MRI Barcode Number

INFORMED CONSENT FOR TESTING, STORAGE AND DISPOSAL OF COLLECTED BLOOD STEM CELLS

SANBS

Registration No. 2000/026390/08

Donation Type	○ Autologous	○ Related Allogeneic (MRD)	○ Unrelated Allogeneic (MUD)	○ HAPLO

INSTRUCTIONS FOR COMPLETION OF FORM

Part A	To be completed for **Autologous** Collections **only**
Part B	To be completed for **Allogeneic** Collections only – **Recipient** of HPC-A Product
Part C	To be completed for **Allogeneic** Collections only – **Donor** of HPC-A Product
NOTE:	***Please cross out sections that is not applicable.*** ***All donors/recipients to complete and sign the SANBS Privacy Statement on last page.***

Part A.1

Autologous Donor/Recipient			
Surname			
Name		**Title**	
Address			
City		**Code**	
Tel No			
ID No			
M/Aid			
M/Aid No			
Hospital			
Cells to be collected at			
Proposed Collection Date			

Guardian (if applicable)			
Relationship to patient			
Surname		**Title**	
Name			
Address			
City		**Code**	
Tel No			
ID No			
Contact Details - Next of kin (Mandatory)			
Surname		**Title**	
Name		**Relationship to recipient**	
Telephone		**Code**	
Cell			

Part A.2: Testing, Storage and Disposal of Collected Cells and Storage of Personal Information (To be completed by the donor/recipient or guardian).	
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. **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 to keep SANBS informed about any changes in contact details. **5.** I understand that my physician will be contacted for approval prior to disposal of my cells. Informed consent for disposal can be obtained from myself or my relatives, who will also have the option of moving my cells for further storage at another facility.	
To indicate consent to Part 1, please sign your name **in the box for** either YES or NO.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part A.3: Research, Data Analysis and Data Presentation from Waste Products for Educational Purposes. (To be completed by the donor/recipient or guardian).	
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 are willing to consent to these options, please sign below. There is no personal financial benefit to you from any research undertaken and you waive all rights to any registered patents. Personal identifiers will not be published or presented.	
Please sign your name in the box of either YES or NO.	
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	X No, I do not consent
Signature:	Signature:
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:

Part A.4: Authorisation (To be completed by the donor/recipient or guardian).

1. I confirm that I have read and signed 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 stem cell or lymphocyte collection.
   c) The need for microbiology testing.
   d) Storage issues, including the need for discard and the use of stem cells for research, service development and education.
   e) The need to store confidential information.

To be completed by Therapeutic Specialist performing the procedure

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

Part A.5: Authorisation for testing and accessing blood results (To be completed by the donor/recipient 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 stem cell collection process on external laboratory platforms, e.g. Lancet, Pathcare, Ampath, NHLS, etc.

√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part A.6: Personal Information (To be completed by the donor/recipient or guardian).

I consent to my personal and special personal details being processed in accordance with applicable legislation.

√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part A.7: Research and Marketing (To be completed by the donor/recipient or guardian).	
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:

Part B.1

Recipient of Allogeneic cells only				**Guardian (if applicable)**			
Surname				Relationship to patient			
Name		**Title**		Surname		Title	
				Name			
Address				**Address**			
City		**Code**		**City**		**Code**	
Telephone Number				**Telephone Number**			
ID Number				**ID Number**			
M/Aid				**Contact Details - Next of kin (Mandatory)**			
M/Aid No				**Surname**		**Title**	
Hospital				**Name**		**Relationship to recipient**	
Cells to be collected at				**Telephone**		**Code**	
Proposed Collection Date				**Cell**			

Part B.2: Testing, Storage and Disposal of Collected Cells and Storage of Personal Information (To be completed by the recipient or guardian).	
1. I understand that fresh or frozen samples of the donated 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. **2.** I understand that the 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 the 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 to keep SANBS informed about any changes in contact details. **5.** I understand that my physician will be contacted for approval prior to disposal of my cells. Informed consent for disposal can be obtained from myself or my relatives, who will also have the option of moving my cells for further storage at another facility. **6.** I give permission for my personal information (related to the donated collection, processing and transplantation) to be held by SANBS. All my records will be kept confidential according to the applicable legislation. **7.** I give permission to my physician to discuss my test results with the recipient's physician.	
To indicate consent to Part 1, please sign your name **in the box for** either YES or NO.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part B.3: Research, Data Analysis and Data Presentation from Waste Products for Educational Purposes. (To be completed by the recipient or guardian).	
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 are willing to consent to these options, please sign below. There is no personal financial benefit to you from any research undertaken and you waive all rights to any registered patents. Personal identifiers will not be published or presented.	
Please sign your name in the box of either YES or NO.	
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	X No, I do not consent
Signature:	Signature:

Part B.4: Authorisation for testing and accessing blood results (To be completed by the recipient 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 stem cell collection process on external laboratory platforms, e.g. Lancet, Pathcare, Ampath, NHLS, etc	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part B.5: Personal Information (To be completed by the recipient or guardian).	
I consent to my personal and special personal details being processed in accordance with the applicable legislation.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part B.6: Research and Marketing (To be completed by the recipient or guardian).	
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:

Part C.1							
Donor of Allogeneic cells only				**Guardian (if applicable)**			
Surname				**Relationship to patient**			
Name		Title		Surname		Title	
				Name			
Address				**Address**			
City				**City**			
		Code				Code	
Telephone Number				**Telephone Number**			
ID Number				ID No			
M/Aid				**Contact Details - Next of kin (Mandatory)**			
M/Aid No				**Surname**		**Title**	
Hospital				**Name**		**Relationship to recipient**	
Cells to be collected at				**Telephone**		**Code**	
Proposed Collection Date				**Cell**			

Part C 2: I consent to undergo medical examination/s (To be completed by the donor or guardian).	
I confirm that I hereby irrevocably give my expressed and informed consent to undergo medical examination/s in order to ascertain whether or not I am fit to donate my peripheral blood stem cells to the patient. To the extent that I am declared medically fit to donate my stem cells, I consent to – • donate my peripheral blood stem cells to the patient ("the primary purpose"); • donate additional peripheral blood stem cells for the following purposes (collectively referred to as the "auxiliary purposes") • the possible future therapeutic use of the stem cells for transplantation into the patient;	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part C.3: 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).	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part C.4: I consent for my donation information to be used anonymously for analysis and presentation for education (To be completed by the donor or guardian).	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part C.5: Authorisation (To be completed by the donor or guardian).

1. I confirm that I have read and signed 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 stem cell or lymphocyte collection.
- **c)** The need for microbiology testing.
- **d)** Storage issues, including the need for discard and the use of stem cells for research, service development and education.
- **e)** The need to store confidential information.

To be completed by Therapeutic Specialist performing the procedure

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

Part C.6: 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 stem cell collection process on external laboratory platforms, e.g. Lancet, Pathcare, Ampath, NHLS, etc.

√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part C.7: Personal Information (To be completed by the donor or guardian).	
I consent to my personal and special personal details being processed in accordance with the applicable legislation.	
√ Yes, I consent	X No, I do not consent
Signature:	Signature:

Part C.8: Research and Marketing (To be completed by the donor or guardian).	
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 (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 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 made 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:	