

## CONSENT FORM

The undersigned (referred to as 'Client') hereby gives consent to have their child's cord blood and / or cord tissue (if opted for in the service agreement) collected at the time of birth by their obstetrician, midwife, phlebotomist or other suitably qualified health professional and understand that maternal blood may need to be drawn at the time of birth.

The client understands that if complications occur during the birth, it may not be possible for the cord blood and/or cord tissue to be collected. The mother and child's health remain the first priority at all times.

The client understands that Cells Limited/Cryo-Save are required to carry out certain tests to confirm the safety and quality of the sample for human transplantation in compliance with UK law and HTA Directions (Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, HTA Direction 003/2010). These tests are serological tests on a blood sample from the birth mother drawn at the time of birth or within 30 days prior or 7 days after the birth; Anti-HIV 1 and 2, Hepatitis B (HBsAg and Anti HBc Ab), hepatitis C (Anti Hep C Ab) and syphilis. Also, validated Nucleic Acid Amplification Technique (NAT) tests (also known as PCR tests) are carried out on the cord blood for the presence of HIV (Human Immunodeficiency Virus), CMV, HBV (Hepatitis B) and HCV (Hepatitis C). The Client also understands that certain extra tests may be carried out if requested by the HTA.

The Client understands that positive results to HIV, would result in the sample being rejected for storage and the Client will be informed before the sample is disposed of. Furthermore if the tests indicate possible presence of HIV or the result is inconclusive or responses to the medical history form indicate risk of infection, then the decision to process and store the sample would rest with the Cryo-Save medical team. The Client understands that based on the results from the maternal blood, Cells Limited/Cryo-Save may decide not to store the sample permanently, in which case the Client will be informed in writing. Positive results showing CMV, Hepatitis B, Hepatitis C and syphilis will also result in the sample being evaluated for storage by the medical team and the fate of the samples will be discussed with the Client. If a positive sample is stored, Cells Ltd / Cryo-Save cannot guarantee that future use of the cells would be possible. The Client also understands that answers on the medical history form indicating possible risk or presence of CJD would result in Cells Limited/Cryo-Save not processing and storing the sample.

The Client understands the benefits and risks associated with the collection of cord blood, cord tissue and maternal blood samples. Long-term benefits of storage of cord blood and cord tissue include the fact that cord blood stem cells and stem cells derived from cord tissue could be used as part of a treatment programme for a variety of life threatening diseases and regenerative treatments. The potential risk is that such therapy may not be effective. The Client understands that although the indications for use of cord blood and cord tissue are expanding, the odds that a family without a defined risk will ever use their child's cord blood are low, and the cord blood and cord tissue stem cells may never be needed.



The Client understands that there is no guarantee that the cord blood and cord tissue stem cells will be a match for any of the members of the family or that cord blood transplant will provide a cure. The Client understands that as with any transplant therapy, success depends on many factors beyond the stem cells themselves including the type of disease, patient condition, the degree of tissue match between recipient and donor as well as other factors and that the physician treating the patient has the final say in deciding whether or not the cells can be used in any particular case.

The client is also aware of alternatives to collecting stem cells from the cord blood and cord tissue. Other sources of stem cells exist including bone marrow and peripheral blood.

The Client understands that there are risks to the mother of having a sample of blood drawn, which may include bruising, redness, discomfort, or inflammation around the needle site.

The client confirms that they have received adequate information and have had the chance to discuss any questions they had with Cells Limited staff. The Client confirms that they have had time to make an informed decision, which has been taken voluntarily and may be withdrawn at any point before the collection of cord blood and/or tissue.

This consent is drawn up in accordance with the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the HTA Directions 003/2010.

Mother's Signature

Dated \_\_\_\_\_

Mother's Name:

Client ID: \_\_\_\_\_

Address: \_\_\_\_\_

Post Code: \_\_\_\_\_

Country: \_\_\_\_\_