



# **Netcells Private Stem Cell Banking** Cord Blood/Tissue Banking and Related Services Agreement



## Agreement between -NETCELLS STEM CELLS (PTY) LTD herein referred to as: Netcells 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).
- 11.2. "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 Netcells website which relate hereto.
- 1.1.3. "Ampath" is Ampath Laboratories. Ampath is the trading name for a group of amalgamated pathology practices that previously functioned independently and subsequently joined to form the incorporated practices of Drs Du Buisson, Kramer, Swart, and Bouwer.
- 1.1.4. "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 occasionally) or any other internationally accredited establishment.
- 1.1.5. "Autologous" means for use by the Child only.
- 1.1.6. "Age of majority" means, in terms of the Children's Act, 38 of 2005 (as amended), 18 (eighteen) years of age.
- 11.7. "Processing Fee" is the fee that covers the processing and testing of the stem cells, as well as the maternal blood test costs.
- 1.1.8. "Child" means the Child who is born and from whose umbilical cord the cord blood and/or cord tissue stem cells are collected.
- 1.1.9.
   "the Client" means the Mother, subject to the following:

   1.1.9.1.
   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.
  - 1.1.9.2. Where the Mother and Father of the Child are both 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.
  - 1.1.9.3. Where the Child attains the age of majority, the Child shall be deemed to be the Client with effect from the date of attainment.
- 11.10. "Client Registration Form" means the Netcells Client Registration Form (CLI-UC-FRM-001) required to be completed by the Client in order to register with Netcells for cord blood and/or cord tissue storage.
- 1.1.11. "CMV" means cytomegalovirus, a herpes type virus.
- 1.1.2. "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 Netcells to transport the cord blood and/or cord tissue, and any relevant documentation for the Client which is to be completed and returned to Netcells.

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- 1.1.13. "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.
- 1.1.4. "Cord tissue" means the cord tissue that contains the mesenchymal stem cells, and other cells contained in the umbilical cord.
- 1.1.5. "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.
- 1.1.16. "Commissioning Parent" means the Parent wishing to have a child as a result of an agreement of surrogacy.
- 1.1.17. "Competent person" means a medical provider who by qualification is competent to advise and/or administer a stem cell transplant.
- 1.1.18. "Cryopreservation" means cooling of the stem cells to a temperature of less than -150 degrees celsius and maintaining it at this temperature.
- 1.1.19. "Days" means any day other than a Saturday, Sunday, or official public holiday in the Republic of South Africa.
- 1.1.20. "Donate" means to give, freely and voluntarily.
- 1.1.21. "Failed" sample means when insufficient cells are present for processing and storage.
- 11.22. "Father" means the man who:

   11.22.1. Conceived the Child (biological father) either through natural conception or articifical reproductive technologies (ART); or

   11.22.2. The legal guardian of the Child, as the case may be (legal father).
- 1.1.23. "HLA typing/match" means matching of genetic material to maximise the chances of a successful transplant.
- 1.1.24. "H.I.V." means human immunodeficiency virus 1 and 2, an AIDS-causing virus.
- 1.1.25. "Hepatitis B and C" means hepatitis B and hepatitis C viruses that affect the liver causing hepatitis, jaundice, and liver dysfunction.
- 1.1.26. "HTLV I and II" means human T-cell lymphotropic virus, a type of retrovirus.
- 1.1.27. "Immediate family" refers to the clients closest relatives, including their parents, siblings, and children.
- 1.1.28. "Informed Consent" means the Informed Consent Form that is required to be signed by the Client in terms of statute and which is contained in the documents in the collection kit.
- 1.1.29. "Maternal bloods" 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.
- 1.1.30. "Mother" means the woman who:
  - 1.1.30.1. Gave birth to the Child (birth mother); or
  - 1.1.30.2. Conceived the Child (biological mother) through artificial reproductive technologies (ART); or
  - 1.1.30.3. Is the legal guardian of the Child (legal mother).
- 1.1.31. "Minimum storage limits" Netcells has set its optimal storage limits in line with international best practice 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. These counts must be equal to, or over 100 000 000 and 200 000 respectively.



