

Consent for the Testing, Storage and Discard of Stem Cells or Lymphocytes

Effective Date: 24/05/18

NOTE FOR HEALTHCARE PROFESSIONAL: Refer to document 2K (INF285) for guidance on completion of this form. This form and accompanying blood samples must be returned at least 1 week prior to a proposed cell collection. For every patient / donor please send blood samples in two 6ml EDTA tubes, plus one 6ml Greiner PPT tube. If blood grouping is required an extra 6ml EDTA tube is needed. If a test for malaria/chagas is required an additional 6ml EDTA tube is needed.

Please return this form to:

2B

Patient / donor (please circle)

Guardian (if applicable)

Title..... Surname.....
 First name.....
 Address.....
 City..... Postcode.....
 Date of birth.....
 NHS no.....
 Hospital no.....
 Cells to be collected at.....
 Hospital for transplant.....

Relationship to patient or donor.....
 Title..... Surname.....
 First name.....
 Address.....
 City..... Postcode.....
 Date of birth.....
 Proposed date of collection.....

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.

Statement of consent

Please read this form carefully. You will soon undergo a stem cell or lymphocyte collection procedure. These cells may be collected from your bone marrow or from your blood. You will be required to complete and sign a separate consent form for the collection procedure. This form will be given to you separately. Once your cells have been collected, they will be tested and stored. When no longer required they may be discarded or used for research. This form is intended to record 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. Testing, Storage and Discard of Collected Cells

I agree to my blood being tested for infections including Hepatitis, Syphilis, HTLV and HIV. If any of these tests are positive I understand that I will be informed and further tests, counselling and clinical follow-up will be arranged as necessary. I understand that fresh or frozen samples of my blood and samples of cells may be used for the purposes of quality control/monitoring, public health monitoring purposes, service development and/or future testing relevant to the quality of my stored cells. I understand that my cells may be frozen and stored until required and that the need for continued storage will be kept under review. I consent for my cells to be discarded by incineration when they are no longer required or they prove unsuitable for clinical use.

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 patient, donor or guardian must sign either YES to indicate consent or NO to withdraw consent in parts 1 to 2 of this form

Part 2. Options

The waste products generated and donation(s) no longer needed may be used for 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 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 :

- Service development, training & educational use
- Ethically approved research by NHSBT and its research partners
- Ethically approved research involving the commercial sector
- Ethically approved research involving the export of tissues for use abroad
- Ethically approved research involving the use of human tissue in animals
- Ethically approved research involving genetic testing

(Initial to indicate your wishes)

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

Applicable NHSBT documents:
 MPD634 – The Use of SCI Referral Forms and Information Sheets
 INF285 – Guidance for Healthcare Professionals in Consenting for the Testing, Storage and Discard of Stem Cells and Lymphocytes

Stem Cell and Immunotherapy Services

2B – continued

Name

Date of birth

Consent for the Testing, Storage and Discard of Stem Cells or Lymphocytes

Part 3. Signatures

To be completed by the patient, donor or guardian

I confirm that I have read and signed the above sections. I have received and understood sufficient information to give informed consent.

Name (print) 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 patient, donor or guardian in accordance with NHSBT guidance document 2K (INF285) 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 patient, donor or guardian. I have read and applied the HTA's codes of practice on the 'Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation' and on 'consent'. I confirm that I have emphasised:

- the rationale for the stem cell or lymphocyte collection and its potential therapeutic benefits;
- the need for microbiology testing;
- storage issues, including the need for discard and the use of stem cells for research, service development and education;

I have provided the patient, donor or guardian with the following leaflets and 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 patient, donor or guardian to the best of my ability and in a way in which I believe he/she can understand.

Name (print) Signature

Job title Date

Important notes (tick if applicable)

Patient, donor or guardian has consented to participation in a clinical trial

Patient, donor or guardian has withdrawn consent

Additional information

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Patient, donor or guardian to sign here