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D5.1 Report of findings from engagement with Member States and recommendations for the enhancement of the WMDA Accreditation Programme including an appendix with the new WMDA Standards.

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1. Foreword

The World Marrow Donor Association (WMDA) promotes product quality and global collaboration through accreditation and standardisation. WMDA members, clinicians, national authorities and donors trust WMDA accreditation as an indication that high quality hematopoietic stem cell products are provided efficiently, and donor safety is ensured. The WMDA accreditation programme is based on the WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries.

The WMDA Standards set forth the minimum guidelines to facilitate hematopoietic stem cell transplantation and cell therapies. The first edition of the WMDA Standards was published in 2003. Periodically the WMDA Standards are updated and reviewed. In 2019, the WMDA worked on the edition that will become effective in 2020. The major objectives of the 2020 edition of the WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries are to:

- process the incoming requests for access to donors/cord blood units arriving from organisations in other countries in a secure way;
- facilitate outgoing requests for international donors/cord blood units for patients in the country where the registry resides;
- coordinate the activities of donor, collection, and transplant centres, and cord blood banks within a registry.

These WMDA Standards will be effective on 1 July 2020. All WMDA certified, qualified and accredited registries are expected to comply with these WMDA Standards. A list of WMDA certified, qualified and accredited registries is publicly available on the WMDA share website.

The WMDA Standards do not set forth all that may be required to conform to governmental regulations or the standards prevailing in the local legal environment. Each WMDA certified, qualified or accredited registry must determine and follow additional laws, regulations, practices and procedures that apply in their local legal and regulatory environment. The WMDA disclaims all representations or warranties, expressed or implied, that compliance with the WMDA Standards will fulfil the requirements of all applicable governmental laws and regulations or the standard of care prevailing in the local legal and regulatory environment.

More background information on the WMDA Accreditation program can be found in Deliverable D5.1 from 2018 - Report on finding from engagement with EU Member States and recommendations from enhancement of the WMDA Accreditation Programme.

This current Deliverable from 2019 - D5.1 Report of findings from engagement with EU Member States and recommendations for the enhancement of the WMDA Accreditation Programme – sets out the findings resulting from engagement with EU member registries in relation to the WMDA Accreditation

Programme. It includes a membership consultation on the 2017 edition of the WMDA Standards and insight into the strengths and weaknesses of the current accreditation programme. Reflecting this insight and evidence, the report includes recommendations for the improvement of the programme, including an annex setting out the defined WMDA 2020 Standards that are reflected in the accreditation journey.

The WMDA Standards are revised in a three-year cycle. For the 2020 edition of the WMDA Standards, the WMDA reached out to the community to ask about potential updates of the WMDA Standards. The WMDA membership indicated that there is upcoming data regulation in the European Union. A group of specialists came together to discuss the impact of these data regulations and how to ensure that all WMDA member organisations comply with the European data regulation

A set of WMDA Standards were developed which are feasible for as well large as small organisations. In 2019, focus group meetings were organised by telephone to develop guidance how to comply WMDA data security standards.

In addition, the WMDA S(P)EAR Committee checked whether the WMDA Standards needed to be updated based on the reported incidents.

As a third step the WMDA membership was requested to submit proposals for changes.

The feedback from the organisations that underwent the process for WMDA qualification and accreditation was analysed as well to be sure that all issues were taken into account when developing the new version of the WMDA Standards.

The WMDA Board reviewed the new WMDA Standards and approved them on July 1, 2019. This allowed the WMDA Accreditation Committee to start with training of the reviewers and the membership on the new WMDA Standards.

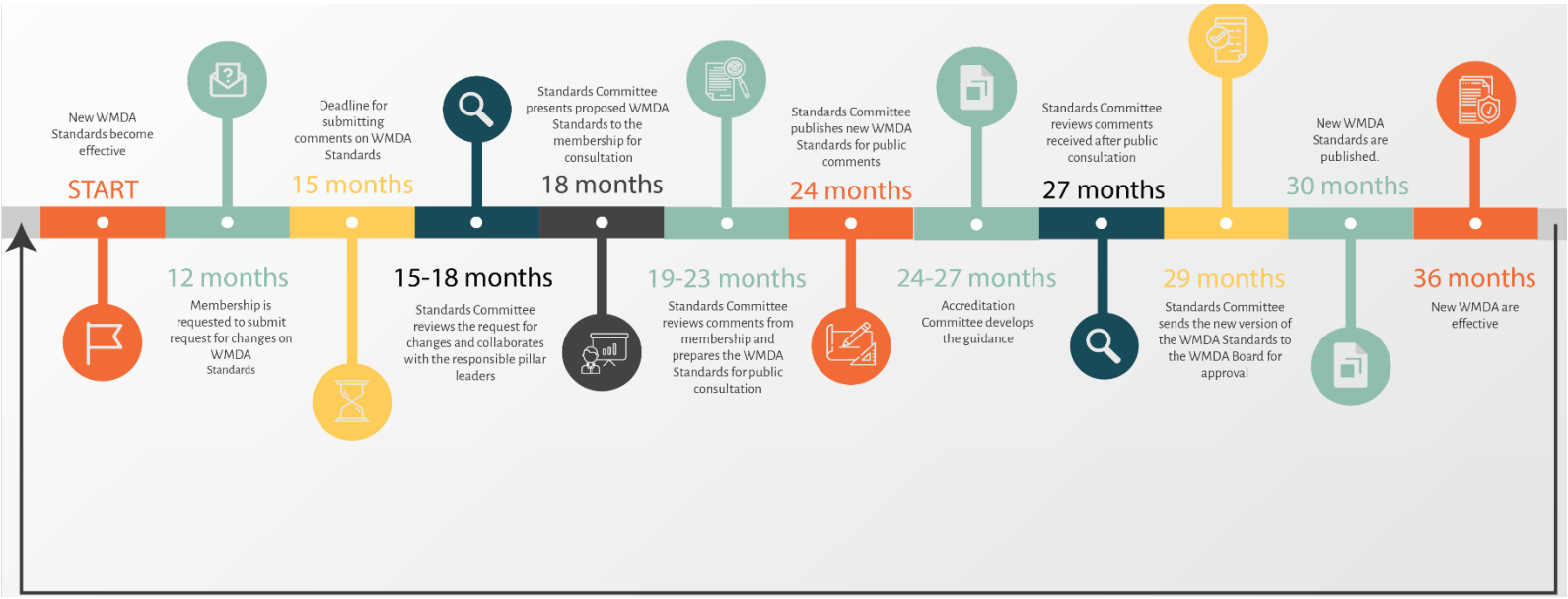
After a workshop, two webinars the Accreditation Steering Committee felt that the education will take time. It was not feasible to achieve the implementation date (January 1, 2020). This observation was discussed with the WMDA Board. The WMDA Board decided to delay the effective date of the new WMDA Standards to July 1, 2020. In the first six months of 2020 several workshop will be scheduled to train the WMDA reviewers and members on the new WMDA Standards.

The publication of the new WMDA Standards allows the WMDA to look critically at the workflows in the accreditation programme. Input for improvements were the surveys that were received from both the reviewers as the applicant registries. The feedback of both surveys form the bases for suggested improvements in the accreditation workflow.

2. WMDA Standards 2020

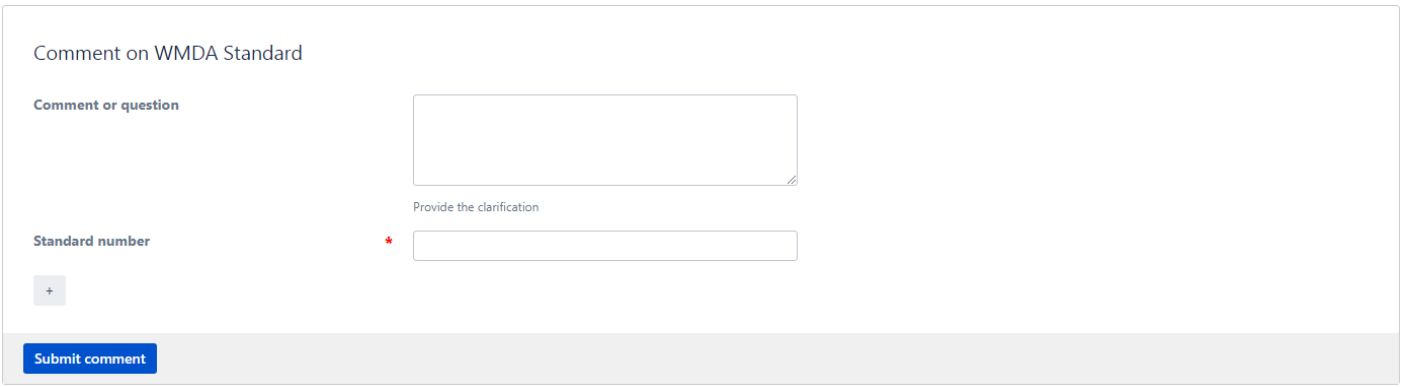
The current version of the WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries is valid from 1 January 2017 till 1 July 2020. *Figure 1* shows the complete timeline of the process working towards new WMDA Standards.

Figure 1. Timeline towards new WMDA Standards



WMDA sent out an invitation to the WMDA membership with the request to submit request for changes on the WMDA Standards 2017 (*Figure 2*). Based on the responses to this survey, the WMDA Standards were updated, which led to the design of the 2020 WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries.

Figure 2. Comment form WMDA Standards 2017



In 2019, the WMDA Standards were under revision, improved, approved by the WMDA Standards Committee and WMDA Board and published on WMDA Share for public consultation (*Figure 3*).

Figure 3. Towards new WMDA Standards 2020 – Timeline

What	Date
Invitation to submit comments	January 2018
Possibility to submit comments	Until 1 June 2018
Consultation WMDA membership at WMDA Fall Meeting and on WMDA website	November 2018
Public consultation WMDA Standards	January 2019 - March 2019
Final review WMDA Standards Subcommittee	March 2019
WMDA Board approval on the new version of the WMDA Standards	17 June 2019
Publication of the WMDA Standards effective on 1 July 2020	1 July 2019
Standards are effective	1 July 2020

The new WMDA Standards 2020 including guidance can be found on the WMDA Share webpage or in Appendix 1 of this report. They will become effective on 1 July 2020.

At that time, the accreditation process will re-start again and WMDA will work towards the future WMDA Standards 2023 (*Figure 4*).

Figure 4. Towards new WMDA Standards 2023 – Timeline

What	months	Date
Current Standards are effective	0	July 2020
Invitation to submit comments or request for changes	12	January 2021
Deadline for submitting comments	15	March 2021
Standards Committee reviews the request for changes	15-18	March 2021 - June 2021
Standards Committee presents proposed WMDA Standards to membership for consultation	18	June 2021
Standards Committee reviews comments from membership	19-23	July - November 2021
Publication of new WMDA Standards for public comments	24	December 2021
Accreditation Committee develops the guidance	24-27	Until March 2022
Standards Committee reviews comments received after public consultation	27	March 2022
WMDA Board approval on the new version of the WMDA Standards	29	June 2022
New WMDA Standards are published	30	July 2022
New WMDA Standards are effective	36	January 2023

3. WMDA Accreditation process - Registries Survey

After each WMAD Qualification or (Re)Accreditation process, a survey is sent out to the registries to ask for feedback on the current Accreditation Process from the relevant applicant organisation (*Figure 5*). The goal of this is to gain insights from members on the support they require to progress through the Accreditation pathway, to see what works and to find out where there is room for improvement. The recommendations of the registries for the enhancement of the Accreditation Programme will be implemented, following consultation with the WMDA members, the Standards Committee and the WMDA Board.

Figure 5. Homepage WMDA Qualification/Accreditation Feedback Survey Registries

WMDA is constantly working to improve the Accreditation Process. The most valuable source of information for that is the feedback we receive from registries who gone through the process themselves.

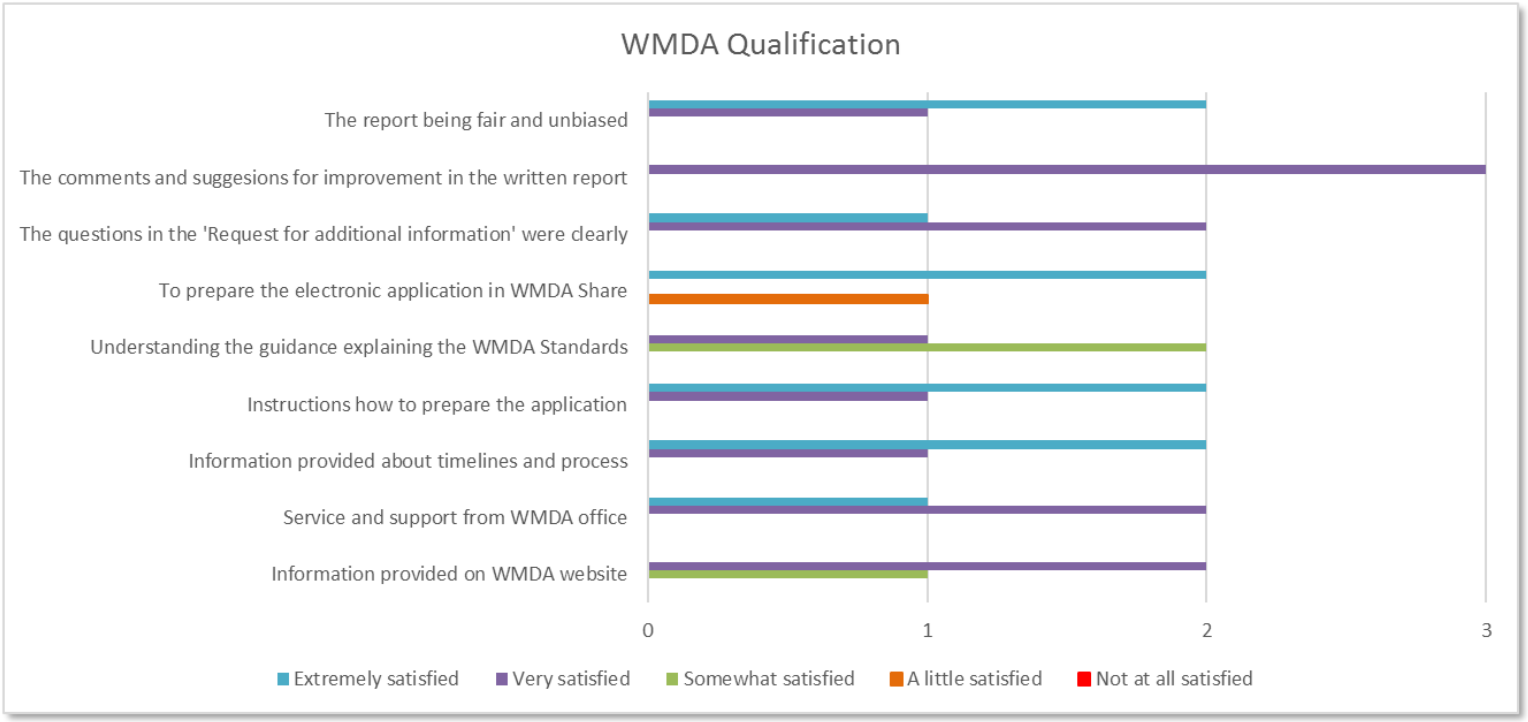
- **3** responses in the period from **October - November 2018**
- **3** responses from **March - June 2019**

WMDA aims to receive more review responses soon.

3.1 WMDA Qualification

There are 3 responses from registries that performed a Qualification process. All of them are from 2019.

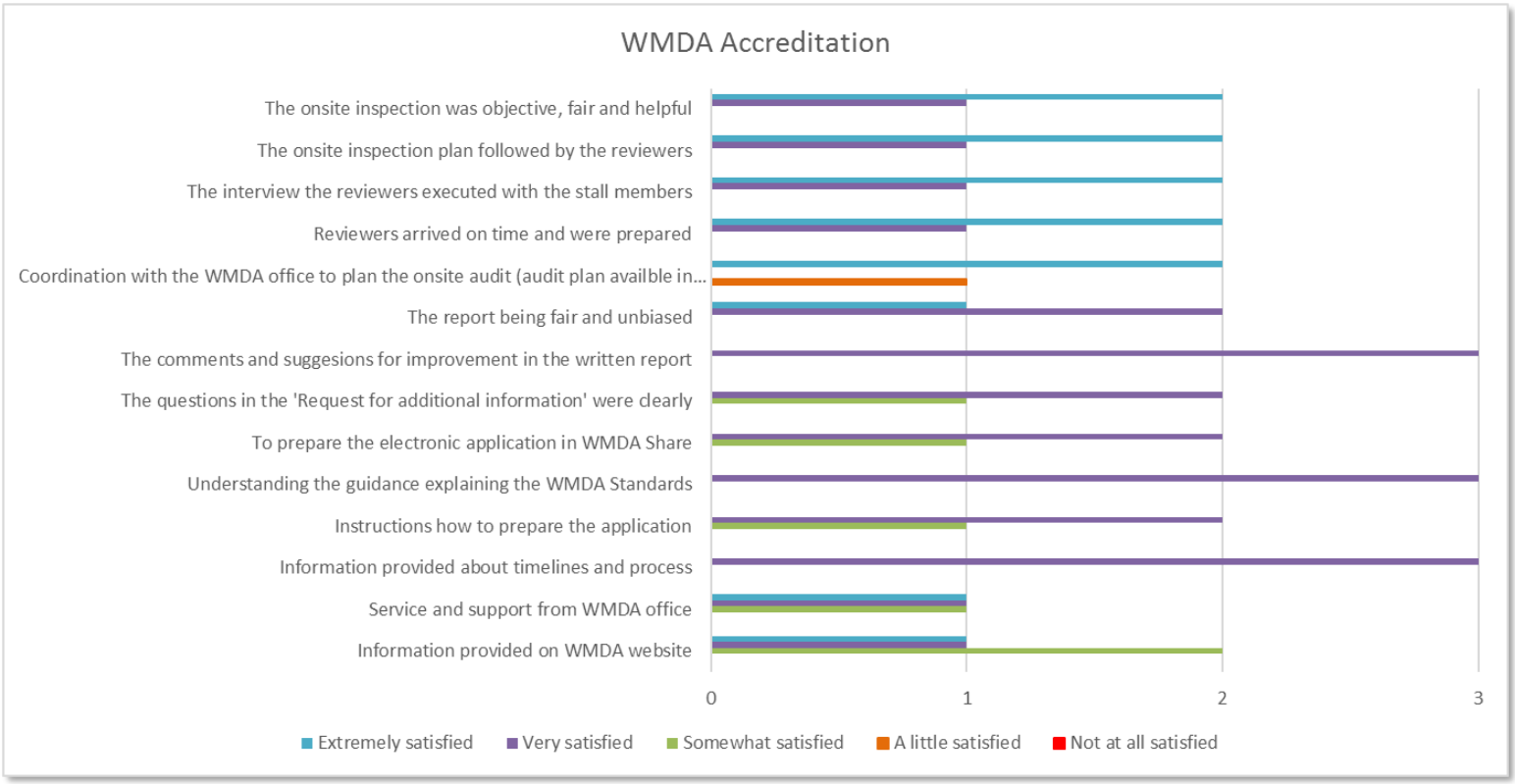
	Not at all satisfied	A little satisfied	Somewhat satisfied	Very satisfied	Extremely satisfied
Information provided on WMDA website			1	2	
Service and support from WMDA office				2	1
Information provided about timelines and process				1	2
Instructions how to prepare the application				1	2
Understanding the guidance explaining the WMDA Standards			2	1	
To prepare the electronic application in WMDA Share		1			2
The questions in the 'Request for additional information' were clearly				2	1
The comments and suggesions for improvement in the written report				3	
The report being fair and unbiased				1	2



3.2 WMDA Accreditation

There are 3 responses from registries that performed an Accreditation process. All of them are from 2018.

	Not at all satisfied	A little satisfied	Somewhat satisfied	Very satisfied	Extremely satisfied
Information provided on WMDA website			2	1	1
Service and support from WMDA office			1	1	1
Information provided about timelines and process				3	
Instructions how to prepare the application			1	2	
Understanding the guidance explaining the WMDA Standards				3	
To prepare the electronic application in WMDA Share			1	2	
The questions in the 'Request for additional information' were clearly			1	2	
The comments and suggesions for improvement in the written report				3	
The report being fair and unbiased				2	1
Coordination with the WMDA office to plan the onsite audit (audit plan availble in timely fashion, contact details reviewers)		1			2
Reviewers arrived on time and were prepared				1	2
The interview the reviewers executed with the stall members				1	2
The onsite inspection plan followed by the reviewers				1	2
The onsite inspection was objective, fair and helpful				1	2



In addition to the above satisfactory rates of the Qualification and Accreditation processes, WMDA also asked open questions:

3.3 Open questions

4. In case you are not at all satisfied or a little satisfied, could you explain to us why.

We consider necessary to improve the on-line tool to avoid misunderstanding, problems at the time of uploading documents. In our particular case, we thought that many of the problems that arose are due to a bad upload of our comments and translations we added in the documents.

The WMDA website is a bit difficult to use. The information can be difficult to find (however when found is often of very high quality). It is also confusing what information that can be found on the WMDA website and what can be found on Share. Guidance for the standards: it is sometimes to specific what type of document that must be provided and the recommendation goes beyond what the standard requires.

- Sometimes, the guidance seem to exceed the standard, and look like additional standards. A guidance should be a help for interpretation, not an additional requirement.

- We had to comply with GDPR, and were not allowed to send some of the documents requested with the application file (these documents were available on site). The guidance should take GDPR into account.

- Data security is a great concern for our registry (and others), and information about the security of the data we provided in the application were not directly available. We asked, and received some information by e-mail. When sending data to WMDA, a registry should know how these data will be handled, stored, destroyed...

- It is not always easy to find information on WMDA Share.

It provides us unbiased external review of all procedures, useful feedback, it allows us to "tune" existing" procedures.

Electronic application in share is laborious and time consuming (anyway I cannot imagine the better way)

5. What was the motivation to apply for WMDA Qualification?

To be recognize national and internationally.

JACIE standards recommend use of donors from WMDA accredited registries.

The Registry is developing in all areas and the qualification process is a way to improve our processes. External reviewers are very important.

This is too early to answer !

At this time, we can say that the reviewers comments were not fully surprising, we had also previously identified some needs of improvement. The reviewer's report will be helping as a motivation to put in place the necessary actions. Accreditation is one motor for continuous improvement.

6. How has the WMDA accreditation/qualification process improved the operation of your organisation?

The qualification process has helped us to review all our internal processes, define indicators and drive forward in the effectiveness of our team

Some SOPs were updated or renewed

Improvements can be managed and followed up in a more systematic way. All processes have been reviewed, first by our self and then by the external reviewers.

Try it because it help will you !

It provides us unbiased external review of all procedures, useful feedback, it allows us to "tune" existing" procedures.

7. What would be your best advice for new registries applying for WMDA qualification/accreditation?

This process, although hard, has helped us to improve our management of the registry considering all departments.

Don't wait

We are not a new registry (started 1992...) and have continuously adapted to the standards over the years. For us the challenge was to describe and document our existing practice.

However, for a new registry the standard can be used as operations are set up or as soon as possible when establishing the registry. The first step is then to do a gap-analysis against the benchmark standards and start filling the gaps. Probably it would be very useful to have a "mentor"-registry or a discussion partner that recently went through the process.

8. If you would like the WMDA to contact your registry about any areas of dissatisfaction, please note the name and e-mail address of the person to be contacted.

Comments: Just a suggestion : when preparing the application file in Share, we need sometimes to extract the file in a Word format in order to work on the phrasing, to verify that the information is exhaustive, and to put the file into a validation circuit. The extraction from Share could be improved, so that we don't loose too much time in reformating the file...

4 WMDA Accreditation process - Reviewers Survey

In addition to the registries that receive a survey after the WMDA Qualification/Accreditation Process, the reviewers receive a survey to assess their own review process and the assessment of their fellow WMDA reviewer's performances. This is to investigate how they feel about performing the review. The outcome of this survey will be used to improve the future review training sessions.

Post review assessment of WMDA reviewers performance

Even though the survey needs to be complete for every reviewer that performs any accreditation review (desk-review or on-site audit), we only have at the moment 10 responses:

- **6** responses in the period from **October - November 2018**
- **4** responses from **March - November 2019**

4.1 Adequacy of the training

All the reviewers feel that the training they have received is appropriate

	Count of What was your role in the review team?	Did you feel adequately trained to perform the review?	
		YES	NO
Experienced reviewer	3	3	
Review team leader	3	3	
Trainee reviewer	4	4	
Grand Total	10	10	0

4.2 Questions about time to prepare and perform the review

All the reviewers have had enough time to perform their reviews

	Did you allocate sufficient time to carefully review the application in advance?		
	YES	NO	Comments
Experienced reviewer	3		Extra time than was expected was needed for this review, but was able to find the extra time needed. This may have been difficult if my work and personal schedule was heavier than it happened to be during he timeframe of this review.
Review team leader	3		
Trainee reviewer	4		Only for benchmark
Grand Total	10		

4.3 Hours spent on the application (excluding the on-site visit)

		Number of hours you spent on the application **excluding the site visit.**
Team Leader	FGM ION 1804	50
	Czech Nat Donor Registry	10
	Spain	40
Average		33,3
Experienced reviewer	ABMDR	7
	Czech National Marrow Donor Registry	8
	Austrian Bone Marrow Donors Registry	10
Average		8,3
Trainee reviewer	Czech National Marrow Donor Registry	34
	France Greffe de Moelle	10
	Danish Registry	50
	Spain	10
Average		26,0

4.4 About the on-site application and on-site checklist

There were **2** reviewers out of **10** that had problems with the on-site application and the checklist.