- 11.32. "Netcells" means Netcells Stemcells (Proprietary) Limited (Registration No. 2016/01111/07), and its respective shareholders, directors, officers, employees, and agents, including marketing agents, and other representatives. Netcells is a company duly registered and incorporated according to the company laws of the Republic of South Africa.
- 1.1.33. "Surrogate Mother" means an adult woman who enters into a surrogate motherhood agreement with a commissioning parent.
- 11.34. "Partial surrogacy" refers to surrogacy where the Surrogate Mother is the genetic parent of the Child.
- 11.35. "Processing/process" means all operations involved in the preparation, isolation, extraction, and cryopreservation of the stem cells from the cord blood and/or tissue.
- 11.36. "Processing laboratory" means the laboratory where cord blood and/or cord tissue is processed, and where the stem cells are cryopreserved and stored.
- 1.1.37. "SABMR" means the South African Bone Marrow Registry, which is a non-profit organisation which conducts highly specialised searches to find matching bone marrow donors for critically ill South African children and adults.
- 11.38. "Recipient" means a patient in need of a stem cell transplant as identified by SABMR.
- 1.1.39. "SANBS" means South African National Blood Service which is a non-profit organisation which provides blood products and services.
- 11.40. "Stem cell(s)" means a cell that has the capability of differentiating into a specialised cell of the body and producing a daughter stem cell (i.e., capable of self-renewal) that is extracted from the umbilical cord blood and/or cord tissue.
- 1.1.41. "Syphilis" means a contagious disease that is characterised by genital ulcers, skin rashes, and lesions that can affect all organs of the body.
- 1.1.42. "Healthcare provider" means inter alia, an obstetrician, midwife, or nurse.
- 1.1.43. "Storage/storing/store" means maintaining the stem cells under appropriate controlled conditions, cryopreserved at less than -150 degrees celsius.
- 1.1.44. "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.
- 1.1.45. "Storage facility" means the cryopreservation storage tank in which the stem cells are stored, and the facility in which it is located.
- 1.1.46. "Suboptimal limits" If a sample is shown to have either or both limits below the minimum limit, the sample is deemed to be "suboptimal". 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 Processing and Storage Fee of that sample.
- 1.1.47. "Signature date" means the date of signature of this Agreement by the last party to sign.
- 1.1.48. "Testing/test" means (subject to the context of use of such term):
  - 1.1.48.1 Maternal blood tests performed on the Mother (in the case of the carrier of the Child) using serology and NAT (nucleic acid) testing and that is tested for transmissible diseases ("maternal blood tests"); and/or

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- 1.1.48.2. 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").
- 1.1.49. "Transmissible diseases" means:
  - 1.1.49.1. H.I.V. -1 and -2 (human immunodeficiency virus)
  - 1.1.49.2. Hepatitis B and hepatitis C viruses
  - 1.1.49.3. Human T-lymphotropic viruses I and II
  - 1.1.49.4. Syphilis
  - 1.1.49.5. CMV (cytomegalovirus)
- 1.1.50. "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, processing, 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 Netcells 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/TISSUE

#### The Client undertakes:

- 4.1. To consult with the relevant healthcare provider, 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 Netcells.
- 4.2. To contact Netcells 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 Netcells to arrange a courier to transport the cord blood and/or cord tissue to the Netcells laboratory within 48 (forty eight) hours of the collection of the cord blood and/or cord tissue.

