
 World Marrow Donor Association	WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries			
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**WORLD MARROW DONOR ASSOCIATION
INTERNATIONAL STANDARDS FOR
UNRELATED HEMATOPOIETIC STEM CELL DONOR REGISTRIES**

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These standards are aimed at enhancing the quality of Stem Cell Donor Registries (shortened as Registries) assisting the grafting physician responsible for patient treatment in the international search for an unrelated donor for their patient. Qualification and Accreditation of individual Registries by the World Marrow Donor Association (WMDA) is an indication that these Registries are committed to follow WMDA standards. These standards promote the quality of procedures necessary to obtain, in the shortest possible time, the appropriate quality and quantity of hematopoietic stem cells of the best unrelated donor suitable for engrafting a patient while protecting the anonymity, health and well being of the volunteer donors. These standards are based on recommendations previously published [Goldman J., Special Report: bone marrow transplants using volunteer donors – recommendations and requirements for a standardized practice throughout the world – 1994 update. Blood 84:2833-2839, 1994.]

These standards set forth only the minimum guidelines for Registries working through the WMDA to facilitate hematopoietic stem cell transplants. The standards do not set forth all that may be required of the Registry to conform to governmental regulations or the standard here prevailing in the relevant community. Each Registry must determine and follow any additional laws, regulations, practices and procedures that apply in their particular community.

The WMDA qualification process does not include a site visit. Registries that apply for first time qualification and who are judged by the review subcommittee as sufficiently prepared to meet all of the required standards will be allowed to submit a full application package for accreditation after a minimum of two (2) years following approval of qualification. The Registry may opt to apply any time after the 2 years up to the full term of 5 years. On-site inspections are performed upon with each submission of a complete application packet.

The WMDA disclaims all representations or warranties, expressed or implied, that compliance with the WMDA standards will fulfill the requirements of all applicable governmental laws and regulations or the standard of care prevailing in the relevant community.


A. OVERVIEW AND DEFINITIONS

1.0 These standards are intended to provide minimum criteria for obtaining WMDA qualification/accreditation.

1.01 In the initial implementation of the accreditation process by WMDA, specific “benchmark” standards have been identified which must be met by a Registry seeking qualification. These standards have been indicated in **bold**. Other standards, not in bold, are not required during the initial implementation process. Registries certified during the initial implementation period will be granted a qualification status based on their commitment to adhere to the “benchmark” standards. The WMDA Board established the maximum length of the initial implementation period at five years. Following the initial implementation phase, requirements to meet specific standards will follow standard 1.02.

1.02 After the initial implementation period is completed, the words “must” and “shall” indicate that deviations are not acceptable. There will be no difference between bolded benchmark standards and non-bolded standards containing the words “must” and “shall”. “Should”, “might”, and “may” are used for recommendations that are not mandatory.

1.03 If governmental laws and regulations differ from the WMDA standards, the requirement to meet local legal standards will be accepted as a valid cause for variation from WMDA standards.

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2.0 DEFINITIONS

Note: The institutions providing hematopoietic stem cells to a patient in another country vary in their organizational structures. The definitions below are aimed at defining the individual elements, which comprise this effort and are not intended to indicate the requirement for a specific organizational structure.

Blood Bank: A Blood Bank is a medical facility at which blood intended for transfusion is drawn and stored.

Cell Processing Unit: The Cell Processing Unit is a medical laboratory facility where hematopoietic stem cells are manipulated prior to transplant. These activities may include the depletion of specific cell types from the graft, selection for specific cell types for infusion, *in vivo* manipulation of cells in the graft, or concentration of the cell product.

Collection Center: The Collection Center is the medical facility at which hematopoietic stem cell collection from selected donors actually takes place. This collection might include marrow aspiration or apheresis. The Collection Center performs the medical work-up of the donor and provides the final approval of the donor for harvest. If umbilical cord blood is collected, the Center is responsible for processing and storage of the cord blood unit. The Collection Center packages the donation for transport to the Transplant Center.

Cord Blood Bank: The Cord Blood Bank is the facility responsible for the collection, processing, testing, banking, and release of cord blood units.


Donors: Donors are defined as (1) Volunteer adult donors of hematopoietic stem cells or (2) Umbilical cord blood units collected after maternal permission (infant donor). These donors are unrelated to the patient seeking a transplant.

Donor Center: The Donor Center is the organization responsible for recruiting, consenting, counseling, and coordinating the testing of prospective donors. The Center monitors the short and long term health of adult volunteer donors who have provided hematopoietic stem cells. The Donor Center maintains a register or database of donors, which may be searched as appropriate.

