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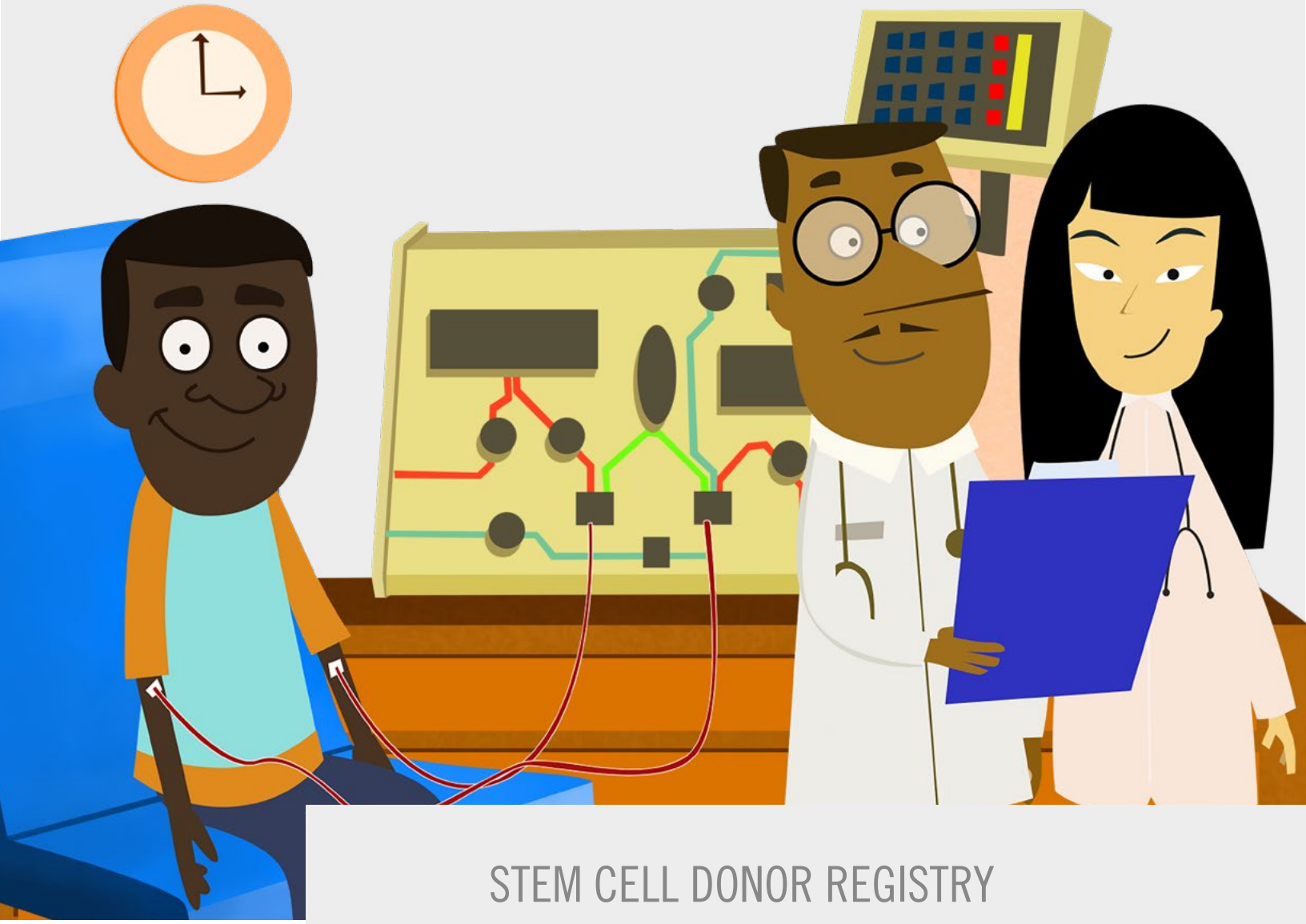

STEM CELL DONOR REGISTRY

Guide for Collection Centres

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TABLE OF CONTENTS

1. Introduction 4
1.1 What is the Guide for collection centres? 4
1.2 Application of standards and regulations 4
1.3 Training 4
2. The Stem Cell Donor Registry 5
3. Confidentiality 6
3.1 General 6
3.2 Identification of donors and recipients 6
3.3 Information about the recipient and the donor during the research and the preparation for donation 6
3.4 Exchange of information between the donor and the recipient post-transplant 6
4. Request for stem cell collection 6
4.1 General 6
5. Receiving and handling the collection request 7
5.1 Receiving the request 7
5.2 Review of the request by the collection centre 8
6. Pre-donation donor evaluation 8
6.1 General 8
6.2 Donor evaluation day and information session 9
6.3 Donor evaluation and eligibility 10
6.3.1 Physical exam 11
6.3.2 Evaluation of the vein and the central venous catheter 11
6.3.3 Screening for infectious diseases 12
6.3.4 Autologous blood donation 12
6.3.5 Information sent to the donor and obtaining consent 12
6.3.6 Prescription verification 13
6.4 Final authorization for donation 14
6.4.1 Donor ineligibility following the discovery of a risk factor 14
6.4.2 Donor examination results that could pose a risk to the recipient 14
6.5 Collection delays 15
6.6 Cancellation of the collection request 15
7. Participation in research 15
8. Details for transportation 15