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4.3. Netcells 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 by the healthcare provider, the Client will contact Netcells telephonically to arrange for the courier.
- 5.2. The courier shall transport the cord blood and/or cord tissue to the Netcells laboratory.
- 5.3. Netcells 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. Netcells undertakes to process the cord blood and/or cord tissue and store the stem cells. Netcells 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 Netcells Agreement and Informed Consent have not been completed, have been incorrectly and/or inadequately filled out or have not been signed; and/or
  - 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 Netcells; 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 Netcells; and/or
     6.1.5. The Registration Fee has not been paid; 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, subject to further options as contemplated in clause 7.1.3 below; and/or
    6.1.9. Less than 10cm of the umbilical cord tissue is received for
  - storage; and/or
    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 Netcells.

## 7. NOTIFICATION

- 71. Once the cord blood and/or cord tissue tests have been taken and/or the stem cells cryopreserved and stored, Netcells shall notify the Client in writing whether:
  - 71.1. The cord blood and/or cord tissue stem cells are suitable for storage, in which case they will be stored in terms of this Agreement; or
  - 71.2. The cord blood and/or cord tissue stem cells are sub-optimal according to the minimum storage limits defined, in which case the Client has the option to elect to:

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- 7.1.2.1. Continue storage of the stem cells; or
- 7.1.2.2. Destroy the stem cells; or
- 71.2.3. Donate them for internal verification and/or validation purposes.
- 71.3.
   The cord blood and/or cord tissue stem cells are deemed as 'failed', and will be discarded.
- 71.4. In Clause 71.2, the Client's express written authorisation will, therefore, 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<br/>fungus during the birth.
- 71.6. In the event that the Client has registered to bank both the cord blood and/or cord tissue and either the cord blood and/or cord tissue are sub-optimal, the Client will still be liable for payment of the Processing and Storage Fees of the optimal cord blood and/or cord tissue.
- 71.7. In the event that one parent is listed as the preferred contact person, Netcells shall fulfil its responsibility in terms of notification by contacting only that parent. Netcells reserves the right to contact the other parent if legally required and/or at its own discretion.

## 8. STORAGE OF THE STEM CELLS

- 8.1. Netcells shall store the stem cells according to set requirements as contained in Netcells Cord Blood and/or Cord Tissue Specification Sheets for the storage period.
- 8.2. Netcells undertakes to contact the Client 6 (six) months prior to the expiration of the storage period, and the Client will have the option to elect to:
  - 8.2.1. Continue storing the stem cells, in which case Netcells 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. In the event that Netcells is unable to reach the Client utilising the contact details provided in the Informed Consent, Netcells will store the stem cells for an additional 12 (twelve) months following the expiration of the storage period.
- 8.4. If the Client fails to contact Netcells within the 12 (twelve) months following the expiration of the storage period, Netcells will proceed to terminate this Agreement and either discard the stem cells, or alternatively, use the sample for internal verification and/or validation endeavours. The Client hereby irrevocably and unconditionally consents to this.
- 8.5. 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.
- 8.6. Netcells shall be entitled to transfer the stored stem cells to an authorised organisation, institution, or person in South Africa or internationally, or relocate its own storage facility at any time after furnishing the Client with written notice thereof.
- 8.7 In the unlikely event that Netcells ceases to continue trading for any reason, Netcells 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.



## 9. RETRIEVALS FOR TRANSPLANT (PREPARATION, TRANSFER, AND SHIPMENT)

- 9.1. Should the Client wish to retrieve the stored stem cells, the Client shall provide Netcells 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 organisation, institution, or person receiving the stored stem cells and any such other information as may be required by Netcells 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 Netcells, 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 Netcells and the cost of this additional laboratory work will be from 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 Netcells with a signed authorisation, within 7 (seven) days of the intended transplant date, by the transplant physician for release of the stem cells by Netcells.
- 9.6. Netcells 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 for the client's immediate family, there will be no cost for retrieval or shipment, however the cost of testing and all related treatment costs of the stem cells will be from the Client's own account. If the stem cells are retrieved for any other purpose or person outside of the clients immediate family as defined and which is not transplant related, the retrieval fee, cost of shipment, cost of testing and all related treatment costs of the stem cells will be from 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. The Client will be liable to settle the processing and utilised storage fees in full if the stem cells are retrieved before the expiration of any selected payment plan period. 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 processing and 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 the Next Biosciences website which is to be paid by the Client as follows:
 10.1. The Registration Fee shall be payable by the Client to Netcells upon registration and prior to the delivery of the Netcells