Extended HLA typing: This typing includes the tests carried out on a specific donor/cord blood unit with the purpose of adding additional information (typing of additional loci or further subtyping at a higher resolution) to an existing HLA assignment. The additional HLA typing may be performed on a stored sample.

Fully Informed Consent: Written documentation that an adult volunteer donor or the maternal donor of umbilical cord blood has been provided with information on the procedure and tests performed, the risks and benefits of the procedure, has understood the information provided, has had an opportunity to ask questions and has been provided with satisfactory responses, and has confirmed that all information provided is true to the best of their knowledge.

Granulocyte colony-stimulating factor (G-CSF): Granulocyte colony-stimulating factor is a cytokine that stimulates the bone marrow to produce granulocytes (white cells) and stem cells and causes these cells to mobilise (move) to the peripheral blood where they can be collected from the veins for transplantation.

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Hematopoietic stem cells: The progenitor cells, which give rise to blood and immune system cells. These cells are found in bone marrow, growth-factor stimulated peripheral blood, and umbilical cord blood. This also includes cells derived from the hematopoietic stem cell preparation, which are used in cell therapies (e.g., mesenchymal and dendritic cells) and donor lymphocyte infusions. The collection of hematopoietic stem cells from adult volunteer donors is intended for infusion into a specific recipient.

Quality System: Organization structure, personnel requirements including qualifications, training and competency, responsibilities, procedures, process and resources defined for implementing and managing quality within the Registry including all activities contributing to the quality, directly or indirectly. The quality system must cover detection, reporting and corrective action related to adverse events and complaints; identification, labeling and tracking of individuals and products; development, implementation, and review of policies and procedures; creation, review, control and maintenance of records; outcome analyses; facilities; and safety. The quality system must be described by the Registry in written documents and a process to audit the quality system must be in place.

Registry: A Registry is a national organization whose responsibility is to process requests originating from within the country and emanating from abroad for hematopoietic stem cells from donors unrelated to the patient including cord blood. The Registry may coordinate the activities of Donor, Collection, and Transplant Centers in the respective country.

Search: The process of identifying a suitable hematopoietic stem cell donor for a patient in need of a transplant.


Serious Events and Adverse Effects Registry (SEAR): a centralized international database recording adverse events occurring during procurement of hematopoietic stem cells that have or may have resulted in harm to an unrelated donor and the outcome of any investigation to determine the cause of the event.

Serious Product Events and Adverse Effects Registry (SPEAR): a centralized international database recording adverse events that impact the quality of a donated cellular product that have or may have resulted in harm to the recipient and the outcome of any investigation to determine the cause of the event.

Standard Operating Procedures (SOP): A compilation of written detailed instructions describing the steps in a process, including materials and methods to be used and the expected end product. The SOP must include a process to regularly review and update procedures. Changes to standard operating procedures must be documented and validated (see also Quality System).

Testing Laboratories: These laboratories perform the histocompatibility, blood group, infectious disease, and other testing of the prospective donors and patients. They may be under the direction of a Registry, Donor Center or Transplant Center or may be separate from these entities.

Traceability: To follow all the steps of a process from beginning to end. The ability to locate and identify a volunteer donor or recipient, their data and cell product, during any stage of the recruitment, testing, collection, donation, transplantation and follow-up process. Traceability also includes the ability to identify the organizational entities (e.g., Registry, Donor Center, Collection Center, Cell Processing Unit, Transplant Center) involved in the international exchange.

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Transplant Center: The Transplant Center is the medical facility at which a patient (recipient) receives a transplant (graft) with hematopoietic stem cells from an unrelated donor or from an umbilical cord blood unit. The Center oversees the immediate medical treatment and provides long-term follow-up of the recipient. The Search Unit undertakes the search for an unrelated donor for specific patients using criteria defined and documented by the Transplant Center. This entity may be contained within a Transplant Center or may be separate from the Transplant Center. If separate, the Search Unit may coordinate searches for one or several Transplant Centers. In the standards, reference to a Transplant Center should be interpreted as a Transplant Center and/or a Search Unit as appropriate. Transplant Centers/Search Units seeking an international donor work through the Registry in their country.

Validation: Establishing documented evidence that particular requirements can consistently be fulfilled. Evaluation and written documentation of the performance of equipment, a reagent, a process or a system with regard to its effectiveness based on its intended use.

Verification typing: This typing includes the tests carried out on a fresh sample of a specific donor or on an attached-segment of a cord blood unit with the purpose of verifying the identity and concordance of an existing HLA assignment. This stage may also be referred to as "Confirmatory Typing (CT)".

