

This information should be read before completing referral form FRM1571 (2C) and consent form FRM1572 (2D).

It is in four sections:

**Section A: Ensuring the Cord Blood Donor Mother's Eligibility**

**Section B: Information on Recording Consent using Form FRM1572 (2D)**

**Section C: What Happens After Collection of Cord Blood**

**Section D: Storage and Discard of Cord Blood**

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## **A. Ensuring the Cord Blood Donor Mother's Eligibility**

A referral for directed cord blood collection usually comes from a transplant consultant at a transplant centre and they complete the referral form FRM1571 (2C). The Healthcare Professional (HCP) completing the donor consent form FRM1572 (2D) is responsible for ensuring the donors eligibility to donate and should have appropriate knowledge of the donor mother and family and of the proposed procedures. Therefore, the FRM1572 (2D) is best completed by the donor consultant responsible for donor care in the transplant centre. Other consultants and healthcare professionals may complete form FRM1572 (2D) but should have undergone training in the assessment of donor suitability and eligibility.

JPAC cord blood donor selection guidelines on tissue safety should be reviewed:

<https://www.transfusionguidelines.org/dsg/cb/guidelines/bl008-tissues-safety-entry>

The wider JPAC guidelines are intended for cord blood collections from unrelated donors but have useful advice on donor suitability (<https://www.transfusionguidelines.org/dsg/cb>) and travel risk

<https://www.transfusionguidelines.org/dsg/gdri>. Donor eligibility should also be assessed according to the HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

The HCP completing the form FRM1572 (2D) is responsible for assessing whether the mother is known to have or be at high risk of Hepatitis, Syphilis, HTLV or HIV and for assessing any travel, residency or behavioural risks of transfusion-transmitted conditions or infections. NHSBT must be informed in advance of delivery if mothers are known to be positive for any transfusion-transmissible infections (TTIs) or have any travel, residency or behavioural risks that should trigger discretionary assessment or testing e.g. malaria risk. [Geographical Disease Risk Index \(transfusionguidelines.org\)](https://www.transfusionguidelines.org) For example, if a mother has lived in any malaria-endemic area for a continuous period of 6 months or more at any stage in her life, malaria testing is needed: <https://www.transfusionguidelines.org/dsg/cb/guidelines/ma001-malaria>. Some information may be available from antenatal screening records. Eligibility may need to be re-assessed near the time of delivery e.g. if a mother has travelled abroad at all in the pregnancy.

If the mother is known to be positive for any TTIs, the appropriateness of cord blood collection must be discussed with an NHSBT consultant.

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## **B. Information on Recording Consent using Form 2D**

This guidance note is intended for use in conjunction with consent form FRM1572 (2D) which documents the mother's consent to go ahead with the collection and storage of cord blood for directed transplantation. Form FRM1572 (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 HCP 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 not suitable for transplant to the intended recipient or is no longer required it will be discarded or, subject to consent, used for research.

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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 HCPs seeking consent) the HTA Code of Practice for Consent and Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). In parts 1 and 2 of form FRM1572 (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 and Testing of Cord and Maternal Blood**

Part 1 explains that a donation of cord blood will be collected after the delivery of the 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 the mother's blood and the cord blood will include Hepatitis, Syphilis, HTLV 1 & 2 and HIV 1 & 2. If any tests for mandatory markers of infection are positive, NHSBT will inform the referring team who would be responsible for 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 sufficient or 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 and bacterial contamination is not uncommon. Delayed clamping of the cord will influence the volume of cord blood that can be collected but NHSBT does not seek to influence local obstetric practices – the wellbeing of mother and baby is the priority.

### **Part 2. Storage and Discard of Collected Cord Blood**

NHSBT will not routinely process or store cord blood collections that are smaller than 50mls or have cell counts lower than  $15 \times 10^7$  TNC. The referrer will be notified in these scenarios and should inform the mother. Once stored, 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 unsuitable for transplant to the intended recipient or are no longer required may be discarded. The decision to store, continue to store or discard the cord blood is made by the referring clinician. See section C below.

