IM-00103

Stem Cell Registry Transplant Centre Reference Manual

Revision # 0

Revision History

Version	Detail
0	StCR-25-000168 – document type conversion from Compendium to Information Material to align with QMS guidelines. Combined the *Stem Cell Registry Transplant Centre Reference Manual* compendium sections: CO-00232, CO-00233, CO-00234, CO-00235, CO-00236, CO-00237, CO-00238, CO-00239, CO-00240, CO-00241, CO-00242, CO-00243, CO-00244, CO-00245, CO-00246, together to create one Information Material document. Updated 'the stem cell registry' to 'the Registry'. Document numbering updated to align with CDI 3.0.

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Section 1 - Introduction

OVERVIEW

This manual provides Canadian transplant centres guidance to obtain services from the Canadian Blood Services Stem Cell Registry (from herein will be referred to as the 'Registry'). The manual includes but is not limited to information regarding the following:

- Search, activation, reservation and work-up processes for unrelated donors and cord blood units
- Post-transplant related activities
- Stem cell registry documents

This manual is not intended to replace internal transplant centre policies and procedures but contains minimum guidance when working with the Registry.

APPLICABLE REGULATIONS AND STANDARDS

Protocols and procedures must be based upon and in compliance with appropriate industry standards and best practices.

In accordance with the Memorandum of Understanding, the Canadian transplant centres must comply with the applicable requirements outlined below.

- Registered establishment with Health Canada
- Health Canada **Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO regulations)**. For more information, visit http://www.hc-sc.gc.ca.
- CAN/CSA-Z900.1, Cells, tissues and organs for transplantation: General Requirements, Canadian Standards Association. For information, visit http://www.csa.ca.

  Note: *Sections/clauses 12.2, 12.3, 13.1.3, 13.2, 14.2.6 and Annex E adhere to current CTO regulations; apply to CBS*
- CAN/CSA-Z900.2.5, Lymphohematopoietic cells for transplantation, Canadian Standards Association,

  Note: *Sections/clauses 12.2.2.2 to 12.2.2.4, 13.1.3, 13.1.3.4, 13.2 and 14.2.3 adhere to current CTO regulations; apply to CBS*
- **Standards of the Foundation for the Accreditation of Cellular Therapy (FACT-NetCord).** For more information, visit, http://www.factwebsite.org/

The Registry is an accredited member of the World Marrow Donor Association, a voluntary, non-profit organization created in 1994 that establishes international guidelines for the collection and transport of hematopoietic stem cells. As a member of the World Marrow Donor Association, the Registry is required to ensure participating Canadian transplant centres adhere to World Marrow Donor Association Standards. For more information, visit https://www.wmda.info/

As a member of the World Marrow Donor Association (WMDA), the Registry has access to their Search and Match Service. The WMDA Search and Match Service maintains and optimizes an electronic databank with centralized data on human leukocyte antigen (HLA) phenotypes and other relevant data of volunteer stem cell donors and cryopreserved cord blood products and make these accessible to the physicians, search coordinators, and other parties worldwide who search for a potential match for their patients.

ACCESS TO THE REGISTRY CONTROLLED DOCUMENTS AND RESOURCES

Some Registry documents and related resources are available on the password protected website https://blood.ca/en/hospital-services/stem-cell-registry-documents

To obtain the password to access this website, contact cbs.stemcellregistry@blood.ca.

The Registry will review and update controlled documents and forms periodically and will notify the transplant centre of any revision prior to implementation.

Controlled Documents

Use of electronic controlled documents is encouraged whenever possible to ensure the most current version of that document is always being used. Any printed copies of controlled documents are considered uncontrolled. If a controlled document must be printed, the transplant centre must ensure the access to and use of the current version at their location.

All Registry forms referenced in the *Stem Cell Registry Transplant Centre Reference Manual* are available in electronic format only. Access to these controlled documents is available on the https://blood.ca/en/hospital-services/stem-cell-registry-documents website, or provided by stem cell registry through the Stem Cells National Systems Solution (SCNSS).

Access to the Stem Cells National Systems Solution (SCNSS)

Requesting Access:

When requesting access to the Stem Cells National Systems Solution application, the *Stem Cells National Systems Solution User Access Agreement* must be completed and sent to stem cell registry.

Send an email to cbs.stemcellregistry@blood.ca ensuring the following information has been included.

- Completed *Stem Cells National Systems Solution User Access Agreement* form
- Contact information (telephone, email, fax)
- Start date

Once the information has been processed and employee training completed, an email will be sent by the Registry to the employee.

Removing Access:

The request to remove employee access must be completed as soon as possible and no later than the user's last day.

Send an email to cbs.stemcellregistry@blood.ca, ensuring the following information has been included.

- User's full name
- Transplant centre name
- Contact information
- Employment end date.

Updating User Information:

Updating existing user information should be completed as soon as possible to ensure user and contact information used within Stem Cells National Systems Solution (SCNSS) is accurate. Send an email to cbs.stemcellregistry@blood.ca indicating the changes required.

System Issues:

For any system issues, including security and passwords, contact the Canadian Blood Services' National Service Desk at 1-877-389-2500 or email Stem Cells National Systems Solution Business Support Team at stemcells.business.support@blood.ca.

Acceptable Use of the Stem Cell National Systems Solution

Users are responsible for protecting the information they use and/or store on their workstations when accessing the Stem Cells National Systems Solution (SCNSS) application in the following ways:

- Users must protect their username and password and not disclose confidential passwords for accounts. The password must be changed immediately should it be suspected that it has been disclosed or compromised.
- Users are required to report weaknesses or breaches (actual or attempted) in security. These events must be reported immediately using the Registry after hours cell phone.
- Users must report incidents of possible misuse or violation of this agreement to the Registry.
- Users must not attempt to access data for which they do not have authorization to do so.

In the event that unauthorized access is detected or suspected, the Registry will contact the user to verify authorization. If verification cannot be obtained, a User's account may be deleted or disabled.

TRAINING

The transplant centre Director/designate is responsible for ensuring training to this manual and Stem Cells National Systems Solution database, where applicable for personnel that are involved in:

- Search and activation processes.
- Transplantation of unrelated stem cell donor and/or cord blood units, including stem cell coordinators, physicians, and support staff (if applicable).

ASSOCIATED DOCUMENTS

F800161 (F801557) *Stem Cells National Systems Solution User Access Agreement*
IM-00106 (CO-00289) *Stem Cells National Systems Solutions User Manual, Section 16: Canadian Transplant Centres*

Section 2 – Overview of Canadian Blood Services Stem Cell Registry

OVERVIEW

Canadian Blood Services Stem Cell Registry (The Registry):

The Registry is a program that finds and matches volunteer donors to patients who require stem cell transplants. Fewer than 25 percent of patients who need stem cell transplants find a compatible donor in their own family. The rest rely on those who have volunteered to donate stem cells to anyone in need. The Registry belongs to an international network of registries and can search available donors all over the world to find a match. By making donor data available worldwide, International Registries have significantly increased the odds of finding a matching donor for any patient anywhere in the world.

The following functions and support services are provided by Canadian Blood Services and the Registry to Canadian programs and International Registries treating transplant patients:

Donor Relations:

Manages the recruitment of potential registrants to be listed on the Registry. Every potential registrant must meet preliminary recruitment criteria related to age, health and willingness to donate to all patients in need. Registrants must provide informed consent to the donation process before being listed on the registry.

Canadian Blood Services' Cord Blood Bank:

Provides an inventory of high-quality cord blood units that are collected and cryopreserved in Canada for use by Canadian or international patients. The units are accessed through the Registry.

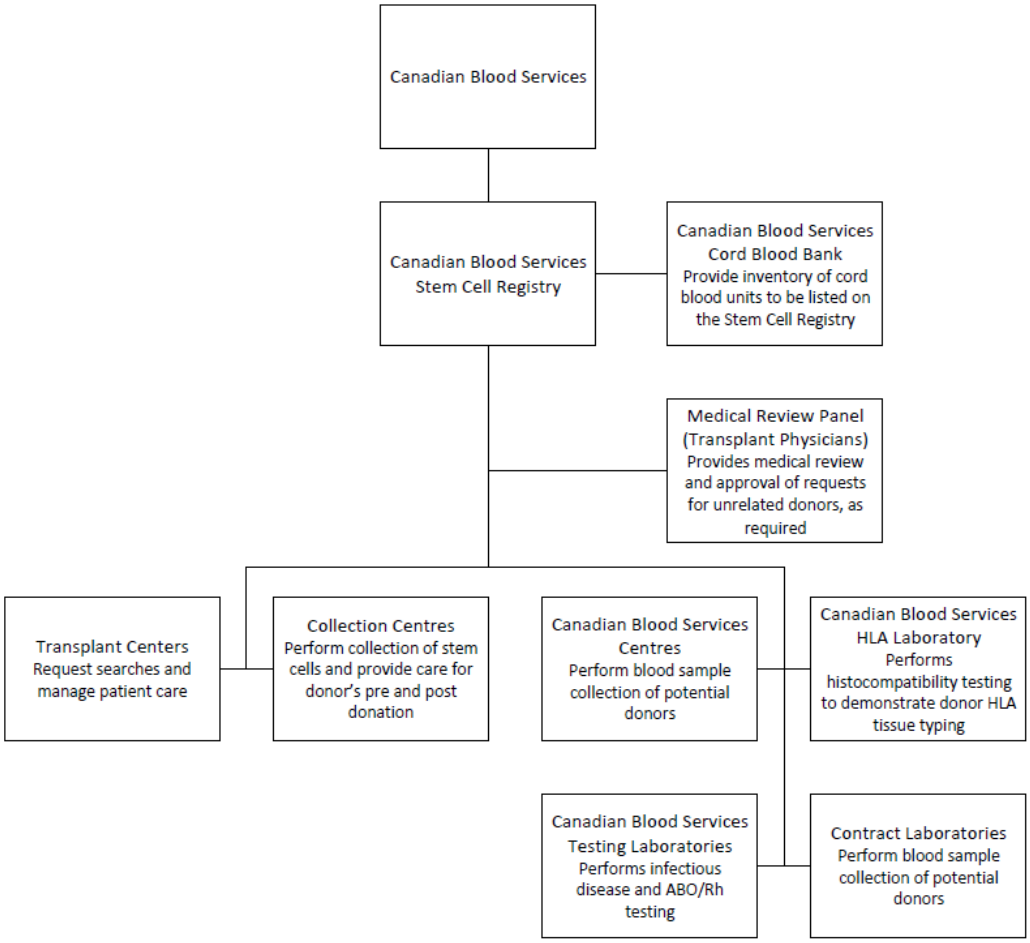
Donor Testing/ASHI Accredited HLA Laboratory:

Quality testing is performed on samples from Registry donors. This ensures accurate matching and that healthy donors are available to patients needing stem cell transplants.

