

# Cord Blood/Cord Tissue Storage Agreement

The following definitions are used in this Agreement:

<b>Child</b>	your child from whose umbilical cord the Sample is taken;
<b>Sample</b>	the sample of cord blood (and stem cells extracted from cord blood) and cord tissue (if any) collected pursuant to this Agreement;
<b>You/your/second party</b>	the person or persons identified as the client on the relevant documentation, or the person(s) having parental responsibility for your child at the relevant time if that should change before they reach the age of 18, and once the child reaches 18, then you/your shall thereafter refer to the child;
<b>SCI/us/we/first party</b>	Smart Cells International Ltd; and
<b>UK Regulatory Authority</b>	the regulatory authority in the UK is The Human Tissue Authority (HTA) which at the relevant time regulates the collection (if the Sample is collected in the UK), processing, storage or use of cord blood, cord tissues and/or stem cells.

This document sets out the terms upon which Smart Cells International Limited (“**SCI**”) agrees that it will process and test your child’s cord blood and/or cord tissue and store your child’s cord blood and/or cord tissue stem cells in an SCI processing and storage facility (“**Facility**”).

This document constitutes a legally binding Agreement between SCI and you (“the **Parties**” and individually a “**Party**”). This Agreement sets out the rights and obligations of the Parties and includes limitations on and exclusions of the liability of SCI to you and to your child or children or anyone else who might want to use the Sample.

By signing this Agreement you agree to the processing and storage of the Sample in any SCI authorised facility and agree that you have been fully informed of and agree:

- to your obligations arising as a result of entering into this Agreement;
- to the conditions and risks involved in this arrangement;
- to the limitations on and exclusions of liability of SCI; and
- that you will pay the costs and expenses as referred to in this Agreement.

If both parents/legal guardians sign this Agreement then you understand that you are both fully liable individually to us for performing your obligations under this Agreement and we are entitled to act on the instructions of either one of you. The parent instructing SCI shall indemnify and keep SCI indemnified against any loss or damage claimed against SCI by the other parent or legal guardian, together with all legal fees incurred by SCI in respect of such claim, where the claim has resulted from SCI acting on the instructions of that instructing parent.

You understand that umbilical cord stem cell transplantation is a treatment that may offer possible future benefits. You also understand that cord blood and/or cord tissue offers a source of stem cells, and you are aware there are alternative sources of stem cells. You understand that cryopreservation of the Sample is an accepted procedure and tests and studies have indicated it is a successful method of preserving stem cells. **However, it is important that you acknowledge that no assurance or guarantee can be made about the benefits or utility derived from it. You also understand that the stem cells may never be needed or used.**

## 1. Fees

- 1.1 You will be provided with information detailing the package you have chosen, the fees payable for that package, the amount of the initial payment and the balance payable following processing of the Sample. The initial payment is due upon placing your order. Refer to local country refund policy for amount to be refunded.

- 1.2 The fees for processing and storage are due 30 days after the storage of the Sample at our Facility. If the Sample is not suitable for storage then the storage element of the fees will not be payable.
- 1.3 You will be notified by SCI once the Sample has been processed whether the Sample is suitable for storage, and of the balance payable for processing and, if the Sample is to be stored, for storage. You will at this time be invoiced for these fees. All invoices are payable within 30 days.

