

Consent form 1

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Oncology Centre (Haematology SDU)
Consent form
 Patient agreement to
 investigation or treatment

Responsible health professional/job title

Special requirements
 (For example, other language/other communication method)

Name of proposed procedure or course of treatment

Allogeneic donor peripheral blood stem cell mobilisation and collection

- G-CSF mobilisation and stem cell collection by leukapheresis
- Stem cell/Lymphocyte collection by leukapheresis (no mobilisation required)

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient. In particular, I have explained:

- The intended benefits of the procedure
- Elective collection & storage of blood or stem cells that may be used as part of your recipients future treatment
- Any serious or frequently occurring risks from the procedures including
 - G-CSF side effects (including bone aches and pains)
 - Apheresis complications (including venous access difficulties, citrate toxicity and hypovolaemia)
 - Unsuccessful mobilisation

Other including those specific to the patient

Any extra procedures that might become necessary during the procedure

- Storage issues including duration and discard
- Need for mandatory donor microbiology testing including HIV, hepatitis B & C & syphilis screening
- Other
- The following information leaflet has been provided:
 Issue no./Issue date:

This procedure will involve: General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

- I have offered the patient information about the procedure but s/he has declined information.
- 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

Important notes: (tick if applicable)

- Patient has consented to participation in a clinical trial.
- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will

Statement of the interpreter (if appropriate)

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

Interpreter's signature Date:

Name (PRINT):

Copy accepted by patient: yes / no (please circle)

Statement of patient/parent/guardian

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which described the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you.

You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

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

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

Please tick boxes to indicate you either agree/disagree to the three points below. Yes No

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research. If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I understand the need for mandatory donor microbiology testing, including HIV, hepatitis B, hepatitis C and syphilis screening.

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.

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

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Female patients between the age of 12 and 50 years please read the following statement

I confirm that I am not pregnant

I understand that I need to avoid becoming pregnant during the course of my treatment

If I think that I might be pregnant, I will inform the staff treating me.

Patient/parent/guardian signature: Date:

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: Date:

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature..... Date:

Name (PRINT): Job Title:

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