Effective Date: 12 March 2024 Revision No: 02 Title: Patient Consent for Search of Unrelated Haematopoietic Stem Cells/ Therapeutic Cells Donor -English Document No: WIBMD220F7

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## HONG KONG BONE MARROW DONOR REGISTRY

Managed by Hong Kong Red Cross Blood Transfusion Service Supported by Hong Kong Marrow Match Foundation



# Patient Consent-for Search for Unrelated Haematopoietic Stem Cells/Therapeutic Cells Donor

### A Information about Haematopoietic Stem Cells/ Therapeutic Cells Transplantation (HSC/TC)

## 1. General information of Haematopoietic Stem Cells / Therapeutic Cells Transplantation (HSC/TC)

Haematopoietic Stem Cells and Therapeutic Cells Transplantation (HSC/TC) is a treatment option for blood diseases, especially leukaemia. With the use of HSC transplantation, patient can receive more aggressive therapy (e.g. chemotherapy with or without radiotherapy) so as to increase the efficacy of killing cancer cells. HSC transplantation is essential in restoring normal marrow population and immune system that is otherwise destroyed by aggressive anti-cancer therapy. TC transplantation may be considered as a subsequent treatment of HSC transplantation to augment the efficacy and killing of cancer cells in selected patients.

#### 2. Procedures and risks

Patient is required to undergo pre-transplant medical evaluation which provides useful baseline information. Upon satisfactory completion of assessment, patient will be treated with high dose chemotherapy with or without radiotherapy. Then the patient will receive the HSC.

In the first 7-10 days after HSC transplantation, patient may experience side effects from the preparative regimen received. These include hair loss, ulcer in the mouth, sore throat or passing loose stool. Some patients are not able to eat and drink and if this happens, nutrients and fluids through an intravenous assess may be required. During this time, normal function of marrow and immune system of patient has been destroyed and patient will have very low blood count (e.g. white blood cells, platelet). As a result, patient may develop serious or even life-threatening complications like infections and bleeding. With the donor cells (HSC/TC) being engrafted, graft-versus-host disease (GVHD) may occur. This rejection may result in from mild to life-threatening complication in the patient.

The above are just some of possible complications that could arise in early phase of HSC/TC transplantation. You are advised to consult the doctor in charge on the details of the transplant procedure, risks and success rate.

#### 3. Cost implications in searching for overseas unrelated donors

In general, the donor choice will be sibling (related donor). However, unrelated donor will be considered if they are not fully or closely matched. In this regard, a donor search is first performed at local registry. Overseas search may then be required if no suitable match is identified locally and patient is required to pay for the fee involved in the overseas search. Further information on the searching procedure and its fee can be obtained from the hospital. Since the process of overseas search is quite complex, it is important for patient to understand the procedure and risks of HSC/TC transplantation before commencing the search.

## 4. Donor suitability assessment

Donor is required to undergo and pass a medical evaluation (including blood tests, chest X-ray and electrocardiogram) before the donation. The purpose of medical evaluation is to rule out any inherent problem of the donor's health to minimize risk to the donor and the intended patient. However, there may be rare circumstances that there is no comparable HSC/TC product available from a conforming donor and the recipient is likely to suffer death or serious morbidity without the product, and in such case the transplant doctor may select a non-conforming donor based on medical needs. Should this happen, the transplant doctor will explain the risk to patient during the consent process.

Form Author: Chang Pui Kei Reviewed by: Jennifer Leung, Chu Chui Yee, Approved by: CK Lee

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#### 5. **Donor eligibility assessment**

Donor is required to screen for communicable diseases, such as hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), human immunodeficiency virus (HIV) and syphilis. Normally, a donor free from the above communicable diseases is considered eligible. However, there may be rare circumstances that there is no comparable product available from an eligible donor and the recipient is likely to suffer death or serious morbidity without the HSC/TC product, and in such case the transplant doctor may select an ineligible donor based on medical needs. Should this happen, the transplant doctor will explain the risk to patient during the consent process.

#### 6. Cryopreservation, storage and disposal policy

HSC/TC product from an unrelated donor is intended for immediate transplantation in the intended patient; in certain circumstances, cryopreservation of HSC/TC prior to the initiation of patient conditioning may be indicated or if the HSC/TC product collected exceeds the infusion need of the patient, the excess HSC/TC product may be cryopreserved and stored for later use. Cryopreservation and storage will take place in processing facilities governed by the Hospital Authority. Every effort will be taken to ensure that the cellular therapy product remains viable during processing and storage. However, there are circumstances when the donated cellular therapy products are no longer required or it is proven unsuitable for clinical use or the cellular therapy products have passed the expiration time. In such situation, the cellular therapy product will be disposed of in accordance with the policy of the processing facility.

#### **Patient's Consent** <u>B</u>

- 1. I declare that I have been thoroughly informed about and consent to the transmission of my personal information to Hong Kong Bone Marrow Donor Registry for the purpose of Search and Match Service. If potential matched donor is found, I am required to attend family conference with the transplant physicians for detailed discussion concerning the transplant procedure, risks and success rate. At that time, I will be required to sign another consent on unrelated allogeneic HSC/TC transplantation before starting further arrangements.
- 2. I have read and fully understand the Personal Information Collection Statement and Privacy Policy Statement provided.

Patient's name:	Patient's signature:	HKID no:	Date:
Patient's Parent/ Guardian name:	Patient's Parent/ Guardian signature:	HKID no:	Date:
Doctor's name:	Doctor's signature:	Hospital:	Date:
Witness's name:	Witness's signature:	Relationship with Patient/Post	Date