WMDA (World Marrow Donor Association): An international non-profit organization which promotes the definition and standardization of ethical, technical, medical and financial aspects of hematopoietic stem cell transplantation involving volunteer donors in one country who give hematopoietic stem cells to unrelated patients in another country.

WMDA Board: The board includes the President, President-elect, Past President, President Emeritus, Vice-Presidents, Secretaries, Treasurer, Chief Executive Officer and Chairs of the WMDA Working Groups.

Work-Up: At this stage, a donor has been identified as an acceptable match for a patient, agrees to donate hematopoietic stem cells, after a full donor information and counselling session, and is medically evaluated for their fitness to donate stem cells.


B. STANDARDS

1.0 General

1.01 A Registry which provides hematopoietic stem cells obtained from either an individual recruited by that organization as a volunteer donor or from a banked umbilical cord blood unit to a patient in another country and facilitates exchanges on behalf of Transplant Centers in its country is eligible for qualification/accreditation by the WMDA.

1.01.1 An organization, which intends to provide stem cells or intends to facilitate exchanges but has not yet done so, is eligible for qualification/accreditation by the WMDA provided that the organization can provide satisfactory documentation of their ability to provide stem cells to patients within their own country following WMDA standards.

1.02 If a Registry is accredited for international exchange of hematopoietic stem cells by an international organization with standards that meet or exceed WMDA standards, that Registry may be given WMDA accreditation following submission of material documenting that accreditation.

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1.03 Changes to the status of a WMD, qualified/accredited Registry that may affect WMD, qualification/accreditation must be brought to the attention of the WMD, in a timely fashion.

1.04 If a Registry relies on other entities to perform some of the duties described in these standards, it is the responsibility of the Registry to ensure that these entities comply with WMDA standards.

1.04.1 If a Registry relies on an independent Donor Center or Cord Blood Bank to recruit and characterize donors, the Registry must ensure that the Donor Center / Cord Blood Bank complies with relevant WMDA standards.

1.04.2 The Registry must ensure that Transplant Centers affiliated with the Registry and requesting a donor from another country meet standards designed to insure that donation of hematopoietic stem cells will only be requested for patients for whom transplantation is a medically acceptable procedure.

1.04.2.1 These Transplant Center standards should be defined by an appropriate national or international organization. In absence of such standards, these standards must be defined by the Registry.

1.04.2.2 The Registry shall have established standards for Transplant Centers that shall be readily accessible to health care professionals involved in hematopoietic stem cell transplantation.

1.04.3 If a Registry relies on an independent Collection Center for the collection of donor hematopoietic stem cells or other donor samples, for donor medical evaluation or for the follow-up of donors, the Registry must ensure that the Collection Center complies with WMDA standards in these areas.

1.04.4 The nature of these affiliations and the duties and responsibilities of each entity must be documented in a written agreement.

1.05 The Registry should abide by other WMDA recommendations in further detail as far as they do not contradict governmental laws and regulations.

1.06 , Registry that intends to request WMD, qualification must be a WMD, organisational member. The Registry must complete the WMD, , nnuual Report Questionnaire.


2.0 General organization of the Registry

2.01 The Registry must be a legal entity or be contained within a legal entity operating within the laws of the country in which the Registry resides.

2.02 The , uthorized Official of the legal entity is responsible for ensuring the Registry's compliance with the WMD, standards and must authorize all official documents related to WMD, qualification/ accreditation.


2.03 The Director or key Registry personnel must have demonstrated experience in program administration in a health care setting.

2.04 The Director or key Registry personnel or consultants must have a sound knowledge of human histocompatibility and hematopoietic stem cell transplantation as documented by the relevant education and experience. , t least one of these individuals must be a physician. These individuals must possess a basic understanding of diseases treatable by hematopoietic stem cell transplantation, comprehend alternative therapies and donor search problems associated with these diseases, understand HL, specificities (serologic, cellular, and DN, -based) and


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haplotypes, and possess a knowledge of Transplant Center, Donor Center, Collection Center, and Registry protocols in their own country and abroad.

