Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

CONSENT FORM FOR BLOOD STEM CELL DONATION (UK)

The original consent form should be retained by the Collection Centre. One copy should then be retained by the donor and a copy forwarded to Anthony Nolan

A. STATEMENT BY HEALTHCARE PROFESSIONAL (Please tick the boxes)

I confirm that the donor for whom consent is being taken has identified themselves by confirming their name, date of birth and home address information supplied to me by Anthony Nolan.

I have explained the proposed procedure of peripheral blood stem cell mobilisation and collection to the volunteer donor and briefly discussed the intended benefits to the patient. In particular, I have explained to the donor:

1. the use of Granulocyte-Colony Stimulating Factor (G-CSF) to mobilise the donor's stem cells and any serious or potential side effects from this drug

2. the need for microbiology testing and in particular the need to test the donor's blood for markers of infection including Syphilis, HIV, HTLV, Hepatitis B, C & E

3. the use of a blood cell separator to collect the donor's stem cells and any serious or potential occurring side effects involved in the procedure

4. the potential need to insert a femoral, internal jugular or sub-clavian central venous line if peripheral access is not adequate, as well as any serious or frequently occurring risks associated with such a procedure. I have also explained that separate donor consent for this procedure would be required

5. the possible short and long-term risks associated with donating peripheral blood stem cells including:

    - Common side effects (>1/10) associated with G-CSF such as bone pain and myalgia (muscle pain), for which paracetamol is often required
    - Less common side effects of GCSF (<1/10) including headache, fatigue, fever, nausea and vomiting, and thrombocytopenia (low platelets).
    - That in extremely rare cases (fewer than 1 in 5000- 10,000) the following side effects may occur:
        - vascular events including intracranial haemorrhage: extremely rare cases reported by an international registry (the majority with underlying risk factors identified such as history of significant head injury).
        - Splenic rupture; causing sudden or severe abdominal pain and bleeding requiring immediate medical attention.
        - anaphylaxis (allergic reaction)
        - pain/discomfort that persists longer than the anticipated recovery time
    - Side effects of the apheresis procedure:
        - hypocalcaemia (sudden drop of calcium in the bloods), which can cause transient pins and needles, numbness muscle spasms, cramps, and in severe untreated cases risk of seizures (extremely rare). This may require calcium tablets or occasionally IV calcium replacement
        - bruising and bleeding at the site of cannulation or central line site
        - the rare possibility of infection or persistent nerve pain or damage at the cannulation site

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

6. that in a small number of donors (fewer than 1 in 100) G-CSF fails to mobilise the stem cells and results in a sub-optimal collection. In these cases, the transplant centre may decide not to infuse the cells, or they may request an additional medication (plerixafor) or a bone marrow stem cell collection in addition, which can be accepted or declined by the donor.

7. to reduce risk of possible exposure to transmissible infections ahead of donation, including unprotected sex with a new or high-risk sexual partner or intravenous drug use, and if such activity occurs to inform Anthony Nolan to facilitate further testing.

8. the requirement to store confidential information in accordance with applicable data protection and related laws and guidance (see section G below)

9. the possible storage of cells, the need for discard of stored material as well as the possible use of cells for research purposes by the transplant centre (which depending on the circumstances, may be outside of the UK and the EEA) ("the Transplant Centre").

10. that a copy of all test results and findings will be sent to Anthony Nolan, and relevant clinical information may be shared with the donor's GP.

11. the potential need for cryopreservation should the transplant centre request this for patient safety.

Please tick this box to confirm you have explained points **1** to **11** to the donor ☐

Please tick this box to confirm you believe the donor understands the information provided and can freely give consent ☐

I confirm that I have read and understood:

- The current versions of the HTA's Codes of Practice on the Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation,

  and on Consent
- The current version of the HTA's Guidance for Transplant Teams and Accredited Assessors and have applied the principles and procedures accordingly. ☐

Signed by Healthcare Professional	**Date of assessment**
First name	**Last name**
Job title	**Collection centre**

