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CONSENT FORM FOR BLOOD STEM CELL DONATION (NON-TRANSPLANT DONOR)

CONSENT TO DONATE STEM CELLS FROM THE BLOOD STREAM BY GRANULOCYTE COLONY STIMULATING FACTOR (G-CSF) TREATMENT AND PERIPHERAL BLOOD STEM CELL (PBSC) DONATION

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 peripheral blood stem cell mobilisation and collection to the donor and discussed the intended use of the cells by the Cell and Gene Therapies Client. In particular, I have explained to the donor:

- a 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
- b the need for microbiology testing and in particular the need to test the donor's blood for markers of infection including Syphilis, HIV, Hepatitis B & C. These test results will be sent to the Cell and Gene Therapies Client
- c 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
- d 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
- e the requirement to store confidential information in accordance with applicable data protection and related laws and guidance (see section C below)
- f the possible storage of cells and the need for discard of stored material
- g 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 g 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

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

B STATEMENT BY DONOR PROCEDURE INFORMATION (Please tick the boxes if you agree and consent)

I've been asked to donate haematopoietic (blood) stem cells for a Cell and Gene Therapies request. After consideration I've voluntarily chosen to donate my cells through the procedure known as a peripheral blood stem cell collection, which involves taking a drug, Granulocyte Colony Stimulating Factor (G-CSF), 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 administration of the drug G-CSF; the donation procedure with the use of a blood cell separator machine (apheresis); and possible short and long-term related risks of peripheral blood stem cell donation.

The World Marrow Donor Association (WMDA) has an on-going commitment to review the safety of G-CSF for healthy donors. In 2015, the Medical Working Group of the WMDA published a [recommendation](#), which was updated in 2017, with years of healthy donor follow-up data from the International Registries across the world. Along with the results of several genetic studies available and a recent survey of forty-two organisations performed by the Medical Working Group of the WMDA. The WMDA has issued the following statement to be included in our consent form, the full statement can be found on the WMDA website <https://www.wmda.info/wp-content/uploads/2017/06/20170905-WGME-Recommendation-GCSF1.pdf>;

Normal individuals are at risk for developing cancer, including leukaemia, lymphoma or other blood diseases throughout their lifetime. G-CSF stimulates normal blood cell growth. In some patients with cancer or abnormal blood cells, it has been shown to stimulate leukemic blood cells. Studies following large numbers of unrelated donors have shown that the risk of developing cancer within several years after the use of G-CSF is not increased compared to donors not receiving G-CSF.

I have read and understood the above statement from the World Marrow Donor Association's Medical Working Group.

I have read and understood the documents entitled:
Information about the Cell and Gene Therapies request

Information about your Peripheral Blood Stem Cell (PBSC) Donation
DOC4545

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I confirm I have 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 confirm that I have received sufficient information and understood the information given to me. Therefore, I give explicit and informed consent to undergo the donation procedure and agree to the following:

- a to receive the drug Granulocyte Colony Stimulating Factor (G-CSF) in order to produce sufficient stem cells in my circulating blood
- b to donate, for a Cell and Gene Therapies request, the necessary cells to be collected by the use of the Blood Cell Separator Machine
- c 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 will be arranged by Anthony Nolan if necessary

Please tick this box to confirm your agreement with points **a** to **c** 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 in routine follow-ups at one week, one month, yearly up to year 6 and then at years 8 and 10 after donation
- d that 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
- e that this consent is automatically withdrawn if I am found not to be fit to donate blood stem cells using a blood cell separator
- f that my anonymised personal data may be shared with third parties, in accordance with applicable data protection and related laws and guidance (see section C below)
- g 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)
- h that I retain the right to withdraw from the process at any stage however this could have an impact on the Cell and Gene Therapies request if withdrawal is on the day of donation

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

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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 the use of the following data by Anthony Nolan:

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

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.

D STATEMENT BY DONOR: USE OF SURPLUS CELLS

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.

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E DONOR AND HEALTHCARE PROFESSIONAL DECLARATION

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

Signed by Donor	Date
Donor Last Name	Donor First Name

HEALTHCARE PROFESSIONAL I confirm that I have witnessed the above donor completing Parts B and C of this form.

Signed by Healthcare Professional (usually same individual in section A)	Date
Healthcare Professional Last Name	Healthcare Professional First Name
Healthcare Professional Title and Email (if not the Healthcare Professional mentioned in section A)	

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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

Signed by Donor	Date
Donor Last Name	Donor First Name

Healthcare Professional

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