# Applicable Laboratory(s):

North Carolina Baptist Hospital (NCBH)

Lexington Medical Center (LMC)

Davie Medical Center (DMC)

Wilkes Medical Center (WMC)

High Point Medical Center (HPMC)

Westchester

Clemmons

# 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 SCTCT 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.

# Scope

i Procedure owner/Implementer: Christina S. Warren/ Emily H. Wilson

ii. Procedure prepared by: Emily H. Wilson

iii. Who performs procedure: Department staff/management

# 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.

# Supplies/Materials

ISBT Printer with accompanying HemaTrax software.

# Procedure Guidelines

1. Print a copy of the *Verification of Product Labeling Form* – *Related or Unrelated, SCT-FORMS-0181, -0182,* and the*Record of Packaging and Receipt Form, SCT-FORMS-0175.*
   1. These forms are owned by the NMDP and are provided to the SCTCT lab by the SCTCT NMDP coordinator.
   2. A copy of the current version is also in the Master Forms book.
2. Obtain forms, labels and packaging necessary for product transfer to the courier (Some forms may arrive electronically via email from the nurse coordinators).
   1. The following should arrive at least one day before the harvest from the NMDP nurse coordinator:
      1. *Final Declaration of Donor Eligibility* SCT-FORMS-0203
      2. Donor Infectious Disease Markers (IDMs) NMDP Form
      3. Circular of Information
      4. Bag delivery tags
      5. Tube labels
      6. *NMDP Form 770/772/773* SCT-FORMS-0331/0332/0333
   2. If these items should not all arrive at least one day before the harvest, contact the SCTCT NMDP coordinators if any items are missing.
3. Complete NMDP product bag label,including any added anticoagulants or time of collection completion.
   1. Use the G1 tracking sheet for recipient information
   2. Refer to *Product Labeling*, SCT-SOP-0152.
4. Prepare the labeling area by removing all other patient’s documentation and labels from the designated area to continue processing.
5. Remove any other identifying label from the product bags and replace with appropriate label made in step C.
   1. Two techs should verify the label change concurrently and with no interruptions.

2. The DIN# shall remain on the product bag at all times – there is a perforation on the

product label that allows this to occur.

3. The *Verification of Product Labeling* form SCT-FORMS-0181/0182 serves as

documentation of this verification.

* 1. Attach removed product bag label to a blank sheet of paper and retain with patient paperwork.
  2. Only one patient is to be relabeled at a time.

1. Complete an *NMDP Product InformationTag, SCT-LABEL-0293* with delivery address and phone number provided by NMDP coordinator and attach one to each product bag.
   1. The *Product InformationTag* has 2 sides to complete.
2. Attach Tie Tag 1, 2, or 3 if applicable as indicated by the declaration of eligibility.
   1. Refer to *FDA Biohazard Labeling Chart*.
3. Take a picture of the product bag when labeling is complete and print for patient file.
   1. Refer to *Laboratory Camera, SCT-SOP-0017*.
4. Relabel any tubes accompanying the product (the number of tubes received will differ depending on the receiving center’s request).
   1. Remove any apheresis EPIC label from the remaining tubes requested by the receiving Center with 2 techs without any interruptions.
   2. Replace the labels with completed green *NMDP tube labels, SCT-LABEL-0197*
   3. Attach removed apheresis labels to a blank sheet of paper and retain with patient paperwork.
5. Take a picture of the tubes and retain a copy in the patient file. 
   1. Refer to *Laboratory Camera, SCT-SOP-0017*
6. Complete *Verification of Product Labeling Form*. A SCTCT labeling tech and a trained second verifier must complete this form. Important checks:
   1. Donor and recipient ID numbers shall be checked against source documentation. (For SCTCT Lab Staff, source document is theEPIC electronic order.
   2. Donor and recipient ID numbers should be checked on ALL BAGS AND TUBES by SCTCT staff and a second verifier.
   3. Make a copy of the completed *Verification of Product Labeling Form* and retain in patient paperwork.
   4. Ensure that all paperwork is present for the courier.
7. Complete the *Record of Packaging and Receipt Form, SCT-FORMS-0175,* Sections Aand the courier Section B.
   1. Make PPE available to courier for sign-out process: Gloves
8. Prepare product for shipping:
   1. Insure that all tubes and products are inside a sealed outer bag.
   2. Allow the courier to pack up all items in accordance with the product label.
      1. Generally, Hematopoietic Progenitor Cells (HPCs), will be transported on cold packs (Credo), and Marrow will be transported at room temperature. The NMDP coordinator will inform you of any deviation from this norm.
      2. The courier will supply ice bricks (already frozen) if needed for transport.
      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.
9. Ensure courier is aware of the location of the handwashing sink after the product handoff is complete**.**
   1. Gloves are discarded.
10. Accompany courier to exit and verify that they have arranged transportation to the airport.

# Literature References:

network.bethematchclinical.org

# Related Procedures/Policies in Navex:

N/A

# Attachments/Linked Documents in Title 21:

1. Verification of Product Labeling- Unrelated – F00835
2. Verification of Product Labeling – Related – F01015
3. Record of Packaging and Receipt – F00836
4. Declaration of Eligibility
5. Donor Infectious Disease Markers – F01060
6. Circular of Information – Oct 2018
7. Form 770 – PBSC Product Analysis – F00169
8. Form 772 – Marrow Product Analysis – F00170
9. Form 773 – Therapeutic Cells, T Cells, Apheresis Procedure and Product Analysis – F00241
10. NMDP PreCollection/Day of Collection Sample
11. Product Identification
12. FDA Ineligible Donor Label Requirements
13. Transport, Delivery, Additional Product Information Tag.
14. Releasing Products to the NDMP – Training Document

15. Product Labeling

16. Laboratory Camera

# Revision Dates: Review Change Summary as represented in Title 21.