Role		**Did you have any problem with the on-line application and/or the onsite checklist.**		
		YES	**NO**	**Comments**
Experienced reviewer	3		3	Suggest the checklists questions be numbered, as final report has a space to reference the checklist question numbers
Review team leader	3	1	2	[Nov 2018] 1.There was no IT checklist. It would help as there were questions arising from the application and RFIs that could be better answered though the checklist 2. Files
Trainee reviewer	4	1	3	[Oct 2018] The on-site checklist for IT-issues was not available. So, we just skipped this part
Grand Total	10	2	8	

4.5 Performance of the Team Leader

What was your role in the review team?		Organized in leading the team activities		A clear communicator		Able to solicit input from all team members and respectful of their opinions		Able to achieve consensus within the team		Comments
		YES	NO	YES	NO	YES	NO	YES	NO	
Experienced reviewer	**3**	2		2		2		2		
Review team leader	**3**									
Trainee reviewer	**4**	4		4		4		4		
Grand Total	**10**	6		6		6		6		

4.6 Performance of the experienced Reviewer

What was your role in the review team?		Prepared adequately for the review?		Able to identify strengths and weaknesses of the application?		Fair and impartial?		If an on-site audit, professional and positive?		Comments
		YES	NO	YES	NO	YES	NO	YES	NO	
Experienced reviewer	3									This review was unique in that I was originally the experienced reviewer, however later became the team leader.
Review team leader	3	2		2		2		2		
Trainee reviewer	4	4		4		4		3		
Grand Total	10	6		6		6		5		

4.7 Performance of the Trainee

What was your role in the review team?		Knowledgeable?		Prepared adequately for the review?		Able to identify strengths and weaknesses of the application?		Fair and impartial?		If an on-site audit, professional and positive?		Comments
		YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	
Experienced reviewer	3	1		1		1		1		1		
Review team leader	3	3		3		3		3		2		I think trainee learned a lot; during on site visit I experienced that it was a bit difficult to work with 3 persons, talking and writing was mainly done by the two
Trainee reviewer	4											I believe a few more training on reviews would be helpful before undertaking one as experienced reviewer; needs some more familiarization with the standards and process of review.
Grand Total	10	4		4		4		4		3		

5. Improvements of the WMDA Accreditation Program

The surveys described in chapter 3 and chapter 4 provide to WMDA a good understanding of the satisfactory rates and especially the open questions include recommendations for the improvement of the program.

The main remark is that the online submission webpage on WMDA Share needs to be improved. Furthermore, better explanation would also help both the registries and the reviewers in using this tool. In general, it could be made more user-friendly.

- The response rate to the registry survey is lower than expected.
  WMDA is planning to improve this by:
  - Sending the survey to all registries that have had an accreditation, reaccreditation or qualification process in 2018 and 2019
  - Emphasising the importance of reviewing the process
  - Sending a reminder to the registry if they have not responded within 2 weeks
  - Contacting the registry via telephone if they have not responded within 1 month

- The response rate to the reviewer survey is lower than expected.
  WMDA is planning to improve this by:
  - Asking the reviewers the reason why they did not submit the survey
  - Raising awareness about the importance of the survey as an improvement tool
  - Making the survey a mandatory form to be submitted after the desk/on-site review
  - Monitoring the submission of the survey

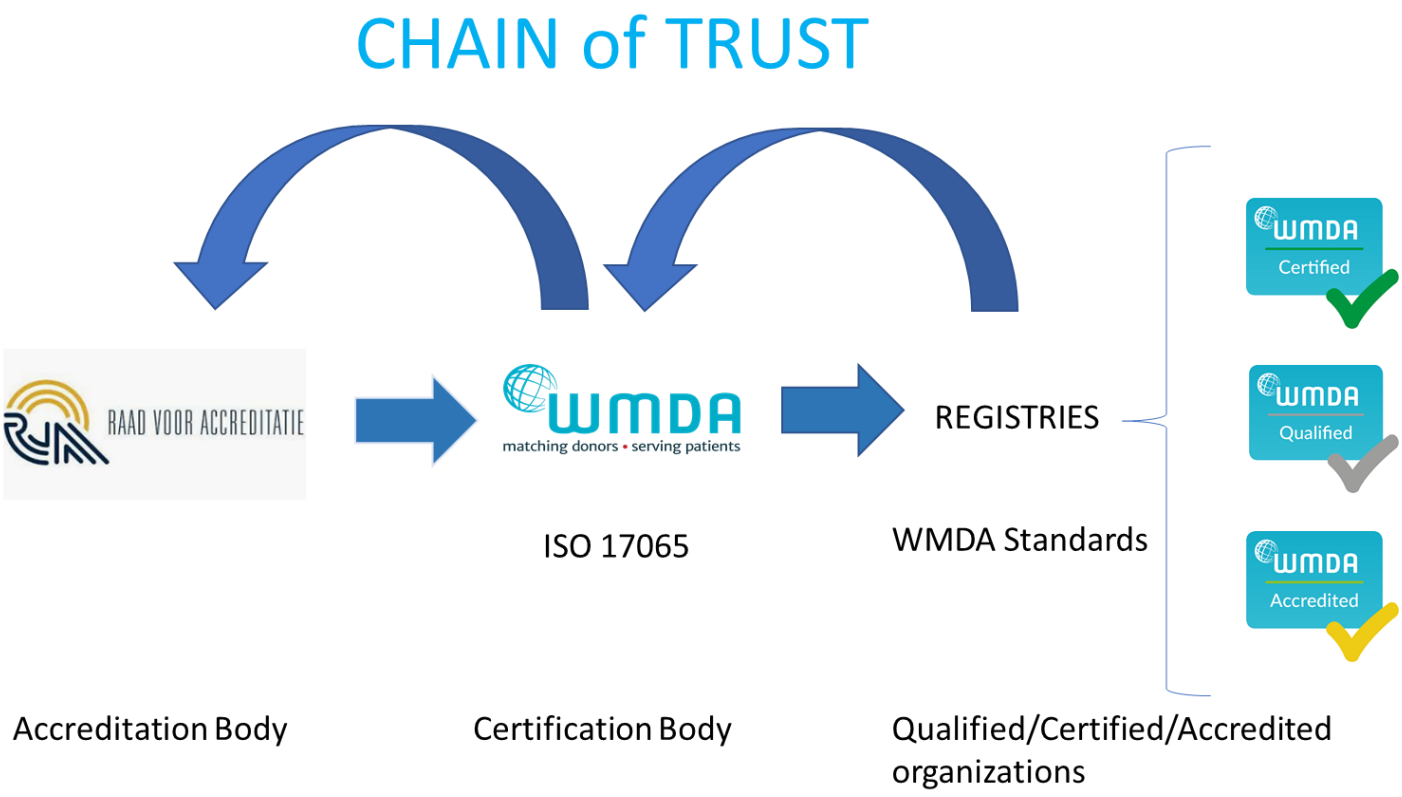
5 Plan for 2020 - ISO Accreditation

WMDA has developed a Qualification/Accreditation program for registries all over the world, to ensure that they comply with internationally accepted standards, the WMDA Standards.

The process for demonstrating that the registries meet the requirements of the standards is called Conformity assessment, so that WMDA is a Conformity Assessment body called a Certification Body (*Figure 6*).

WMDA is exploring if it is feasible to be recognised by an internationally accepted entity that accredits certification bodies (*Raad voor Accreditation* - Dutch Accreditation Council). For the Accreditation of WMDA as a Certification Body, WMDA must fulfil the requirements of ISO 17065. For 2020, the WMDA will explore this further.

Figure 6. Schematic overview ISO Accreditation process WMDA



Appendix 1. WMDA Standards 2020 including Guidance

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- 10. Financial and legal liabilities
  - Responsibilities
  - Fee schedule
  - Invoicing
  - Payment
  - Legal liability

A. Introduction and definitions

1. Introduction

1.01 WMDA has a two-level process to become WMDA accredited:

- The first time that a registry applies, the registry will become WMDA certified or WMDA qualified if the registry complies with the 'benchmark' WMDA Standards. Depending on the level of activity of a registry, the registry will become either WMDA certified (low activity) or WMDA qualified (activity above a specific level). The process to become a WMDA certified or WMDA qualified registry will not include an on-site inspection.
- The second time that a registry applies and if the registry has a sufficient level of activity, the registry will become WMDA accredited if the registry complies with all WMDA Standards. The process will include an on-site inspection. Accreditation status can be renewed.

1.02 For purposes of the WMDA Standards, the term "must" means that the Standard is to be complied with at all times. The term "should" indicates an activity that is recommended or advised, and for which there may be effective alternatives. The term may or might is permissive, indicating that the practice is acceptable, and not necessarily recommended.

2. Definitions/abbreviations

Note: Organisations, defined as a “registry” in the WMDA Standards, providing hematopoietic stem cells to a patient in another country vary in their administrative structures. The definitions below are aimed at defining the individual elements that comprise this effort and are not intended to indicate the requirement for a specific organisational structure.

click here to expand definition list..

ABO	Major human blood group including erythrocyte antigens, A, B and O
Agreement	A formal arrangement between organisations as to a course of action to supply a service

ASHI	American Society for Histocompatibility and Immunogenetics
Benchmarked standards	A subset of the WMDA Standards that are considered the most critical for registry quality. This subset of standards is the basis for the evaluation of certification or qualification status.
Blood collection centre	A medical facility where blood intended for testing and/or transfusion is drawn and stored.
Cell processing unit	A medical laboratory facility where hematopoietic stem cells are manipulated prior to hematopoietic stem cell transplantation/cellular therapy. These activities may include the depletion of specific cell types from the graft, selection for specific cell types for infusion, ex vivo manipulation of cells in the graft, or concentration of the cell product.
Central venous catheter (CVC)	A catheter placed in a vein in the neck (internal jugular vein), chest (subclavian or axillary vein) or in the groin (femoral vein).
Collection centre	A medical facility where hematopoietic stem cell collection from donors takes place. This collection might include marrow aspiration or apheresis. The collection centre physician, or designee, performs the medical workup of the donor and provides the final approval of the donor for collection. The collection centre packages the stem cell donation for transport to the transplant centre.
Cord blood bank	A facility responsible for donor management and the collection, processing, testing, cryopreservation, storage, listing, reservation, release, and distribution of cord blood units.
Cord blood collection site	A location where the infant donor is delivered and the cord blood unit is collected.
Courier	An individual properly trained and qualified in transport of hematopoietic stem cell products.

Donor	A person who is the source of cells or tissue for a cellular therapy product. Donors are volunteers and unrelated to the patient in need of a transplant. The WMDA Standards refer to three types of donors: • volunteer donors who have passed a minimum age established by national law or their eighteenth (18th) birthday when no regulation exists; • infant donor from whose placenta and/or umbilical cord the cord blood is obtained; • maternal donor who carries the infant donor to delivery.
Donor centre	An organisation responsible for donor recruitment, consenting, testing, management and the collection of donor personal, genetic, medical data.
EFI	European Federation of Immunogenetics
Extended typing	This HLA 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 purpose of this typing is to ascertain the level of HLA match between donor and recipient. The additional HLA typing may be performed on a stored sample.
G-CSF	Granulocyte colony-stimulating factor is a cytokine that stimulates the bone marrow to produce granulocytes (white cells) and haematopoietic stem cells and causes these cells to mobilise (move) to the peripheral blood where they can be collected from the veins for transplantation.
Global registration identifier for donors (GRID)	The global registration identifier for donors provides format for registries and donor centres that issue donor identifiers. The GRID assures that every donor is assigned a globally unique identifier.
HSC	Hematopoietic stem cells (defined also as hematopoietic progenitor cell-HSC) are the 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.
Hematopoietic stem cell transplantation	A medical procedure involving transplantation/cellular therapy of hematopoietic stem cells.

HLA	Human leukocyte antigen
IDM	Infectious disease marker
Must	To be always complied with
Patient/Recipient	Individual in need of transplantation/cellular therapy is a patient; a patient who has received a cellular therapy is a recipient.
Product	A cellular therapy product that contains hematopoietic stem cells and/or other nucleated cells intended for therapeutic use.
Product code	Unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor and to all records describing the handling and final disposition of the product.
Qualification	Qualification is the process of proving that a system, supplies and equipment work correctly. For example, a new cord blood collection process must be validated; a shipping container used must be qualified first. By convention, the word validation is always used for software.
Quality management system	A system that documents policies, procedures and responsibilities for achieving quality within an organisation and a process to audit the quality system. The system includes: • Personnel requirements such as qualifications, training, competencies, and responsibilities; • Detection, reporting of, and corrective action(s) taken, related to adverse events and complaints; • Identification, labelling and tracking of individuals and products; • Development, implementation, and review of policies and procedures; • Creation, review, control and maintenance of records; • Outcome analyses; • Description of facilities and safety considerations.

Registry	An organisation responsible for coordination of the search for hematopoietic stem cells from donors (including cord blood) unrelated to the potential recipient. • The patient registry or requesting registry is the registry that acts on behalf of their transplant centres. • The donor registry or providing registry is the registry that provides the hematopoietic stem cell product.
Rh	A specific antigen present on the surface of red blood cells, Rhesus
SAE	(serious adverse event) - Risk of Harm: Any untoward occurrence associated with the procurement, testing, processing, storage, and distribution of tissues and cells that might lead to the transmission of an infectious disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.
SAR	(serious adverse reaction) - Harm: An unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.
Search	The process of identifying a suitable stem cell source for a patient in need of a transplant.
Should	Recommended or advised, but effective alternatives may exist.
S(P)EAR Committee	A WMDA Committee responsible for review of all events/reactions reported to WMDA as potential risk of harm or harm. The Committee evaluates the events/reactions' imputability (i.e., whether the event can be attributed to the donation or transplantation process) and impact.
Standard operating procedures (SOP)	A compilation of documented 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 SOPs must be documented and authorised.

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 centre or transplant centre or may be separate from these entities.
Total nucleated cell (TNC) count	The number of cells with a nucleus in a cord blood unit.
Traceability	The ability to locate and identify a donor or recipient, their data and cell product, during any stage of the recruitment, testing, collection, donation, transplantation/cellular therapy, and follow-up process. Traceability also includes the ability to identify the organisational entities (e.g. registry, donor centre, collection centre, cell processing unit and transplant centre) involved in the international exchange.
Transplant centre	A medical facility where a patient (recipient) receives a transplant (graft) with hematopoietic stem cells from an unrelated donor or from an umbilical cord blood unit. The transplant centre 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 centres. This entity may be contained within a transplant centre or may be separate from the transplant centre. If separate, the search unit may coordinate searches for one or several transplant centres. In the WMDA Standards, reference to a transplant centres should be interpreted as a transplant centre and/or a search unit as appropriate. Transplant centres/search units seeking an international donor work through the registry in their country.
Valid signed informed consent	Signed documentation indicating that a 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, that they have understood the information provided, have had an opportunity to ask questions, have been provided with satisfactory responses and have confirmed that all information provided is true to the best of their knowledge. The informed consent is valid when it complies with national regulation.

Validation	Validation is the process of providing documented evidence that a specific process will consistently produce a product meeting its predetermined specifications and quality. Qualification is the process of proving that a system, supplies and equipment work correctly. For example, a new cord blood collection process must be validated; a shipping container used must be qualified first. By convention, the word validation is always used for software.
Verification typing	This HLA 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. The purpose of this typing is to ensure that the donor/cord blood unit is the same individual/unit whose HLA typing was listed on the search report used to select the donor. This stage was historically to be referred to as "confirmatory typing (CT)".
WISP	A set of comprehensive guidelines and policies designed to safeguard all confidential and restricted data maintained at the registry
WMDA Data Use Agreement	Agreement between WMDA and the registry listing donors and/or cord blood units.
WMDA Share	The membership website of WMDA with the domain name: https://share.wmda.info
World Marrow Donor Association (WMDA)	The World Marrow Donor Association, abbreviated as WMDA, strives to ensure that patients worldwide have equal access to high quality cells for transplantation from donors whose rights and safety are protected. WMDA promotes global collaboration and the sharing of best practices among its members for the benefit of stem cell donors and patients. WMDA aims: • *Optimising 'Search, Match & Connect'*: Provide a global platform that facilitates access to the most suitable stem cell source for a transplant patient; • *Supporting global development*: Support members to develop and grow, so that more transplant patients find the most suitable match; • *Promoting donor care*: Ensure that the rights and safety of stem cell donors are promoted and protected; • *Ensuring quality*: Promote product quality and global collaboration through accreditation and standardisation.

Workup	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 hematopoietic stem cells.

B. Standards

Purpose of guidance: The guidance lists information and evidence (e.g., SOPs, forms, policies) that are most effective in demonstrating compliance to a standard. In some cases, completed documents are requested but this is not for all standards. The guidance is the same for both qualification and accreditation applications. Alternative approaches and documents are listed with the wording “might”. In the absence of the suggested documentation, the registry is expected to provide information/evidence demonstrating how compliance is achieved by their registry and/or an explanation for their inability to comply, if applicable (e.g., provide a reference to a conflicting local regulation). Reviewers should remain open to the possibility, if the suggested information or evidence is not provided, that alternative approaches fulfilling the intent of the standard may be accepted.

Explanation of the symbols:

x = Yes, required

o = Recommended, not required

0	No.	Benchmark standard	STANDARDS	Guidance to WMDA Standards	Short application	Self certification / qualification	Self accreditation
1	1		1. General				

1	1.01		A WMDA regular member organisation is eligible for WMDA certification or WMDA qualification as a first step, followed by WMDA accreditation as a second step.	*Note*: Provide with the shortened application **References**: • Global Trends Report • data.wmda.info (website to access) **Explanation**: WMDA has several types of membership for registries. The first step is to become a provisional member, followed by the step to become a regular member organisation. To be eligible to apply for WMDA certification/qualification /accreditation, a registry must provide evidence that they are providing hematopoietic stem cells from volunteer unrelated donors or banked umbilical cord blood units to patients in another country. • A minimum of six (6) donations within the last three years with 2 of the 6 for international patients is required to be eligible for WMDA qualification/accred itation for volunteer	x		

				donors as a stem cell source. The remaining 4 donations may be for national patients. • A minimum of 6 cord blood unit shipments within the last three years with 2 of the 6 for international patients is required to be eligible for WMDA qualification / accreditation for cord blood as a stem cell source. The remaining 4 stem cell shipments may be for national patients. • If the minimum activity is not reached by the registry, the registry can apply for WMDA certification (instead of WMDA qualification) A registry applying for WMDA qualification for both unrelated donors and cord blood units must meet the criteria for both stem cell sources. A registry that is already WMDA qualified or WMDA accredited for both stem cell sources must meet the criteria for the minimum number of			

				donations for volunteer donors in its application for (re)accreditation; it does not need to continue to meet the criteria for cord blood shipments. Registries that have affiliated donor management entities (for example, donor centre, collection centre) located in a country different from the country where the registry resides are confronted with challenges in terms of different national regulations, communication between two distant entities potentially speaking different languages with different cultures, unclear lines of authority, etc. This requires additional clarification within an application for qualification/accreditation. These international partnerships do not include the situation where the registry's database is hosted by another registry. **Information/evidence to be provided (or equivalent alternative)**:			

				• To document international donation, a copy of the last WMDA Global Trends Report (see WMDA Standard 1.03). If the number of shipments is lower than 6, the registry must also provide copies of the two previous WMDA Global Trends Reports to demonstrate that they meet the criterion of 6 donations/cord blood unit shipments within the last three years. • Whether the registry facilitates the import of hematopoietic stem cells on behalf of transplant centres in their own country, although the import is not required • An overall picture of the activity over several recent years in terms of donations facilitated/cord blood units shipped, samples shipped, number of cord blood units/adult volunteers in database			

				• One or more organisational charts that describe the general structure of the registry. A chart should indicate the number of donor centres, cord blood banks, collection centres and transplant centres that are affiliated with the registry. A chart should describe the interaction of the registry with other entities that might oversee the registry operations e.g., if the registry is within the structure of a hospital or if the registry is overseen by a government agency. A chart might describe the internal units of the registry such as search, workup, IT, finance and advisory groups. • If the registry has an international partnership, the following information will help demonstrate compliance with WMDA Standards: ○ Organisational chart			

				describing the entire network of the registry ○ Service level agreement (SLA) defining international partnership including assignment of authority. If the international entity is formally part of the registry, a Service Level Agreement might not be needed. ○ Documentation that each entity has some legal standing as required by laws and regulations in the respective country. This could be included in the SLA. ○ Availability of medical			

				support in second country for donor health issues ○ Description of how two entities communicate; policy for interpretation if two countries speak different languages or defined common working language. This could be included in the SLA. ○ In case of a collection center outside of the country of registry, requirement for license or accreditation by national or international entities (for example, FACT-JACIE) might be included in			

				the SLA. For a donor centre, audits by registry focused on WMDA standards with the information as to whether staff performing audits travel to the second country. ○ Documentation of how different Infectious Disease Marker (IDM) risks are handled. This could be included in the Service Level Agreement. ○ Secure data transmission between all involved organisations. This could be included in the SLA. ○ Evidence of compliance			

				with WMDA Standards in each organisation according to distribution of tasks and responsibilities. Cross-walk of relevant regulations between the two countries.			

1	1.02	x	**If a registry is accredited for international exchange of hematopoietic stem cells by an international organisation with standards that meet or exceed WMDA Standards, that registry may be given WMDA certification/qualification following submission and evaluation of material documenting that accreditation.**	**Benchmark standard** **Explanation**: Accreditation by other organisations will be evaluated by WMDA prior to accepting their accreditation as equivalent to WMDA certification/qualification /accreditation. An ISO certification for quality management is not equivalent to WMDA qualification/accreditation based on the WMDA Standards. It is, however, helpful to comply with the standard in Section 2 on quality management. A cooperative agreement with NMDP is not equivalent to accreditation based on the WMDA Standards. Accreditation of the HLA laboratory by ASHI or EFI is not equivalent to accreditation of a registry based on the WMDA Standards. *Note*: The WMDA has approved the NetCord-FACT standards as almost equivalent to the WMDA Standards. This means that there will be a			

				shortened application process if the cord blood bank is NetCord-FACT accredited. NetCord-FACT accredited cord blood banks serving as a registry can contact the WMDA office and ask for more details on how to apply for WMDA qualification as a NetCord-FACT accredited bank. **Information/evidence to be provided (or equivalent alternative)**: • A copy of the registry's certificate or a letter from the international accrediting organisation stating that the entity is accredited. This document must accompany a reduced application.			

1	1.02.1	x	**If not all the WMDA Standards are covered by this international accreditation, evidence of compliance with the WMDA Standards that are not covered must be provided.**	**Benchmark standard** **Explanation**: WMDA will identify which WMDA Standards are not covered by the existing accreditation. The entity will then submit an application packet that describes how they comply with the remaining WMDA Standards. **Information/evidence to be provided (or equivalent alternative)**: • Documentation showing how the registry complies with remaining WMDA Standards			

1	1.02.2		If governmental laws and regulations differ from the WMDA Standards, the requirement to meet local legal standards will be accepted as a valid cause of deviation from WMDA Standards.	**Explanation**: A registry may be regulated by local laws and regulations that differ from WMDA Standards. If this is the case, the registry should document the difference by providing a copy of the local law or regulation. If there are no differences, indicate that this WMDA Standard is "not applicable". **Information/evidence to be provided (or equivalent alternative)**: • Copy of a country's legal regulations that differ from WMDA Standards with appropriate explanation in English of the relevant sections • Documentation that the registry meets the local laws and regulations			

1	1.03	x	**A registry that intends to request WMDA certification or WMDA qualification or that has obtained WMDA certification, qualification or accreditation must participate in the annual WMDA Global Trends Report.**	**Benchmark standard** *Note*: Provide with the shortened application **References**: • Global Trends Report • data.wmda.info (website to access your registry data) **Explanation**: WMDA performs an annual survey to collect information on the exchange of hematopoietic stem cells and the activities of the registries. A WMDA certified/qualified/accredited registry must participate in this survey annually. Registries intending to apply for WMDA certification or qualification must also participate in the survey. **Information/evidence to be provided (or equivalent alternative)**: • A copy of the last submitted WMDA annual Global Trends questionnaire	x		

1	1.04	x	**The registry's operational and regulatory information as per the WMDA survey must be available on WMDA Share. These requirements should be reviewed by the registry at least annually and must be updated as significant changes occur.**	**Benchmark standard** *Note*: Provide with the shortened application **Reference**: • WMDA Share on Database **Explanation**: Operational information includes: Address and contact details of a registry, invoice address, contact phone numbers, email address, emergency contact; the accreditation status; details about affiliated cord blood banks; names and contact information for key personnel; general work schedule/business hours and times the registry is closed. Each country may have specific requirements for the import or export of hematopoietic stem cells. For example, the country may require an imported product to have certain forms accompanying it. These requirements must be described by the registry and published on WMDA Share. The	x	x	x

				registry should make sure that these requirements are up to date. Each registry has appointed an organisation profile administrator who is responsible for keeping the data accurate. **Information/evidence to be provided (or equivalent alternative)**: • A link to the information of the registry on WMDA Share or a screenshot showing the operational information of the registry • A link to WMDA Share or a screenshot showing the registry's listing of regulatory requirements			

1	1.05	x	**Changes to the status of a registry that may affect WMDA certification, qualification or accreditation must be brought to the attention of the WMDA in a timely fashion.**	**Benchmark standard** *Note*: Provide with the shortened application **Reference:** • WMDA Share information including form to be used **Explanation**: The registry should have a policy or procedure to notify the WMDA office (accreditation@wmda.info) about significant changes to the general organisation or the status of the registry that may affect WMDA certification/qualification / accreditation. The policy should describe how and who will notify the WMDA office in case of significant changes. The registry should indicate to the reviewers that they have this policy/procedure ready for implementation once qualified. Examples of significant changes are: change of legal status, change of location, change in key personnel, observation	x		

				that registry is no longer in compliance with a WMDA Standards. This requirement is different from updating the registry profile on the Share website. This WMDA Standard requires notification of the WMDA office. The office will notify the Accreditation Steering Committee that will evaluate the impact of the change on the registry's certification/qualification /accreditation status. **Information/evidence to be provided (or equivalent alternative)**: • Procedure/policy regarding WMDA notification about significant changes			

1	1.06		If a registry relies on an independent donor centre or cord blood bank to recruit and characterise donors/umbilical cord blood units, the registry must ensure that the donor centre/cord blood bank complies with relevant WMDA Standards. The nature of these affiliations and the duties and responsibilities of each entity must be documented in an agreement.	*Note*: This WMDA Standard is also covered in the on-site audit checklist *Note*: See guidance for Standard 1.01 if a donor centre is in a country different from the country where the registry is housed **Reference**: • Donor center audit guidelines are in preparation **Explanation**: This WMDA Standard focuses on the relationship of the registry with its donor centres and cord blood banks. The structure of a registry can vary from country to country. In some registries, the activities of a registry may be performed by more than one entity. For example, the registry might be affiliated with independent donor centers and/or independent cord blood banks. Alternatively the registry might itself recruit and manage donors internally.			

				Regardless of the structure of the registry, the application for WMDA certification/qualification /accreditation must cover all entities that contribute to the operation of a registry as related to the donor centre/cord blood bank. This include entities that support: • recruitment • donor counselling • maintenance of the donor database • facilitation of requests for donor samples and data • facilitation of the donation • follow-up of the donor post-donation If a registry relies on an independent donor centre/cord blood bank, a mechanism should be in place to have the WMDA requirements available for donor centres and cord blood banks (e.g., a website explaining the WMDA Standards).			

