

Stem Cell Registry Transplant Centre Reference Manual

Section 1 - Introduction

Revision # 1

Legacy Doc Number 60 020

Revision History

| Version | Detail |
|-----------|----------------------------------------------------------------------------------------------|
| 1 Amdt. 0 | CR #17603: New document created from UBMTC0101 as per corporate LINK project |
| 0 | Migration from CDI 2.0 to CDI 3.0 |
| 1 Amdt. 0 | EdCR-24-000140, Update Manuals to remove version date CAN/SCA to remove reference to 2017/17 |

OVERVIEW

This manual provides Canadian transplant centres guidance to obtain services from the Canadian Blood Services Stem Cell Registry (stem cell 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 stem cell 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/

Stem Cell Registry Transplant Centre Reference Manual Section 1 -Introduction

The stem cell 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 stem cell 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 stem cell 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 Canadian Blood Services Stem Cell Registry Controlled Documents and Resources

Some stem cell 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 stem cell 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 stem cell 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 <u>cbs.stemcellregistry@blood.ca</u> 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 stem cell 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 <u>cbs.stemcellregistry@blood.ca</u>, 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 user name 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 stem cell registry after hours cell phone.
- Users must report incidents of possible misuse or violation of this agreement to stem cell 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 stem cell 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

CO-00289 Stem Cells National Systems Solutions User Manual, Section 16: Canadian Transplant Centres

SUMMARY PAGE



Legacy Document Number: 60 020 EtQ Document Number: CO-00233

Revision: 1

Title: Stem Cell Registry Transplant Centre Reference Manual Section 1 - Introduction

Advance Training Effective Date:

Effective Date: 2024-08-30

Approval Signatures:

Andrea Winters;Final Signature;2024-08-15 2:51:08 PM EDT

Carolyne Hunt; Final QA Signature; 2024-08-15 4:23:15 PM EDT

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Rev 01 Page 1 of 1