**Checklist: Criteria to List Donors and/or Cord Blood Units**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Contact details** | | | | | | | |
| **Name organisation** | | |  | | | | |
| **Visit address** | | |  | | | | |
| **Postal code** | | |  | | | | |
| **City** | | |  | | | | |
| **Country** | | |  | | | | |
| **Website** | | |  | | | | |
| **Social media links (Facebook, etc.)** | | |  | | | | |
| **E-mail address donor for WMDA website** | | |  | | | | |
| **E-mail address for search requests** | | |  | | | | |
| **24h emergency number** | | |  | | | | |
| **Invoice information** | | | | | | | |
| **Organisation** | | |  | | | | |
| **Invoice address** | | |  | | | | |
| **Postal code/city** | | |  | | | | |
| **Country** | | |  | | | | |
| **VAT** | | |  | | | | |
| **Financial e-mail address** | | |  | | | | |
| **Key positions** | | | **Name** | | | **E-mail Address** |
| **Chief Executive Officer/Director** | | |  | | |  |
| **Medical Director** | | |  | | |  |
| **Data Protection Officer** | | |  | | |  |
| **Search Coordinator** | | |  | | |  |
| **World Marrow Donor Day Contact** | | |  | | |  |
| **Organisation Profile Administrator** | | |  | | |  |
| **Area** | **Requirement** | **Description** | | **How to comply when registry applies for listing** | **Please provide here your information** | | | |
| 1. Legal  regulatory | 1.1 Legal entity | The organisation meets the local regulatory standards | | 1. Certificate of local health authorities\*[[1]](#footnote-1) 2. In case there is no legal framework, a recommendation of recognised physician supporting the development of the registry\* 3. Regulatory information provided on WMDA Share: <https://share.wmda.info/x/DAAwBw> | 1. Certificate of local health authorities   Yes No Pending   1. If no or pending, please provide the name of the physician supporting the registry:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Regulatory information provided to WMDA   Yes No Pending | | | |
| 2. Operational | 2.1 Year-round operations | The organisation must be able to respond to requests in a timely manner and have English speaking staff and an emergency (24hx7) telephone number available | | 1. Operational and regulatory information provided on WMDA Share: <https://share.wmda.info/x/DAAwBw> 2. Name of English-speaking person | 1. Operational information provided to WMDA   Yes No Pending   1. Name + e-mail address English-speaking person:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | 2.2 Expertise staff | The organisation has access to physicians who can assist in making medical decisions and to HLA consultants | | 1. Name of physician working with the registry/cord blood bank 2. Name of HLA expert working with the organisation | 1. Name + e-mail address physician:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Name + e-mail address HLA expert:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | 2.3 System to track search activity and product provision | The organisation has the capacity to facilitate requests. The organisation should be prepared to fulfil requests coming from other countries for blood samples, verification typing or infectious disease marker (IDM) testing or shipping cord blood units on a timely basis. The provisional member should also be prepared to collect and transport adult stem cells and/or cord blood products to other countries on a timely basis | | 1. Statement that it is allowed to ship blood samples and stem cell products internationally\*[[2]](#footnote-2) 2. Experience in provision of stem cells (number of searches, number of verification/extended typing requests and number of workup requests) over the last 12 months | 1. Confirmation that it is possible to provide blood samples and stem products internationally   Confirmed   1. Experience:   Number of searches: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Number of verification/extended typing requests:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Number of workup requests:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | 2.4 Communication | The organisation has a computer, printer, internet, phone and e-mail | | 1. Statement of confirmation\*[[3]](#footnote-3) | 1. Confirmation that infrastructure is available to receive requests.   Confirmed | | | |
| 3. Quality | 3.1 Testing | The organisation has a collaboration with an HLA lab and an IDM lab. The registry makes sure that it complies with quality indicators such as standards of testing and HLA typing | | 1. Name of the HLA lab 2. Name of the IDM lab 3. Provide accreditation certificate of the HLA lab\* 4. Provide certificate of the IDM lab\* | 1. Name HLA-lab:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Name IDM-lab:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Certificate provided Yes No 2. Certificate provided Yes No | | | |
|  | 3.2 Accreditation | The organisation is accredited | | Name(s) of the Accreditation Bodies | ☐Not applicable  ☐FACT-NetCord  ☐AABB  Other (please specify)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 4. Donor care | 4.1 Informed consent | The organisation meets certain ethical requirements, particularly in the consenting of donors and maternal donors | | Provide an English version (translated if not originally in English) copy of the informed consent\*[[4]](#footnote-4) | Provided Not provided | | | |
|  | 4.2 Donor education | The organisation has documents on donor education (informed consent, data collection, donor testing and screening, product collection, adverse events) | | Provide donor education materials\* | Provided Not provided | | | |
|  | 4.3 Donor protection | Financial responsibility in place to protect the donor (in case of injury or death) during the collection and recovery process | | Written commitment or copy of insurance policy\* | Financial responsibility in place:  Yes No Pending | | | |
|  | 4.4 Donor protection | The organisation collaborates with a collection centre/medical facility that meets the minimum criteria defined in WMDA Standards | | Written commitment or copy of contract with collection centre\* | Collaboration with collection centre/medical facility (in case cord blood bank):  Yes No Pending  Name collection centre:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | 4.5 Adverse events | Procedure in place to report serious adverse events and reactions to requesting organisation and WMDA | | 1. Name of SPEAR reporter 2. Confirmation that SPEAR reporter has watched the WMDA SPEAR webinar (find link here: <https://youtu.be/wLzWbcHYoCQ>) | 1. Name SPEAR reporter:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. Confirmation of attendance webinar:   Yes No Pending | | | |
| 5. WMDA specific | 5.1 ION | The registry needs to register an ION at ICCBBA or through WMDA | | ION number registered at ICCBBA (or WMDA) | Yes No Pending  ION-number is: \_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | 5.1.1 ION of affiliated entities | If the registry uploads data from affiliated entities that carry their own ION, please list which of these entities (donor centre, cord blood banks) are routinely evaluated by the registry for compliance with WMDA Standards. | | 1. ION / Name donor centre  2. ION / Name of cord blood bank | ☐Yes ☐No ☐Pending ☐Not applicable | | | |
|  | 5.2 XML test file | Organisation submits a test file in XML file format to check if the data are according to WMDA data standards | | 1. Provide GRID donor ID-number in XML test file 2. Confirmation from WMDA office that the test file is correct\*[[5]](#footnote-5) 3. Registered contact person for data upload | 1. GRID number implemented:   Yes No Pending   1. Test file is correct   Yes No Pending   1. Name data upload contact person:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | 5.3 Data use agreement and Data Security Compliance | The organisation has signed the data use agreements implemented by WMDA member organisations | | 1. Signed DUA with WMDA visible on <https://share.wmda.info/x/GosZGQ> 2. Signed Peer Review & Consultation Questionnaire <https://share.wmda.info/pages/viewpage.action?pageId=328962414&preview=/328962414/367859320/Peer%20review%20and%20consultation%20questionnaire%20version%201.docx> | 1. Signed?   Yes No Pending   1. Signed?   Yes No Pending | | | |

