

**STANDARD OPERATING PROCEDURES MANUAL
CORD BLOOD (HPC, Cord Blood or HPC, CB)(PART II)
OF THE
MARROW DONOR PROGRAM BELGIUM**

Marrow Donor Program Belgium

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VERSION

Approval General Assembly and date of implementation	Alterations to Document	Status
Version 01/2010 - 01/09/2010	SOP and forms	Approved
Version 02/2011 – 01/02/2012	SOP and forms	Approved

REVIEW AND UPDATE

Every 3 years, a profound review of the SOP is necessary by the members of the MDPB-vzw/asbl and MDPB-R Board. If there are no major changes the SOP is prolonged annually. New and revised policies and procedures shall be reviewed by the members of the MDPB-vzw/asbl and MDPB-R Board prior to implementation. This review is approved by the members in the General Assembly. This review shall be documented.

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1. INTRODUCTION

The Marrow Donor Program Belgium (MDPB) consists of the MDPB-Registry (MDPB-R) within the Belgian Red Cross and the MDPB-vzw/asbl, a non-profit corporation under Belgian law.

The MDPB-R is responsible for the administrative and financial management of the MDPB. The MDPB-vzw/asbl is responsible for medical and scientific management. The medical advisory committee (MAC) of the MDPB-vzw shall be consulted for any medical question/procedure not covered by the SOP.

This Standard Operating Procedures Manual HPC, Cord Blood Part II (SOP CB) covers all procedures involving HPC, Cord Blood products. (All procedures involving unrelated volunteer donors, criteria for Donor Centers, Collection Centers and Transplant Centers and related procedures are covered in the Standard Operating Procedures Manual Part I). The SOP intends to provide practical information to all MDPB users or coworkers. Deviation of procedures from these standards must be submitted in advance to the Board of the vzw/asbl of the MDPB.

The Medical Director of the participating Cord Blood Bank is responsible for ensuring the center's compliance with these standards.

A separate collaboration agreement covers the procedures to assure the proper functioning of the software application "Syrenad" facilitating the search process for unrelated donors and cord blood units.

2. CORD BLOOD BANKS ACCREDITATION CRITERIA

2.1. CB banks affiliated to MDPB shall fulfil the following criteria

- 2.1.1. The Cord Blood Bank (CBB) must have a valid FAGG-AFMPS certification (the certificate must be provided to MDPB-R in due time).
- 2.1.2. The CBB should at least be registered at FACT.
The CBB has a valid FACT-NETCORD certificate.
The CBB is in process of (re-) accreditation:
Initial registration submitted at the latest on *01/01/2011*; or:
Checklist submitted (with or without planned date for inspection) at the latest on *01/07/2012*; or:
Inspection done with pending list of additional questions, but no re-inspection (focused or complete) needed at the latest on *01/01/2013*.
- 2.1.3. The CBB must comply with US Food and Drug Administration (FDA) Donor Eligibility requirements, which includes ensuring that each CBB within the MDPB-R must register with the U.S. Food and Drug Administration (FDA) to obtain an establishment registration number.
- 2.1.4. All typings must be performed at an ASHI or EFI accredited lab.

2.2. Requirements regarding the inventory

- 2.2.1. Have an inventory of at least 500 HLA-A, B and DR typed cord blood units (for existing banks at least 1000 units).
- 2.2.2. Informed consent forms and medical questionnaires must be approved by the MDPB-R following all relevant national and international (including, but not limited to FAGG-AFMPS, FDA, NMDP-USA, FACT-Netcord, WMDA) standards and regulations (for medical history questionnaire).
- 2.2.3. The CBB must have an inventory of validated CBUs with (at least) the following requirements and test results available:
- CBB identifier
 - Unique unit identifier
 - HLA typing
 - HLA A serological equivalent_1
 - HLA A serological equivalent_2
 - HLA B serological equivalent_1
 - HLA B serological equivalent_2
 - HLA A molecular_1
 - HLA A molecular_2
 - HLA B molecular_1
 - HLA B molecular_2
 - HLA DRB1_Molecular_1
 - HLA DRB1_Molecular_2
 - HLA DQB1_Molecular_1 (optional)
 - HLA DQB1_Molecular_2 (optional)
 - HLA DPB1_Molecular_1 (optional)
 - HLA DPB1_Molecular_2 (optional)
 - HLA Cw1_Molecular_1 (optional)

HLA Cw1_Molecular_2 (optional)

- Infectious disease markers (following FACT-NETCORD standards and National law) on **maternal sample**:

	Option 1		Option 2		
	On delivery		On delivery	After 6 months	Prior to release (if possible)
	Serology	NAT	Serology	Serology	NAT
HIV		X			
Anti HIV1 and 2 antibodies	X		X	X	
HBV		X			X
HBs Ag	X		X	X	
HBc antibody	X		X	X	
HCV		X	X	X	X
Anti HCV antibodies	X		X	X	
Anti HTLV I/II antibodies	X		X		
Syphilis serology	X		X		
Anti CMV antibodies (optional)	X		X		

: Usually not valid as IDM if done on a sample of more than 6 months. It is yet seen as clinically relevant information and should be mentioned as such.

- Volumes
 - Pre-processing
 - Post-processing
- Processing method
- Cell counts
 - Pre processing (only post processing in EMDIS)
 - TNC or WBC (after subtraction of nucleated RBC)
 - CD34⁺ cells (optional)
 - CFU-GM (optional)
 - Post processing prior to cryopreservation
 - TNC the new units must contain at least 50.10⁷ TNC post processing.
 - Or WBC (after subtraction of nucleated RBC)
 - Total CD34⁺ cells
- Prior to release

CFU from the final cord blood unit (only for units with a segment)
Hemoglobinopathy testing

- Viability
- Number of fractions
- CB Status
- Date of first entry in the database (optional)
- Date of last update (optional)
- Date of birth
- Infant gender
- ABO/Rh
- Maternal risk factors and family medical history
- Bacterial (aerobic-anaerobic) and fungal culture results
- A unit summary in English

3. PROCEDURES

3.1. Recruitment of maternal donors and informed consent:

The criteria following FACT-Netcord, WMDA standards and national law must be fulfilled.