Information Technology:

Stem Cells National Systems Solutions (SCNSS) is the IT platform that brings together the Registry, Canadian Blood Services' Cord Blood Bank and the Canadian transplant and collection centres through an online access. SCNSS contains all information related to the operation of the registry as well as the related activities of the Canadian transplant and collection centres. SCNSS is also connected in real time to some international registries via European Marrow Donor Information System (EMDIS) and/ or WMDA Match-Connect.

Canadian Blood Services Stem Cell Registry Network



ASSOCIATED DOCUMENTS:

None

Section 3 - Confidentiality

OVERVIEW

The Canadian transplant centre must have a process in place to protect the anonymity of the donor and the patient in accordance with the relevant privacy laws and regulations.

DONOR AND PATIENT RECORDS

The *Canadian Blood Services Stem Cell Registry Privacy Notice for Patients* is to be given to every patient prior to initiating a search as it informs the patient how their personal information will be used and shared in order to conduct a search.

Donor and patient will only be referred to by their identification number and patient name (if necessary) when sending confidential information via external computer networks.

Files must be stored in such a way as to prevent access by unauthorized parties. Personal information (e.g. Health Screening Questionnaire) related to the donor must be filed separately from the patient records.

DONOR INFORMATION DURING SEARCH AND WORK-UP

No identifying donor information (ex: name, age, gender, location) will be revealed to the patient, or patient's family and friends.

Personal health information/records necessary to determine donor suitability are required for the benefit of the patient's health and are provided to the transplant centre by Canadian Blood Services Stem Cell Registry (herein known as the 'Registry'). The transplant centre may share this information with the patient and/or patient's family for the purpose of Exceptional Distribution

The product should be examined to ensure that the donor identification number is the only identifying information regarding the donor.

RECIPIENT INFORMATION DURING SEARCH AND WORK-UP

The patient will only be referred to by their identification number on any correspondence between the Registry and the collection center.

No personal identifying patient information (ex: name, age, gender, location) will be revealed to the donor by the Registry or the collection centre.

EXCHANGE OF DONOR/RECIPIENT INFORMATION POST-TRANSPLANT

Anonymous correspondence may be exchanged between a Registry donor and patient immediately post-transplant and will be facilitated by the Registry. No gift exchange is permitted.

The exchange of identifying information between a Registry donor and patient is not permitted until one year post-transplant. If the donor and patients wish to release personal information to each other, a signed consent must be obtained from both parties prior to such release.

Due to the varying regulations of international registries, the possibility exists that some donors and patients will not be permitted to exchange anonymous correspondence, to meet or correspond directly, regardless of stem cell registry policies.

For additional information contact cbs.stemcellregistry@blood.ca

No correspondence is permitted between patients and Canadian/international cord blood unit donors and/or mothers and their family.

ASSOCIATED DOCUMENTS:

IM-00076 *Canadian Blood Services Stem Cell Registry Privacy Notice for Patients*
IM-00077 *REGISTRE DE DONNEURS DE CELLULES SOUCHES DE LA SOCIÉTÉ CANADIENNE DU SANG ÉNONCÉ DE CONFIDENTIALITÉ À DESTINATION DES PERSONNES EN ATTENTE D'UNE GREFFE DE CELLULES SOUCHES*

Section 4 – Requesting Patient Searches

OVERVIEW

All Canadian Transplant Centres (CTC) who signed a Data Sharing Agreement with the Registry, will be authorized access to the Stem Cell Registry Stem Cells National Systems Solution (SCNSS) database to directly conduct their patient searches.

To initiate a patient search, the Registry requires a minimum HLA-A, HLA-B, HLA-C, and HLA-DRB1 typing at Common, Intermediate and Well-Documented alleles (CWD) level.

A World Marrow Donor Association (WMDA) Donor search will automatically be run using default search settings as soon as a new or reactivated patient is saved and will be automatically rerun by WMDA on a regular basis with Active patient status. The search settings can be modified for a patient when required.

WMDA Cord Blood Unit (CBU) and Fax International search requests need to be manually created as needed.

Search Assistance:

The Registry strongly recommends obtaining high resolution typing results for HLA-A, B, C, DRB1 and DQB1 as soon as possible. Performing high resolution typing will aid in quickly identifying the best matched donors or Cord Blood Units.

The Registry Search Analyst (SA) can be consulted by a Follow-Up task or an email regarding how to adjust the 'Settings' of a search request to ensure optimal donors/CBUs are captured.

A Difficult Search Review will be completed by the Registry Seach Analyst as required. This is an in-depth analysis of the issues that make the search difficult. A tailored search strategy is provided in which specific donors and/or Cord Blood Units, are highlighted and extended typing or verification typing requests may be suggested. The Registry will do its best to provide an urgent search review in three business days, and a standard search review in five business days.

Repeating Searches:

New prospective donors/cord blood units are continually being added to the Registry and International Registries. Therefore, repeating the searches of applicable registries as determined by the Canadian Transplant Centre is important for patients who have not found an acceptable matched registrant/Cord Blood Unit. As WMDA automatically performs a refresh of Active patients searches on a regular basis Canadian Transplant Centre only need to manually request repeat searches of applicable Fax International Registries or Cord Blood Banks as needed.

DEFINITION OF SEARCH OPTIONS:

- WMDA Donor – Search World Marrow Donors Association Search & Match Service database for donors
- WMDA CBU – Search World Marrow Donors Association Search & Match Service database for Cord Blood Units
- Fax International – Search International Registry or Cord Blood Bank

Note[1]: ***FAX International search should only be used for donors that do not have a GRID, or in cases where the donor or Cord Blood Unit is not available in the WMDA search results (for example, from a registry that may not frequently upload donors/ Cord Blood Units to WMDA).***

Note[2]*:** ***Bone Marrow Donors Worldwide (BMDW) has been rebranded to World Marrow Donor Association (WMDA) Search & Match service and you may see these terms used interchangeably.

PROCESS

Steps/Descriptor	Instructions
4.1. Submit Search Request	4.1.1. Submit search request as per **IM-00106** *Stem Cells National Systems Solutions User Manual, Section 16*: *Canadian Transplant Centres.* ***Note[1]:*** *Ensure correct entry of as much information as required to initiate or reactivate a patient search request. Not providing all information may cause a delay of a search request being fulfilled.* • Search for patient profile • Ensure patient's status is Active, if patient profile is found • Create patient profile, if no patient profile exists • Attach copy of patient's HLA laboratory typing • Attach Patient's HLA antibody test report and HLA family typing report if available. 4.1.2. If the system identifies a potential duplicate patient file, a warning message will appear. It will not be possible to request any searches or activations before the Stem Cell Registry Seach Analyst completes an assessment. ***Note[2]:*** *If unable to access SCNSS, send the following to the Stem Cell Registry:* • *Completed World Marrow Donor Association Preliminary Search Request form. To obtain WMDA forms, visit https://www.wmda.info/professionals/optimising-search-match-connect/wmda-forms/* • *Copy of patient's HLA laboratory typing report.*

Steps/Descriptor	Instructions
4.2. Run Search	4.2.1. Request WMDA Cord Blood Unit search and Fax international search(es) as required. ***Note[1]:*** *WMDA Donor search is automatically run with default settings.* 4.2.2. Receive and view Match Results/Search Reports. • WMDA Donor search • WMDA Cord Blood Unit search if requested • Receive notification from Stem Cell Registry Search Analyst that FAX international search reports are available, if requested. ***Note[2]:*** *WMDA Donor search and WMDA Cord Blood Unit search are automatically re-run on a regular basis for patients with Active status. Search Settings can be changed to get different Match Results. Fax International re-run searches need to be manually requested - as required.* 4.2.3. Save *Match Results* in the WMDA Donor/ Cord Blood Unit search if satisfactory. Use Acknowledge button to remove the pink background of the existing records in Match Results. ***Note[3]:*** *If unable to access Stem Cell National Systems Solution (SCNSS):* • *Receive WMDA search reports from Stem Cell Registry Search Analyst when available* • *Send request or Fax International Search based on WMDA search report to Stem Cell Registry Search Analyst* • *Receive Fax International search report, if requested from Stem Cell Registry Search Analyst when available.*

Steps/Descriptor	Instructions
4.3. Update Patient Search Request	4.3.1. Search for patient profile. 4.3.2. Update existing patient profile, according to changes required. • Open existing patient profile and update (refer to **Step 4.2** if need to re-run searches). ***Note[1]:*** *If HLA typing has been updated, new match run will be performed automatically on existing WMDA search(es). Any Fax International Search requests will have to be manually requested again with the new typing, as needed.* ***Note[2]:*** *If there is no activity related to the patient profile after 6 months, the patient status will automatically be changed to Stopped with status reason No Activity in the last 6 Months and a task will be sent to notify the Canadian Transplant Centre.* ***Note[3]:*** *If unable to access Stem Cell National Systems Solution (SCNSS):* • *Send updated World Marrow Donor Association Preliminary Search Request form and HLA Lab reports if applicable. To obtain World Marrow Donor Association forms, visit https://www.wmda.info/professionals/optimising-search-match-connect/wmda-forms* • *Receive updated WMDA search reports from the Stem Cell Registry Search Analyst* • *Receive Fax International search reports, if requested, from the Stem Cell Registry Search Analyst.*
4.4. Requesting Difficult Search Review	4.4.1. A Difficult Search Review can be requested as needed. Click the button titled “Request Difficult Search Review” found on the WMDA Donor Search. Complete the HLA Matching Criteria and Save. 4.4.2. A task titled “Patient – Difficult Search Review Completed” will be received in the Worklist when the Search Analyst completes the review. The completed review is a non-editable SYS11 form and can be found in the Patient Profile/Attachments assignment block.

Steps/Descriptor	Instructions
4.5. Patient Transfers	4.5.1. Notify the Stem Cell Registry Search Analyst at search.analyst@blood.ca indicating the patient has been transferred to another Transplant Centre prior to making any changes in patient's profile in SCNSS. 4.5.2. Receive notification from the Stem Cell Registry Search Analyst to proceed with accepting patient transfer from another Transplant Centre and perform search(es). Refer to **Step 4.1.** ***Note***: *Activations previously requested and not tested will be subject to review by the Stem Cell Registry to determine whether the activation can be cancelled or must continue. The Stem Cell Registry will notify the Transplant Centre if the cancellation request is declined or accepted.*

ASSOCIATED DOCUMENTS:

Sys11, *Difficult Search Review form*
S10, *Preliminary Search Request (World Marrow Donor Association form)*
IM-00106 (CO-00289), *Stem Cells National Systems Solutions User Manual: Section 16 Canadian Transplant Centres*
CO-00238, *Stem cell Registry Transplant Centre Reference Manual, Section 14, Postponements and Cancellations*

Section 5 - Requesting Donors for Extended HLA Typing (eHLA), Verification Typing (VT), Reservations, IDMs and Miscellaneous Sample

OVERVIEW

Canadian transplant centres may request the following at any one time:

Request	Maximum
Extended HLA (eHLA)	20 Canadian Blood Services Stem Cell Registry Donors 20 International Donors
Verification Typing (VT) (also known as Confirmatory Typing)	3 Canadian Blood Services Stem Cell Registry Donors 3 International Donors
Infectious Disease Markers (IDM) only	6 Canadian Blood Services Stem Cell Registry Donors 6 International Donors
Miscellaneous Samples	No maximum Canadian Blood Services Stem Cell Registry Donors No maximum International Donors
Reservations	No maximum Canadian Blood Services Stem Cell Registry Donors No maximum International Donors

These limits may be exceeded on a case-by-case basis in consultation with a Canadian Blood Services Stem Cell Registry (stem cell registry) Search Analyst.

