MRI Number

DONOR CONSENT FOR THE COLLECTION OF DONOR LYMPHOCYTES

SANBS
Registration No. 2000/026390/08

I, _____

hereby consent to undergo the procedure for the collection of donor lymphocytes.

The referring Medical Specialist

Dr._____,

has fully explained the entire procedure to me, including the potential benefits and risks associated with undergoing this procedure.

I acknowledge that the South African National Blood Service (SANBS) will be performing this procedure at the request of the Medical Specialist. I further acknowledge that I have been given the opportunity to ask the SANBS staff to explain any aspect of the procedure on which I would like clarity or further information.

I understand that the donor lymphocyte procedure (DLI) is being performed according to standard international practice. I also acknowledge and accept that, occasionally, donors may experience adverse effects. I have read the information on potential adverse effects as described on page 2 below. While no untoward effect is expected during (or following) the procedure, I understand that the Blood Service's legal liability is limited in this regard.

INFORMATION

Donating Lymphocytes

Donor lymphocytes are collected in a hospital or SANBS apheresis/therapeutic unit. Before the collection, venous access must be established and can be done in the following way:

1. A needle can be placed in a peripheral vein in each of your arms (or two needles may be placed in peripheral veins in one arm).
   If alternative venous access is required (e.g. your peripheral veins are not suitable for venesection), your attending doctor will discuss it with you.

Blood is removed through the needle and passed through a machine called a blood cell separator. This process is called apheresis. The machine collects your lymphocytes, and the rest of your blood is given back to you through the other needle. One collection is normally required. During the collection you will need to lie in a recliner chair or bed for approximately three to four ours.

With each collection, samples of blood will be taken at the start, middle (if required) and end of each procedure to measure your blood cell counts. Once completed, your collection will be tested to determine the number of cells harvested.

Please see pamphlet (INF-STS-019) for more information.

Potential Adverse Events

More frequent:

- Pain and bruising where needles are put into the veins.
- Lowered platelet count. In addition to collecting lymphocytes the blood cell separator also collects platelets. Platelets help stop bleeding. If your platelet count after the first collection is low, your doctor will assess whether or not it is advisable to do second collection. Platelet counts usually return to normal levels within two to four weeks after collection of lymphocytes. You are strongly advised not to participate in any contact sports for a month after your collection (and until your platelet count has been checked by your referring doctor on your follow up visit).

Less frequent:

- Light-headedness.
- Nausea.
- Transient numbness and tingling.
    - To prevent clotting, your blood will be mixed in the machine with an 'anticoagulant' (citrate) during the lymphocytes collection. When the blood is returned to you, the anticoagulant can cause numbness and tingling of the fingertips or around the mouth. If you feel numbness and tingling, you must tell the nurse operating the machine. These symptoms are easily treated with a calcium supplement but, if not treated, could progress to muscle cramps.

Rare:

- Faint due to transient low blood pressure.
- Chills during the process.
- Bleeding in the arm.
- Inability to return your blood due to a malfunction of the cell separator machine. If the machine does malfunction you could lose about 300ml of blood. This is unlikely to cause harm.
- There is a small chance of being hospitalized for observation because of side effects from the donation.

Potential Benefit:

The successful harvesting of lymphocytes will assist with further management of the recipient.

Authorisation (To be completed by the donor or guardian)

1. I confirm that I have read the above sections. I have received and understood sufficient information to give informed consent.
2. I have had the opportunity to discuss this information with:_____
3. Any questions I might have about this procedure and its risks and consequences have been answered to my satisfaction.
4. I may contact _____ at _____ if I have any questions regarding this procedure or if I have any unexpected or severe side effects.
5. I will receive a copy of this consent.
6. I have the right to change my mind at any time, including after I have signed this form.

Name (print)	Signature	Date

NOTE

1. I understand that it is the responsibility of the clinical physician to provide the donor/recipient with the following information:
    - **a)** The nature of the proposed procedures and any particular concerns.
    - **b)** The rationale for the lymphocyte collection.
    - **c)** The need for microbiology testing.
    - **d)** Storage issues, including the need for discard and the use of cells for research, service development and education.
    - **e)** The need to store confidential information.

Name (print)	Signature	Date	Job Title

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 (print)	Signature	Date	Job Title

I consent for my donation(s) to be used anonymously for service development, ethically approved research or education when they are no longer required.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

I consent for my donation information to be used anonymously for analysis and presentation for education.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Authorisation for testing and accessing blood results (To be completed by the donor or guardian)	
1. I consent to the testing of blood grouping, syphilis, hepatitis B, hepatitis C and HIV, as well as such extended testing that may be necessary to ensure the safety and quality of the product. **2.** I consent for SANBS to access the relevant and appropriate blood results related to the lymphocyte collection process on external laboratory platforms, e.g. Lancet, Pathcare, Ampath, NHLS, etc.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Personal Information	
I consent to my personal and special personal information being processed in accordance with the SANBS Privacy Statement attached hereto.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Research and Marketing	
I consent to my personal information (such as contact details) being used by SANBS (and its appointed third party marketing suppliers) for purposes of sending me marketing communications relating to future blood drives, and related or new products, offerings and services in accordance with the SANBS Privacy Statement attached hereto.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

SOUTH AFRICAN NATIONAL BLOOD SERVICE NPC ("SANBS"): PRIVACY STATEMENT

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 give your consent for them(*)***

6. You agree that SANBS may process your Personal Information for the following purposes:

6.1. To verify the accuracy, correctness, 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;

6.2. 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;

6.3. To contact you and provide counselling if you test positive for HIV or another medical condition in accordance with applicable health legislation;

6.4. For administrating blood drives and donations and the administration of blood or blood products to patients.

6.5. To contact you where you have specifically consented to receiving notifications and marketing information about SANBS's blood drives, promotions, news or updates relating SANBS.

6.6. To conduct market, statistical and academic research, (in terms of which any Personal Information has been de-identified and anonymised); and/or

6.7. To update and customise our blood and blood product donation drives.

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 third parties such as our suppliers, phlebotomists, academics, laboratory officers and researchers. We ensure that the third parties will keep your Personal Information confidential and all data will be made anonymous to the extent possible and where appropriate. No Personal Information will be mad available to a third party unless that third party has agreed to abide by strict confidentially and security protocols that we require. If we publish the results of any research, you will not be identified by name. If we want to share your Personal Information for any other reason, we will do so only with your permission.

9. We may in limited instances process your information using automated means (without human intervention in the decision-making process) to make a decision about where to allocate your blood or blood product.

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) until you ask us to delete or destroy it. 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 and you consent and agree to be bound to the terms and conditions of this Privacy Statement.

SIGNED AT:		**DATE:**	
SIGNATURE:			
FULL NAME			

(*) If consenting on behalf of a minor, please provide:

Name of Minor:	
Relationship to minor:	