MRI Number

DONOR / PATIENT CONSENT FORM FOR THE COLLECTION OF PERIPHERAL HAEMATOPOIETIC BLOOD STEM CELLS (HPC-A) (B)

SANBS
Registration No. 2000/026390/08

Please print legibly as this is a medico legal document.

Donation Type	☐ **Autologous**	☐ **Related Allogeneic**	☐ **Unrelated Allogeneic**	☐ **HAPLO**

NOTE: Please ensure that you complete and sign the SANBS Privacy Statement on FRM-STS-041.

Donor Details (Use SABMR numbers if applicable)			
Surname		Title	
Name			
ID or DOB			
Gender			
Address			
City		Code	
Tel No			
Medical Aid (Not required if Allogeneic)			
Medical Aid Number (Not required if Allogeneic)			
Hospital			
File number			

Recipient Details (Allogeneic Collections only) (Use SABMR numbers if applicable)			
Surname		Title	
Name			
ID or DOB			
Address			
City		Code	
Tel No			
Medical Aid			
Medical Aid Number			
Hospital			
File Number			

Collection of Cells

1. The method of collecting blood stem cells is called apheresis, a procedure that involves processing my blood using a machine to remove some stem cells and returning other blood cells. These machines have been widely used to collect certain types of blood cells from normal people to be used for transfusions.
2. **Before I donate, venous access must be established and can be done in two ways:**
   a) A needle can be placed in a vein in each of my arms (or two needles may be placed in veins in one arm) OR
   b) A specialist can insert a central venous catheter (with an access and return line) into a large vein in my upper chest or neck or groin using a sterile technique.
   - **The central venous catheter can be placed under local anaesthetic.**
3. **NOTE:** The catheter placement, blood stem cell mobilisation and collection by apheresis are standard procedures.

Donor		DOB	

Collection Procedure

1. Occasionally, a donor may experience side effects during this procedure. It is important that the apheresis staff be made aware of any adverse symptoms you might experience. There may be some discomfort and perhaps bruises from needle sticks. 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 the 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 metabolizes the anticoagulant within four (4) hours. Significant clotting in in the machine or malfunctions of the centrifuge bowl may cause the collection to be stopped and could results in the loss of approximately a half pint of your blood. If you experience side effects, you may ask to withdraw from the scheduled procedures/study.
2. 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 day) decrease in your red blood cell count. This mild anaemia should cause not symptoms and you should quickly make new cells to replace those donated.
3. Occasionally, a donor/patient may experience temporary periods of low blood pressure during the apheresis procedure, but this problem can quickly be corrected with infusions of e.g. normal saline (salt water).
4. The following can occur if a central venous catheter is used to collect blood during the blood stem cell collection:
   - Infection can occur. This risk is reduced by good hygiene and care of the catheter.
   - Haemothorax can occur. Trained specialists insert central venous catheters and x-rays are taken to identify and treat a haemothorax as soon as it has been identified.
5. **There is negligible risk of acquiring HIV infection (and or other blood born 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.**

Ownership of Collected Blood Stem Cells

1. 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 that intended recipient or his/her legal representative.

Conditions of Storage and Disposal of Collected Peripheral Blood Stem Cells

1. It is possible that cells will be placed in frozen storage. Because of this possibility, the intended recipient of the cells will be asked to sign a "Consent for Testing, Storage and Disposal of Collected Blood Stem Cells" by SANBS Specialised Therapeutic Services. This agreement will detail the terms for the storage, transfer, and disposal of any unused cells.
2. The intended recipient will be given a copy of this signed agreement for his/her records

Benefits

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.

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.

Donor		DOB	

Authorisation (To be completed by the donor or guardian)
1. I give SANBS permission to keep record of my personal information and to disclose this information with other relevant healthcare professionals and to obtain medical information, if essential, for medical purposes only. All my records will be kept confidential according to applicable legislation and I can review my results if required. **2.** I authorise the collection facility medical and nursing staff to perform the apheresis procedure. **3.** I have received and read the "Donor Information Leaflet - Peripheral Blood Stem Cell Collection (PBSC)" **4.** I have had the opportunity to discuss this information with: _____ **5.** I understand the procedure and why it is being done. **6.** Any questions I might have about this procedure and its risks and consequences have been answered to my satisfaction. **7.** I may contact Sr. _____ at _____ if I have any questions regarding this procedure or if I have any unexpected or severe side effects. **8.** I will receive a copy of this consent. **9.** I have not been coerced in the decision to collect blood stem cells. **10.** I have the right to change my mind at any time, including after I have signed this form.

Financial Implications
All costs incurred during the blood stem cell collection, processing and storage of collected cells will be discussed by my clinical physician.

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 a trained Interpreter (where appropriate) provided by Clinical Facility			
I have interpreted the information above to the donor/patient or guardian to the best of my ability and in a way in which I believe he/she can understand.			
Name (print)	**Signature**	**Date**	**Job Title**

To be completed by the staff member performing the Haematopoietic Stem cell collection			
1. I confirm that I have provided the following documentation to donor/recipient or guardian (if applicable): • *Patient Education: Haematopoietic Progenitor Cells Apheresis collection (HPC-A) Stem Cell Apheresis* (INF-STS-003). • *Informed Consent* (INF-STS-015). **2.** I confirm that I have discussed the following with the donor/patient or guardian (if applicable): • The collection procedure, potential therapeutic benefits and possible risks. • The ownership of the collected stem cells. • The need to store confidential information. **3. NOTE: It is the responsibility of the clinical physician to provide the donor/recipient or guardian (if applicable) with the rationale for the stem cell or lymphocyte collection.**			
Name (print)	**Signature**	**Date**	**Job Title**