**Overview of documents to provide**

Certificate of local health authorities

In case there is no legal framework, a recommendation of recognised physician supporting the development of the organisation

Statement that it is allowed to ship blood samples and stem cell products internationally

Statement that technical infrastructure for communication is in place

Accreditation certificate of the HLA lab

Certificate of the IDM lab

English version (translated if not originally in English) copy of the informed consent

Donor education materials

Written commitment or copy of insurance policy that financial responsibility in place to protect the donor (in case of injury or death) during the collection and recovery process

Written commitment or copy of insurance policy that financial responsibility in place to protect the donor (in case of injury or death) during the collection and recovery process

Written commitment or copy of contract with collection centre to prove collaboration with collection centre

Confirmation from WMDA office that the test file is correct

Signed Data Use Agreement

Signed Peer Review & Consultation Questionnaire

**Status of items pending**

|  |  |
| --- | --- |
| **Requirement** | **Status** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

1. \* Provide the document(s) as proof [↑](#footnote-ref-1)
2. \*Provide the document(s) as proof [↑](#footnote-ref-2)
3. \* Provide the document(s) as proof [↑](#footnote-ref-3)
4. \* Provide the document(s) as proof [↑](#footnote-ref-4)
5. \* Provide the document(s) as proof [↑](#footnote-ref-5)