9. Product collection 16
9.1 General 16
9.2 Additives 16
9.3 Labelling 16
9.4 Collection 16
9.5 Quality control 17
9.6 Pick-up of the product by the courier 17
9.7 Documents to provide to Héma-Québec 17
10. Post-donation 18
10.1 General 18
11. Post-donation follow-up 18
12. Non-compliance and declaration of adverse reactions 19
12.1 Definition 19
12.2 Responsibilities of the collection centre 19
12.3 Responsibilities of Héma-Québec 19

Original text in French. In the event of a discrepancy between the English and French versions, the latter will prevail.

1. INTRODUCTION

1.1 What is the Guide for collection centres?

This guide describes the processes pertaining to the evaluation of donors enrolled in Héma-Québec's Stem Cell Donor Registry for the purpose of stem cell and leukocyte product collection.

It is not intended to replace the collection centre's (CC's) internal policies and procedures but rather to identify minimum requirements for compliance with regulations and standards established by Health Canada and the World Marrow Donor Association (WMDA).

1.2 Application of standards and regulations

CCs and stem cell laboratories must comply with the Safety of Human Cells, Tissues and Organs for Transplantation Regulations. For more information, visit the Health Canada Web site: **www.hc-sc.gc.ca**.

Under these regulations, CCs are also required to comply with the Canadian Standards Association (CSA) standard sections referenced therein:

- Cells, Tissues and Organs for Transplantation: General Requirements (Z900.1);
- Lymphohematopoietic Cells for Transplantation (Z900.2.5).

For more information please refer to: **www.csagroup.org**.

Héma-Québec is accredited by the World Marrow Donor Association (WMDA), a non-profit organization created in 1994 that establishes international guidelines for the collection, distribution and transportation of hematopoietic stem cells.

The information contained in this document is aimed at maximizing the quality of stem cell products prepared for recipients and the safety of stem cell donors all over the world.

As an organization accredited by the WMDA, Héma-Québec must ensure that the CCs and transplant centres (TCs) under its supervision comply with the WMDA standards that apply to them. For more details on the WMDA, please refer to: **www.wmda.info**.

CCs must follow industry best practices. They must also meet the standards of the Foundation for the Accreditation of Cellular Therapy (FACT), as agreed under the memorandum of understanding between Héma-Québec and the CCs. To consult FACT standards and requirements please refer to: **www.factwebsite.org**.

In the event that the CC has to collect a product destined for the United States, it is mandatory that it be registered as a facility under the U.S. Food and Drug Administration (FDA). For more information or to register please refer to: **www.fda.gov**.

1.3 Training

The CC is responsible for ensuring that all team members involved in the collection process (of stem cells from unrelated donors) are trained in accordance with this document.

2. THE STEM CELL DONOR REGISTRY

Héma-Québec is responsible for the Stem Cell Donor Registry, which includes a list of unrelated donors and the only public cord blood bank in Québec; it provides stem cell products for patients, both in Canada and internationally. The Héma-Québec Registry coordinates all the steps related to stem cell requests, from the search to the transplant, including:

- donor recruitment;
- maintenance of the Québec computerized database;
- search for compatible unrelated donors and cord blood units for recipients in Québec or abroad;
- preparation of the selected donors for the donation;
- donor collection;
- banking and distribution of cord blood units;
- HLA typing (Human leukocyte antigen).

The Héma-Québec Stem Cell Donor Registry team is comprised of:

- a medical director;
- a department director;
- a department manager, search and distribution;
- advisors;
- medical secretaries;
- clerks;
- a scientific director.

Donors who enroll in the Héma-Québec Stem Cell Donor Registry provide samples taken by mouth swab. These samples are analyzed in the Héma-Québec HLA laboratory, certified by ASHI (American Society for Histocompatibility and Immunogenetics).

In order for a Québec donor to donate stem cells, the recipient's diagnosis and donor-recipient HLA compatibility must meet the requirements for allogeneic transplants:

- **Diagnosis:** According to a list of indications for transplant preapproved by Héma-Québec's medical director.
- **HLA compatibility:** Ten antigens are normally considered important in determining compatibility: HLA-A, HLA-B, HLA-C, HLA-DRβ1 and HLA-DQβ1. The minimum compatibility level is set at 7/8 considering the high-resolution HLA-A, HLA-B, HLA-C and HLA-DRβ1 loci.

Héma-Québec conducts a preliminary assessment of the donor's medical and behavioral history according to its criteria. This evaluation also includes a screening for infectious disease markers at the Héma-Québec laboratory, as prescribed by Health Canada.

Héma-Québec is a member of World Marrow Donor Association (WMDA), an international database in which Québec donors are listed under the code ION-6912. For more information on this organization, please visit: **www.wmda.info.**

3. CONFIDENTIALITY

3.1 General

- It is essential that the CC protect the anonymity of the donor and the recipient in accordance with laws and regulations.