- 2.05 The Registry must have a mechanism like physician readily available to assist with routine medical decisions regarding donor selection and donation.
 - 2.05.1 The Registry must have a mechanism such as a medical review panel to assist the Registry with making unbiased decisions regarding nonstandard, high risk or experimental hematopoietic stem cell donation or other related procedures.
- 2.06 The Registry should have direct daily access to expert consultants in the areas pertinent to the operation of the registry to assist the Registry in establishing policies and procedures.
- 2.07 The staff of the Registry must be trained and knowledgeable about their duties. The Registry must conduct and document staff training and maintain training records and reference manuals.
- 2.08 The Registry must retain a staff large enough to assume the volume and variety of services required to perform international searches within a time based on goals as recommended in WMDA procedures for unrelated donor search while maintaining the confidentiality of patient and donor.
- 2.09 The Registry must have a fixed physical location.**
 - 2.09.1 The location must have sufficient space so that all work can be carried out in an environment designed to minimize errors, reduce risks to health and safety, and maintain confidentiality.
- 2.10 The Registry must have sufficient communication links to facilitate searches.**
 - 2.10.1 These links must include telephone, fax, and international telematics links (email, internet).
- 2.11 The Registry must have a system of quality management to assess, ensure, conduct and improve the quality of its operations.
 - 2.11.1 The Registry must maintain written policies and protocols for all procedures performed in the Registry. This must include standard operating procedures, guidelines and report forms.**
 - 2.11.2 The Registry should have an operational disaster recovery plan.
- 3.0 Donor recruitment for the Registry and donors selected for specific patients
 - 3.01 Entities involved in donor recruitment must meet any relevant international and national laws and regulations.
 - 3.02 The recruitment of donors must be performed under the direction of individuals who are experienced in recruitment of donors and in management activities including education, consenting, counseling, confidentiality, and medical screening. These individuals must be appropriately qualified and provided with timely and relevant training. The training and experience of these individuals must be documented.
 - 3.03 The willingness to become a donor must be the individual choice of each adult donor or each maternal donor of a cord blood unit, that is, donations must be voluntary. Donors must be willing to donate on behalf of any patient being treated in any part of the world. Donors must not be paid for their donation but may be reimbursed for expenses incurred during the donation process, for example, time lost from work or travel to the Collection Center.**
 - 3.03.1 Prior to the donation, a donor must be free to withdraw at any time.**

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- 3.04 To ensure confidentiality, the identity of donors must be protected. Procedures to ensure donor confidentiality must be established. The Registry must have a written policy listing the conditions under which donors and recipients might be informed of each other's identity. These policies must comply with governmental laws on disclosure.**
- 3.05 , adult donors and maternal donors of cord blood units must be informed regarding their potential role in the donation of hematopoietic stem cells, the risks involved in the donation, and the tests to be performed on the donor.**
- 3.05.1 Fully informed and legally valid written consent must be obtained from all adult volunteer donors at the time of workup.**
- 3.05.2 Signed consent must be obtained initially at the time of recruitment.**
- 3.05.3 Signed consent may be obtained at other stages of the matching and donation process.
- 3.05.4 Consent must be obtained if donor blood or other biological material or information is stored and/or used for the purpose of an ethically approved research project.**
- 3.05.5 Consent documents must meet criteria established based at a minimum on WMDA guidelines. 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 by the donor and must include the signature by the qualified staff involved in donor counseling.
- 3.05.6 Donors must be fully informed about the administration of any medical intervention (e.g., administration of G-CSF) and its known side effects.**
- 3.05.7 The identity of the donor must be verified by the qualified staff signing the consent form.
- 3.05.8 Consent documents signed by volunteer donors must be available for review by individuals designated by the Registry or national authorities to evaluate the Registry.**
- 3.06 Requirements for donor health affecting the eligibility of donors must be established.**
- 3.06.1 The details of the tests to be performed and the questions to be asked during health screening and medical evaluation should comply with WMDA recommendations in these areas.
- 3.06.2 Adult volunteer donors
- 3.06.2.1 An initial health screening may be performed at the time of recruitment.
- 3.06.2.2 , health screening must be performed at time of verification typing.**
- 3.06.2.3 , medical examination must be performed at the time of workup.**
- 3.06.2.4 If a donor is subjected to a medical intervention (e.g., administration of G-CSF) as part of the hematopoietic stem cell harvest process, the Registry must have appropriate policies and procedures to protect the health and safety of the donor and of the recipient.**
- 3.06.2.4.1 These policies should include the procedure regarding the type of harvest (peripheral blood stem

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cells versus bone marrow) in the case of failed mobilization.

3.06.3 Umbilical cord blood and infant donor

3.06.3.1 A health screening of the maternal donor for communicable risk transmission shall be performed to include status at time of delivery.

3.06.3.2 A medical and genetic history of the infant donor's family shall be obtained and documented.

3.06.3.3 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.

3.06.3.3.1 This history should be updated in a reasonable post delivery time frame to capture risks not immediately detected at birth in particular in the case when the first screening was done early in pregnancy.

3.06.3.4 Hemoglobinopathy testing on the infant donor or the cord blood unit shall be performed prior to the release of the cord blood unit.

3.06.3.5 A Cord Blood Bank must review all source documentation prior to release of the cord blood unit for transplantation and have a policy in place describing what information is passed on to the Transplant Center and how that communication will take place.