Donors requested for eHLA or IDM only requests will be released once results have been provided to the transplant centre.

INFECTIOUS DISEASE TESTING

Canadian Blood Services laboratories performing Infectious Disease Markers (IDMs) are licensed by Health Canada and use assay test kits approved in Canada for donor screening. Some international registries do not routinely perform IDMs on their donors at the time of verification typing. Therefore, the transplant centre may choose to perform their own IDMs on international donors or initiate a separate IDM request at the time verification typing is requested.

VERIFICATION TYPING

The purpose of verification typing is to ensure that the donor being selected for donation is the same individual whose HLA typing was listed on the search report. Verification typing must be performed at a minimum of HLA-A, B, C, DRB1 DNA based typing at high resolution prior to a hematopoietic stem cell donation.

DONOR RESERVATIONS

Registry donors will be automatically reserved for a patient at verification typing for 60 days after their blood samples have been drawn and 30 days from the date the shipment details are sent for miscellaneous sample requests. Registry donors may be held for an additional three months from the date of the extended reservation request. While most international registries will extend reservations for an additional three months, some may have varying policies.

Extensions to this time period will be considered on a case by case basis if accompanied by a rationale indicating the proposed date of transplant and the patient's medical status.

Reservation requests can be made when a donor requires reservation and the verification typing request has expired. The donor is then reserved for 90 days from the date of the reservation request.

Individual reservation activation may be requested under the following circumstances; otherwise another request type must be made.

- Donor previously completed verification typing and/or donated for the requested patient. Transplant centre must provide copies of the verification typing results.

- Donor previously completed more than 2 verification typings for any patient and the last verification typing was completed within the past 2 years.

MISCELLANEOUS SAMPLES

Samples for miscellaneous and non-routine tests may be requested on a case by case basis.

PROCESS

6.1. Requesting Donor(s) for Activation

6.1.1. Add international donor to Search Results if it does not exist, as per **IM-00106** *Section 16: Canadian Transplant Centres*.

6.1.2. Request donor for desired activation type.

If…	Then…
Extended HLA (eHLA),	• Activate donor for eHLA • Select all typing to be completed. ***Note[1]:*** *Only the services offered by the registry will be available.* ***Note[2]:*** *When selected typing requested has previously been performed, the request will automatically complete and existing typing results will be provided.*
Verification Typing (VT),	• Activate donor for verification typing • Review sample requirements and update as required. ***Note[1]:*** *The Canadian Blood Services Stem Cell Registry has a maximum request of 50 mls for donors.* ***Note[2]:*** *IDM Testing (including ABO/Rh and Anti-body Screen (AbScr) for Canadian Blood Services Stem Cell Registry donors* • *HIV (HIV-1/2 antibody/antigen)* • *NHIV (HIV NAT)* • *HCV (Anti-HCV)* • *NHCV (HCV NAT)* • *HBsAg* • *HTLV (Anti-HTLV 1/II)* • *SYP (syphilis)* • *CMV (Anti-CMV)* • *HBc (Anti-HBc)* • *NHBV (HBV NAT)* • *NWNV (WNV NAT - at work-up only)* • *CHAGA (Chagas) (only performed for donors at risk for the disease* • *Testing for international donors is performed as per international registry policy.*
IDM only,	• Activate donor for 'IDM Only' request • Select desired IDM testing to be completed.

5.1. Requesting Donor(s) for Activation (continued)

5.1.2. (continued)

If…	Then…
Miscellaneous Samples,	• Activate donor for Miscellaneous Sample • Review sample requirements and update as required ***Note:*** *The Canadian Blood Services Stem Cell Registry has a maximum request of 50mls for donors.* • Enter note describing the intended testing to be performed on the samples.
Reservations	• Activate *Canadian Blood Services Stem Cell Registry* donor for Reservation. • Send task requesting international donor reservation as per CO-00289 *Section 16: Canadian Transplant Centres.*

Note[1]: *If unable to access Stem Cells National Systems Solutions (SCNSS), circle the Global Registration Identifier for Donors (GRID) on the Match Results report and indicate the desired activation type to be completed and send the report to the stem cell registry.*

Note[2]: *Refer to Section 6 for further information on requesting Work-Up of a Canadian or international donor.*

5.2. Receive Activation Information and Completed Test Results

5.2.1. Receive test results and information in response to activation request:

If…	Then…
eHLA,	• Receive eHLA results.
Verification Typing,	• Receive shipment details of scheduled samples to be drawn • Notify stem cell registry if samples are not received 2 days after expected delivery • Receive IDM results, if provided by international registry • Receive information on donor parity and history of sensitizing events, if applicable • Receive additional donor eligibility information obtained during the donor health screening, if applicable. • Inform stem cell registry at least two business days before scheduled sample draw in order to cancel verification typing. ***Note:*** *Stem Cell Registry Medical Conditions Chart (MCC) and Health Screening Questionnaire (HSQ) can be located on https://blood.ca/en/hospital-services/stem-cell-registry-documents*
IDM only,	• Receive IDM results.
Miscellaneous Samples,	• Receive shipment details of scheduled samples to be drawn • Notify stem cell registry if samples are not received 2 days after expected delivery.
Reservations,	• Receive confirmation or denial of the reservation request.

Note: *If unable to access Stem Cells National Systems Solution (SCNSS), contact cbs.stemcellregistry@blood.ca to send applicable test results and information.*

5.2.2. Inform the stem cell registry immediately if transplant centre to store samples received without performing testing.

5.3. Send Completed Test Results

5.3.1. Report results to stem cell registry immediately or within 60 days of sample collection.

5.3.2. Proceed as indicated in table below.

If…	Then…
eHLA,	• N/A

Verification Typing,	• Enter HLA test results, typing method, HLA test date and HLA Laboratory
	• Indicate if donor should be:
	  • Released, including reason
	  • Reserved, including rationale for request, transplant timeline, preferred product and donor rank
	• Attach the following to activation:
	  • All applicable laboratory reports
	  • Any abnormal or reactive IDM results obtained on Canadian or international donor samples.

IDM only,	• N/A

Miscellaneous Sample,	• Enter HLA test results, typing method, HLA test date and HLA Laboratory, if applicable
	• Attach the following to activation:
	  • All applicable laboratory reports
	  • Any abnormal or reactive IDM results obtained on Canadian or international donor samples
	  • Any non-typing test results
	• Inform stem cell registry.
	Note: *Donor will be automatically released from request upon reporting of test results.*

Reservations,	• N/A

Note [1]: *If unable to access Stem Cells National Systems Solution (SCNSS), complete World Marrow Donor Association "Donor HLA Verification Typing Results" form, or international registry equivalent if applicable. Indicate typing results will not be provided if donor is released prior to completion of the typing.*

ASSOCIATED DOCUMENTS:

IM-00106 (CO-00289), *Stem Cells National Systems Solutions User Manual: Section 16 Canadian Transplant Centres*

CO-00239, *Stem Cell Registry Transplant Centre Reference Manual, Section 14 – Postponements & Cancellations*

Section 6 – Requesting a Donor for Work-up

OVERVIEW

1. WORK-UP REQUEST

The Registry will coordinate the work-up of Canadian or international unrelated donors upon receipt of a formal request from the Canadian transplant centre.

Work-up requests for Registry donors are subject to review and approval by the stem cell registry Medical Review Panel in the following cases:

- Patient's disease not listed in **CO-00211**, Stem Cell Registry Medical Conditions Chart, Appendix 3, List of Standard Diagnoses for Allogenic Stem Cell Transplant
- Additional products will be requested as part of a planned protocol
- Additional donation request from the same donor
- Request is unusual.

The work-up of a donor may take approximately four to six weeks from the date of request to product collection. This time frame may vary depending on donor and collection centre or international registry availability. The Registry should be notified immediately if there may be changes in the patient's condition that would result in a postponement or cancellation of the transplant. Additionally, in order to ensure timeliness of processing requests, the transplant centre should ensure adequate coordinator coverage to be able to reply to Registry queries within 1 business day.

The collection centre or international registry may have varying procurement techniques including the filtering, media, additives and anticoagulants used. Any additional information or specific criteria that are required should be requested at the time of work-up activation to ensure the collection centre or international registry can accommodate the additional requirements.

Donors who are approaching the maximum age to donate require consideration on suitability because a subsequent donation may not be possible.

To request a donor participation in research, refer to Section 13, Research Requests.

2. SIMULTANEOUS VERIFICATION TYPING /WORK-UP

In urgent situations, a simultaneous verification typing/work-up of a donor may be requested; however; the risk associated with the potential discovery of a typing discrepancy or donor information that is considered a risk to the recipient must be carefully considered. The request may be declined subject to the international registry policy. The transplant centre must submit the verification typing results to the stem cell registry prior to donor clearance.

3. BACK-UP DONORS

The Registry strongly recommends that the transplant centre requests at least one back-up donor be placed on hold. Registry donors may be held for a maximum of three months from the date of the extended reservation request. Extensions to this time period may be requested if accompanied by a rationale indicating the proposed date of transplant and the patient's medical status. Reservation depends on the willingness of the donor. The policies may vary for international registries.

A transplant centre may request up to 2 Registry donors for work-up per patient. The number of donors permitted for work-up may vary with the international registry policies. Written rationale must accompany the work-up request for a 2nd donor.

4. INFECTIOUS DISEASE MARKERS (IDMS)

Once selected for work-up, donors will be tested for infectious disease markers (IDMs) within 30 days of the collection.

The IDM testing for Registry donors is performed by Canadian Blood Services and the results are provided to the transplant centre at the time of donor clearance.

IDM testing for international donors is performed as per international registry policy. The Registry will forward the completed Infectious Disease Marker Testing to be Performed at Work-up form to the transplant centre on behalf of the international registry. This form may contain additional information including tests that were unable to be performed, additional tests performed other than those listed or; any day of collection testing. If the international registry is not able to perform all the required testing the transplant centre can request additional precollects.

IDM testing performed by the transplant centre, with abnormal or reactive results must be reported to the Registry, except for CMV status.

5. DONOR CLEARANCE

Any concerns raised by the collection centre or international registry prior to donor clearance will be documented and communicated immediately.

The transplant centre must not start patient preparative conditioning until all donor clearance documents have been provided by the stem cell registry.