				The registry must also ensure that the donor centre/cord blood bank complies with WMDA Standards in these areas. This may be done by performing regular audits of their donor centres/cord blood banks to monitor compliance. Alternatively, an audit by another accrediting agency (for example, NetCord-FACT) may suffice. **Information/evidence to be provided (or equivalent alternative)**: • A copy of a signed letter of agreement or similar document (e.g., service level agreement) which outlines the roles and responsibilities. The registry should provide one example of a signed agreement with a donor centre and one with a cord blood bank (if applicable) in the application package and indicate that			

				similar agreements exist with the other donor centres/cord blood banks. • The policy/procedure to monitor donor centre/cord blood bank compliance with applicable WMDA Standards • If audits are performed, an audit checklist or form to document that it checks for compliance with all of the relevant WMDA Standards *Note*: If national laws and regulations define the roles and responsibilities, it is not necessary to repeat this information in the agreement; however, the application should include documentation of these laws and regulations. *Note*: It is not necessary to mention the WMDA within the document as long as the registry is clear as to the requirements that must be met.			

1	1.07		The registry must ensure that transplant centres affiliated with the registry and requesting a donor from another country meet standards designed to ensure that donation of HSC will only be requested for patients for whom transplantation is a medically acceptable procedure. The nature of these affiliations and the duties and responsibilities of each entity must be documented in an agreement.	*Note:* This WMDA Standard is also covered in the on-site audit checklist *Note:* See guidance for Standard 1.01 if a transplant centre is in a country different from the country where the registry is housed **Reference**: • Transplant center guidelines are in preparation **Explanation**: This WMDA Standard focuses on the relationship of the registry with its transplant centres. Some registries serve as an intermediary and perform international searches for the transplant centres in their country or region. The intent of this WMDA Standard is to ensure that donors are not misused by providing stem cells for non-standard treatments. The registry is expected to have a policy to ensure that their represented			

				transplant centres are appropriately registered and/or accredited as required by applicable laws and regulations. A transplant centre accredited by FACT-JACIE meets this WMDA Standard. If a registry collaborates with a non-accredited transplant centre, the registry should have a policy with regard to which cellular therapy procedures are medically acceptable. A registry must have established a documented agreement with the transplant centres it represents. The agreement or contract must indicate the nature of the relationship, divisions of tasks performed and clearly outline the responsibilities related to compliance with the relevant WMDA Standards. It is not necessary to mention the WMDA within the document as long as the registry is clear about the requirements that must be met.			

				Information/evidence to be provided (or equivalent alternative): • The policy regarding transplant centre registration/accreditation including a process of how accreditation is assessed over time • One example of a signed agreement with a transplant centre and indicate that similar agreements exist with the other transplant centres			

1	1.07.1		These transplant centre standards should be defined by an appropriate national or international organisation. In absence of such standards, they must be defined by the registry.	**Explanation**: The registry must have established guidelines for the transplant centres that it represents (for example, transplant centres in the country or region of the registry). The guidelines can be the guidelines of international societies, like FACT-JACIE, or can be developed by the national health authority or by the registry. **Information/evidence to be provided (or equivalent alternative)**: • Source (registry, international society, etc.) of guidelines for the participating transplant centres • Guidelines if defined by the registry			

1	1.07.2		The standards for transplant centres must be readily accessible to relevant healthcare professionals.	**Explanation**: The registry must, at a minimum, list the requirements for the national or regional transplant centres affiliated with the registry such that these requirements are readily available upon request. The requirements should be available in English. They may be available on the registry's website. Alternatively, a statement that the requirements are available on request may be put on the registry's web site with a link or e-mail address. **Information/evidence to be provided (or equivalent alternative)**: • A description of how health care professionals can access the standards for transplant centres. This might be a link to the registry's webpage.			

1	1.08		If a registry relies on an independent collection centre for the collection of 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 centre complies with WMDA Standards. The nature of these affiliations and the duties and responsibilities of each entity must be documented in an agreement.	*Note:* The cord blood collection site is overseen by the cord blood bank and is covered in WMDA Standard 1.06. *Note:* This WMDA Standard is also covered in the on-site audit checklist *Note:* See guidance for Standard 1.01 if a collection centre is in a country different from the country where the registry is housed **Reference**: • Lara-Weisshaupt et al. Audits of collection and apheresis centers: guidelines by the WorldMarrow Donor Association Working Group Quality and Regulation. *B one Marrow Transplantation (2019) 54:244–257* **Explanation**: This WMDA Standard focuses on the relationship of the registry with its collection			

				centres. If a registry relies on an independent collection centre for the collection of donor hematopoietic stem cells or other donor samples, for donor medical evaluation, or for the follow-up of donors, a mechanism must be in place to have the WMDA requirements available for collection centres (e.g., a website explaining the WMDA Standards). The registry must ensure that the collection centre complies with WMDA Standards in these areas. Compliance may be monitored in different ways. In some cases, the competent authority may oversee compliance with tissue and cell requirements. In other cases, the collection centre may be accredited and audited by FACT-JACIE. In other cases, the registry itself might audit the collection centre. A registry must have a documented agreement with the collection centres it uses. The agreement or contract must indicate the nature of the relationship,			

				division of tasks performed and clearly outline the responsibilities related to compliance with the relevant WMDA Standards. It is not necessary to mention the WMDA within the document as long as the registry is clear as to the requirements that must be met. **Information/evidence to be provided (or equivalent alternative)**: • An example of a documented agreement with a collection centre and indicate that similar agreements exist with the other centres. • The policy for compliance of the collection centre with relevant WMDA Standards • If audits are performed by the registry: an audit checklist or form. It is not necessary to submit a completed checklist/form.			

				Note: If national laws and regulations define the roles and responsibilities, it is not necessary to repeat this information in the agreement; however, the application should include documentation of these laws and regulations.			

1	1.09		The registry must have a policy and procedure to review WMDA recommendations.	*Note*: Provide with the shortened application *Note:* This WMDA Standard is also covered in the on-site audit checklist **Reference**: • WMDA publications and other unpublished recommendations **Explanation**: The registry must have a policy to be aware of new WMDA recommendations and is expected to have a procedure to crosscheck them with the registry's policies and procedures. The registry does not have to comply with the recommendations but it needs to consider the recommendations and adopt them, if appropriate. The policy should include who is responsible and the time frame for routine review. If the registry is already qualified or accredited by WMDA, the report from the last WMDA external review may contain	x	o	o

				recommendations for change. This report should be used to guide the registry toward strengthening its compliance with WMDA Standards. Regular participation in the WMDA working groups may be helpful to be aware of WMDA recommendations but cannot replace a written policy/procedure. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure for review of WMDA recommendations • If the registry has already been qualified or accredited by WMDA, a copy of the last external review report; describe how the registry has responded to any weaknesses noted in that report			
2	**2**		2. General organisation of the registry				

2	2.01	x	**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.**	**Benchmark standard** **Reference**: • A gift for life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 1 General organisation of a registry **Explanation**: The registry must be able to provide evidence of its legal identity. Is the organisation a private foundation, a public entity recognised by the Ministry of Health, a not-for-profit organisation, or a service unit inside a hospital/university? The document to be provided might be articles of incorporation, articles of association, certificate of society or a national law forming the organisation. The document may be in the national language of the country, but the registry should include the document in their submission. It would be helpful to identify and/or translate the sentences in			

				the document that are most relevant to establishing the legal identity or to provide a short paragraph describing the document. It is not necessary to translate the entire document. **Information/evidence to be provided (or equivalent alternative)**: • Evidence of the registry's legal identity			

2	2.02	x	**The authorised official of the legal entity is responsible for ensuring the registry's compliance with the WMDA Standards. The authorised official must authorise all official documents.**	**Benchmark standard** **Explanation**: The authorised official is an individual taking responsibility for the registry's compliance with WMDA Standards, and who may also be authorised to accept legal agreements on behalf of the registry. This individual is also responsible for ensuring that all the entities performing work for the registry fully abide by all the national laws/regulations and WMDA Standards. The authorised official is someone who holds a senior position in the registry (e.g., registry director, chief executive officer, chief financial officer, or chair of the board overseeing the registry). If the registry is included within a larger entity like a hospital, the authorised official should be someone directly responsible for the operation of the registry (i.e., it does not have to be the head of the hospital).			

				Information/evidence to be provided (or equivalent alternative): • The name and title of the authorised official clearly documented, preferably in the organisational chart of the registry • The cover sheet of the WMDA application *Note*: Other main registry agreements (for example: Service Level Agreements) provided to document compliance with other standards may be signed by the authorised official depending on the structure of the registry.			

2	2.03		The director or key registry personnel must have demonstrated experience in program administration in a health care setting.	**Explanation**: At least one key person in the registry (for example, person in management or member of the executive committee of the registry) is expected to have experience in program administration within a health care related setting. The percent of effort for this individual should be sufficient according to the workload of the registry. There are no specific guidelines for the required percentage effort. **Information/evidence to be provided (or equivalent alternative)**: • The name, title and percent effort of the program administration expert, preferably in the organisational chart of the registry • The curriculum vitae (CV) or a description of credentials and experience of this individual demonstrating			

				sufficient training and experience in program administration within a health care related setting *Note:* inform the key registry personnel that their CV is uploaded on the WMDA Share for the purpose of a registry application and will be reviewed by the review team			

2	2.04	x	**The director or key registry personnel or consultants must have expertise in human histocompatibility and hematopoietic stem cell transplantation and cell therapies as documented by the relevant education and experience. At 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 HLA specificities (serologic and DNA-based) and haplotypes, and possess a knowledge of transplant centre, donor centre, collection centre, cord blood bank (if applicable), and registry protocols in their own country and abroad.**	**Benchmark standard** **Explanation**: At least one key registry person (for example, person in management or member of the executive committee of the registry) must have knowledge of and experience in hematopoietic stem cell cellular therapy. This could be the registry director or another key registry person (for example, chief medical officer). One key person must be a physician. The physician should be appropriately licensed to practice medicine in the country and have specialist registration or completed higher specialist training in one or more of the following specialties: hematology, medical oncology, immunology or pediatric hematology/oncology. While the physician described above may also be knowledgeable about histocompatibility, the registry might also employ an individual with			

				experience in histocompatibility. If the registry does not have a key person with this specific knowledge, the registry must have direct access to a consultant with knowledge of and experience in histocompatibility (HLA) assessment. Percent of effort for these individuals should be sufficient according to the workload of the registry. There are no specific guidelines for the required percentage effort. These individuals should participate in continuing medical or professional development opportunities in relevant areas such hematology, cellular therapy, donor safety, immunology, quality management. **Information/evidence to be provided (or equivalent alternative)**: • The name, title and percent effort of the expert(s), preferably in the organisational			

				chart of the registry • The curriculum vitae (CV) or description of credentials and experience of these individuals demonstrating sufficient training (e.g., medical degree for the physician), experience (e.g., list of publications) in HLA and/or hematopoietic stem cell cellular therapy, and continuing education *Note:* inform the key registry personnel that their CV is uploaded on the WMDA Share for the purpose of a registry application and will be reviewed by the review team			

2	2.05		The registry must have a qualified and trained healthcare professional readily available to assist with routine medical decisions regarding donor selection and donation.	**Explanation**: The registry must have an individual assisting with donor selection and donation in specific situations, such as abnormal laboratory results of the donor, abnormal medical history, specific requirements of the transplant centre, etc. This person(s) should be experienced in donations and/or transplant medicine. The person(s) may be an employee of the registry or an independent contracted person(s). The individual(s) must be readily available to assist in routine decisions. Percent of effort for this individual should be sufficient according to the workload of the registry. There are no specific guidelines for the required percentage effort. The individual(s) should participate in continuing medical or professional development opportunities in relevant areas such hematology,			

				cellular therapy, donor safety, immunology, quality management. **Information/evidence to be provided (or equivalent alternative)**: • The curriculum vitae (CV) or description of credentials/academic degree(s) and experience of the health care professional demonstrating relevant training and/or experience in donation and/or transplant medicine • Policy or procedure(s) describing the utilisation of this role within the registry processes, if available • Description of the process and average time required to access the individual(s) when assistance is required *Note:* inform the healthcare professionals that their CV is uploaded on the WMDA Share for			

				the purpose of a registry application and will be reviewed by the review team			

2	2.05.1		The registry must have a procedure to access a medical review panel to assist the registry with making unbiased decisions regarding nonstandard, high risk or experimental hematopoietic stem donation or other related procedures.	**Explanation**: A group of medical professionals with sufficient experience in transplant medicine will help the registry make qualified and unbiased/independent decisions in non-standard situations like developmental transplant indications, requirements of cell processing, second and subsequent donations, cryopreservation of the stem cells (due to emergency situations), participation in medical trials. These professionals may also be utilised by the registry for development of policies and procedures, standard indications for transplants, etc. **Information/evidence to be provided (or equivalent alternative)**: • Procedure or policy describing the role of the medical panel within the registry and the process for accessing these professionals			

				• The names, positions and credentials/academic degrees of the members of the medical review panel *Note:* inform the medical review panel that their CV is uploaded on the WMDA Share for the purpose of a registry application and will be reviewed by the review team			

2	2.06		The registry must have direct access to expert consultants in the areas pertinent to the operation of the registry to assist the registry in establishing policies and procedures.	**Explanation**: Direct access to internal personnel and/or external expertise/consultants will help the registry to establish various policies and procedures the registry needs for daily operations, particularly to be in compliance with national laws and international standards. These experts may be, for example, a lawyer, accountant, tax advisor, IT expert, infectious disease expert, quality management expert. Registries are not required to have internal expertise in all these areas. **Information/evidence to be provided (or equivalent alternative)**: • A list and/or organisational chart describing the internal and external expert individuals the registry consults with for key areas of their operations • For critical areas, such as an			

				individual responsible for the registry's IT system, quality management system, etc., provide the curriculum vitae (CV) or description of the individual's credentials/academic degree(s) and relevant experience *Note:* inform the involved persons that their CV is uploaded on the WMDA Share for the purpose of a registry application and will be reviewed by the review team			

2	2.07		The registry staff must be trained and knowledgeable about their duties. The registry must conduct and document staff training and maintain training records.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: Policies/procedures should be established for identifying training needs and for providing operational training and continuing education for registry staff. The staff of the registry must be educated and trained according to their level of responsibility. A system of training for existing staff/new staff and for ongoing competency should be implemented. In addition to operational training processes, key registry personnel should be encouraged to participate in continuing education activities such as reviewing publications and attending lectures and conferences. Education and training activities must be documented including date, topic of training/education, name of trainee(s)/attendee(s).			

				Information/evidence to be provided (or equivalent alternative): • Quality manual, policy and/or procedure(s) that describes the registry's training system • A list of general educational opportunities provided in the last year, for example, a yearly registry meeting with education lectures, external conferences, etc.			

2	2.07.1	x	**At least one member of the registry staff must be able to communicate in English and be available as needed to facilitate international searches.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: List the individual(s) and their English skills. The registry should also describe how it ensures that there is an English-speaking staff member available for international searches, considering that there may be assistance required outside of normal work hours. **Information/evidence to be provided (or equivalent alternative)**: • Name of the English speaking person(s) responsible for facilitating international searches • Indicate if English is the person's native language and, if not, provide documentation of their language skill. Examples of			

				documentation include: (1) A college transcript with credits for English language courses; (2) An internationally recognised education or training certificate as provided by TOEFL or International English Training System (IELTS); or (3) A curriculum vitae (CV) and/or description of the person's experience demonstrating a significant time undertaking training or education in an English-speaking country • Describe how English language support is provided for searches that might require assistance outside of normal work hours.			

2	2.08	x	**The registry must retain a staff large enough to assume the volume and variety of services required to perform international searches within a timeframe in accordance with WMDA metrics for unrelated donor search while maintaining the confidentiality of patient and donor.**	**Benchmark standard** *Note*: Provide with the shortened application **Reference**: • Key Performance Indicators (KPI) from the WMDA Global Trends Report (https://data.wmda.info) • WMDA Share webpage with KPI Information **Explanation**: The staff of the registry at all levels must be large enough to perform all services required for international searches within an adequate time frame as recommended by WMDA metrics (KPI). **Information/evidence to be provided (or equivalent alternative)**: • An organisational chart of the registry listing key departments and their responsibilities. It is not necessary to list every member	x	x	

				of the registry but the chart might indicate the number of individuals in each department. The chart might also list the names of key registry personnel such as the director, the business administrator, and the physician expert. • Include information on the percent of efforts of the key registry personnel • Policy or procedure used by the registry to ensure that staff activities related to a patient and their donor are separated to provide confidentiality • Description of any staff size/resource-related factors/actions being taken by the registry or its associated entities to address time-based KPIs not meeting the			

				WMDA target values			
2	2.09	x	**The registry must have a fixed physical location.**	**Benchmark standard** *Note*: Provide with the shortened application **Explanation**: The registry must have a full/street address (not a PO box) where the registry is physically located. **Information/evidence to be provided (or equivalent alternative)**: • The complete address of the registry to which correspondence or materials might be sent	x		

2	2.09.1		The location must have sufficient space to ensure that all work can be carried out in an environment designed to minimise errors, reduce risks to health and safety, and maintain confidentiality.	*Note*: This WMDA Standard is covered in the on-site audit checklist **Explanation**: The physical working environment must be conducive to safe and healthy working. The space must also be of sufficient size/layout to protect confidentiality of patient and donor written and spoken information (for example, visibility and accessibility to electronic and hard copy files, privacy during phone conversations, etc.). **Information/evidence to be provided (or equivalent alternative)**: • A floor plan/map or description of the space occupied by the registry showing the general working areas and facilities (including the dimensions of the areas in square feet or meters). Indicate on the map how some areas might be physically separated to ensure			

				the confidentiality of data. *Note*: the registry may provide a very general map if it has security concerns.			

2	2.10		The registry must have a system of quality management to assess, ensure, conduct and improve the quality of its operations.	*Note* : An ISO-9001 certificate of the registry's operations/quality system may be provided as sole evidence of compliance (described below) *Note*: Provide with the shortened application *Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference:** • WMDA Quality Manual (word template) • WMDA key performance indicators from the WMDA Global Trends Report **Explanation**: A system of quality management is required to ensure a registry meets basic quality management requirements set forth by regulatory and voluntary accreditation entities, and contributes to well-functioning internal	x		

				operations and processes. The quality management system can be documented, for example, in a quality manual, operations manual and/or other policy(ies) or procedure(s). The WMDA quality manual template describes the elements of a quality management system with the following broad topics: (1) general organisation information; (2) personnel; (3) work environment, equipment and safety; (4) key processes; (5) documents and records management; (6) problem management; (7) suppliers and services management; (8) information management; and (9) monitoring and review. The quality system should also include risk management and a strategic plan as described in separate WMDA Standards. **Information/evidence to be provided (or equivalent alternative)**:			

				• If the registry is ISO-9001 accredited, it can provide a copy of its certificate as evidence of compliance with this WMDA Standard and is not required to submit additional evidence of compliance. Note: If the registry is part of a larger organisation, the ISO certificate must include the registry operations/quality system. • The quality manual or alternate document(s) containing information about the registry's quality system • The name and credentials of the individual who oversees quality management, preferably documented on the organisational chart • The procedure(s) that details the registry's			

				document and records management processes • The procedure(s) that details the registry's problem/incident management processes • Evidence that the registry carries out regular systematic monitoring of its operational activities, for example, by providing a blank internal audit checklist and an auditing timetable. It is not necessary to show a checklist that has been completed, just the form. • WMDA key performance indications (KPI) compared to the expected level. This can be provided in the application as a screen shot. Provide information about contributing factors and/or			

				actions being taken by the registry to address KPIs not aligned to the WMDA target values.			

2	2.10.1	x	**The registry must maintain documented policies and procedures for all processes performed in the registry. This must include manual of operations, standard operating procedures, and forms.**	**Benchmark standard** *Note*: Provide with the shortened application the table of contents and the operations/quality manual **Explanation**: The registry must have evidence of standard operating procedures (SOP) (i.e., work instructions) for all of its procedures. The over-arching manual of operations, together with SOPs and further policies, should comply with national laws and should meet or exceed benchmark standards promulgated by the WMDA and national regulatory agencies. These policies and procedures ensure that all registry activities are consistent with established requirements. At a minimum, the registry SOPs and policies should cover the following items: • Donor recruitment • Donor consent • Donor characterisation	x		

				• Donor evaluation • Donor confidentiality • Information management • Search procedures • Subsequent donations • Collection, processing and transport • Follow-up of patient and donor • Financial and legal responsibility *Note*: If the registry does not have already implemented written policies and procedures, it will be impossible to prepare them after submission of the letter of intent. They should be prepared in advance of the sending a letter of intent to the WMDA office. **Information/evidence to be provided (or equivalent alternative)**: • A table of contents listing the titles of all the registry SOPs • The registry's operations manual and/or			

				quality manual as applicable • Applicable sections of key SOPs and operations/quality manuals that relate to WMDA Standards should be translated into English and provided within the responses to specific WMDA Standards as evidence of compliance			

2	2.10.2		The registry should have a plan to provide crisis response, business continuity and disaster recovery.	**References:** • Pingel et al. World Marrow Donor Association Crisis Response, Business Continuity, and Disaster Recovery Guidelines. *Biology of Blood and Marrow Transplantation (2012) 18:1785-1789* • WMDA International Emergency Task Force **Explanation**: It is important that the registry be prepared for emergencies and has developed a plan for how it will cope with the situations. Emergencies could include, for example, an epidemic where many key staff are ill and unable to work, a fire that destroys the workplace, a strike that prevents air travel, or a breakdown of the IT system.			

				Information/evidence to be provided (or equivalent alternative): • Table of contents from operational business continuity and disaster recovery plans to provide the registry responses to emergency situations			

2	2.10.3		(NEW) The registry should have a documented risk management plan to mitigate against risks, and processes to manage risks or incidents should they arise.	*Note*: Provide with the shortened application **Explanation**: As part of the quality management system, the registry should have a documented risk management plan which includes: (1) ongoing identification of risks which may cause a deviation from expected process or strategic outcomes; (2) assessment of the likelihood and impacts of potential risks; (3) a plan to prevent and/or mitigate risks; (4) a plan for management of risks/incidents should they occur; (5) a process for regular review and assessment of records to identify recurring problems, potential points of failure, or need for process improvement. **Information/evidence to be provided (or equivalent alternative)**: • Document (policy or procedure) describing the registry's risk management plan	x	o	o

2	2.10.4		(NEW) The registry should have a strategic plan.	*Note*: Provide with the shortened application **Explanation**: The registry should have a documented strategic plan that defines their operational and quality objectives and defines the organisation-wide actions needed to achieve those goals. The strategic planning process should consist of the following elements: (1) developing an understanding of the current internal and external environments; (2) defining a high level strategy and a basic organisational level strategy; (3) operational planning and identification of specific action items; (4) ongoing refinement and evaluation of performance, culture, communications, data reporting, and other strategic management issues. **Information/evidence to be provided (or equivalent alternative)**: • Document (policy or procedure)	x	o	o

				describing the registry's strategic plan			
3	**3**		3. Donor recruitment, consenting, screening and testing of donors				
3			**Recruitment**				

3	3.01		The registry must ensure that entities involved in donor recruitment meet applicable laws and regulations.	**Explanation**: Donor recruitment processes differ considerably between and within registries, including the target groups they focus on. Some registries include donor centres that vary in their recruitment targets. This WMDA Standard requires the registry to explain the legal framework in which donor recruitment takes place. **Information/evidence to be provided (or equivalent alternative)**: • If local regulations that guide recruitment exist, copies of relevant sections must be provided by the registry in their application. If the regulations are not written in English, label and translate any relevant phrases or provide a short summary in English. • If no specific legislation applies or if it is not very			

				detailed, policies and procedures outlining how donors are recruited and how the registry or its affiliated donor centres comply with national health and safety regulations/guidelines			

3	3.02		Recruitment of donors must be performed by professionals trained for recruitment, under the direction of individuals who are experienced in recruitment of donors and in management activities including education, consenting, counselling, 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.	**Reference**: • Schmidt et al. Qualifications and training of adult stem cell donor recruiters: recommendations by the World Marrow Donor Association. *Bone Marrow Transplantation (2013) 48(1):148-50* . **Explanation**: A head of recruitment manages the work of recruiters. They are responsible for: • Controlling the recruitment processes • Decisions on specific recruitment activities • Supervision of recruiters including volunteer recruiters • Training and education of recruiters A recruiter is an individual who is actively			

				involved in the stem cell donor recruitment process and who communicates directly with potential new donors regarding the recruitment and/or role of potential donors. Recruiters may be employees of donor registries or donor centres or volunteers. Recruiters are responsible for: • Counselling of potential stem cell donors • Checking donor eligibility • Collection of donor informed consent and donor identification data • Maintaining authenticity, integrity and confidentiality of donor data • Collection of samples for HLA typing The recruiters must receive adequate training and educational material. Training elements are: importance of the task, functions of the donor registry/donor centre,			

				registration process including donor eligibility criteria, when to defer donors, informed consent/confidentiality issues, sample collection. The training of the recruiters must be documented, for example, in staff personnel training records. **Information/evidence to be provided (or equivalent alternative)**: • Curriculum vitae (CV) or a description of credentials and experience of the individual(s) who is the head of recruitment • A policy describing the training procedures for recruiters and supervisors • Training manual for recruiters *Note*: The registry does not need to provide an example of individual training records. *Note:* inform the head of recruitment that CV is			

				uploaded on the WMDA Share for the purpose of a registry application and will be reviewed by the review team			
3			**Donor rights**				

3	3.03	x	**The willingness to become a donor must be the individual choice of each donor, 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 and may be reimbursed for expenses incurred during the donation process.**	**Benchmark standard** **References**: • Boo et al. Remuneration of hematopoietic stem cell donors: principles and perspective of the World Marrow Donor Association. *Blood (2011) 117(1):21-5* . • Bakken et al. Donor commitment and patient needs. *Bone Marrow Transplantation (2004) 33(2):225-30* • Shaw et al. Donor safety: the role of the WMDA in ensuring the safety of volunteer unrelated donors: clinical and ethical considerations. *Bone Marrow Transplantation (2010) 45(5):832-8* **Explanation**: The purpose of this WMDA Standard is to			

				ensure that every donation is voluntary and altruistic. The donor must understand that the patient might live in another country. Reimbursement should be documented within the policy of the responsible registry and may include loss of earnings or travel to the collection centre. Reimbursement of expenses should be discussed with donors at the time of selection for transplant. **Information/evidence to be provided (or equivalent alternative)**: • A translated version of the registry's informed consent and a recruitment brochure that includes a statement about the volunteer/ altruistic nature • Donor reimbursement policy • English translation of the checklist or form where the donor is informed about			

				reimbursement. It is not necessary to include a completed form.			