3.2 Identification of donors and recipients

- When information is sent by email, donors and recipients must be identified solely by a number and their initials.
- Records must be filed and stored under lock and key to prevent unauthorized staff from having access to them.

3.3 Information about the recipient and the donor during the research and the preparation for donation

- **No personal information about the recipient (name, age, sex, location) may be sent to the donor or a member of the donor's family.**
- Only information on the donor's health status may be sent to the TC by Héma-Québec if and only if this information determines eligibility and influences the final selection of the donor. In this case, the TC is responsible for informing the recipient of the donor's health status, in accordance with Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

3.4 Exchange of information between the donor and the recipient post-transplant

- After the transplant, anonymous exchanges between the donor and the recipient are allowed. The exchange of personal information is allowed only if there is mutual consent between the donor and the recipient, and the post-transplant waiting period specific to each registry is respected. For Québec, this period is one year following the donation. Both parties must sign the appropriate consent forms for the exchange to take place.
- The CC must ensure that no personal information (name, age, address) is included in any correspondence between the recipient and the donor, and it must forward this correspondence to Héma-Québec.
- Héma-Québec ensures that no personal information is disclosed and verifies the content in order to maintain confidentiality.
- No exchange of gifts, objects or money is allowed under these circumstances.
- Rules pertaining to the exchange of information between a donor and recipient may vary from one registry to another. It is possible therefore, that no exchange of personal information, meeting or correspondence be allowed, based on registry guidelines.

4. REQUEST FOR STEM CELL COLLECTION

4.1 General

Héma-Québec receives stem cell collection requests from Canadian and international registries and serves as a link between Québec CCs and registries outside Québec or TCs in Québec.

Héma-Québec acts as the liaison between the CC and the donor when the latter is preparing to donate. Héma-Québec protects the donor's interests throughout the donation process and acts as a resource to the donor.

The CC must inform the donor of the various collection methods, in accordance with its internal policies.

It is very important that the CC ensure adequate availability in order to respond to any donor emergency.

Any communication or correspondence between the CC and the TC or a registry outside Québec must go through Héma-Québec. Exchanges between the CC and TC may be authorized by Héma-Québec in exceptional circumstances.

5. RECEIVING AND HANDLING THE COLLECTION REQUEST

5.1 Receiving the request

Upon receipt of a stem cell collection request, Héma-Québec must first:

- verify the donor's file and assess eligibility according to Héma-Québec's criteria manual (e.g., exclusions, medical history);
- contact the donor to confirm availability and willingness to proceed with the donation.

Héma-Québec then sends the following Héma-Québec documents (or their international equivalents) to the CC for predonation preparation:

- "Workup Request" (ENR-02650) or "Requête de préparation au don de cellules souches" (ENR-02649).
- "Confirmation of stem cells collection" (ENR-01660) or "Confirmation de prélèvement de cellules souches" (ENR-01658).
- "Donor Medical Review" (ENR-01752) or "Révision médicale du donneur" (ENR-01804).
- "Donor Medical Examination" (ENR-01768) or "Évaluation médicale du donneur" (ENR-01803).
- "Application for Additional Donation" (ENR-01697), "Requête pour un don supplémentaire" (ENR-03575) or equivalent (if applicable).

<u>As well as the following forms, according to the type of donation:</u>

- Bone marrow:
  - "Discussion avec un donneur de HPC, Marrow (centre collecteur)" (ENR-01661) (in French only).
  - "Verification of HPC, Marrow Prescription" (ENR-01690) or "Vérification de la prescription pour HPC, Marrow" (ENR-01796).
  - Collection Center Report: "Formulaire de collecte de HPC, Marrow (ENR-01662) (in French only) "
  - "HPC, Marrow Product Collection Report" (ENR-01663) or" Rapport de collecte de HPC, Marrow" (ENR-01664).

- Peripheral stem cells stimulated by G-CSF:
  - "Discussion avec un donneur de HPC, Apheresis (centre collecteur)" (ENR-01665) (in French only);
  - Verification of HPC, Apheresis Prescription" (ENR-01691) or "Vérification de la prescription de HPC, Apheresis" (ENR-01798).
  - Collection Center Report: "Formulaire de collecte de HPC, Apheresis" (ENR-01666) (in French only);
  - "HPC, Apheresis Product Collection Report" (ENR-01667) or "Rapport de collecte de HPC, Apheresis" (ENR-01668).
- DLI Leukocytes:
  - "Discussion avec un donneur de MNC, Apheresis (centre collecteur)" (ENR-01692) (in French only);
  - "MNC, Apheresis DLI Prescription Verification" (ENR-01693) or "Vérification de la prescription / DLI par Aphérèse" (ENR-01797).
  - Collection Center Report: " Formulaire de collecte de MNC, Apheresis" (ENR-01694) (in French only);
  - "MNC, Apheresis Product Collection Report" (ENR-01670) or "Rapport de collecte de MNC, Apheresis" (ENR-01669).

