DukeMedicine

Division of Cellular Therapy

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National Marrow Donor Program Stem Cell Donation Procedure

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ABMT-COLL-004
NATIONAL MARROW DONOR PROGRAM
STEM CELL DONATION PROCEDURE

1 PURPOSE

1.1 To describe the procedure required for apheresis using the Terumo Spectra Optia Apheresis System (Optia). This procedure is for the collection of Peripheral Blood Stem Cells (PBSC) or T-Lymphocytes (DLIs) from a donor identified by the National Marrow Donor Program (NMDP). For information on using the Optia system, refer to the Spectra Optia® Apheresis System Operator's Manual.

2 INTRODUCTION

2.1 The collection of PBSC and DLIs by apheresis allows patients to be treated with high dose chemotherapy. NMDP related and/or unrelated allogeneic PBSC donors are stimulated with colony stimulating factor (CSFs) supplied by an NMDP approved pharmacy prior to donation. NMDP related and/or unrelated allogeneic DLIs are collected in the steady state without CSFs being administered.

2.2 Every effort is made to use peripheral intravenous (PIV) access for apheresis. If PIV access is not adequate to maintain blood flow, a temporary/non-tunneled central venous catheter (CVC) will be placed in Interventional Radiology (IR) using ultrasound guidance and confirmed by radiograph.

2.3 Apheresis collections are performed in the Adult Blood and Marrow Transplant (ABMT) Clinic in treatment chairs or beds, separated by curtains to prevent improper labeling, mix-ups, contamination or cross contamination of cellular products. Overhead lighting and adequate ventilation is present. All cellular products are collected at room temperature. Sinks are present in each treatment area for hand hygiene. North Pavilion (NP) pharmacy is available to dispense apheresis related medications, if needed.

2.4 Duke Life Flight is available to respond to emergencies and to transport donors to Duke North emergency room or inpatient ABMT. Emergency equipment including code cart, Automated External Defibrillator (AED), suction, and oxygen are available and in close proximity to the apheresis area. NMDP donors who have a CVC will be transported to and from Duke Hospital by Duke Life Flight or accompanied by a member of the ABMT medical or nursing staff.

3 SCOPE AND RESPONSIBILITIES

3.1 The apheresis nurse is responsible for the collection of PBSCs and DLIs products using Optia.

3.2 The apheresis nurse, ABMT apheresis attending physician, and Advance Practice Providers (APPs) are responsible for patient/donor care during apheresis.

3.3 The ABMT transplant coordinator (TC) is responsible for verifying donor eligibility requirements are completed, product verification with stem cell lab (STCL) and courier service using chain of custody documentation.

4 DEFINITIONS/ACRONYMS

4.1 ABMT: Adult Blood and Marrow Transplant

4.2 ACLS: Advanced Cardiac Life Support

4.3 AED: Automated External Defibrillator

4.4 APP: Advanced Practice Provider

4.5 CBC: Complete Blood Count

4.6 CMNC: Continuous Mononuclear Cell Collection

4.7 CMP: Complete Metabolic Panel

4.8 CSF: Colony Stimulating Factor

4.9 DLI: T-Lymphocytes/Donor Lymphocyte Infusion

4.10 EMR: Electronic Medical Record

4.11 LDH: Lactic Dehydrogenase

4.12 MD: Medical Doctor

4.13 mL: milliliter

4.14 NMDP: National Marrow Donor Program

4.15 PBSC: Peripheral Blood Stem Cells

4.16 PIV: Peripheral Intravenous Access

4.17 PPE: Personal Protection Equipment

4.18 SOP: Standard Operating Procedure

4.19 TC: NMDP Transplant Coordinator

4.20 WBC: White Blood Cell

4.21 DHIS: Duke Hospital Information System

5 MATERIALS

5.1 Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC).*

6 EQUIPMENT

6.1 Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC).*

7 SAFETY

7.1 Follow all safety-related Standard Operating Procedures (SOPs) and wear all required Personal Protective Equipment (PPE) when handling blood and body fluids. PPE includes but is not limited to gloves, gowns, surgical masks, goggles, and/or face shields. Hand hygiene should be performed before and after patient contact and prior to Optia set-up. All Optia tubing connection will be made using aseptic technique.

