

Blood stem cell donors – Regulatory issues

This document gives an overview of the conditions for requests regarding unrelated donors from *Swiss Blood Stem Cells*.

These conditions have to be accepted by the transplant physician before requesting. Deviations from the conditions must be approved by *Swiss Blood Stem Cells* before a request can be accepted and/or a donation can take place.

1. Search requests for international recipients

On searching the Swiss donor registry, a match list will be provided. For registries not connected to EMDIS an updated match list will only be provided on request.

2. Typing requests

Information on the recipient's age and diagnosis must be provided by the transplant centre with the request.

2.1. Extended typing:

Requests are accepted for extended typing on:

- HLA-A, -B, -C, -DRB1, -DRB3, -DRB4, -DRB5, -DQB1, -DPB1

The typing will be performed in an EFI/ASHI accredited laboratory.

2.2. Confirmatory typing / Verification Typing:

Requirements to request a confirmatory typing from a Swiss donor:

- For recipients over 70 years of age, additional information on disease stage, comorbidities and the recipient's Karnofsky index is required.
- A Confirmatory Typing / Verification Typing of the donor must be performed on a second sample (drawn independently from the initial sample) by the EFI/ASHI accredited laboratory of the transplant center

The standard reservation period after receiving the CT results is 90 days.

2.3. Extension of donor reservation before WorkUp request

An extension of the reservation can be requested if the donor has been definitively selected. A written request can be made to extend the reservation for a maximum of another 90 days.

The written request must include the following information:

- Current status of the patient
- Confirmation that the donor has been selected for transplantation for this patient
- Expected Timeframe of Transplantation
- Statement as to why the patient cannot be transplanted currently.

All request for extension are subject to review and approval by *Swiss Blood Stem Cells*.

2.4. HAC (Health and Availability Check)

A HAC may be requested during search or at start of Workup (backup donor) to obtain information about a particular donor's availability. A HAC is not a substitute for a CT.

Requirements to request a HAC from a Swiss donor:

- For recipients over 70 years of age, additional information on disease stage, comorbidities and the recipient's Karnofsky index is required.
- In addition, high resolution HLA-A, -B, -C and HLA-DRB1 typing is required for both recipient and donor.

- There must be no more than two 1st field typing level mismatches on these 4 loci between the donor and the recipient

3. Stem cell requests

Requirements to request blood stem cells from a Swiss donor:

- A Confirmatory Typing of the patient and the donor must be performed before the Donor Final Clearance is obtained
- The donor as well as the recipient must be typed HLA-A, -B, -C and HLA-DRB1 high resolution
- There must be no more than two 1st field typing level mismatches on these 4 loci between the donor and the recipient

3.1. Request for Cryopreservation

Cryopreservation must be authorised by Swiss Blood Stem Cells and donor's consent must be obtained.

A request must contain the following information:

- Reason for cryopreservation and health status of the patient (Medical Statement of the TC)
- Specific transplant date and probability that the transplant can take place

Three working days before the donor starts G-CSF, the transplant centre must reconfirm the planned transplant date and whether the patient is currently assessed as being suitable for transplant.

4. Subsequent donations

Two donations of either peripheral blood stem cells or bone marrow are permitted. The maximum number of donations is limited to three. The minimum interval between two donations is 30 days.

A Swiss donor may donate for 2 recipients at most.

5. Use of the collected stem cells

The collected cells are delivered exclusively for the purpose of haematopoietic stem cell transplantation to the designated recipient. Cells in excess may be stored for future infusion to the same recipient only.

No other use of the collected cells is permitted. Cells which are not used for transplantation of the designated recipient must be disposed of properly. *Swiss Blood Stem Cells* must be informed of the use and/or disposal of the product and the corresponding date. Information on disposal is only necessary if the entire product was destroyed.

6. Anonymity

The policy of complete anonymity between donor and recipient is applied strictly in Switzerland, this for reasons of donor and recipient protection. The donor receives no information on the recipient, the recipient is allowed to know only factors, that could be relevant to the outcome of the transplantation (such as age, gender, blood group of the donor).

A single exchange of anonymous letters is permitted between donor and recipient after the transplantation, exclusively through *Swiss Blood Stem Cells*.