5.2 Review of the request by the collection centre

- The CC must verify the forms and confirm receipt of the aforementioned collection request (point 5.1) to Héma-Québec as soon as possible.
- If the CC cannot proceed with the collection dates requested by the TC, it must notify Héma-Québec as soon as possible so that an agreement can be made to establish a new collection date that suits the donor, CC and TC.
- If the CC has questions regarding the cell concentration requested by the TC, it must notify Héma-Québec in writing as soon as possible.
- Once the appointments for donation preparation have been confirmed, the CC must complete the form "Confirmation of Stem Cell Collection" (ENR-01660) and send it to Héma-Québec.

  Note: If the collection is to take place over a two-day period, the time at which the product can be released must be indicated for each collection day.

- Héma-Québec sends the TC a confirmation of the collection date accepted by the donor and the CC, and then informs the CC of the date when the recipient will begin the preparatory treatment, if necessary.

6. PRE-DONATION DONOR EVALUATION

6.1 General

Once the predonation examination date has been determined, the donor must be evaluated by a physician who is a member of the CC's stem cell collection team. If the CC and TC are part of the same facility, the physician responsible for the donor evaluation and collection must be different from the physician responsible for the recipient's treatment.

Héma-Québec's registry includes donors from various cultural communities and uses the services of certified interpreters as required. A member of the family or medical team cannot serve as an interpreter to the donor. It is Héma-Québec's responsibility to find an interpreter for the donation preparation evaluation and the collection day.

Héma-Québec is emphatic that the potential donor must not be influenced or pressured in the decision to make a donation.

6.2 Donor evaluation day and information session

Héma-Québec provides the donor with the following documents regarding the various procedures during an information session:

- Reimbursement of fees for stem cell collection;
- "Estimate of Donor Costs/Expenses" (ENR-01766) or "Estimation des coûts/dépenses du donneur" (ENR-01765).
- "Confidentiality Agreement" (ENR-01673) or "Politique de confidentialité" (ENR-01672).
- "Report Any Changes in your Health" (ENR-01754) or "Signaler tout changement à votre état de santé" (ENR-01753).
- " Post-Donation Survey One Week & 30 Days" (ENR-01686) or "Suivi postdon : une semaine et 30 jours" (ENR-01683).
- "Consent for Additional Donation" (ENR-01675) or "Consentement pour un don additionnel" (ENR-01674).

As well as the following documents, according to the type of donation:

- Bone marrow:
  - "Intent to Donate Bone Marrow" (ENR-01689) or "Intention de donner de la moelle osseuse" (ENR-01680).
  - "Pre Donation Survey: Bone Marrow" (ENR-01687) or "Sondage prédon : moelle osseuse" (ENR-01777).
  - "Post Donation Survey: 2 weeks (Marrow)" (ENR-01734) or "Suivi postdon : 2 semaines (moelle)" (ENR-01733).
  - Letter that the donor must provide to his or her employer (if applicable).
- Peripheral stem cells stimulated by G-CSF:
  - "Intent to Donate Stimulated Stem Cells" (ENR-01740) or "Intention de donner des cellules souches stimulées" (ENR-01739).
  - "Pre-donation Survey: First Stimulated Stem Cell Donation" (ENR01756) or "Sondage prédon : premier don de cellules souches stimulées" (ENR-01755).
  - "Information Regarding Granulocyte Colony Stimulating Factor (G-CSF)" (ENR-01775) or "Renseignements sur le facteur stimulant les colonies de granulocytes (G-CSF)" (ENR-01774).
- DLI Leukocytes:
  - "Intent to Donate Leukocytes" (ENR-01744) or "Intention de donner des leucocytes" (ENR-01743).
  - "Pre-Donation Survey: Leukocytes" (ENR-01746) or "Sondage prédon: leucocytes" (ENR-01745).

It is also during the pre-donation evaluation that the CC explains to the donor the various collection methods and the risks associated with each of them, as indicated in the following forms (available in French only) to be filled out:

- “Discussion avec un donneur de HPC, Marrow (centre collecteur)” (ENR-01661).
- “Discussion avec un donneur de HPC, Apheresis (centre collecteur)” (ENR-01665).
- “Discussion avec un donneur de MNC, Apheresis (centre collecteur)” (ENR-01692).

Héma-Québec asks the donor to sign an “Intent to Donate" consent form, based on the type of donation. It is the CC’s responsibility to obtain written and informed consent from the donor regarding the collection procedure, in accordance with standards and regulations.

If the donation involving G-CSF injections is chosen, an evaluation of the collection site will be performed. The CC is also responsible for informing the donor of the injections he or she will receive and of the possible use of a central venous catheter. In the event that a bone marrow donation has been chosen, the CC discusses with the donor the anesthesia options offered (general or epidural) according to its policies.

The CC must have a procedure in place to confirm the donor’s identity and ensure the confidentiality of all donor information in accordance with section 3 of this document and applicable local laws and regulations.

The donor will be questioned by Héma-Québec concerning his or her current health status, medical history, high risk behaviours related to communicable diseases and travel to endemic areas in preparation for donation. To this end, form “Health Screening Questionnaire” (ENR-01763) or “Questionnaire médical” (ENR-01762) will be used.

