CONSENT FORM FOR HAEMATOPOIETIC STEM CELL COLLECTION AND PROCESSING

Registration No. 2000/026390/08

INSTRUCTIONS FOR COMPLETION OF FORM (Tick type of donation)			
Part A	To be completed for **Autologous** Collections **only**	○ **Autologous**	
Part B	To be completed for **Allogeneic** Collections only – **Recipient**	○ **MRD**	○ **HAPLO**
Part C	To be completed for **Allogeneic** Collections only – **Donor**	○ **MUD**	
NOTE:	***All donors and recipients are to complete and sign the SANBS Privacy Statement on the last page. A full privacy statement is available on SANBS.org.za.***		

Part A							
Autologous Donor/Recipient				**Guardian/Next of kin (Mandatory)**			
Surname		**Title**		**Surname**		**Title**	
Name				**Name**			
Address				**Address**			
	Code				**Code**		
Email address				**Email address**			
Tel/Cell No.				**Tel/Cell No.**			
ID No.				**ID No.**			
Medical Aid				**Relationship to donor/recipient**			
Medical Aid No.							
Hospital							

Part B							
Recipient of Allogeneic cells only				**Guardian/Next of kin (Mandatory)**			
Surname		**Title**		**Surname**		**Title**	
Name				**Name**			
Tel/Cell No.				**Tel/Cell No.**			
ID No.				**ID No.**			
Medical Aid				**Relationship to recipient**			
Medical Aid No.				**Recipient's Address**			
Hospital							

Part C							
Donor of Allogeneic cells only				**Guardian/Next of kin (Mandatory)**			
Surname		**Title**		**Surname**		**Title**	
Name				**Name**			
Tel/Cell No.				**Tel/Cell No.**			
ID No.				**ID No.**			
Medical Aid				**Relationship to donor**			
Medical Aid No.				**Donor's Address**			
Hospital							

Donor		DOB	

Donor Work-Up

The safety of the recipient and the donor is of paramount importance. Therefore, you as the donor will be scheduled for various appointments in order for us to ensure that you meet the medical criteria for stem cell collections and that we re-infuse a safe and healthy stem cell product to the recipient.

- Usually, these appointments are scheduled for 1 day, +/- 30 days prior to your actual stem cell collection.
- Appointments will include:
  - Meeting the Collection Team that will guide and assist you throughout the process
  - Blood testing
  - Lung Functions
  - Heart Sonar
  - X-rays
  - Donor Suitability assessment – this will include a physical assessment
  - Vein assessment
  - Completion of documentation
  - Education

1. I agree to undergo the evaluation tests and medical examination/s as described before in order to determine my suitability for donation. I understand that until all checks have been carried out and reviewed by a physician, my donation is not guaranteed.
2. Where relevant, I consent to the release of relevant health information to the transplant physician, stem cell collection healthcare practitioner, stem cell processing staff and recipient physician.
3. I have received and read the following donor informational leaflet:
   3.1. Patient Education: Haematopoietic Progenitor Cells Apheresis Collection (HPC-A).

○ Yes, I consent	○ No, I do not consent

Testing of Blood and Accessing Results

Samples of blood will be drawn from a vein in your arm and the following laboratory tests will be performed:

- Full Blood Count
- Calcium and Magnesium – comprehensive metabolic panel
- U&E – urea and electrolytes
- Pregnancy test (all females)
- ABO Blood group
- Viral markers, e.g., human immunodeficiency virus (HIV), cytomegalovirus (CMV), toxoplasmosis, hepatitis B and C, Epstein-Barr virus (EBV), herpes, HTLV I/II, malaria, varicella and syphilis.

I consent for SANBS to access the relevant and appropriate blood results related to the stem cell collection process on external laboratory platforms, e.g., Lancet, Pathcare, Ampath, NHLS, etc.

○ Yes, I consent	○ No, I do not consent

Mobilisation

1. After approval of the transplant, you will be provided with a prescription for Neupogen (Filgrastim) that must be submitted to a pharmacy.
2. After receipt of medication, the JACIE Transplant Coordinator will educate you on the medication itself, possible side effects, administration thereof and the recording of administration.
3. These injections will usually be started 7 days before the stem cell collection.
   3.1. You will give the self-injections once per day, at the same time each day, 5 days in a row. You must take the injections at the same time every day. You may choose a health care worker to administer the injections.
   3.2. A medical examination, including blood tests, prior to starting the injections will be performed.

I consent to the administration of G-CSF growth factors (self-injections of Neupogen / Filgrastim).

