(archived) CBB Survey 2015 WO-1352

CBB Survey 2015

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| 1. General Information | |
|--|----------------------|
| Name of CBB | Cell and Tissue Bank |
| CBB Director | Fabrizio |
| CBB Director | Scatena |
| Address | Via Paradisa, 2 |
| | <u> </u> |
| Address | 56124 |
| Address | Pisa |
| Phone Number | +39050995522 |
| Date CBB Started Collecting Cord Blood Units (month/day/year) | 01/07/2004 |
| Number of Public Cord Blood Units | 1,131 |
| Planned Number of Public Cord Blood Units Stored in 2015 | 50 |
| Lists on BMDW | No |
| Affiliated with National Stem Cell Donor Registry | Yes |
| Registry Affiliation | IBMDR |
| 2. Cord Blood Units in Inventory | |
| Current Processing Method | Liquid+ red auto |
| Year Current Process Method Started | 2007 |
| Percent of Units Plasma and RBC Reduced (automated) | 50 |
| Percent of Units No Volume Reduction | 50 |
| 3. Accreditations, Licenses and Certifications | |
| FACT-Netcord | No |
| AABB | No |
| Competent Authority/ National Health Authority | No |
| Audited by National Stem Cell Registry | No |
| ISO | Yes |
| 4. Cord Blood Collection | |
| Current Collection Practice Is the collection In/Ex -Utero or both? | Ex-utero |
| Collection Bag | Double needle |
| | Manual |
| Agitation during Collection | |
| Agitation during Collection 5. Conditioning/Transport from Collection Site to CBB | |

| 9. Storage | |
|--|--|
| Current Post Processing Threshold for Accepting a CBU for Public Use Viability | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use CFU | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use CFU-GM | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Double Platform | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Single Platform | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use | 130 |
| Extra Material Currently Stored | Maternal plasma/serum |
| Extra Material Currently Stored | Maternal material for DNA extraction |
| Extra Material Currently Stored | Maternal DNA |
| Extra Material Currently Stored | Plasma/cord blood |
| Extra Material Currently Stored | Cord blood material for DNA extraction |
| Extra Material Currently Stored | Cord blood DNA |
| 8. Testing | |
| Current Packaging for Storage | Additional separate segments |
| Current Packaging for Storage | More than one segment |
| Current Packaging for Storage | Canister |
| Current Packaging for Storage | Overwrap |
| Current Target Cryopreservation Volume (mL) | 80.0 |
| Current Cryobag | Multiple bags |
| Current Cryobag | Single bag (one fraction) |
| Current Cryoprotectant Additive | Other: Albumin, NaCl |
| Current Cryopreservation Method | Other: Liquid nitrogen |
| Pre Freeze Processing Methods- Current | SEPAX |
| Pre Freeze Processing Methods- Unit in Inventory | Other: Manual without volume reduction |
| Pre Freeze Processing Methods- Unit in Inventory | SEPAX |
| 7. Processing and Packaging | |
| Time from Collection to Processing | up to 48H |
| Post Processing/ Pre Freeze CD34+ Cell Count | Yes |
| External Proficiency Testing for QC of FACS Lab | UKNEQAS |
| Method for CD34 Remuneration | ISHAGE guidelines |
| Completed Prior to Accepting a CBU | Medical history, collection report, informed consent |
| 6. Pre-Processing Evaluation | |
| Temp. for Storage and Transport | Temperature between +2 to +8°C |
| Transport Conditions | Insulating transport container |
| | T. Control of the Con |

| Type of Storage Container Used | Conventional storage tank vapor phase |
|--|---------------------------------------|
| Type of Storage Container Used | Conventional tank liquid phase |
| Monitoring of Storage | Centralized alarm system local |
| Monitoring of Storage | LN2 level |
| Monitoring of Storage | Temperature monitoring |
| 10. HLA Typing | |
| Current Level of HLA Typing at Time of Listing | LR |
| Current Level of HLA Typing at Time of Listing HLA-B | LR |
| Current Level of HLA Typing at Time of Listing HLA-C | |
| Current Level of HLA Typing at Time of Listing HLA-DRB1 | LR |
| Current Level of HLA Typing at Time of Listing HLA-DQB1 | |
| Current Level of HLA Typing at Time of Listing HLA-DPB1 | |
| Accreditation of HLA Lab | EFI accredited lab |
| Average Turnaround Time for Extended HLA Typing Results in days | ?10 |
| Attached Segment Used for Confirmatory/ Verification Typing | No |
| Units Listed without Attached Segment and have not been Previously Typed on Attached Segment | Yes |
| Percentage of CBUs that have an Attached Segment | 90-100% |
| Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement | Yes |
| 11. Reservation and Cancellation Policies | |
| What Point is a CBU Reserved for a Patient | Reservation request |
| Length of Time a CBU can be Reserved in days | 30 |
| Reservation Fee | No |
| Reservation Cancellation Fee in Absence of Shipment Request | No |
| Can Reservation be Extended | Yes |
| Is a Unit Report Provided on a Unit that is Reserved for Another Patient | No |
| Is TC Informed when CBU is Released | No |
| 12. Release and Shipment | |
| Hemoglobinopathy Screening Performed Prior to Release | Yes |
| Criteria to Ship a CBU Viability and Cell Count | 40 |
| Criteria to Ship a CBU HLA Identity Testing | Yes |
| Current Packaging for Shipment to TC | Overwrap |
| Current Packaging for Shipment to TC | Separate segment |
| Current Packaging for Shipment to TC | 2 attached segments |
| Time Between Shipment Request and Sending CBU | 1-2 weeks |
| Fee for Shipment Cancellation | Yes |

| Dry Shippers Validated to Maintain Temperature of at least -150 for 48 hours Beyond Expected Arrival | Yes |
|--|------------------------------|
| Electronic Temperature Data Logger on All Dry Shippers | Yes |
| Who Selects Transport Company | Requesting transplant centre |
| Shape of Transport Container | Cubic |
| 13. Adverse Events Reporting | |
| Who are S(P)EARS Reported To National Registry | Yes |
| Who are S(P)EARS Reported To Transplant Center | Yes |

14. Pictures of cord blood units in the inventory

15. Infectious Disease Marker (IDM) CURRENTLY performed.



Holiday Calendar

| Team Calendars |
|----------------|
|----------------|