8 PROCEDURE

8.1 Donor Evaluation:

8.1.1 One or more clinic visits, either in person or virtually, may be arranged for donor evaluation. The ABMT TC will coordinate the donor workup. NMDP donor evaluation will include medical history, exam, medical record review, donor screening labs, and other appropriate age related testing. The donor evaluation is performed in the ABMT Clinic prior to mobilization. This evaluation will be performed by an Attending Medical Doctor (MD) or Advance Practice Provider (APP) that is not the primary transplant physician. All evaluation are performed in a private clinic examination/consultation room where confidentiality can be maintained. Refer to APBMT-COMM-001 *Donor Selection, Evaluation and Management*.

8.1.2 During this visit, the NMDP donor will complete the APBMT-COMM-001 FRM3 *Donor Health History Questionnaire*. This questionnaire will be reviewed by the attending MD or APP to identify any exceptions. The APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* will be filed in the NMDP red chart, which is provided by the TC. Unexpected responses or "yes" questions will be explained in the remarks section of the APBMT-COMM-001 FRM3 *Donor Health History Questionnaire.* Refer to APBMT-COMM-001 *Donor Selection, Evaluation and Management* for more information.

8.1.3 The NMDP donor will be evaluated for PIV access by the TC and an apheresis nurse. If PIV access is evaluated to be insufficient for peripheral collection, the NMDP donor will be scheduled for a CVC insertion.

8.1.4 If an NMDP donor requires CVC placement for apheresis, they must be transported from IR to the ABMT Clinic by Duke Life Flight or accompanied by a member of the ABMT medical or nursing staff. If the CVC must be kept in overnight, the NMDP donor will be admitted to the ABMT inpatient unit for observation. Arrangements will be made by the TC and/or apheresis nurse.

8.2 Apheresis Donor Mobilization:

8.2.1 Filgrastim (Neupogen), a type of CSFs, is the preferred CSF provided by an NMDP approved supplier source, however, other forms of CSF may be given if Filgrastim (Neupogen) is unavailable. Filgrastim (Neupogen) cannot be ordered for NMDP donors from the NP pharmacy.

8.2.2 The TC will have the CSF delivered, labeled, and stored in the ABMT medication refrigerator in the medication room of the Treatment Room.

8.2.3 Each day of CSF administration, the NMDP donor assessment form will be completed by the care nurse prior to the administration. For possible dose reductions related to symptoms, refer to the NMDP Guidelines for Filgrastim (Neupogen) dose reduction table located in the NMDP donor

red notebook for Neupogen related toxicities. Contact the apheresis attending MD for CSF dose reduction or dose hold orders. Contact the TC with the plan of care. The NMDP Medical Director can also be contacted for questions regarding donor care.

8.2.4 The NMDP donor must be observed for fifteen minutes following the first injection of CSF. If after fifteen minutes there are no signs of systemic or local skin reactions, no further observation is necessary. If a reaction occurs within the first fifteen minutes, the donor should be treated as necessary and observed for at least another forty-five minutes.

8.2.5 CSF should be injected subcutaneously in the upper arms or abdomen using a small gauge needle. On days 1-4, Neupogen should be administered at the same approximate time each day if feasible. The fifth dose should be administered at least one (1) hour prior to the initiation of the first apheresis.

8.3 Donation Day Donor Assessment:

8.3.1 On day one (1) of donation perform patient identification and assessment, refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC)* for additional information. Completed the associated NMDP forms located in the red NMDP chart. If dose reduction is needed, refer to the NMDP Guidelines for Filgrastim (Neupogen) dose reductions for donor symptoms.

8.3.2 The APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* should be completed within 30 days of donation. If the APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* is outdated, re-administer it and have it signed by the Apheresis Attending MD.

8.3.3 See ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC)* and/or the electronic medical record (EMR) for daily lab draws. The NMDP may require extra labs to be drawn each day of collection. The tubes will be provided by the TC and will be placed with the NMDP Red chart. Refer to ABMT-COLL-011 *Venipuncture Procedure.*

8.4 Collection Procedure:

8.4.1 Review the NMDP prescription to determine if there are special collection or laboratory processing requirements. The final collection product prior to laboratory processing must be no less than 215 ml.

8.4.1.1 Refer to ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC)* for Optia collection procedure. For information on using the Optia System, refer to the Spectra Optia® Apheresis System Operator's Manual.

Note: If an abbreviated collection time is anticipated due to high donor counts or low cell dose order, the final collection bag volume can be increased by increasing the collect pump flow rate on Optia. Refer to the Spectra Optia® Apheresis System Operator's Manual.

NOTE: If the total volume of cells and additional plasma exceeds fifteen (15) percent of the donor's extracorporeal volume, the Apheresis Attending MD will be notified. The TC will be contacted if the requested plasma volume cannot be collected. Refer to the Spectra Optia® Apheresis System Operator's Manual.