○ Yes, I consent	○ No, I do not consent

Donor		DOB	

Venous access

Before you donate, venous access must be established and can be done in two ways:

1. A needle can be placed in a vein in each of your arms (or two needles may be placed in your veins in one arm)
   OR
2. A central venous catheter (with an access and return line) can be inserted into a large vein in your upper chest, neck or groin using a sterile technique by a specialist.
   a. The placement and use of a central venous catheter placed in the chest or neck may result in a haemo-pneumo- or haemopneumothorax. Trained specialists insert central venous catheters, and x-rays are taken to identify and manage any complications.

NOTE: The central venous catheter will be placed under local anaesthetic.
The catheter placement, blood stem cell mobilisation and collection by apheresis are standard procedures.

I consent to the insertion of a peripheral or femoral line (central venous catheter) by a licensed health professional.

○ Yes, I consent	○ No, I do not consent

Collection Procedure

1. The method of collecting blood stem cells is called "apheresis", which means to "take away". This procedure involves processing your blood using a machine to remove stem cells and return the other blood cells. The machine is called a cell separator.
2. A donor is allowed to refuse collection and to withdraw consent once given. The consequences of this will be explained by the Collection Team.
3. The collection procedure takes 6 – 8 hours for 2 – 3 days or until a minimum number of cells has been collected.
4. Occasionally, a donor may experience side effects during this procedure. The apheresis staff must be made aware of any adverse symptoms you might experience. There may be some discomfort and perhaps bruises from the needle placement. You may experience a sour taste in the mouth and/or numbness and tingling around the mouth, feet or hands. This is caused by one of the anticoagulants (ACD) added to your blood. If this occurs, please notify the apheresis staff, as slowing the rate of infusion may eliminate the problem. Anticoagulants are necessary to prevent the blood from clotting when it circulates in the machine. The body typically metabolises the anticoagulant within four (4) hours. Significant clotting in the machine or malfunctions of the centrifuge bowl may cause the collection to be stopped and could result in the loss of approximately half a pint of your blood. If you experience side effects, you may ask to withdraw from the scheduled procedures/study.
5. Your platelet count may decrease by 30 – 50% at the end of the procedure. This decrease in platelet count will not affect your blood's ability to form clots in the event of subsequent cuts or injuries. The number of white cells removed by this procedure will quickly be replaced by new cells, and there is no associated increased risk of susceptibility to infections. The most common risk is a temporary (1 – 2 days) decrease in your red blood cell count. This mild anaemia should not cause symptoms, and you should quickly make new cells to replace those donated.
6. Occasionally, a donor may experience temporary periods of low blood pressure during the apheresis procedure, but this problem can quickly be corrected with infusions, for example, normal saline (salt water).
7. The following can occur if a central venous catheter is used to collect blood during the blood stem cell collection:
   7.1. Infection can occur. This risk is reduced by good hygiene and care of the catheter.
8. **There is negligible risk of acquiring HIV infection (and or other blood-borne viruses) during an apheresis procedure since blood drawn and returned is my own and is processed within sterile, disposable equipment at all times during the procedure.**

I authorise the collection facility medical and nursing staff to perform the apheresis procedure.

○ Yes, I consent	○ No, I do not consent

Marketing

If you agree that SANBS may keep you updated about any offers and new products that are made available from time to time. SANBS and contracted third-party service providers may communicate with you about these.

I consent to receiving marketing communication from SANBS.

○ Yes, I consent	○ No, I do not consent

Donor		DOB	

Storage and Disposal of Collected Haematopoietic Stem Cells

1. I understand that fresh or frozen samples of my blood and samples of cells may be used for the purposes of quality control/monitoring, public health monitoring purposes, service development and/or future testing relevant to the quality of my stored cells. If your sample/s is used for these purposes, your personal details will not be made available.
2. I understand that my cells may be frozen and stored until required and that the need for continued storage will be kept under review for a maximum period of two (2) years, after which I will be given the option to keep cells at current storage facility at additional costs or to transfer the stored cells to another facility.
3. I consent for my cells to be discarded at the discretion of the SANBS Medical Director / Transplant Director when they are no longer required or they prove unsuitable for clinical use, in accordance with applicable laws and regulations.
4. I understand that it is my (as the recipient) responsibility as well as the Clinical Facility's to keep SANBS informed about any changes in contact details.
5. I understand that my physician will be contacted for approval prior to the disposal of my cells. Informed consent for disposal can be obtained from me or my relatives, who will also have the option of moving my cells for further storage at another facility.

○ Yes, I consent	○ No, I do not consent

Ownership and Use of Collected Blood Stem Cells

If I am donating the cells for someone other than myself, I accept that the cells will become the property and sole responsibility of the intended recipient listed on this consent. All rights and decisions regarding the cells and their disposition will be given to the intended recipient or his/her legal representative.

