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

*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 use of the cells for medical research & treatments. 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 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
1. 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

1. the requirement to store confidential information in accordance with applicable data protection and related laws and guidance (see section D below)
2. the possible storage of cells and the need for discard of stored material
3. 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.

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| --- | --- |
| Please tick this box to confirm you have explained points **1** to **8** to the donor | ☐ |
| Please tick this box to confirm you believe the donor understands the information provided and can freely give consent  | ☐ |

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| I confirm that I have read and understood:* The current version of the HTA’s Code of Practice G: Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation,

and on Consent* The current version of the HTA’s Code of Practice A: Guiding Principles & the Fundamental Principle of Consent
 | ☐☐ |

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| --- | --- |
| **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)**

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| --- | --- |
| I’ve been asked to donate haematopoietic (blood) stem cells for a medical research & treatments project. 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
* 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 for a medical research & treatments project, collected by the use of the apheresis machine

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

In addition, I understand that:

1. 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
2. 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
3. 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

1. this consent is automatically cancelled if I am found not to be fit to donate blood stem cells using a blood cell separator machine
2. I may withdraw my consents at any time by speaking with my Anthony Nolan coordinator or the staff at the donor collection centre, however this may have an impact on the medical research & treatments project if withdrawal is on the day of donation

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| Please tick this box to confirm your agreement with points **4** to **8** above |  ☐ |

**C. STATEMENT BY DONOR: USE OF SURPLUS CELLS**

On occasion, there may be surplus cells from this collection which Anthony Nolan or medical researchers may request to use for future medical research & treatment projects. 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 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.
5. my cells will be disposed of, when they are no longer required or prove unsuitable for use, in a manner which meets applicable regulations for the disposal of biohazardous materials

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| Please tick this box to confirm your agreement with points **1** to **5** above |  ☐ |

**OR**

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

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| **D. STATEMENT BY DONOR: PRIVACY** |
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| 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**](https://www.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, and the medical research & treatments client | ☐ |
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| Any analysis of the stem cells I donate, which I understand may be stored by the medical research & treatments client  | ☐ |
| All health and medical information I provide, which I understand may be stored by Anthony Nolan in order to establish I am medically fit to donate  | ☐ |
|  |
| My pseudonymised personal data, that may be shared with third party organisations, in accordance with applicable data protection and related laws and guidance | ☐ |
| I understand that I have the right to access my medical information in accordance with applicable data protection and related laws and guidance | ☐ |
|  |
| Anthony Nolan may be requested to share the HLA data we hold on our records with the medical research & treatments client to assist with their project. We will only share your HLA data if it is necessary and relevant for the project, and if you have given consent for us to do this below. If we share your HLA data, it will be assigned an ID number and will only be identified to the researcher or developer by this ID number. They will not receive any information that identifies you directly.  |
|  |
| Please tick this box if you give your consent for Anthony Nolan to share your HLA data, which we hold on our database, with medical research & treatment clients | ☐ |

**E. DONOR AND HEALTHCARE PROFESSIONAL DECLARATION**

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

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| 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 and D of this form.

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| 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) |

**F. 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**

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| 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  |