The information obtained is sent to the CC, along with the collection method accepted by the donor, his or her availability and any restrictions. In the event that information provided by the donor poses a potential risk to the recipient according to its pre-established medical criteria (MAN-00511), the Héma-Québec Registry will inform the TC in writing before coordinating the stem cell collection. If the TC agrees to go ahead with this collection in spite of the information obtained, it must confirm this in writing to the Héma-Québec Registry. Héma-Québec will inform the CC of any correspondence with the TC.

Héma-Québec will send the form “Health Screening Questionnaire” (ENR-01763) or “Questionnaire médical” (ENR-01762) to the CC before the donor’s pre-donation evaluation.

Héma-Québec will make the necessary arrangements to perform the donor infectious disease marker screening within 30 days prior to the donation date. The results will be sent to the CC as soon as they are available. The analyses performed by the Héma-Québec laboratory are done using Health Canada-approved kits for the detection of infectious diseases. The results must be evaluated by the CC prior to the final authorization for the donation.

6.3 Donor evaluation and eligibility

- The CC medical team evaluates the donor’s eligibility to donate stem cells based on its procedures and in accordance with the Health Canada CTO Regulations and applicable standards of the Canadian Standards Association (CSA).

Note: A criteria manual has been developed based on the recommendations of the World Marrow Donor Association WMDA medical committee. To consult it, visit **https://share.wmda.info/display/DMSR/WMDA+Donor+Medical+Suitability+Recommendations+Main+page**

6.3.1 Physical exam

- The following diagnostic analyses must be performed to meet the minimum Health Canada, FACT and WMDA standards, as well as other industry best practices:
  - ECG and chest x-ray (if indicated and for any donor aged 40 or older);
  - complete blood count with differential;
  - biochemical profile: BUN, creatinine, electrolytes, liver function, blood glucose;
  - pregnancy test for women of childbearing age;
  - infectious disease markers (analysis performed by Héma-Québec);
  - blood type and antibody screening;
  - sickle cell anemia screening for Black, Mediterranean and Arab donors;
  - any other analysis deemed necessary by the CC.

  If the CC physician determines that medical tests or an additional medical evaluation are required, the CC must:

  - inform Héma-Québec immediately if these analyses or medical evaluations are likely to delay the donation;
  - inform the donor of the abnormal results, make the necessary arrangements for the additional analyses and provide Héma-Québec with a regular update of the results.

6.3.2 Evaluation of the vein and the central venous catheter

- Where stem cell products cannot be taken from the peripheral veins, it is possible to use a central venous catheter. According to the U.S. National Marrow Donor Program (NMDP) statistics, about 18% of women and 3% of men require the use of a central venous catheter. If the CC determines that central venous access is required, it must make the necessary arrangements and obtain the consent of the donor.

  Note: Héma-Québec does not encourage the use of central venous access unless the donor's peripheral venous access is very limited or inaccessible. Central venous catheters should be used only when, following a thorough evaluation, it is determined that access to the peripheral veins is not possible, cannot be obtained or has failed.

- The CC is responsible for assessing the donor's veins and discussing with him or her the risks and benefits of various venous access options prior to the collection of PBSC or leukocytes (DLI). The vein assessment and evaluation of other collection methods must be included in the donor evaluation process. The insertion of a central catheter in the femoral vein is preferred since the incident rate is lower than when the insertion is made in the subclavian or jugular vein. However, the decision of where to insert the catheter is left to the treating physician.
- The use of central catheters is required in the two following situations:
  - **Inadequate venous access is detected during the donor assessment.** The insertion of a catheter

requires a written justification from the physician in charge and this justification must be included in the documentation provided by Héma-Québec. The collection of bone marrow as a substitute collection must also be discussed with the donor.

- **Venous access fails during the donor collection procedure,** making it necessary to insert a central line to complete the procedure. Should the donor refuse the central line, the collection of bone marrow may be considered as a substitute collection. An incident report must also be filed in the Héma-Québec Registry.

- The catheter insertion must be performed in a hospital by a qualified and experienced physician, according to the CC's policies and procedures describing the method for vein assessment and insertion of the central venous catheter. Any catheter inserted above the navel must be verified by x-ray.
- The CC must ensure adequate medical coverage during an apheresis procedure performed using a central venous catheter. If the insertion of a central catheter was not planned, Héma-Québec must be notified immediately and receive written justification from the physician in charge.

6.3.3 Screening for infectious diseases

- Héma-Québec performs the screening for infectious diseases within 30 days prior to stem cell collection and before preparing the recipient for the transplant. It includes:
  - Serology (syphilis)
  - Anti-CMV
  - Anti-HTLVI/II
  - Anti-HCV
  - Anti-HIV 1/2
  - Anti-HBc
  - NAT HIV-HCV-HBV
  - NAT WNV
  - Chagas (if the donor is considered at risk)
  - HBsAg
- The donor's blood and Rh group are also analyzed.
- The analysis results are sent to the CC as soon as possible.