I consent to the following:

- donate my Haematopoietic stem cells to the recipient ("the primary purpose");
- donate additional Haematopoietic stem cells for the following purposes (collectively referred to as the "auxiliary purposes")
- the therapeutic use of donated stem cells

○ Yes, I consent	○ No, I do not consent

Benefits and Financial Implications

1. Related Allogeneic and Syngeneic Donors: There is no direct benefit that may come to me by being a donor.
2. Autologous Donor: The cells collected may benefit me in the course of treatment. However, there is no guarantee that the collection will be adequate to either cure or lessen the severity of my disease or condition.
3. Alternatives to peripheral blood stem cell donation include bone marrow donation.
4. Financial costs incurred during the blood stem cell collection, processing and storage of stem cells have been discussed with my treating doctor and the collection facility staff.
   - Where relevant, if medical aid fails to cover the financial cost of the above procedures the recipient of the stem cell product will be held liable.

After Collection (if required)

1. My clinical condition will be assessed after the procedure and the SANBS collection team will complete a formal handover to the clinical team.
2. The clinical team will monitor me post-procedure.
3. I have been advised to have someone accompany me in traveling home after my outpatient blood stem cell collection. After the procedure, I will be given a contact number to call if I feel ill.

Research

The waste products generated and donation(s) no longer needed may be used for research, data analysis and data presentation for educational purposes. If you give consent to SANBS to process your personal information for this purpose, please sign below. There is no personal financial benefit to you from any research undertaken, and you waive all rights to any registered patents. Research projects that could potentially use these waste products will be approved by the SANBS HREC. Personal identifiers will not be published or presented.

1. I consent for my donation(s) to be used anonymously for service development, ethically approved research or education when they are no longer required (to be completed by the donor or guardian).
2. I consent for my donation information to be used anonymously for analysis and presentation for education (to be completed by the donor or guardian).
3. I agree that any waste products remaining after the processing of my cells may be used anonymously for service development, ethically approved research (approved by SANBS Human Research Ethics Committee) or education.

○ Yes, I consent	○ No, I do not consent

Authorisation (To be completed by the donor or guardian)

1. I confirm that I have read and understood the above information and that I have been informed by the health care professional about the nature, conduct, potential benefits and risks of haematopoietic stem cell collections.
2. I confirm that I have read and acknowledged the above sections. I have received and understood sufficient information to give informed consent.
3. Any questions I might have had about this procedure and the information received have been answered to my satisfaction.
4. I understand that I will be informed of all test results in confidence and that I will be advised regarding further counselling and care, should it be required. My personal information will not be released to anyone without my written consent.
5. I understand that should I be found ineligible during the screening period, I cannot hold the South African National Blood Services liable for my treatment and care.
6. I have not been coerced into the decision to collect blood stem cells.
7. I have the right to change my mind at any time, including after I have signed this form.
   7.1. I understand that my refusal to donate can have serious consequences to the intended recipient if done after the pre-conditioning has been initiated.
8. Female donors: I agree that I must not fall pregnant or breastfeed before the stem cell donation.
9. I consent to the reporting of my collection results to local and international registries and that my name will be kept confidential at all times.
10. All my records will be kept **confidential** according to applicable legislation and I can review my results if required
11. I will receive a copy of this consent.
12. I may contact the following number if I have any questions regarding this procedure or if I have any unexpected or severe side effects: **Cell: 082 *555*-9294.**

To be completed by the Guardian (if applicable)

Name and Surname	Signature	Date
Relationship to donor/recipient		
Contact details		

To be completed by the Autologous / Allogeneic Donor

Name and Surname	Signature	Date

To be completed by the Interpreter (where appropriate).

I have interpreted the information above to the patient or guardian to the best of my ability and in a way in which I believe he/she can understand.

Name and Surname	Signature	Date	Job Title

To be completed by the staff member performing the Haematopoietic Stem Cell collection

1. I have provided the donor with all relevant informational leaflets.
2. I have discussed the following aspects with the donor and/or their legal guardian (where applicable):
   - Pre-procedure work-up, assessments and blood testing requirements
   - Mobilisation process, venous access options and associated risks
   - Stem cell collection procedure, potential therapeutic benefits and possible risks
   - Ownership, storage, and possible disposal of collected stem cells
   - Confidentiality, data registration, and conditions for research or secondary use
3. I have confirmed that the donor (or guardian) understood the information provided and was given an opportunity to ask questions, all of which were answered satisfactorily.
4. I have advised the donor that their personal information will be processed and stored in compliance with the Protection of Personal Information Act (POPIA).
5. I understand that it is the responsibility of the clinical physician to provide the donor with the following information:
   - The nature of the proposed procedures and any particular concerns
   - The rationale for the stem cell or lymphocyte collection
   - The need for microbiology testing
   - Storage issues, including the need for discard and the use of stem cells for research and service development

Name and Surname	Signature	Date	Job Title

SOUTH AFRICAN NATIONAL BLOOD SERVICE NPC ("SANBS"): PRIVACY STATEMENT (To be completed by all donors, recipients or guardians (as applicable).

