

**Duke**Medicine

Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-COLL-001 FRM2**DOCUMENT TITLE:**

Apheresis Checklist FRM2

DOCUMENT NOTES:**Document Information****Revision:** 11**Vault:** ABMT-Collections-rel**Status:** Release**Document Type:** ABMT**Date Information****Creation Date:** 17 Jan 2024**Release Date:** 26 Jan 2024**Effective Date:** 26 Jan 2024**Expiration Date:****Control Information****Author:** MC363**Owner:** MC363**Previous Number:** ABMT-COLL-001 FRM2 Rev **Change Number:** ABMT-CCR-336

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Patient ID label

Donor's Provider/Coordinator: _____ Donor's Disease: _____

Donor's Initial Clearance Date: _____ Priming Method/Start Date: _____

Instructions: Complete questions below prior to apheresis donation. Write the expiration date, if applicable. Mark/check the appropriate box to indicate completion.

Prior to Apheresis:

1. <u>Physician order for Apheresis:</u>	<input type="checkbox"/>
2. <u>Apheresis Consent</u> Completed by physician or designee	<input type="checkbox"/>
3. <u>Summary of Donor Eligibility</u> *HPC (PBSC), MNC, Bone Marrow (BM) and Granulocyte (PMN) Donations: Required FDA Communicable Disease tests must be drawn within 30 days of apheresis. *DLI, NK Cell Donations: Required FDA Communicable Disease tests must be drawn within 7 days of apheresis	<input type="checkbox"/> Expires: _____
4. <u>Adult Donor History Questionnaire</u> *Allo and NMDP only (<i>Send original to lab</i>) Must be updated every: HPC (PBSC), MNC, Bone Marrow (BM) and Granulocyte (PMN) Donations within 30 days of apheresis *DLI, NK Cell Donations within 7 days of apheresis	Expires: _____ <input type="checkbox"/> <input type="checkbox"/> N/A
5. <u>HCG:</u> Exclusions: Hx of hysterectomy or >55 years old, or >50 years with 12 months since last menses or >45 years old with 18 months since last menses	<input type="checkbox"/> <input type="checkbox"/> N/A
6. <u>HLA Typing</u> Mark N/A for NMDP and Autologous Donors	<input type="checkbox"/> <input type="checkbox"/> N/A
7. <u>Documentation of Venous Access</u>	<input type="checkbox"/>

Day of Apheresis Procedure:

Instructions: Complete questions below on day of apheresis procedure. Mark/check the appropriate box to indicate completion.

1. <u>Date</u>	____/____/____
2. Barcode (DIN Label):	
3. <u>Patient ID Band Review</u> Verify donor's name and DOB prior to each procedure	<input type="checkbox"/>
4. <u>Draw Type and Screen</u> Add Day 1 Apheresis Slip and for every NMDP collection	<input type="checkbox"/>
5. <u>Correct Visit Type Review</u> Request the correct visit type ONLY on day of procedure	<input type="checkbox"/>
6. <u>Interim Donor Health Questionnaire</u> Perform donor safety/suitability prior to each procedure	<input type="checkbox"/>

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Patient ID label

<u>Machine Inspection</u>	
a. Inspect the machine for cleanliness prior to use	<input type="checkbox"/>
b. Verify the machine is in maintenance compliance	<input type="checkbox"/>
c. Document machine quality control record	<input type="checkbox"/>
7. <u>Material/Supply Inspection</u> Verify materials/supplies pass visual inspection	<input type="checkbox"/>
8. <u>Temperature and Humidity Review</u> Verify the temperature and humidity is within range	<input type="checkbox"/>
9. <u>Apheresis Run Sheet</u> Document machine, material/supply, and temperature/humidity information	<input type="checkbox"/>
10. <u>Product Bag Documentation</u> Verify Demographic information with patient and attach to the product bag	<input type="checkbox"/>
11. <u>Apheresis Log Record</u> Document appropriate information in the ABMT Apheresis Log	<input type="checkbox"/>
12. <u>BMT Smart Form</u> Document appropriate information in the BMT smart form	<input type="checkbox"/>
13. <u>Product Base Label(s) Creation</u> Using Hema-Trax system, create label	<input type="checkbox"/>
14. <u>Product Base Label(s) Verification</u> Product label verification is performed by 2 RN staff members and documented using initials.	_____/____
15. <u>Biohazard Label</u> Apply Biohazard label if applicable	<input type="checkbox"/>
	<input type="checkbox"/> N/A
16. <u>Peer to Peer Paperwork Review</u> GDP review of apheresis paperwork prior to scanning and sending to STCL	_____/____
17. <u>Complete Apheresis Plan Day</u>	<input type="checkbox"/>
18. <u>Adverse Event Record</u>	<input type="checkbox"/>
	<input type="checkbox"/> N/A
19. <u>Chain of Custody Form</u>	<input type="checkbox"/>
20. <u>RN Signature</u>	