- 3.1.1. Consent documents must meet criteria established based at a minimum on WMDA guidelines and following the FDA regulations. In addition to information on the process, risks and benefits, documents must include information on the collection and protection of donor data and the right of the donor to medical confidentiality and to receive medical information. Documents must be written clearly in terms understood and signed by the mother and must contain following information:
 - The right of the mother to refuse the collection without prejudice at any time.
 - The overall purpose and participation of the mother and infant donor.
 - An explanation of the processing procedure and activities in terms the mother can understand.
 - The possible risks and benefits to the mother and/or infant donor.
 - The possible alternatives to participation.
 - The intent of the donation for unrelated use.
 - If the CBU is intended for unrelated allogeneic use, the mother shall be informed that the CBU is a donation that will be made available to other individuals and will not necessarily be available to the infant donor or the infant donor's family at a later date.
- 3.1.2. The maternal donor does not receive payment for the donation.
- 3.1.3. Informed consent shall be obtained and documented from the mother, while she is able to concentrate on the information and is not distracted by aspects of labour.
- 3.1.4. All aspects of participation in CB donation shall be discussed with the mother in a language and with terms that she understands.
- 3.1.5. The mother shall have an opportunity to ask questions.
- 3.1.6. The mother will be asked to provide personal and family medical history.
- 3.1.7. Personnel will be permitted to review the medical records of the mother and infant donor.
- 3.1.8. Reference cord blood samples and maternal samples will be collected and stored for future testing.
- 3.1.9. The CBB will maintain linkage for the purpose of notifying the infant donor's mother or family and/or her physician of communicable or genetic diseases, whenever possible.
 - The CBB retains the right to follow up with the mother or her primary physician at a future date.
 - Information related to the infant donor and the infant donor's family shall remain confidential and is only available for review by individuals designated by the CBB or by national authorities to evaluate the CBB.
 - Linkage between the infant donor and mother with the CBU shall be maintained indefinitely.
- 3.1.10. Possible uses of the CBU for purposes other than clinical transplantation and the CBB's policies for disposal of CBUs must be mentioned in the informed consent.

3.2. Eligibility: Requirements for donor health affecting the eligibility of donors must be established

- 3.2.1. The health screening and medical evaluation guidelines must comply with WMDA recommendations.
- 3.2.2. Eligibility forms are required for all CB's collected on or after May 25, 2005 to be in compliance with U.S. Food and Drug Administration (FDA) eligibility requirements.
- 3.2.3. A health screening of the maternal donor for communicable risk transmission shall be performed to include status at time of delivery.
- 3.2.4. A medical and genetic history of the infant donor's family shall be obtained and documented.
- 3.2.5. A history of the current pregnancy and delivery and the infant donor's status at birth shall be obtained and documented to include any findings that might suggest possible disease transmission through the cord blood unit. This history shall be updated no later than 14 days after delivery.
- 3.2.6. Hemoglobinopathy testing on the infant donor or the cord blood unit shall be performed prior to the release of the cord blood unit.
- 3.2.7. The maternal donor of the cord blood unit has the right to receive the results of the health screening.
- 3.2.8. The HLA matching between CBU and patient is the responsibility of the transplant center.

3.3. Initial search request

- 3.3.1. Cord searches can be requested by a Belgian accredited Transplant Center (TC), any International Registry (HUB) or any European EBMT accredited Transplant Center (if no HUB available in that country) or by an accredited US Transplant Center. The request is free of charge for the partner HUB/Transplant Center.
- 3.3.2. Each initial search request has to be sent on a specific form (MDPB001 preliminary search request v2 2011) except for requests from Belgian Transplant Centers or International registries sent through EMDIS.

The search request must include the following information on the patient:

- date of request,
- last and first name,
- date of birth,
- body weight,
- ABO and Rh blood group,
- diagnosis,
- disease status,
- HLA A, B, C, DRB1 and DQB1 typing: performed preferably by molecular typing.

And the following administrative information:

- identity of requesting institution,
- name of transplant physician and institution,
- contact person.

3.3.3. Following the submission of an initial search request for a Belgian patient or international patient at MDPB-R, a search report on cord blood units of the Belgian CBB is sent to the requesting Transplant Center by MDPB-R. Cord search results for Belgian patients and International patients of EMDIS connected countries will be sent via Syrenad, cord search results for International patients not connected via EMDIS will be sent via email.

Search results will be sent the same working day after receiving the request or at the latest the next working day

On the report appear:

- the number and codes of 0 mismatch CBUs (6/6)
- the number and codes of 1 mismatch CBUs (5/6)
- the number and codes of 2 mismatch CBUs (4/6)

With the following information:

- CB ID = BECB followed by the local bank identifier
- HLA TYPING
- Birth date
- Availability status
- Collected volume in ml
- Total nucleated cells (10^E8) post processing
- Total CD34+ cells post processing
- Method of volume reduction

3.4. Dispatch of complementary information: Full unit report

Upon request the complementary CB information can be provided by the CBB following FACT-NETCORD requirements.

3.5. Further tests when a potential CB has been identified

The partner hub/Transplant center may require additional tests or typings to be done on the unit:

3.5.1. Request for additional typing

The cord blood high resolution typing requests can be requested via EMDIS (Syrenad) by Belgian and international EMDIS connected registries. Other countries must complete the form "MDPBCB002 Request for further DNA based cord typing v2 2011".

