Stem Cell and Immunotherapy Services

NHS Blood and Transplant

Consent for Directed Cord Blood Collection, Testing and Cryopreservation

Effective Date: 24/05/18

2D

NOTE FOR HEALTHCARE PROFESSIONAL: Refer to document 2L (INF286) for guidance on completion of this form.
The Healthcare Professional completing this form is responsible for ensuring the donors eligibility to donate as per the JPAC/SABTO tissue donor selections guidelines.

Details of the donor's mother

Title ..... Surname .....

First name .....

Address .....

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City ..... Postcode .....

Date of birth .....

Intended recipient (if applicable)

Title ..... Surname .....

First name .....

Date of birth .....

Transplant Consultant .....

Hospital .....

Address .....

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 visit our website www.nhsbt.nhs.uk or call us on 0300 123 2323.

Statement of consent

Please read this form carefully. This form records your consent for cord blood to be collected from your placenta. Once the blood has been collected, it will be tested, stored, and, when no longer required, discarded or used for research. This form also records your consent for these procedures. You have the right to change your mind at any time, including after you have signed this form. **Part 1 must be signed and Part 3 completed for the procedure to go ahead. Part 2 contains options for consent.**

Part 1. Collection of cord blood, testing, storage and discard of collected blood

A donation of cord blood and your blood will be collected after the delivery of your child and placenta, or at the time of a Caesarean section should that be necessary. I hereby declare my willingness to donate my placental cord blood for the specific use of a member of the family. I agree to the collected cord blood and my blood being tested for infections including Hepatitis, HIV 1 & 2, HTLV-1, HTLV-2 and Syphilis. If any tests are positive I understand that I will be informed and further tests, counselling and clinical follow-up arranged as necessary. I understand that my consent can be withdrawn. I understand that the collected cord blood will be tissue-typed.

I understand samples of the collected cord blood and my blood may be used for the purposes of quality control, monitoring, and/or public health monitoring purposes. I understand that the NHS Blood and Transplant cannot guarantee a collection will be possible or the suitability for transplant although every effort will be made to ensure a successful cord blood donation is made and stored.

I agree that a suitable donation will initially be stored for a period of one year following which storage will be under continuous review. I agree to the storage of samples for future testing relevant to the use of stored cells. I agree to the donation being discarded if upon review the donation is no longer required or is deemed to be unsuitable.

To indicate consent to Part 1, please sign your name in the box of either YES or NO.

Yes, I consent	No, I do not consent
Signature.....	Signature.....

The mother must sign either YES to indicate consent or NO to withdraw consent in Parts 1 to 2 of this form

Applicable NHSBT documents:

INF286 – *Guidance for Healthcare Professionals in Consenting for the Collection, Testing and Cryopreservation of Cord Blood for Directed Transplantation*

INF1153 – *Information for mothers regarding Directed Cord Blood Collection*

Human Tissue Authority Code of practice – Consent and HTA Guidance document for establishments working with Umbilical cord blood

Department of Health Reference Guide to Consent for examination or Treatment

Part 2. Options

The waste products or samples remaining after the processing of the collected cord blood, and donations that are no longer needed may be used for training, service development or ethically approved research. If you are willing to consent to these options please initial below. There is no personal financial benefit to you from any research undertaken and you waive all the rights to any registered patents.

I agree that any waste products remaining after the processing of my cells, and any part of my donation(s) when they are no longer required, be used anonymously for :

(Initial to indicate your wishes)

	Yes, I consent	No, I do not
Service development, training & educational use	Initial.....	Initial.....
Ethically approved research by NHSBT and its research partners	Initial.....	Initial.....
Ethically approved research involving the commercial sector	Initial.....	Initial.....
Ethically approved research involving the export of tissues for use abroad	Initial.....	Initial.....
Ethically approved research involving the use of human tissue in animals	Initial.....	Initial.....
Ethically approved research involving genetic testing	Initial.....	Initial.....

2D – continued

Mother's name	Date of birth

Consent for Directed Cord Blood Collection, Testing and Cryopreservation

Part 3. Signatures

To be completed by the mother

I confirm that I have read and signed the sections on the front of this form. I have received and understood sufficient information to give informed consent.

Signature..... Date.....

To be completed by the Healthcare Professional with appropriate knowledge of the proposed procedures

I confirm that I have counselled and consented the mother in accordance with the NHSBT guidance document 2L (INF286) and the department of *Health Reference Guide to Consent for Examination or Treatment*. I have discussed the nature of the proposed procedures, and have discussed any particular concerns of the mother. I have read and applied the HTA's Code of practice for consent and the HTA's Guidance document for establishments working with Umbilical cord blood.

I confirm that I have emphasised:

- the rationale for the cord blood collection and its potential therapeutic benefits
- the need for microbiology testing and tissue typing
- storage issues, including the need for discard and the use of cord blood for research, service development and education

I have provided the mother with INF1153 – Information for Mothers Regarding Directed Cord Blood Collection (2R) and the following leaflets/tapes:

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Name (print)..... Signature.....

Job title..... Date.....

To be completed by the interpreter (where appropriate)

I have interpreted the information above to the mother to the best of my ability and in a way in which I believe she can understand.

Name (print)..... Signature.....

Job title..... Date.....

Additional information.....

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