



# Karaiskakio Foundation

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## POL 07 Second & Subsequent donations

### REVISION HISTORY

Rev	Version (Date)	Description of change	Author	Effective date	Reviewed by	Signature
0	Feb 2007	Initial Release	AK	01/06/2007	LK	
1	Jan 2012	Change of WMDA standards	AK	15/01/2012	PC	
2	Jan 2017	Change of standards and ISO 15189 format	AK	20/03/2017	PC	
3	Dec 2020	New WMDA standards	AK	01/01/2021	PC	

Prepared by	AK	Reviewed by	MK	Authorized by	PC
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	<b>POL 07 Second &amp; Subsequent donations</b>		

## 1. Principle

This policy aims to describe the procedure followed in the case where a second or a subsequent donation is requested.

### 07.01 Donor Information

The donors are informed of the possibility of a second or a subsequent donation of bone marrow or peripheral hematopoietic stem cells and for a subsequent donation of blood components at the time of VT by means of the Donor Information Booklet. The donor is informed in more detail of such a possibility during counseling at workup.

The donor has always the right to refuse to a 2nd or subsequent donation.

### 07.02 Donor Willingness

The donor consent for donation is obtained in the case of subsequent donation of BM, PBSC, and of any other blood component as it is CYBMDR policy that informed consent should be secured before each and every harvest donation.

The donor willingness or unwillingness for a subsequent donation is secured at the first donation and this is communicated to the requesting registry and transplant center by email.

### 07.03 Policy of Second (apheresis) or Subsequent Donations Communication Between Hubs

The prescription of a subsequent request should be communicated by the TC of the patient through the requesting registry to CYBMDR. No attempt should be made to contact the donor directly or indirectly by other means.

Upon receipt of the prescription request for a subsequent donation, the donor registry should confirm the receipt by sending email to the requesting registry.

A request for completion of a medical report (the Previous Transplant History) stating the reason for the need of a subsequent donation should be immediately communicated to the registry. The medical director approves the request. If needed, the Medical Director requests review of the subsequent graft request by the Medical and Scientific Advisory Committee for final decision.

Appendix 8.01 describes in detail the criteria and guidelines used by the review committee and medical director of CYBMDR for approval of a graft prescription request. The decision is communicated back to the registry for the analogous actions.

#### ➤ **Second Donation (apheresis); for PBSC only**

When a prescription of PBSC is received by a transplant center through the national registry of the recipient, the CD34+ cells are evaluated by the medical director to estimate according to the recipient and donor weight if a 2nd donation or apheresis will be required. The medical director has the right not to consent to carrying out the harvest procedure if the amount requested is not reasonable or the prescription is not clinically justified.

In the case of BM, only one donation is allowed. The nucleated cells are counted from a sample taken during the procedure of harvest so as to estimate the remaining harvesting volume needed to reach the required amount set by the transplant center.

In the case of PBSC, only one subsequent apheresis is allowed always on the following day of the 1st apheresis.

The CD34+ cells are counted immediately after the 1st apheresis and depending on the amount obtained, a 2nd apheresis is performed or not:

- A result of greater or equal to  $3 \times 10^6$  CD34+cells/kg weight of recipient is accepted as such and a 2nd apheresis is not performed. This is communicated to the transplant center.
- A result of less than  $3 \times 10^6$  CD34+cells/kg weight of recipient but greater than  $2 \times 10^6$  requires immediate consultation with the TC. If the TC accepts the graft as such, 2nd apheresis is not performed. Otherwise, the medical director is informed and upon approval and consent of the donor, a 2nd apheresis takes place on the following day and the TC is informed.

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- A result of less than  $2 \times 10^6$  at 1st apheresis may imply the need of BM collection Vs 2nd apheresis and in this case immediate consultation with the medical director follows. BM can take place only upon the medical director's decision and consent of the donor and the harvest center. Second apheresis can take place again upon the medical director's decision and consent of the donor and the harvest center. The TC is informed accordingly.
- The donor has the right to withdraw from a 2nd session of PBSC but the effect this may have on the recipient should be stressed out. In such a case, the requesting registry and transplant center are informed and depending on their decision, the process is either cancelled (see cancellation procedures in SOP 10) or the product from the 1st apheresis is accepted and the procedure continues as normal.

### ➤ Subsequent Donations; Same Donor, Same Recipient

A CYBMDR donor requested for a subsequent donation may only proceed to such a donation for the same recipient; a donor who has undergone BM or PBSC for a given patient is inactivated from the database immediately after donation and cannot be used for another recipient.

*The donor cannot proceed to a subsequent donation unless 4 weeks have elapsed since the first donation.*

*The number of subsequent donations by a donor for the same recipient is limited to two and only one of these may be hematopoietic stem cells.*

- **Medical Director Review:**

When a subsequent donation request for BM, PBSC or other blood components from the same donor is received for the same recipient, a Previous Transplant History Report from the transplant center must accompany the request explaining the reason for the need of a subsequent donation. Upon approval from the Medical Director and confirmation that request is pertinent, the donor and the collection center are formally informed.

- **Time Intervals Between Subsequent Donations:**

The minimum time intervals between the first and second donation are given in Table 1. These intervals represent the time between collections and not between first collection and request for a second collection.

**Table 1. Time intervals between first and second donation.**

		First Donation	
		Bone Marrow	Peripheral Blood Stem Cells
Second Donation	Bone Marrow	4 weeks	4 weeks
	Peripheral Blood Stem Cells	4 weeks	4 weeks*
	Unmobilized Leukapheresis	4 weeks	4 weeks
	Whole Blood Collection	4 weeks	2 weeks

\* In general, a second donation of PBSC should not be undertaken if the donor was a "non-mobilizer" at the time of first donation. The donor is informed and a consent form is signed if willing to proceed to a subsequent donation. Every subsequent donation requires consent of the donor.

**Table 1. Time intervals between first and second donation.**

	First Donation

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		Bone Marrow	Peripheral Blood Stem Cells
<b>Second Donation</b>	<b>Bone Marrow</b>	4 weeks	4 weeks
	<b>Peripheral Blood Stem Cells</b>	4 weeks	4 weeks*
	<b>Unmobilized Leukapheresis</b>	4 weeks	4 weeks
	<b>Whole Blood Collection</b>	4 weeks	2 weeks

**BM or PBSC:** the same procedure is followed as for the 1st collection including the workup and counseling.

**DLI & Other blood components:** for DLI and other blood components request, the donor undergoes only the laboratory tests and infectious disease markers. A corresponding consent form must be signed by the donor.

### 7.03.1 Specific Details Documentation

All the relevant details concerning the request are communicated along with the Previous Transplant History Report to the Medical Director for approval.

### 7.03.2 Policy availability

The policy is available to the TC upon request and is visible via WMDA share.

## 2. Documents

1. WMDA standards,
2. WMDA recommendations