## **2. Collection of the Sample**

- 2.1 Where SCI recommends, and is applicable, persons qualified to collect a Sample, we ensure that these individuals are familiar with the collection processes and have the right to collect Samples.
- 2.2 You acknowledge and agree that if the Sample is not collected in accordance with the collection procedure protocol, that it may affect the viability of the Sample for storage and/or future use. You further understand that if the Sample is not collected by a trained and licensed person, SCI may be required to destroy the Sample by the UK Regulatory Authority.
- 2.3 You understand that the Sample is normally discarded after delivery, appropriated for medical research or stored in a public banking facility and that the decision to collect, process and store your child's Sample is a voluntary act on your part.
- 2.4 You understand that there are risks with any medical procedure, that there may be additional considerations or unforeseeable circumstances during the delivery of your child which may affect the collection of the Sample. The safety and care of the child and mother are of primary concern. You therefore acknowledge and agree that a qualified medical professional may, for any reason and at their discretion, refuse to collect the Sample. This is not something within the control of SCI. If the Sample is not collected for any reason, you may terminate this Agreement by notifying SCI in writing within 14 days of your child's birth and returning the collection kit intact and in good condition, refer to local country refund policy for amount to be refunded.
- 2.5 Once the Sample has been collected, it is your responsibility to ensure that the Cord Blood and/or Cord Tissue Identification Form is signed to confirm that it is your child's Sample contained in the collection kit. If you have more than one child and have more than one collection kit, you must clearly identify each child on their respective collection kit.
- 2.6 SCI cannot be held responsible for any loss, damage or deterioration of the sample during transit from the collection centre to SCI.

## **3. Regulatory Tests**

- 3.1 It is a regulatory requirement that a sample of maternal bloods is provided. The maternal blood must be taken at the time of delivery or no later than 7 days after the birth of your baby.
- 3.2 A number of mandatory tests will be performed on the blood including HIV, Syphilis, Hepatitis B, Hepatitis C, HTLV if indicated by the maternal health questionnaire and any other disease that may be specified by legislation and which may change from time to time. We will not store the samples if the maternal blood donor has tested positive for HIV.
- 3.3 It is your responsibility to ensure maternal blood tests are completed on time. Failure to supply a suitable maternal blood sample taken at the correct time may mean that SCI is unable due to regulatory requirements to store the Sample. In this event, you will still be liable for payment of fees in respect of transportation, processing and storage up to the end of the month in which the Sample is destroyed. The cost of performing these maternal blood tests is included in the cost of the service.

## **4. Processing, Storage and Withdrawal**

- 4.1 You are responsible for contacting SCI as soon as possible following the birth of your child in order that a courier can be arranged by SCI to transport the Sample to the SCI processing and storage facility.
- 4.2 SCI appoints a courier for the transportation of the Sample to the Facility. Details of how to pack the Sample to ensure safe transportation and delivery are included in your collection kit. On receipt, your Cord Blood/Cord Tissue Sample will be processed and stored at our facility in the UK.
- 4.3 You consent to the following activities being undertaken by SCI:
  - 4.3.1 performing all tests on the Sample required by the UK Regulatory Authority.
  - 4.3.2 the transfer of the Sample from one Facility to another Facility, following the provision to you of written notice; and
  - 4.3.3 the transfer of the location of any Facility at which the Sample is stored following the provision to you of written notice.

- 4.4 The Sample, as well as any maternal blood sample, shall at all times be owned by you and the Sample shall be subject to your exclusive control until the child reaches the age of 18, when ownership and control over the Sample shall automatically transfer to the child.
- 4.5 SCI agrees to make a full refund of processing and storage fees paid if within the first 12 months from the storage date the Sample is retrieved for therapeutic use.
- 4.6 No additional costs will be incurred for the transportation of the sample at any time if required for therapeutic use.
- 4.7 If before the child reaches the age of 18 another person is granted parental responsibility for that child, that person may enforce your rights under this agreement. We reserve the right to request supporting evidence of legal guardianship, including documents issued by a court of law, before acting on the instructions of any person purporting to have parental responsibility for your child.
- 4.8 SCI will only accept requests for release of stored samples from you if the child is under 18 when the request is made, or from the child if he or she has reached the age of 18 when the request is made.
- 4.9 Once the child reaches 18, in the event of any conflict between your request and the requests of your child, we will be bound by the requests of your child.
- 4.10 SCI's obligations and liabilities are expressly limited to the services described in sections 2, 3 and 4 above and no other services are provided. SCI is not responsible for providing any other services.
- 4.11 SCI cannot be held responsible for any loss, damage or deterioration of the Sample once it has left SCI's possession and control for provision to a third party for any reason.
- 4.12 If a sample is required for therapeutic use, SCI will arrange release of the sample according to SCI's procedure and current regulatory requirements. The transplant centre will be responsible for any ongoing storage, transit, processing, testing, clinical use or disposal.