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- 10.1.2. The Processing and Storage Fee shall be due and payable once the Client has received notification (meaning confirmation of storage by Netcells 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-authorised and separately invoiced to the Client.
- 10.3. Included in the processing and 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 cord 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 cord tissue) to the Netcells laboratory, will be for the Client's own account. Where a pregnancy is assisted by surrogacy, the maternal blood will need to be collected from the Surrogate Mother.
- 10.4. The Client may select to pay the Processing and Storage Fee in accordance with a monthly payment plan as indicated in the Client Registration Form and the Next Biosciences website. 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 Parents' financial obligations.
- 10.5. Where a pregnancy has been assisted by partial surrogacy and the Surrogate Mother exercises her right to terminate the surrogacy agreement within 60 (sixty) days of the Child being born, the commissioning parent will be responsible to pay the Processing and Storage Fees in full and to recover these funds from the Surrogate Mother as expenses incurred in terms of the agreement.
- 10.6. 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).
- 10.7. The Client acknowledges that the failure to effect payment of any fee or cost timeously may result in the termination of this Agreement by Netcells in terms of Clause 14.3, after written notice to the Client.

## 11. WARRANTIES

- 11.1. The Client acknowledges that Netcells 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 aforegoing, with respect to:
  - 11.1.1. The suitability of the cord blood and/or cord tissue 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 cord tissue 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 this clause 12, the maximum amount of any and all liability which Netcells (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

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in respect of any and all actions or omissions of Netcells under any and all circumstances shall be the total amount paid by the Client to Netcells as set out hereunder.

- 12.2. The Client further acknowledges that Netcells 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 cord tissue and stem cells.
- 12.3. Netcells 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. Netcells shall not be held liable for any loss or damage to the cord blood and/or cord tissue 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

#### Netcells may:

- 13.1. Transfer the location of the processing laboratory.
- 13.2. Transfer the storage facility.
- 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 Netcells, transfer to one or more persons their 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 Clients rights, Netcells may, in its entire discretion, recognise the authority of any other person to represent the Client.

#### 14. TERMINATION

- 14.1. Netcells 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 Netcells 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 Netcells' 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 Netcells be unable to extract any stem cells from the cord blood, or should the cord blood yield insufficient stem cells according to Netcells internal quality and accreditation requirements, then no storage shall take place, and accordingly, the Client shall not incur any liability in regard to the processing and storage fee.

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- 14.1.4. 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.
- 14.1.5. In the event of the Client not responding to Netcells within
  12 (twelve) months after the expiration date of the storage period, despite Netcells 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 Netcells, in the event of:
  - 14.2.1. The Client terminating prior to the birth of the Child, the Client will be refunded the proportionate unutilised portion of the Registration, Processing, and Storage Fee.
  - 14.2.2. The Client terminates after the birth of the Child, where the stem cell kit has been used and/or processing of the stem cells has taken place; the Client will be liable for the Registration and Processing Fees and will be refunded the unutilised portion of the Storage Fee.
- 4.3. 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 verification and/or validation purposes; or
  - 14.3.4. Donated to the SABMR for use by a recipient in need, if the stem cell unit fits the cord blood requirements of SABMR.
- 14.4. Notwithstanding the aforegoing, this Agreement will be terminated on withdrawal by the Client of all their stored stem cells for transplant and any unutilised storage fees will be refunded. The Client will be liable to settle the processing and utilised storage fee in full if the agreement is terminated before the expiration of any selected payment plan period.
- 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 Parents and/or Client undertakes to provide Netcells with complete and accurate contact information of the Parents and/or Client and the Child, in writing, as is required by Netcells. The Parents and/or Client also agrees to provide any other information that may be required by Netcells 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 Parents and/or Client and the Child.
- 15.2. If any information that the Parents and/or Client has provided to Netcells changes or is no longer valid, the Parents and/or Client acknowledges that it is their responsibility to advise Netcells promptly, and in writing, of all such changes or invalidity.
- 15.3. Netcells shall use all reasonable endeavours to keep confidential all information relating to the Parents and/or Client and/or Child. Personal information will only be held in Netcells hardcopy 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 Parents and/ or Client and/or Child's healthcare provider and/or competent person for their internal confidential records or otherwise as requested by the Parents and/or Client and/or Child in writing. Information may also be released for the purposes of performing Netcells' obligations under this Agreement. None of the information held on Netcells' database will otherwise be disclosed or released to any third parties other than those required by law.