3	3.04	x	**Donors must be informed regarding their potential role in the donation of hematopoietic stem cells, the risks involved in the donation, and the tests that the donor may undergo.**	**Benchmark standard** **References**: • A Gift for Life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 2 Recruitment of volunteer donors • Shaw et al. Donor safety: the role of the WMDA in ensuring the safety of volunteer unrelated donors: clinical and ethical considerations. *Bone Marrow Transplantation (2010) 45(5):832-8* **Explanation**: The donor must be informed about their potential role in the donation. Information may be given through literature, video, telephone or face to face. Written information should be provided to reinforce all other forms of communication. The information may be on			

				consent forms and/or in educational material. The level of detail of the information may vary depending on the stage of the process i.e., less information at recruitment and more at workup. The donor should be provided with information on the principles, general procedures, restrictions and risks of providing blood samples and hematopoietic stem cells (either via bone marrow or peripheral blood stem cell donation). At no time should the information be coercive. The registry should have a policy in their operational manual explaining the documentation given to the donor at the time of registration, and at the time of workup (and at other steps if available). The registry should also describe who is responsible for the donor education and how they ensure that the donor is well informed (e.g., the role of donor advocates; who should protect and			

				promote the interests, well-being and safety of the donor) **Information/evidence to be provided (or equivalent alternative)**: • The donor information policy • Example(s) of donor information provided, detailing risks involved			

3	3.05	x	**Donors must be informed about the use of any medical intervention and its known risks and/or side effects.**	**Benchmark standard** **References**: • Pahnke et al. Current use of biosimilar G-CSF for hematopoietic stem cell mobilisation. *Bone Marrow Transplantation (2018) doi: 10.1038/s41409-018-0350-y* • Mobilising agents (G-CSF) • Donor Medical Suitability Wiki **Explanation**: The donor may be exposed to risk through medical intervention such as the administration of G-CSF (granulocyte colony-stimulating factor) or the insertion of a central venous catheter. It is important that any donor receives information as to the potential risks. **Information/evidence to be provided (or equivalent alternative)**: • Information given to the donor			

				regarding these risks			

3	3.06	x	**A donor must be free to withdraw at any time.**	**Benchmark standard** **Reference**: • Bakken et al. Donor commitment and patient needs. *Bone Marrow Transplant. 2004 Jan;33(2):225-30* **Explanation**: The registry must include in donor information that hematopoietic stem cell donation is undertaken voluntarily, and that withdrawal is permitted at all times. The registry should describe this in its operational manual. The consent forms and/or educational material must also include this information. **Information/evidence to be provided (or equivalent alternative)**: • Policy on withdrawal • Donor information and consent forms that state the ability to withdraw			

3	3.07	x	**To ensure confidentiality, the identity of donors must be protected. The registry must have policies and procedures in place to ensure donor confidentiality.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: Each registry must have a well-defined policy on preserving donor confidentiality, as the identity of the donor must be protected from disclosure. This policy outlines who has access to the donor information and how the access is controlled. For example, the policy should include the assignment of an anonymous identifier to the donor so that their identity can be protected during the search process. Some countries might have a privacy law. If a privacy law applies, the registry should describe the impact of the law on the registry's confidentiality policy. **Information/evidence to be provided (or equivalent alternative)**:			

				• Policy about confidentiality • An example of an anonymised search report to demonstrate compliance			

3	3.08		The donor has the right to receive the results of any health screening affecting their health status. The registry must have a policy regarding the provision of such information.	*Note* : Provide with the shortened applica tion **Explanation**: The registry must have a policy describing how the donor is given the results of their health screening. The policy should describe how donors will be informed of serious positive Infectious Disease Marker (IDM) results or other abnormal medical findings and how they will be counseled as to the impact and implications of the findings and any consequences that there might be to his/her health. The method of communication should be appropriate to the situation. **Information/evidence to be provided (or equivalent alternative)**: • Policy about how donor is informed • If available, standard operating procedure or form	x	o	o

3			**Counselling, timing and format of consent**				

3	3.09	x	**Valid informed consent must be obtained initially at the time of recruitment.**	**Benchmark standard** **References**: • Boo et al. Remuneration of hematopoietic stem cell donors: principles and perspective of the World Marrow Donor Association. *Blood (2011) 117(1):21-5* . • Bakken et al. Donor commitment and patient needs. *Bone Marrow Transplantation (2004) 33(2):225-30* • Shaw et al. Donor safety: the role of the WMDA in ensuring the safety of volunteer unrelated donors: clinical and ethical considerations. *Bone Marrow Transplantation (2010) 45(5):832-8* **Explanation**: The wording of the consent form will vary			

				according to the legal requirements of the country. However, it is recommended that the consent form (and/or the donor informational material) cover the information listed in the counselling standard below. The registry must ensure that donors sign/electronically submit a consent form at recruitment. **Information/evidence to be provided (or equivalent alternative)**: • Consent form used at recruitment. Translation into English of the consent forms will be required. *Note*: It is not necessary to include a signed/completed form, avoid to share personal data			

3	3.10	x	**Donors must be counselled when selected for further tests and when selected as a donor for a specific patient.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy that details: (1) The information to be provided to the donor; (2) At which stage in the process the information is provided; and (3) How information is provided (i.e., verbally or by means of a printed leaflet, etc.). The registry's consent forms should include appropriate information on the risks of donation. The consent forms themselves do not have to contain descriptions of the risks providing appropriate reference is made to other documents where the risks are described. The consent documents will be in the national language of the country. The consent and other information documents should cover the risks of each type of donation (bone marrow, peripheral			

				blood, cord blood unit) as appropriate. The registry is also expected to have donor information documents. **Information/evidence to be provided (or equivalent alternative)**: • Donor consent form • Donor information material in the national language of the country and an English translation of the relevant portions			

3	3.10.1		Counselling for donors selected for specific patients must include anonymity of the donor and patient, requirement forfurther blood samples before donation, requirement for infectious disease and other testing, risk of donation, possible duration of loss of time from normal activities and duration thereof, location of the collection, the potential 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 cellular products, alternative collection methods and whether blood or other biological material is reserved for research purposes.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • Bakken et al. Donor commitment and patient needs. *Bone Marrow Transplantation (2004) 33(2):225-30* **Explanation**: The registry is expected to have a policy indicating the elements to be included within their donor counselling process. These elements must, as a minimum, include: • the principles and risks of donation • donation for any recipient in need, including an international patient • donation not being remunerated • anonymity of the donor and patient, the			

				confidentiality of personal data • requirement for further blood samples before donation • requirement for infectious disease and other testing (e.g., HLA), possibility that some of the sample material may be stored for an indeterminate period for the purposes of undertaking further HLA typing and IDM testing • HLA type, blood group, and IDM (identifiable only through a unique and anonymous donor identification number) being available to international registries and transplant centres • the implications of transmission of infectious and other diseases from donor to patient • possible duration of loss of time			

				from normal activities • location of the collection • requirement for collection of autologous blood, if there is any • 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 collection methods and whether blood is reserved for research purposes If the counselling is undertaken by a third party, the registry is expected to ensure compliance through the use of, for example, approved checklists, service level agreement, and/or audits. The registry may also indicate in the donor information that the donor is free to have a third party (donor			

				advocate, family member) included during the donation process. **Information/evidence to be provided (or equivalent alternative)**: • Consent forms and donor informational material and any forms or checklists used in counselling the donor. Translation into English of the consent forms will be required.			

3	3.11	x	**Valid signed informed consent must be obtained from donors at the time of workup.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The wording of the workup consent form will vary according to the legal requirements of the country. However, it is recommended that the consent form confirms the following: • The donor has discussed, with a suitably qualified person, the collection procedures permissible, and understands the related risks (e.g., anaesthesia, infection, possibility of short- and long-term adverse effects of hematopoietic growth factors) • The donation method elected by the donor or requested by the transplant centre			

				• All information has been given in a clear and understandable manner and opportunity provided to ask questions and have these answered fully and satisfactorily • The volunteer's right to withdraw consent and the volunteer's understanding of the consequences for the patient if he/she withdraws consent after the transplant protocol has commenced • The hematopoietic stem cells will be received by an anonymous recipient. The patient must remain anonymous permanently if the patient elects this or if it is the policy of the responsible registry. • A further blood sample will be taken to test for infectious disease			

				markers (IDM). The donor should be asked to clarify the manner in which he/she would wish to be informed of a positive result. • The donor will be contacted after the donation to ensure that the donation has had no ill effects. **Information/evidence to be provided (or equivalent alternative)**: • Workup consent form translated into English. It is not necessary to include a completed form.			

3	3.11.1		Informed consent documents must meet established criteria. 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. Documentation must be in a language understood by the donor and, at workup, must include the signature(s) of qualified staff involved in donor counselling.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The informed consent processes vary among registries and cord blood banks. It is important that the registry describe in their policy how they comply with national regulations and relevant WMDA Standards. **Information/evidence to be provided (or equivalent alternative)**: • Copies of unsigned consent forms used at various stages of donation and English translations • Informational brochures given to the donor at various stages with an English translation of the relevant portions • The registry's policy on informed consent			

3	3.12		The identity of the donor must be verified, at a minimum, at workup and at collection, by the qualified staff signing the consent form.	**Explanation**: The registry is expected to have a procedure to verify the donor's identity. This can be done by the physician who performs the medical health examination/checkup or by a person from the registry/donor centre who is conducting/performing the donor information session. In some countries it is general practice that donors are asked for identification information e.g., the individual's unique social security number. **Information/evidence to be provided (or equivalent alternative)**: • Standard operating procedure to verify identity • A document used when donor identity is verified (e.g., form, checklist) with a line for staff signature			

3	3.13	x	**Valid signed informed 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.**	**Benchmark standard** **References**: • King et al. Unrelated hematopoietic stem cell donors as research subjects reference on research. *Bone Marrow Transplantation (2011) 46:10–13* • WMDA Form (F10 Formal request and prescription for HPC-Marrow; HPC- Apheresis and/or MNC-Apheresis) **Explanation**: The donor has the right to know if their information, samples or products are to be used in other ways than for the standard management of the patient. This is reflected in the WMDA prescription and verification forms where a disclaimer states that the cell products collected from a donor are intended solely for the purpose of therapeutic treatment for a patient, and no other			

				uses of these cells are permissible. In addition, laws of individual countries frequently also regulate the usage of human blood or cells, particularly when samples or products are shipped abroad. The registry should explain if the use of information or biological material for research studies is allowed by law and/or by the registry itself, and under which conditions. If it is allowed, the registry should have a procedure to provide the donor with appropriate information. An appropriate research consent form must be signed by the donor prior to the collection of any biological samples or donor information for research. **Information/evidence to be provided (or equivalent alternative)**: • Standard operating procedure for collection of research samples • If applicable, an example of a			

				research consent form			
3	3.14	x	**Consent documents signed by donors must be available for review by individuals designated by the registry or national authorities to evaluate the registry.**	**Benchmark standard** **Explanation**: Since consent documents must be available, the registry should define the procedures and responsibilities for storing signed consent forms. The registry should have easy access to these forms for review by individuals authorized to evaluate the registry. **Information/evidence to be provided (or equivalent alternative)**: • Standard operating procedure regarding availability of signed consents • Service level agreements relating to any off-site storage of consent forms			
			Donor characteristics				

3	3.15	x	**Information on donor age and gender must be collected at the time of recruitment.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry should have a policy regarding information about the donor collected at the time of recruitment. This must include collecting information on donor age and gender. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure regarding collection of age and gender information • An anonymized search report showing that age and gender of donors are reported			

3	3.16	x	**Prospective donors selected for hematopoietic stem cell collection must have passed a minimum age established by applicable law or their 18th birthday if no local regulations exist.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry should have a policy concerning age limits for donation in accordance with applicable regulations. The WMDA recommends that a donor must have reached a minimum age of 18 years old. A registry may accept donors younger than 18 if their national law allows it. Lower age limits should be outlined in donor information brochures and detailed in the policies and procedures of the registry. **Information/evidence to be provided (or equivalent alternative)**: • Policy and/or excerpt from applicable law addressing minimum age • Sample of donor information materials			

				describing age limits			

3	3.16.1		The upper age limit for prospective donors selected to donate hematopoietic stem cells should not exceed sixty (60) years. The registry must have a policy and procedure to remove donors from the registry.	*Note*: Provide with the shortened application **Explanation**: The upper age limit for donation should be detailed in the registry's policies and procedures and included in donor education materials. Note that this WMDA Standard applies only to donors unrelated to the patient. **Information/evidence to be provided (or equivalent alternative)**: • Policy and/or procedure regarding upper age for donation • Policy and/or procedure how to remove donors from the registry when they pass the upper age limit • Sample of donor information materials addressing age • Recent copy of processing report of Search & Match Service indicating donor age • Anonymised search report	x	o	o

				showing the age of a donor			
			Donor testing				

3	3.17		Testing must be carried out by laboratories that meet standards established by local regulation.	**Explanation**: The testing described in this WMDA Standard refers to all forms of testing such as HLA typing, blood group and infectious disease testing. The registry should have a policy and/or procedure to ensure that the testing performed on the donor's sample is performed in compliance with national and/or international guidelines. It is recommended that each testing laboratory be licensed and/or accredited by a national or international regulatory agency and participate in a national or international quality programme. The participation in an external proficiency-testing programme alone is not sufficient to ensure quality. The registry should have a procedure to ensure that accreditation of testing entities is current. **Information/evidence to be provided (or equivalent alternative)**:			

				• The registry should indicate the approximate number and types of laboratories contributing data to the registry • If national regulatory programmes, the registry should provide a broad description of the accreditation requirements and describe the accrediting organisations • If the registry works with more than one testing entity, only one example of a certificate for each testing type might be provided although the registry must indicate if similar certificates exist with all entities. For example, provide one accreditation certificate from an infectious disease-testing laboratory, one accreditation certificate from a blood group typing laboratory,			

				one from an HLA typing laboratory. The registry should ensure that the certificate provided is not out of date. • Policy or procedure for ensuring that accreditation of testing laboratories is current			

3	3.17.1	x	**Testing must be carried out in a manner to ensure the accuracy of the data.**	**Benchmark standard** **Explanation**: The registry should have a policy or procedure to ensure that the donor test results (HLA, infectious disease, blood group, etc.) are accurate. This might include a requirement for the laboratory to be accredited and a process to ensure that accreditation is current. The registry might also have other procedures to ensure accuracy, for example, double entry of data, electronic data transfer, process to retest a subset of samples, etc. **Information/evidence to be provided (or equivalent alternative)**: • Policy and/or procedure for ensuring that accreditation of testing laboratories is current • Description of processes which confirm data accuracy (may be included in different standard			

				operating procedures)			

3	3.18		Registries must have established approaches to monitor and ensure the accuracy and completeness of the data listed in the donor database, including a system to ensure the quality of HLA typing results.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • HLA discrepancy survey **Explanation**: This WMDA Standard is focused on how the registry monitors and ensures the quality of the test data that they store (HLA type, blood type, IDM). One approach the registry might take is to participate in the WMDA project surveying misassigned HLA types at the extended or verification typing stages. **Information/evidence to be provided (or equivalent alternative)**: • Document that describes how the quality of all testing data (HLA, blood type, IDM) is monitored and ensured. This might include, for example, copies of accreditation certificates or KPI			

				data from the HLA discrepancy survey.			
3	3.19		The results of the donor assessment including the results of any laboratory tests and medical evaluation must be documented and maintained.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy for documenting and maintaining donor assessment results describing method of data storage (e.g., paper, electronic) and time frames for the retention of documentation. **Information/evidence to be provided (or equivalent alternative)**: • Policy for documenting and maintaining donor assessment data *Note*: WMDA Standard requires 30 years as time maintained			
3			**Histocompatibility testing and ABO grouping**				

3	3.20		A minimum of HLA-A, -B, -C, -DRB1 DNA-based typing results must be defined prior to listing newly recruited donors.	*Note:* Provide with the shortened application *Note:* This WMDA Standard is also covered in the on-site audit checklist **Reference**: • A document on HLA typing recommendation is under development **Explanation**: The registry is expected to have a policy for HLA typing of newly recruited donors that includes a description of the HLA loci defined. The minimum standard of HLA typing in this version of standards does not apply to donors typed prior to the implementation of this WMDA Standard i.e., donors recruited prior to the effective date of this standard do not need to have further HLA testing to meet the minimum typing requirement in this standard.	x	o	o

				Information/evidence to be provided (or equivalent alternative): • Policy on HLA typing at recruitment • A search report showing the HLA typing of donors • Recent copy of a processing report of Search & Match Service that shows HLA assignments			

3	3.20.1		(NEW) The registry must use HLA testing laboratories that are capable of carrying out DNA–based intermediate and high-resolution HLA-typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), or other accrediting organisations providing histocompatibility services appropriate for hematopoietic stem cell transplantation.	*Note:* Provide with the shortened applica tion **Explanation**: The registry is expected to have a policy and procedure to ensure that the testing performed is in compliance with national and/or international guidelines. Each testing laboratory must be licensed and/or accredited by an appropriate agency and participate in a national or international quality program. The participation in an external proficiency-testing program alone is not sufficient to ensure quality. If the registry works with more than one HLA laboratory, only one example of a certificate needs to be provided although the registry must indicate if similar certificates exist with all entities. The registry should ensure that the certificate provided is not out of date.	x	o	x

				Information/evidence to be provided (or equivalent alternative): • A policy or procedure for ensuring that accreditation of HLA testing laboratories is current • Copy of an accreditation certificate from one HLA testing laboratory			

3	3.21	x	**The ABO blood group and Rh factor testing of donors must be done at the verification typing stage if the donor's blood group has not been previously determined.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy covering testing of the blood groups. This WMDA Standard emphasizes that donor blood group testing must be done at the verification typing stage at the latest. The registry's policy for testing performed at the verification stage should include a statement specifying that testing of the blood group must be performed if this has not already been done previously. If already available, retesting is not required. The registry must routinely provide the results of ABO blood group and Rh factor testing at the verification typing stage. **Information/evidence to be provided (or equivalent alternative)**:			

				• Donor testing form and/or the policy or procedure for blood group testing			
3			**Medical assessment and infectious disease testing**				

3	3.22	x	**Donor health requirements regarding the suitability of donors must be established.**	**Benchmark standard** **References**: • Lown et al. Unrelated adult stem cell donor medical suitability: recommendations from the World Marrow Donor Association Clinical Working Group Committee. *Bone Marrow Transplantation (2014) 49:880-886* • Donor Medical Suitability Wiki **Explanation**: When an individual is recruited as a donor, the primary goal is to determine if the donor is in good health to protect the donor from the risk of damage to his/her own health and to protect the recipient from transmissible diseases. It is, therefore, an essential task for the registry to establish requirements for the donor's health evaluations.			

				The requirements, types of screening provided, and medical evaluation may be different depending on the phase of the search. Information should include (1) Requirements for donor health, (2) List of infectious disease markers tested, (3) Screening done at various stages. Full medical assessment must be performed at the time of workup. **Information/evidence to be provided (or equivalent alternative)**: • Policies/procedures describing health evaluation at the different steps (registration of a new donor, verification typing, and work up) • Medical evaluation form(s)			

3	3.22.1		An initial health screening should be performed at the time of recruitment.	**Explanation**: A medical questionnaire may be completed at the time of recruitment. **Information/evidence to be provided (or equivalent alternative)**: • Health screening form used at recruitment, if available			

3	3.22.2	x	**A health screening including infectious disease testing must be performed at time of verification typing.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **References**: • Lown et al. Unrelated adult stem cell donor medical suitability: recommendations from the World Marrow Donor Association Clinical Working Group Committee. *Bone Marrow Transplantation (2014) 49:880-886* • Donor Medical Suitability Wiki **Explanation**: The administration of a medical questionnaire or other form of health screening must take place at the time of verification typing. **Information/evidence to be provided (or equivalent alternative)**:		o	o

				• The health questionnaire • Procedure outlining IDMs performed at the verification typing stage			

3	3.22.2.1		Information on the number of pregnancies (including all pregnancies, whether or not a child was born) and history of other prior sensitizing events such as transfusion must be obtained from donors at time of verification typing.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy/procedure regarding information collected at verification typing. The policy/procedure must include the requirement for an assessment of number of pregnancies and history of other prior sensitizing events. **Information/evidence to be provided (or equivalent alternative)**: • Questionnaire provided at verification typing to show that questions concerning pregnancy and other sensitizing events are included • Policy/procedure requiring assessment of sensitizing events			

3	3.22.3	x	**Policies for testing the donor selected for workup must be established and must include medical history, physical examination, and laboratory tests in order to determine the donor's fitness to donate.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist References: • Lown et al. Unrelated adult stem cell donor medical suitability: recommendations from the World Marrow Donor Association Clinical Working Group Committee. *Bone Marrow Transplantation (2014) 49:880-886* • Donor Medical Suitability Wiki **Explanation**: Every selected donor undergoes medical evaluation before donation. The registry must have a policy regarding donor health evaluation. **Information/evidence to be provided (or equivalent alternative)**:			

				• Policy for donor testing at workup • Donor health questionnaire, medical evaluation form and/or sample of report from evaluating physician			

3	3.22.3.1		This examination must be performed or supervised by a physician who is not the primary treating physician overseeing the care of the patient.	**Explanation**: The registry is expected to have a policy and/or procedure to ensure the independence of the evaluating/supervising physician. If the transplant centre seems to be the only plausible source for evaluating the potential donor, the registry must describe how they ensure that the personnel involved in the health examination session and information session with the donor are not engaged in the treatment of the patient and preferentially should have no knowledge about the patient. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure ensuring the physician evaluating the donor does not care for the patient		o	o

3	3.22. 3.2	x	**Female donors of childbearing potential must have a pregnancy test and be counselled to avoid pregnancy during the workup stage before use of mobilising agents, collection or initiation of the recipient's preparative regimen, whichever occurs first.**	**Benchmark standard** Note: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: Since pregnancy is a contraindication for donation, the registry is expected to have a policy indicating that pregnancy is a reason for temporary deferral. It is especially important that the donor realizes that once the donor begins GCSF mobilisation or the patient begins the preparative regimen, the risk to the patient becomes much greater if the donor is unable to proceed. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure on counselling the donor about pregnancy • Donor medical form and donor-counselling checklist showing that pregnancy status is discussed			

				and evaluated during the workup stage			

3	3.23	x	**The donor's medical history taken at the time of medical examination for donation must include questions to identify risk of disease transmissible through transplantation.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **References**: • Lown et al. Unrelated adult stem cell donor medical suitability: recommendations from the World Marrow Donor Association Clinical Working Group Committee. *Bone Marrow Transplantation (2014) 49:880-886* • Donor Medical Suitability Wiki **Explanation**: This WMDA Standard focuses on infectious diseases, genetic diseases (e.g., autoimmune diseases) and disseminated malignancies. Other diseases relevant to cellular therapy should also be included.			

				Information/evidence to be provided (or equivalent alternative): • Checklist of transmittable diseases (e.g., infectious diseases, genetic defects or disseminated malignancies) that is used when a donor is being evaluated for a specific patient • A procedure for how the result of the donor evaluation is conveyed to the transplant centre prior to donation			

3	3.24	x	**Infectious disease testing, as defined in 3.22.2, of donors 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 local regulation.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • Shaw et al., Donor safety: the role of the WMDA in ensuring the safety of volunteer unrelated donors: clinical and ethical considerations. *Bone Marrow Transplantation (2010) 45(5):832-8* **Explanation**: This WMDA Standard is intended to demonstrate that testing meets WMDA standards at a minimum. Additionally, required national testing is also to be listed. The transplant centre should be informed regarding the infectious disease markers that will be tested and those that may be available upon request.			

				Information/evidence to be provided (or equivalent alternative): • A list of diseases included in infectious disease testing in the registry. This documentation could be either a form used to record donor health or a copy of the procedure for this purpose. *Note*: Local practice may exclude HTLV testing from mandatory testing. In these cases, the registry needs to provide a policy outlining how HTLV testing can be organised for international recipients.			

3	3.24.1		Selected donors should be tested for local diseases that are important to consider in hematopoietic stem celltransplantation. Donors who have recently travelled outside their country should be evaluated for infectious diseases prevalent in the areas of travel.	**Explanation**: Other regional infectious diseases may be relevant when testing a donor prior to a hematopoietic stem cell donation. **Information/evidence to be provided (or equivalent alternative)**: • A list of relevant regional diseases and a copy of a testing form, if one is used • A copy of national testing requirements may be submitted to show which additional tests are routinely performed for this reason			

3	3.25	x	**Infectious disease markers must be measured within thirty (30) days of the hematopoietic stem cell/cellular product collection and the results must be provided to the transplant centre before commencement of patient conditioning.**	**Benchmark standard** **Explanation**: Other regional infectious diseases may be relevant when testing a donor prior to a hematopoietic stem cell donation. **Information/evidence to be provided (or equivalent alternative)**: • A list of relevant regional diseases and a copy of a testing form, if one is used • A copy of national testing requirements may be submitted to show which additional tests are routinely performed for this reason			

3	3.26		The donor must be counselled in case of positive transmissible disease test results.	**Explanation**: The registry is expected to have a policy and/or procedure describing how it ensures that a donor is counselled in case there is some abnormal finding during medical evaluation. This may be described in a standard operation procedure, operations manual, or in an informed consent. The procedure should include who (e.g., a medical doctor) and how the information will be provided, and who will provide follow-up care. **Information/evidence to be provided (or equivalent alternative)**: • Policy/ procedure/form about donor counselling if medical finding			
4	**4**		4. Umbilical cord blood and maternal donor recruitment, consenting, screening, testing and review/release of cord blood units.				