## 5. Terms and Termination

The Sample shall be stored for the term paid for by you, subject to the conditions in this paragraph.

- 5.1 SCI reserves the right to refuse to process and/or store Sample storage for any reasonable reason, including but not limited to:
  - (a) if the Sample has been unlawfully procured
  - (b) if the volume of cord blood is less than our minimum requirement
  - (c) if the Sample is determined to be unsuitable for storage
  - (d) the Sample has been incorrectly packaged
  - (e) if any part of the collection kit has been replaced
  - (f) if the maternal blood donor has tested positive for HIV.
- 5.2 In the event that SCI refuses to process or store the Sample pursuant to paragraph 5.1, you consent to SCI destroying the Sample.
- 5.3 In the event that SCI refuses to process or store the Sample pursuant to paragraph 5.1, you will not be charged processing or (if the Sample is not stored), storage fees. In the event that either the cord blood or tissue is processed, you will be liable for the processing for that service only. In either case you will be fully liable for the balance of any phlebotomy services provided by SCI (Phlebotomy service is provided in the UK only).
- 5.4 SCI sets a minimum cell count for storing cord blood units based on current transplant technology. In the event your cord blood unit is below these criteria, you will be notified. If you wish to continue to store that unit, processing and storage fees will apply.
- 5.5 This Agreement may be cancelled by you at any time prior to the collection of the Sample at birth by written notice to SCI. You will not be charged the balance and please refer to your local country refund policy for amount to be refunded.
- 5.6 If the Sample is accepted for storage, the Sample will be stored at our Facility and this Agreement shall be in full force and effect for the period of storage paid for, unless otherwise terminated on its terms.
- 5.7 In the event that full payment has not been received within thirty days of an invoice being sent to you, SCI may terminate this Agreement, destroy the stored Sample, and take such steps as may be necessary to recover the processing and storage fee as well as the cost incurred in disposing of the Sample.

- 5.8 SCI will notify the child of the end of the storage period six months prior to the end of the twenty five (25) year storage term by writing to the last address you have given to SCI. We also attempt to contact you via email or telephone call if we do not receive a response to our notice within 60 days of writing to the child, we reserve the right to dispose of and destroy the stored Sample in each case without sending any further notice to you.
- 5.9 If SCI does not receive a response from you after sending notice to the address last notified to SCI or to the address of your child if they are over 18 and you have provided their address details, SCI shall have the right to, without further notice, destroy the Sample.
- 5.10 If you elect to continue to permit SCI to continue store the Sample on your behalf, SCI will invoice you for continuing storage costs at its then current rates stated in the notice.
- 5.11 If you wish to continue to store the Sample with SCI, you shall make full payment for the next period of storage as specified at the time.
- 5.12 The Sample will be destroyed unless invoices for continuing storage are paid within 30 days.
- 5.13 If at any time you request that the Sample is to be transferred, then we will release the Sample to you. We will not cover the cost or be responsible for the preparation of the sample, shipping containers, transportation or future storage.

## **6. Guarantee**

- 6.1 We guarantee to you that:
  - (a) The collection kit is of satisfactory quality and fit for the purpose of collecting the Sample and maternal blood as set out in the Sample collection procedure protocol and this Agreement and is, at the date supplied, compliant with the UK Regulatory Authority requirements.
  - (b) The services to be provided by SCI pursuant to this Agreement will be provided using reasonable care and skill.
- 6.2 You acknowledge and accept that we cannot give any guarantees with respect to any:
  - (a) suitability of the Sample for the future treatment of diseases as this will be dependant on the circumstances of each individual case;
  - (b) successful treatment of diseases through Sample transplantation;
  - (c) advantages of Sample stem cell transplantation over other types of treatment, whether using stem cells or otherwise;
  - (d) the tests we carry out cannot be exhaustive and we cannot guarantee that the Sample is not contaminated before we accept it for storage.
- 6.3 Nothing in this Agreement shall affect your statutory rights.