The Cord Blood Banks will receive all typing requests via Syrenad and must report the results via Syrenad. After having received a typing request via Syrenad, the cord blood unit will automatically be reserved for 60 days. When the unavailability date expires, the cord blood unit will be automatically set to availability again. When entering the typing results, the cord blood unit will be again reserved for a renewed period of 60 days.

MDPB-R coordinates the invoicing to the National Transplant Center and the International Registry. MDPB-R will pay fees to the HLA labs after having received

the funds, and after having received invoices from the HLA labs (order forms will be sent to the labs listing all typings performed).

3.5.2. Various tests

For tests that are not listed in the MDPB fee list, specific agreement on fees to be charged must be made in advance between the partner hub/Transplant Center, the bank and MDPB .

The following tests are done at the bank level depending on agreement with laboratories accredited or licensed in accordance with applicable laws – regulations approved by the governmental authority:

- Additional IDMs,
- Hemoglobinopathy screening,
- Specific tests as needed.

3.6. Samples prior to shipment

The Transplant Center may need reference samples from the CBU or from the mother. The Transplant Center, if connected with EMDIS, must activate the DNA sample or maternal sample via Syrenad or in case of a non EMDIS country, the samples can be requested via the form “MDPBCB003 cord blood sample request v2 2011”.

The following samples can be requested:

- Cord blood Plasma (stored at -80°C)
- Cord blood cells (stored in liquid nitrogen)
- Cord blood DNA (stored at -80°C)
- Maternal serum or plasma (stored at -80°C)
- Maternal cells (stored in liquid nitrogen or -80°C)
- Maternal DNA (stored at -80°C)
- Other

The CBB shall inform the shipment of the sample via Syrenad or using the cord blood sample procurement form: “MDPBCB004 cord blood sample procurement v2 2011”.

After having received a blood sample request via the application Syrenad, the cord blood unit will be automatically reserved for 60 days. When the unavailability date expires, the cord blood unit will be automatically set to availability again. When entering the blood sample arrival date, the cord blood unit will be again reserved for a period of 60 days.

The bank will organise the sample shipment.

Invoices for DNA samples and Maternal samples for IDM testing prior to transplantation are invoiced by the Cord blood banks to the MDPB-R the form “MDPBCB011 additional info invoice cord transport v2 2011” must be attached. Billing should occur within 40 days of service completion. The MDPB-R will re-bill to destination of the International Registry and follow up settlement of payments by sending monthly statements of account.

3.7. Cord blood unit reservation

To reserve a cord blood unit the Transplant center must complete the “MDPBCB005 cord blood unit reservation v2 2011” form. Upon reception of this form the cord blood will be marked as “reserved” for 60 days (in Syrenad). To extend the reservation, the TC should resend the Cord blood unit reservation form.

The Cord Blood Bank must change in Syrenad the availability status of the cord blood to “unavailable” indicating the “end of unavailability date”. (Via option: UPDATE). After this date, the cord blood will be automatically available again.

3.8. Cord blood unit request for transplantation

3.8.1. The CBB and MDPB-R shall retain indefinitely documentation of requests for CBUs, requests for reference samples and maternal samples, requests for and results of testing, and transportation and shipping of CBUs and samples between facilities.

3.8.2. Before a CBU is released, a sample obtained from a contiguous segment of that CBU shall be tested cfr.3.8.4. pre-release checks.

3.8.3. Any histocompatibility discrepancy shall be resolved and communicated to the MDPB-R.

Discrepancies must be reported using the “MDP004 discrepant typing v2 2011”. The Transplant Center finding the discrepant type must complete section A, the CBB must complete section B and return via the Registry to the Transplant Center specifying the type of error: clerical error or technical error.

The CBB checks the Cord Blood Unit for fulfillment of all criteria for release and transplantation (according FACT - NETCORD).

3.8.4. When requesting a cord blood unit for transplantation the Transplant Center must complete the form “MDPBCB006 cord blood unit request for transplantation (HPC, CB) v2 2011”.

The following items must be completed:

Section : CBU and patient identification.

CB identification: HLA typing

Pre-release control typing (LR) done: yes (date) / pending

Patient Identification

Section: Pre-release checks

The **following tests** to be done on the CB on time of release can be requested and should be done prior to initiation of the recipient's conditioning:

1. a. The **Verification typing** is the typing performed from a contiguous segment before the unit is released and shipped to a Transplant Center to confirm the HLA identity of the unit, the minimum requirement is to perform HLA A,B, DRB1 by LR.

1. b. When there is no contiguous segment on the unit, the Transplant Center or registry must be informed of the type of sample used for this typing.

2. Viability/clonogenic testing from contiguous segment if possible or from a cord blood reference sample.

3. Reference sample Mother: maternal haplotype or request (not required)

4. Viable CD34+ and / or CFR.

5. Other tests can be specified.

The Cord Blood Bank will confirm which requested test will be available.

Section: Shipping instructions

The Transplant center must complete the proposed shipping dates and specify if the CBB will ship the unit in a dry shipper (returned by the TC within 48 hours.) or if a courier will pick up the unit.

Section: Delivery address

The TC must complete the delivery address.

3.9. Transportation and shipping of cryopreserved cord blood units

- 3.9.1. Procedures for transportation and shipping of cryopreserved CBUs shall be designed to protect the integrity of the CBU and the health and safety of personnel in accordance with applicable laws (FDA, IATA, FACT, Netcord).
- 3.9.2. The CBB organizes the transport with a certified, validated courier of his choice. If the TC wants to organize the transport with the shipper of the CBB of another lab, the CBB is no longer responsible
- 3.9.3. The CBB shall have a written policy to obtain the following data from the receiving facility about the CBU upon receipt:
 - 1. Date and time of receipt.
 - 2. Integrity of the dry shipper.
 - 3. Internal temperature of the dry shipper.
 - 4. Integrity of the CBU.