6.3.4 Autologous blood donation

- For a bone marrow collection, the CC will need to determine whether it is necessary for the donor to donate autologous blood before making the donation.
- The CC is responsible for advising and informing the donor about the risks and benefits of donating autologous blood.
- If an autologous blood donation is required, Héma-Québec will make the necessary arrangements to proceed with the request according to Héma-Québec's internal policy.

6.3.5 Information sent to the donor and obtaining consent

- The CC must inform the donor of the content outlined in the following documents (available in French only):
  - "Discussion avec un donneur de HPC, Marrow (centre collecteur)" (ENR 01661);
  - "Discussion avec un donneur de HPC, Apheresis (centre collecteur)" (ENR 01665);
  - "Discussion avec un donneur de MNC, Apheresis centre collecteur)" (ENR01692).

- The CC must obtain valid and legal consent from the donor in accordance with CC policies. The consent form must also be signed by the health professional involved in the donor evaluation.
- The CC is responsible for prescribing G-CSF and must provide a copy of the prescription to Héma-Québec. The initial dosage should not exceed 10 mcg/kg/day, as recommended by the WMDA. Should the CC decide that it must increase the dose of G-CSF, it must notify Héma-Québec in writing and indicate the reason for the increase. In this case, the dose should not exceed 16 mcg/kg/day.
- In cases where cell mobilization fails, the CC must consider the possibility of emergency bone marrow collection. The donor must have been notified of the possible change in procedure during his or her medical evaluation and must have received all the information regarding this new procedure and its justification. The CC must notify Héma-Québec of any concerns the donor may have and his or her refusal and/or eligibility for this unforeseen procedure.
- It is the CC's responsibility to make the necessary arrangements for the administration of the G-CSF and the scheduling of the necessary blood tests. It is also the CCs responsibility to explain the G-CSF injection procedure and requirements to the donor.
  - The CC is responsible for assessing the risk of severe allergic reactions at the time of the first injection.
  - The donor must remain in observation for 30 minutes after the injection to check for signs of allergic reactions.
  - G-CSF should ideally be administered in a medical setting (clinic, CLSC, hospital), by a health professional. The donor may be accompanied by a third party. The donor should be advised of signs of allergic reactions.
  - If the product is to be administered by a person who is not a health professional, the hospital must adequately train all persons involved in the administration of the drug.
- If the product is not administered in a hospital setting, the CC will provide the donor with vials of G-CSF, the material needed to safely transport it and administer it and material for syringe disposal.
- The CC shall provide the donor with all the information regarding the persons to be contacted and instructions in the event of an emergency when taking the G-CSF. The CC must ensure that there is a person on duty to respond to the donor.

6.3.6 Prescription verification

- The CC must verify the prescription to determine whether it is possible to meet the specific needs of the TC; taking into account the requested concentration, filtering, transport solution, additives, anticoagulant, etc.
- The CC must evaluate the donor to determine if the amount of cells requested by the TC is attainable according to the following guidelines:
  - bone marrow:
    - the maximum volume taken from the donor should not exceed 20 ml/kg.
    - the average cell count for a bone marrow is 0.22×10^8/ml.
  - PBSC: the average yield from processing one litre of blood is approximately 30×10^6 CD34+ cells.

  - The average yield by leukapheresis from processing one litre of blood is approximately $10x10^8$ mononuclear cells.
- The CC must notify Héma-Québec as soon as possible when it foresees a problem with the TC request. The CC must complete one of the following three forms:
  - "Verification of HPC, Marrow Prescription" ((ENR-01690) or "Vérification de la prescription pour HPC, Marrow" (ENR-01796).
  - "Verification of HPC, Apheresis Prescription" (ENR-01691) or "Vérification de la prescription de HPC, Apheresis" (ENR-01798).
  - "MNC, Apheresis DLI Prescription Verification" (ENR-01693) or "Vérification de la prescription / DLI par aphérèse" (ENR-01797).

6.4 Final authorization for donation

After determining that the donor is medically fit to donate stem cells, the CC must complete the following forms and return them to Héma-Québec **before** the recipient begins the preparatory regimen:

- "Donor Medical Review" (ENR-01752) or "Révision médicale du donneur" (ENR-01804) (section 1).
- "Donor Medical Examination" (ENR-01768) or "Évaluation médicale du donneur" (ENR-01803).
- Results of medical examinations

6.4.1 Donor ineligibility following the discovery of a risk factor

- After determining that the donor is ineligible for the donation due to risk factors, the CC must complete section 2 of form "Donor Medical Review" (ENR-01752) or "Révision médicale du donneur" (ENR-01804) and forward it to Héma-Québec.
- Upon receipt of the document, the Héma-Québec Registry cancels the preparation for donation and informs the registry having initiated the donor search, which, in turn, will notify the TC.
- The CC must inform the donor of the reason (s) that led to the donation being cancelled and the measures to be taken. The CC must also inform the donor's family doctor of any abnormal findings.