4	4.01		All parties involved in maternal donor recruitment and in cord blood collection must meet applicable laws and regulations.	*Note*: If the cord blood bank is accredited by NetCord-FACT, many of the standards in this section are already covered by that accreditation (More information) **Reference**: • A Gift for Life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 6 Cord blood banking **Explanation**: This WMDA Standard requires the registry to explain the legal framework in which maternal donor recruitment and collection takes place. **Information/evidence to be provided (or equivalent alternative)** : • If local regulations that guide recruitment exist, a copy of these regulations with key			

				sections/phrases translated into English or provide a short summary in English • If no specific legislation applies or if it is not detailed, the registry's policies and procedures outlining how maternal donors are recruited and how the registry and/or its affiliated cord blood banks comply to this WMDA Standard *Note:* if your cord blood bank is NetCord-FACT accredited, you can upload here the certificate from NetCord-FACT			

4	4.02		The recruitment of maternal donors must be performed under the direction of individuals who are experienced in recruitment of maternal donors and in management activities including education, consenting, counselling, 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.	*Note*: Provide with the shortened application **Explanation**: Recruitment of maternal donors is usually carried out by a cord blood bank, cord blood collection centre or maternal donor physician. A cord blood collection site may be in a maternity unit in a hospital, a birthing clinic, or in a home environment. The collection service may be staffed entirely by employees of the cord blood bank, by health care professionals of the maternity unit/birthing clinic, or a mixture of both. A cord blood collection site may use qualified health care professionals and cord blood bank staff to perform some or all of the activities involved in recruitment, consent, donor selection, donor screening and umbilical cord blood collection. The recruiters must receive adequate training and educational material. Training elements are: importance of the task, functions of the cord	x	o	o

				blood bank, registration process including maternal donor eligibility criteria, when to defer donors, informed consent/confidentiality issues, sample collection. The training of the recruiters should be documented, for example, in staff personnel training records. **Information/evidence to be provided (or equivalent alternative)** : • A policy describing the training procedures for recruiters of maternal donors • Training manual for recruiters *Note*: The registry does not need to provide an example of individual training records *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4			**Maternal donor and infant donor rights**				

4	4.03	x	**The willingness to donate cord blood must be the individual choice of each maternal donor, that is, donations must be voluntary. The maternal donor must be willing to donate to any patient being treated in any part of the world and must not be paid for their donation.**	**Benchmark standard** **Explanation**: The purpose of this WMDA Standard is to ensure that every cord blood donation is voluntary and altruistic. The maternal donor must understand that the patient might live in another country. The willingness to donate cord blood must be an individual choice of the mother. She must have the opportunity to ask questions that clarify the process of cord blood donation and be free to withdraw at any time prior to donation. **Information/evidence to be provided (or equivalent alternative)** : • Translated version of the informed consent and/or a recruitment brochure that includes statements regarding the voluntary non-payment nature of donation and a statements regarding the			

				possibility the donation could be provided to any patient in need anywhere in the world • Any standard operating procedures or policies relevant to consent and counselling of (potential) maternal donors *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.04	x	**Maternal donors of cord blood units must be informed regarding their potential role in the donation of cord blood, the collection procedure, the long-term storage of the cord blood, the possible risks for and benefits to the maternal donor and/or infant donor, the tests to be performed on the maternal biological samples and on the donated cord blood.**	**Benchmark standard** **Explanation**: The maternal donor must be informed about their potential role in the donation. Information may be given through literature, video, telephone, via a website, or face to face. Written information should be given out to reinforce all other forms of communication. The information may be provided on consent forms and/or in educational material. The maternal donor should be provided with information on the principles, general procedures, tests performed, restrictions and risks to the maternal and the infant donors. At no time must the information be coercive. Information must be provided in a language fully understandable by the maternal donor, and ample time should be given for the donors to understand the donation process. The registry should have a policy describing the			

				documentation given to the maternal donor at the time of counselling and consenting. The registry should also describe who is responsible for the donor education and how they ensure that the donor is well informed about the donation process. **Information/evidence to be provided (or equivalent alternative)** : • Maternal donor information policy or procedure • Educational material and/or consent form that state the basic information about cord blood donation *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.05	x	**The maternal donor must be informed about the right to withdraw her consent for the donation of cord blood without prejudice at any time before delivery.**	**Benchmark standard** **Explanation**: The registry must include in maternal donor information and/or in the informed consent form that cord blood donation is undertaken voluntarily, and that withdrawal of the decision to donate is permitted up to the time of delivery. Please note that the registry may allow the mother to request removal of the unit from the bank at any time (also after delivery) and this would be permissible under this standard. The registry or cord blood bank should have a description within its policies or procedures of how withdrawal of consent pre-collection or post-banking occurs, including how banked material is discarded and the unit listing is removed from search. The consent forms and educational material should also include this information.			

				Information/evidence to be provided (or equivalent alternative) : • Policy or procedures about withdrawal • Maternal donor information and consent forms that state the ability to withdraw before delivery and, if applicable, after banking *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.06	x	**To ensure confidentiality, the identity of maternal donors and infant donors must be protected. Documented policies and procedures must be in place to ensure donor confidentiality.**	**Benchmark standard** *Note:* This WMDA Standard is also covered in the on-site audit checklist **Explanation**: Each registry or cord blood bank is expected to have a well-defined written policy or procedure describing how it ensures preservation of maternal and infant donor confidentiality, as the identity of the donor must be protected from disclosure. The policy or procedure should outline who has access to the donor information and how the access is controlled. For example, it should include a description of system used for the assignment of anonymous identifier(s) to the maternal donor and cord blood unit so that their identity can be protected during the search process. If the maternal and cord blood unit have different identifiers, a description of how			

				linkage is maintained should also be provided. Some countries or regions might have a privacy law. If a privacy law applies, the registry or cord blood bank should describe the impact of the law on the confidentiality policies or procedures of the registry and bank. **Information/evidence to be provided (or equivalent alternative)** : • An example of a search report including a cord blood unit • Relevant policies or procedures about confidentiality • Any applicable local privacy laws			

4	4.07		The maternal donor has the right to receive the results of any health screening affecting the health status of the maternal or infant donor. The registry must have a policy whether and how the maternal donor is informed.	*Note*: Provide with the shortened application **Explanation**: The registry / cord blood bank is expected to have a policy or procedure describing how the mother is given the results of the maternal and infant health screening if necessary to inform her of any health issues. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure about the maternal access to health screening results *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation	x	o	o
4			**Counselling, timing and format of consent**				

4	4.08	x	**Valid signed informed consent must be obtained and documented while the maternal donor is able to concentrate on the information and is not distracted by aspects of labour.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The wording of consent forms will vary according to the legal requirements of the country. However, it is recommended that the consent form(s) (and/or the donor informational material) cover the information listed in the counselling standard below. The registry must ensure that maternal donors are comfortable and able to sign an informed consent form prior to active labour and delivery of the infant donor. Two stage consent processes are permissible; for example, a consent form for collection of the cord blood unit could be utilized before birth and a more in-depth consent form for storage could be utilized after the birth. **Information/evidence to be provided (or equivalent alternative)** :			

				• A translated example of the recruitment consent form and the donor informational material • Relevant policies or procedures about the consenting process *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.08.1		Informed consent documents must meet established criteria. In addition to information on the collection procedure, intent of donation for unrelated use, possible risks and benefits, documents must include information on the protection of donor identity, donor data and the right of the maternal donor to medical confidentiality and to receive medical information. Documentation must be in a language understood by the maternal donor and must include the signature(s) of qualified staff involved in maternal donor recruitment.	**Explanation**: The registry/cord bank is expected to have a written policy or procedure indicating the elements to be included within their donor counselling and consenting process. These elements must as a minimum include: • the principles and risks of donation • donation for any recipient in need, including an international patient • donation not being remunerated • anonymity of the donor and patient, the confidentiality of personal data • requirement for maternal blood samples during donation • requirement for infectious disease and other testing (e.g., HLA), possibility that some of the sample material may be stored for an indeterminate			

				period for additional IDM testing and HLA typing in the future • right of donor to receive results of health screening • HLA-type, blood group, and IDM (identifiable only through a unique donor number) being available to international registries and transplant centres • the implications of transmission of infectious and other diseases from donor to patient • mother's right to withdraw the consent at any time prior to delivery If the donor recruitment is undertaken by a third party, the registry is expected to ensure compliance through the use of, for example, approved checklists, contract agreement, and audits.			

				Information/evidence to be provided (or equivalent alternative) : • Consent forms and donor informational material, forms and/or checklists used in counselling and consenting of maternal donors for cord blood donation *Note*: Do not submit any completed forms with personal data *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.09	x	**Valid signed informed consent must be obtained if maternal or infant donor blood, cord blood units or other biological material or information is stored and/or used for the purpose of an ethically approved research project.**	**Benchmark standard** **Reference**: • King et al. Unrelated hematopoietic stem cell donors as research subjects reference on research. *Bone Marrow Transplantation (2011) 46:10–13* **Explanation**: The maternal donor has the right to know if the information, samples or products are to be used other than hematopoietic cellular therapy. For example, when testing shows insufficient volume and the unit is used for research instead.The registry /cord blood bank should explain if the use of information or biological material for research studies is allowed by law and/or by the registry / cord blood bank itself, and under which conditions. If it is allowed, the registry / cord blood bank should have a procedure to provide the maternal donor with appropriate			

				information. A consent for research can be included in the cord blood donation consent form or a separate consent form signed by the maternal donor prior to the collection of any biological samples for research. **Information/evidence to be provided (or equivalent alternative)** : • Donor information brochure and a consent form for research use of donor-provided biological materials or data, if applicable *Note*: Do not submit any completed forms with personal data *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.10	x	**Consent documents signed by maternal donors must be available for review by individuals designated by the registry or national authorities to evaluate the registry.**	**Benchmark standard** **Explanation**: Since consent documents must be available, the registry / cord blood bank should define the procedures and responsibilities for securely storing signed consent forms. The registry should have easy access to these forms for review by individuals authorized to evaluate the registry. **Information/evidence to be provided (or equivalent alternative)** : • Relevant procedures and responsibilities for securely storing signed consent forms • Service level agreements relating to any off-site storage of consent forms *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4			**Cord blood unit characteristics**				
4	4.11	x	**Date of collection, time of collection and gender associated with the cord blood unit must be registered at the time of collection.**	*Note*: Provide with the shortened application **Benchmark standard** **Explanation**: Date of collection, time of collection and gender must be recorded for each cord blood unit. **Information/evidence to be provided (or equivalent alternative)** : • Example of a cord blood unit report that lists this information	x	o	o

4	4.12		The total nucleated cell count must be obtained in the final product prior to cryopreservation for listing a unit in the registry database.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The total nucleated cell count must be evaluated using a fresh sample of cord blood obtained and tested after processing prior to cryopreservation. **Information/evidence to be provided (or equivalent alternative)** : • Policy/procedure about TNC testing • Example of a cord blood unit report that lists this information			
4			**Testing**				

4	4.13		Testing of maternal and infant donor samples must be carried out by laboratories that meet standards established by local regulation.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The testing described in this WMDA Standard covers all forms of testing such as HLA typing, blood group, hemoglobinopathy and infectious disease testing. The registry is expected to have a policy and procedure to ensure that the testing performed on the maternal and infant donors' samples are in compliance with national and/or international guidelines. It is strongly recommended that each testing laboratory be licenced and/or accredited by a national or international regulatory agency and participate in relevant national or international quality assurance programmes. The participation in external proficiency-testing programmes alone is not sufficient to ensure quality. The registry should have a process to ensure that			

				accreditation of testing entities is current. **Information/evidence to be provided (or equivalent alternative)** : • The registry should indicate the approximate number and types of laboratories contributing data to the registry • If national regulatory programmes, the registry should provide a broad description of the accreditation requirements and describe the accrediting organisations • If the registry works with more than one testing entity, only one example of a certificate for each testing type might be provided although the registry must indicate if similar certificates exist with all entities. For example, provide one accreditation			

				certificate from an infectious disease-testing laboratory, one accreditation certificate from a blood group typing laboratory, one from an HLA typing laboratory. The registry should ensure that the certificate provided is not out of date. • Policy or procedure for ensuring that accreditation of testing laboratories is current			

4	4.13.1	x	**Testing must be carried out in a manner to ensure the accuracy of the data.**	**Benchmark standard** **Explanation**: The registry is expected to have a written policy or procedure to ensure that the maternal and infant donor test results (HLA, infectious disease, blood group, etc.) are identified accurately. This procedure should include a requirement for the laboratory to be accredited and a process to ensure that accreditation is current. The registry might also have other procedures to ensure accuracy, for example, double entry of data, electronic data transfer, process to retest a subset of samples, etc. **Information/evidence to be provided (or equivalent alternative)** : • Procedure for ensuring that accreditation of testing laboratories is current • Other procedures to ensure accuracy if relevant			

4	4.14		Registries must have established approaches to monitor and ensure the accuracy and completeness of the data listed in the cord blood unit database, including a system to assure the quality of HLA typing results.	**References** : • HLA discrepancy survey • Key Performance Indicators information **Explanation**: This WMDA Standard is focused on how the registry monitors and ensures the quality of the test data that they store (HLA, blood type, IDM). One approach the registry might take is to participate in the WMDA project surveying misassigned HLA types at the extended or verification typing stages. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure that describes how the quality of all testing data (HLA, blood type, IDM) is monitored and ensured. This might include, for example, copies of accreditation certificates or KPI data from the HLA			

				discrepancy survey			
4	4.15		The results of the maternal and infant donor assessment including the results of any laboratory tests and medical evaluation must be documented and maintained.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy for documenting and maintaining donor assessment results, including possible methods of data storage (e.g., paper, electronic) and time frames for the retention of documentation. **Information/evidence to be provided (or equivalent alternative)** : • Policy for documenting and maintaining results *Note*: WMDA Standard requires 30 years as time maintained.			
4			**Histocompatibility testing and ABO grouping**				

4	4.16		A minimum of HLA-A, -B, -C, -DRB1 DNA-based typing results must be defined prior to listing umbilical cord blood units.	*Note :* Provide with the shortened application *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy for HLA typing of newly processed cord blood units. This document should describe the HLA loci typed. The minimum standard of HLA typing in this version of standards does not apply to historically banked units i.e., units banked prior to the effective date of this WMDA Standard do not need to have further HLA testing to meet the minimum typing requirement in this standard. **Information/evidence to be provided (or equivalent alternative)** : • Policy on HLA typing • Example of a search report showing the HLA types of recently	x	o	o

				banked cord blood units • Recent copy of a processing report of Search & Match Service that shows HLA assignments			

4	4.16.1		(NEW) The cord blood bank must use HLA testing laboratories that are capable of carrying out DNA–based intermediate and high-resolution HLA-typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), or other accrediting organisations providing histocompatibility services appropriate for hematopoietic cell transplantation.	*Note*: Provide with the shortened application **Explanation**: The registry is expected to have a policy and procedure to ensure that the testing performed is in compliance with national and/or international guidelines. Each testing laboratory must be licensed and/or accredited by an appropriate agency and participate in a national or international quality program. The participation in an external proficiency-testing program alone is not sufficient to ensure quality. If the cord blood bank works with more than one HLA laboratory, only one example of a certificate needs to be provided although the registry must indicate if similar certificates exist with all entities. The registry should ensure that the certificate provided is not out of date.	x	o	x

				Information/evidence to be provided (or equivalent alternative) : • A policy or procedure for ensuring that accreditation of HLA testing laboratories is current • Copy of an accreditation certificate from one HLA testing laboratory			

4	4.17	x	**The ABO blood group and Rh factor testing must be done prior to listing a cord blood unit for search.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: This WMDA Standard emphasizes that the blood group testing must be complete before the unit is listed in the registry. The registry is expected to have a policy covering testing of the blood groups. **Information/evidence to be provided (or equivalent alternative)** : • Policy on blood group testing • Example of a cord blood unit report showing blood group			
4			**Medical assessment and Infectious disease testing**				

4	4.18	x	**Requirements for maternal and infant donor health regarding eligibility of donation must be established.**	**Benchmark standard** **Explanation**: This WMDA Standard requires the registry/cord blood bank to show that the cord blood bank has a process in place to evaluate the health of the mother of the donor / cord blood unit. The policy should ensure that cord blood units are evaluated for the potential of inherited disorders and/or history of disease that may be transmissible. It should also ensure that cord blood units deemed unacceptable for these risks not be kept in inventory. The cord blood bank, in accordance with the registry standards and national laws, must have established maternal donor eligibility criteria. The donor's medical history should be evaluated before the cord blood unit can be listed by the registry. **Information/evidence to be provided (or equivalent alternative)** :			

				• Requirements for maternal donor health screening • List of infectious disease markers tested (including travel or residential disease risk exposure) • Screening for other diseases like malignancy or autoimmune diseases • Medical evaluation form • Policy and procedure for the management of cord blood units with unacceptable results *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.19		A health screening of the maternal donor for diseases transmissible through transplantation must be performed and included in the status at the time of delivery.	**Explanation**: Upon delivery or soon thereafter (suggest within 7 days of delivery), information previously provided during the screening must be verified, including changes to infectious risk history that may have occurred since the time of completion of the initial screening process. **Information/evidence to be provided (or equivalent alternative)** : • Policy for this follow-up and a screening form *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.20	x	**A maternal blood sample, obtained within seven (7) days before or after collection of the cord blood unit, must be tested 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 local regulation.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry/cord blood bank is expected to have a policy and/or procedure for maternal infectious disease testing within seven days before or after collection of cord blood. The document should state which infectious diseases are tested for, must include the disease markers listed in the standard as well as any IDMs to be tested due to travel or residential history. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure for maternal infectious disease testing within seven days before or after delivery/collection of cord blood unit • Documentation / tools the registry /			

				cord blood bank utilizes to interpret infectious disease marker results and decisions regarding the fate of units where reactive / positive results are obtained • Any supporting documentation on how the registry / cord blood bank identifies whether or not to test for other markers based on relevant travel and / or residential history of the maternal donor *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.20.1		Maternal donors should also be tested for local diseases that are important to consider in transplantation. Maternal donors who have recently travelled outside their country should also be evaluated for infectious diseases prevalent in the areas of travel.	**Explanation**: If other regional infectious diseases are relevant when testing a maternal donor prior cord blood donation, the registry should have a list of these diseases and a testing policy and/or procedure. **Information/evidence to be provided (or equivalent alternative)** : • A copy of national testing requirements may be submitted to show which additional tests are routinely performed for this reason • Procedure and/or form for testing for local or other relevant infectious diseases			

4	4.21		A medical and genetic history of the infant donor's family must be obtained and documented.	**Explanation**: The registry / cord blood bank is expected to have a policy or procedure to obtain the history of the infant donor's family. Family should include: (1) parents (including egg, sperm or embryo donor , if applicable); (2) grandparents; (3) siblings as of the time of donation; and (4) parent's siblings. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure for obtaining history and screening form • Documentation describing the fate of units affected by information obtained from the family's medical and genetic history *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.22		Hemoglobinopathy testing on the infant donor or the cord blood unit must be performed prior to shipment of the cord blood unit for transplantation.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry / cord blood bank is expected to have a policy or procedure to perform or obtain hemoglobinopathy testing results of the infant or unit. Results may be obtained from, for example, a national infant donor hemoglobinopathy screening programme. Alternatively, the cord bank may perform testing directly on the cord blood or send samples to a suitable 3rd party accredited laboratory. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure for hemoglobinopathy testing on the infant donor or the cord blood unit • Policy or procedure describing the fate of cord blood			

				units impacted by hemoglobinopathy testing and / or how the result is communicated to the transplant programme prior to shipment *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.23		A history of the current pregnancy, delivery and the infant donor's status at birth must be obtained, documented and reviewed to include any findings that might suggest the possibility of disease transmission through the cord blood unit.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy or procedure to obtain the current pregnancy, delivery, and infant donor's status at birth. **Information/evidence to be provided (or equivalent alternative)** : • Follow-up policy or procedure and a screening form *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.23.1		The history of the infant donor should be updated and maternal screening should be repeated within a reasonable time frame post-delivery to capture risks not immediately detected at birth, in particular in cases where the first screening was done early in pregnancy.	**Explanation**: Maternal donor follow-up should be obtained and documented on post-donation clinical condition of infant and maternal donor that may potentially affect the eligibility of cord blood product for allogeneic transplant. The reasonable post-delivery time frame should be determined and written in a policy or procedure but it is suggested that the follow-up should occur at least 2 weeks after birth but within the first year after birth with a second follow-up at cord blood unit reservation. **Information/evidence to be provided (or equivalent alternative)** : • Policy for follow-up of maternal donor and infant post-donation *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.23.2		The maternal donor must be provided with information to contact the cord blood bank if the infant donor develops a serious disease later in life.	**Explanation**: Materials given to the maternal donor must describe the importance of contacting the bank if the infant develops a serious disease like cancer or an autoimmune disease. **Information/evidence to be provided (or equivalent alternative)** : • Information provided to the maternal donor or a counselling checklist that includes this information *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.24		The maternal donor must be counselled in the case of positive disease results that pose health risks to the maternal donor or infant donor.	**Explanation**: The registry / cord blood bank is expected to have a written policy or procedure describing how it ensures that maternal donors are counselled in cases where there are some abnormal finding during medical evaluation of maternal and infant donor. The process may involve the counselling being performed by cord bank or registry medical staff, be facilitated by the donor's general medical practitioner, the clinical team who oversaw the birth or experts from a national public health organisation. Whoever delivers the counselling should be appropriately qualified and trained to understand any disease associated with the abnormality and the potential impact of delivering the news regarding abnormal findings. Responsibilities and the process should be clearly described in a procedure, operation manual, or in an informed consent.			

				Information/evidence to be provided (or equivalent alternative) : • Policy and/or procedure for maternal donor counselling *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

4	4.25		The cord blood bank must review all source documentation prior to shipment of the cord blood unit for transplantation and must have policies and procedures in place describing what information should be passed on to the transplant centre and how that communication will take place.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry / cord blood bank is expected to have a policy or procedure to ensure that the bank reviews and approves the documentation prior to shipment and how this documentation is provided to the transplant centre. The review of documentation may be performed by the bank's medical director or another individual trained to identify any potential health risks related to the donation. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure describing the cord blood bank's responsibility for the review of documentation *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard			

				through the NetCord-FACT accreditation			

4	4.26		Prior to shipment, the identity of the cord blood unit must be verified through verification typing from an attached segment of the cord blood unit or through any other validated procedure.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry / cord blood bank is expected to have a procedure to ensure that the cord blood unit to be shipped is the cord blood unit with the typing and IDMs listed in the search database. The cord blood bank must have a testing procedure to ensure identity of the cord blood unit; this testing can be a minimal HLA typing or some other identity testing. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure describing how the identity of the cord blood unit is ensured *Note:* If your cord blood bank is NetCord-FACT accredited, you comply to this WMDA Standard through the NetCord-FACT accreditation			

5	**5**		5. Information technology and information management				
5			**System documentation**				

5	5.01		Any registry system must be accompanied with adequate documentation detailing its specification, validation, maintenance, administration and operation; including hardware, software, the network architecture and external connections.	*Note* : Provide with the shortened application **Reference**: • A Gift for Life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 7 Information technology and data management **Explanation**: The registry must possess documentation regarding how all aspects of the computer system works. This is particularly important, for example, if a registry were to subcontract the development or maintenance of its information technology (IT) system and then wish to change its subcontractor. Similarly, if the IT system is developed and maintained internally, but key staff leaves, it is important to have all aspects of the system documented.	x		

				Information/evidence to be provided (or equivalent alternative) : • General description of critical information technology components such as the hardware, software, network architecture and external connections used to access registry data. For example, a generic system diagram of data flow from an internet connection into the registry, which generates a search report. Note: The registry should not provide a detailed overview as it might be a security risk • Table of contents from the documentation of information technology systems used for storing and maintaining registry data			

				• Any relevant certifications such as ISO that apply to IT and a description of what IT activities are covered by the certificate **Technical details:** It is recommended that the registry: • Document critical information technology (IT) components such as the hardware, software, database and network architecture and external connections used to access registry data. For example, the registry might have a system diagram of data flow from an internet connection into the registry, which generates a transplant search report and have defined hardware requirements for system operation.			

				• Document in user manual/technical documentation and procedures how all IT systems and software are used to maintain the registry in an operational state including minimal software requirements. • Have a policy, standard and/or procedure that describes how software and hardware are maintained. For example, the registry should have a policy that describes how the registry demonstrates compliance with manufacturer or vendor specifications around routine/preventative/regular component maintenance. • Have a policy, standard and/or procedure that describes how to select and implement new hardware parts of			

				an IT system. Selection might be based on purchase from a trusted vendor and/or purchase of new, rather than used, hardware. • Maintain a quality assurance plan (as part of an implemented system development life cycle (SDLC) or other development methodology). The SDLC describes a process for planning, creating, testing, and deploying an information system. This methodology should include tracking of user testing and approval.			
5			**System security**				

5	5.02		Electronic connection and communication between organisations must be coordinated and performed with greatest possible care minimising vulnerabilities and exploitation risks.	*Note* : Provide with the shortened application **Explanation**: Registries are expected to employ cybersecurity principles and apply a framework to their electronic communications (and the systems which support them). *[Cybersecurity is the protection of sensitive information stored or accessed on the internet from attack through the internet.]* A base principle is that malicious activity should be anticipated and care taken to minimise risks associated with such activity. There should be a yearly review whether current practices are still up to date. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure that describes how the registry prevents unauthorised access to donor and transplant records when	x		

				data is transmitted between registries For example, document that describes the encryption technologies used to move data from on registry to another. • IT policy showing the frequency of updates of the virus checking software **Technical details:** It is recommended that the registry: • Anticipate malicious activity and understand the risks associated with electronic communications, particularly when pertaining to human subjects • Take steps to minimise the potential risks by implementing and by employing cybersecurity principles and tools, such as: o Email encryption			

				using, for example, Transport Layer Security (TLS) ○ Firewalls to shield access to internal networks or block attacks through packet filtering ○ Routine vulnerability scanning and routine penetration testing ○ An intrusion detection system to detect attacks as they occur and assist with post-attack forensics			
5			**Business continuity**				

5	5.03		Redundant, reliable software and hardware architecture should be used to minimise the probability of failure or data loss and the possible length of a down time.	*Note* : Provide with the shortened application **Reference**: • Pingel et al., World marrow donor association crisis response, business continuity, and disaster recovery guidelines, *Biol Blood Marrow Transplantation (2012) 18(12):1785-9* **Explanation**: It is important for the registry to have reliable software and hardware that allow the registry to be operational as much as possible. To meet this standard, the registry should, for example, have a back-up system in case the primary system(s) fail(s); always use redundant storage systems (RAID), have maintenance contracts and replacement plans for IT equipment; a means to monitor and control the environment to protect specialised IT equipment and a plan to recover vital technology	x		

				infrastructure and systems following a natural or human-induced disaster. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure that addresses system fault tolerance i.e., how the registry identifies and recovers from system failure. For example: does the registry have a back-up server if the first server fails? **Technical details:** It is recommended that the registry have: • Written business continuity/disaster recovery plan that includes a set of policies, tools and procedures that describe how the registry identifies and recovers from system failure. • Critical systems designed to			

				provide failover capability (i.e., ability to switch to a standby) in servers, systems or networks requiring near-continuous availability and a high degree of reliability. • Maintenance contracts, or internal abilities, to reduce the probability of data loss or failure. This should include a service level agreement that establishes a short replacement time for critical system components. • An uninterruptible power supply (UPS) and/or backup generator to keep systems going in the event of a power failure. • Policy/procedure to protect against environmental factors for specialised IT equipment and devices to monitor and control the			

				environment. The document should include how to manage facilities, including power and communications equipment. It should cover humidity controls, air conditioning, and dust control. • Fire prevention/mitigation systems such as alarms and fire extinguishers.			

