INSTITUTE FOR CLINICAL AND EXPERIMENTAL MEDICINE Czech Stem Cells Registry



Criteria to access a CSCR donor

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 organisation EBMT, CIBMTR or NMDP
- 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 diagnose should meet prevailing clinical practice – for reference see the EBMT recommendations.

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

Stem cells donation

- TC must send completed Formal request and collection forms to CSCR.
- selected donor should be minimum 8 of 10 patient match from A, B, C, DRB1, DQB1*HR loci
- requested volume of pre-collection samples shall not exceed 50 ml
- BM volume requested shall not exceed 20ml/kg donor weight
- Maximum volume BM collected is 1500 ml
- PBSC request shall not exceed 5x 10⁶/kg patient's weight. Higher request must be explained and reasoned and it will be checked by CSCR medical director or Ethical committee.
 - o If after first apheresis a CD34+ cell count of 95% of the requested cell count is not obtained, the second apheresis will be undertaken only when donor's condition allows it.

Research/Clinical studies

Requesting TC must submit:

- request from the investigator for the donor enrolment
- 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.



Tel.: +420 261 361 011/2346



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Subsequent Donation Requests

Donors can donate only for the patient whom they already donated their first graft.

Minimum time between the first and second donation*

		First graft		
		ВМ	PBSC	
Second graft	вм	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		
		ВМ	PBSC	DLI
Third graft	ВМ	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.

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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 2 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 lab 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

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 (CT)

Donor

- RS status from reception request until blood is drawn / max. 1 month
- RS status for 2 months after blood samples drawing
- can be prolonged upon request from TC /registry of patient

CBU

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