6.4.2 Donor examination results that could pose a risk to the recipient

- If the donor presents a health problem that could be detrimental to the recipient, the CC must complete section 3 of the form "Donor Medical Review" (ENR-01752) or "Révision médicale du donneur" (ENR-01804) and send it to Héma-Québec as soon as possible.
- Héma-Québec will forward the form to the international registry and the TC for review. Once the section 4 of the form has been completed by the TC and the international registry, Héma-Québec will resend it to the CC.
- If the TC and the international registry approve the donor after being informed of the potential risks identified by the CC, stem cell collection may proceed as planned.

The decision to proceed with the collection of stem cells from a donor with a health problem or a potential risk factor that could affect the quality of lymphohematopoietic cells will be made by the TC once it has assessed the impact on the recipient.

The TC is responsible for establishing requirements for exceptional distribution of product and consulting with the recipient, according to applicable regulations.

6.5 Collection delays

- Héma-Québec will notify the CC of any delay in the collection timeline due to the TC and the international registry. The CC will be notified of the new timeline as soon as it is disclosed by the aforementioned parties.
- Upon receipt of the new collection dates proposed by the TC and the international registry, Héma-Québec will notify the CC to proceed with the steps to prepare for donation.
- Depending on the steps completed before the donation was postponed, the Héma-Québec advisor will inform the CC of the steps to be completed again when the preparation for donation is resumed.
- Héma-Québec will repeat infectious disease marker screening if first results exceed the 30 day window prior to the collection date. The results will be sent to the CC as soon as possible.
- If the delay is more than eight weeks, Héma-Québec will forward the following forms to the CC: “Revision and Confirmation of Post-Delay Donor Clearance” (ENR-03583) or “Révision et confirmation de l’autorisation au don après délais” (ENR-01671) and an update of the “Health screening questionnaire” (ENR-01763) or “Questionnaire medical” (ENR-01762).
  - If the CC determines that the donor does not need to be re-examined, the CC must complete form “Revision and Confirmation of Post-Delay Donor Clearance” (ENR-03583) or “ Révision et confirmation de l’autorisation au don après délais” (ENR-01671) and return it to Héma-Québec.
  - If the donor needs to be re-examined, the CC must complete a new authorization for donation and return it to Héma-Québec, as described in section 6.4.

6.6 Cancellation of the collection request

- Héma-Québec will notify the donor and the CC should there be a cancellation of the collection request received from the TC or the international registry.

7. PARTICIPATION IN RESEARCH

At the request of the TC, donors may be invited to participate in a research protocol. The studies in which donors are asked to take part must comply with the law and be approved by Héma-Québec’s research ethics committee.

The CC is responsible for obtaining the donor’s informed consent for his or her participation in any research protocol at the request of Héma-Québec.

8. DETAILS FOR TRANSPORTATION

It is the TC’s responsibility to hire a courier (the person responsible for transporting and delivering the stem cell product) and to arrange for the product to be handed over to him or her within an acceptable timeframe in order to ensure its viability and quality. The TC is responsible for ensuring that the courier has all the material required to safely transport the product according to the specifications of the TC.

- The TC will complete form “Stem Cell Product Transportation Details” (ENR-01701) or “Information du transport de cellules souches” (ENR-01711) or the equivalent international form, and forward it to the CC through Héma-Québec prior to the collection date. These forms indicate:
  - the name of the courier taking possession of the product;
  - the courier’s travel itinerary;
  - the name of the hospital or TC where the product will be delivered;
  - an emergency telephone number.
- The CC must notify Héma-Québec of any concerns it may have regarding the courier’s itinerary.
- The courier must contact the CC on arrival in the city where the CC is located.

9. PRODUCT COLLECTION

9.1 General

The CC physician is responsible for collecting stem cells, as described in form “Workup Request” (ENR-02650) or “Requête de préparation au don” (ENR-02649) or the equivalent international form.

9.2 Additives

The addition of substances, anticoagulants and additives to the collected product must be in accordance with the applicable prescription verification form previously agreed upon with the TC:

- “Verification of HPC, Marrow Prescription” (ENR-01690) or “Vérification de la prescription pour HPC, Marrow” (ENR-01796).
- “Verification of HPC, Apheresis Prescription” (ENR-01691) or “Vérification de la prescription de HPC, Apheresis” (ENR-01798).
- “MNC, Apheresis DLI Prescription Verification” (ENR-01693) or “Vérification de la prescription /DLI par aphérèse” (ENR-01797).

9.3 Labelling

All labelling of products and samples must meet the requirements outlined in Health Canada’s Safety of Human Cells, Tissues and Organs for Transplantation Regulations. For more information please visit: **www.hc-sc.gc.ca**.

In addition, labelling must comply with FACT standards. For more information on ISBT 128 international labelling standardization please refer to: **www.iccbba.org.**

9.4 Collection

- The CC must perform the collection according to the prescription previously agreed upon with the TC.
- The CC must verify the identity of the donor and collect the requested product according to their standards and procedures.

