

# (archived) CBB Survey 2015 WO-1364

## CBB Survey 2015

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|                                                                                       |                                                                            |
|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| <b>1. General Information</b>                                                         |                                                                            |
| Name of CBB                                                                           | JP McCarthy Cord Stem Cell Bank                                            |
| CBB Director                                                                          | Voravit                                                                    |
| CBB Director                                                                          | Ratanatharathorn, MD                                                       |
| Address                                                                               | 4100 John R.                                                               |
| Address                                                                               | mail code HW04HO                                                           |
| Address                                                                               | 48201                                                                      |
| Address                                                                               | Detroit, MI                                                                |
| Phone Number                                                                          | 313-966-7263                                                               |
| Website                                                                               | <a href="http://www.karmanos.org/cordblood">www.karmanos.org/cordblood</a> |
| Date CBB Started Collecting Cord Blood Units<br><small>(month/day/year)</small>       | 07/09/2001                                                                 |
| Number of Public Cord Blood Units                                                     | 2,835                                                                      |
| Planned Number of Public Cord Blood Units Stored in 2015                              | 300                                                                        |
| Lists on BMDW                                                                         | No                                                                         |
| Affiliated with National Stem Cell Donor Registry                                     | Yes                                                                        |
| Registry Affiliation                                                                  | National Marrow Donor Registry--Be The Match                               |
| <b>2. Cord Blood Units in Inventory</b>                                               |                                                                            |
| Current Processing Method                                                             | Vapour+ red manual                                                         |
| Year Current Process Method Started                                                   | 2001                                                                       |
| Percent of Units Plasma and RBC Reduced (manual)                                      | 100                                                                        |
| <b>3. Accreditations, Licenses and Certifications</b>                                 |                                                                            |
| FACT-Netcord                                                                          | Yes                                                                        |
| AABB                                                                                  | No                                                                         |
| Competent Authority/ National Health Authority                                        | No                                                                         |
| Audited by National Stem Cell Registry                                                | Yes                                                                        |
| ISO                                                                                   | No                                                                         |
| Other                                                                                 | FDA registration                                                           |
| <b>4. Cord Blood Collection</b>                                                       |                                                                            |
| Current Collection Practice<br><small>Is the collection In/Ex -Utero or both?</small> | In-utero                                                                   |
| Current Antiseptic                                                                    | Betadine                                                                   |
| 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                                                                                            | 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 CD34                             |
| Method for CD34 Remuneration                                                                                    | ISHAGE guidelines                                    |
| External Proficiency Testing for QC of FACS Lab                                                                 | Yes, other                                           |
| External Proficiency Testing for QC of FACS Lab                                                                 | College of American pathology, stem cell technology  |
| 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                                                                | Volume reduction with HES-Manual                     |
| Pre Freeze Processing Methods- Current                                                                          | Volume reduction with HES manual                     |
| Additives Currently in Use                                                                                      | HES                                                  |
| Additives Currently in Use                                                                                      | Other: DMSO/Dextran 40                               |
| Current Cryopreservation Method                                                                                 | Conventional CRF                                     |
| Current Cryopreservation Method                                                                                 | Other: Thermo model 7454                             |
| 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                                |
| <b>8. Testing</b>                                                                                               |                                                      |
| Extra Material Currently Stored                                                                                 | Cord blood DNA                                       |
| Extra Material Currently Stored                                                                                 | Cord blood material for DNA extraction               |
| Extra Material Currently Stored                                                                                 | Plasma/cord blood                                    |
| Extra Material Currently Stored                                                                                 | Maternal DNA                                         |
| 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<br>TNC                                     | 90                                                   |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10 <sup>6</sup> ) Single Platform | 1.25                                                 |

|                                                                                                     |                                                  |
|-----------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10^6) Double Platform | 1.3                                              |
| 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                                                                               | System default                                   |
| 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                                             |                                                  |
| 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                                          |                                                  |
| 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                                  | ?10                                              |
| Attached Segment Used for Confirmatory/ Verification Typing                                         | Yes                                              |
| Units Listed without Attached Segment and have not been Previously Typed on Attached Segment        | No                                               |
| Percentage of CBUs that have an Attached Segment                                                    | 90-100%                                          |
| Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement                 | Yes                                              |
| <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                                                     | It is kept on hold until the NMDP releases hold. |
| 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                                                  | 50                                               |

|                                                                                                      |                                                                  |
|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Criteria to Ship a CBU<br>HLA Identity Testing                                                       | Yes                                                              |
| Current Packaging for Shipment to TC                                                                 | Metal canister                                                   |
| Current Packaging for Shipment to TC                                                                 | Overwrap                                                         |
| Current Packaging for Shipment to TC                                                                 | Protective sleeve                                                |
| Current Packaging for Shipment to TC                                                                 | Transport rack                                                   |
| 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                                                                        | CBB                                                              |
| Who Selects Transport Company                                                                        | NMDP selects and arranges the shipment of the CBU. Quick Courier |
| Shape of Transport Container                                                                         | Mushroom                                                         |
| <b>13. Adverse Events Reporting</b>                                                                  |                                                                  |
| Who are S(P)EARS Reported To<br>Internal Report                                                      | Yes                                                              |
| Who are S(P)EARS Reported To<br>National Registry                                                    | Yes                                                              |

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



#### 15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1364-IDM-2015.pdf

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## Holiday Calendar

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| Team Calendars |
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