8.4.2 Follow the ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC)* for the collection practices.

8.4.3 Labeling the cellular product and plasma bags is completed prior to the end of the apheresis procedure. The NMDP donor and recipient identification number and recipient weight will be recorded on the tie tag. The recipient weight can be found on the NMDP prescription and will be placed on the recipient side of the cellular product tie tag and on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*. Refer to COMM-PAS-003 *Labeling Cellular Therapy Products.*

8.4.4 Complete the following forms:

8.4.4.1 STCL-GEN-009 FRM1 Cellular Product Chain of Custody FRM1

8.4.4.2 APBMT-COMM-001 FRM4 Interim Donor History Questionnaire

8.4.4.3 COLL-019 FRM1 Optia CMNC Run Sheet.

8.4.5 At completion of day (1) apheresis procedure, draw a post donation complete blood count (CBC) and manual differential. Document the results in the red chart provided by TC.

8.5 <u>IF A SECOND DAY OF APHERESIS IS NEEDED:</u>

NOTE: CSF cannot be administered the second day of collection without the approval of the NMDP Medical Director.

8.5.1 Complete APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire.*

8.5.2 NMDP and Apheresis Lab tests includes:

8.5.2.1 Pre and post apheresis CBC and manual differential.

8.5.2.2 Comprehensive Metabolic Panel (CMP) and Magnesium.

8.5.2.3 Type and screen.

8.5.2.4 Peripheral blood stem cell count.

8.6 Day #2 collection will be deferred if the NMDP donor platelet count is 80,000/microliter or less. The TC and Apheresis Attending MD will be contacted with the platelet count.

8.7 A donor follow up assessment will be done by the NMDP staff.

8.7.1 In addition, the collecting facility TC will call the donor within 24 to 72 hours post collection.

8.7.2 If there are issues or concerns, the TC will call weekly until all issues have been resolved. All documentation will be recorded in EMR.

8.8 Completion of Procedure:

8.8.1 Deliver cellular product to the STCL from apheresis area using a validated cooler.

8.8.2 Apheresis nurse completes the STCL-GEN-009 FRM1 *Cellular Product Chain of Custody FRM1* for hand-off to STCL staff.

8.8.3 STCL performs STCL-DIST-001 JA2 *Outgoing NMDP Products-STCL Checklist* and re-labels the product(s) according to NMDP requirements.

8.8.4 STCL completes the STCL-GEN-009 FRM1 *Cellular Product Chain of Custody FRM1* for hand-off to ABMT TC.

8.8.5 TC/designee performs product verification. The Product Verification Form is completed and is placed in the red chart.

8.8.6 TC/designee checks the integrity of the product with the NMDP appointed courier, while the NMDP appointed courier completes the Record of Packing and Receipt. A copy of this record and receipt is placed in red chart.

8.8.7 Once everything has been completed, the TC will scan all the NMDP donor paperwork, including lab results, forms, and receipts into the ABMT DocuWare site.

9 RELATED DOCUMENTS/FORMS

9.1 APBMT-COMM-001 FRM3 *Donor Health History Questionnaire*

9.2 APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire*

9.3 ABMT-COLL-019 *Optia Continuous Mononuclear Cell Collection (CMNC)*

9.4 ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*

9.5 STCL-GEN-009 FRM1 *Cellular Product Chain of Custody FRM1*

9.6 ABMT-COLL-001 FRM2 *Apheresis Checklist*

9.7 Note APBMT-GEN-001 FRM3 *Physician Leukapheresis Procedure Note*

9.8 APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing*

9.9 ABMT-COLL-001 FRM2 *Apheresis Checklist*

9.10 STCL-DIST-001 JA2 *Outgoing NMDP Products-STCL Checklist*

9.11 Education sheet: NMDP Donation

10 REFERENCES

10.1 NMDP Protocol, current version

10.2 NMDP website

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
10	M. Christen	Formatting changes throughout document. Acronyms defined throughout document. Removed Neupogen throughout document and replaced with CSF where appropriate. Removed redundant information Section 5 and 6: Added Master Control document number and name of SOP relating to collection. Section 8: Updated verbiage of procedure to reflect current practices. Section 8.8: Updated completion procedure to reflect current practices. Section 9: Updated with MC names and current versions.

Signature Manifest

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ABMT-COLL-004 National Marrow Donor Program Stem Cell Donation Procedure

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