The transplant centre physician is responsible to determine the final decision to proceed with a donor. When applicable, the transplant centre will complete the documentation for exceptional distribution as per the **Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations.**

PROCESS

6.1. Requesting a Donor for Work-up	6.1.1. Activate the donor for work-up, complete and send the following forms to stem cell registry: • *Workup Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis or international registry* equivalent if applicable, ***Note[1]:*** *Refer to Section 6 Appendix 1: Recommended Procedure for Calculating Total Nucleated Cells.* ***Note[2]:*** *If cryopreservation requested, indicate in Stem Cell National Systems Solution (SCNSS) as per* ***IM-00106*** *Stem Cell National Systems Solutions User Manual, Section 16* • HLA laboratory typing reports for patient and donor • Research information and donor consent to participate, as per *Section 13, Research Request* if applicable.
6.2. Receive Information from Stem Cell Registry	6.2.1. Receive confirmation if donor willing to proceed with collection and additional donor information, if provided. • If collection centre or international registry is unable to accommodate the requested collection date(s), negotiate mutually acceptable dates. 6.2.2. Receive work-up schedule, completed *Infectious Disease Marker Testing to be Performed at Work-up* form, if applicable and courier instructions, if available. 6.2.3. Confirm acceptance of the collection date(s) and provide the date the patient will begin preparative conditioning if applicable and planned infusion date. 6.2.4. Receive courier waybill/tracking number for pre-collect samples, if applicable. 6.2.5. Receive completed *Qualification of an External Collection, Processing and/or Testing Facility* form or international registry equivalent, if provided. 6.2.6. Contact Canadian Blood Services Stem Cell Registry immediately for request to cryopreserve entire product. 6.2.7. Receive decision from Canadian Blood Services Stem Cell Registry if request approved or denied. If denied, inform the stem cell registry if proceeding with work-up. 6.2.8. If requesting to postpone or cancel, refer to Section 14, Postponements and Cancellations

6.3.	Receive Notification of Donor Clearance	6.3.1. Receive the following stem cell registry donor clearance documents or international registry equivalent: • Applicable Prescription Verification, if provided • IDM Results • *Collection Centre Donor Medical Examination* • *Collection Centre Donor Medical Review form* • *Health Screening Questionnair*e (Canadian Blood Services Stem Cell Registry donors only) • Signed donor consent to participate in research study as per Section 13, Research Requests, if applicable. 6.3.2. Refer to Section 14, *Postponements and Cancellations* for additional information pertaining to donor clearance in the case of a postponement.
6.4.	Donor Findings Associated with Recipient Risk	6.4.1. Evaluate the risk for the patient, following requirements for Exceptional Distribution as per Health Canada **Safety of Human Cells, Tissues and Organs for Transplantation Regulations** as applicable. 6.4.2. Complete transplant centre section of the *Collection Centre Donor Medical Review* or international registry equivalent, if provided and forward to stem cell registry to confirm if proceed with collection or cancel the work-up request and release donor. 6.4.3. Complete and maintain Exceptional Distribution documentation in the patient's record.
6.5.	Review of Prescription Verification	6.5.1. Sign the Prescription Verification form, if provided. Send to stem cell registry prior to starting patient preparative conditioning.
6.6.	Courier Details	6.6.1. Complete and send the following forms, or international registry equivalent to stem cell registry: • *Pre-Transplant Work-up Courier Details* • Copy of the courier itinerary 6.6.2 Receive *Courier Letter* and airport notification memo, if applicable.
6.7.	Product Receipt and Infusion	6.7.1. Complete the *Transplant Centre Product Infusion Record* and send to stem cell registry. Refer to Section 4, *Requesting Patient Searches* to update the patient search status. 6.7.2. Inform the stem cell registry if product was discarded. 6.7.3. Report immediately any product integrity issues or any unexpected recipient adverse reactions/events associated with the infusion of the product. Refer to Section 11, *Quality/Adverse Event Reporting*.

SECTION 6 APPENDIX 1: RECOMMENDED PROCEDURE FOR CALCULATING TOTAL NUCLEATED CELLS

1. Enter the desired number of nucleated cells per kg recipient weight. A typical cell dose might be 3.0 x 10^8 cells/kg.
2. Enter the recipient's weight in kilograms.
3. Multiply the desired cells per kg by the recipient's weight. Enter the result as the total nucleated cells required for the recipient.
4. Enter the number of additional nucleated cells to be used for quality assurance/transplant centre laboratory.
5. Add lines 3 and 4 together, the sum equals the TOTAL nucleated cells requested from the donor.

   A sample calculation:

   3.0 x 10^8 nucleated cells/kg

   x 78.2 kg

   = 234.6 x 10^8 nucleated cells

   \+ 1 x 10^8 cells for quality assurance/transplant centre lab

   = 235 x 10^8 total nucleated cells requested

In addition, an estimate can be made on the minimum marrow volume based on the total nucleated cell count (using an average 0.22 cells/ml). The maximum volume removed from the donor should not exceed 20 ml/kg of donor weight.

The remaining sections of the prescription must be completed in accordance with transplant centre requirements. Spaces are provided for pre-collection blood samples, peripheral blood samples and marrow tubes requested on the day of collection and any specific instructions for media or anticoagulants to be added to the marrow.

ASSOCIATED DOCUMENTS

F800017 (F800879), Infectious Disease Marker Testing to be Performed at Work-up
F800020 (F801503), Workup Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis
F800021 (F801505), Pre-Transplant Workup-Courier Details
F800023 (F801507), Transplant Centre Product Infusion Record
F800025 (F801509), Prescription Verification - HPC, Marrow
F800026 (F801510), Prescription Verification - HPC, Apheresis & MNC, Apheresis
F800034 (F801541), Collection Centre Donor Medical Review
F800035 (F801542), Collection Centre Donor Medical Examination
F800038 (F801554), Health Screening Questionnaire
F800173 (F801606), Qualification of an External Collection, Processing and/or Testing Facility
IM-00106 (CO-00289), Stem Cell National Systems Solutions User Manual, Section 16
CO-00211 (60 019), Stem Cell Registry Medical Conditions Chart, Appendix 3, List of Standard Diagnoses for Allogenic Stem Cell Transplant

Section 7 – Requesting a Cord Blood Unit

OVERVIEW

The Registry will liaise with international cord blood banks and the Canadian Blood Services' Cord Blood Bank to coordinate activation and procurement requests of cord blood units on behalf of a Canadian transplant centre. All communication from transplant centres must be sent through the Registry. When direct communication with a cord blood bank is required, the transplant centre must obtain approval from the stem cell registry.

The transplant centre may make various requests for Canadian Blood Services' Cord Blood Bank or international cord blood units and limits may be exceeded on a case-by-case basis in consultation with the Registry.

Request Type	Maximum number of Requests for Transplant Centre
Cord Blood Unit Report	No limit
Extended HLA typing (eHLA)	20 Canadian Blood Services' Cord Blood Bank cord blood units Unlimited International cord blood units
Verification Typing (VT)	3 Canadian Blood Services' Cord Blood Bank cord blood units Unlimited International cord blood units
Miscellaneous Sample/Segments	3 Canadian Blood Services' Cord Blood Bank cord blood units Unlimited International cord blood units
Infectious Disease Markers (IDMs) only	Not available for Canadian Blood Services' Cord Blood Bank cord blood units Unlimited for International cord blood units
Post Thaws (PT)	3 Canadian Blood Services' Cord Blood Bank cord blood units Unlimited International cord blood units
Reservations	3 Canadian Blood Services' Cord Blood Bank cord blood units Unlimited International cord blood units

CANADIAN BLOOD SERVICES' CORD BLOOD BANK CORD BLOOD UNITS

Cord blood units are automatically reserved for a maximum of 60 days at verification typing, post thaw and for miscellaneous sample requests and 90 days for reservation requests and will automatically be released from the search unless an extension (maximum 3 months) is requested.

Extended HLA typing requests are reserved until the results have been provided.

International Cord Blood Banks

International cord blood banks have differing policies with respect to reservation of a cord blood unit. The Canadian Blood Services Stem Cell Registry will consult with the appropriate international cord blood bank to confirm their reservation policy. Extended reservations may be considered by the international cord blood bank if a detailed rationale and/or treatment plan is provided by the transplant centre.

Cord Blood Unit Reports

Cord blood unit reports contain baseline information such as HLA typing, gender, date of collection, CD 34+ count, total nucleated cells (TNC), viability, and maternal infectious disease markers results. The transplant centre should request the report to provide further details about the cord blood unit.

Testing

Maternal (IDM) testing is completed at time of Canadian Blood Services' Cord Blood Bank cord blood unit collection, and will not be repeated. Canadian Blood Services does not perform IDM testing on Canadian Blood Services' Cord Blood Bank cord blood units.

Supplemental IDM testing may be requested for markers that were not previously completed by the international cord blood bank subject to approval and is dependent on sample availability.

Any discrepant IDM results identified by the transplant centre must be communicated to the stem cell registry for investigation, except for CMV status.

Once search results and supplemental reports have been provided, the transplant centre may request the cord blood bank to perform additional typing on a cord blood unit, or request the shipment of a cord blood unit sample for a transplant centre to perform their own typing.

Some cord blood banks will not repeat verification typing for HLA markers which are already available on the supplemental report, and may not provide a cord blood unit sample for verification typing until formal procurement of the cord. The stem cell registry will provide information to the transplant centre regarding specific cord blood bank policies upon request.

Canadian Blood Services' Cord Blood Bank performs verification typing on a cord blood unit segment. Post thaw testing is automatically performed with a verification typing request if it has not already been performed.

Some cord blood banks request that patient samples be provided for verification typing by their HLA laboratory prior to release of the cord blood unit. The stem cell registry will notify the transplant centre and provide associated instructions if applicable.

Releasing a Cord Blood unit

Whenever possible, the transplant centre should allow 2 weeks for the cord blood bank to complete internal quality control processes and to make arrangements for the shipment of the cord.

When verification typing is not performed prior to cord procurement, the transplant centre must ensure verification typing results are available prior to initiating patient preparative conditioning. If a transplant centre requests a Canadian Blood Services' Cord Blood Bank cord blood unit as urgent and the timeframe will not allow pre-release post thaw and/or verification typing to be performed prior to shipment, then the transplant centre must complete a form authorizing the cord blood bank to ship the cord under Exceptional Distribution. It is strongly advised that the patient's preparatory conditioning does not begin until the cord blood unit arrives at the transplant centre. Canadian Blood Services' Cord Blood Bank and the Canadian transplant centre are responsible to keep a copy of the notice of Exceptional Distribution documentation. The final selection of a suitable cord blood unit is the responsibility of the transplant centre physician. If a cord blood unit is an Exceptional Distribution it must be released to distribution in accordance to Health Canada **Safety *of Human Cells, Tissues and Organs for Transplantation Regulations***. The transplant centre physician must indicate in writing their desire to proceed with the cord blood unit.

