

Cord Blood - Regulatory issues

This document gives an overview on the conditions for requests and shipment of Swiss Cord Blood Units (CBU) from *Swiss Blood Stem Cells (SBSC)*, which are stored in a public or hybrid Cord Blood Bank.

1. Additional Data (Cord Blood Unit Data)

Additional data for CBU can be requested at any time and free of charge.

2. Extended typing requests

Requests are accepted for extended typing on:

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

These extended typings

- are performed on the initial sample which was used for the typing at timepoint of registration
- will be done at the National Reference Laboratory for Histocompatibility in Geneva, Switzerland (EFI accredited)

The Cord Blood Unit remains reserved for 90 days after transmission of the typing results. An extension of the reservation can be requested for a maximum of another 90 days.

3. DNA-sample request for CT

Conditions for acceptance of a DNA-sample request:

- The CBU and the recipient are at least HLA-A, -B low resolution and -DRB1 intermediate resolution typed
- There are no more than two 1st field typing level mismatches on these 3 loci between the CBU and the recipient

DNA-samples are shipped by a courier designated by SBSC. The shipping costs will be charged in addition to the DNA-sample fee.

A request for shipment of an attached segment will be accepted only following the request for shipment of the CBU.

4. Maternal serum request

A maternal serum sample request will be accepted only following the request for shipment of the CBU.

5. Unit request

To request a CBU, the form "[1518_FOR_Formal_Request_Cord](#)" has to be submitted.

6. Unit Shipment

Before shipment of a CBU, Confirmatory Typing / Verification Typing must be performed and the result must be available before the CBU is shipped. Furthermore, a Confirmatory Typing of the patient must be performed before the definite release of the unit for shipment.

At Confirmatory Typing / Verification typing

- the CBU must be high resolution typed at HLA-A, -B, -C, -DRB1, if a high resolution typing is not already previously available. Otherwise a low resolution typing of HLA-A, B and DRB1 is sufficient.
- the typing must be performed in an EFI/ASHI accredited laboratory on an attached segment (if available), otherwise on an independent sample

The CBU must arrive at the transplant center before the start of recipient conditioning.



The collected cells are delivered exclusively for the purpose of haematopoietic stem cell transplantation of the designated recipient. 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 CBU and the corresponding date.

7. Anonymity

Complete anonymity must be guaranteed between the mother/donor of CBU and the recipient.