CONSENT TO DONATE LYMPHOCYTES FROM THE BLOODSTREAM

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 donor lymphocyte 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 use of a blood cell separator to collect the donor's lymphocytes and any serious or potential occurring side effects involved in the procedure

3. the possible short and long-term risks associated with donating lymphocytes including:

- hypocalcaemia (sudden drop of calcium in the bloods) due to the citrate (ACD-A) used in the apheresis procedure, which can cause transient paraesthesia (pins and needles, numbness), muscle spasms, cramps, and in severe untreated cases risk of seizures (extremely rate). This may require calcium tablets or occasionally IV calcium replacement
- bruising and bleeding at the site of venepuncture or central line site
- the possibility of infection of the venepuncture site

4. 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

5. the initial infusion to the patient of a small quantity of the total cells collected and the cryopreservation of the remaining cells, which will be given in escalating doses to the patient over a period of several months

6. the potential need for cryopreservation of the total cells should the transplant centre request this for patient safety

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 the volunteer donor's GP and to Anthony Nolan

Donor last name lastname	Donor first name Firstname	Donor ID an_donorfullid an_donorinternationalregistry

Please tick this box to confirm you have explained points **1** to **9** 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**

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

I've been advised that the patient to whom I have previously donated haematopoietic (blood) stem cells would benefit from further treatment with a donation of specific therapeutic cells known as lymphocytes. After consideration I have voluntarily chosen to proceed with a further donation of these cells through a collection process known as apheresis ☐

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)
- the possible short and long-term risk of this procedure ☐
- 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. to donate lymphocyte cells to a patient, collected using the apheresis machine

Please tick this box to confirm your agreement with point **1** to **2** above ☐

I understand that:

3. there is a possibility that I may be asked to donate cells to this patient again. 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
4. 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 **3** to **4** above ☐

In addition, I understand that:

5. 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

6. my recovery will be monitored by Anthony Nolan and I agree to participate in routine follow-ups after one month, then yearly up to six years. Follow-ups will then be at eight and 10 years after donation

7. the primary responsibility for the lymphocyte collection rests with the medical and other professional staff who undertake the procedure

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

9. 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 **5** to **9** 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 LYMPHOCYTE DONATION

On occasion, a transplant centre may request to freeze (cryopreserve) all 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 lymphocyte 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 ☐

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 ☐

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	☐
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	☐
I understand that if clinically relevant for the patients' health, my health and medical information may be shared between the transplant centre and 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_donorfullid an_donorinternationalregistry

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_donorfullid an_donorinternationalregistry

H. 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