The data regarding the transfer of the cord blood unit must be informed via the form "MDPBCB007 cord blood unit transfer plan (HPC, CB) v2 2011":

Section A: to be completed by the Cord Blood Bank.

The CBB will confirm the transfer arrangements:

- a courier from the TC will pick up the unit with their own shipment equipment or equipment of the CBB
- the CBB will ship the unit in a dry-shipper specifying: date and time of delivery to the transport company, the Job number or Airway bill number, the date and time of arrival at the Transplant Center and the shipment address.

Section B: To be completed by the Transplant Center and to be faxed to the MDPB-R/CBB.

The TC must agree with the transfer plan and accept to pay the CB release fees (according to MDPB-R fees) plus transport fees if applicable.

- 3.9.4. Once an unrelated CBU has left the CBB premises, it shall not be returned to the general CBB inventory.

- 3.9.5. Transportation and shipping records must be maintained by the bank according to standards and requirements.
The form “MDPBCB008 transport of cord blood unit audit (HPC, CB) v2 2011” must be completed and accompany the CBU shipment.
- Section A: To be completed by the CBB
 - Section B: To be completed by the courier.
 - Section C: To be completed by the TC and faxed back to the MDPB-R/CBB.

3.10. Import

CB from CBB located outside the EU should be imported by a registered Belgian stem cell bank. Procedures should be in place accordingly at the TC (as required by law 2008 : HGR/CSS Nr8271, RD 19 december 2008, RD 28 september 2009 FAGG)

3.11. Clinical outcome data

Clinical outcome data shall be collected by individual banks and shall be shared with the Registry.

After transplantation of a patient with cells from an unrelated cord blood unit provided through the MDPB-R, the Transplant Center must report post transplant clinical outcome to the MDPB-R at regular intervals. This is done by completing form “MDPBCB009 cord blood post transplant follow up report (3 months – 1 year) (HPC, CB) v2 2011” (3 months after shipment, 1 year after transplantation). The MDPB-R will send a copy to the CBB. The Cord blood bank must also complete the “Cord Blood Transplantation – Registration Form for CB Banks” and send the filled questionnaire to Eurocord.

4. OFFICIAL FORMS

MDPB001 initial search request v2 2011

MDPBCB002 request for further DNA based cord typing v2 2011

MDPBCB003 cord blood sample request v2 2011

MDPBCB004 cord blood sample procurement v2 2011

MDPBCB005 cord blood unit reservation v2 2011

MDPBCB006 cord blood unit request for transplantation (HPC, CB) v2 2011

MDPBCB007 cord blood unit transfer plan (HPC, CB) v2 2011

MDPBCB008 transport of cord blood unit audit (HPC, CB) v2 2011

MDPBCB009 cord blood post transplant follow up report (3 months – 1 year) (HPC, CB) v2 2011

MDPBCB010 update request cord SOP and forms v2 2011

MDPBCB011 additional info invoice cord transport v2 2011

MDPBCB012 fee schedule cord v2 2011

MDPB004 discrepant typing v2 2011

MDPB042 accreditation form cord blood bank v2 2011

MDPB048 notification of missing status report v2 2011

Cord blood transplantation – Registration Form For CB Banks

5. LIST OF CORD BLOOD BANKS

Bruxelles (ULB)

Institut Bordet
Banque de sang de cordon
Unité de thérapie hématologique
Boulevard de Waterloo 121
1000 Bruxelles
Prof. Dominique Bron
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Contact Person : Dr. Sc. Alain Delforge
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fax 0032 2 541 36 11

Bruxelles (UCL)

Banque de sang de cordon
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10 avenue Hippocrate
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Gent

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(in collaboration with Rode Kruis – Vlaanderen)
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Liège

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Laboratoire de Thérapie Cellulaire et Génique
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4000 Liège
Dr. Etienne Baudoux
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fax 0032 4 366 83 91

Leuven

UZ Leuven campus Gasthuisberg
Leuvense Navelstrengbloedbank
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3000 Leuven
Prof. Dr. T. Devos
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6. LIST OF PICK UP ADDRESSES

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7. Tasks / responsibilities of THE CORD BLOOD BANK and the MDPB-R and MDPB- vzw/asbl scientific committee

7.1. MDPB-R

7.1.1. CRITERIA

MDPB-R must be a legal entity that guarantees administrative and financial operation with a fixed physical location.

The Director or key Registry personnel must have the necessary skill in this field of activity documented by education and experience. At least one of these individuals must be a physician.

The MDPB-R must maintain records of its activities and must maintain a database of volunteer donor information and cord blood information. All patient and donor records must be stored to ensure confidentiality according to WMDA Standards: cord blood and patient identity must remain confidential during the search process. The access to cord blood and patient data information as the transmission must be organized that unauthorized access is prevented – confidentiality is guaranteed.

MDPB-R must comply with a quality management system that comprises Standard Operating Procedures (SOP's), staff training and education and guarantees compliance with the applicable standards as approved by the VZW/ASLB. The MDPB-R must have personnel who can communicate in English.

7.1.2. TASKS

Administrative and financial management of the Belgian cord program.

