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Requirements for Cord Blood Units – Regulatory issues

1. Introduction

This document describes the regulatory issues for the collection, storage and shipment of cord blood units as defined by SBSC. All other requirements are specified in the FACT/NetCord Standards, which must be observed/fulfilled by the CB-collection centre and the CBB.

2. Collection procedures

Each cord blood bank is responsible to check the compliance of the collection criteria implemented in the collection centers (questionnaires, informed consent, collection procedure, cell counts and transport) with the FACT/NetCord Standards and Swiss Blood Stem Cells Prescriptions (current Policy and 1417_Nabelschnurblutspendekritierien_D for the donation criteria). Compliance is confirmed with the signature “release for registration” on the form 2356_FOR_Cord_Blood_Unit_Data CBU_Registration.

3. CBU registration requirement for TNC

The CBU must contain a minimum of 100 x 10^7 nucleated cells after processing / before banking / cryopreservation. However, the target count is 125 x 10^7 TNC. To achieve this aim, SBSC strongly recommends a TNC count of over 150 x 10^7 before processing.

4. Processing procedures and sample storage

Each cord blood bank shall have processing procedures and sample storage specifications in place that comply with the FACT/NetCord Standards.

5. IDMs

Testing of following IDMs must be performed from a maternal sample collected within 7 days before or after collection of the CBU:

- HBsAg (hepatitis B surface antigen)
- Anti-HBc (antibodies to hepatitis B core antigen)
- HBV NAT (hepatitis B virus by Nucleic Acid Testing)
- Anti-HCV (antibodies to hepatitis C virus)
- HCV NAT (hepatitis C virus by Nucleic Acid Testing)
- HEV NAT (hepatitis E virus by Nucleic Acid Testing)
- Anti-HIV 1 and Anti-HIV 2 (antibodies to human immunodeficiency virus 1 and 2)
- HIV NAT (human immunodeficiency virus by Nucleic Acid Testing)
- STS (serologic test for syphilis)
- Anti-HTLV 1/2 (antibodies to human T-lymphotropic virus 1 and 2)
- Anti-CMV (antibodies to Cytomegalovirus)
- Additional testing for transmissible diseases according to travel history / where applicable (e.g. malaria, tropical viruses such as Zika virus, Chagas disease)

All maternal samples should have negative or non-reactive test results with the exception of:

- Cytomegalovirus antibodies
- Hepatitis B core antibody: Maternal samples that are hepatitis B core antibody positive may be accepted if they are hepatitis B negative by DNA testing
- Treponema pallidum (syphilis): Maternal samples that are Treponema pallidum (syphilis) screen positive but negative using a specific confirmatory test may be accepted

Microbial cultures of the CBU unit obtained after processing prior to cryopreservation shall be performed using a permissive system for the growth of aerobic and anaerobic bacteria and fungi.

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CBUs for unrelated use must be free of microbial contamination.

6. HLA-Typing

See POL_006_HLA_Typing.

7. CBU-Request and shipment

When samples of a CBU are requested for extended or confirmatory typing, the CBB must review the registration data, verify that any subsequent information has been added and confirm completeness of the data with the signature “release for request” on 1439_FOR_Cord Blood Unit Data_CBU_Request.

Should the CBU be requested for transplantation, confirmatory typing (CT) must be performed and the result must be available before shipment of the unit. The CBU must be typed HLA-A, -B, -C, -DRB1 high resolution at least once (see POL_006).

Haemoglobinopathy testing must be performed for unrelated CBUs regardless of the family’s ethnic background. As the federal law for genetic testing in humans (GUMG) defines that parent / child must be informed about the haemoglobinopathy testing, CBBs must have a process for the contactability of parent / child. The process includes two different approaches which are based on the outcome of the test results: haemoglobinopathy test without findings or haemoglobinopathy test with findings.

The CBU can be released for shipment once haemoglobinopathy, potency and viability testing have been initiated and CT has been performed.

The final release for shipment is granted by SBSC.

For details on shipment / transportation see POL_015.