

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 the Human Tissue Authority (Quality and Safety for Human Application) Regulations as implemented by Directions 002/2018.

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

Maternal Health Questionnaire

Medical Questions

Yes No

- | | | |
|---|--------------------------|--------------------------|
| 1. Do you have any health problems that could affect collection of your baby's cord blood? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Are you currently taking any prescription medications? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Have you been diagnosed with or exposed to HIV (Aids) and likely to test positive for this? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Have you been diagnosed with Hepatitis B, and likely to test positive for this? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Have you been diagnosed with Hepatitis C, 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"/> |
| 7. 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"/> |
| 8. Have you ever received a transfusion of blood or blood products or an organ transplant? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Have you ever suffered from Malaria? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Have you or anyone in your family been diagnosed with Creutzfeldt-Jacob Disease (CJD)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. 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"/> |
| 12. 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"/> |
| 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"/> |

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

As part of our HTA licence requirements, with regard to HTLV I and/or HTLV II, we also have to ask you the following questions:

16. In which country were you born? _____
17. In which country was your baby's father born? _____
18. Please list countries where you have ever lived _____
- _____
19. Please list countries where your baby's father has ever lived _____
- _____
20. Please state the countries of your parent's birth and countries where your parents have ever lived _____
- _____
21. Please state countries where any sexual partners you may have had have been born or lived in _____
- _____
22. Please list all countries have you travelled to or resided in during your pregnancy _____
- _____

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 _____