3.06.4 The adult volunteer donor and the maternal donor of the cord blood unit have the right to receive the results of their health screening.

3.07 Prospective unrelated adult volunteer donors selected for hematopoietic stem cell harvest must have passed a minimum age established by national regulations or their 18th birthday if no regulations exist and an upper age-limit for donation must be stipulated after which donors will be removed from the Registry.

3.07.1 That upper age limit should not exceed 60 years.

4.0 Donor characterization

4.01 Testing must be carried out by laboratories, which meet standards established by the government or prevailing in the relevant community for performing these services.


4.02 The HLA typing laboratory must fulfill standards established by the government or prevailing in the relevant community for such testing.

4.03 Testing must be carried out in a manner to ensure the accuracy of the data.


4.03.1 The Registry, which intends to request WMDA accreditation, should participate in the WMDA discrepant HLA typing scheme.

4.04 The histocompatibility testing of donors must include identification of HL, loci considered essential for transplant success.

4.04.1 A minimum of HLA-A,-B,-DRB1 should be defined at serologic split or low resolution prior to listing the donor on the Registry. If not all the newly recruited donors are DR typed, the Registry should have a reasonable policy and strategy for selective DR typing of some donors.

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- 4.04.2 A minimum of HLA-A,-B,-DRB1 must be defined, on a second biological sample, at serologic split or low resolution prior to donation for a specific patient.
- 4.04.3 DNA-based testing is recommended for HLA-A,-B.
 - 4.04.3.1 If serology is used for HLA-A,-B, a DNA-based method must be used to define antigens in the population tested which are frequently missed and/or misassigned.
- 4.04.4 DNA-based testing is required for HLA-DRB1.
- 4.04.5 Registries must have established approaches to monitor and ensure the quality of HLA types listed in the donor database.
- 4.05 The medical history of donors selected for specific patients must include questions to identify persons at risk of disease transmissible through transplantation, (e.g., infectious diseases, genetic defects or disseminated malignancies) according to WMD, recommendations.**
- 4.06 Infectious disease testing of adult volunteer donors or maternal donors of cord blood units selected for specific patients must include testing for diseases thought to be important to consider in hematopoietic stem cell transplantation. Testing must monitor infection with human immunodeficiency virus (HIV), Human T-cell lymphotropic virus I and II, hepatitis B virus, hepatitis C virus, cytomegalovirus (CMV), *Treponema pallidum* (syphilis) and other infectious agents as defined by national health authorities.**
 - 4.06.1 Selected donors should also be tested for locally important diseases that are important to consider in transplantation. Donors who have recently traveled outside of their country should also be evaluated for infectious agents prevalent in those locations.
 - 4.06.2 For cord blood donation, a maternal blood sample, obtained within 7 days before or after collection of cord blood unit, shall be tested for evidence of infectious disease markers.
 - 4.06.3 Registries must also have the capability of shipping donor/maternal, blood/serum samples to the appropriate Transplant Center in the event the Transplant Center requires additional infectious disease testing.
- 4.07 The blood group testing must include identification of , BO blood group and Rh factor.**
 - 4.07.1 The blood group testing of volunteer unrelated donors must be done at the verification typing stage if the donor's blood group has not been previously determined.
 - 4.07.2 Blood group testing must be done on a pre-cryopreservation sample from each cord blood unit.
- 4.08 Blood cell counts of adult volunteer donors selected for specific patients must be performed at the workup stage.**
- 4.09 Information on donor age and gender must be collected at the time of recruitment.**
- 4.10 Information on donor parity and history of other prior sensitizing events such as transfusion should be obtained from adult volunteer donors during the verification typing stage.
- 4.11 Female adult volunteer donors of childbearing years must have a pregnancy test performed during the work-up stage.**
- 4.12 Other appropriate information on the donor such as racial/ethnic group might be collected subject to national legislation.
- 4.13 The results of the donor assessment including the results of any laboratory tests and medical evaluation must be documented and maintained.

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5.0 Information Technology and Information Management

5.01 General Information Management

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

5.01.1 The Registry must maintain records of its activities and must maintain a database of volunteer donor information.

5.01.2 , II 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.

5.01.2.1 The Registry must assign a unique and anonymous identifier to each adult volunteer donor, each donor cellular product, and each cord blood unit. This identifier must be used to track each volunteer donor and cord blood unit with their associated data and biological material and their participation in the donation process long term.

5.01.2.2 The Registry's documentation must describe the rules for handling information pertaining to patients, donors and search processes.

5.01.3 The system of quality management shall include an assessment of all electronic functions to ensure that errors and problems are reported and resolved.

5.01.4 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.