ACCREDITATION STATUS OF INTERNATIONAL CORD BLOOD BANK

Accreditation status of international cord blood banks may be determined by visiting the Cord blood bank/registry website or the FACT/NetCord, AABB, or WMDA websites. The Registry will provide the qualification status of the international cord blood bank at time of cord blood unit procurement if not previously requested by transplant centre.

PROCESS

<table>
<tr><th>Steps/Descriptor</th><th>Instructions</th></tr>
<tr><td>8.1. Requesting Cord Blood Unit for Activation</td><td>
8.1.1. Add international cord blood unit to match Results, if it does not exist.

8.1.2. Complete and submit international cord blood unit specific forms as required.
8.1.3. Contact the stem cell registry to confirm if specific forms are required by the international cord blood bank.
Note: The stem cell registry will provide the applicable forms for completion. EMDIS registries do not require forms for cord blood unit reports, extended HLA (eHLA) or Reservation requests.
8.1.4. Select the cord blood unit and activate for the following, as applicable:
<table>
<tr><th>If Requesting…</th><th>Then…</th></tr>
<tr><td>Cord Blood Unit Report,</td><td>• Activate request.</td></tr>
<tr><td>Extended HLA (eHLA),</td><td>• Activate cord blood unit for eHLA
• Select all typing to be completed.
Note[1]: Only the services offered by the registry will be available.
Note[2]: When selected typing requested has previously been performed, the request will automatically complete and existing typing results will be provided.</td></tr>
<tr><td>Verification Typing (VT),</td><td>• Activate cord blood unit for verification typing
• Select the desired verification typing package if more than one typing option is offered.
Note[1]: Post thaw may automatically be included if not previously performed.
Note[2]: Verification typing is performed by the cord blood bank.</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Steps/Descriptor</th><th>Instructions</th></tr>
<tr><td>7.1. Requesting Cord Blood Unit for Activation (continued)</td><td>
7.1.4. Select the cord blood unit and activate for the following, as applicable: (continued)
<table>
<tr><th>If Requesting…</th><th>Then…</th></tr>
<tr><td>Miscellaneous Samples,</td><td>• Activate cord blood unit for Miscellaneous Sample
• Select desired sample type
• Review “Ship to’ information and request update, if required.</td></tr>
<tr><td>Infectious Disease Marker (IDMs) only,</td><td>• Activate cord blood unit for ‘IDM Only’ request
• Select IDMs testing to be performed.
Note[1]: The options available may vary with the cord blood banks.
Note [2]: The “IDMs” option is to request the full cord blood bank’s IDM package.
Note[3]: IDMs not applicable for Canadian Blood Services’ cord blood units</td></tr>
<tr><td>Post thaw,</td><td>• Activate cord blood unit for post thaw
• Indicate testing to be performed, for international cord blood units
• Activate request, for Canadian Blood Services cord blood units</td></tr>
<tr><td>Reservation,</td><td>• No further action required.</td></tr>
</table>
Note[1]: If unable to access Stem Cells National Systems Solution (SCNSS), notify stem cell registry at cbs.stemcellregistry@blood.ca.

Note[2]: Complete the international cord blood bank specific forms and send forms, when applicable.

8.1.5. Receive completed Qualification of an External Collection, Processing and/or Testing Facility form, if requested.
</td></tr>
</table>

<table>
<tr><th>Steps/Descriptor</th><th>Instructions</th></tr>
<tr><td>8.2. Receive Activation Information and Completed Test Results</td><td>8.2.1. Receive results and/or information in response to the activation request, if applicable.
<table>
<tr><th>If requesting …</th><th>Then…</th></tr>
<tr><td>Cord Blood Unit Report,</td><td>• Receive report
• Notify stem cell registry if additional information is required.</td></tr>
<tr><td>Extended HLA (eHLA),</td><td>• Receive results.</td></tr>
<tr><td>Verification Typing,</td><td>• Receive results
• Receive post thaw results if previously not completed prior to verification typing request</td></tr>
<tr><td>Miscellaneous Sample,</td><td>• Receive shipment details
• Notify stem cell registry if samples are not received within 2 days of expected arrival.</td></tr>
<tr><td>Post Thaw,</td><td>• Receive results.</td></tr>
<tr><td>Reservations,</td><td>• Receive acceptance or denial of request.
Note: Reservation period may be changed from requested periods based on international registry policies.</td></tr>
<tr><td>IDMs only,</td><td>• Receive results.</td></tr>
</table>
Note[1]: If unable to access Stem Cells National Systems Solutions (SCNSS), contact stem cell registry to send applicable test results and information.
Note[2]: Canadian Blood Services Stem Cell Registry will notify the transplant centre if status of cord blood unit changes. Cord blood unit may be temporarily unavailable while investigation is ongoing.</td></tr>
</table>

Steps/Descriptor	Instructions
8.3. Send Completed Test Results to Stem Cell Registry	8.3.1. Report results to stem cell registry within 60 days of sample collection. 8.3.2. Attach test results, when applicable and inform stem cell registry.
8.4. Request Procurement of a Cord Blood Unit	8.4.1. Contact the stem cell registry to confirm if specific international cord blood bank forms are required. ***Note:*** *The stem cell registry will provide the applicable forms for completion.* 8.4.2. Activate cord blood unit for work-up and send the following documents to the stem cell registry: • *Request for Shipment of Cord Blood Unit* or international cord blood bank specific cord blood unit procurement forms • Copy of Patient HLA typing • Copy of cord blood unit HLA typing, if available. 8.4.3. Provide rationale if cord blood unit arrival date is requested to arrive on or after the patient preparative conditioning start date. 8.4.4. Review "Ship to" information and request update as per **IM-00106** *Stem Cells National Systems Solutions User Manual* Section 16, if required.

Steps/Descriptor	Instructions
8.5. Receive Cord Blood Unit Shipment and Additional Information, for an International Cord Blood Unit	8.5.1. Receive shipping details and additional cord blood unit information, if provided. ***Note[1]:*** *The Canadian Blood Services Stem Cell Registry will organize shipment of the cord blood unit with World Courier if the international cord blood bank does not provide this service.* ***Note[2]*** *Canadian Blood Services Stem Cell Registry makes the arrangements with customs brokerage company to clear customs as required for international cord shipments once the cord blood bank has provided cord itinerary.* ***Note[3]:*** *Information may not be received in advance of cord blood unit shipment, especially if limited timelines.* 8.5.2. Receive *Qualification of an External Collection, Processing and/or Testing Facility* form, if not previously received. 8.5.3. Inform the stem cell registry if any additional information required.
8.6. Reporting Receipt and Infusion of an International Cord Blood Unit	8.6.1. Confirm receipt of the cord blood unit, complete applicable international registry forms if required. 8.6.2. Notify the stem cell registry if cord blood unit is not received on day of expected arrival. 8.6.3. Receive cord blood unit shipment dry shipper temperature data log, if provided. 8.6.4. Send completed *Transplant Centre Product Infusion Record,* and cord blood bank form(s), when applicable. 8.6.5. Report immediately to stem cell registry any issue with the integrity of the product or an unexpected recipient adverse reaction/event occurs. Refer to Section 11, *Quality/Adverse Event Reporting.* Inform the stem cell registry if cord blood unit not infused and/or product discarded.
8.7. Receive Cord Blood Unit Shipment Information for a Canadian Blood Services' Cord Blood Bank Cord Blood Unit	8.7.1. Receive shipping details and additional cord blood unit information, if applicable. ***Note:*** *Post thaw/verification typing results and statement of suitability will be provided prior to shipment of cord blood unit on the Cord Blood Unit Suitability Assessment and Release form.*

Steps/Descriptor	Instructions
8.8. Management of Canadian Blood Services' Cord Blood Bank Cord Blood Unit Suitability	8.8.1. Receive *Cord Blood Unit Suitability Assessment and Release* form from the stem cell registry indicating cord blood unit eligibility status. 8.8.2. Complete Section B of *Cord Blood Unit Suitability Assessment and Release* form, if exceptional distribution is required, as per Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations. 8.8.3. Send completed forms to the stem cell registry authorizing or declining shipment of the requested cord blood unit.
8.9. Reporting Receipt of a Cord Blood Unit	8.9.1. Complete *Cord Blood Unit Receipt* form received with cord blood unit shipment and send to the Registry within 24 hours of receipt. 8.9.2. Notify the Registry if cord blood unit is not received on day of expected arrival.
8.10. Receive Temperature Data Log	8.10.1. Receive cord blood unit shipment dry shipper temperature log.
7.11. Reporting Infusion of a Cord Blood Unit	7.11.1. Complete *Cord Blood Unit Thawing and Infusion Report* received with cord blood unit shipment and send to the stem cell registry within 24 hours of infusion. 7.11.2. Report immediately any issue with the integrity of the product or an unexpected recipient adverse reaction/event occurs. Refer to Section 11, *Quality/Adverse Event Reporting.* 7.11.3. Inform stem cell registry if product not infused and/or discarded.

ASSOCIATED DOCUMENTS:

IM-00106 (CO-00289), *Stem Cells National Systems Solutions User Manual, Section 16: Canadian Transplant Centres*
F800007 (F800147), *Cord Blood Unit Thawing and Infusion Report*
F800009 (**F800150),** *Cord Blood Unit Receipt*
F800010 (F800152), *Cord Blood Unit Suitability Assessment and Release*
F801670 (F801508), *Request for Shipment of Cord Blood Unit*
F800173 (F801606), *Qualification of an External Collection, Processing and/or Testing Facility*

Section 8 – Requesting Additional Products

OVERVIEW

Registry donors will be permitted to donate hematopoietic stem cells a maximum of two times (includes any previous unrelated and related stem cell donations). This does not apply to unstimulated leukocyte donations or MNC, Apheresis. All requests for additional donations for the same patient will be submitted to the stem cell registry Medical Panel for review and approval.

The criteria and policies for additional product donation requests can vary among international registries. The Registry will provide information regarding an international registry's policy upon request from the transplant centre.

After the initial collection, the donor will advise the Registry of his/her willingness to donate an additional product if requested by the transplant centre in the future. The Registry will notify the transplant centre *only* if the donor has indicated unwillingness to proceed with an additional donation. If the donor agrees to a second donation, he/she will remain unavailable for other recipients for one year from the date of donation.

In the event additional products will be requested from a donor as part of a planned treatment protocol, the transplant centre must include this information at the time of the first work-up request. Such protocols will be subject to review by the stem cell registry Medical Panel, and if approved, will be discussed with the donor at the time of the initial work-up.

The Registry does not require specific intervals between donations, however, at a minimum the donor must be considered recovered from a previous donation (minimum 4-6 weeks after engraftment and with medical panel approval) before being approached to make a subsequent donation.