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Instructions

Prior to Apheresis:

Place a check in the appropriate box ☒ **only** if the requirement has been met. If requirement is not applicable place a check in the appropriate box ☒ with **not applicable (N/A)** in the space provided.

Patient ID label	Place the printed patient identification label over the box provided. The printed label contains a bar code that is not the same as the ISBT-128 bar code.
Donor's Provider/Coordinator	Document the patient's provider and coordinator's name.
Donor's Diagnosis	Document the patient's diagnosis and/or reason for collection.
Donor's Initial Clearance Date	Document the initial date the donor was deemed eligible
Priming Method/Start Date	Document the donor's priming method and start date.
Physician order for Apheresis	<ul style="list-style-type: none"> The order will have the type of collection, date of collection, and goal. Located in the donor's electronic medical record (EMR) Original paper order will be filed in donor's stem cell lab record.
Apheresis Consent	<ul style="list-style-type: none"> Applicable for both autologous and allogenic collections. Physician or designee will obtain signature.
Summary of Donor Eligibility (APBMT-COMM-001 FRM3) *Send to STCL with every product daily.	<ul style="list-style-type: none"> Communicable disease testing is required for all allogenic products collected. This form is to be completed, reviewed for exceptions and signed prior to the patient arriving for apheresis. HPC, MNC, and PMN donation: the communicable disease tests must be drawn within 30 days of donation. DLI, NK Cell donation: the communicable disease tests must be drawn within 7 days of donation. This form, completed and signed, will cover all donations occurring within the required time periods. This form may be copied and used for each donation occurring within the required time periods, with the current barcode affixed. Fill in expiration date of the panel so it can be resent if it expires before or during apheresis.
Adult Donor History Questionnaire Allo and NMDP only Completed, reviewed for exceptions and signed by MD/Designee prior to apheresis. Must be updated every: <u>30 days for HPC, MNC, BM, and PMN</u> <u>7 days for DLI/NK cell donation</u>	<ul style="list-style-type: none"> The Adult Donor History Questionnaire is required to be completed for all Allogeneic and NMDP donors. HPC, MNC, and PMN donations: update every 30 days. DLI, NK Cell donations: update every 7 days. This form is to be completed, reviewed for exceptions and signed prior to the patient/donor arriving for apheresis. If there are any exceptions on the Donor Questionnaire: Section C of the Summary of Donor Eligibility form must be completed. Scan the Original Adult Donor History Questionnaire into the electronic medical record and Send to the lab for filing with product information.
HCG (Female Donors of childbearing age, prior to starting gCSF)	<ul style="list-style-type: none"> Done prior to starting growth factor or apheresis. Check the electronic medical record, for result.
HLA Typing	<ul style="list-style-type: none"> FDA required HLA testing should be performed on all allogenic donors.
Documentation of Venous Access	<ul style="list-style-type: none"> Check the electronic medical record, for report. If placed elsewhere, check chart for documentation of placement.

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Instructions

Day of Apheresis Procedure:

Place a check in the appropriate box ☒ **only** if the requirement has been met. If requirement is not applicable place a check in the appropriate box ☒ with **not applicable (N/A)** in the space provided.