5	5.04	x	**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.**	**Benchmark standard** *Note* : Provide with the shortened application **Explanation**: A backup is the process of copying data to preserve it in case of equipment or software failure. The registry must perform backups and document how often they are performed. The registry must have tested the restoration of its system using backups, and the system must be able to restore the system quickly from backups. Points to consider: • How much data can a registry afford to lose? If a backup is performed once a week, up to 7 days data may be lost. Could the registry recover that information? • How long would it take to restore the system? If critical hardware is lost, how quickly can it be replaced and the	x	x	

				data restored on to it? How long might the registry be out of action? • If backups are not stored offsite, a critical event (for example, fire or flood) might destroy all the data and all the backup copies. • Data backup should form part of a broader business continuity plan. There is little benefit in having a recent backup of the system if damage to premises and equipment means there is no computer to restore the backup to or no office to put the computer in. **Information/evidence to be provided (or equivalent alternative)** : • Policy or procedure showing the frequency of backups of donor database and of			

				user data and describes restoration tests • Report or copy of a log from the last time the registry performed a restore test of the back-up • Table of contents of the registry's business continuity plan related to IT. **Technical details:** It is recommended that the registry: • Back up all relevant data and systems. Documentation of the backup plan and recovery tests must be available. • Maintain a backup plan for all relevant systems including o Timeline o Responsible person / function o Retention time (i.e., how many backups are stored)			

				○ Location of the backups (preferentially off-site) • Restore all backups at least once a year to ensure that the backups are working correctly • Include data backup as part of a broader Business Continuity Plan (BCP). The broader BCP should be described and should cover at least: ○ Premises ○ Equipment (including communications) ○ Staff (including travel to any alternate site) ○ Definition of data priority ○ Data backup and restore			

				procedures • Determine whether incremental backups (just changes since previous backup) are sufficient for an everyday backup and whether a full backup could be run every week.			

5	5.05		(NEW) In the event of termination of operations, the registry should ensure continued adherence to data protection and record retention standards.	*Note* : Provide with the shortened application **Explanation**: If the registry terminates its operations, it should ensure that its records, especially of previous transplants, are maintained for traceability and that any and all personal identifying information is protected. This might be accomplished by transferring this information to another entity. This entity must assume all of the responsibilities (data protection and document retention) held by the source registry. Registry procedures must comply with locally applicable law regarding preservation of medical records. This WMDA Standard does not address transferring donors to a different registry so that they can be accessed for searching patients. **Information/evidence to be provided (or equivalent alternative)** :	x	o	o

				• Policy and/or plan for data protection upon termination of operations **Technical details:** It is recommended that the registry have: • A policy and plan for identifying relevant data and records and how to proceed with these in case of termination of operations. There are two aspects to consider: ○ Data security: protecting personal identifying data. ○ Data retention: Maintaining records important for patient care, that is, data on donors who provided stem cells to patients			

				• A plan for transferring these data and records to a responsible organisation. The registry might also elect to destroy personal identifying data. • A list of requirements that must be met by the entity assuming responsibility for the data and records.			
5			**Maintenance**				

5	5.06		The system of quality management must include an assessment of all electronic functions to ensure that errors and problems are reported and resolved.	*Note* : Provide with the shortened application **Explanation**: Registries must maintain a quality control plan, which specifies how systems will be tested/assessed against the expected functionality of that system. This includes a process by which identified defects will be documented, triaged, prioritised and remediated. Quality assurance and quality control represent two important, but distinct, aspects of quality management. Quality assurance is process-oriented and proactive. It aims to prevent defects by ensuring quality in the process(es) used to develop software and designing the registry's software system and its associated infrastructure (for example, ensuring interoperability of the entire IT system). Quality control is product-oriented and aims to identify defects within the developed software system and its associated	x		

				infrastructure (i.e., testing). **Information/evidence to be provided (or equivalent alternative)** : • Quality assurance plan to assess electronic functions • Description of the system handling and tracking IT incidents • Record of checks/tests done on the latest version of the registry software before going live with the latest new release **Technical details:** It is recommended that the registry: • Maintains a quality control plan encompassing all registry systems. The plan should include: ○ The functional test plan(s) for registry software			

				systems; to ensure the developed software system and its associated infrastructure is behaving as expected ○ The regression test plan(s) for ensuring that previously developed and tested software and its associated infrastructure continues to work as expected after the introduction of system changes ○ A description of, or reference to, the defect			

				○ management process; for issues detected during the testing phase ○ A description of, or reference to, the incident management process; for stakeholder reported issues once software is live			

5	5.07		System modifications must be managed through a documented change management process.	*Note* : Provide with the shortened application **Explanation**: It is important to be able to document why and where changes were made, who made the changes, what the changes were, and when the changes were made. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure for change management of the system **Technical details:** It is recommended that the registry has: • One or several systems in place which tracks changes to all relevant IT systems and documents these changes.	x	o	x

5	5.08		(NEW) Registry information technology systems must be maintained to ensure that the used software is up to date to minimise security risks and to make sure that all systems are running properly.	*Note* : Provide with the shortened application **Explanation**: Security patches are released for software as new risks are identified. It is important that the registry software itself and other pieces of software it relies on, for example, operating system and email system, are kept as up to date as practical. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure describing the frequency of updates to the system software **Technical details:** It is recommended that the registry has: • A policy that spells out the process to be followed regarding security patches, including appropriate time intervals, and	x	o	x

				documentation that evidences the process being followed • Considered inclusion of security patches for office applications. Trojans and viruses often come from client machines and can impact all files accessible from that particular client.			
5			**Software development**				

5	5.09		(NEW) Registry software developed in-house must follow a documented software development process.	*Note*: Provide with the shortened application **Explanation**: If software is developed in-house, a software development process must be in place. The registry must have a system in place to make sure that software development is done in a controlled way and that the software is tested before using it to complete tasks. This will also include a plan for quality management of the new software. If software was developed in house prior to the date that this WMDA Standard was implemented, this policy applies to that software only if it is subsequently updated. **Information/evidence to be provided (or equivalent alternative)** : • If software is developed in-house, policy and/or procedure that describes the software management process	x	o	x

				• If software is developed in-house, a copy of documentation from the planning, scheduling, testing and deploying of a recent major software release. • If software is not developed in-house, indicate that this WMDA Standard is not applicable **Technical details:** It is recommended that the registry has: • A policy/procedure that covers the software development life cycle: ○ Requirements ○ Design ○ Engineering ○ Construction ○ Testing ○ Debugging ○ Development of quality			

				management plan ○ Deployment • Maintenance			
5			**Registry operations - traceability**				

5	5.10	x	**The registry must maintain records of its activities and must maintain a database of volunteer donor and/or cord blood unit information.**	**Benchmark standard** *Note: Provide with the shortened application* **Explanation** : The registry is expected to be an active WMDA member, demonstrated by submitting to the global trends report of its activities and by uploading the donor and cord blood data on a regular base to the Search & Match Service (at least monthly) and by storing its database electronically. A database is any organized collection of data, typically aligned towards the organisation's analytical or data sharing needs (i.e., searching the donor listing or reporting of registry activities to WMDA). Electronic storage of the database may range from a spreadsheet to a Database Management System (DBMS). A DBMS is a computer-software application that will aid in the capture, extraction or analysis of data.	x	o	o

				Information/evidence to be provided (or equivalent alternative) : • Policy and/or procedure that describes the retention schedule of donor records. The policy should cover the entire life cycle of the donor information from initial submission to potential removal of the donor and product information from the registry. • Overview description of the database information system(s) used, including the maintenance of the archived paper documents (for example: donor consent signature). **Technical details:** It is recommended that the registry: • Maintains documentation of			

				registry IT systems, including: ○ The database system in use ○ The database design/schema ○ Software applications utilized to support registry operations ○ The network architecture and any connections to the Internet • Maintains policies for: ○ Ensuring the integrity of the data within the database, including tracking of changes to the data ○ Retention of data within the database			

				○ Access control to the database • has backup and recovery of the database			

5	5.11	x	**All patient and donor/cord blood unit communications and records must be stored to allow for traceability of the donors/cord blood units from recruitment through the donation process, and post-donation/shipment.**	**Benchmark standard** *Note*: Provide with the shortened application **Explanation**: Traceability is the ability to locate and identify a donor or recipient, their data and cell product, during any stage of the recruitment, testing, collection, donation, cellular therapy, and follow-up process. Traceability also includes the ability to identify the organisational entities (e.g., registry, donor centre, collection centre, cell processing unit and transplant centre) involved in the international exchange. While protecting identities, the registry must also have systems and processes in place that allow it to trace, track and link the donor (and any associated blood and produce samples) to the recipient, and vice versa. IT systems used by the registry must produce and track unique identification numbers by product.	x		

				Information/evidence to be provided (or equivalent alternative) : • Policy and/or procedure describing the retention of and access to donor records • Policy and/or procedure describing how donors, products, and recipients are linked **Technical details:** It is recommended that the registry: • Ensures IT systems track patients, donors, cord blood units, cellular products, and the relationship(s) between them, through the use of unique and anonymous identifiers.			

5	5.12		Each step in the search process must be documented with all relevant attributes, including a date and time stamp.	*Note*: Provide with the shortened application **Explanation** : Every time there is activity in the patient search, the activity must be documented, preferably electronically, and time-stamped so that changes can be tracked to see who initiated the activity and when. Activities include patient registration, test requests made by the physician, and subsequent communication as to donor status. **Information/evidence to be provided (or equivalent alternative)** : • Report that demonstrates that tracking of each step of the search process occurs. For example, an initial search report, test requests made by the physician, and subsequent communication as to donor status. Remove any personal	x	o	o

				identifiers before submission. **Technical details:** It is recommended that the registry uses: • Date and time in ISO 8601 format (e.g., YYYYMMDD and hhmmss using a 24 hr clock).			

5	5.13		The information history of relevant data must be recorded.	*Note*: Provide with the shortened application **Explanation**: Any significant changes to a donor, cord blood unit or patient file must be recorded to show a history of changes. An example of significant changes would be the recruitment consent, follow-up consents and test results of a donor. These changes should be demonstrated with an electronic report. **Information/evidence to be provided (or equivalent alternative)** : • Example of change log for a specific information element before and after user editing. For example, the recruitment consent and follow-up consents as well as test results. Remove any personal identifiers before submission.	x		

				Technical details: It is recommended that the registry: • Maintains an electronic audit log. This log will provide documentary evidence of the sequence of activities that have affected the file and include: (1) Date and time of the update; (2) The details of the system user who made the update; and (3) The before and after values of the change made to the data attribute. Access to the audit log must be subject to restrictions based on user roles.			
5			**Registry operations - data transmission**				

5	5.14	x	**The registry must have sufficient communication links to facilitate searches, including backup methods if the principal link is unavailable.**	**Benchmark standard** *Note*: Provide with the shortened application **Explanation**: It is recommended that the registry be linked by multiple communication devices (for example, telephone, email, fax) to other registries and other relevant entities. Contact information for the registry is expected to be readily available. The registry should have an out of hours phone number for emergencies and this number should be readily available to those involved in an emergency. **Information/evidence to be provided (or equivalent alternative)** : • Contact information for the registry (address, email, web page, phone numbers) posted in Share in English • Example of how emergent contact information is disseminated	x	o	o

				Technical details: It is recommended that the registry has: • Several alternative and independent communication devices (e.g., internet and phone) • A public record of options for communication with the registry that is posted on the registry's web site and on WMDA Share. • An emergency phone number that is staffed 24 hours a day and 7 days a week.			

5	5.15		When transferring data between organisations, there must be a validated protocol for the transfer of data. Both the transferring organisation and the receiving organisation must have policies to verify data.	*Note*: Provide with the shortened application **Explanation**: It is important that both parties have a method to confirm that the data sent matches the data received. A validated process suggests a repeatable process. The same, or similar, process should be applied for each donor centre or cord blood bank providing data to the registry. **Information/evidence to be provided (or equivalent alternative)**: • Policy and/or procedure describing information is transferred and verified as correct (for example, how the registry's cord blood bank or donor centres provide the unit's/donor's data to the registry or how the registry provides data to Search & Match	x		

				Service of WMDA (at least monthly). • Copy of euro report from data transfer from the donor centre to the registry or some other record of accurate information transfer **Technical details:** It is recommended that the registry: • Maintains technology to move data from one registry to another through, for example, Search & Match Service (BMDW) or mirroring of data. • Validates the process and retain records of documenting the validation • Maintains a policy or procedure that outlines how data integrity is maintained throughout the process and how data is validated.			

				• Documents the process by which data is transmitted to the registry, including: ○ The involvement of any registry IT systems for data entry, data transmission, data validation or data storage ○ The quality assurance process applied to these registry IT systems			

5	5.15.1	x	**Any HLA-related information stored, presented or communicated by the registry must follow WMDA guidelines for the use of HLA nomenclature.**	**Benchmark standard** *Note* : Provide with the shortened application **References**: • Bochtler et al., World Marrow Donor Association guidelines for use of HLA nomenclature and its validation in the data exchange among hematopoietic stem cell donor registries and cord blood banks, *Bone Marrow Transplantation (2007) 39(12):737-41* • Bochtler et al., An update to the HLA Nomenclature Guidelines of the World Marrow Donor Association, 2012, *Bone Marrow Transplantation (2013) 48(11):1387-8* **Explanation**: The World Health Organisation (WHO) has established the guidelines	x	x	

				for HLA nomenclature (http://hla.alleles.org). The WMDA has standardized the extensions to these guidelines which are commonly used in registry practice . **Information/evidence to be provided (or equivalent alternative)** : • Policy for the use of HLA nomenclature • Search report: remove name and date of birth of patient and any other personal identifying information **Technical details:** It is recommended that the registry: • Maintains a policy describing its use of HLA nomenclature, including provisions for how genetic ambiguity is managed (e.g., through utilization of multiple allele codes, genotype list (GL) strings, or			

				other standardized means) (Bochtler et al., 2007; 2012; Milius et al. 2013, 2016) • Has the ability to produce a search report showing HLA assignments, with all personally identifiable information (PII) removed • Documents the process by which registry IT systems are updated with new releases of the HLA nomenclature, and for ensuring backward compatibility with prior release			

5	5.15.2	x	**The registry, or its designee, must assign a unique and anonymous identifier to each donor, each maternal donor and each cellular product to ensure confidentiality. This identifier must be used to track each donor and cord blood unit with their associated data and biological material and their participation in the donation process long term.**	**Benchmark standard** *Note*: Provide with the shortened application **Reference:** • GRID information **Explanation**: The donor identifier must be unique and link all samples and products. The donor identifier should be independent of any information related to the subject being identified. For an additional level of privacy, identifiers could be generated prior to use. Please note the WMDA initiative to implement GRID as a standardised identifier. Cord blood banks may use GRID or another international standard for identifiers. **Information/evidence to be provided (or equivalent alternative)** : • Policy for assignment of identifiers and how identifiers link the donor,	x	x	

				recipient and product • Search report: remove name of the patient and any other personal identifying information **Technical details:** It is recommended that the registry: • Maintain documentation describing the unique and anonymous identification of patients, donors, cord blood units and cellular products • Ensure IT systems honor/accept the unique and anonymous identifiers generated by other registries (including GRID)			

5	5.16		The registry listing donors must use GRID to issue donor identifiers at the time that WMDA makes GRID mandatory.	*Note* : Provide with the shortened application **References:** • GRID information • ICCBBA website • Sorensen et al. Inadvertent completely HLA-mismatched allogeneic unrelated bone marrow transplant: lessons learned. *Bone Marrow Transplantation (2016) 51: 1016-1018* **Explanation**: This WMDA Standard is aimed at preventing two donors from having the same identifier. The global registration identifier for donors (GRID) secures a unique donor identification number in a standard format utilized by hematopoietic stem cell donor registries, donor centers that issue donor identifiers. The unique identifier reduces the risk of misidentification of a donor. A GRID identifier is 19 alphanumeric characters beginning with an ION. The ION is issued	x	o	x

				by ICCBBA. The ION is a GRID issuing organisation number unique to each registry. Cord blood banks may use GRID or another international standard for identifiers. **Information/evidence to be provided (or equivalent alternative)** : • Policy for use of GRID as donor identifier. If not yet in use, a plan and timeline to implement GRID • If GRID has been implemented, search report or copy of product label or donor report illustrating the use of GRID: remove name of patient and any other personal identifying information **Technical details:** It is recommended that the registry: • Utilizes GRID as a donor identifier. If the registry is not currently using GRID, it must have			

				a plan and timeline for implementing GRID within the published WMDA timetable. Cord blood units may continue to be identified by a comparable international labeling system e.g., ISBT 128. The implementation plan must also address non-IT impacts of GRID implementation, such as how policies and procedures will be impacted, as well as communication and training plans for the registry's partnerships with transplant, donor and product collection centers. • Maintains a mapping between GRID and any historical donor identifiers assigned, sent or received • Avoid codifying any identifying characteristics within GRID assignments (for			

				example, name/location of donor centre)			
5			**Registry operations - quality**				

5	5.17	x	**Search reports must generate lists of suitably matched donors/cord blood units in a reasonable time frame.**	**Benchmark standard** *Note* : Provide with the shortened application **Reference**: • Bochtler et al., A comparative reference study for the validation of HLA-matching algorithms in the search for allogeneic hematopoietic stem cell donors and cord blood units, HLA *Bone Marrow Transplantation (2016) 87(6):439-48* • Bochtler et al., World Marrow Donor Association framework for the implementation of HLA matching programs in hematopoietic stem cell donor registries and cord blood banks, *Bone Marrow Transplantation (2011) 46(3):338-43* **Explanation**:	x	x	

				This standard applies to the algorithm that selects donors and/or cord blood units that are HLA matched or potentially matched to a searching patient. For cord blood units, the total nucleated cell dose must also be considered in selecting units to show as a match. The registry must also exclude unavailable donors from appearing on search reports. For example, a donor who is deceased should not appear on search reports or a donor who has passed the age limit should not appear on a search report. The registry must be able to provide a response to requests for searches quickly, preferably within a few hours, but not later than 24 hours of when the search request was received. It is important for the search results to be provided quickly so that the physician has a full understanding of all potential matches around the world. This timing of the response can be monitored by ensuring that search reports show the date a search request			

				was received as well as the date the search report was provided to the requester. **Information/evidence to be provided (or equivalent alternative)** : • Search report: remove name of patient and any other personal identifying information • Documentation on the time it takes for a physician to successfully obtain the first preliminary search report after it has been requested. For example, provide an example of a search report that shows the date a search request was received as well as the date the search report was provided to the requester. Personal identifying information must be removed. • Documentation that the registry			

				has used the database provided by the WMDA Information Technology Working Group, which is designed to evaluate the donor selection algorithm and determines that it functions as designed. • Policy and/or procedure describing how the registry excludes unavailable donors from appearing on search reports. For example, a donor who is deceased should not appear on search reports or a donor who has passed the age limit should not appear on a search report. **Technical details:** It is recommended that the registry: • Utilizes a search algorithm that is based on the			

				advice of histocompatibility experts with knowledge of the optimal HLA matching criteria. These experts must also understand HLA nomenclature and equivalencies between various HLA assignments (Bochtler et al., 2012). The WMDA Information Technology Working Group can provide a database designed to evaluate the donor selection algorithm and determine that it functions as designed (Bochtler et al., 2016). • Review the WMDA metrics on the average response time for search requests and have a policy for addressing any deficiencies in the registry's response time			

				compared to the metric			

5	5.18	x	**Each printed report must be dated.**	**Benchmark standard** *Note*: Provide with the shortened application **Explanation**: Every printed report must be dated. This covers all reports, not just search reports. Each time a search report is printed, it should contain the print date so that, if multiple reports are run for a patient, one can determine the most current report. **Information/evidence to be provided (or equivalent alternative)** : • Search report: remove name of the patient and any other personal identifying information **Technical details:** It is recommended that the registry uses: • Date and time in ISO 8601 format (e.g., YYYYMMDD and	x	x	

				hhmmss using a 24 hr clock).			
5			**Registry operations - protection personal data**				

5	5.19	x	**The access to personal donor and patient data as well as the transmission of these data between organisations must be coordinated in a way that accidental or unauthorised access, destruction or modification is prevented.**	**Benchmark standard** *Note* : Provide with the shortened application **Explanation**: A secure environment is one that can not be accessed by the general public or unauthorised persons. These protections include, but are not limited to, transmissions of personal data over open networks, including internet email, EMDIS, etc. The registry must have sufficient security in place to make sure that unauthorised people or systems cannot break into the system (intentionally or unintentionally) and modify or destroy records. To protect confidentiality (names and other personal identifiable information in the registry database), avoid the use of donor and recipient names in communications and ensure that access to the database is controlled by individual user accounts and passwords. Ensure that any paper records used by staff are not left unattended during the	x	x	

				day, and locked at the end of the work day. Paper records not intended for long time archives should be properly destroyed to avoid reassembly. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure that defines how the records are protected from accidental or unauthorised access, destruction and modification. • Policy and/or procedure that describes physical security to facilities and files. For example, the standards would address areas such as physical access authorisations and control, monitoring of physical access and records of visitor access • Policy or procedure that describes how			

				new users are granted access to the registry software, the training they receive before access ias granted, and how access is removed after an employee's departure **Technical details:** It is recommended that the registry: • Maintains a policy to ensure privacy of patient/donor information in the context of external communications, email, fax, remote access: ○ The document should describe network security techniques and related management procedures (e.g., firewalls,			

					security appliances, network segmentation, intrusion detection) to authorise access and control information flows to and from networks. ○ The document should describe how the registry secures the exchange of sensitive data, including sensitive transaction data, only over a trusted path or medium with controls to provide authenticity of content,			

				proof of submission and proof of receipt. ○ The document should include how email accounts used to transmit sensitive information are established. • Ensures communication of confidential donor or patient information is not undertaken by public or unsecured email; or by fax in an open location or when multiple persons have access to the fax device. • Maintain a policy covering access controls for registry IT systems, including the granting and revoking of access: ○ The policy should			

				describe how the registry determines the level of access appropriate for a user and which IT systems are required. ○ The policy should describe the process for revoking the access of an employee who has left the organisation ○ The policy should describe how access to the IT system itself is controlled by passwords or other means such as two factor			

				authentication (e.g. token codes or other secondary access codes in addition to passwords). ○ The policy should explain what the minimum requirements for a password are. • Maintain written documentation of each user's access to registry IT systems • Provide training to staff on maintaining the security of their access to the registry IT system. Educate users as to the precautions they must take to prevent access to user accounts by third parties (e.g. discouraging behaviours such as sharing passwords or			

				leaving devices unlocked when unattended).			

5	5.20		(NEW) The registry must formally assign a security role to be accountable for the oversight and governance of the registry's security and privacy risks and related controls.	*Note* : Provide with the shortened application **Reference:** WMDA Share page with examples of job descriptions of DPOs **Explanation** : The Data Protection Officer (DPO) is responsible for overseeing security and privacy at the registry. Registries without expert privacy and security professionals on-staff may choose to retain a third party to provide DPO responsibilities. **Information/evidence to be provided (or equivalent alternative)** : • Selection from Written Information Security Policy (WISP) describing the security role of the Data Protection Officer (DPO) **Technical details:** It is recommended that the registry:	x	o	x

				• Has a Data Protection Officer (DPO) whose job description includes the following responsibilities: ○ Advise the registry and their employees on regulatory obligations for security and privacy ○ Monitor the registry's compliance to security and privacy regulations ○ Advise on security and privacy risk assessments ○ Oversee compliance to Data Use Agreements between the registry			

				and its third parties whereby personal information is shared ○ Serve as a contact point for WMDA Security and Privacy Committee and other WMDA DPOs with security and privacy inquiries Note: An example of a job description of the DPO can be found at Security & Privacy			

5	5.21		(NEW) The name and contact information of the security role must be posted on the registry's information profile posted on WMDA Share.	*Note*: Provide with the shortened application **Explanation**: It is important that the Data Protection Officer (DPO) for each registry be readily available to DPOs from other registries. **Information/evidence to be provided (or equivalent alternative)** : • Name and contact information (business phone and email address) of the Data Protection Officer (DPO) posted in Share by including a screen shot or link to Share **Technical details:** It is recommended that the registry: • Posts the necessary information including the first and last name of their Data Protection Officer along with phone number and email	x	o	x

				contact on WMDA Share in the section of the registry's organisational profile that is accessible to WMDA members. This information should also be posted on the registry's web page depending on local regulations.			

5	5.22	x	**(NEW) A Written Information Security Policy must be documented and maintained.**	**Benchmark standard** *Note* : Provide with the shortened application **Reference:** WMDA share page with examples of a WISP **Explanation** : The policy must describe how the registry will protect the security of personal identifying information. **Information/evidence to be provided (or equivalent alternative)** : • Written Information Security Policy (WISP): Entire policy written in English • Copy of the page from the WISP showing the date of last review and DPO approval **Technical details:** It is recommended that the registry: • Creates and maintains a WISP that includes the	x	x	x

				following minimum information: ○ The organisation's Data Protection Officer who is accountable for the oversight and governance of the organisation's security and privacy risks and related controls ○ Access control policies, including policies for ensuring user access remains aligned with job responsibilities as user onboard, change, or terminate their			

				employment ○ Directives on how system vulnerabilities will be proactively detected and security patches will be systematically deployed and verified ○ Instructions to personnel on reporting potential security concerns or incidents ○ Evidence that the WISP has been updated, approved by management and communicated to all personnel annually			

				○ Evidence that all personnel have agreed to abide by the WISP as a condition of employment or contract ○ Evidence that all personnel receive regular training on the topics of information security and data privacy obligations and risks • Consider alignment of the information security program to a credible regulatory framework (e.g., ISO 27001) and maintain evidence of control testing. • Use the supervisory authority's security			

				framework and any existing third party security and privacy audits as evidence of compliance to this requirement.			

5	5.23		(NEW) Prior to collecting, processing or sharing personal information, all unnecessary identifiers must be removed from the data set. Where it has not been possible to remove all personal identifiers, the data should be encrypted before it is copied to removable or portable media, or transmitted using unsecured channels.	*Note* : Provide with the shortened application **Explanation**: It is recommended that all portable and removable media used to store personal information enforce data encryption by design. Prior to collecting, processing or sharing personal information, all unnecessary identifiers should be removed from the data set. Pseudonymized or identifiable donor or patient information should be encrypted when transmitted over open networks (e.g., internet). Pseudonymized data are data where the identity of the data subject is removed in such a way that additional information is required to re-identify the subject. For example, a donor is assigned an anonymous identifier but the donor center retains the link between the anonymous identifier and the donor identity. So a transplant center, for example, cannot identify the actual	x	o	x

				donor unless it had access to the information from the donor center. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure to remove unnecessary identifiers or to encrypt a dataset **Technical details:** It is recommended that the registry: • Takes the necessary steps to avoid the disclosure of donor or patient personal information. Even pseudonymized data (i.e. data where the most identifying data points, such as name and full address, have been removed or replaced) can be put together with other datasets (such as census data or marketing data) to allow			

				identification of a donor. For this reason, if data cannot be fully anonymized, it must be encrypted before it is placed on easily removable physical media (such as USB stick, DVD or portable hard drive) or before it is sent via unsecured data connections (such as the internet, email or file sharing services like DropBox or Google Drive). • Defines the extent of information that must be provided to specific entities. For example, donor information provided to a Transplant Center (e.g., anonymous identifier, age, gender, HLA type) will be more extensive than that provided to an HLA typing laboratory (only anonymous identifier). Patient			

				names should be replaced with an anonymous identifier.			