PROCESS

8.1. Requesting an Additional Donation	8.1.1. Send the following stem cell registry forms or international registry equivalent to the stem cell registry: • *Work up Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis* • *Previous Transplant History* ***Note:*** *The National Marrow Donor Program (NMDP) requires World Marrow Donor Association (WMDA) forms to be completed for all additional donation requests, which can be found at https://wmda.info/professionals/optimising-search-match-connect/wmda-forms/.* 8.1.2. Provide any additional information, if requested by the stem cell registry Medical Panel or Medical Director. 8.1.3. Receive approval of the request and refer to Section 6, *Requesting a Donor for Work-up.*

ASSOCIATED DOCUMENTS:

F800020 (F801503) *Work up Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis*
F800022 (F801506) *Previous Transplant History*

Section 9 – Product Transport

OVERVIEW

The transport of hematopoietic stem cells (HPC) and other products from the Registry and international donors, for therapeutic use, must be arranged and provided by the requesting Canadian transplant centre. The transplant centre must designate a suitable courier to be responsible for hand delivery of the product within an acceptable time frame to ensure the quality and viability of the product(s). The transplant centre must provide and document training of their designated courier with respect to confidentiality, level of responsibility, required tasks, and accountability.

Some international registries may provide courier services for delivery of a product. The stem cell registry will request information from the international registry pertaining to these services and associated costs upon request.

The Bruce Denniston Society has established a group of experienced volunteer couriers, many are active or retired RCMP members. For information, visit http://dennistonsocietyottawa.org or contact the Registry.

The transplant centre is required to maintain policies and procedures for all aspects related to the transportation, shipment and receipt of HPCs and other products in accordance with applicable regulations and standards based upon the guidelines outlined in this policy.

If a commercial courier company is used, the transplant centre must establish a service level agreement with the courier company. The company needs to understand that their "normal" business/ transport procedures will not apply to the transportation of stem cell products. The company must be able to provide trained couriers and services that meet the guidelines contained in this document. The transplant centre must be involved with the courier company in the development of the service and the training of the couriers.

Cord blood units will be shipped in a dry shipper to the transplant centre via a commercial courier company arranged by the cord blood bank or by the Registry as indicated in Section 7*, Requesting a Cord Blood Unit.*

In exceptional circumstances, transplant centres may contact the Registry to request assistance in arranging courier services.

The Registry must be notified by the transplant centre of any problems encountered by the courier during pick-up and/or transport of the product.

1. COURIERS

a. Courier Qualification

To be selected as a courier, the person **must**:

- Not be related to the donor or patient
- Be an experienced independent traveler, with experience with international travel for international product pick-ups
- Possess a current, valid passport (for international transport) with an expiry at least 3 months past return date.
- Have or be provided with a mobile/cell phone; phone must have international roaming capability/connectivity for international HPC transport
- Have no other obligations until after the product has been delivered
- Have access to a credit card with a reasonable limit
- Be trained in all policies and procedures of the transplant centre required for the transportation of HPC prior to being assigned to a HPC transport
- Have adequate command of the English language or the language(s) used in the countries to be visited for international transport.

It is preferable that the courier has experience in transporting HPC within Canada prior to acting as an international courier.

b. Courier Responsibilities

The courier's sole responsibility should be to transport the HPC from the collection centre/international registry to the transplant centre in the shortest time possible and at the temperature requested by the transplant centre.

The courier **must**:

- Remain in possession of the HPC product with the product in their vision at all times
- Carry documentation relating to transportation of the HPC product
- Verify accuracy of information on HPC labels and if applicable, specimen labels
- Place the product bags and samples properly in the cooler
- Ensure that the HPC do not pass through X-ray screening at security checkpoints*
- Monitor and maintain the required temperature of the product as per transplant centre instructions
- Deliver the HPC directly to the designated person at the transplant centre or processing laboratory
- Inform the transplant centre of possible delays

- Communicate with and obtain direction from the transplant centre regarding any issues related to cell count yields which do not meet transplant centre requirements
- Not consume alcohol or sedative drugs while transporting the HPC
- Maintain patient and donor confidentiality
- Not accept gifts for the recipient from the collection centre/international registry
- Refrain from purchasing items such as alcohol and tobacco (unless duty-free) while travelling which may cause delay in clearing customs.
- Provide documentation of product labeling verification and log of any transport issues to transplant centre.

*If airport security requires inspection of the product, the product bag(s) may be removed from the container and the container may be x-rayed, while the product inspection is performed by hand under the supervision of the courier.

Effects of cumulative X-ray screening on HPC product viability has not been determined, therefore if the transport of the HPC would be prevented by refusal to allow X-ray screening of the HPC, then the courier should permit the cells to pass through the X-ray screening device in a single instance.

c. Courier Documents

The courier should carry the following documentation:

- Airline and/or train ticket or electronic ticket information
- Photo identification
- Passport and/or Visa/ entry permits (for international transport)
- Accommodation reservation information
- Travel insurance, including medical (must be arranged by transplant centre)
- Name, address and 24-hour phone number of contact at the collection facility and the stem cell registry emergency cell phone number
- Name, address and 24-hour phone number of contact at the transplant centre
- Letter(s) from the transplant centre and/ or international registry (a courier letter is provided to the transplant centre for the courier by the stem cell registry; courier should have several copies to leave with the collection centre/international registry or airport officials as required and should show the letter(s) to officials upon arrival at security to avoid delays)
- Verification of Prescription for HPC collection, if available
- Donor infectious disease marker (IDM) testing results (most recent results and within 30 days of collection)
- Import/ export permits for HPC as required by local authorities (export permits may be provided by the international registry; import permits are not required in Canada)

- Applicable HPC product, *Product Report* and any accompanying documentation provided by collection centre/international registry
- Circular of Information (AABB or equivalent)
- Customs documents (provided by transplant centre and/or collection centre/international registry)
- Copy of the Customs Border Services Agency (CBSA) notification sent by stem cell registry (stem cell registry notifies CBSA regarding courier itinerary at entry point into Canada).
- Copy of the notification sent by stem cell registry to airport security staff which is required at applicable international airports
- Exceptional Distribution documentation, including information on how the product does not meet the requirements, if applicable.

d. Luggage

Most airlines, especially on international flights, strictly enforce the limit on the number, size and weight of items that may be carried as cabin baggage including the cooler used for transportation of HPC. Therefore, couriers should be aware that although carriage of personal items as cabin baggage is recommended, many international airlines will require couriers to check in their personal luggage. When not used for the transportation of HPC, unfrozen coolant packs may need to be checked in.

The HPC product must never be placed inside checked luggage or inside the courier's personal cabin baggage. It is recommended that the HPC product be placed under the seat in front of the courier.

e. Confidentiality

The courier must not be identified to any personnel who are not directly involved with the collection and/or transport of donor stem cells. The courier must not have personal contact with the donor, recipient, donor's relative or friends. If the courier is known to the patient/patient's family (e.g. courier is a transplant centre coordinator), the patient/patient's family should not be aware the person is serving as the courier.

Any correspondence, (including gifts or photographs) between the donor and recipient is not to be accepted by the transplant centre courier or collection centre/international registry staff on the day of the collection.

The courier must ensure that labels on the outer transport container do not compromise donor/ recipient confidentiality. The product bags should be examined to ensure that the Global Registration Identifier for Donors (GRID) is the only identifying information regarding the donor.

f. Insurance

The transplant centre must confirm couriers are covered by travel insurance including medical for international destinations. It is recommended that the courier's institution has product liability insurance if possible.

g. Courier Flights

The transplant centre is responsible to make appropriate flight arrangements for the courier, taking in to account the following:

- Flights must be booked with minimum stopovers
- Appropriate aisle seat allocation should be requested with sufficient room to enable the courier to check the temperature of the HPC during transit
- The courier must be aware of alternative modes of transport if substantial delays arise
- Backup flights should be arranged by the transplant centre if permitted by the airline. It is strongly recommended that the transplant centre book a back-up flight in the case of a possible 2-day collection and as a contingency in the event that the courier encounters an issue with the primary flight
- For long haul flights the courier should arrive and make contact with the collection centre at least one day prior to the scheduled collection. If the courier arrives on the weekend, contact should be made with the collection centre as directed or on the next business day. If courier wishes to arrive on or after the first day of collection, the transplant centre should request the stem cell registry verify in advance that these plans are acceptable to the collection centre/international registry.
- All changes in original transport arrangements must be communicated immediately to the transplant centre.

To provide priority status to Canadian couriers travelling with Air Canada operated flights, the stem cell registry has developed a process through the Air Canada MEDA desk. Stem cell couriers (or their travel agent) have 2 options to contact the Air Canada MEDA desk once their date of travel /flights are known and /or booked to ensure the airline is aware that the courier will be carrying stem cell product:

- Phone: 514-205-7271, 514-369-7039 or 1-800-667-4732

- Email the Air Canada MEDA desk (email: acmedical@aircanada.ca) with the following information:
  - Booking reference number
  - Permanent file number: 6137392466
  - Flight Ticket #
  - Dimensions of the cooler
  - Weight of the cooler

- The MEDA desk agent will update the reservation to reflect the Air Canada MEDA designation status (travelling with live product), provide a confirmation email stating that they have been approved to travel with live tissue, in addition to their ticket (once issued) being annotated as a MEDA courier.
- **The courier must check-in at the check-in counter (no WEB / Kiosk/mobile check-in).**

If the scheduled product pick-up time is late in the day, the transplant centre may request the Registry contact the collection centre/international registry to store the cells overnight.

The transplant centre must send the *Pre-Transplant Work-up Courier Details* form or international registry equivalent to the stem cell registry, with a copy of the courier's itinerary prior to the date of the donor's first granulocyte colony stimulating factor (G-CSF) injection, if applicable, or no later than 4 days before the courier's departure, whichever is earlier.

2. GROUND TRANSPORTATION

When the transplant centre, in consultation with the Registry and the collection centre, determines that the most efficient method of transportation of the product is by car, the following must be considered to ensure that the transport of the product will not be delayed should the car breakdown, be involved in an accident, or held up by other road conditions or unrelated events.

- Two couriers should accompany the HPC so that one courier may stay with the car while the other accompanies the product by other means of transport
- Both couriers must have a valid driver's licence
- An up-to-date GPS navigation system should be available
- A hard copy of the travel route must be available
- Couriers must have or be provided with a mobile phone
- Couriers must keep the product in their physical possession at all times
- Couriers must be aware of alternative modes of transport in case substantial delays arise
- All changes to original transport arrangements must be communicated immediately to the stem cell registry
- Couriers are responsible for their driving behaviour. Traffic fines are to be paid by the courier, not by the transplant centre or stem cell registry
- Insurance must be confirmed.

3. LABELLING

Labelling must adhere to International Air Transport Authority (IATA) regulations and to requirements outlined in the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations) concerning the safe handling and transport of biological material. Information regarding these requirements can be found at the following websites: www.iata.org and https://laws-lois.justice.gc.ca/. Labelling must also comply with *FACT-JACIE, International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration* (FACT-JACIE) standards.