1. When you engage with SANBS, you trust us with Personal Information about yourself, including Special Personal information relating to your health and sex life and where relevant, your child. We are committed to protecting your right to privacy.
2. The purpose of this Privacy Statement is to set out how we collect, use, share and otherwise process your Personal Information, in line with the Protection of Personal Information Act, 4 of 2013 ("POPI"). Defined terms such as "Personal Information", "Process", and "Special Personal Information" have the meanings given to them in POPI.
3. You have the right to object to the processing of your Personal Information and any information that you provide is entirely voluntary. However, it is important to note that SANBS requires your consent to process your personal information in order for you to donate blood and blood products. If you do not consent and accept these terms and conditions, you will not be able to donate blood or blood products.
4. SANBS will keep your Personal Information strictly confidential and will ensure that it takes appropriate reasonable technical and organisational measures to keep your Personal Information safe, secure and protected from unauthorised access.
5. *If you are giving consent for SANBS to Process Personal Information of a person under the age of 18 (a minor) you confirm and warrant that you are the legal guardian of such minor and that you have the legal authority to provide this consent. SANBS reserves the right to request proof of legal guardianship before proceeding (*).*
6. You agree that SANBS may process your Personal Information for the following purposes:
   a. To verify the accuracy, correctness, and completeness of any information provided (or not) to SANBS in the course of the blood or blood product donation process and when completing the Consent Form;
   b. To examine and test any blood and blood products that you donate, including testing for diseases and medical conditions such as HIV and testing your blood type;
   c. To contact you and provide counselling if you test positive for HIV or another medical condition in accordance with applicable health legislation;
   d. For administrating donations and the administration of blood or blood products to patients.
   e. To conduct market, statistical and academic research (in terms of which any Personal Information has been de-identified and anonymised); and/or
   f. To update and customise our blood and blood product donation database.
7. We will ensure that any third party with whom we share your Personal Information agrees to treat your information with the same level of protection as we are obliged to If a third party asks SANBS for any of your Personal Information, we will share it with them only if you have already given your consent for the disclosure of the information to that third party, or we have a legal or contractual duty to give the information to that third party.
8. Your Personal Information may be shared with approved third parties strictly for the purposes outlined above, and where possible, data will be de-identified or anonymised. No third party may access your identifiable information without your prior consent, unless legally required.
9. We may, in limited instances, use automated means to assist in processing your information (e.g., allocation of blood products). However, no decision that significantly affects your rights, health, or access to services will be made without appropriate human oversight, in compliance with Section 71 of POPIA.
10. If you have consented to receiving marketing communications from us where specified in the Consent Form, you agree that SANBS may keep you updated about any offers and new products that are made available from time to time. SANBS and contracted third-party service providers may communicate with you about these. Please let SANBS know if you do not wish to receive any marketing by contacting us using the opt-out details provided.
11. You have the right to request that SANBS confirm what Personal Information SANBS holds about you free of charge. We will take all reasonable steps to confirm your identity before providing details of our Personal Information.
12. You agree that SANBS may retain your Personal Information for as long as we may require it (for example, to comply with statutory retention periods) or until you ask us to delete or destroy it, such deletion or destruction will be conditional to the applicable law. You have the right to ask us to update, correct or delete your Personal Information, unless the law requires us to keep it. Where we cannot delete your Personal Information, we will take all practical steps to de-identify it.
13. SANBS may change the Privacy Statement at any time. The current version is available on https://sanbs.org.za/.
14. If you believe that SANBS have used your Personal Information contrary to this Privacy Statement, you have the right to lodge a complaint with the Information Regulator, under POPI, but we encourage you to first follow our internal complaints process to resolve the complaint. Please contact our Chief Information Officer {011 761-9000} if you have any questions about how we process your personal information or if you have a complaint.
15. Contact details for the Information Regulator: The Information Regulator (South Africa) – SALU Building – 316 Thabo Sehume Street – Pretoria Tel: 012 406 4818 – Fax: 086 500 3351 – inforeg@justice.gov.za

When you sign this Consent Form, you confirm that you have read and understood the Privacy Statement, have had the opportunity to ask questions, and that any questions raised were answered to your satisfaction. Please access the full statement on https://sanbs.org.za/.

	Donor			**Recipient**		
SIGNATURE:		**DATE:**			**DATE:**	
NAME AND SURNAME:						
SIGNED AT:						

(*) If consenting on behalf of a minor, please provide:	
Name and Surname of Minor:	
Relationship to minor:	