5	5.24		(NEW) Evidence of compliance to the requirements for data protection must be maintained for a minimum of six (6) years.	*Note* : Provide with the shortened application **Explanation**: The following list is an example of the most common types of documents that would be retained for the time required, when applicable. • Notices of privacy practices • Authorizations for the disclosure of PHI (Protected Health Information) • Risk assessments and risk analyses • Disaster recovery and contingency plans • Information security and privacy policies • Incident and breach notification documentation • Privacy complaint and resolution documentation • Evidence of PII (personally identifiable information) access surveillance	x	o	x

				• IT security assessments • Evidence of maintained update cycle and penetration testing for internet facing servers **Information/evidence to be provided (or equivalent alternative)** : • Policy for retention of documents related to data protection **Technical details:** It is recommended that the registry: • Maintains a policy for data protection which covers the requirements of the national law and the WMDA standards.			

5	5.25		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.	*Note* : Provide with the shortened application **Explanation**: Records must be kept in an organised and retrievable manner for at least 30 years so that if there is a need to investigate the origin or final destination of a product or sample, it could be done in a reasonable period of time (e.g., 5 working days). **Information/evidence to be provided (or equivalent alternative)** : • Policy for document retention **Technical details:** It is recommended that the registry: • Maintain a policy for storage of records pertaining to donation ○ The policy should demonstrate compliance with the minimum	x		

				standard of storing records for at least 30 years post-donation ○ The policy should describe the requirements for safe / secure archival of records in both electronic and paper formats ○ The policy should describe the process by which archived records may be accessed (including time frames required) • Maintain a policy for the backup and recovery of the registry database • Maintain a written agreement with any entity storing			

				their physical or electronic records off-site, describing how confidentiality is protected			

5	5.26		(NEW) If the registry has internet-facing web applications which process pseudonymized or identifiable donor or patient information, independent penetration testing must be performed annually. Any identified security vulnerabilities must have a documented remediation plan. Risks identified by this testing must be formally overseen by the registry's security role.	*Note* : Provide with the shortened application **Explanation**: This is an additional standard for WMDA registries with internet facing web applications (i.e., if registry has applications operating over the internet that use donor or patient identifying data). Computers with an interface to the internet are at risk of being penetration by ill-willing individuals / organisations with various malicious intend (e.g. demanding ransom). While accessing data via the Internet, it is necessary to ensure the security of the application providing the data with regular security tests against data leakage. Although computer systems may not change regularly, the external threats to web applications change often, so the penetration test should be at least annual. The breadth and depth of this testing may be varied, but some level	x	o	x

				of penetration testing should be performed annually. Penetration testing is an authorized, simulated attack on a computer system, performed to evaluate the security of the system. The test is performed to identify weaknesses, including the potential for unauthorized parties to gain access to the system's features and data. Pseudonymized data are data where the most identifying data points, such as name and full address, have been removed or replaced. These data are not deidentified because there is a link to the identities in the registry or donor center. **Information/evidence to be provided (or equivalent alternative)** : • If applicable, a policy and/or procedure describing the frequency fo penetration testing and for			

				addressing risks identified **Technical details:** It is recommended that the registry has: • System architecture that could/should include a separation of data servers and internet servers with a specially protected server ("de-militarized-zone", "firewall") in between mediating data between the front and back end. These servers need to be kept up to date and tested for safety regularly. • A policy that spells out the process to be followed, and documentation that evidences the process being followed, including remediation for any weaknesses identified.			

				• A plan for penetration testing and records of it being carried out. The breadth and depth of this testing may vary but the registry should consider best practices to ensure that the testing is sufficient. Any risks or weaknesses identified by these tests should be recorded and reviewed by the person in the registry who is responsible for data security. Action should then be put in place as soon as possible to address these issues. • A record of testing results that is evaluated by the Data Protection Officer at least once a year.			

5	5.27	x	**(NEW) If the registry downloads the WMDA global file containing pseudonymised donor and cord blood data, it must perform annual security assessments against all systems which process data from the WMDA donor file. Any identified security vulnerabilities must have a documented remediation plan. The assessment, results and remediation plan must be formally overseen by the registry's security role.**	**Benchmark standard** *Note* : Provide with the shortened application **Explanation**: This is an additional standard for WMDA registries who receive the WMDA donor download file. This file requires special security measures. Therefore, the registry must, in addition to the security requirements of these standards, perform annual security assessments against all systems which process data from the WMDA donor file. It is necessary to ensure the security of all downloaded and processed donor data with regular security tests of the IT systems to prevent data leakage of any kind. This includes both external and internal security risks. **Information/evidence to be provided (or equivalent alternative)** : • If applicable, policy and/or procedure for the frequency of risk	x	x	x

				assessments and for addressing risks identified • Description of the role of the Data Protection Officer in this evaluation **Technical details:** It is recommended that the registry: • Has a policy/procedure for performing security assessments of all system parts processing WMDA donor file • Evaluates the record of security assessments results by the data protection officer at least once a year.			
5			**Third parties**				

5	5.28		If the registry has functions needed for information management that are performed by, or with the help of, qualified third parties, the third party appointed must comply with the relevant WMDA security standards and WMDA Data Use Agreement for the functions which they are providing. Responsibilities of both parties must be described in writing.	*Note* : Provide with the shortened application **Explanation**: This WMDA Standard covers the instances where the IT support staff are not direct employees of the registry (e.g., a company or a university). by including a screen shot or link to Share It is important to make sure that whomever is hired to work with the registry's computer system: • Has the appropriate experience • Complies with the same WMDA standards as would be required for in-house service provision. This includes compliance with the WMDA Data Use Agreement. • Has clearly defined responsibilities. **Information/evidence to be provided (or equivalent alternative)** :	x	o	x

				• Service level agreements if a third party performs key activities **Technical details:** It is recommended that the registry has: • Documentation of a service level agreement with third parties responsible for performing any IT support functions. For example, a third-party agreement for hosting an Internet available application, which includes system maintenance routines and vulnerability patching of the hosted environment. • Documentation describing the expertise required for any significant outsourced information technology support. For example, describe the electronic			

				forensic skills necessary in a third party which performs discovery services for the registry, or the skills necessary to perform disaster recovery, or business continuity services. • Documentation of a service level agreement describing how confidentiality is protected			
6	**6**		6. Facilitation of search requests				
6			**Communication**				

6	6.01	x	**Critical communications among registries and other organisations must be in legible writing or transmitted via an electronic system.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist • Reference: A Gift for Life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 3 Donor search request **Explanation**: The registry is expected to ensure that all critical communication with the donor centre, collection centre and transplant centre/foreign registry is in writing or through an established electronic system and accomplished in a timely manner. Communications should be type-written, not written by hand. The registry should be capable of receiving and handling requests from transplant centres and from other registries in a standardised manner. The registry should have access to a dedicated fax			

				machine, e-mail, and may maintain a web page. The registry may also utilise a type of search tool similar to EMDIS (European Marrow Donor Information System). **Information/evidence to be provided (or equivalent alternative)**: • Contact information, at a minimum, phone, fax, and e-mail • If applicable, a description of the registry's electronic search tool(s)			

6	6.01.1		These communications should contain a signature of authorisation and be sent by fax or email or should be submitted through authorised access to a communication system.	**Reference**: • WMDA Forms **Explanation**: The communication between parties involved in registry work and processes should be traceable. It should be possible to identify the person who completed the task. If using forms, a signature should be present. If using a group e-mail, the person sending the message should be identified within the message. If using an individual e-mail, the e-mail account should be identifiable to the registry. If using any electronic system, the registry is expected to have a procedure for authorisation, for example, to allow user access. **Information/evidence to be provided (or equivalent alternative)**: • Samples of forms with the signature line and date of issue; there is no need to include copies of all			

				forms. Completed forms should not be included. • The procedure for accessing registry communication systems and identification of persons using the email/electronic system *Note*: Do not submit any completed forms with personal data			

6	6.01.2	x	**Donor and patient identity must remain confidential throughout the search process so that only appropriate registry or affiliated personnel have access to these data.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy regarding confidentiality of donor/patient information. The policy should include the following elements: • Physical barriers to protect information, for example, swipe card access, locked rooms, locked cabinets, etc. • Means for exchange of Information contained in communications which may compromise donor/recipient confidentiality • Description of what information third party organisations such as collection centres, donor centres, and			

				transplant centres are allowed to have, and how this is controlled; Including appropriate confidentiality clauses in their third party contracts • Confidentiality training for staff or having staff sign confidentiality agreements **Information/evidence to be provided (or equivalent alternative)**: • Policy regarding confidentiality of donor/patient • A search report (with patient information removed) showing that donors are not named but listed with an anonymous identifier • Any relevant national privacy laws and indicate their impact on registry operations if appropriate			

				Note: Do not submit any completed forms with personal data			
6			**General Requirements**				

6	6.02		The registry must have a mechanism to assess donor requests from organisations acting on behalf of international patients.	**Reference:** • WMDA Share - operational information **Explanation**: The registry must to be able to handle international search requests. The registry is expected to have formal requirements for submission of a search request available to requesting transplant centres and registries. The requirements and forms may be available on the registry website and/or WMDA Share. **Information/evidence to be provided (or equivalent alternative)**: • A description of how international searches are handled. Provide any policies/procedures and forms that are applicable. *Note*: Do not submit any completed forms with personal data			

6	6.02.1	x	**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 organisations authorised to provide hematopoietic stem cell treatment.**	**Benchmark standard** **References**: • King et al. Unrelated hematopoietic stem cell donors as research subjects reference on research. *Bone Marrow Transplantation (2011) 46:10–13* • Confer et al. WMDA Guidelines for subsequent donations following initial BM or PBSCs. *Bone Marrow Transplantation (2011) 46: 1409-1412* ; update in progress **Explanation**: This WMDA Standard has two parts: • What are the criteria that must be met before a volunteer donor from the registry is allowed to donate? This is to ensure that the donor avoids futile			

				examinations and donations. • How the criteria are made available to the public. The Donor Care Pillar of WMDA recommends that the registry's policy include the following: • Information required from the transplant centre about the patient prior to search and/or release of a donor (age, disease and stage, weight, etc.) • Transplant centre responsibility to inform the patient (e.g., assurance that the patient is aware of the right of the donor to withdraw, the policy about subsequent donations, etc.) • Donor informed consent for the donation • Transplant centre credentials such as accreditation status or other evidence of compliance with			

				national or international standards • Transplant indications for which a donor can be released for the specific patient • Donors as research subjects • Patient HLA typing (resolution and loci) and samples required prior to search and/or release of a donor • Minimal HLA matching requirements between patient and donor. This may differ from the matching requirements used by the transplant centre for donor selection. • Subsequent donations (e.g., number, route and timing of subsequent donations) • Maximum volume or number of procedures for blood or marrow collection			

				The registry must have a mechanism to make this information accessible for transplant centres and registries, for example, a reference to the registry website. This information should be available in English. **Information/evidence to be provided (or equivalent alternative)**: • A policy listing conditions under which donors are available for patients • A description of how the policy is made available			

6	6.02.2		(NEW) If the registry criteria are not met, the registry must raise any concerns or questions to the requesting organisation.	*Note*: Provide with the shortened application **Explanation**: Should specific criteria (for example, level of compatibility) or patient characteristics (for example, age, diagnosis) require further information or results that do not meet the registry's minimum criteria, this must be communicated to the requesting registry/transplant centre. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure describing the acceptable minimum criteria and how these cases are managed. The document should outline how incoming requests are verified and how denials or requests for further information are communicated to	x	o	x

				transplant centres or registries.			

6	6.02.3		A donor/cord blood unit selected for a specific patient must be placed on a “reserved” status from the time of verification typing until the donation/cord blood unit shipment date is reached.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry is expected to have a policy indicating that a donor or cord blood unit is ‘reserved’ for a specific patient once a verification typing request or workup request has been received. Reserved means that the donor does not appear as available on the search reports of other patients. There may be separate policies for donors requested for verification typing and those requested for workup. **Information/evidence to be provided (or equivalent alternative)**: • The policy about the reserved status. Reservation of donors may also be included in automated systems (e.g., EMDIS or Search			

				& Match Service of WMDA).			
6	6.02.4		If the donation/shipping date is not scheduled or is delayed, a maximum time limit and the procedures for granting exceptions for this status must be set in writing and be readily accessible to health care professionals involved in hematopoietic stem cell transplantation.	**Explanation**: The registry policy must have a specified 'reservation' time limit for donor/cord blood reservation together with an option to extend the reservation. **Information/evidence to be provided (or equivalent alternative)**: • A policy/procedure describing how to request an extension and the process for approval/rejection • A link to or a description on how professionals can access this information			
6			**Testing**				

6	6.03	x	**Registries must respond to search requests and to requests for additional information and donor/cord blood/maternal samples within a time period consistent with WMDA metrics and in a defined manner.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • WMDA key performance indicators • Instructions how to export your KPIs **Explanation**: The registry is expected to have a policy or procedure for the timely response to requests received. Additionally, the WMDA has a set of key performance indicators that can be used to compare the registry's performance with that of other registries. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure for the processing of requests upon receipt, including			

				acceptable time frames • The latest WMDA Global Trends Report questionnaire (past three years) of the registry, showing the time frames for responses. Indicate the percentage of typings and shipments of blood samples that have met the recommended time frames on the most recent WMDA report. • A sample of a search result report that indicates the time from search submission to the time the search report was sent to the requester (all personal identifiers should be removed before submission) *Note*: Do not submit any completed forms with personal data			

6	6.03.1		Registries or their associated donor centres/cord blood banks must have the capability of shipping samples, if available, to the facility indicated by the transplant centres if required for further testing. The sample must be appropriate for the testing required.	**Reference:** • Instruction how to prepare export of WMDA Global Trends Report **Information/evidence to be provided (or equivalent alternative)**: • The policy or procedure for shipping donor, cord blood or maternal samples to a transplant centre for additional infectious disease or other testing • The registry should show that they have shipped samples by referring to data from the WMDA Global Trends Report			
6	6.04		Verification typing of:	Verification typing of:			

6	6.04.1		the adult donor at a minimum of HLA-A, -B, -C, -DRB1 DNA based typing at high resolution must be performed prior to a hematopoietic stem cell donation for a specific patient.	*Note* : Provide with the shortened application **Reference**: • Nunes et al. Definitions of histocompatibility typing terms: Harmonization of Histocompatibility Typing Terms Working Group. *Human Immunology (2011) 12:1214-1216* **Explanation**: The purpose of verification typing is to ensure that the individual being selected for donation is the same individual whose HLA typing was listed on the search report used to select the donor. Because of the likelihood that two random individuals share some HLA types, it is important to type several HLA loci spanning the HLA region. This retesting should be performed on a sample from the donor different from that used in the recruitment typing or, for cord blood, from a segment attached to the	x	o	o

				unit. Donor verification typing results should be available prior to the first G-CSF injection and product collection. This WMDA Standard does not cover “extended typing” which is used to establish the level of match between donor and recipient. Extended typing can be used as verification typing if the sample requirements are met. **Information/evidence to be provided (or equivalent alternative)**: • A policy for HLA typing of the donor selected for a specific patient. This document should describe the HLA loci typed.			

6	6.04.2		the cord blood unit at a minimum of HLA-A, -B, -DRB1 DNA based typing must be performed prior to shipment for a specific patient in a way that at least one typing result (previous or extended typing) for each locus is at high resolution.	**Reference**: • Nunes et al. Definitions of histocompatibility typing terms: Harmonization of Histocompatibility Typing Terms Working Group. *Human Immunology (2011) 12:1214-1216* **Explanation**: The purpose of verification typing is to ensure that the cord blood unit being selected for donation is the same unit whose HLA typing was listed on the search report used to select the donor. Because of the likelihood that two random individuals share some HLA types, it is important to type several HLA loci spanning the HLA region. This retesting should be performed from a segment attached to the unit. Unit verification typing results should be available prior shipment to the transplant centre.		o	o

				Information/evidence to be provided (or equivalent alternative): • A policy for HLA typing of the unit selected for a specific patient. This document should describe the HLA loci typed.			

6	6.05		The policy of the registry regarding repetition of the database search for a specific patient must be defined and readily accessible to health care professionals involved in hematopoietic stem cell transplantation.	**Explanation**: This WMDA Standard is about the repeat search for a donor. For example, if a search is submitted and a search report is provided, does the registry continue to include the patient on searches run regularly after that first report? Must a new search request be submitted for a repeat search? **Information/evidence to be provided (or equivalent alternative)**: • Policy regarding repeated searches including how they are handled and processed. Information provided should also include how transplant centres or other registries are informed of the policy.			
6			**Workup - shipment request**				

6	6.06	x	**The donor centre/cord blood bank must be informed of the proposed date(s) of transplant at the time a specific donor/cord blood unit is requested for transplantation for a specific patient. If a volunteer donor will be the source of HSC, the donor must also be informed. The transplant centre must specify the latest date by which the donor centre must approve the eligibility of a donor for donation of HSC for a specific patient (i.e., provide donor clearance).**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference:** • WMDA Forms **Explanation**: The registry's workup forms are expected to include the following: dates of patient's conditioning, graft infusion date, proposed collection dates, and donor clearance date. The registry should provide the donor centre with all forms including the requested workup schedule, patient status and degree of urgency. Donor centre and registry should have a communication system in place to inform the transplant centre in case the donor can't be reached in a reasonable number of days after the workup request or when some complications occur.			

				Information/evidence to be provided (or equivalent alternative): • Policy/procedure indicating how donor centre and donor are notified of the proposed workup schedule with any applicable forms. Registry policy should include a reasonable time frame for providing/confirming the schedule to the transplant centre. • Forms including (1) workup form; (2) donor clearance form; (3) workup checklist *Note*: Do not submit any completed forms with personal data			

6	6.06.1		Prior to transplantation, the registry must have a process for communicating the donor's preference to the appropriate transplant centre in a timely fashion to indicate the type of cells and to communicate any other donor-specific issues that may impact the transplantation. Nevertheless, the donor must be free to change their mind at a later date.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • WMDA forms **Explanation**: The registry is expected to have a policy or procedure that describes how the transplant centre is advised of donor preferences and other related issues which may result in the postponement or cancellation of the stem cell collection (e.g., type of products the donor is or is not willing or capable of providing; any potential or permanent donor deferral reasons). This type of notification may be communicated via a form or letter that is used as standard in the communication with transplant centres. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure for informing the			

				transplant centre/registry of critical information pertaining to the donor which could impact the collection or transplant • Template of forms or letters that are used to communicate critical information to the transplant centre/registry. *Note*: Do not submit any completed forms with personal data			

6	6.06.2	x	**The registry must have a process to communicate issues related to donor health and the release of an increased risk product to the transplant centre.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry must have a policy and/or procedure that describes the communication of donor-related issues/behaviors considered to have a potential to be of increased risk to the recipient and which may require an exceptional release of the product. For example, where the donor may have a communicable or hereditary disease that could negatively impact the recipient. Some examples include (but not limited to) traveling to countries at high risk for HIV-O or Zika, positive screening tests results for communicable diseases, diagnosis or treatment of syphilis, certain vaccinations, behavior that is high risk for communicable diseases or family history of relevant hereditary diseases. The policy/procedure should			

				include a documentation of clinical need and signature of the transplant centre physician. **Information/evidence to be provided (or equivalent alternative)**: • Policy and, if available, a form used to communicate this information to the transplant centre			

6	6.06.3		An increased risk product should be released by exception only when there is a documented clinical need for the product and when approved by the physician of the transplant center.	**Explanation**: The policy and/or procedure that describes the release of products that are considered to have increased risk should include a documentation of clinical need and signature of the transplant centre physician. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure and, if available, a form used to document the willingness of the transplant centre to proceed with the collection regardless of the increased risks to the recipient			
6			**Post donation**				

6	6.07	x	**The registry must have a documented policy listing the conditions under which donors and recipients might be informed of each other's identity. This policy must comply with local regulation on disclosure.**	**Benchmark standard** **Explanation**: Some registries allow donor and recipient to be informed of each other's identity while others may not. The policy must include if the exchange of information is permitted and under which circumstances. **Information/evidence to be provided (or equivalent alternative)**: • Policy describing the conditions under which donors and recipients might be informed of each other's identity. If this is not allowed, the registry should submit a policy indicating this.			
7	**7**		7. Second and subsequent donations of HSC and/or blood products for the same patient				

7	7.01	x	**The registry must have a documented policy regarding the process to be followed when a transplant centre requests a subsequent donation and the time frame for the process of approval.**	**Benchmark standard** **Reference**: • Confer et al. WMDA Guidelines for subsequent donations following initial BM or PBSCs. *Bone Marrow Transplantation (2011) 46: 1409-1412* ; update in progress **Explanation**: The registry might have a policy for how a request for a second donation from the same donor to the original recipient is handled. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure/ form used for a subsequent donation			

7	7.01.1		This policy must include the specific details that the transplant centre should provide to justify the need for a subsequent donation.	**Reference**: • Confer et al. WMDA Guidelines for subsequent donations following initial BM or PBSCs. *Bone Marrow Transplantation (2011) 46: 1409-1412* ; update in progress **Explanation**: The registry might have a form or template for a request that needs to be completed to justify a subsequent donation request. The specific items that should be included on the form are: (1) basic current clinical data of the recipient's disease, (2) current status of recipient, (3) reason for the request, and (4) if the request should be considered urgent. **Information/evidence to be provided (or equivalent alternative)**:			

				• The policy or procedure • Any form and/or template for the request and/or copy of the instructions that the registry provides to transplant centres who wish to make a second donation request			
7	7.01.2		This policy must be readily available to relevant health care professionals.	**Explanation**: The registry must explain how the policy is made available to transplant centres. For example, the policy can be made available on the registry webpage or as a letter or form that can be sent to the transplant centre upon request. The policy should be in English. **Information/evidence to be provided (or equivalent alternative)**: • A link to a website or otherwise a description of how the policy is made available.			

8	**8**		8. Collection, processing and transport of hematopoietic progenitor cells				

8	8.01	x	**Collection of hematopoietic stem cells and any other collected cells intended for therapeutic use, must be performed at a collection centre/cord blood collection site conforming to local regulation.**	**Benchmark standard** **Reference**: • A Gift for Life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 4 Collection and transportation **Explanation**: It is the responsibility of the registry or cord blood bank to ensure that all collection centers are conforming to local or national regulations. If there are no local/national regulation, the registry could establish its own regulations or rely on international recognised accreditations such as JACIE-FACT or FACT-NetCord or AABB. If local laws and regulations differ from the WMDA Standards, the requirement to meet local legal standards will be accepted as a valid cause of deviation from WMDA Standards.			

				Information/evidence to be provided (or equivalent alternative): • A description of collection centres and cord blood banks that are affiliated with the registry (the organisational chart provided for WMDA Standard 1.01 can be used) • Evidence of accreditation of the collection centre and the cord blood bank. For example, provide an example of current certificate from a collection centre and one from a cord blood bank to show accreditation by JACIE, FACT, NetCord-FACT, AABB or provide a single example of national/local equivalent accreditation status. An internet link to that information is acceptable. • In the absence of a national or local			

				regulation, the registry may indicate that the registry has established its own requirements. The registry might then provide a document that specifies these requirements and how those requirements are assessed. If an audit is performed by the registry, a copy of the audit checklist used.			

8	8.02	x	**The collection centre/cord blood collection site must ensure the identity, safety and privacy of the donor and the confidentiality of the donor and cord blood data.**	**Benchmark standard** *Note*: If the collection center is licensed by the government or holds FACT-NetCord, AABB or FACT-JACIE accreditation, this may be supplied as evidence for compliance with this WMDA Standard. **Reference**: • Lara-Weisshaupt et al. Audits of collection and apheresis centers: guidelines by the WorldMarrow Donor Association Working Group Quality and Regulation. *Bone Marrow Transplantation (2019) 54:244–257* **Explanation**: The collection centre and cord blood bank are expected to have policies and/or procedures for ensuring the identity of the donor (unrelated volunteer or maternal donor) and for ensuring their safety and			

				protecting their identity and data. It is the responsibility of the registry to ensure that the collection centre and cord blood bank fulfills these requirements which could be demonstrated by including this in a Service Level Agreement or by performing an annual audit to assess compliance with this standard or by including an accreditation certificate from FACT-NetCord, AABB or FACT, JACIE. **Information/evidence to be provided (or equivalent alternative)**: • Policies, procedures or Service Level Agreement. For example, provide a blank audit form that indicates that the registry ensures that the collection centre/cord blood bank complies with this WMDA Standard.			

8	8.03	x	**The collection centre/cord blood bank collection site and the collection of hematopoietic stem cells or other donor cellular products must be under the direction of trained and experienced health care professionals.**	**Benchmark standard** *Note*: If the collection center is licensed by the government or holds FACT-NetCord, AABB or FACT-JACIE accreditation, this may be supplied as evidence for compliance with this WMDA Standard. **Reference**: • Lara-Weisshaupt et al. Audits of collection and apheresis centers: guidelines by the WorldMarrow Donor Association Working Group Quality and Regulation. *Bone Marrow Transplantation (2019) 54:244–257* **Explanation**: The collection centre should have procedures for identifying training needs and providing training for collection centre staff and any staff performing collection activities. Likewise, a cord blood bank should have similar procedures for			

				their cord blood collection sites. Education and training should be documented in writing. It is the responsibility of the registry to ensure that the collection centre/cord blood bank fulfills these requirements by including this in a service level agreement or by performing a regular audit. **Information/evidence to be provided (or equivalent alternative)**: • Documentation on how the registry assures compliance, for example, a blank collection centre or cord blood bank audit form that checks the training and experience of the staff or Service Level Agreement with a collection centre requiring accreditation or licensing *Note*: It is not necessary to provide individual training documents for			

				specific staff members. It is not necessary to provide job specification for individual staff.			