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

B. STATEMENT BY DONOR PROCEDURE INFORMATION (Please tick the boxes)

I've been told I'm a match for a patient in need of a stem cell transplant. I provided blood samples to confirm compatibility, and I've been asked to donate haematopoietic (blood) stem cells. After consideration I've voluntarily chosen to donate my cells through the procedure known as a mobilised peripheral blood stem cell collection (PBSC), which involves taking a drug to increase the number of stem cells my body produces and then giving blood to collect the stem cells ☐

The healthcare professional named in section A has clearly explained to me:

- the donation procedure, including the use of a blood cell separator machine (apheresis) and the administration of the drug G-CSF (Granulocyte Colony Stimulating Factor) ☐
- the possible short and long-term risks related to the collection
- that if sexually active to take extra precautions ahead of my donation to reduce the risk of contracting an infection that could be passed to the patient
- if I have any new sexual partners between now and the donation, to inform Anthony Nolan via my coordinator

I have received and understood the information provided to me by Anthony Nolan and have been given the opportunity to ask questions. Any questions have been answered to my satisfaction. I believe I have been given sufficient information to give my informed consent to proceed with the donation. I agree to:

1. undergo blood tests to ascertain my fitness to donate and to check that my blood does not contain evidence of important infections including those caused by the Syphilis, HIV, HTLV and Hepatitis B, C & E viruses. I understand that if the results of any of these tests are abnormal, I will be informed. I also understand that further tests, counselling and clinical follow-up will be arranged by Anthony Nolan as necessary
2. receive G-CSF in order to produce sufficient stem cells in my circulating blood
3. donate stem cells to a patient, collected by the use of the apheresis machine

Please tick this box to confirm your agreement with points **1** to **3** above ☐

I understand that:

4. there is a possibility I may be asked to donate cells to this patient on a second occasion. I am willing to be approached in the future to discuss and consider this, but also understand that I am free to decline a request for a further donation at any time
5. I may withdraw my consents at any time by speaking with my Anthony Nolan coordinator or the staff at the donor collection centre. The basic risks to the patient have been explained to me and I fully understand the life-threatening implications for the patient if I withdraw after the patient has commenced pre-transplant conditioning treatment

Please tick this box to confirm your agreement with points **4** to **5** above ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

In addition, I understand that:

6. I cannot be given a guarantee that a specifically named healthcare professional will perform the procedure, although the healthcare professional will have the required training and experience

7. my recovery will be monitored by Anthony Nolan and I agree to participate in routine follow-ups post-donation, as well as annually up to six years. Follow-ups will then be at eight and 10 years after donation

8. my stem cells will be given to a patient whose anonymity will be maintained for at least two years, and who may remain anonymous permanently

9. the patient who receives my cells may be of any age, race or religion and be living in any part of the world

10. the primary responsibility for the blood cell collection and associated G-CSF therapy rests with the medical and other professional staff who undertake the procedure

11. this consent is automatically cancelled if I am found not to be fit to donate blood stem cells using a blood cell separator machine

12. transplant is carried out in the hope that it will cure the patient. Sadly however, the patient may not be cured and may not survive in the longer-term

Please tick this box to confirm your agreement with points **6** to **12** above ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

C. STATEMENT BY DONOR: STORAGE, USE AND DISCARD OF CELLS AT TRANSPLANT CENTRE

I understand that:

1. some of my blood, cells or DNA (which may be taken from blood or cells provided by me prior to, or at the time of, donation) may be stored for the purposes of undertaking tests to monitor and appropriately treat the patient of this particular transplant

2. a small part of my donation may be stored as a source of therapeutic cells to be administered to the patient after the transplant if needed

3. fresh or frozen samples of my blood, cells or DNA may be used for the purposes of quality control monitoring, clinical audit, public health surveillance purposes and/or future testing relevant to the quality of my stored cells

4. my cells will be disposed of, when they are no longer required or prove unsuitable for clinical use (or for research, if I have provided consent), in a manner which meets applicable regulations for the disposal of biohazardous materials

Please tick this box to confirm your agreement with points **1** to **4** above ☐

Further testing of the cells following infusion to the patient

I understand that:

- Following my cells being infused into the patient, the transplant centre may carry out testing to support the patient's recovery. These tests may include genetic screening, as well as screening for other blood disorders. These tests are performed on the patient and not directly on my blood samples. However, as the patient's blood cells are made from donor stem cells, in rare cases these tests may find a genetic variant thought to have originated from donor cells, your cells.
- Confirming if a genetic variant originated from donor stem cells or recipient cells is not possible without additional confirmatory genetic testing.
- Some genetic findings of potential donor origin may be relevant to my health and wellbeing, or the health and well-being of my children (or future children).