5.01.5 Records must be maintained for an appropriate period of time, at least as dictated by national laws or standards. Key documents related to donor traceability must be maintained at a minimum for thirty (30) years following donation. Data storage may be on paper or in electronic form.

5.02 System Administration

5.02.1 The key components of a Registry's hardware, software and network architecture and external connections must be adequately documented.

5.02.2 Electronic connection and communication with the outside world must be organized and performed with greatest possible care minimizing vulnerabilities and exploitation risks.


5.02.3 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.

5.02.4 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.


5.02.5 The overall system documentation must provide all information necessary for trained and skilled staff to keep the IT systems operational.

5.03 System Development

5.03.1 A procedure for the definition, specification, implementation, validation and authorization of relevant systems (software, hardware,

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- network) must be established and documented. Each such process itself must be appropriately documented on a continuous basis.
- 5.03.2 Any such system installed must be accompanied with adequate documentation for its maintenance (in particular detail if developed in house), administration and operation.
- 5.03.3 Any modifications to such systems must be performed in a way fulfilling 5.03.1 and 5.03.2.
- 5.03.4 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.
- 5.04 Essential Functionality of IT Systems
- 5.04.1 Search algorithms must provide lists of suitably matched donors in a reasonable time frame.
- 5.04.2 Each printed report must be dated.
- 5.04.3 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.
- 5.04.4 The information history of relevant data should be recorded.
- 6.0 Facilitation of search requests
- 6.01 Critical communications between Registries or between a Registry and a Transplant Center must be in writing.**
- 6.01.1 These communications should contain a signature of authorization and be sent by fax or email or should be submitted through authorized access to a communication system like EMDIS.
- 6.02 Registries must respond to search requests and to requests for additional information and/or an aliquot of donor (or maternal if cord blood) sample within a time period consistent with WMD, recommendations and in a defined manner.**
- 6.02.1 The policy of the Registry regarding repetition of the database search for a specific patient should be defined.
- 6.02.2 The Registry must have an effective mechanism to provide access to international patients.
- 6.03 Donor and patient identity must remain confidential during the search process so that only appropriate Registry personnel have access to these data.**
- 6.04 A donor selected for a specific patient must be placed on a “reserved” status from the time of verification typing until the donation date is reached.
- 6.04.1 A maximum time limit and the procedures for granting exceptions for this status should be set in writing.
- 6.05 , dult volunteer donors must be counseled when selected for further tests and when selected as a donor for a specific patient.**
- 6.05.1 Counseling for donors selected for specific patients must include anonymity of the donor and patient, requirement for further blood samples before donation, requirement for infectious disease and other testing, risk of donation, possible duration of loss of time from normal activities, location of the harvest, requirement for collection of autologous blood, donor’s right to withdraw and consequences for the patient, details of insurance coverage, possible subsequent donations of hematopoietic stem cells or blood products, alternative

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collection methods and whether blood is reserved for research purposes.

6.05.2 The adult volunteer donor should be informed if the donation involves a clinical trial performed for a patient.

6.06 The Donor Center must be informed of the proposed date(s) of transplant at the time a specific donor/cord blood unit is requested for stem cell donation on behalf of a specific patient. If an adult volunteer donor will be the source of stem cells, the donor must also be informed. The Transplant Center must specify the latest date by which the Donor Center must approve the eligibility of a donor for donation of hematopoietic stem cells for a specific patient (i.e., provide donor clearance).

6.07 The adult volunteer donor must be medically examined to ascertain fitness to donate. This examination must be performed or supervised by a physician who is not a member of a team who has cared for the patient.

6.07.1 Policies for testing of the donor must be established and must include medical history, physical exam, and laboratory tests.

6.07.2 Infectious disease markers must be measured within 30 days of the hematopoietic stem cell harvest and the results must be provided to the Transplant Center before commencement of patient conditioning.

6.07.2.1 Markers that must be tested include, at a minimum, human immunodeficiency virus, Human T-cell lymphotropic virus I and II hepatitis B virus, hepatitis C virus, *Treponema pallidum* (syphilis), cytomegalovirus, and other infectious agents as defined by national health authorities.

6.07.3 Policies for counseling the donor in the case of positive identification of donor health risk such as the presence of an infectious disease should be established.


6.08 The Registry must make their policy for the minimum criteria needed to allow a specific donor to be available for a specific patient readily accessible to the appropriate parties, such as national/international organizations authorized to provide hematopoietic stem cell treatment.

6.08.1 This policy might include a minimum level of HLA match, guidelines for patient-specific criteria such as specific diseases or disease stages for which transplantation is not considered appropriate, the optimal amount of marrow aspirated based on the weight of the donor, or requirements for Transplant Center credentials.


