Wake Forest Baptist Medical Center	**Releasing Products to the National Marrow Donor Program (NMDP)**	**Dept:**	324316
		Dept Name	SCTCT Processing Lab
		Effective Date:	8/6/2010
		Revised Date:	11/2018
Name & Title: CLIA Laboratory Medical Director		**Contact:**	JH Simmons/CS Warren
Signature:	Refer to Title 21	**Date:**	

1. General Procedure Statement:

A. Purpose: Healthy donors have Hematopoietic Progenitor Cells, Apheresis (HPC,A) or Hematopoietic Progenitor Cells, Marrow (HPC,M) collected at Wake Forest Baptist Medical Center via apheresis or in the operating room. The HPC,A or HPC,M are subsequently tested and labeled by the BMT Processing Lab and signed over to a courier from the NMDP. The courier delivers the HPC,A or HPC,M cells by hand to their final destination.

B. Responsible Department/Scope:

i Procedure owner/Implementer: Julie H. Simmons/ Christina S. Warren/ Emily H. Wilson
ii. Procedure prepared by: Emily H. Wilson
iii. Who performs procedure: Department staff/management

C. Definitions:

NMDP: National Marrow Donor Program
HPC,A: Hematopoietic Progenitor Cells, Apheresis
HPC,M: Hematopoietic Progenitor Cells, Marrow
IDM: Infectious Disease Markers
BMT: Blood and Marrow Transplant
PPE: Personal Protective Equipment
ISBT: International Society of Blood Transfusion

 : Indicates a step where a picture should be taken.

D. Sections: n/a

E. Protocols:

1.0 Forms that are controlled by the NMDP can be accessed at network.bethematchclinical.org with an appropriate password.
2.0 The NMDP will supply forms manually if contacted at 1-704-921-1925.
3.0 A master copy of each form is in the Master Forms book regardless of who controls the form.
4.0 Labeling of products should be performed on the day of collection.
5.0 All products and tubes leaving the institution should have a photograph taken after labeling that should be retained with the patient chart.
6.0 All labels and tags shall be completed with indelible black ink and any blanks on labels shall be filled in with "N/A".

2. Procedure:

Chemical Risk Assessment: Low
Biological Risk Assessment: Low
Protective Equipment: Gloves, Lab Coat

Supplies: None
Reagents: None
Equipment: None
Specimen Requirements: HPC or marrow product

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
1.0	**Print a copy of the** *Verification of Product Labeling Form* **–** *Related or Unrelated, Attachments 1 and 2,* **and the** *Record of Packaging and Receipt Form, Attachments 3.* 1.1 These forms are owned by the NMDP and are provided to the BMT lab by the NMDP coordinator. 1.2 A copy of the current version is also in the Master Forms book.	
2.0	**Obtain forms, labels and packaging necessary for product transfer to the courier (Some items may arrive electronically).** 2.1 The following should arrive at least one day before the harvest from the NMDP nurse coordinator: *a) Final Declaration of Donor Eligibility, Attachment 4* *b) Donor Infectious Disease Markers (IDMs) Attachment 5* *c) Circular of Information, Attachment 6* *d) Bag delivery tags, Attachment 7* *e) Tube labels, Attachment 8* *f) NMDP Form 770/772/773, Attachments 9,10,11.* 2.2 If these items should not all arrive at least one day before the harvest, contact the NMDP coordinator if any items are missing, 1-704-921-3571 or 1-704-921-3572.	
3.0	**Complete NMDP product bag label, including any added anticoagulants or time of collection completion and affix the NMDP bag label to the product bag.** 3.1 Refer to ***Product Labeling, BMT.Routine.1033***	
4.0	**Prepare the labeling area by removing all other patient's documentation and labels from the designated area to continue processing.**	