- 7.1.2.1. Management of the cord blood database. The Coordinator and Board of the Registry define which equipment to be used in line with the International procedures. The coordinator acts as the Belgian representative at International meetings of the registries.
- 7.1.2.2. Searches for patients from Belgium and abroad: consultation of the cord database of the MDPB-R (incl. Belgian Cord Blood Bank) and all registries connected into the BMDW through EMDIS, BMDW (Internet) or by fax and of the Netcord network of Cord Blood Banks.
- 7.1.2.3. Transmission of requests from Belgian Transplant Centers or Transplant Centers abroad.
- 7.1.2.4. Once a cord blood has been selected by the Transplant Center, the Registry is coordinating the communication between the Transplant Center and the CBB.
- 7.1.2.5. The MDPB-R must keep complete and accurate financial records for all services provided and requested according to national laws and regulations as well as international standards.
- 7.1.2.6. The MDPB-R must have sufficient staff dedicated to perform all accounting duties.
- 7.1.2.7. Fee structure
 - 7.1.2.7.1. A clear fee schedule detailing payment terms shall be available upon request. Changes in the fee schedule should be provided to interested parties thirty days prior to implementation.
(MDPB012 fee schedule cord v2 2011)

- 7.1.2.7.2. Any cost not standardized or, for any reason, not accessible through such a schedule (e.g. courier charges) should be estimated and communicated in advance to the requesting Registry and/or the Transplant Center.
- 7.1.2.7.3 Cancellation fee: After the CBB receives the formal request for delivery of a cord blood unit, the tests for Quality Assurance will be performed, including viability and GFU-GM. As the samples stored for these QA tests will be used, the test cannot be repeated and therefore the unit cannot be returned to the file of available CBUs. The full amount of delivery of a cord blood unit is due.
- 7.1.2.8. Invoices for international patients are made by the Registry and sent to the requesting center for
- Typing requests
 - Cord blood
 - Cancellation of shipments.
- Prices are defined by the Board of the MDPB-vzw/asbl. Payments are made to the Registry. The Registry will distribute a fee as agreed between the different parties involved after receiving an invoice from the Cord Blood Bank. (The Registry will send order forms to the involved centers for all services rendered).
- DNA / maternal samples including shipment, and shipment of cord blood units are invoiced by the CBB to the MDPB-R. The CBB must attach the form "MDPBCB011 additional info invoice cord transport v2 2011". Billing to the MDPB-R should occur within 40 days of service completion. The MDPB-R will re-bill to destination of the International Registry or TC and follow up settlement of payments by sending monthly statements of account.
- 7.1.2.9. Statistics: the Registry collects monthly updates on the activities of the Registry.
- 7.1.2.10. Maintain an updated list of participating Cord Blood Banks and HLA typing centers. Printing and distribution of SOPs, forms, brochures and leaflets to all centers as defined during the board meetings or upon request.
- 7.1.2.11. Day to day contact with the Belgian and foreign centers in accordance to the national SOPs, guidelines defined by the Board and the International guidelines. Consults with the vzw. for any medical/scientific question for which no procedures have been defined during previous board meetings to obtain a consensus.
- 7.1.2.12. The MDPB-R is not responsible for the operational management of Cord Blood Banks. It won't bare responsibility of quality assurance as to the cord blood collection, banking, release and shipment.

7.2. Cord Blood Bank

7.2.1. CRITERIA

The Center must agree, abide by these standards, policies, and procedures of the MDPB and the MDPB-R.

- 7.2.1.1. The Cord Blood Bank (CBB) shall consist of an integrated team, under a single identified CBB Director, bearing final responsibility for donor management: collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of cord blood units; and recipient follow-up.
- 7.2.1.2. The CBB, each CB Collection site, and each CB Processing Facility shall operate in compliance with Applicable Law and these Standards. The CBB shall be registered and/or accredited with the appropriate governmental authority for the activities performed.
- 7.2.1.3. The CBB must have access, by reciprocal agreement, to the following facilities accredited, certified or licensed in accordance with governmental regulations:
 - Histocompatibility Laboratory accredited by EFI and/or ASHI.
 - Hematology Laboratory including red cell typing
 - Laboratory for Infectious Disease Markers and other tests defined by the standards.
- 7.2.1.4. CBB (and associated IMS) is fully responsible for the effective management of its registered cord blood units.
- 7.2.1.5. CBB (and associated IMS) is connected with the MDPB-R that is in charge of centralizing data and searching for patients and provides a list of newly registered cord bloods to MDPB-R on a monthly basis.
- 7.2.1.6. Each CBB is responsible for regularly updating information on its cord blood to, check availability, to delete cord bloods no longer available and for transmitting electronically consequently all available information to the MDPB-R.
- 7.2.1.7. In no way, the name of the infant CB donor or donating mother should appear together with the name of (potential) recipient on the same document. This is to strictly respect the complete confidentiality of donor and recipient.
- 7.2.1.8. The cord blood must always be identified by her/his code number.
- 7.2.1.9. the CBB shall have written collaborative agreements with facilities collecting cord blood units.
- 7.2.1.10. The CBB (and associated IMS) must be able to organize the shipping of a DNA, maternal serum or other sample of the selected cord blood unit (CB) upon specific request of the requiring Transplant Center.
- 7.2.1.11. The (and associated IMS) must organize and coordinate with the Courier charged of the CB transport, the preparation, packaging and shipment of the CB to the requiring Transplant Center.
- 7.2.1.12. The CBB must have documented Standard Operating Procedures for:

equipment maintenance / facility management / materials management / record management / product distribution / donor suitability / product suitability / quality management

7.3. Cord Blood Bank - MDPB-R interactions and communications

All communication must be shared with all three parties: TC, MDPB-R and CBB.

