CB banking specifics ION-6459

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Section 1 General Info

| Question | CBB answer |
|--|--------------------------------|
| The information has been reviewed in year : | |
| Name of the cord blood bank: | Bionet Corporation Taipei City |
| Number of cord blood units the cord blood bank plans to store for public use (unrelated patients): | |

Section 2 Cord Blood Units in Inventory

| Question | CBB answer | |
|---|------------|--|
| Current processing method(s): | | |
| Plasma and RBC reduced (automatic) | checkfalse | |
| Plasma reduction only | checkfalse | |
| Plasma and RBC reduced (manual) | checkfalse | |
| RBC reduction only | checkfalse | |
| Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use). | | |
| < 125 : | | |
| 125 - 149 : | | |
| 150 - 199 : | | |
| 200 - 250 : | | |
| > 250 : | | |

Section 3 Cord Blood Collection

| Question | CBB answer |
|---|------------|
| Current practice for collecting cord blood: | |
| Current antiseptic: | |
| Collection bag: | |
| Agitation during collection: | |

Section 4 Conditioning and transport from Collection Centre to cord blood bank

| Question | CBB answer |
|--|------------|
| Secondary bag used by the cord blood bank (sealed, plastic bag or similar to avoid any leakage): | |
| Transport conditions: | |
| Insulating transport container | checkfalse |
| Active refrigeration system | checkfalse |
| Passive refrigeration system (gel, blocks) | checkfalse |
| Electronic temperature probe | checkfalse |
| Non-electronic temperature probe | checkfalse |
| Qualified transporter | checkfalse |
| Unqualified transporter | checkfalse |
| Air transport | checkfalse |
| Ground transport | checkfalse |
| Other, | checkfalse |
| Temperature range for storage and transportation of fresh product: | |

Section 5 Evaluation

| Question | CBB answer |
|--|------------|
| Pre-processing Evaluation: Current threshold for accepting a cord blood unit for public use in the cord blood bank: | |
| Net weight in grams (excluding bag and anticoagulant) before processing | |
| TNC (10E7) before processing | |
| Viability CD45 positive cells (%) | |
| Viability CD45 positive cells (method) | |
| Viability CD34 positive cells (%) | |
| Viability CD34 positive cells (method) | |
| Criteria that are completed before accepting a cord blood unit for public use in the cord blood bank | : |
| Medical History | checkfalse |
| Collection Report | checkfalse |
| Informed Consent | checkfalse |
| Maternal IDM results | checkfalse |
| Temperature and integrity of the bag | checkfalse |
| Other, | checkfalse |
| Used method for CD34 enumeration: | |
| The cord blood banks uses external proficiency testing for QC of the cord blood banks FACS lab: | |
| The cord blood bank performs post processing/pre-freeze CD34 cell count: | |
| Acceptable time from collection to processing: | |

| Question | CBB answer |
|--|------------------|
| The pre-freeze processing method(s) cord blood bank uses at any st | age in time: |
| AXP | checkfalse |
| SEPAX | checkfalse |
| Optipress | checkfalse |
| Prepacyte | checkfalse |
| Manual- plasma and red cell reduction | checkfalse |
| RBC/plasma reduction with HES | checkfalse |
| Ficoll sedimentation | checkfalse |
| Centrifugation and volume reduction | checkfalse |
| No processing | checkfalse |
| Manual- plasma reduction only | checkfalse |
| Other, | checkfalse |
| The current pre-freeze processing method(s): | |
| AXP | checkfalse |
| SEPAX | checkfalse |
| Optipress | checkfalse |
| Prepacyte | checkfalse |
| Manual- plasma and red cell reduction | checkfalse |
| RBC/plasma reduction with HES | checkfalse |
| FicoII sedimentation | checkfalse |
| Centrifugation and volume reduction | checkfalse |
| No processing | checkfalse |
| Manual- plasma reduction only | checkfalse |
| Other, | checkfalse |
| Additives currently in use in addition to anticoagulants and DMSO du | ring processing: |
| HES | checkfalse |
| Prepacyte | checkfalse |
| Plasmalyte | checkfalse |
| Albumin | checkfalse |
| Isotonic salt solution NaCl (saline) | checkfalse |
| No additive | checkfalse |
| Other, | checkfalse |
| Cryoprotectant additives currently in use: | |
| Cryopreservation method currently in use: | |
| BioArchive | checkfalse |
| MVE 1850 Vapor freezer | checkfalse |
| Programmed cryopreservation with Air Liquid program (FREEZAL) | checkfalse |
| Programmed freezer | checkfalse |
| Two-step (equilibrium) freezing | checkfalse |

| Cryobag currently in use: | |
|--|------------|
| Currently used packaging when a unit is stored: | |
| Segments currently stored with the unit by the cord blood bank: | |
| One attached segment | checkfalse |
| Two or more attached segments | checkfalse |
| Separate segments detached from the bag, but stored with the CBU | checkfalse |
| Other samples | checkfalse |
| None | checkfalse |

Section 7 Testing

| Question | CBB answer | |
|---|--------------------|--|
| Does your cord blood bank currently sto | re extra material? | |
| Cord blood DNA | checkfalse | |
| Cord blood material for DNA extraction | checkfalse | |
| Plasma/cord blood | checkfalse | |
| Maternal DNA | checkfalse | |
| Maternal material for DNA extraction | checkfalse | |
| Maternal plasma/serum | checkfalse | |
| HLA typing at time of listing: | | |
| HLA-A | | |
| HLA-B | | |
| HLA-C | | |
| HLA-DRB1 | | |
| HLA-DRB2 | | |
| HLA-DPB1 | | |

Section 8 Storage

| Question | CBB answer | |
|--|------------|--|
| The following type(s) of storage container is currently used by the cord blood bank: | | |
| BioArchive tank | checkfalse | |
| Conventional storage tank-Vapor phase | checkfalse | |
| Conventional tank-Liquid phase | checkfalse | |
| Double walled liquid Nitrogen | checkfalse | |
| Type following type(s) of storage monitoring is currently by the cord blood bank: | | |
| Alarm on individual tanks only | checkfalse | |
| Centralized system-local | checkfalse | |
| Centralized system-remote monitoring | checkfalse | |

| LN2 level | checkfalse |
|---------------------------|------------|
| Lid opening | checkfalse |
| System default | checkfalse |
| Temperature monitoring | checkfalse |
| No temperature monitoring | checkfalse |

Section 9 Adverse Events Reporting

| Question | CBB answer |
|---|------------|
| Adverse Event Reporting used by the cord blood bank | |
| Competent authority | checkfalse |
| Internal report | checkfalse |
| National registry | checkfalse |
| Transplant centre | checkfalse |
| WMDA | checkfalse |