

# (archived) CBB Survey 2015 WO-1343

## CBB Survey 2015

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|                                                                        |                                                                                           |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>1. General Information</b>                                          |                                                                                           |
| Name of CBB                                                            | BloodworksNW Cord Blood Services                                                          |
| CBB Director                                                           | Carol                                                                                     |
| CBB Director                                                           | Taylor                                                                                    |
| Address                                                                | 921 Terry Ave.                                                                            |
| Address                                                                | 98104                                                                                     |
| Address                                                                | Seattle                                                                                   |
| Phone Number                                                           | 206-689-6302                                                                              |
| Website                                                                | <a href="http://bloodworksnw.org">bloodworksnw.org</a>                                    |
| Date CBB Started Collecting Cord Blood Units<br>(month/day/year)       | 01/01/1998                                                                                |
| Number of Public Cord Blood Units                                      | 11,996                                                                                    |
| Planned Number of Public Cord Blood Units Stored in 2015               | 850                                                                                       |
| Lists on BMDW                                                          | Yes                                                                                       |
| Affiliated with National Stem Cell Donor Registry                      | Yes                                                                                       |
| Registry Affiliation                                                   | NMDP                                                                                      |
| <b>2. Cord Blood Units in Inventory</b>                                |                                                                                           |
| Current Processing Method                                              | Vapour+ red auto                                                                          |
| Previous Processing Method                                             | Vapour+ red manual                                                                        |
| Previous Processing Method                                             | Vapour- red manual                                                                        |
| Year Current Process Method Started                                    | 2012                                                                                      |
| Percent of Units Plasma and RBC Reduced (manual)                       | 70                                                                                        |
| Percent of Units Plasma and RBC Reduced (automated)                    | 30                                                                                        |
| <b>3. Accreditations, Licenses and Certifications</b>                  |                                                                                           |
| FACT-Netcord                                                           | No                                                                                        |
| AABB                                                                   | Yes                                                                                       |
| Competent Authority/ National Health Authority                         | No                                                                                        |
| Audited by National Stem Cell Registry                                 | Yes                                                                                       |
| ISO                                                                    | No                                                                                        |
| Other                                                                  | A Biologic License Application has been submitted to the US Food and Drug Administration. |
| <b>4. Cord Blood Collection</b>                                        |                                                                                           |
| Current Collection Practice<br>Is the collection In/Ex -Utero or both? | In-utero                                                                                  |

|                                                                      |                                                      |
|----------------------------------------------------------------------|------------------------------------------------------|
| Current Antiseptic                                                   | Chlorhexidine                                        |
| Collection Bag                                                       | Single needle                                        |
| Agitation during Collection                                          | Manual                                               |
| <b>5. Conditioning/Transport from Collection Site to CBB</b>         |                                                      |
| Secondary Bag Used                                                   | Yes                                                  |
| Transport Conditions                                                 | Qualified transporter                                |
| Transport Conditions                                                 | Insulating transport container                       |
| Transport Conditions                                                 | Passive refrigeration system                         |
| Transport Conditions                                                 | Electronic temperature probe                         |
| Transport Conditions                                                 | Air transport                                        |
| Transport Conditions                                                 | Ground transport                                     |
| Temp. for Storage and Transport                                      | Other (lower limit +1-35°C, higher limit +6-30°C)    |
| <b>6. Pre-Processing Evaluation</b>                                  |                                                      |
| Completed Prior to Accepting a CBU                                   | Medical history, collection report, informed consent |
| Current Threshold for Accepting a CBU                                | Viability threshold CD45                             |
| Method for CD34 Remuneration                                         | Other                                                |
| Method for CD34 Remuneration                                         | ProCount                                             |
| External Proficiency Testing for QC of FACS Lab                      | CAP                                                  |
| Post Processing/ Pre Freeze CD34+ Cell Count                         | Yes                                                  |
| Time from Collection to Processing                                   | up to 48H                                            |
| <b>7. Processing and Packaging</b>                                   |                                                      |
| Pre Freeze Processing Methods- Unit in Inventory                     | SEPAX                                                |
| Pre Freeze Processing Methods- Unit in Inventory                     | Volume reduction with HES-Manual                     |
| Pre Freeze Processing Methods- Current                               | SEPAX                                                |
| Additives Currently in Use                                           | HES                                                  |
| Current Cryopreservation Method                                      | Conventional CRF                                     |
| Current Cryoprotectant Additive                                      | Ready for use DMSO-Dextran                           |
| Current Cryobag                                                      | Single bag 80:20                                     |
| Current Target Cryopreservation Volume (mL)                          | 25.0                                                 |
| Current Packaging for Storage                                        | Overwrap                                             |
| Current Packaging for Storage                                        | Canister                                             |
| Current Packaging for Storage                                        | More than one segment                                |
| Current Packaging for Storage                                        | Other: Two or three attached segments                |
| <b>8. Testing</b>                                                    |                                                      |
| Extra Material Currently Stored                                      | Cord blood material for DNA extraction               |
| Extra Material Currently Stored                                      | Plasma/cord blood                                    |
| Extra Material Currently Stored                                      | Maternal material for DNA extraction                 |
| Extra Material Currently Stored                                      | Maternal plasma/serum                                |
| Current Post Processing Threshold for Accepting a CBU for Public Use | 50                                                   |