7.4. MDPB-VZW/ASBL - Scientific committee

- 7.4.1. The MDPB-vzw/asbl is responsible for general medical/scientific content and follow up of the SOP. The MDPB-vzw/asbl consist of a general assembly, a board and a number of committees.
- 7.4.2. The MDPB-vzw/asbl provides medical/scientific support to its members.
- 7.4.3. The MDPB-vzw/asbl is responsible for the SOPs: design, regularly reviews and amendments (distribution by the Registry). The board may incorporate urgent amendments into the SOP but all changes must be approved by the general assembly.
- 7.4.4. The MDPB vzw/asbl supports information campaigns in relation to stem cell transplantation in general and unrelated donor actions and provides the scientific content of the brochures/leaflets.
- 7.4.5. The general assembly of the MDPB-vzw/asbl elects the board of the MDPB-vzw/asbl every 4 years.
- 7.4.6. The general assembly of the MDPB-vzw/asbl. designates the members of the medical advisory committee (MAC) for a term of 4 years. The MAC must be consulted for any medical question / procedure not covered by the SOP and this committee will take the final decision.
- 7.4.7. The general assembly of the MDPB-vzw/asbl. designates the members of the quality assurance committee (QAC) for a term of 4 years. The QAC is responsible for the annual review of all patient follow-up report forms,. The annual report of the QAC shall be reviewed by the board of the MDPB-vzw/asbl and then submitted for final approval by the General Assembly of the MDPB-vzw/asbl.
- 7.4.8. Upon proposal by the board of the MDPB-vzw/asbl, the general assembly of the vzw/asbl decides on the list of centers that will be accepted as participating CBB.
- 7.4.9. The board of the MDPB-vzw/asbl takes all necessary steps to ensure compliance of participating centers with the SOP. This may include temporary suspension of accreditation by the Board members, to be confirmed by the General Assembly members of the vzw. The formal procedure allows the suspension and if appropriate the re-establishment procedure to be submitted and replied to via electronic mail.

7.5. Service level agreement between MDPB-R and its cooperative centers

A service level agreement will be signed between the MDPB-R and the Cord Blood Banks to delineate their respective medical, operational and financial responsibilities. Each CBB will keep its own name and will retain visibility towards its donors, participating donor centers and sponsors”

This agreement will be signed by the General directors of Rode Kruis Vlaanderen and Croix Rouge de Belgique, and the president of the MDPB-vzw/asbl by the one hand and by the General or Medical director and the Financial director of the Cord Blood Bank on the other hand.

7.6. Quality assurance program

7.6.1. The MDPB shall have a regularly updated quality assurance program.

7.6.2. This program shall include formal accreditation of the CBB by the MDPB-vzw/asbl on a regular basis.

- The criteria for accreditation of CBB's are listed in the SOP.
- The accreditation shall be granted for a minimum of 1 year and a maximum of 3 years.
- Towards the end of the previous accreditation period, the board of the MDPB-vzw/asbl
- shall decide the duration of the next accreditation period.
- The board of the MDPB-vzw/asbl shall review the status of CBB before expiration of the current period of accreditation. This review shall include compliance with the SOP and verification of all accreditation criteria as listed in the SOP. If necessary, the board may decide to perform on-site visits.
- The board of the MDPB-vzw/asbl then prepares a list of centers proposed for accreditation. The general assembly of the MDPB-vzw/asbl takes the final decision on that list of accredited centers.

7.6.3. The quality assurance program shall include a formal annual review of the clinical outcome of CB. This review shall be performed by the Quality Assurance Committee (QAC) of the MDPB-vzw/asbl. The annual report of the QAC shall be reviewed by the board of the MDPB-vzw/asbl and then submitted for final approval to the General Assembly of the MDPB-vzw/asbl.

7.6.4. Serious product events and adverse effects Registry (SPEAR)

When a serious event or adverse effect has occurred the report “Spear form” has to be completed for the central reporting system of Serious events and Adverse Effects Registry of WMDA. (a centralized international database recording adverse event that impacts the quality of a donated cellular product and that has or may have resulted in harm to the recipient and the outcome of any investigation to determine the cause of the event).

The CBB must complete the form and send it to the MDPB-R. This incident must also be reported to FAGG-AFMPS by the bank (copy MDPB-R). Adverse events, occurring within 6 weeks after CB transplantation, have to be reported to the CBB, releasing the CB.

General issues:

The general principles request that events likely to result from a defect in the stem cell product should be reported if they lead to one or more of the following outcomes in the recipient:

1. Death
2. Life-threatening disease
3. Unexpected hospitalization or considerable prolongation of existing hospitalization.
4. Persistent of significant disability/incapacity.

Specific issues related to products (CBU) which should be reported:

- Any serious impairment of the quality of the stem cell product including coagulation and contamination
- Serious problems in transportation
- Wrong stem cell product transfused
- Any serious unpredicted transmissible infection
- Any serious unpredicted non-infectious transmissible disease

7.6.5. **Missing status report**

If any report of the above chapters has not been provided after 5 reminders by the staff of the MDPB-R, the file will be closed off. In case the information cannot be provided, the form “MDPB048 notification of missing status report v2 2011” must be completed.

The form will be evaluated by the quality assurance committee.

8. INFORMATION TECHNOLOGY AND INFORMATION MANAGEMENT

8.1. General information management

Appropriately interpreted, the regulations in this section apply likewise to electronic, paper based or otherwise manual processes.

- 8.1.1. The Registry must maintain records of its activities and must maintain a database of cord blood information.
- 8.1.2. All patient and donor communications and records must be stored to ensure confidentiality and to allow for traceability of the donors and steps of the donation process.
 - 8.1.2.1 The Registry must assign a unique and anonymous identifier to each cord blood unit. This identifier must be used to track cord blood unit with their associated data and biological material and their participation in the donation process long term.
 - 8.1.2.2 The registry's documentation must describe the rules for handling information pertaining to patients, donors and search processes.
 - 8.1.2.3. The system of quality management shall include an assessment of all electronic functions to ensure that errors and problems are reported and resolved.
 - 8.1.2.4 The access to donor and patient data information in the registry as well as the transmission of this information to and from the registry must be organized in a way that accidental or unauthorized access, destruction or modification is prevented and confidentiality is guaranteed.
 - 8.1.2.5 Records must be maintained for an appropriate period of time, at least as dictated by national laws or standards. Key documents related to cord traceability must be maintained at a minimum for thirty (30) years following donation. Data storage may be on paper or in electronic form.

