

CRITERIA TO ACCESS A CSCR DONOR

Requests not meeting these criteria must be reasonably justified and may not be approved by CSCR. If more information is needed or request is denied – requesting TC/registry will be informed in writing.

International Transplant Centres

- must be registered with appropriate national authority as allogeneic transplant centre.
- must be registered with the appropriate national or international transplant outcome organization - EBMT, CIBMTR etc.
- patient must be informed on indications for transplant and their results on the transplant procedure and must sign informed consent.

Clinical indication for transplant

- Patient diagnosis should meet prevailing clinical practice – for reference see the EBMT recommendations.

Preliminary search request

- Preliminary search for patients' older than 65 years will be performed, however, for further requests (VT, Work-up) rationale is necessary - e.g. confirmation of good patient status, current treatment and expected success rate of transplantation.
- Repeated searches are performed upon request from the requesting registry (doesn't apply for EMDIS searches in active state)

Preliminary search request must include patient's:

- given name and surname
- date of birth
- diagnosis
- weight
- sex
- HLA typing results – min. A, B, DRB1* low resolution
- contact information of the requesting institution

Donor verification typing (VT)

- TC must provide CSCR with patient's minimum HLA- A, B, C, DRB1, DQB1* High resolution.
- Requested volume of blood samples should not exceed 50 ml
- Volume and number of tubes may differ from the request as the size and type of tubes used by our DC can vary
- sample arrival date is advised 1-2 days before the sample delivery whenever possible
- IDM's are automatically performed and sent within a week after blood drawing
- TC shall send sample testing result to CSCR within 2 months after the blood samples reception

Health and availability check (HAC)

- may be performed upon request. This procedure is preferred for donors who underwent VT at least once in the past. (Charged according to current CSCR fee schedule.)
- Donor will be reserved if requested

Reservation procedure

Extended typing

- RS status until the results are sent to requesting institution /max. 6 weeks
- RS status after typing is held for 14 days

Verification typing

Donor

- RS status from reception request until blood is drawn / max. 1 month
- RS status for 2 months after blood samples drawing
- RS status can be prolonged for up to 3 months after VT result is received

CBU

- RS status for 2 months after DNA sample shipment / VT typing in the local laboratory
- can be prolonged upon request from TC/registry of patient

Stem cells donation

- TC may ask for combined VT + work-up procedure in urgent cases
- TC must send completed Formal request and prescription forms to CSCR
- TC must provide CSCR with minimum A, B, C, DRB1, DQB1*HR patient's HLA typing
- Patient's HLA typing must be performed on 2 different blood samples (VT resolution must be sufficient to verify patient's identity – at least **A, B, DRB1*LR**) - result must be available **before the donor begins mobilisation or proceeds to collection, or the patient begins with the preparative regimen, whichever is earliest.**
- selected donor should be minimum 8 of 10 patient match from A, B, C, DRB1, DQB1*HR loci
- requested volume of **pre-collection** samples should not exceed **50 ml**
- **BM volume requested should not exceed 20ml/kg donor weight.** Maximum volume BM collected is 1500 ml.
- **PBSC request should not exceed 5x 10⁶/kg** patient's weight. Higher request must be explained and reasoned and it will be checked by CSCR medical supervisor and/or review board.
- If after **first apheresis a CD34+ cell count of 90%** of the requested cell count is not obtained, the second apheresis will be undertaken only when donor's condition allows it.

Donor as back-up

- TC can request the donor as back-up. TC shall inform CSCR about the tentative work-up schedule. In this case, donor will be contacted and informed, that if they agree they will remain reserved for the patient but may not be finally requested to donate. No action is taken in respect with the CC schedule arrangements.
- Parallel work-up is possible only in exceptional cases. TC must properly justify the request. Such requests are assessed on case-by-case basis and acceptance is not guaranteed. Donor will be contacted and informed, that if they agree, the work-up procedure starts. (Cancellation charges apply according to the current CSCR fee schedule.)

Subsequent Donation Requests

- This condition applies also for failed mobilization cases
- Donors can donate only for the patient whom they already donated their first graft.

Minimum time between the first and second donation*

		First graft	
		BM	PBSC
Second graft	BM	Not allowed	1 – 3 months**
	PBSC	1 – 3 months **	Not allowed
	DLI (unstimulated leukapheresis)	1 – 3 months **	1 – 3 months **

Minimum time between the second and third donation *

		Second graft		
		BM	PBSC	DLI
Third graft	BM	Not allowed	Not allowed	6 months
	PBSC	Not allowed	Not allowed	6 months
	DLI	6 months	6 months	6 months

* Whether donor will be cleared for subsequent donation depends solely on collection centre physician decision with respect to donor's current health assessment.

** Optimal time interval from the first donation would be 3 months, however, this period may be shortened given the patient's urgent need of graft and donor's health condition. Minimum time between donations must be at least 1 month.

Research/Clinical studies

Requesting TC must submit:

- request from the investigator for the donor enrollment
- IRB approval
- study protocol
- information for participating donor
- Informed consent form
- Donor must be properly informed on the nature of research and must sign informed consent providing the requirements for testing or collection beyond standard are involved.

Cord blood unit

Request for extended typing

- typing can be performed by Czech EFI accredited laboratory upon request
- DNA sample (up to 10 ng of DNA) in ambient temperature may be sent (shipment on dry ice possible upon request)
- CSCR shall be advised of the typing results within 3 months period

IDM testing

- Other samples available for shipment for testing of IDM which are not done by Czech Cord Blood bank: maternal plasma, maternal full blood

Confirmatory typing

- CSCR performs A, B, DRB1*LR confirmatory typing from the contiguous segment after receipt of formal recruitment request – usually 3 days before unit shipment

Unit shipment

- TC must send completed **F049 Cord blood unit request form** or its equivalent to CSCR
- selected unit should be minimum 4 of 6 patient match from A, B*LR and DRB1* HR loci