6.09 Prior to transplant the Registry must have a process for communicating the adult volunteer donor's preference for type of stem cell harvest and for communicating any other donor-specific issues (e.g. availability to subsequent donations) that may impact the transplant to the appropriate Transplant Center in a timely fashion although the donor must be free to change their mind at a later date.

7.0 Second and subsequent donations of hematopoietic stem cells and/or blood products for the same patient

7.01 , dult volunteer donors must be fully informed in advance of the original donation regarding the possibility of and possible procedures involved with a subsequent donation of hematopoietic stem cells or blood products intended for therapeutic use for the same patient and the risks involved in the second donation.

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- 7.02 After the donation the Registry must have a process for collecting information on the donor's willingness to participate in a subsequent donation although the donor must be free to decline a subsequent donation at the time that it is requested.
- 7.03 The Registry must have a written policy regarding the process to be followed upon a request by a Transplant Center for a subsequent donation.**
- 7.03.1 This document might include the specific details that should be provided by the Transplant Center to document the need for a subsequent donation, identification of any medical review committee, and details regarding the time frame of the process and the planned conditioning regimen.
- 7.03.2 The policy must be publicly available.
- 8.0 Collection, processing and transport of hematopoietic stem cells
- 8.01 Collection of hematopoietic stem cells and any other collected cell products intended for therapeutic use must be performed at a Collection Center that fulfills standards established by the government or prevailing in the relevant community for such a facility. The Collection Center must ensure the identity, safety and privacy of the donor. The Collection Center and the procurement of hematopoietic stem cells must be under the direction of trained and experienced professional staff.**
- 8.02 , utologous donor blood must be collected at a blood collection center that fulfills national and/or regional and/or international guidelines for such a facility.**
- 8.03 Written policies and procedures must be in place to ensure the identity, quality and quantity of the collected cells. These must include policies for communication between the Transplant Center, Collection Center and Cell Processing Unit regarding the number of cells required.**
- 8.03.1 This may include the collection of such information from the Transplant Center receiving the donated stem cells.
- 8.04 Written documentation of the characteristics of the collected and potentially processed product important in facilitating the transplant must be provided with the cells according to applicable guidelines. The documentation and label, at a minimum, must include information on the number of cells collected, the donor's unique identification code, donor , BO group, identification of the patient, date and time of collection, any processing details, and name and contact information of the Transplant Center. Labeling of the product must ensure the identity of the product.**
- 8.05 Cells must be transported in a timely and reliable fashion to meet Transplant Center requirements for the quality and quantity of the cell product upon arrival at the Transplant Center. Packaging must comply with national and international regulations. Policies and procedures documenting the transport process must be stipulated.**
- 8.05.1 These policies may include criteria for the designated courier, describe information and resources available to the courier, plans to address disruption of travel, transport temperature, communication procedures used to contact the Transplant Center, to ensure receipt by the Transplant Center, procedures to avoid damage of the cells, and procedures to maintain anonymity of patient and donor.
- 8.06 Serious adverse events impacting the cellular product and hence potentially the patient's health must be submitted to a WMD, sponsored international centralized database of such events (SPE, R).**

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9.0 Follow-up of patient and donor

9.01 The Registry must have policies and procedures for the short-term follow-up and care of adult volunteer donors for conditions related to the hematopoietic stem cell donation. Short term is defined as within the first year following donation.

9.02 The Registry must have policies for the long-term follow-up and care of adult volunteer donors for conditions related to the hematopoietic stem cell donation. Long term is defined as the time period following the first year after donation and extending for at least four years.

9.03 Donor health issues post-donation potentially affecting the health of a patient having received a hematopoietic stem cell donation from that donor must be reported to the Transplant Center.

9.04 , dverse events affecting donors undergoing harvest of hematopoietic stem cells and occurring long term as a consequence of the donation must be defined, identified, documented, investigated and corrective action taken. Similar actions must be taken for adverse events occurring due to Registry operations and impacting the health and safety of donors or patients.

9.04.1 Reports of adverse events affecting a donation must be submitted to the Registry involved in the transplantation if the event might affect an initial or subsequent donation. Other individuals or groups should be notified as appropriate.

9.04.2 The Registry must comply with governmental regulations including requirements to report such adverse events to a regulatory agency.

9.04.3 Serious adverse events occurring at the Registry or at its associated entities must be submitted to a WMD, sponsored international centralized database of such events (SE, R).

9.05 Cells or DNA from donor and recipient should be preserved for research purposes by the Registry if approved by national legislation in the countries of the patient and donor.