8.2. System administration

- 8.2.1. The key components of a Registry's hardware, software and network architecture and external connections must be adequately documented.
- 8.2.2. Electronic connection and communication with the outside world must be organized and performed with greatest possible care minimizing vulnerabilities and exploitation risks.
- 8.2.3. Redundant or fault tolerant software and hardware architecture should be used as much as technically and economically feasible to reduce the probability of failure or data loss and the possible length of a down time.
- 8.2.4. Backup of all systems and data must be performed regularly at reasonable intervals. Backups must be validated by data restoration tests. These activities must be documented.
- 8.2.5. The overall documentation system must provide all information necessary for trained and skilled staff to keep the IT systems operational.
- 8.2.6. A procedure for the definition, specification, implementation, validation and authorization of relevant systems (software, hardware, network) must be established

and documented. Each such process itself must be appropriately documented on a continuous basis.

- 8.2.7. Any such system installed must be accompanied with adequate documentation for its maintenance (in particular detail if developed in house), administration and operation.
- 8.2.8. Any modifications to such systems must be performed in a way fulfilling 5.03.1 and 5.03.2.
- 8.2.9. Reliance on any one individual should be minimized and critical technical components should be redundant wherever possible.
- 8.2.10. Any function described in 5.01, 5.02 and 5.03 may be performed by or with the help of third parties (e. g. a company or a university). If so, the registry must make sure that the qualification of the respective partner and the quality of the service provided fulfills all requirements specified here. Responsibilities of both parties must be described in writing.

8.3. Essential Functionality of IT Systems

- 8.3.1 Search algorithms must provide lists of suitably matched donors in a reasonable time frame. The software program Syrenad guarantees the generating and processing of EMDIS messages three times a day.
- 8.3.2 Each printed report must be dated.
- 8.3.3 Each step in the search process (e. g. patient registration and any request, result or update) shall be documented with all relevant attributes and a time stamp.
- 8.3.4. The information history of relevant data should be recorded.

8.4. Software application Syrenad

The software application SYRENAD facilitates the search process for unrelated donors and Cord blood units for the benefit of patients in need of a stem cell transplantation. SYRENAD provides a link with international registries (connected to the EMDIS network) and operates in accordance with international procedures and in compliance with the SOP'S. (Collaboration agreement between the participating parties).

8.5. Upload of new cord blood units in Syrenad

Only new cord bloods entries will be accepted. (Technical note on the import of Cord Blood data into Syrenad – version 1st of April 2010).

8.6. Collaboration Cord Blood Banks - MDPB-R

The CBB and MDPB-R work in close collaboration on future projects to be implemented in new EMDIS releases.

9. ABBREVIATIONS AND TERMINOLOGY

The following abbreviations cover terms used in these standards:

<i>Adverse event</i>	Any unintended and unfavorable sign, symptom, abnormality, or condition temporally associated with an intervention, medical treatment, or procedure that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.
<i>CD34</i>	The 115 kD glycoprotein antigen, expressed by a small portion of cord blood cells, that is defined by a specific monoclonal antibody (anti-CD34) using the standardized cluster of differentiation (CD) terminology. Hematopoietic progenitor cells are largely contained within the CD34 cell population of cord blood units.
<i>Colony forming unit (CFU)</i>	A clonogenic cell able to produce hematopoietic colonies <i>in vitro</i> under specific conditions in the presence of appropriate colony stimulating factors and defined by the type of mature progeny that develop.
<i>Collection:</i>	Any procedure for procuring and labeling cellular therapy products, regardless of technique
<i>Communicable disease:</i>	A disease or disease agent for which there may be a risk of transmission by a cord blood unit either to a recipient or to the people who may handle or otherwise come in contact with the cord blood unit.
<i>Verification typing</i>	A test performed on a second sample of a specific CB donation at the request of a Clinical Program to confirm the original typing and/or to reaffirm the identity of the CB donation. <i>Contiguous segment:</i> A sealed length of tubing integrally attached to the cord blood unit that contains a sample representative of the cord blood unit that may be used for testing.
<i>Cord blood (CB):</i>	The infant's blood remaining in the placenta and umbilical cord after the umbilical cord has been clamped.
<i>Cord Blood Bank (CBB):</i>	An integrated team under a single Cord Blood Bank Director responsible for donor management and the collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of cord blood units.
<i>Cord blood banking (CB banking):</i>	The processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution of cord blood units intended for administration.