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
5.0	**Remove any other identifying label from the product bags and replace with appropriate label made in step 3.0.** 5.1 Two techs should verify the label change concurrently and with no interruptions. 5.2 The Verification of Product Labeling form serves as documentation of this verification. 5.3 Attach removed product bag label to a blank sheet of paper and retain with patient paperwork. 5.4 Only one patient is to be relabeled at a time.	
6.0	**Complete an** *NMDP Product Delivery Tag, Attachment 7***, with delivery address and phone number provided by NMDP coordinator and attach one to each product bag.** 6.1 The *Product Delivery Tag* has 2 sides to complete.	
7.0	**Attach Tie Tag 1, 2, or 3 if applicable.** 7.1 Refer to ***FDA Biohazard Labeling Chart, Attachment 13***.	
8.0 	**Take a picture of the product bag when labeling is complete and print for patient file.** 8.1 Refer to *Laboratory Camera, BMT.Routine.1031*.	
9.0	**Relabel any tubes accompanying the product (the number of tubes received will differ depending on the receiving center's request).** 9.1 Remove any apheresis EPIC label from the remaining tubes requested by the receiving Center with 2 techs without any interruptions. 9.2 Replace the labels with completed green *NMDP tube labels, Attachment 8.* 9.3 Attach removed apheresis labels to a blank sheet of paper and retain with patient paperwork.	
10.0 	**Take a picture of the tubes and retain a copy in the patient file.** 10.1 Refer to *Laboratory Camera, BMT.Routine.1031*.	
11.0	**Complete** *Verification of Product Labeling Form***. A BMT labeling tech and a trained second verifier must complete this form. Important checks:** 11.1 Donor and recipient ID numbers shall be checked against source documentation. (For BMT Lab Staff, source document is the *Physician Order form, Attachment 12.*) 11.2 Donor and recipient ID numbers should be checked on ALL BAGS AND TUBES by BMT staff and a second verifier. 11.3 Make a copy of the completed *Verification of Product Labeling Form* and retain in patient paperwork. 11.4 Ensure that all paperwork is present for the courier.	

<table>
<tr><th>STEPS</th><th>INSTRUCTIONS</th><th>CHANGE/ APPROVAL</th></tr>
<tr><td>12.0</td><td>Complete the Record of Packaging and Receipt Form, Attachment 3, Sections A and C, and the courier Section B.

Make PPE available to courier for signout process: Lab Coat, Gloves

<table><tr><th>Section</th><th>Responsibility to Complete</th></tr><tr><td>A</td><td>BMT Technologist</td></tr><tr><td>B</td><td>Courier</td></tr><tr><td>C</td><td>BMT Technologist OR Courier</td></tr><tr><td>D</td><td>Receiver</td></tr></table></td><td></td></tr>
<tr><td>13.0</td><td>Prepare product for shipping:

Make PPE available to courier for signout process: Lab Coat, Gloves

13.1 Generally, Hematopoietic Progenitor Cells (HPCs), will be transported on cold packs, and Marrow will be transported at room temperature. The NMDP coordinator will inform you of any deviation from this norm.
13.2 The courier will supply ice bricks (already frozen) if needed for transport. Some extra ice bricks are stored in the Blood Bank -20°C freezer.
13.3 Place product in cooler provided by courier with ice bricks (if indicated). Also place any tubes requested by the receiving center in the cooler. Ice bricks should not be directly touching product; They may be separated by cardboard inserts or blue underpads.</td><td></td></tr>
<tr><td>14.0</td><td>Ensure courier is aware of the location of the handwashing sink after the product handoff is complete.

14.1 Gloves are discarded.
14.2 Lab coat is dirty and stored in laundry bag.</td><td></td></tr>
<tr><td>15.0</td><td>Accompany courier to exit and verify that they have arranged transportation to the airport.</td><td></td></tr>
<tr><td></td><td>EXPECTED OUTCOME RESULTS: Products shall be relabeled and verified prior to release to the NMDP for transport via courier.</td><td></td></tr>
<tr><td></td><td>ACCEPTABLE RANGES: n/a</td><td></td></tr>
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3. Review/Revised/implemented:

All procedures must be reviewed according to the Document Control Protocol.
All new procedures and procedures that have major revisions must be signed by the CLIA Director.
All reviewed procedures and procedures with minor revisions can be signed by the designated section medical Director or designee

4. Related Procedures:

- *Product Labeling, BMT.Routine.1033*
- *Laboratory Camera, BMT.Routine.1031*

5. References: network.bethematchclinical.org, email correspondence attached.

6. Attachments:

1. Verification of Product Labeling- Unrelated – F00835 rev. 5
2. Verification of Product Labeling – Related – F01015 rev. 4
3. Record of Packaging and Receipt – F00836 rev. 3
4. Final Declaration of Donor Eligibility
5. Donor Infectious Disease Markers – F01060 rev. 1
6. Circular of Information – Oct 2018
7. NMDP Product Delivery Tags – L0005, rev. 6
8. NMDP Tube Labels – L00017 v 2.0
9. Form 770 – PBSC Product Analysis – F00169 rev. 4
10. Form 772 – Marrow Product Analysis – F00170 rev. 4
11. Form 773 – Therapeutic Cells, T Cells, Apheresis Procedure and Product Analysis – F00241 rev. 3
12. HPC Donor Lymphocyte Physician's Order Form
13. FDA Biohazard Labeling Chart