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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 donor coordinator is responsible 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 not limited to gloves, gowns, surgical masks, goggles, and/or face shields. Hand hygiene 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 may be arranged for donor evaluation. The Adult Transplant Coordinator (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-002 Adult Donor History Questionnaire. This questionnaire will be reviewed by the attending MD or APP to identify any exceptions. The APBMT-COMM-002 Adult Donor 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-002 Adult Donor 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  Only Filgrastim (Neupogen), a type of CSFs, provided by an NMDP approved supplier source can be administered to the NMDP donor. Neupogen cannot be ordered for NMDP donors from the NP pharmacy.

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

8.2.3  Each day of Neupogen 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 Neupogen 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 Neupogen. 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 Neupogen should be injected subcutaneously in the upper arms or abdomen using a small gauge needle. Neupogen dose shall not exceed 1200mcg/day. Max of two (2) mLs of Neupogen should be injected in any one site. 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-002 Adult Donor Health History Questionnaire should be completed within 30 days of donation. Complete the Interim Donor History Questionnaire. If the APBMT-COMM-002 Adult 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) 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.

**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 STCL-GEN-009 FRM1 *Cellular Product Chain of Custody FRM1*, APBMT-COMM-003 *Interim Donor History Questionnaire*, ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet*, and Apheresis Nursing Standard Plan of Care.

8.4.5 At completion of day (1) apheresis procedure, draw a post donation complete blood count (CBC) and manual differential.

8.5 **IF A SECOND DAY OF APERATURES IS NEEDED:**

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

8.5.1 Complete APBMT-COMM-003 *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. In addition, the collecting facility TC will call the donor within 24 to 72 hours post collection. If there are issues or concerns, the TC will call weekly until all issues have been resolved. All documentation will be recorded in the electronic health record (EMR).

8.8 Completion of Procedure:
8.8.1 Product delivered to the STCL from apheresis area.
8.8.2 Chain of custody performed for hand-off to STCL staff.
8.8.3 STCL performs checklist and re-labels the product(s).
8.8.4 Chain of custody performed for hand-off to donor coordinator.
8.8.5 Donor coordinator/designee perform product verification. The product verification form stays in the patient file.
8.8.6 Donor coordinator/designee checks the product with the courier as courier completed Record of Packing and Receipt. Copy is placed in patient’s file.

9 RELATED DOCUMENTS/FORMS

9.1 FRM1 Adult Donor History Questionnaire APBMT-COMM-002 Adult Donor Health History Questionnaire
9.2 FRM5 Interim Adult History Questionnaire APBMT-COMM-003 Interim Donor History Questionnaire
9.3 Terumo Spectra Optia: WBC Operation ABMT-COLL-019 Optia Continuous Mononuclear Cell Collection (CMNC)
9.4 FRM1 Optia Leukapheresis Run Sheet ABMT-COLL-019 FRM1 Optia CMNC Run Sheet
9.5 FRM1 Cellular Product Chain of Custody STCL-GEN-009 FRM1 Cellular Product Chain of Custody FRM1
9.6 FRM2 Apheresis Checklist ABMT-COLL-001 FRM2 Apheresis Checklist
9.7 FRM3 Physician Leukapheresis Note APBMT-GEN-001 FRM3 Physician Leukapheresis Procedure Note
9.8 FRM4 Summary of Donor Eligibility APBMT-COMM-005 Summary of Donor Eligibility and Infectious Disease Testing
9.9 Education sheet: NMDP Donation

10 REFERENCES

10.1 NMDP Protocol, current version
10.2 NMDP website
### 11 REVISION HISTORY

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<td>09</td>
<td>M. Christen</td>
<td>Formatting changes throughout document. Acronyms defined throughout document. Section 1.1: Updated to reflect current practice and current apheresis machine. Section 2.1: Added NMDP related and unrelated donors to capture possible donor collections. Section 2.2: Added non-tunneled catheter. Section 3: Updated scope and responsibilities by performer. Section 5 and 6: Added Master Control document number and name of SOP relating to collection. Section 7: Added hand hygiene and tubing connection techniques. Section 8: Updated verbiage of procedure to reflect current practices. Section 8.8: Created completion procedure to reflect current practices. Section 9: Updated with MC names and current versions.</td>
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ABMT-COLL-004 National Marrow Donor Program Stem Cell Donation Procedure

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