    1. any genetic findings from the patient, thought to have originated from donor cells, that are considered of clinical significance, or are of uncertain significance at the time of testing, will be shared with me in order to arrange appropriate genetic counselling and testing, which I can accept or decline.

    2. any genetic findings from the patient, thought to have originated from donor cells, that are not considered of clinical significance, or are of uncertain significance at the time of testing, will not be routinely shared with me.

Please tick this box to confirm your agreement to being informed of any clinically significant findings of potential donor origin (points **1** and **2**) ☐

OR

If you **do not** want to be informed of any clinically significant genetic findings of potential donor origin, even if life-threatening or preventable conditions or when withholding information may be harmful, please tick here ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

D. STATEMENT OF DONOR: CRYOPRESERVATION OF PBSC DONATION

On occasion, a transplant centre may request to freeze (cryopreserve) the donated stem cells, to be infused to the patient on a later date. This may be due to patient issues, scheduling or logistics issues.

In addition to consenting to the donation procedure in the terms set above in section B:

1. I voluntarily consent to the cryopreservation of my cells, if necessary, and understand that the stem cells collected during the PBSC donation process may be cryopreserved for infusion at a later date
2. If my cells are cryopreserved, I give consent for my cells to be discarded if they are no longer required or prove unsuitable for clinical or research use, and in this event, I will be informed by Anthony Nolan
3. If discarded, I understand they will be disposed of appropriately according to applicable regulations for the disposal of biohazardous materials

Please tick this box to confirm your agreement with points **1** to **3** above ☐

OR

I do not consent to my cells being cryopreserved ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

E. STATEMENT BY DONOR: USE OF CELLS FOR RESEARCH

On occasion, there may be cells remaining in the product bag post-transplant and Anthony Nolan or transplant centres may request to use these remaining cells for research purposes. This may also be the case with the full donation if, for any reason, the transplant cannot take place. In these cases, requests are assessed and approved by a properly constituted research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that:

1. Some or all of my blood, cells or DNA from this collection could be used in a non-identifiable way for future medical research projects. I will not benefit financially from any research undertaken and I waive all rights to any registered patents

2. My participation in the storage of my blood, cells or DNA for research is voluntary. Refusal to participate will not affect my status on the Anthony Nolan register as a stem cell donor or result in the loss of any benefits such as follow-up care following my donation

3. My pseudonymised data may be used to support such research and will be used in accordance with the Anthony Nolan Privacy Policy

4. I have the right to withdraw consent for the use of my blood, cells or DNA for research without it affecting my status on the Anthony Nolan register as a stem cell donor or resulting in the loss of any benefits, such as follow-up care post-donation. I understand that once my cells have been used for a research study, they will not be able to be withdrawn from that study.

Please tick this box to confirm your agreement with points **1** to **4** above ☐

OR

Please tick this box to confirm that you do not want your blood, cells or DNA to be used for future research ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

F. STATEMENT BY DONOR: ANTHONY NOLAN PATIENT DONOR PROJECT

Anthony Nolan is undertaking a research study that we would like you to consider joining. This study is investigating the importance of HLA matching (tissue typing) and other genetic factors that have been shown to influence the outcome of unrelated stem cell transplants.

Although this research will not directly alter results in this specific transplant, it is hoped that in future it will enable us to advise which donor should be chosen in the event that no fully matched donor is available, but where there is a choice of partially matched donors.

We are asking UK donors and all patients who receive stem cells from a UK donor to join this research project. The DNA extracted from this sample will only be used for matching studies in our laboratory (i.e. only looking for factors to do with outcome in haematopoietic stem cell transplants). It will be stored within the Research Institute, with a unique coding number for the duration of the study (i.e. only the researchers will be able to link the sample to the person who provided it).