- 15.5. By signing this Agreement, the Parents and/or Client consents to Netcells holding the Parents and/or Client and/or Child's personal data for the purposes of performing Netcells' obligations under this Agreement.
- 15.6. It is the responsibility of the Parents and/or Client to notify Netcells 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. Netcells may, from time to time, send out electronic information by email, WhatsApp, or SMS to the Parents and/or Client, to update the Parents and/or Client on developments regarding Netcells and the stem cell industry in general. The Parents and/or Client may at any time opt out from receiving this communication by written notification.

## 16. COMPLIANCE WITH THE PROTECTION OF PERSONAL INFORMATION ACT (POPIA)

- 16.1. The Parent understands that Netcells and the SABMR takes the privacy of its patients very seriously and has implemented reasonable security measures to guard against the unauthorised disclosure of private patient information in line with the Protection of Personal Information Act (POPIA).
- 16.2. The Parent acknowledges that its personal information may be disclosed within the Netcells team for the purposes of providing services.
- 16.3. The Parent acknowledges that its personal and special personal information will be kept for the required storage and retention periods according to, and in line with, legislation/regulations applicable to the medical and healthcare industry.
- 16.4 Netcells will collate the information shared to provide the Parent with information on other services which may be relevant to them and may also use this information to inform the Parent about any changes to the services offered from any of the companies forming part of the Next Biosciences group of companies.

By sharing information with Netcells, the Parents consent to the use of information as above.

#### 17. DOMICILIUM AND NOTICES

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

# Signed



**Chief Executive Officer** Netcells Stemcells (PTY) LTD

## Client Details

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## 18. DISPUTES

- 18.1. In the event of any dispute, disagreement, or claim arising between the Netcells 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.
- 18.2. 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.
- 18.3. The provisions of this clause shall not preclude either the Client or Netcells 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.

#### 19. ENTIRE AGREEMENT

19.1 This Agreement, the appendices, all references to terms and conditions contained on the Netcells 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.

#### 20. VARIATION AND CANCELLATION

20.1 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.

## 21. INDULGENCES

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

# **Signed by Parents**

Mother		
Father		
Date		
Client cell phone number	 	

#### **Email address**

Galaxy Building International Business Gateway Corner New Road and 6th Road Midrand, 1685, Johannesburg PO Box 53, Halfway House, 1685 **Netcells Stemcells** (Pty) Limited trading as Next Biosciences Registration No.: 2016/341111/07

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## **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 authorised to sign this document on behalf of my Child. I authorise Netcells 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']

## 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 diseases:

- Malignancies (leukaemia, lymphoma, multiple myeloma, solid tumours)
- Anaemia (Fanconi's anaemia, sickle cell disease, thalassaemia)
- Bone marrow failures (aplastic anaemia, pancytopaenia)
- Immunodeficiency (SCID, Kostmann syndrome, Wiskott-Aldrich syndrome, lymphoproliferative disorder, ataxia telangiectasia, DiGeorge syndrome)
- Inborn errors of metabolism (adrenoleukodystrophy, Gaucher's disease, Krabbe disease, Niemann-Pick disease, 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 and bone repair)
- Sports injury (tendon and ligament repair)
- Cardiology (heart muscle regeneration)
- Reconstructive surgery (fat grafts)
- 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 provider that will perform the collection.