ISBT 128 labelling should be used. Information regarding this international labelling standardization system is available at www.iccbba.org.

a. Labelling of Product and Samples and Accompanying Documentation

Labels must be legible and must be printed using indelible ink; labels and accompanying documentation should contain the following information, at a minimum:

- Unique numeric or alphanumeric product code
- Global Registration Identifier for Donors (GRID), clearly labelled as such
- Recipient identification code
- Type/proper name of product
- ABO group and Rh type of donor
- Collection date, time and time zone at end of collection
- Product volume/cell count, if available
- Bag number and total number of bags
- Mandatory statements if applicable in accordance with FACT standards
- The "Biohazardous Infectious Material pictogram", if applicable.

b. Labelling of Transport Container

The outside of the cooler must be labelled according to the transplant centre's procedures and include information as outlined in the example below:

MEDICAL SPECIMEN – HANDLE WITH CARE **WARNING: Contains human cells for transplant** **DO NOT X-RAY** **Do not place near heat** **Do not freeze** **Do not delay delivery**

- "Biohazardous Infectious Material" pictogram, if applicable
- Name of collection centre, its civic address and contact information
- Name of the transplant centre, its civic address and contact information
- Registration number of source establishment (transplant centre), clearly labelled as such.

c. Additional Documentation to Accompany Product

In addition to details on the HPC product and exterior container label, the accompanying documentation should include the *Product Delivery Information* (included on the *Work up Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis* form) completed by the transplant centre in the event that the product is separated from the courier.

4. PACKING PRODUCT FOR TRANSPORT

a. Containers

The transplant centre is responsible to provide the courier with all transport equipment, according to their internal protocol, including at a minimum, the following:

- An isothermal transport box or a thermally insulated cooler made of rigid, puncture-proof material adequate to withstand leakage of contents, shocks, pressure changes
- Cooler and coolant or ice packs, or isothermal temperature shells
- Programmed data loggers or thermometers with an exterior temperature display
- Disposable gloves, which may be needed for assistance with inspection of HPC.

Packaging and shipping containers should be validated to maintain the required temperature for shipment of non-cryopreserved HPC in excess of the anticipated transit time, under the expected range of external temperatures.

The transplant centre should not assume that a collection centre/international registry will provide any of the above equipment. Any request for the collection centre/international registry to provide supplies such as ice packs should be negotiated through the stem cell registry in advance of the courier departure to pick up the product.

The recommended transit temperature for HPC is between 2-24 degrees Celsius. If transport is expected to exceed 24 hours for HPC, marrow or 12 hours for HPC, Apheresis, the product should be brought to below 10 degrees Celsius and then transported between 2-10 degrees Celsius.

Data loggers should be used to record the temperature of the HPC during transportation but thermometers with a protected probe and exterior temperature display may be used.

The transplant centre must maintain procedures for packing and ensuring maintenance of the required temperature during transport and must train the courier to these procedures. The following guidelines may be taken into consideration.

b. Cooler and Coolant Packs

- Attach the probe of a thermometer or data logger if available to the outer bag, either between product bags or under the product bag
- Arrange bags, pre-chilled or pre-frozen coolant packs and any insulating material as specified by the transplant centre for adequate temperature control over the estimated transit time in the cooler
- Bags of HPC must be thermally insulated from frozen coolant packs to avoid spot freezing
- Rock the cooler gently at specified intervals if requested
- Check the temperature every 1 to 2 hours from the external data display if not using data loggers and record the temperature. The temperature of the HPC should be maintained at no less than +2°C; this is easily achievable if the temperature monitor is secured externally on the lid of the cooler. There is no need to open the cooler.

c. Isothermal Transport Box

- Place the HPC with a data logger or temperature probe inside the temperature shell (frames and extenders) that has been preconditioned at +4°C and secure top with a rubber band
- Place the temperature shell with other preconditioned temperature shells inside the isothermal stem cell box
- Lock the isothermal box
- If the elements and extender frames have been conditioned correctly and the HPC has been pre-cooled to +4°C, the isothermal box will maintain the temperature of HPC between +4°C and +8°C for up to 50 hours without intervention by the courier.

d. Additional Samples

Additional samples should be placed inside specimen transport containers or plastic bags prior to placing in cooler or isothermal transport box with the product.

5. COURIER TASKS

a. Arrival at the City of Collection Centre

Upon arrival at the city where the collection centre/international registry is located, the courier must contact the designated person at the collection centre/international registry in order to:

- Confirm arrival, contact and travel details
- Deliver the cooler and coolant packs or isothermal shells (if required by the transplant centre and/or collection centre/international registry). Place the coolant packs at –4°C or –20°C (freezer) as instructed by CTC or the isothermal temperature shells at +4°C. Coolant packs may be placed inside a labelled bag in a refrigerator or freezer at the courier's hotel. Arrangements for use of fridge or freezer at the hotel must be arranged for by the transplant centre when booking the courier's accommodations
- Confirm the time and location for pick-up of the product
- Confirm transportation from the collection centre/international registry to the airport or train station.

b. On the Day of Collection

On the day of collection, the courier must:

- Arrive at collection centre/international registry at arranged time and location
- Make contact with designated contact person
- Carry personal identification (e.g. passport, photo identification) and the documentation required for the transport of the product
- Crosscheck with the collection centre/international registry representative the product type, number and labelling of bags containing HPC the cell count and the addition of anticoagulant against the Prescription for HPC
- Pack HPC and additional specimens into the cooler according to instructions provided by the transplant centre
- Collect and check all accompanying paperwork provided by the collection centre/international registry
- Not add heparin, antibiotics or any other additive to the HPC marrow during transportation
- Declare the product on all customs forms as required
- Supervise any visual inspection of the product during transport.

c. On Arrival to the City of the Transplant Centre

Upon arrival at the city where the transplant centre is located, the courier must:

- Travel immediately to the transplant centre or processing laboratory according to instructions provided by transplant centre
- Contact the designated staff member at the transplant centre or processing laboratory for hand over
- Record the time of delivery and temperature of the product upon arrival
- Cross check the product and sample tubes against the details provided by the collection centre/international registry and the Prescription for HPC
- Visually inspect the bags and the product for anomalies such as visible clumping
- Record and report to transplant centre any events or incidents during transport
- Sign for delivery of the product to the transplant centre
- Alert transplant centre staff regarding documents requiring completion and return to the collection centre/international registry post-delivery and/ or post-transplant.

ASSOCIATED DOCUMENTS:

F800015 (F800838), *Product Report*

F800020 (F801503), *Work up Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis*

F800021 (F801505), *Pre-Transplant Work-up Courier Details*

Section 10 – Recipient Updates Post-Transplant

OVERVIEW

An important part of the donation process is the collection of recipient information post-transplant. Such information is essential to monitor the overall effectiveness of the Registry program, to provide required data to the World Marrow Donor Association (WMDA), and to compile survival and engraftment data essential to analysis of best practices. Some post-transplant information may be provided to the donor.

The Registry will request a recipient update at 3 months and 1 year post-transplant for statistical purposes and may include a request for an update for the donor at that time. Transplant centres are encouraged to inform the Registry as soon as possible if there is a recipient death, of the inability to obtain an update, or if the recipient has declined to consent to release information to the donor.

In accordance with international regulations where applicable, Registry donors and recipients may exchange anonymous correspondence anytime post-transplant. All correspondence will be screened by the Registry to maintain confidentiality. Any information that may identify the age, sex, name, or location of the donor or recipient will not be permitted and/or forwarded. The Registry does not allow the exchange of gifts or photographs.

The donor and recipient will be permitted to exchange their personal information (name, address, etc) only if both parties agree, and after the wait period as deemed by each international registry or Canadian transplant centre has been observed. The wait period for Registry donors is one year post-transplant.

The exchange of maternal personal information with a cord stem cell transplant recipient is not permitted.

Due to the varying regulations of international registries, the possibility exists that some recipients and donors will not be permitted to exchange anonymous correspondence or personal information, regardless of the Registry's guidelines.

PROCESS

10.1. Recipient Update/ Reporting of Recipient Death	10.1.1. Receive request from the stem cell registry. 10.1.2. Complete the *Patient Update Post-Transplant* or *Patient Update Post Transplant HPC-CBU* form and send to stem cell registry. 10.1.3 Update patient profile in Stem Cells National Systems Solution (SCNSS) in case of recipient death.
10.2. Donor-Recipient Anonymous Correspon-dence	10.2.1. Counsel the recipient/family not to include personal information such as their age, sex, name, or location in the card or letter for a donor. 10.2.2. Send correspondence to stem cell registry.
10.3. Requests for Exchange of Personal Information	10.3.1. Receive request to establish direct contact between donor and recipient or recipient's family if recipient has passed away. 10.3.2. Contact the recipient or immediate family member. 10.3.3. Advise the recipient or immediate family member to review the risks and benefits of the exchange. 10.3.4. Provide recipient or recipient's family the following forms to be completed: • *Consent to Release Personal Information to Donor* • *Consent to Release Family Contact Information.* 10.3.5. Inform stem cell registry that consent has been declined, if applicable. 10.3.6. Send completed consent form to stem cell registry. 10.3.7. Receive donor's information from stem cell registry. 10.3.8. Send donor's information to the recipient, or the recipient's family.

ASSOCIATED DOCUMENTS:

F800039 (F801605), *Patient Update Post-Transplant*
F800172 (F801604), *Consent to Release Personal Information to Donor*
F800175 (F801613), *Consent to Release Family Contact Information*
F800041 (F801618), *Patient Update Post Transplant HPC-CBU*

Section 11 – Quality/Adverse Event Reporting

OVERVIEW

The Registry defines a "Quality Event" as any unplanned occurrence, problem or undesirable event, or incident that represents a departure from approved processes or procedures, specification or manufacturer's instructions or from what is required, expected or acceptable, from a product and/or transfusable & transplantation services standpoint."

A quality event occurring at or discovered by the transplant centre must be reported immediately to the Registry.

The transplant centre will be responsible to investigate and report to the Registry the root cause of any quality event that occurs in their facility and must identify and implement corrective action(s) to prevent a quality event from re-occurring in the future.

The transplant centre must report any errors, accidents, quality events, and adverse recipient events to Health Canada as per the **Safety of Human Cells, Tissues and Organs for Transplantation Regulations** and **Guidance Document for Source Establishments – Reporting Adverse Reactions to Human Cells, Tissues and Organs.** For further information, refer to: http://www.healthcanada.gc.ca.

The transplant centre must also inform the Registry of any quality event which is thought to be associated with the product. The Registry will report all serious defects in the stem cell product to the WMDA Serious Product Events and Adverse Events Registry (SPEAR). The SPEAR reporting criteria include, but are not limited to, any events that lead to one or more of the following outcomes in the recipient:

- Death
- Life-threatening disease
- Unexpected hospitalization or considerable prolongation of existing hospitalization
- Persistent or significant disability/incapacity.