|                                                                                                     |                                        |
|-----------------------------------------------------------------------------------------------------|----------------------------------------|
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10^6) Single Platform | 1.25                                   |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10^6) Double Platform | NA                                     |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CFU-GM                      | NA                                     |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CFU                         | Growth                                 |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>Viability                   | 85                                     |
| <b>9. Storage</b>                                                                                   |                                        |
| Type of Storage Container Used                                                                      | Conventional storage tank vapor phase  |
| Monitoring of Storage                                                                               | Centralized alarm system local         |
| Monitoring of Storage                                                                               | LN2 level                              |
| Monitoring of Storage                                                                               | Temperature monitoring                 |
| <b>10. HLA Typing</b>                                                                               |                                        |
| Current Level of HLA Typing at Time of Listing<br>HLA-A                                             | HR                                     |
| Current Level of HLA Typing at Time of Listing<br>HLA-B                                             | HR                                     |
| Current Level of HLA Typing at Time of Listing<br>HLA-C                                             | HR                                     |
| Current Level of HLA Typing at Time of Listing<br>HLA-DRB1                                          | HR                                     |
| Current Level of HLA Typing at Time of Listing<br>HLA-DQB1                                          | HR                                     |
| Current Level of HLA Typing at Time of Listing<br>HLA-DPB1                                          |                                        |
| Accreditation of HLA Lab                                                                            | ASHI accredited lab                    |
| Average Turnaround Time for Extended HLA Typing Results<br>in days                                  | 8                                      |
| Attached Segment Used for Confirmatory/ Verification Typing                                         | Yes                                    |
| Units Listed without Attached Segment and have not been Previously Typed on Attached Segment        | Yes                                    |
| Percentage of CBUs that have an Attached Segment                                                    | 75-90%                                 |
| Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement                 | No                                     |
| <b>11. Reservation and Cancellation Policies</b>                                                    |                                        |
| What Point is a CBU Reserved for a Patient                                                          | Reservation request                    |
| Length of Time a CBU can be Reserved<br>in days                                                     | Other                                  |
| Length of Time a CBU can be Reserved<br>in days                                                     | As long as transplant center requires. |
| 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                                                                 | Yes                                    |

|                                                                                                      |                              |
|------------------------------------------------------------------------------------------------------|------------------------------|
| <b>12. Release and Shipment</b>                                                                      |                              |
| Hemoglobinopathy Screening Performed Prior to Release                                                | Yes                          |
| Criteria to Ship a CBU<br>Viability and Cell Count                                                   | NA                           |
| Criteria to Ship a CBU<br>HLA Identity Testing                                                       | Yes                          |
| Current Packaging for Shipment to TC                                                                 | Overwrap                     |
| Time Between Shipment Request and Sending CBU                                                        | 0-3 days                     |
| Fee for Shipment Cancellation                                                                        | No                           |
| 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                                                                         | Mushroom                     |
| <b>13. Adverse Events Reporting</b>                                                                  |                              |
| Who are S(P)EARS Reported To<br>Competent Authority                                                  | Yes                          |
| Who are S(P)EARS Reported To<br>Internal Report                                                      | Yes                          |
| Who are S(P)EARS Reported To<br>National Registry                                                    | Yes                          |
| Who are S(P)EARS Reported To<br>Transplant Center                                                    | Yes                          |

## 14. Pictures of cord blood units in the inventory





15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1343-IDM-2015.pdf

**Holiday Calendar**

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