## **7. Limit of SCI's Liability**

- 7.1 If due to the default or negligence of SCI or its contractors the Sample is damaged or destroyed, the maximum amount for which SCI shall be liable to you shall be £10,000 (ten thousand UK pounds).
- 7.2 If SCI or its contractors through their default or negligence cause damage to real or personal property (other than to the Sample) or cause any other loss or damage (save for personal injury or death caused by their negligence), their liability shall be limited to the amount of the fees paid by you pursuant to this Agreement, less any sums payable pursuant to paragraph 7.1.
- 7.3 Without prejudice to any other limitation (whether effective or not) of SCI's liability, SCI shall not in any circumstances be liable (whether in contract, tort or for breach of statutory duty or otherwise) for any loss of profits, use, opportunity, goodwill, business or anticipated savings, for any indirect or consequential losses or for any third party claims in connection with this Agreement/the Sample (in each case irrespective of any negligence or other act, default or omission of SCI (or its employees or agents) and regardless of whether such loss or claim was foreseeable or not or whether SCI has been informed of the possibility of such loss).
- 7.4 No term of this Agreement shall limit or exclude any liability to the extent that liability might not by law be limited or excluded.
- 7.5 SCI or personnel collecting the Sample shall not be liable to you when due to unforeseen circumstances, the collection of the Sample is not possible, or the amount of blood and/or cord tissue taken proves to be insufficient or the Sample is contaminated or otherwise compromised.

- 7.6 You acknowledge and understand that we shall not be liable to you, or be considered to be in breach of this Agreement, because of any delay in performing, or any failure to perform, any of our obligations if the delay or failure was due to your acts or omissions.
- 7.7 Should there be loss of the Sample whilst in the care of SCI, which was within SCI's control, SCI will reimburse a proportion of the storage fees prepaid (on a pro rata basis for the remaining storage term).
- 7.8 It shall not be a breach of this Agreement if SCI is unable to timely perform or to perform at all any of its obligations under this Agreement due to circumstances beyond our reasonable control, including but not limited to, industrial action, war, and acts of terrorism, acts of God, traffic accidents, changes in legislation or prohibition or enactment of any kind.
- 7.9 SCI shall not be liable to you for any loss or damage suffered by you or any other person as a result of your failure to comply with the terms of this Agreement.

## **8. Confidentiality and Data Protection**

- 8.1 SCI will use all reasonable endeavours to keep confidential all information relating to you and your child. All Samples to be tested will be labelled with unique reference numbers and bar coded.
- 8.2 SCI is registered under the Data Protection Act 1998 and will process all personal data in accordance with its obligations under that Act. By signing this Agreement, you consent to SCI, for the purposes of this Agreement and/or as from time to time required by UK law or the UK Regulatory Authority:
- (a) collecting, recording, storing (on our secure database and database backup) checking, transferring (within the EEA) and processing your medical (including sensitive data) and personal data and the medical (including sensitive data) and personal data of your child (together, "the **Data**"), including the results of any tests on the Sample and maternal blood test results, and sending you regular news letters from SCI;
  - (b) supplying the Data to third parties to which SCI has subcontracted any of its obligations to you under this Agreement or to which SCI transfers the Sample pursuant to paragraph 10.2, and for those third parties to record, store, check, and transfer (to or within the EEA) the Data for the purpose of fulfilling those subcontracted obligations;
  - (c) disclosing Data as required by law and/or to your child's medical practitioner on request;
  - (d) making Data available to any Company in the same group as SCI, the UK Regulatory Authority and potential purchasers of the Company and/or of substantially all its assets relating to the business of the collection and storage of stem cells and cord blood and tissue; and
  - (e) SCI supplying copies of its records relating to the Sample, including the Data, to a third party (who might be located outside the EEA) if the Sample is, at your request, transferred to that third party, whether for storage or use.
- 8.3 Save as otherwise provided in this paragraph 8, SCI agrees that it will not, without receiving your permission in writing, show or pass the Data regarding your Sample or maternal blood tests to a third party.

