Donor last name lastname	Donor first name firstname	Donor ID an_gridformatted

CONSENT TO DONATE STEM CELLS FROM A BONE MARROW COLLECTION

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 a bone marrow stem cell collection to the volunteer donor and briefly discussed the intended benefits to the patient. In particular, I have explained to the donor:

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

2. the need for a general anaesthetic and any possible serious or frequently occurring side effects from this procedure

3. the process of bone marrow aspiration and any serious or frequently occurring risks or side effects that may be involved in the procedure

4. the need to be admitted to hospital for two nights and to rest at home for up to 2 weeks after discharge to help recovery and to reduce, where possible, side effects following the procedure

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

   - after the procedure it is expected for haemoglobin to be lower, because the bone marrow contains many red cells. In some cases, they may become anaemic. I have explained that there may be a need of oral iron (approximately for 3 months in this situation) or if the pre-harvest ferritin is low, IV iron may be necessary on the day of admission for the bone marrow harvest
   - that surgical wounds will be present after the procedure (between 1 – 3 puncture sites) on each side of the lumbar vertebrae)
   - that the major risk of harvest is associated with anaesthesia and include (uncommon & extremely rare) the following: aspiration pneumonia, pulmonary embolus, ventricular tachycardia, cerebral infarction and cardiac arrest
   - surgical pain: should the harvesting needle breach the sacroiliac joint
   - the specific procedure related risks including bacteraemia, local infection and/or haematomas (bruises) at the harvest puncture sites, post-operative fever, fractured iliac crests and in extremely rare cases: broken aspiration needles requiring surgical removal, transient pressure neuropathies (numbness) spinal headache and bone marrow or air emboli
   - the possibility that a blood or platelet transfusion may be required during or after the procedure

6. 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

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

8. 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 or Anthony Nolan (which depending on the circumstances, may be outside of the UK and the EEA) ("the Transplant Centre").

9. that a copy of all test results and findings will be sent to Anthony Nolan

10. 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 **10** above 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_gridformatted

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 bone marrow transplant, 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 bone marrow stem cell collection ☐

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

- the donation procedure, including the general anaesthetic
- 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. undergo a general anaesthetic for the purpose of donating marrow for a patient requiring a bone marrow transplant
3. donate the necessary amount of my bone marrow to a patient

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
6. Following my cells being infused, 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. In rare cases these tests may result in findings which may be relevant to my health and wellbeing, and I may be contacted by Anthony Nolan to discuss these

Please tick this box to confirm your agreement with points **4** to **6** above ☐

Donor last name lastname	Donor first name firstname	Donor ID an_gridformatted

In addition, I understand that:

7. 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

8. I will be given further opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure

9. 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.

10. 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

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

12. the primary responsibility for the bone marrow collection rests with the medical and other professional staff who undertake the procedure

13. this consent is automatically cancelled if I am found not to be fit to donate stem cells by bone marrow collection

14. 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 **7** to **14** above ☐

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 ☐

D. STATEMENT OF DONOR : CRYOPRESERVATION OF BONE MARROW 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 this bone marrow 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_gridformatted

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_gridformatted

F. 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 samples I provide, which I understand will be tested for markers of infection including syphilis, HIV, HTLV and Hepatitis B, C & E	☐
The results of 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 for 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 understand that if the patient is based outside of the UK, my personal data will be shared with an international donor registry and/or international transplant centre in accordance with the Anthony Nolan Privacy Policy	☐
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 and EEA.	☐
I understand that I have the right to access my medical information in accordance with applicable data protection and related laws and guidance	☐

Donor last name lastname	Donor first name firstname	Donor ID an_gridformatted

G. 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_gridformatted

G. 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