


| | | | | |
|---|---|---------------------------------|---------------|------------|
|  | WMDA Guidance Addition New Affiliated Entity to Registry | | | |
| | Document type | Guidelines | Approved by | WMDA Board |
| | Document reference | OIDS-1000-G-NAE | Approval date | 2/22/2023 |
| | Version | 0 | Approval | approved |
| | Pillar / Scope | PO/Publications&Recommendations | Status | Public |

WMDA Guidance for Addition of New Affiliated Entity to Registry

Prepared by: Organisational Implications for Donor Status (OIDS) Task Force: Carolyn Hurley (chair, Georgetown University), Ann O’Leary (Anthony Nolan), Julia Pingel (DKMS Registry), Pinelopi Samara (Orama Elpidas), Ingrid Tistl (ZKRD), Ioanna Varela (Orama Elpidas), Jane Ward (SABMR), Office: Lydia Foeken, Matilde Lartategui; Quality & Regulatory Working Group: Sigal Manor (Ezer Mizion Bone Marrow Donor Registry)

Approved by WMDA Board for posting: February 22, 2023.

When an organisation adds a new affiliated entity (e.g., donor centre, cord blood bank, transplant centre, collection centre, commercial courier) to provide a service in the identification, assessment, collection and/or transport of haematopoietic stem cells, it will need to determine the level of risk for the primary organization and for other WMDA members and take steps to reduce or eliminate that risk.

- A low level of risk might be assigned to an entity within the country of the primary organisation
 - that is already accredited by an international organisation like JACIE/FACT
 - or has successfully been audited by the organization
 - and/or has been audited by the responsible authorities.
- Increased risk might be assigned to a newly formed entity with little to no experience in providing the required service(s) and which does not fulfill any of the above attributes or to a new cross-border affiliated entity where multiple challenges associated with an international collaboration exist.

Registries should have an audit procedure in place to evaluate new affiliated entities for compliance with WMDA Standards. WMDA has published several checklists for auditing the affiliated entity, which can be performed prior to including the services in day to day activities. The primary organization might also consider delaying some services associated with the affiliated entity (e.g., requesting donors for a new transplant centre or listing donors from a new donor centre) for sufficient time to ensure the affiliated entity has all the necessary policies and procedures in place and followed.

If the-WMDA certified/qualified/accredited (C/Q/A) registry has a number of issues to work out (e.g., donor centre in a country different from the country of the registry), then the registry should document their audit of the new entity with WMDA during the mid-cycle surveillance or at the time of renewal of their accreditation status. This will allow the registry to submit a more substantial amount of documentation that can be evaluated by the participating reviewer(s).