

Donor last name lastname	Donor first name firstname	Donor ID an_gridformatted
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## CONSENT FORM FOR THE COLLECTION OF THERAPEUTIC CELLS (NON-TRANSPLANT DONOR)

### CONSENT TO DONATE LYMPHOCYTES FROM THE BLOOD STREAM

The original consent form should be retained by the Collection Centre, one copy 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 donor and discussed briefly the intended use of the cells by the Cell and Gene Therapies Client. In particular, I have explained to the donor:

- a 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, Hepatitis B & C. These results will be sent to the Cell and Gene Therapies Client
- b 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
- c the requirement to store confidential information in accordance with applicable data protection and related laws and guidance (see section C below)
- d the possible storage of cells and the need for discard of stored material
- e that a copy of all test results and findings (including HIV) will be sent to the donor's GP and to Anthony Nolan

Please tick this box to confirm you have explained points a to e above to the donor

If the donor is aged 16 or 17 I have assessed the donor using Gillick principles and confirm that the donor has sufficient intelligence to enable him or her to understand fully the proposed procedure

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. I have also read and understood the current version of the HTA's Guide to Quality and Safety for Human Tissues and Cells for Patient Treatment and have applied the principles and procedures accordingly

Signed by Healthcare Professional		Date Of Assessment
Title	Last Name	First Name
Job Title		Collection Centre

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

I've been asked to donate specific cells known as lymphocytes for a Cell and Gene Therapies request. After consideration I've voluntarily chosen to donate my cells through the procedure known as apheresis.

The Healthcare Professional named in section A has clearly explained to me: the use of a blood cell separator machine (apheresis); and possible short and long-term related risks of this procedure.

I have read and understood the documents entitled:

Information about your Lymphocyte Donation DOC4521

Information about the Cell and Gene Therapies request

I have also been given the opportunity to ask questions about the procedure as well as the Cell and Gene Therapies request and these have been answered to my satisfaction. I believe that I have received and understood sufficient information to give my explicit and informed consent to undergo the donation procedure. I agree to the following:

- a to donate, the necessary cells to be collected by the use of the Blood Cell Separator Machine to 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, Hepatitis B, Hepatitis C and HIV 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 if necessary.
- b

Please tick this box to confirm your agreement with points a and b above

In addition I understand the following:

- a that any additional medical procedures not 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
- b that I cannot be given a guarantee that a specifically named person will perform the procedure although the person will have appropriate experience
- c that my recovery will be monitored by Anthony Nolan and I agree to participate a routine follow-up at one month (30 days).
- d that the primary responsibility for the lymphocyte collection rests with the medical and other professional staff who undertake the procedure
- e that this consent is automatically withdrawn if I am found not to be fit to donate using a blood cell separator

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- f that I have the right to access my medical information in accordance with applicable data protection and related laws and guidance (see section C below)
- g that my anonymised personal data may be shared with third party organisations in accordance with applicable data protection and related laws and guidance (see section C below)
- h that I retain the right to withdraw from the process at any stage but the implications for the Cell and Gene Therapies request have been explained to me

Please tick this box to confirm your agreement and consent with points **a** to **h** above

### C STATEMENT BY DONOR: PRIVACY

I have read and understood the Anthony Nolan Privacy Policy accompanying this form (also available online at <https://www.anthonynolan.org/privacy>) and each of the sections above and I understand and agree to them.

I give my consent to Anthony Nolan processing and storing the following data:

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, Hepatitis B & C, which I specifically consent to the use of

The results of such blood tests and my HLA data which I specifically consent to Anthony Nolan sharing with my GP and the Cell and Gene Therapies Client

Any analysis of the blood cells I donate, which I understand may be stored by the Cell and Gene Therapies Client and Anthony Nolan, where I have agreed, for research purposes.

All health and medical information I provide, which I understand may be stored by the Cell and Gene Therapies Client

I understand that I may withdraw my consents at any time, and further details are provided in the Anthony Nolan privacy policy as to how I may do so but the basic risks to the Cell and Gene Therapies request have been explained to me.

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## D STATEMENT BY DONOR: USE OF CELLS FOR RESEARCH

I understand the following:

That surplus tissue/DNA from this collection could be used anonymously for future medical research projects, which would have to be approved by a properly constituted research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards. I will not benefit financially from any research undertaken and I waive all rights to any registered patents. Furthermore, I understand that my cells will be disposed of when they are no longer required or prove unsuitable for use, in a manner which meets applicable national and EU regulations and directives for the disposal of biohazardous materials.

Please tick this box if you agree to the above statement. **OR**

I do not want my surplus tissue or DNA to be used for future research and understand this means that my cells will be disposed of in a manner which meets applicable national and EU regulations and directives for the disposal of biohazardous materials.

## E DONOR AND HEALTHCARE PROFESSIONAL DECLARATION

**DONOR** I confirm that I have read and completed Parts B, C, and D of this form.

<b>Signed by Donor</b>	<b>Date</b>
<b>Donor Last Name</b>	<b>Donor First Name</b>

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**F CONFIRMATION OF CONSENT**

***TO BE COMPLETED BY THE DONOR AND THE 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 still wish to proceed with the blood stem cell donation and 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

<b>Signed by Donor</b>	<b>Date</b>
<b>Donor Last Name</b>	<b>Donor First Name</b>

**Healthcare Professional**

<b>Signed by Healthcare Professional</b>	<b>Date</b>
<b>Healthcare Professional Last Name</b>	<b>Healthcare Professional First Name</b>

*Please note the original consent form should be retained by the Collection Centre, one copy retained by the donor and a copy forwarded to Anthony Nolan.*