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in accordance with the accompanying Cord Blood/Tissue Storage and Related Services Agreement. I authorise South African National Blood Service (SANBS) and Ampath Laboratories to perform tests on my blood for transmissible diseases, known as maternal blood tests.

Should the Mother be unable to sign due to medical reasons, the Father, or designated legal guardian of the unborn child, may sign consent.

- 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 vaginal delivery or caesarian section), the umbilical cord is clamped and my Child is safely handed over.
- 2.4 The healthcare provider will clean the umbilical cord with a suitable antiseptic to limit contamination. This does not eliminate all risks of contamination of the blood. The needle of the collection bag is then inserted into the umbilical vein. The bag will fill with cord blood. Once the flow of blood stops, the needle will be removed from the umbilical cord 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, which will be couriered 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 provider will clean the cord with a suitable antiseptic to limit contamination. This does not eliminate all risks 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 provider collects the cord blood and/or cord tissue using the collection kit provided by Netcells.
- 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, including the protection of my Child and myself, my healthcare provider would be entitled to refuse to collect the cord blood and/or cord tissue. I will not hold Netcells or my healthcare provider responsible for my healthcare provider'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.
- 4.5 I understand that there is always 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. Netcells tests every cord blood unit for these contaminants.

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- 4.6 I understand that the cord blood and/or cord tissue collected may be insufficient and/or not viable for storage with Netcells 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 provider to collect the cord blood and/or cord tissue after the birth of my Child and to furnish it to Netcells 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 HLAtype match that I, the Mother of the Child, or the Child, decides to donate the stem cells to.
- 5.4 I understand that Netcells 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 themself would not be recommended (for example certain inherited genetic 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 to store my Child's own cord blood and/or cord tissue stem cells.
- 5.7 Pertaining to cord blood stem cells only:
  - 5.71 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.
  - 5.72 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 that 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 (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.

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- 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 the 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. Depending on the specific treatment required, other laboratory work may be additionally required. Next Biosciences does not currently offer this service. The cost of this extraction and culture by another laboratory, will be from 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 Netcells uses internationally accepted methodology. We are, therefore, not able to determine post thaw cell yield at the 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. Prepublished 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, and return the form to Netcells with the collection kit. I understand that this part of my medical history will be reviewed by the appropriate Netcells staff.
- 6.3 l agree to provide information related to our family's medical and genetic history, where necessary and available.
- 6.4 I understand that it is my responsibility to have a sample of my own blood taken by venipuncture (the usual method for blood tests) within seven days prior to delivery, or seven days after the delivery, in order to be tested for transmissible diseases. Failing to do so may result in my Child's sample not being accepted for use by a transplant clinic or physician.
- 6.5 I am responsible for and will ensure that I have my blood sample taken by a healthcare provider at the hospital or clinic where I am delivering my baby. The blood sample will be taken in the blood tests tubes provided by Netcells 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.
- 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 characterised by genital
  - 6.7.3 Syphilis (a contagious disease that is characterised 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).

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6.7.5 Human T-cell lymphotrophic virus (HTLV I/II) (a sexually transmitted virus that can cause adult T-cell leukaemia/lymphoma as well a neurological disorders such as paralysis of lower limbs. It can also be transmitted via blood or body fluid transmission).

6.8 Netcells' 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 from 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 Netcells' disclosure of the results of my blood tests to my healthcare provider, to any other stem cell storage facility to which I have authorised 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 Netcells may be required to report such results under applicable law and regulations.