After the study is completed, we would like to store the donor/patient sample pairs in a anonymised form (i.e. the details cannot be traced back to an individual person). The purpose of this is to enable us to test these samples for any genetic factors related to stem cell transplantation that may be discovered in years to come. These samples will be owned by Anthony Nolan. All that will be required from you will be a blood and/or a buccal swab sample (mouth swab). If you choose not to join this study, it will not affect your treatment/donation in any way.

I understand the following:

1. I have read and fully understood the above information regarding participating in an Anthony Nolan research study.

2. I have had the opportunity to ask questions and have received satisfactory answers.

3. my participation is voluntary and if I choose not to provide a blood and/or buccal cell sample (mouth swab), my treatment/donation will not be affected in any way.

4. I agree to take part in the study by providing a blood and/or buccal cell sample (mouth swab).

5. I agree that my blood and/or buccal cell sample (mouth swab) can be retained after the study completes (in a anonymised form).

6. Anthony Nolan will use and store my personal data in accordance with the Anthony Nolan Privacy Policy and that I may withdraw my consent to the use of my personal data, at any time, in accordance with the terms of this policy.

Please tick this box to confirm your agreement with points **1** to **6** above ☐

OR

I <u>do not</u> want to be part of this study ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

G. STATEMENT BY DONOR: PRIVACY

I give my consent to Anthony Nolan processing and storing the following data as per the Anthony Nolan privacy policy (available at **anthonynolan.org/privacy**), specifically:

The data I have provided in this form ☐

Any analysis of the blood sample I donate, which I understand will be tested for markers of infection including syphilis, HIV, HTLV, and Hepatitis B, C & E ☐

The results of such blood tests, which I specifically consent to Anthony Nolan sharing with my GP, if deemed necessary for medical reasons ☐

Any analysis of the stem cells I donate, which I understand may be stored by the transplant centre and/or Anthony Nolan for patient transplant and, if I have agreed, for research purposes ☐

All health and medical information I provide, which I understand may be stored by the Transplant Centre and Anthony Nolan in order to establish I am medically fit to donate to a patient ☐

My pseudonymised personal data that may be shared with third party organisations including but not limited to the European Group for Blood and Marrow Transplant registry, to analyse factors that contribute to the outcome of transplants, in accordance with applicable data protection and related laws and guidance ☐

I consent to Anthony Nolan's transfer of my data (in pseudonymised form) to countries without the same data protection laws as the UK/EU for the purposes stated in the Anthony Nolan privacy policy. Anthony Nolan agrees to protect my data as described in its Privacy Policy and provide adequate protection for transfers to countries outside the UK ☐

I understand that I have the right to access my medical information in accordance with applicable data protection and related laws and guidance ☐

Additional statement only relevant to participants in the Anthony Nolan Patient Donor Project:

Additionally, and only where I have agreed to participate in the research detailed in Section F, I give my consent to Anthony Nolan to use the data provided in this form and a sample of my DNA for the purposes of the research outline at section F above. ☐

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

H. DONOR AND HEALTHCARE PROFESSIONAL DECLARATION

DONOR I confirm that I have read and completed parts B, C, D, E and F of this form.

Signed by Donor	Date
Donor first name	Donor last name

HEALTHCARE PROFESSIONAL I confirm that I have witnessed the above donor completing parts B, C, D, E and F of this form.

Signed by Healthcare Professional (usually same individual in section A)	Date
Healthcare Professional first name	Healthcare Professional last name
Healthcare Professional title (and email if not the Healthcare Professional mentioned in section A)	

Donor last name lastname	Donor first name Firstname	Donor ID an_gridformatte

I. CONFIRMATION OF CONSENT

TO BE COMPLETED BY THE DONOR AND HEALTHCARE PROFESSIONAL WHEN THE DONOR IS ADMITTED FOR THE PROCEDURE

DONOR please tick the relevant box

I confirm that I have no further questions and that I wish to proceed with stem cell donation. ☐

I confirm that I have not been coerced, paid, or received any inducement in relation to this donation. ☐

OR

I withdraw my consent and will not be proceeding ☐

Signed by Donor	Date
Donor first name	Donor last name

HEALTHCARE PROFESSIONAL

Signed by Healthcare Professional	Date
Healthcare Professional first name	Healthcare Professional last name
Job title	Collection centre