### **Part 3. Options for Use of Waste Products or Cells that Would Otherwise Be Discarded**

Part 3 shows options for which the mother may wish to give consent. If the donation is unsuitable for transplant to the intended recipient or is authorised for discard, 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.

### **Part 4. Signatures**

This section is for the mother to confirm she has had sufficient information and to document her consent to cord blood collection, testing and storage. The signature of mother is needed here and of the HCP and interpreter (if used) in section 5.

### **Part 5. Confirmation of donor eligibility and discussions around consent.**

This section should be completed by the HCP with appropriate knowledge of the donor mother and family and of the proposed procedures. The HCP completing this form is responsible for assessing donor eligibility and should consider guidance in section A above.

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## **C. What Happens After Collection of Cord Blood**

### **Receipt of Collection in NHSBT CMT Processing Facility**

Cord blood collections that are 50mls or above with a TNC count of  $15 \times 10^7$  or above will be processed in the CMT facility. Bacteriology screening is undertaken, and any positive results are relayed to the referring clinician by e-mail and included in the final report on the product. Antibiotic sensitivities will usually be available. Referring clinicians are advised to inform mothers of any issues affecting the usability of their DCB donation including any that test positive for bacteria.

### **Processing of Cord Blood**

Directed cord blood (DCB) donations are not routinely volume or red cell- reduced in NHSBT processing facilities and so are likely to need a thaw-wash procedure if they are issued. In rare cases, for example, where the CB donor is known to be an HLA match for a recipient who definitely needs a transplant and volume/red cell reduction would be helpful, referring consultants may discuss the feasibility of processing with the CMT laboratory and medical staff.

### **HLA Typing**

The CMT laboratory will arrange HLA typing of the collected DCB unit and send a report to the referring consultant.

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## **D. Storage and Discard of Cord Blood**

The CMT laboratory will keep the DCB unit in storage until they receive notification for discard by the referring clinician. Ongoing payment will be required until discard of the CBU is made in accordance with national guidance.

Cord blood, samples and products which are unsuitable for transplant to the intended recipient or are no longer required may be discarded. The decision to store, continue to store or discard the cord blood is made by the referring clinician. If the collection is successful, the cord blood will initially be stored for one year. The need for continued storage of matched donations should be kept under continuous review and, if a clinical need is identified then cells may be retained for longer.

### **a) Disposal of cells still in storage**

Circumstances where cells will not be needed include:

- the cells are not an HLA match for the intended recipient
- if a disease appears to be cured
- if a disease has progressed such that further treatment with the stored cells will not be helpful.
- If the intended recipient has become unsuitable for further treatment with the cells for any reason, for example significant health problems
- If the intended recipient has died
- Where a CBU has been collected for family history CBU and the transplant physician and family agree there is no need for ongoing storage.

Cells will usually be discarded in these circumstances but, if a clinical need is identified then cells may be retained for a longer period.

### **b) Disposal of cells unsuitable for clinical use**

Examples of such circumstances include:

- If the child who donated the cord blood has been diagnosed with a disease rendering their donation unsuitable to be used for a transplant
- If the cells cannot clearly be identified so it is unclear who donated them. This can happen with cells stored for long times
- Damaged storage bags. The bags are very brittle in storage and can crack. There could be a risk of cell loss or leakage
- Very low number of cells that are insufficient for a transplant
- Bacterial contamination (although option of use with antibiotic cover should be considered)
- Cells that do not appear to be capable of growing when laboratory tests are done on them.

# INF286/5 2L- Information and Guidance for Healthcare Professionals on Collection of Cord Blood for Directed Transplantation



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If any issues affecting the suitability of cells are identified, the transplant physician responsible for the child's care would review the information on the donation and, in conjunction with the medical director of the cell storage facility, decide whether the cells could be used or not.

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Applicable documents: Department of Health Reference Guide to Consent for Examination or Treatment  
Human Tissue Authority guidance for establishments involved in cord blood collection

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