#### 7. TESTING

#### 7.1 Cord blood

I understand that:

- 7.1.1 Netcells will undertake tests on my Child's cord blood to ascertain the nature, number, and viability of the stem cells to be cryopreserved.
- 71.2 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 from my account, and/ or that of my Child.
- 71.3 Netcells will not release the stem cells until Netcells has received the HLA-typing results (if required), and approval from the recipient's transplant physician and Parent(s).
- 71.4 Reference samples of the cord blood will be stored for future testing of HLA-type, 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.

#### Cord tissue

7.2

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 have been 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.

## **Client Details**

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## 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 from my account, and/or that of my Child.

## 9. DISCLOSURE OF HEALTH INFORMATION

- 9.1 Netcells, SANBS, and Ampath 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 healthcare 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 authorise Netcells to disclose such information to healthcare 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 authorise Netcells to disclose such information for research purposes in an anonymous manner and always maintaining Next Biosciences' confidentiality obligations in terms hereof.

## 10. COMPLIANCE WITH THE PROTECTION OF PERSONAL INFORMATION ACT (POPIA)

- 10.1 I understand that Netcells and the SABMR takes the privacy of its patients very seriously and has implemented reasonable security measures to guard against the unauthorised disclosure of private patient information.
- 10.2 I acknowledge that my personal information, or that of my Child, may be disclosed within the Netcells team for the purposes of providing services.
- 10.3 I acknowledge that my personal and special personal information, and that of my Child, will be kept for the required storage and retention periods according to and in line with legislation/regulations applicable to the medical and healthcare industry.
- 10.4 Where personal information is processed, it is done in the ordinary course of Netcells' business for a legitimate purpose, and in accordance with applicable law. Personal information will only be used for the purpose for which it was originally or primarily collected.
- 10.5 I acknowledge that the information supplied by myself is true and correct and that I am responsible for updating my information to ensure that it is correct.

## 11. CORD BLOOD DISPOSAL

11.1 If the cord blood that is collected has low cell counts or low cell viability and is not recommended for storage according to Netcells minimum storage limits and standards at the time of processing, I will be informed by Netcells about the possible options available to me.

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- 11.2 I have the choice to proceed with storage and will sign a disclaimer in order to do so, or if I decide not to proceed with storage, I will sign a disclaimer to either donate the cord blood for internal verification/validation purposes, or to discard it.
- 11.3 I understand that Netcells 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.

## 12. VALIDATION

12.1 I authorise Netcells 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.

## 13. DISCLOSURE OF INFORMATION

13.1 I authorise Netcells 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 and deidentified manner.

### 14. INFORMATION SERVICES

- 14.1 I have received information regarding the risks, benefits, discomforts, and alternatives to stem cell collection, testing, processing, and storage.
- 14.2 I am entitled to donor advocacy services in the form of access to the Netcells' medical staff to ask questions, and have these answered to my satisfaction. I am also able to ask my own healthcare provider questions should I need to.
- 14.3 I have received a written copy of Netcells' contact information for any questions related to cellular therapy products.

#### 15. WARRANTIES AND LIMITATION OF LIABILITY

- 15.1 I confirm that I have read, understood, consented, 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.
- 15.2 Notwithstanding anything that may be construed to the contrary, the maximum amount of any and all liability which Netcells (and its respective shareholders, directors, officers, employees, and agents, including marketing agents and other representatives) may incur to the Client in terms of processing, testing, and storage of the stem cells, or in respect of any and all actions or omissions of Netcells under any and all circumstances shall be the total amount paid by the Client to Netcells.

Signed

#### Dr Yvonne Holt

Chief Medical Officer Netcells Stemcells (PTY) LTD

# Client Details

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# **Signed by Parents**

Mother

## Date

Galaxy Building International Business Gateway Corner New Road and 6th Road Midrand, 1685, Johannesburg PO Box 53, Halfway House, 1685

T 011 697 2900 www.nextbio.co.za **Netcells Stemcells** (Pty) Limited trading as Next Biosciences Registration No.: 2016/341111/07