Stem Cell and Immunotherapy Services

Guidance for Healthcare Professionals in Consenting for the Collection, Testing, and Cryopreservation of Cord Blood for Directed Transplantation

NHS Blood and Transplant

Effective Date: 24/05/18

Data Protection and Privacy Assurance
All information provided to NHS Blood & Transplant is used in accordance with the General Data Protection Regulation and all other relevant privacy and data protection laws. To find out more about your privacy rights please visit our website www.nhsbt.nhs.uk or call us on 0300 123 2323.

2L

Recording Consent Using Form 2D

The Healthcare Professional completing this form is responsible for ensuring the donors eligibility to donate as per the JPAC/ SABTO tissue donor selection guidelines.

This guidance note is intended for use in conjunction with consent form 2D (FRM1572) which documents the mother's consent to go ahead with the collection of cord blood for directed transplantation. Form 2D is not a legal waiver if a mother, for example, does not receive enough information on which to base her decision, then the consent may not be valid, even though the form has been signed. Mothers are also entitled to change their mind after signing the form.

This guidance is intended to be an *aide-mémoire* to healthcare professionals, by providing a check-list of the kind of information mothers should be offered, and by enabling the mother to have a written record of the main points discussed. In no way, however, should the written information provided for the mother be regarded as a substitute for face-to-face discussions with the mother.

As the consenting healthcare professional this guidance note is intended to help you explain:

- the necessity for microbiological testing and provision of counselling if required.
- that once collected, cord blood will be tested and stored until required.
- that if the cord blood is no longer required it will be discarded or, subject to consent, used for research.

This guidance note is intended to be used in conjunction with the Department of Health's *Reference Guide to Consent for Examination or Treatment* (which sets out the general legal and ethical principles for healthcare professionals seeking consent). HTA Code of Practice for Consent and HTA guidance document for establishments working with umbilical cord blood.

In parts 1 and 2 of form 2D, the mother must sign in either the Yes box to indicate consent is given or sign in the No box if consent is not being given. Part 3 must also be completed.

Part 1. Collection of Cord Blood, Testing, Storage and Discard of Collected Cord Blood

A donation of cord blood will be collected after the delivery of your child or at the time of a caesarean section should that be necessary. If the baby is delivered before 34 weeks' gestation, the decision to collect shall be based on evaluation of infant donor safety by the professional responsible for delivery.

Microbiological testing of your blood and the cord blood is necessary to minimise disease transmission. Tests for some organisms and viruses are mandated. These include Hepatitis, Syphilis, HTLV 1 & 2 and HIV 1 & 2. If any tests for mandatory markers of infection are positive, mothers will be informed and further tests, counselling, and clinical follow-up arranged as necessary.

Blood samples are stored frozen and may be retrieved at a future date should, for example, tests for new infectious agents be developed and mandated. In addition, tests are also necessary to assure the quality of collected and processed materials.

NHSBT cannot guarantee that a cord collection will be possible or that any cord blood collected will be suitable for transplant, although every effort will be made to ensure a successful donation is made and stored. It is known that some attempted collections fail due to disruption of the cord or placenta at the time of delivery. If the donation is unsuitable for transplant to the intended patient, it may be discarded.

The need for continued storage of matched donations, unless transplanted, is kept under continuous review with the potential recipient's transplant team. Cord blood, samples and products which are no longer required may be discarded. The decision to store the cord blood is made by the referring clinician.

Part 2. Options

This section shows options for which the mother may wish to give consent. If the donation is unsuitable for transplant to the intended recipient, it may be used for research (subject to ethical approval where appropriate and may involve the commercial sector, genetic testing or the use of human tissue in animals), for service development (the introduction of new procedures) or for education and training (under the auspices of a bona fide institution). There may be occasions when samples are exported for research purposes abroad. Cord blood donations generally require some form of processing before they can be transplanted or stored. This process generates residues or waste products. These residues may also be kept in long-term storage. Cord blood will not be used for research purposes without consent from the donor. Donors will not benefit financially from any research. Donor identity will not be revealed when providing materials for research. Treatment will not be affected in any way should the mother not wish to consent to the use of her cells for research

Applicable documents:

Department of Health
Reference Guide to Consent for Examination or Treatment

Human Tissue Authority
Guidance document for establishments working with umbilical cord blood