<i>Cord blood collection:</i>	The procurement of cord blood for banking and administration before and/or after the placenta is delivered. <i>Ex utero:</i> The collection of cord blood cells from the placental and/or umbilical cord vessels after the placenta has been delivered. <i>In utero:</i> The collection of cord blood cells from the placental and/or umbilical cord vessels after the infant donor has been delivered and separated from the umbilical cord, but before the placenta has been delivered
<i>Cord blood unit (CBU):</i>	The nucleated cells including stem and hematopoietic progenitor cells harvested from placental and umbilical cord blood vessels from a single placenta after the umbilical cord has been clamped. HPC, Cord Blood is the proper name of a cord blood unit. Unless otherwise specified, the term cord blood unit in this document refers to any cord blood unit regardless of method of collection or intended use.
<i>Cryopreservation:</i>	The processing of viable cells or tissues that consists of cooling the product to a very low temperature where viability is maintained
<i>Eligible:</i>	An infant donor and/or mother who meet(s) all donor screening and testing requirements related to transmission of communicable disease as defined by Applicable Law.
<i>Engraftment:</i>	The reconstitution of hematopoiesis or other cellular functions with cells from a donor.
<i>Hematopoietic Progenitor Cells (HPC):</i>	Self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluri-potent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).
<i>HPC, CB</i>	HPC, Cord Blood
<i>HUB</i>	Stem cell registry, coordinating center for each country.
<i>IMS</i>	<i>Intermediate structure</i>
<i>Ineligible:</i>	An infant donor and/or mother who does not meet all donor screening and testing requirements related to transmission of communicable disease as defined by Applicable Law
<i>Labeling:</i>	Steps taken to identify the original cord blood unit collection and any products or product modifiers, to complete the required reviews, and to attach the appropriate labels.
<i>Mother. Any of the following:</i>	The woman who carries the infant donor to its delivery; may be the genetic mother or a surrogate mother. <i>Genetic mother:</i> The woman from whose egg the infant donor develops; the egg donor. <i>Mother:</i> When used unmodified, the term mother refers to the mother who is both the genetic

	and birth mother. <i>Surrogate mother:</i> The woman who carries an infant donor not genetically her own from an embryo to delivery. Under circumstances of a surrogate mother carrying the infant donor to term and the cord blood unit being collected, both the surrogate and the genetic mother shall be considered for purposes of communicable disease screening and testing; the genetic mother shall be considered for purposes of genetic information.
<i>Nonconforming cord blood unit:</i>	Any cord blood unit that does not completely meet the requirements specified by these Standards, the Cord Blood Bank, and/or the requirements for donor eligibility as defined by Applicable Law.
<i>Outcome analysis:</i>	The process by which the results of a therapeutic procedure are formally assessed.
<i>Reference samples:</i>	Aliquots of cells, plasma, serum, or cellular material from the cord blood unit, the umbilical cord, or the placenta that can be used to confirm the identity, HLA typing, or genetic or communicable disease information associated with a single cord blood unit. Such samples may or may not be contiguous segments.
<i>Release:</i>	The removal of a cord blood unit from quarantine or in-process status when it meets specified criteria.
<i>Reservation:</i>	A temporary allocation of a cord blood unit to a specific recipient to prevent consideration of that cord blood unit for another recipient.
<i>Rh:</i>	The abbreviation for the Rhesus system of human red cell antigens; is used in this document to refer to the Rh (D) antigen only unless otherwise specified.
<i>Sterility testing:</i>	The processes used to screen for the presence of microbial agents.
<i>Storage:</i>	Holding cord blood units for future processing and/or distribution.
<i>Syrenad</i>	Search software application
<i>Time of collection:</i>	The time of day that the cord blood collection is completed.
<i>Total Nucleated Cells (TNC)</i>	The total nucleated cells (red and white) in the graft portion of the collection (without aliquots). Using the NETCORD standards the number of cells required are total nucleated cells including erythroblasts, and obtained directly from the automatic counter.
<i>Unique Identifier:</i>	A numeric or alphanumeric sequence used to designate a specific cord blood unit with reasonable confidence that the identifier will not be used for another purpose, including for another cord blood unit.
<i>Viability:</i>	Living cells as defined by dye exclusion, flow cytometry, or progenitor cell culture.

10. REFERENCE DOCUMENTS

SPEAR

Spear Manual Version 1.2 September 2010

11. STANDARDS

The Centers must agree to abide by the standards, policies, and procedures of the (current version):

AFMPS-FAGG	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten · Agence Fédérale des Médicaments et des Produits de Santé www.fagg-afmps.be
ASHI	American Society for histocompatibility and immunogenetics. www.ashi-hla.org
BELGIAN STANDARDS	HGR/CSS standards Nr 8271 (Hoge Gezondheidsraad / Conseil supérieur de la Santé) (2 July 2008) www.portal.health.fgov.be/portal Belgian law and subordinate Decrees
EBMT	European Group for Blood and Marrow Transplantation Operational Manual (2004 Revised Edition) EBMT Transplant guidelines and accreditation Indications for unrelated HSCT transplantation : “Bone Marrow Transplantation : special report 2006, 37, 439-449 : allogeneic and autologous transplantation for haematological diseases, solid tumours and immune disorders: definitions and current practice in Europe”. P.Ljungman et al.” www.ebmt.org
EFI	European Federation for Immunogenetics www.efiweb.eu
EMDIS	European Marrow Donor Information System www.emdis.net
EUROPEAN DIRECTIVES	2004/23/EC of 31 March 2004 (standards of quality, safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells) 2006/17/EC of 8 February 2006 (Technical requirements for the donation, procurement and testing of human tissues and cells)

	<p>2008/86/EC of 24 October 2006 (Implementation of 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. http://ec.europa.eu/health/ph_threats/human_substance/legal_tissues_cells_en.htm</p>
FACT-Netcord	<p>The international Netcord foundation https://office.de.netcord.org/index.html http://www.factwebsite.org/main.aspx?id=102</p>
FDA	<p>US Food and Drug Administration www.fda.gov</p>
NMDP	<p>National Marrow Donor Program www.marrow.org</p>
SOP	<p>Standard Operating Procedures Manual - Part I (unrelated volunteer donors)</p>
SOP CB	<p>Standard Operating Procedures Manual Cord Blood - Part 2 (cord blood products)</p>
WMDA standards	<p>World Marrow Donor Association International standards for unrelated hematopoietic stem cell donor registries. (1st November 2008) www.worldmarrow.org</p>
EUROCORD	<p>International Registry on Cord Blood Transplantation. Eurocord registry operates on behalf of the European Group for Blood and Marrow Transplantation (EBMT) www.eurocord.org</p>