Date	<ul style="list-style-type: none"> Document the date of procedure
Bar Code Label (ISBT-128)	<ul style="list-style-type: none"> Required for product identification and reference each collection. Send remainder to lab daily with product.
Patient ID Band	<ul style="list-style-type: none"> Ensure the patient has a correct ID band on. Verify patient name, spelling and birth date with the patient. Verify the history number with the EMR.
Type and Screen	<ul style="list-style-type: none"> The Type and Screen is a method of patient identification for auto/allo donors. A Type and Screen is required to be drawn on the first day of apheresis. A Type and Screen is required to be drawn every donation day for NMDP donors
Correct Visit Type	<ul style="list-style-type: none"> If the patient goes on the apheresis machine, route the correct visit type
Interim Donor History Questionnaire:	<ul style="list-style-type: none"> Completed for all Auto and Allo donors. Complete each day of collection. Attach Bar Code Label.
Machine Inspection	<ul style="list-style-type: none"> Verify the machine for cleanliness prior to collection Verify the machine is in maintenance compliance Document machine quality control record
Material/Supply Inspection	<ul style="list-style-type: none"> Verify all supplies needed for the apheresis procedure passes the visual inspection prior to loading the machine.
Temperature & Humidity Check	<ul style="list-style-type: none"> Record temperature & humidity and place a check in the box if results are within acceptable range. Contact Apheresis lead or designee if results are not within acceptable ranges.
Apheresis Run Sheet:	<ul style="list-style-type: none"> Complete each day of collection. Attach Bar Code Label. Scan into EMR and send Original to lab each day.
Product Bag Documentation	<ul style="list-style-type: none"> Place the demographic labels (STCL) as follows: Auto: Place the patient label on the side of the tag that the “patient weight” is to be recorded. Allo: Place the patient label on the side of the tag that the “patient weight” is to be recorded and record recipient’s weight. Then, place the donor label on the opposite side. Place a Bar Code Label, then tie the labeled demographic tags onto the HPC product and plasma bag.
Apheresis Log Book:	<ul style="list-style-type: none"> Scan the barcode and patient’s label. Record information each day of collection.

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Instructions

BMT Smart Form	<ul style="list-style-type: none"> • Enter the dates of mobilization and apheresis in the boxes provided in the EMR. • Enter the target information and total collected.
Product Base Label Creation	<ul style="list-style-type: none"> • These product-specific identification labels are required to be placed on the collection bags for each collection. • Document the product label information using the Hema-Trax software, which includes: <ul style="list-style-type: none"> ○ The start and expiration date and time. ○ Volume of bag and the amount of ACD-A is present • Attach Bar Code Label in the left upper corner, above the date of collection. • Apply label to collection bag(s) before patient is unhooked from the machine
Product Label(s) Verification	<ul style="list-style-type: none"> • All information on the Base Label and demographic tags are verified by two (2) RN staff members. Initial at completion.
Biohazard Label	<ul style="list-style-type: none"> • Placed on product (HPC) and plasma bag if there are any pending or reactive communicable disease tests, with the exception of CMV. .
Peer to Peer Paperwork Review	<ul style="list-style-type: none"> • Review paperwork between two (2) RN staff members to ensure correct GDP and information is appropriate. Initial at completion.
Complete Apheresis Plan Day	<ul style="list-style-type: none"> • Complete the apheresis plan after procedure has been completed.
Adverse Events Record	<ul style="list-style-type: none"> • Required to be completed only if an adverse event occurs during apheresis. • Record any side effects/symptoms experienced. • File in Adverse Events Record file in Apheresis.
Chain of Custody Form:	<ul style="list-style-type: none"> • Complete each day of collection. • Attach Bar Code Label. • Send to lab daily with product.
RN Signature	<ul style="list-style-type: none"> • Signature of the RN performing the apheresis procedure.

Signature Manifest**Document Number:** ABMT-COLL-001 FRM2**Revision:** 11**Title:** Apheresis Checklist FRM2**Effective Date:** 26 Jan 2024

All dates and times are in Eastern Time.

ABMT-COLL-001 FRM2 Apheresis Checklist**Author**

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