8	8.04	x	**If required, autologous donor blood must be collected at a blood collection centre conforming to the local regulation.**	**Benchmark standard** **Explanation**: It is not necessary to collect autologous donor blood but, if this is a routine practice, the registry is expected to have a policy regarding the accreditation/licensure of the blood collection centre. **Information/evidence to be provided (or equivalent alternative)**: • The policy on collecting autologous donor blood • Evidence that autologous blood collection is carried out by an accredited/licensed authority. A specific internet link to that information is acceptable or an example of a Service Level Agreement with a blood collection centre requiring accreditation or licensing.			

8	8.05	x	**If a donor is subjected to a medical intervention as part of the collection process, the registry must have documented policies and procedures to protect the health and safety of the donor and of the recipient.**	**Benchmark standard** **Explanation**: It is important for a registry to have consistent and documented approaches when medical intervention is necessary. Examples of medical intervention include: G-CSF administration, bone marrow collection under general anaesthesia, and central venous catheter use. The registry is expected to have policies and procedures and, where appropriate, Service Level Agreements with collection centres detailing the acceptable procedures for mobilisation, collection and donor follow-up. **Information/evidence to be provided (or equivalent alternative)**: • The policy and procedure • The information that is provided to the donor explaining the process and risks			

8	8.05.1		These policies must include the procedure to follow in case of failed mobilisation, including the potential to switch to a bone marrow collection if necessary.	*Note*: Provide with the shortened application **Explanation**: The registry must have a policy regarding the procedures to occur in the case where mobilisation of stem cells fails. **Information/evidence to be provided (or equivalent alternative)**: • The policy and procedures • Information provided to the donor to explain the consequences of failed mobilisation	x	o	x

8	8.05.2	x	**The registry must have a policy concerning the use of Central Venous Catheter in donors to ensure that a Central Venous Catheter is only used in exceptional circumstances. Those circumstances must be documented.**	**Benchmark standard** **Explanation**: The use of a Central Venous Catheter (CVC) should be limited to exceptional cases and this should also be stated in the Service Level Agreement with the collection centre. The registry must have a policy for those exceptional cases. **Information/evidence to be provided (or equivalent alternative)**: • The policy highlighting the section that references documentation of the circumstances when a CVC might be used • The information provided to the donor to explain the risks of CVC use			

8	8.05.3	x	**The registry must have a policy that protects the safety of the donors with a Central Venous Catheter inserted.**	**Benchmark standard** **Explanation**: The policy should cover, at a minimum, the need for the following (these can also be in a Service Level Agreement): • Requirement for peripheral venous assessment at the time of donor medical evaluation • Requirement to discuss alternative methods of donation • Consenting procedures (and counselling) for CVC insertion, including identifying the staff member who conducts the information session • Qualifications and expertise of the person(s) permitted to insert the CVC • Permissible sites for CVC insertion • The requirement for radiological guidance for all CVC inserted			

				above the umbilicus, if locally available • The need for in-hospital care for all donors with CVCs, cared for by appropriately trained personnel • Procedures for care and advice to be given to all donors following removal of CVC **Information/evidence to be provided (or equivalent alternative)**: • The policy or SLA for insertion of a CVC			

8	8.06	x	**Documented policies and procedures must be in place to ensure the identity, quality and quantity of the collected cells are communicated appropriately amongst the transplant centre, collection centre/cord blood bank and cell-processing unit.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • WMDA forms **Explanation**: There must be a policy to indicate the flow of communication between the registry, the collection centre(s) or cord banks, and the transplant centre. The policy should reference the use of forms to communicate this information. For example, a policy that indicates the use of WMDA forms for prescription and verification typing would meet this standard. If non-WMDA forms are used, there should be a process to ensure that all information on the WMDA form is included. Information from the transplant centre including details of quantity, cell counts and volume must be			

				transmitted to the collection centre. Likewise any potential limitations of the actual or estimated volume of hematopoietic stem cells on the HSC prescription form used by the collection centre must be communicated to the transplant centre. **Information/evidence to be provided (or equivalent alternative)**: • A standard operating procedure or policy that gives details of the communications with transplant centres, collection centres, cord blood banks • The procedures for review of the requests for collections from transplant centres • An example of forms/documents used to provide a request to the collection centres. The registry might provide a example of a blank stem cell prescription			

				form and verification form. • A procedure describing how the collection centre communicates back to the registry the feasibility to collect the requested amount of cells and any anticipated problems			

8	8.07	x	**Documentation of the characteristics of the collected product important in facilitating transplantation must be provided with the cells according to applicable guidelines. The documentation and/or label, at a minimum, must include information on the name of the product and product code, the number of cells collected, the donor's unique identifier, donor ABO/Rh group, identification of the patient, date and time of collection, any processing details, and name and contact information of the transplant centre.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The use of WMDA forms would ensure that all relevant information is captured. If registry-specific or collection centre-specific forms are used, there might be a process to ensure that, at a minimum, the information indicated on the WMDA forms is collected. The accompanying documentation and/or label must include: • name of the product and product code • the number of cells collected • the donor's unique identifier • donor ABO/Rh group • identification of the patient • date and time of collection (only in case of volunteer donors)			

				• any processing details • name and contact information of the transplant centre Product labelling must follow national or international standards. The registry should send a traceability form to the transplant centre to confirm the identity of the product, and to capture information related to the date and the time the product was received and infused, processing, counts, amount used/cryopreservation of surplus, engraftment data, adverse events, etc. Records documenting the individual who accepted the product should be retained. **Information/evidence to be provided (or equivalent alternative)**: • Forms/documentation that the collection centre uses as distribution records that contains a minimum data set			

				as described in the standard • An example of product labeling • Any form completed by the transplant centre upon receipt of the product if one is used			

8	8.07.1		The registry should utilise an international coding and labeling system for the donation number to ensure the identity of the product.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference:** • Circular of information for the use of cellular therapy products **Explanation**: Examples of internationally approved coding systems include ISBT128, Single European Code (SEC), Eurocode, or European Tissue Code (EUTC). **Information/evidence to be provided (or equivalent alternative)**: • Copy of product label with a description of which coding system is used			

8	8.08	x	**Critical transport conditions, such as temperature and time limit must be defined to maintain the required cell properties.**	*Note*: Provide with the shortened application **Benchmark standard** **Explanation**: Typically, either the supplying registry or the receiving registry will take responsibility for the transport. If there is no hub, the transplant centre may serve this role. If not responsible for the transport, the supplying registry might ensure that transport instructions are available. This is important to ensure that the donor doesn't undergo a needless procedure if cells are damaged during transport. Packaging instructions should be provided to the courier. Registry 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 centre to ensure receipt	x	x	x

				by the transplant centre, procedures to avoid damage of the cells, and procedures to maintain anonymity of patient and donor. **Information/evidence to be provided (or equivalent alternative)**: • Policy describing responsibility for providing packaging instructions and for defining transport conditions • Document describing packaging instructions			

8	8.08.1	x	**Cells must be transported by a trained person in a timely and reliable fashion to meet transplant centre requirements for the quality of the cell product upon arrival at the transplant centre.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist Reference: • World Marrow Donor Association (WMDA) Guidelines for Couriers and the Transportation of Hemopoietic Progenitor Cells (HPC-BM, Apheresis and Therapeutic Cells-T Cells) **Explanation**: Typically, either the supplying registry or the receiving registry will take responsibility for the courier and be designated as the courier registry. If there is no hub, the transplant centre may serve this role. It is the responsibility of the courier registry to ensure that the courier is properly trained. The courier registry is deemed to have provided the courier if they are			

				either directly using a courier from within their organisation or have arranged for collection and delivery of the product by a third party (e.g., a specialised courier company). The registry providing the donor might request the training policy of the courier registry/transplant centre or might send their policy on conditions of transport to the courier registry / transplant centre. **Information/evidence to be provided (or equivalent alternative)**: • Policies and procedures to describe the transport of products from the collection centre or cord blood bank • If a commercial courier is used either for import or export by the registry, a contract or Service Level Agreement should make it clear in			

				the specification (details) of this service. Provide one example of a service level agreement if this occurs. • If an in-house courier is used either for import or export by the collection centre or registry, details on the courier duties, responsibilities, and training			

8	8.08.2		Policies and procedures for training and qualification of individuals acting as courier and documenting the transport process should follow WMDA guidelines. The entity providing the courier is responsible for ensuring that the transport takes place according to WMDA guidelines.	**Reference:** • World Marrow Donor Association (WMDA) Guidelines for Couriers and the Transportation of Hemopoietic Progenitor Cells (HPC-BM, Apheresis and Therapeutic Cells-T Cells) **Explanation**: Couriers, whether in-house or commercial, should be trained or qualified to carry products **Information/evidence to be provided (or equivalent alternative)**: • Description of courier training or SLA with a courier company			

8	8.08.3		The container/package must be secure and ensure that the cells are maintained in the specified conditions. All containers and packages need to be qualified as fit for purpose.	*Note* : Provide with the shortened application **References:** • WMDA Validation of product transportation containers • World Marrow Donor Association (WMDA) Guidelines for Couriers and the Transportation of Hemopoietic Progenitor Cells (HPC-BM, Apheresis and Therapeutic Cells-T Cells) **Explanation**: All containers and packages need to be qualified as fit for purpose. **Information/evidence to be provided (or equivalent alternative)**: • A policy or procedure that addresses container qualification	x	o	x

8	8.08.4		Procedures for transportation and shipping of collected hematopoietic stem cells and cord blood units must be defined and qualified.	*Note : Provide with the shortened application* *Note:* This WMDA Standard is also covered in the on-site audit checklist **References**: • WMDA Validation of product transportation containers • World Marrow Donor Association (WMDA) Guidelines for Couriers and the Transportation of Hemopoietic Progenitor Cells (HPC-BM, Apheresis and Therapeutic Cells-T Cells) **Explanation**: Policies or procedures for transport of the product must be in place. These might 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	x	o	x

				contact the transplant centre to ensure receipt by the transplant centre, procedures to avoid damage to the cells, and procedures to maintain anonymity of patient and donor. Typically, either the supplying registry or the receiving registry will take responsibility for the transport and be designated as the courier registry. If there is no hub, the transplant centre may serve this role. **Information/evidence to be provided (or equivalent alternative)**: • If a commercial courier is used, a contract or Service Level Agreement must make it clear in the specification (details) of this service. Provide one example of a service level agreement if this occurs. • If an in-house courier is used (either from the collection			

				centre/registry), details on their duties and responsibilities • Description of training of couriers • If the transplant centre assumes responsibility for the transport, the registry representing the transplant centre should provide a policy that demonstrates how it ensures that the transport meets WMDA requirements			

8	8.08.5		In case of transport of a cord blood unit, the dry shipper must contain an electronic data logger that continuously monitors temperature throughout the transportation or shipping period.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: This WMDA Standard covers only the shipment of a specific unit from the cord blood bank to a transplant centre for a specific patient. **Information/evidence to be provided (or equivalent alternative)**: • Procedure that requires that a logger is required for shipment of cord blood			

8	8.08.6		Records of transport must be maintained to allow tracing of the product.	**Explanation**: The transport record must be stored to allow traceability. The transport record may contain a record of the temperatures over the period of travel, courier details, times of transport and product handovers. The registry should send a traceability form to the transplant centre to confirm the identity of the product, and to capture information related to the date and the time product was received and infused, processing, counts, amount used/cryopreservation of surplus, engraftment data, adverse events, etc. Records documenting the individual who accepted the product must be retained. **Information/evidence to be provided (or equivalent alternative)**: • Procedure regarding how records of transport are stored			

				• Where traceability records are stored • Procedure or other document describing how a copy of the transport record from a past delivery can be obtained			

8	8.09	x	**Serious Adverse Events affecting a cellular product intended for a specific patient must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Events must be submitted to the WMDA S(P)EAR Committee.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **References**: • Shaw et al. Towards a global system of vigilance and surveillance in unrelated donors of haematopoietic progenitor cells for transplantation. *Bone Marrow Transplantation (2013) 48: 1506-1509* • Adverse events (SEAR/SPEAR) **Explanation**: The registry is expected to have a procedure detailing how product adverse events are reported to WMDA and the responsibilities. The procedure should describe the responsibilities of the registry and of its affiliated entities such as transplant, collection, donor centre and cord		o	o

				blood bank for the initial management, follow-up and reporting of adverse events. Those procedures should outline what to report, time frame for doing this and also how the events are investigated. The registry may have a form used to document adverse event details, investigation and outcome. It is important that the registry have a mechanism to investigate the cause of an adverse event and to take steps to prevent another from occurring. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure related to adverse events impacting a product. The policy should include a reference to reporting the Serious Adverse Events to the WMDA S(P)EAR Committee.			

8	8.10	x	**Serious Adverse Reactions impacting the cellular product and hence potentially the patient's health must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Reactions must be submitted to the WMDA S(P)EAR Committee.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **References**: • Shaw et al. Towards a global system of vigilance and surveillance in unrelated donors of haematopoietic progenitor cells for transplantation. *Bone Marrow Transplantation (2013) 48: 1506-1509* • Adverse events (SEAR/SPEAR) **Explanation**: The registry's procedures are expected to include a process for reporting serious adverse events affecting a product to the WMDA Serious Adverse Events Registry. **Information/evidence to be provided (or equivalent alternative)**:			

				• Policy or procedure related to adverse reactions impacting a product and potentially the patient's health. The policy might include a reference to reporting the Serious Adverse Reactions to the WMDA S(P)EAR committee.			
8	8.10.1		Reports of Serious Adverse Reactions affecting the donated cellular product must be communicated to the registry/organisations involved in the transplant if the event might affect the transplantation or subsequent donation. Other individuals or groups should be notified as appropriate.	**Explanation:** The patient's registry must be notified if the adverse reaction may have an impact on the patient's health. The registry is expected to have a procedure for these events. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure/ form covering how and to whom information pertaining to adverse reactions is provided		o	o

8	8.10.2	x	**Serious Adverse Reactions occurring due to registry operations and impacting the health and safety of donors or patients must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Reactions must be submitted to the WMDA S(P)EAR Committee.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **References**: • Shaw et al. Towards a global system of vigilance and surveillance in unrelated donors of haematopoietic progenitor cells for transplantation. *Bone Marrow Transplantation (2013) 48: 1506-1509* • Adverse events (SEAR/SPEAR) **Explanation**: The registry is responsible for reporting serious adverse reactions due to registry operations. This might, for example, include corruption of the registry's donor database impacting ongoing searches or mishandling of confidential information resulting in release of a donor's identity. The registry's			

				procedures must include a process for reporting serious adverse reactions to the WMDA S(P)EAR Committee. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure related to adverse reactions due to registry operations potentially impacting the donor or patient's health and safety. The policy should include a reference to reporting to the WMDA S(P)EAR committee.			
9	**9**		9. Follow-up of patient and donor				

9	9.01	x	**The registry must have policies and procedures for the follow-up and care of donors immediately following the donation.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • A Gift for Life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 5 Post donation • WMDA Forms • Halter et al. Allogeneic hematopoietic stem cell donation-standardized assessment of donor outcome data: a consensus statement from the Worldwide Network for Blood and Marrow Transplantation (WBMT). *Bone Marrow Transplantation (2012) 48: 220-225* . **Explanation**:			

				The registry must have policies and procedures for short-term follow-up of the donors. The policies should clearly describe how tracking is ensured for example, which registry-affiliated entity is responsible, including definition of personal responsibility and competence. The policy should define the time between contacts with the donor. The registry may have forms to collect the follow-up information. The follow-up is for all donors, not just those who have experienced conditions related to donation. It is not specified how many times and when, but the registry must have a policy and it must be reasonable. For example, a policy might be to have a follow-up immediately after the donation and at established times if no relevant problem is found. **Information/evidence to be provided (or equivalent alternative)**:			

				• Policy or procedure for short term follow-up and any forms			

9	9.02		The registry must have policies and procedures for the long-term follow-up and care of donors for conditions related to the HPC donation, including a mechanism for donors to contact the registry to report related medical concerns for a minimum of ten (10) years after donation.	*Note*: This WMDA Standard is also covered in the on-site audit checklist **Reference**: • WMDA Forms • Halter et al. Allogeneic hematopoietic stem cell donation-standardized assessment of donor outcome data: a consensus statement from the Worldwide Network for Blood and Marrow Transplantation (WBMT). *Bone Marrow Transplantation (2012) 48: 220-225* **Explanation**: The registry must have a policy and procedure to describe how long-term donor tracking is performed. The policies should clearly describe how the tracking is ensured and who it applies to. Registries may perform long term follow-up of donors who		o	o

				have had donation issues or may follow a subset or all donors long term. In situations where this is logistically difficult (for example, when donors become unavailable over time), the registry may choose a different strategy. For example, they may counsel all donors about the need to inform the registry of any conditions that occur which they feel might relate to donation, and provide a mechanism to contact the registry if such conditions occur in the future. A 10-year limit is acceptable for a maximum window for reporting. Limitations in alternative strategies to monitor donor health long term should be considered in developing a long term follow-up plan. Policies and procedures are expected to cover care of the donor for any donation-related conditions. Donors who do have conditions related to the donation should be followed until			

				the condition has been resolved. The registry should have a policy and/or procedure to collect long term (at a minimum 10 years) outcome data from donors in situations where the long term effect of a treatment is not known e.g., where the donor has received a stem cell mobilising agent that has not yet been adequately tested for long-term effects. As such, all donors who have commenced the donation procedure (at least a single dose of growth factor administered) should be covered by this policy. This includes volunteers whose donation has not gone to completion. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure and any forms about long term follow-up • Information on how donors will contact the registry, if an			

				issue occurs long term			

9	9.03	x	**Serious Adverse Events and Reactions affecting donors undergoing collection of HSC and/or cellular product, occurring both in the long term and/or the shortterm as a consequence of the donation must be identified, documented, investigated and remedial and/or corrective action taken. The Serious Adverse Reactions must be submitted to the WMDA S(P)EAR Committee.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **References**: • Shaw et al. Towards a global system of vigilance and surveillance in unrelated donors of haematopoietic progenitor cells for transplantation. *Bone Marrow Transplantation (2013) 48: 1506-1509* • Adverse events (SEAR/SPEAR) **Explanation**: The registry is expected to have a documented process which addresses the identification and management of adverse donor events or reactions to be reported (SAE/SAR). It should describe the responsibilities of the registry and of its affiliated entities such as collection, donor centres and cord blood banks for		o	o

				the initial management, follow-up and reporting of adverse events. The registry may have a form used to document adverse event details, investigation and outcome. It is important that the registry have a mechanism to investigate the cause of an adverse event and to take steps to prevent another from occurring. **Information/evidence to be provided (or equivalent alternative)**: • Policy or procedure related to adverse events			

9	9.04	x	**The registry must comply with local regulations including requirements to report such adverse reactions to a regulatory agency.**	**Benchmark standard** *Note*: This WMDA Standard is also covered in the on-site audit checklist **Explanation**: The registry must indicate whether it is required to report adverse events to a regulatory agency. If the registry is required to report to a regulatory agency, the associated reporting process should be described in the registry's policies/procedures. **Information/evidence to be provided (or equivalent alternative)**: • If relevant, the name and a short description of the regulatory agency. An extract of the relevant legislation might be submitted in the application. • A policy or procedure describing this reporting activity including a copy			

				of a blank form, if used.			
9	9.05	x	**Donor health issues post-donation potentially affecting the health of a patient having received an HSC/cellular product from that donor must be reported to the requesting registry/transplant centre.**	**Benchmark standard** *Note:* This WMDA Standard is also covered in the on-site audit checklist **Explanation:** The registry is expected to have a policy or procedure concerning donor health issues post-donation that potentially might affect the health of the patient (recipient). The policy should define the responsible registry entity and the process of how such information is provided to the transplant centre and to whom it is provided. The registry may have a form to collect this information. **Information/evidence to be provided (or equivalent alternative)**: • Policy/procedure and any forms for reporting donor health issues		o	o

9	9.06		Registries should require their national transplant centres to submit data to regional or international patient outcome databases in order to collect clinical outcome data of the transplanted recipients.	**Explanation**: It is important that patient follow-up information be collected and provided to a database so that outcomes can be evaluated. For example, the registry might require submission of specific data to the EBMT or the CIBMTR or a regional database. The registry should have a policy or procedure for collection and submission of the data by transplant centres. The data required should be defined, e.g., engraftment, acute GVHD before 100 days. **Information/evidence to be provided (or equivalent alternative)** : • Policy and/or procedure describing how and by whom clinical outcome data is collected			
10			10. Financial and legal liabilities				
10			**Responsibilities**				

10	10.01	x	**The registry must keep complete and accurate financial records for services provided and requested according to local regulations.**	**Benchmark standard** **Reference**: • A gift for life: the essential WMDA handbook for stem cell donor registries & cord blood banks, 2nd edition, chapter 8 Finance and administration **Explanation**: The registry is expected to comply with common financial/accounting standards and to have policies and standard operating procedures covering this area. **Information/evidence to be provided (or equivalent alternative):** • A table of contents covering the relevant financial standard operating procedures • Latest audited financial report. If there is no audited financial report, the registry might instead provide			

				documentation describing the infrastructure and processes in place to keep financial records (standard operating procedures, software, etc.) and a policy describing the governance and management of financial policies.			

10	10.02	x	**A registry must have adequate administrative structures and financial resources to guarantee the settlement of all invoices in due course and to perform accounting duties.**	**Benchmark standard** **Information/evidence to be provided (or equivalent alternative):** • Registry policy for management of payables • Documentation indicating guarantee of payment of services • An organisational chart with the accounts/finance department listed. Describe the number of staff responsible for finance/accounting and a brief description of the main job duties of each section. It is not necessary to list individual staff or provide a detailed description of their job duties. The chart utilised in WMDA Standard 1.01 can be used. • The name of the programme administrator, their credentials			

				and their percent effort			
10			**Fee schedule**				
10	10.03		The registry must have available a fee schedule detailing payment terms for extended and verification HLA testing, infectious disease marker testing, product procurement, cancellation fee and other related services upon request.	**Information/evidence to be provided (or equivalent alternative):** • The current fee schedule. If fees differ for national and international patients, the international fee schedule should be provided. • Documentation describing policy and fees for billing/payment of services provided when a collection is cancelled after the final donor selection. Include a copy of the fee schedule with this issue noted.		o	o

10	10.03.1		The registry should have a procedure to communicate changes in the fee schedule to interested parties thirty (30) calendar days prior to implementation.	**Information/evidence to be provided (or equivalent alternative):** • Policies/procedures for how changes to the fee schedule are communicated to interested parties before implementation		o	o
10	10.04		The registry should have a procedure to communicate any cost not standardised or, for any reason, not accessible through a fee schedule and to ensure that the requesting registry is informed in advance.	**Explanation**: An example of a non-standardised test is when a donor requires additional medical tests to determine their suitability. The registry should have a policy and/or procedure indicating when and how these fees are communicated to others. **Information/evidence to be provided (or equivalent alternative):** • Policy/procedure/ form describing non-standardised costs and exceptions.			
10			**Invoicing**				

10	10.05		The providing registry must have a procedure to invoice to the requesting registry/transplant centre for requested services.	**Information/evidence to be provided (or equivalent alternative):** • Standard operating procedure including payment time frames, payment approval roles, structure and delegation guidelines • An example of an invoice for different services			

10	10.06		Invoicing should occur within sixty (60) calendar days of service completion.	**Explanation**: Invoicing is expected at the time of service provision, although weekly, monthly or bi-monthly invoicing is acceptable. Service completion is defined by the date when all results of a request are sent to the requesting registry or a stem cell product is shipped. **Information/evidence to be provided (or equivalent alternative):** • Policy or standard operating procedure describing the billing time frame			
10			**Payment**				

10	10.07		The requesting registry must have a procedure to ensure guarantee of payment for requested services.	**Information/evidence to be provided (or equivalent alternative):** • Documentation such as a standard operation procedure describing payment routines including rules and payment deadlines			
10	10.07.1		If the requesting registry cancels the service, the registry providing the service may expect full payment, provided that the services can not be cancelled and results are reported within thirty (30) calendar days of the cancellation date.	**Information/evidence to be provided (or equivalent alternative):** • Documentation such as a standard operation procedure or policy describing payment routines including rules and payment deadlines related to cancellations			

10	10.08		The requesting registry is liable for all expenses incurred on behalf of the organisations they serve.	**Explanation**: The registry requesting a donor or donor information/samples from another registry or cord blood bank on behalf of their national transplant centres is responsible for payment of the expenses of that request. The requesting registry should have a policy and procedure to collect funds from their transplant centres, institutions or persons who have requested these services. In cases where there is no national registry, it is the obligation of the requesting organisation to address the payment details. **Information/evidence to be provided (or equivalent alternative):** • Registry's policy for management of receivables including collection of receivables • Description of how the registry handles non-recoverable payment from			

				transplant centres, patients or institutions			
10			**Legal liability**				

10	10.09	x	**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 HSC procurement process. The registry is responsible for all reasonable expenses incurred by the donor.**	**Benchmark standard** **References**: • Egeland et al. Donor and liability insurance of donor registries, donor centers, and collection centers – recommendations . *Bone Marrow Transplantation (2004) 33: 467–470* . • Boo et al. Remuneration of hematopoietic stem cell donors: principles and perspective of the World Marrow Donor Association. *Blood (2011)117(1):21-5* . **Information/evidence to be provided (or equivalent alternative):** • A policy describing coverage of the donor's medical expenses and insurance at all stages of the donation procedure			

				including medical events occurring as a consequence of the donation (during short or long term follow-up). • A procedure explaining how and at what stages of the procedure the donor is informed of his/her rights regarding insurance and expenses. • Examples of printed materials given to the donor with information about expenses and insurance.			

10	10.10		The registry, or its designee, should offer disability and death benefits to donors.	**Reference**: • Egeland et al. World Marrow Donor Association Ethics Working Group: Donor and liability insurance of donor registries, donor centers, and collection centers--recommendations. *Bone Marrow Transplantation (2004) 33(5):467-70* . **Information/evidence to be provided (or equivalent alternative):** • Information on current disability and death insurance coverage. If this is in the native language of the country, the registry should label and translate the key phrases related to the standard or provide a short paragraph in English describing the document. If this is not covered			

				by an insurance policy, the registry should provide a policy that explains how donors are insured.			

10	10.11		The registry should maintain liability insurance.	**Reference**: • Egeland et al. World Marrow Donor Association Ethics Working Group: Donor and liability insurance of donor registries, donor centers, and collection centers--recommendations . *Bone Marrow Transplantation (2004) 33(5):467-70* . **Explanation**: Liability insurance protects the registry from lawsuits e.g., if a patient's family sues the registry for not finding a donor. **Information/evidence to be provided (or equivalent alternative):** • A copy of a current liability insurance document including type of coverage. If this is in the native language of the country, the registry should			

				label and translate the key phrases related to the standard or provide a short paragraph in English describing the document.			