## **9. Assignment by SCI**

- 9.1 SCI may at any time assign, transfer or deal in any other manner with any or all of its rights and obligations under this Agreement and may sub-contract or delegate in any manner any or all of its obligations under this Agreement to any third party or agent. This assumes that the third party or agent is authorized to do so.
- 9.2 If SCI assigns any or all of its rights under this Agreement, SCI may disclose to a proposed assignee any information in its possession that relates to this Agreement or its subject matter, the negotiations relating to it and the other party which is reasonably necessary to disclose for the purposes of the proposed assignment.

## **10. Duration of this Agreement and Notice**

- 10.1 If you wish to terminate this Agreement before the end of the paid for storage period, you must provide SCI with not less than 60 days notice.
- 10.2 If at any time SCI is unable or unwilling to continue to store the Sample pursuant to this Agreement, SCI has an agreement with a third party who would take over SCI's obligations to you with respect to storage. In this event, SCI would provide you with at least 60 days prior written notice of the Sample and related records being transferred to that third party.
- 10.3 You will immediately notify SCI in writing of any changes to your information, including changes of address, notification upon your child reaching the age of 18 and of their address at that time. All notifications to SCI shall be sent to: Smart Cells International, Unit 7 Chancerygate, Horton Close, West Drayton, UB7 8EW, or such other address as we notify you of from time to time in writing.

**11. General**

- 11.1 The Parties agree that this Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.
- 11.2 The Parties agree that the courts of England and Wales shall have exclusive jurisdiction over any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).
- 11.3 No failure or delay by SCI to exercise any right or remedy provided under this agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that or any other right or remedy.
- 11.4 This Agreement begins on the day you sign the agreement, and termination of the agreement ends on the day we cease to store your Sample at our Facility.
- 11.5 This Agreement constitutes the whole agreement between the Parties and supersedes all previous agreements between the Parties relating to its subject matter. Each Party acknowledges that, in entering into this Agreement, it has not relied on, and shall have no right or remedy in respect of, any statement, representation, assurance or warranty (whether made negligently or innocently) other than as expressly set out in this Agreement. Nothing in this clause shall limit or exclude any liability for fraud.

for and on behalf of Smart Cells International Limited



Signed \_\_\_\_\_  
**Shamshad Ahmed**  
Chief Executive

Date As postmarked \_\_\_\_\_

Signed \_\_\_\_\_  
Parent/Guardian

Print Name \_\_\_\_\_

Date \_\_\_\_\_

Office Use Only
Affix barcode here

## Statement of Consent

Please read and complete this document carefully. This form records your consent for these procedures. You have the right to withdraw your consent to all or any of these procedures.

### Collection of cord blood/cord tissue

I hereby consent to the collection of my child's cord blood/cord tissue.

I understand that collection of the cord blood/cord tissue must be carried out by a qualified healthcare practitioner in accordance with HTA Direction 001/2006, para 34d.

I understand that SCI reserves the right to refuse to process cord blood/cord tissue that has not been collected in accordance with their collection protocol and by a qualified healthcare practitioner.

Following collection of the cord blood/cord tissue, I understand that I must telephone SCI as soon as practically possible to arrange for it to be collected.

### Storage and discard of umbilical cord blood/cord tissue

I understand that it is not possible for SCI to provide guarantees or assurances relating to potential clinical use of cord blood/tissue or successful therapeutic results.

I understand SCI cannot guarantee the viability of any cord blood or cord tissue and that SCI cannot process cord blood where the volume is less than 15ml. I will be notified if my child's cord blood has a cell count that does not meet SCI's current criteria for storage. I will be notified if cord blood or cord tissue does not meet SCI's current transit criteria from collection to the laboratory. The cells present in the sample of stored cord tissue will not be further analysed for quality or quantity.