- For a PBSC collection, the CC must evaluate the amount of CD34+ that it can collect from the donor before it is able to hand over the product to the courier. In the event that the collection takes place over two days and the courier wishes to have the product before the cell count is completed, the CC will send the result to the TC through the Héma-Québec Registry.
- In the event that the CC anticipates a problem in obtaining the requested cell concentration, the CC must immediately inform Héma-Québec and the courier of the proposed solutions, such as planning a second collection day or opting for bone marrow collection. The courier is responsible for obtaining instructions from the TC for all questions related to an issue of the cell count not meeting TC standards. Héma-Québec will contact the registry involved.
- The CC must report to Héma-Québec any unexpected or adverse event related to the donor. Refer to the section on non-compliances and adverse reaction reports.

9.5 Quality control

- Product quality control must be carried out immediately after collection to ensure that the safety, viability and integrity of the product meet CC criteria.
- Any discrepancies, deficiencies or problems that may affect the integrity of the product must be reported to Héma-Québec and the information will be sent to the TC if necessary. See section on non-compliances and adverse reaction reports.

9.6 Pick-up of the product by the courier

- Two people must verify the product label; this verification must be documented.
- Product and sample labels must be legible and printed with indelible ink.
- The CC must ensure that the labels and accompanying documents contain the minimum information to be provided in accordance with the FACT standard.
- In order to maintain confidentiality, the donor's name must not be affixed to the product.
- The CC must verify the identity of the courier before handing over the product.

9.7 Documents to provide to Héma-Québec

- On the day of the donation, the CC must complete the following applicable form:

  Product collection report

  Note: One copy of the report must be given to the courier and a second sent to Héma-Québec.

  – "HPC, Marrow Product Collection Report" (ENR-01663) or "Rapport de collecte de HPC, Marrow" (ENR-01664);
  – "HPC, Apheresis Product Collection Report" (ENR-01667) or"Rapport de collecte de HPC, Apheresis" (ENR-01668);
  – "MNC, Apheresis Product Collection Report" (ENR-01670) or "Rapport de collecte de MNC, Apheresis" (ENR-01669).

Collection centre report

Attention: Do not provide these documents to the courier.

- "Formulaire de collecte de HPC, Marrow" (ENR-01662) available in French only;
- "Formulaire de collecte de HPC, Apheresis" (ENR-01666) available in French only;
- "Formulaire de collecte de MNC, Apheresis" (ENR-01694) available in French only.

10. POST-DONATION

10.1 General

The donor must remain under observation after the donation and receive his or her discharge according to the CC's internal protocols. The CC will give the donor the instructions to follow after the donation and a contact number in case of emergency. The CC is responsible for assessing whether the donor should take an iron supplement following a bone marrow donation.

Donors living more than 150 km from the CC are encouraged to stay near the CC on the day before the donation. In some cases, the donor must report to the CC for a post-donation follow-up.

Air travel is allowed 24 hours after the donation (for all collection types) unless otherwise instructed by the CC.

Héma-Québec recommends that donors be accompanied for the donation as well as for a minimum of 24 hours after the donation. In cases where the donor cannot be accompanied by a friend or relative, it will be Héma-Québec's responsibility to find an alternative.

11. POST-DONATION FOLLOW-UP

Héma-Québec follows up with the donor through questionnaires and telephone calls until he or she is fully recovered. Follow-ups are done 1 week and 30 days post donation. In the event that the donor experiences an adverse effect following the donation, Héma-Québec will notify the CC so that he or she can be evaluated if necessary.

The CC medical team must ensure that the donor consults with a family physician two weeks after donating bone marrow to ensure that the donor is recovering well and that his or her iron levels are adequate.

Héma-Québec asks all donors to complete a survey one year after donation. Héma-Québec is responsible for the follow up based on the survey results.

12. NON-COMPLIANCE AND DECLARATION OF ADVERSE REACTIONS

12.1 Definition

Héma-Québec defines non-compliance as any deviation from a requirement.

12.2 Responsibilities of the collection centre

Any non-compliance that arises or is discovered by the CC must be reported to Héma-Québec in writing as soon as possible.

For any non-compliance occurring at the CC, the CC will be responsible for analyzing the causes and implementing corrective actions in their environment. The CC must submit to Héma-Québec a report of the results and/or corrective actions taken.

The CC must notify Héma-Québec of any adverse reaction using the form "Serious Event Reporting" (ENR-00114) of "Rapport d'événement grave" (ENR-00113) or situation that may have occurred during or after the donation period (e.g., prolonged recovery period) and that may require medical follow-up or hospitalization resulting from persistent or significant donor disability.

In addition to reporting these events to Héma-Québec, the CC is responsible for reporting errors and accidents, non-compliances related to the product as well as adverse effects experienced by donors, in accordance with Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation Regulations. For more information: **www.hc-sc.gc.ca**.

12.3 Responsibilities of Héma-Québec

Héma-Québec is responsible for notifying the TC or the registry responsible for the recipient of any information that may affect the recovery of the patient.

Héma-Québec will inform the WMDA of any adverse events or situations that occur that are considered critical such as:

- death of the donor;
- event placing the donor's life in danger;
- prolonged hospitalization;
- persistent or serious disability;
- defective or damaged stem cell product container.

Original text in French. In the event of a discrepancy between the English and French versions, the latter will prevail.