9.06 The Registry should have access to clinical outcome data of the transplanted patients.

10. Financial and legal liabilities

10.01 Responsibilities


10.01.1 **The Registry must keep complete and accurate financial records for all services provided and requested according to national laws and regulations as well as international standards.**

10.01.2 The Registry must have sufficient staff dedicated to perform all accounting duties.


10.02 Fee structure

10.02.1 A clear fee schedule detailing payment terms for HLA testing, infectious disease marker testing, harvest and other related services should be available upon request. Changes in the fee schedule should be provided to interested parties thirty days prior to implementation.

10.02.2 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.

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- 10.02.3 If the harvest procedure is cancelled after the final donor selection, the Collection Center and/or Donor Center and/or Registry are entitled to charge for services performed prior to notice of cancellation. This practice must be noted on the fee schedule.
- 10.03 Billing
- 10.03.1 The Registry providing donor stem cells or any other requested service should bill to and request payment from the Registry requesting the donor stem cells or service.
- 10.03.2 Billing should occur within sixty days of service completion.
- 10.04 Payment
- 10.04.1 A Registry requesting a service for a patient or forwarding such a request from a Transplant Center guarantees the payment of completed services. If the requesting Registry cancels the service, the reporting Registry shall expect full payment provided that the services are completed and reported within 30 days of the cancellation date.
- 10.04.2 , **Registry must have adequate administrative structures and financial resources to guarantee the settlement of all invoices in due course.**
- 10.04.3 It is the responsibility of the requesting Registry to collect funds from any person or institution ultimately covering these expenses. If it is unable to collect funds from the originating institution, the Registry shall be liable for expense incurred.
- 10.05 Legal liability
- 10.05.1 **The Registry must assume responsibility and establish procedures for all donor medical expenses including the pre-collection physical examination, the collection procedure and all post-collection medical expenses that are directly related to the donation. No donor should assume financial liability for any portion of the follow up testing and/or stem cell harvest/procurement process. The Registry is responsible for all reasonable expenses incurred by the donor.**
- 10.05.1.1 The Registry should offer disability and death benefits to all stem cell donors. These benefits might be provided through insurance coverage.
- 10.05.2 The Registry should maintain liability insurance.


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Examples of organizations offering accreditation, on an international level, related to Registry operations

Area of Accreditation	Organization
Transplant Center	Joint Accreditation Committee ICST (International Society for Cellular Therapy) and EBMT (European Group for Blood and Marrow Transplant) (JACIE)
	Foundation for the Accreditation of Cellular Therapy (FACT)
	National Marrow Donor Program (NMDP)
Collection Center (Marrow and / or Peripheral Blood Progenitor Cells)	JACIE
	FACT
Umbilical cord blood bank operations	Netcord / FACT
Donor Centres	National Marrow Donor Program (NMDP)
Processing Laboratory	JACIE
	FACT
Histocompatibility assessment	European Federation for Immunogenetics (EFI)
	American Society for Histocompatibility and Immunogenetics (ASHI)
General Administration and other relevant sections	ISO 9001

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Changes to Standards document

Date of Revision	Alterations to Document	Status
May, 2003	Completion of standards	Board approved, Discussed at Dreieich meeting & approved subsequently
May, 2004	Reworded standard 1.01 in Overview and Definitions to remove the word "pilot"	Board approved, Tokyo meeting
March, 2005	Added new standard 6.08 on contact of transplant center with donor requests for harvest type etc	Board approved, Prague meeting
November, 2005	Revised Chapter 10; added changes to 6.01.1 on communication with signature	Board approved, Minneapolis;
May, 2006	Revised standards based on EU directives	Board approved, Cape Town meeting
November, 2006	Revised Chapter 5; added changes to 6.02.2	Board approved, Minneapolis;
March, 2007	Added changes in 2.05, 3.0, 3.06.1, 4.05, 4.06 9.03, 10.02.3	Board approved, Lyon
November 2007	7.03.2 changed from "should" to "must" on making policy publicly available 8.07 new standard on SPEAR but it is a "should"	Board approved, e-mail communication November 2007
April 2008	Changes made to incorporate cord blood into the standards	Board approved
June 2010	Reworded definitions. Added changes in 1.01, 1.04.2.2, 3.05.5, 3.06.1,4.05, 4.07.1, 5.01.5, 6.08, 7.02, 8.06, 9.04.3, 9.06. Added new standards: 1.06, 3.05.6, 3.06.2.4, 3.06.3.3.1, 3.06.3.5, 4.03.1	Board approved October 2010, Minneapolis, MN, USA
December 2011	Defined the first step of the Accreditation Process as Qualified	Board approved, November 2011, Minneapolis, USA