I understand that SCI may dispose of or test cord blood/cord tissue as a means of product validation if the material does not meet the criteria for storage. Intermittently excess cord tissue needs to be tested by Smart Cells as a means of product validation.

Do you agree to SCI undertaking cord blood/cord tissue product validation as described above? Yes  No

### Collection and testing of maternal blood samples

I consent to a sample of my blood being taken for the purposes of establishing the suitability of the cord blood/cord tissue for processing and storage.

I agree to my blood being tested for infections including Hepatitis B, Hepatitis C, Syphilis, HIV and HTLV if indicated by the maternal health questionnaire as well as any other disease that may be specified by current legislation. I understand that the results of these tests will be made available at my request.

I understand that SCI does not provide medical advice or treatment and that I should consult my medical practitioner in the event of that any results are positive.

I understand that if the maternal blood results show a positive result for HIV, no samples will be processed and all samples will be discarded in line with company policy.

### My personal data

I give permission for my personal information including details of my medical history and that of my child to be shared only with medical staff involved in transplant or treatment should the sample be required for transplant or treatment. I also consent to the details of any test results relating to me and my child being shared only with the physician involved with the transplant or treatment.

I agree to SCI keeping my records for the period of the agreed contract. SCI will not share my personal data with any other party without my prior permission.

I confirm I have read and understood **ALL** of this statement of consent.

Mother's signature \_\_\_\_\_

Print name: \_\_\_\_\_

Date: \_\_\_\_\_

Office Use Only

Affix barcode here

# You must complete both sides of this document

## Maternal Health Questionnaire

### Medical Questions

Yes No

- |   |                          |                          |
|---|--------------------------|--------------------------|
| 1. Have you <b>or your baby's father</b> ever lived in, or were born in, the Caribbean Basin, Central Africa, South Japan or South America?                       | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Are you <b>or your baby's father</b> native American Indians?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Do you have any health problems that could affect collection of your baby's cord blood?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Are you currently taking any prescription medications?   | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Have you been diagnosed with or exposed to HIV (Aids) and likely to test positive for this?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Have you ever tested positive for HTLV I and/or HTLV II?   | <input type="checkbox"/> | <input type="checkbox"/> |
| As part of our HTA licence requirements we also have to ask you the following questions:  |                          |                          |
| 6a. Have your parents ever lived in or were born in the Caribbean Basin, Central Africa, South Japan or South America?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 6b. Have you ever had sexual partners who have lived in or were born in Caribbean Basin, Central Africa, South Japan or South America?                            | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Have you been diagnosed with Hepatitis B, and likely to test positive for this?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Have you been diagnosed with Hepatitis C, and likely to test positive for this?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. In the past twelve months have you had any body piercing, tattoo, acupuncture, or accidental needle stick injury or come in contact with someone else's blood? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Have you ever received a transfusion of blood or blood products or an organ transplant?   | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Have you ever suffered from Malaria?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Have you or anyone in your family been diagnosed with Creutzfeldt-Jacob Disease (CJD)?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Do you or your immediate family have any inherited blood disorders?   | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Are you Diabetic (please indicate if gestational diabetes)?   | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Have you ever been diagnosed with Cancer or Leukaemia?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Have you been resident in or travelled to an area with active transmission of Chikungunya, Dengue, Zika Virus or West Nile Virus during this pregnancy?       | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Have you been diagnosed with or had symptoms suggestive of Chikungunya, Dengue, Zika or West Nile Virus infection during this pregnancy?                      | <input type="checkbox"/> | <input type="checkbox"/> |

If you have answered YES to any of the questions above please give details:

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I certify that I have answered the above questions truthfully and to the best of my knowledge. I am aware that information provided here will be made available to the relevant physician should the sample be required for transplant/treatment.

Mother's Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_