MRI Number

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

SANBS
Registration No. 2000/026390/08

Please print legibly as this is a medico legal document.

Donation Type	☐ **Autologous**	☐ **Related Allogeneic MRD**	☐ **Unrelated Allogeneic MUD**	☐ **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			

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

Donor		DOB	

Testing of Blood

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.

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 there off 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. It is very important that you 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.

Venous access

1. Before you donate, venous access must be established and can be done in two ways:
   1.1. 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
   1.2. A central venous catheter (with an access and return line) can be inserted into a large vein in your upper chest or neck or groin using a sterile technique by a specialist.
   - **The central venous catheter can be placed under local anaesthetic.**
2. **NOTE:** The catheter placement, blood stem cell mobilisation and collection by apheresis are standard procedures.

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 other blood cells. The machine is called a cell separator.

2. The collection procedure takes 4 – 6 hours for 2 – 3 days or until a minimum number of cells has been collected.

3. 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 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 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.

4. 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 not cause symptoms and you should quickly make new cells to replace those donated.

5. 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).

6. The following can occur if a central venous catheter is used to collect blood during the blood stem cell collection:
   6.1. Infection can occur. This risk is reduced by good hygiene and care of the catheter.
   6.2. 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.

7. 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.

Donor		DOB	

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.

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 have received and read the following donor informational leaflets:
2.1. HPC-A Donor Education: G-CSF Mobilisation.
2.2. Patient Education: Haematopoietic Progenitor Cells Apheresis Collection (HPC-A).
2.3. Informed Consent.

3. Any questions I might have had about this procedure and the information received have been answered to my satisfaction.

4. I agree to undergo the evaluation tests 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.

5. I agree to have my blood drawn in order to undergo HIV testing.
- I have completed *Informed Consent for HIV Testing* (FRM-STS-052).

6. I understand that I will be informed of all tests results in confidence, and that I will be advised regarding further counselling and care, should it be required. It will not be released to anyone without my written consent.
- I understand that should I be tested positive or found ineligible during the screening period, I cannot hold the South African National Blood Services liable for my treatment and care.

7. I consent to the release of relevant health information to the transplant physician, stem cell collection health care practitioner, stem cell processing staff and recipient.

8. **I consent to the administration of G-CSF growth factors (self-injections):** _____

9. I authorise the collection facility medical and nursing staff to perform the apheresis procedure.
- I consent to the insertion of a peripheral or femoral line (central venous catheter) by a licensed health professional.

10. I have not been coerced in the decision to collect blood stem cells.

11. I have the right to change my mind at any time, including after I have signed this form.
- I understand that my refusal to donate can have serious consequences to the intended recipient if done after the pre-conditioning has been initiated.

12. Female donors: I agree that I must not fall pregnant or breastfeed before the stem cell donation.

13. 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.

14. All my records will be kept **confidential** according to applicable legislation and I can review my results if required

15. I will receive a copy of this consent.

16. 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.**

Donor		DOB	

Financial Implications
Financial costs incurred during the blood stem cell collection, processing and storage of stem cells has been discussed

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 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 donor with the relevant informational leaflets. **2.** I confirm that I have discussed the following with the donor/patient or guardian (if applicable): • Work-up procedure. • Testing of blood. • Mobilisation. • Venous access. • Collection procedure, potential therapeutic benefits and possible risks. • Ownership of the collected stem cells. • Conditions of storage and disposal. • Data Registration. • Confidentiality.			
Name (print)	**Signature**	**Date**	**Job Title**