matching relative; and to government agencies as may be required under applicable law and regulations.
- 9.4 I authorize Next Biosciences to disclose such information for research purposes in an anonymous manner and always maintaining Next Biosciences' confidentiality obligations in terms hereof.

10. Cord Blood Disposal

- 10.1 If the Cord Blood that is collected has low cell count or low cell viability and is not recommended for Storage according to Next Biosciences storage limits and standards, I will be informed by Next Biosciences about the possible options available to me.
- 10.2 I have the choice to continue Storage and will sign a disclaimer in order to do so, or if I decide to discontinue Storage I will sign a disclaimer to either donate the Cord Blood for internal research/validation purposes or to discard it.

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10.3 I understand that Next Biosciences will retain confidentiality of the sample and that the Stem Cells will not be used for any other purposes than those set out in the Storage Agreement and Informed Consent.

11. Validation

11.1 I authorize Next Biosciences to Cryopreserve and Store any excess Cord Blood and/or Cord Tissue (that would normally be discarded) and routinely perform validation testing on this, to ensure the ongoing viability of the stored Cord Blood and/or Cord Tissue.

12. Disclosure of Information

12.1 I authorize Next Biosciences to use (research, study and publish) information obtained from the Collection, Testing, Processing, Cryopreservation and Storage of the Cord Blood and/or Cord Tissue Stem Cells in an anonymous manner.

Signed

Chief Medical Officer
Next Biosciences (PTY) LTD

13. Information Services

- 13.1 I have received information regarding the risks, benefits, discomforts, and alternatives to Stem Cell Collection, Testing, Processing and Storage.
- 13.2 I am entitled to donor advocacy services in the form of access to the Next Biosciences' medical staff to ask questions and have these answered to my satisfaction. I am also able to ask my own health care provider questions should I need to.
- 13.3 I have received a written copy of Next Biosciences' contact information for any questions related to cellular therapy products.

14. Warranties and Limitation of Liability

14.1 I confirm that I have read, understood and agreed to be bound by all parts of the Cord Blood/ Tissue Storage and Related Services Agreement, in particular Clause 11 and 12 of the Cord Blood/Tissue Storage and Related Services Agreement.

Signed by Parents

The Client

Date

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