CB banking specifics ION-3105

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Section 1 General Info

| Question | CBB answer |
|--|---|
| The information has been reviewed in year : | |
| Name of the cord blood bank: | Hong Kong Red Cross Blood Transfusion Service Cord Blood Bank |
| Number of cord blood units the cord blood bank plans to store for public use (unrelated patients): | 10000 |

Section 2 Cord Blood Units in Inventory

| Question | CBB answer |
|---|------------|
| Current processing method(s): | |
| Plasma and RBC reduced (automatic) | checktrue |
| 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: | In-utero and ex-utero |
| Current antiseptic: | Chlorhexidine Alcohol |
| Collection bag: | Single needle |
| Agitation during collection: | Manual |

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): | yes |
| Transport conditions: | |
| Insulating transport container | checktrue |
| Active refrigeration system | checkfalse |
| Passive refrigeration system (gel, blocks) | checktrue |
| Electronic temperature probe | checktrue |
| Non-electronic temperature probe | checkfalse |
| Qualified transporter | checktrue |
| Unqualified transporter | checkfalse |
| Air transport | checkfalse |
| Ground transport | checktrue |
| Other, | checkfalse |
| Temperature range for storage and transportation of fresh product: | Defined (above +8°0 |

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 | 60 - 69.99 grams |
| TNC (10E7) before processing | < 125 |
| Viability CD45 positive cells (%) | NA- not evaluated pre-processing |
| Viability CD45 positive cells (method) | 7AAD |
| Viability CD34 positive cells (%) | 80 - 89% |
| Viability CD34 positive cells (method) | 7AAD |
| Criteria that are completed before accepting a cord blood unit for public use in the cord blood bank | C. |
| Medical History | checktrue |
| Collection Report | checktrue |
| Informed Consent | checktrue |
| Maternal IDM results | checktrue |
| Temperature and integrity of the bag | checktrue |
| Other, | checkfalse |
| Used method for CD34 enumeration: | ISHAGE guidelines |
| The cord blood banks uses external proficiency testing for QC of the cord blood banks FACS lab: | yes |
| The cord blood bank performs post processing/pre-freeze CD34 cell count: | yes |
| Acceptable time from collection to processing: | 24-48H |

Section 6 Processing-Packaging

| Question | CBB answer |
|---|------------------|
| The pre-freeze processing method(s) cord blood bank uses at any sta | age in time: |
| AXP | checkfalse |
| SEPAX | checktrue |
| Optipress | checkfalse |
| Prepacyte | checkfalse |
| Manual- plasma and red cell reduction | checktrue |
| RBC/plasma reduction with HES | checkfalse |
| FicoII sedimentation | checkfalse |
| Centrifugation and volume reduction | checktrue |
| No processing | checkfalse |
| Manual- plasma reduction only | checkfalse |
| Other, | checkfalse |
| The current pre-freeze processing method(s): | |
| AXP | checkfalse |
| SEPAX | checktrue |
| 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 dur | ring processing: |
| HES | checkfalse |
| Prepacyte | checkfalse |
| Plasmalyte | checkfalse |
| Albumin | checkfalse |
| Isotonic salt solution NaCl (saline) | checkfalse |
| No additive | checkfalse |
| Other, HESPAN | checktrue |
| Cryoprotectant additives currently in use: | DMSO |
| Cryopreservation method currently in use: | |
| BioArchive | checktrue |
| 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: | Single bag (two fractions) | |
| Currently used packaging when a unit is stored: | Metal canister and overwrap | |
| Segments currently stored with the unit by the cord blood bank: | | |
| One attached segment | checkfalse | |
| Two or more attached segments | checktrue | |
| 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 | checktrue | |
| Plasma/cord blood | checktrue | |
| Maternal DNA | checkfalse | |
| Maternal material for DNA extraction | checkfalse | |
| Maternal plasma/serum | checktrue | |
| HLA typing at time of listing: | | |
| HLA-A | Low resolution | |
| HLA-B | Low resolution | |
| HLA-C | Not performed | |
| HLA-DRB1 | High Resolution | |
| HLA-DRB2 | Not performed | |
| HLA-DPB1 | Not performed | |

Section 8 Storage

| Question | CBB answer | |
|--|------------|--|
| The following type(s) of storage container is currently used by the cord blood bank: | | |
| BioArchive tank | checktrue | |
| Conventional storage tank-Vapor phase | checkfalse | |
| Conventional tank-Liquid phase | checktrue | |
| 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 | checktrue |
| Centralized system-remote monitoring | checktrue |
| LN2 level | checktrue |
| Lid opening | checkfalse |
| System default | checktrue |
| Temperature monitoring | checktrue |
| No temperature monitoring | checkfalse |

Section 9 Adverse Events Reporting

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