INFORMED CONSENT FOR LEUKAPHERESIS

Registration No. 2000/026390/08

General Information

All apheresis procedures have basic principles in common: Blood is withdrawn through a needle or catheter and mixed with an anticoagulant as it is drawn. The blood is pumped through the cell separator and the desired components are collected in a sterile plastic container. Most of the blood in the cell separator is then returned to the patient. All equipment used is commercially available, and all materials coming in contact with the study participant's blood are sterile, only used once and then destroyed.

Therapeutic Apheresis is the process of withdrawing blood from a study participant, removing a specific component/component and subsequently reinfusing the remaining component/components to treat or palliate/ease a disease for Research purposes.

Therapeutic Apheresis consists of the following procedures:

- **Leukapheresis** – Selective removal of leucocytes from withdrawn blood for research reasons/purpose
- **Cytapheresis** – The removal of platelets and/or white blood cells for therapeutic reasons.
- **Selective apheresis** – The removal of a specific component in plasma (non-cellular, e.g. cholesterol) for therapeutic reasons.

The risks associated with therapeutic apheresis include, but are not limited to, the following:

- **Weakness, nausea or feeling faint** as a result of anxiety or decrease in blood volume. Such episodes can be controlled readily by the immediate return of red blood cells and an increase in fluid replacement.
- **Tenderness at the needle site**. Needles may be placed in one or two veins during the entire apheresis procedure. Both the presence of the needle and saline infusion may cause some local discomfort.
- **Localised infection at the needle puncture site**. Such a risk is extremely small because an aseptic technique is used throughout the procedure.
- **Loss of red blood cells**: leakage or breakage of the plastic tubing or containers may occur and thus prevent the return of the red blood cells to the patient.
- **Possible anticoagulant discomfort**: Sodium citrate, an anticoagulant, is added to the red blood cells and plasma to prevent blood clotting. Sodium citrate is metabolized by the body. Although it is not toxic, it can sometimes cause temporary symptoms of tingling of the lips and/or fingers and increased muscle tension during the return of blood.
- **Premature termination of procedure**: Since the removal of blood and return of blood is accomplished using needles and tubing, it is possible that clotting could occur in the needles or tubing and this may lead to the termination of the individual procedure.
- **Haemolysis**: (bursting of the red blood cells) There is a small chance of the red blood cells bursting due to a malfunction of the machine; this is extremely rare and is carefully monitored. In the event of haemolysis, the procedure would be discontinued.
- **Air Infusion**: Although the machine is equipped with an air detector to prevent air bubbles, there is a remote possibility of an air bubble entering the donor. The consequence of this unlikely event could be severe.

INFORMED CONSENT

PROCEDURE:
I, the undersigned hereby voluntarily consent to the performance of the following: Leukapheresis
I hereby authorise designated SANBS personnel to perform the above-mentioned procedure which will include: • The withdrawal of my blood by either a continuous or intermittent flow cell separator; • The extraction of the appropriate blood component;
Name and Surname _____ **Date of birth: day/month/year [__][__]/[__][__]/202[__]** **Signature**_____ **Date: day/month/year [__][__]/[__][__]/202[__]**

RESEARCH CONSENT		
I consent to my personal information and special personal information being processed in accordance with the SANBS Privacy Statement attached hereto.	Yes	No

SOUTH AFRICAN NATIONAL BLOOD SERVICE NPC ("SANBS"): PRIVACY STATEMENT FOR THERAPEUTIC APHERESIS PROCEDURES.

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 undergo therapeutic apheresis procedures, procedures where SANBS withdraws your blood and extracts certain components from the blood before re-infusing the blood with the desired component(s) to treat or palliate a disease. If you do not consent and accept these terms and conditions, you will not be able to undergo the procedure. 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 the 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, and completeness of any information provided (or not) to SANBS in the course of the therapeutic apheresis procedure and when completing the Consent Form;
   6.2. To allow SANBS to examine and process the blood that is withdrawn from you, including extracting certain components and thereafter reinfusing certain desired components for purposes of your care or treatment;
   6.3. To contact you and provide further information where required;
   6.4. For administrating therapeutic apheresis procedures;
   6.5. To contact you where you have specifically consented to receive notifications and marketing information about SANBS's therapeutic procedures, promotions, news or updates relating to 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 therapeutic apheresis procedures.
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 made available to a third party unless that third party has agreed to abide by the 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).

10. If you have consented to receive 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 at 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: Day/month/year**	**[__][__]/[__][__]/202[__]**
SIGNATURE:			
FULL NAME			