The Registry will notify the transplant centre immediately if a donor health issue is identified that may affect the well-being of the recipient.

ASSOCIATED DOCUMENTS:

None

Section 12 - Search and Transplant Related Costs

OVERVIEW

Costs associated with searching for and obtaining stem cell product(s) from an unrelated donor or cord blood unit are categorized and defined in this section.

Fee schedules for international registries can change frequently. Contact the Registry to obtain fee information for a specific registry.

Search Activation Costs

Search costs are defined as costs associated with searching for and identifying an unrelated donor or cord blood unit (e.g. extended HLA typing (eHLA), verification typing (VT) collection and shipment of blood samples, cord blood unit sample/segment and post-thaw testing.)

The Registry will pay for the costs of all search related activations on unrelated donors. The transplant centre is responsible to cover all search activation costs related to cord blood units.

> ***Note:*** *Verification typing samples requested at work-up are considered pre-collects and will be re-billed to the transplant centre.*

Any costs not covered by the Registry will be rebilled to the transplant centre by the Registry.

Any testing performed by the transplant centre will not be covered by the Registry.

Transplant Costs

Transplant costs are defined as all costs incurred after the identification of a suitable stem cell product (i.e. after the donor has been requested for work-up, cord blood unit requested for procurement). These costs can vary depending on where the product is originating.

Costs for a Canadian Donor

Product Fee: There is no charge for the product procurement.

Donor Expenses: Canadian transplant centres will be billed by Canadian Blood Services for donor insurance and may be billed for other donor expenses related to work-up and donation (see below*). If donor costs are expected to exceed $4000, an estimate of these costs will be provided to the transplant centre prior to donor collection for approval.

*Donor Expenses:

- All medical history, physical evaluation and laboratory tests (if not covered by provincial health plan)
- Parking and taxi expenses
- Medication as required (e.g., iron supplements)
- Mileage
- Other travel expenses (i.e., economy airfare, train, ferry, bus)
- Per diem allotment (meals and incidentals), if donor has traveled away from home for collection centre appointment(s) and product collection
- Per diem allotment (meals and incidentals), for a companion if the donor has traveled away from home for product collection
- Child care expenses
- Homecare aid for 24 hours after collection, if required
- Hotel expenses, if applicable
- Car rental expenses.

Collection Centre Fees: The Canadian collection centre will bill the Canadian transplant centre directly for collection fees. Fees may vary between collection centres.

Postponement Related Costs: The transplant centre can incur charges for repeat pre-collect samples, repeat medical assessment, donor expenses, and other costs incurred by postponement and/or cancellation of a work-up. Charges will be determined on a case by case basis.

Costs for an International Donor

Product Fee:	The Registry will receive the invoices from the international registry and pay for services rendered. The Registry will then rebill these costs to the transplant centre.
Donor Expenses:	International registries differ in how they bill for donor expenses. All donor expenses will be paid by the Registry and rebilled to the transplant centre.
Collection Centre Costs:	There will be no extra charge. These are part of the flat fee that the Registry pays for product procurement.
Postponement Related Costs:	Some international registries charge a flat fee for postponement of a scheduled collection; however, the Registry may also receive invoices for repeat pre-collect samples, repeat medical assessment, donor expenses, and other costs incurred by postponement of a work-up. Postponement related charges will be re-billed to the transplant centre.

Cancellation Costs

If the collection procedure is cancelled after the work-up of the selected donor has commenced, Canadian Blood Services will pay for any costs incurred and rebill the Canadian transplant centre for services rendered prior to notice of the cancellation.

Courier Costs

The transplant centre is responsible to make the necessary arrangements for their courier travel and cover the associated costs.

If a Canadian transplant centre requests an international courier, the international registry charges the transplant centre directly.

ASSOCIATED DOCUMENTS:

None

Section 13 – Research Requests

OVERVIEW

The Registry recognizes that researchers both inside and outside Canada will, at times, seek the participation of stem cell registry and/or international donors in research studies.

Canadian Donors

As the donor's advocate, Canadian Blood Services has an obligation to ensure that the participation of unrelated Canadian donors in research complies with provincial and federal legislation and with the Canadian Tri-Council Policy on Human Subjects Research.

Principal Investigators requesting access to Registry donors will need to submit a research protocol application to Canadian Blood Services. Canadian Blood Services will assess the request to ensure that it complies with it's policies that it can support the study and that it is approved by it's Research Ethics Board (REB). If participation is approved, informed consent must be obtained from the donor.

Canadian Blood Services REB approvals are granted for a period of one year and must be renewed on an annual basis for the duration of the study. A maximum of four renewals may be granted (i.e., for an overall study period of five years).

Principal Investigators must submit their study protocols well in advance of the start of their study to ensure all requirements can be met within anticipated timelines. Typically, an application will take two months to go through the Canadian Blood Services review process but depending on the complexity of the application this process may take longer.

International Donors

Research requests involving participation of an international donor are subject to the review and approval of the international registry Research Ethics Board or equivalent. The Registry, on behalf of the Canadian transplant centre will forward the research protocol, Research Ethics Board (REB) approval letter and other documentation to the international registry. The Registry will be the primary contact between the transplant centre and international registry until REB approval is confirmed. If approval is obtained, a copy of the REB approval and copies of approval letters for protocol amendments and annual renewals will be kept at the Registry.

PROCESS

13.1. Obtaining study protocol approval from Canadian Blood Services for studies involving Canadian Donors	13.1.1. Send the following documentation to Canadian Blood Services Stem Cell Registry to obtain approval of the study protocol: • Copy of the study protocol, • Sample of Donor Consent form, • Canadian transplant centre or international registry's internal research ethic board (REB) approval letter. 13.1.2. Receive from Canadian Blood Services the Canadian Blood Services *Research Ethics Board Application* form or international registry equivalent when applicable. 13.1.3. Send completed *Research Ethics Board Application* form or international registry equivalent when applicable. 13.1.4. Receive notification that approval has been obtained.
13.2. Obtaining Informed Consent from Donors in Research	13.2.1. Receive notification from the stem cell registry donor's decision to participate in the study. 13.2.2. Receive from the stem cell registry confirmation of donor consent, if applicable.

ASSOCIATED DOCUMENTS:

Research Ethics Board Application

Section 14 - Postponements and Cancellations

OVERVIEW

Stopping / Suspending Searches

Canadian patient searches remain active in Stem Cells National Systems Solution (SCNSS) until such time that the transplant centre stops or suspends the patient search.

Stopping a patient search will initiate the request to stop all activation requests. Cancellation of open activations will be assessed to determine if request can or cannot be cancelled. The stem cell registry will notify the transplant centre of the outcome of the request.

Suspending a patient search will allow the current searches to remain active and allow for additional search requests to be run, but new activation requests, such as extended HLA (eHLA) or verification typing (VT) requests cannot be made.

Postponements/Cancellations

Canadian Blood Services Stem Cell Registry (stem cell registry) will postpone the work-up process to a maximum of 6 months (in total) from the date of the work-up activation, provided the donor is agreeable. The length of time a work-up can be postponed is subject to the international registry policy. The transplant centre is to contact the stem cell registry when ready to resume the work-up.

Cancelling a work-up will release the donor. A work-up should only be cancelled if the patient will not be proceeding to transplant. If in doubt, request a postponement to ensure the donor remains on hold for the patient.

The transplant centre may incur additional charges associated with the postponement or cancellation of a work-up. Refer to Section 12 *Search and Transplant Related Costs* for additional information.

PROCESS

14.1 Stop/Suspend Patient Search	14.1.1 Stop/suspend patient search as per **IM-00106**, *Stem Cells National Systems Solutions User Manual, Section 16.* ***Note[1]:*** *Any open Activation for the patient will be evaluated to determine if they can be cancelled. Attempts to cancel all open activations will be made but may not be possible to cancel upon request. The stem cell registry will notify the transplant centre of the activation cancellation resolution."* ***Note[2]:*** *If unable to access SCNSS notify stem cell registry Search Analyst at search.analyst@blood.ca to stop or suspend a patient search with a reason.*
14.2 Cancelling an Activation Request	14.2.1 Request cancellation and provide reason. ***Note[1]:*** *If unable to access SCNSS, send request for cancellation of activation with reason to cbs.stemcellregistry@blood.ca.* ***Note[2]:*** *An activation request cannot be cancelled if sample has already been shipped* 14.2.2 Receive cancellation acceptance or denial from the stem cell registry, if applicable.

14.3 Requesting Postponement of a Work-up	14.3.1 Request postponement of work-up, including rationale for the request and timeframe regarding new collection dates, if known. Refer to 14.1 to suspend patient search, if applicable. 14.3.2 Receive confirmation of postponement from the stem cell registry. 14.3.3 Send request to resume the work-up to the stem cell registry, with new collection date(s), and indicate if repeat pre-collect samples are required. Refer to Section 4 *Requesting Patient Searches* to reactivate patient search, if applicable. ***Note[1]:*** *Some international registries do not provide repeat pre-collect samples.* ***Note[2]:****A new work-up request is required if resuming 6 months after initial work-up activation date.* 14.3.4 Receive the following information if donor clearance was provided prior to the postponement request: • Interval physical examination requirement determined by collection centre/international registry • Repeated *Health Screening Questionnaire* and IDMs if required, to be current within 30 days of collection.
14.4 Requesting Cancellation of a Work-up	14.4.1 Request cancellation of work-up including the reason for the cancellation. 14.4.2 Receive confirmation of cancellation from the stem cell registry. 14.4.3 Refer to 14. 1 if the patient search is to be cancelled. ***Note[1]****: Requesting cancellation of a work-up will release the donor. If planning to resume the work-up at a later date, request postponement as per step 14.3.*

ASSOCIATED DOCUMENTS:

IM-00106 (CO-00289), *Stem Cells National Systems Solutions User Manual: Section 16, Canadian Transplant Centres*

F800038 (F801554), *Health Screening Questionnaire*

Appendix 1 - References - Regulations and Standards

References – Regulations and Standards

Regulation/Standard	Transplant Centre Manual Associated Section
CAN/CSA-Z900.1, Cells, tissues and organs for transplantation: General Requirements, Canadian Standards Association	1
CAN/CSA-Z900.2.5, Lymphohematopoietic cells for transplantation, Canadian Standards Association,	1
FACT-JACIE, International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration	1, 9
Safety of Human Cells, Tissues and Organs for Transplantation Regulations, SOR/2007-118 (CTO Regulations)	1, 3, 6, 7, 9, 11
WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries, World Marrow Donor Association (WMDA)	1, 2, 5, 6, 9
World Marrow Donor Association (WMDA) Guidelines for couriers and the transportation of haemopoietic progenitor cells (HPC-BM, apheresis and therapeutic cells- T Cells)	9
Hazardous Products Regulations, (SOR/2015-17), Schedule 3	9
IATA Dangerous Goods Regulations	9
ICCBBA ST-004, Labelling of Cellular Therapy Products	9