Template Consent for Testing, Storage and Discard of Cellular Therapy Products

Patient / donor (please circle)

Surname.....

First name.....

Address.....

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

Date of birth.....

NHS no.....

Hospital no.....

Guardian (if applicable)

Relationship to patient or donor……

Surname……...

First name……..

Address……..

City…….Postcode……...

Date of Birth……..

Proposed date of collection.....

Hospital for transplant……

Cells to be collected at……..…

Statement of consent *Please read this form carefully.*
You will soon undergo a stem cell or lymphocyte collection procedure. You will be required to complete and sign a separate consent form for the collection procedure. 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.

Parts 1,2,4 & 5 must be signed and completed for the procedure to go ahead. Part 3 contains options for consent. The procedure can go ahead even if you opt out of alternative uses of waste cells in Part 3.

Part 1. Testing *(Please circle)*

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. **Yes / No**

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 surveillance purposes, service development and/or future testing relevant to the quality of my stored cells. **Yes / No**

Part 2. Storage and Discard

I understand that my cells may be frozen and stored until required. The need for continued storage will be reviewed. After 5 years, cells may be discarded. If a clinical need is identified then cells may be retained for longer.

Please indicate Yes to <u>either</u> option A <u>or</u> option B below *(circle selected option)***:**

A. I consent for my cells to be discarded by incineration when they are no longer required, or they prove unsuitable for clinical use as explained in the information leaflet [*ref*]. **Yes / No**

OR…..

B. I would like to be contacted at the time of planned discard of my cells. **Yes / No**

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

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 indicate 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:

Use of waste products	**I consent** *(please circle)*
Service development, training & educational use	**Yes / No**
Ethically approved research by [*this trust*] and its research partners	**Yes / No**
Ethically approved research involving the commercial sector	**Yes / No**
Ethically approved research involving the export of tissues for use abroad	**Yes / No**
Ethically approved research involving the use of human tissue in animals	**Yes / No**
Ethically approved research involving genetic testing	**Yes / No**

Part 4. Storage of Personal Information

All information provided to [*the hospital trust*] is used in accordance with the General Data Protection Regulation and all other relevant privacy and data protection laws.

I give permission for my personal information to be held on the Stem Cell Transplant programme databases and for the Stem Cell Transplant programme staff to share this information where this is essential for medical purposes**.**	**Yes / No**

Part 5. Signatures - To be completed by the patient, donor or guardian.

I confirm that I have read and signed the above sections. I have no further questions at this time and feel that I have received and understood sufficient information to give informed consent.

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

Role (if patient or donor is not the signatory)…….

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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 [*hospital]* policy. I have read and applied the HTA's codes of practice on consent and, for allogeneic donors, the 'Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation.

I have discussed the nature of the proposed procedures and have discussed any particular concerns of the patient, donor or guardian.

I confirm that I have emphasised:
• the rationale for the collection and its potential therapeutic benefits;
• the need for microbiology testing;
• storage issues, including the need for discard and the use of cells for research, service development and education;

I have provided the patient, donor or guardian with the following leaflets and/or weblinks:
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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.....

Patient, donor or guardian to sign here (if either of the above boxes ticked):

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

Role of person signing……