Consent form

Allogeneic donor peripheral blood stem cell (PBSC) mobilisation and collection

Cancer directorate (Haematology)

Interpreter's statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed
(interpreter): .................................................................Date: ...........................................

Name (PRINT): ..............................................................................................................

Or, please note the language line reference ID number: ........................................
Consultant or other responsible health professional

Name and job title:........................................................................................................................................................................

☐ Any special needs of the patient (eg help with communication)?.............................................

A) Name of proposed procedure or programme of treatment

(include brief explanation if medical term not clear)  Patient’s side: left / right / N/A

Allogeneic donor peripheral blood stem cell mobilisation and collection

☐ GCSF mobilisation and stem cell collection by leukapheresis

☐ Stem cell / Lymphocyte collection by leukapheresis (no mobilisation required)

B) Statement of health professional (details of treatment, risks and benefits)

1  I confirm I am a health professional with an appropriate knowledge of the proposed procedure / treatment, as specified in the hospital’s consent policy. I have explained the procedure/treatment to the patient. In particular, I have explained:

a) The intended benefits of the procedure / treatment (please state)

☐ Elective collection and storage of blood or stem cells that may be used as part of your recipients future treatment

b) The possible risks involved. Addenbrooke’s always ensures any risks are minimised. However all procedures / treatments carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient

☐ G-CSF side effects (including bone aches and pains)

☐ Apheresis complications (including venous access difficulties, citrate toxicity and hypovolaemia)

☐ Unsuccessful mobilisation

☐ Need for mandatory donor microbiology testing including HIV, hepatitis B&C, HLTV and syphilis screening
c) What the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient……………………………………………………………………

d) Any extra procedures that might become necessary during the procedure / treatment such as:

☐ Blood transfusion ☐ Other procedure (please state, for example anaesthetic)

• Storage issues including duration and discard
• Need for mandatory donor microbiology testing including HIV, hepatitis B& C and syphilis screening

2 The following information leaflet has been provided:

Version, reference and date:………………………………………………………………..

Or ☐ I have offered the patient information about the procedure but this has been declined.

☐ I confirm that I have read and applied the HTA’s code of practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation and the HTA’s code of practice on consent.

3 This procedure will involve:

☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation ☐ None

Signed (Health professional): Date: DD / MM / YYYY

Name (Print): Time: HH : MM

Designation: Contact / bleep no:
I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding. I confirm that the information about my health I have provided is complete and correct to the best of my knowledge. An additional information leaflet explaining what consent means is available on request. Please feel free to ask for a copy to read before putting a tick in the relevant boxes for the following questions:

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<tr>
<td><strong>Patient has consented to participation in a clinical trial</strong></td>
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<tr>
<td><strong>See also advance directive / living will</strong></td>
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1. **Use of tissue and medical imaging for clinical research**
   a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for research which may include genetic research
   - Yes
   - No
   
   b) I agree that relevant sections of my medical record, including medical imaging, may be looked at by researchers, or by relevant regulatory authorities, where my tissue is being used for research. I give permission for these individuals to have access to my records.
   - Yes
   - No

2. **Photography, audio or visual recording**
   a) I agree to the use of any of the above type of recordings for the purpose of diagnosis or treatment
   - Yes
   - No
   
   b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting
   - Yes
   - No

3. **Medical training**
   I agree to the involvement of medical and other students as part of their formal training
   - Yes
   - No

4. **Female patients aged 12-55 years. Is there any chance you might be pregnant?**
   I understand that I need to avoid becoming pregnant during the course of my treatment and, if I think I might be pregnant, I will inform the staff treating me
   - Yes
   - No
Medical testing
I understand the need for mandatory donor microbiology testing, including HIV, hepatitis B, hepatitis C and syphilis screening

Yes  No

Data collection
I understand that data about me will be held electronically and may be passed between the European Bone Marrow Transplant Registry (The Netherlands) and the International Bone Marrow Transplant Registry (USA), to facilitate research and my care

a) I understand that information about me will be passed to the recipients physicians and may be discussed with the recipient

Yes  No

Research
I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

Yes  No

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Yes  No

I/We consent to partially anonymised clinical data being shared with regional/national/international data collections, as appropriate, with the aim of improving patient outcomes. Partially anonymised data is data that cannot identify you as the person by the holders of the data collections but the Trust would be able to link this back to the information that it holds about you.

Yes  No

I/We understand that my initials and date of birth will be shared.

Yes  No

I have listed below any procedures that I do not wish to be carried out without further discussion.
I have read and understood the patient information entitled ‘Consent’ and the above additional information. I agree to the procedure / treatment.

Signed (Patient): 
Name of patient (Print):

If signing for a child or young person; delete if not applicable
I confirm I am a person with parental responsibility for the patient named on this form

Signed: 
Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below:

Signed (Witness):
Name of witness (Print):
Address:

D) Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): 
Name (Print): 
Job title:

E) Confirmation of patient consent

Confirmation of consent (where the procedure/treatment has been discussed in advance). On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure/treatment to go ahead.

Signed (Health professional): 
Name (Print): 
Job title: