DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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DOCUMENT TITLE:
Summary of Donor Eligibility and Infectious Disease Testing FRM2

DOCUMENT NOTES:

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APBMT-COMM-001 FRM2 (Patient Label)

Summary of Donor Eligibility & Infectious Testing

Product Donation Date: _____ **DIN**:_____

Product Type: ☐ Autologous ☐ Allogeneic	**Program:** ☐ ABMT ☐ PBMT

Section A: Donor testing:

Donor Testing Performed: ☐ LabCorp ☐ Duke Labs ☐ Other Testing Site: _____

Instructions: Check whether the sample is Reactive (Positive), Non-Reactive (Negative), or Pending.

	Infectious Disease Testing:	**Results:**		
1.	Hepatitis B Surface Antigen (HBs-Ag)✹	☐ Positive	☐ Negative	☐ Pending
2.	Hepatitis B Core Total Antibody (HBc-Ab)✹	☐ Positive	☐ Negative	☐ Pending
3.	Hepatitis C Virus Antibody (HCV-Ab)✹	☐ Positive	☐ Negative	☐ Pending
4.	Treponema pallidum (syphilis) Antibody Screen	☐ Reactive	☐ Non-Reactive	☐ Pending
5.	Cytomegalovirus CMV Total Antibody	☐ Reactive	☐ Non-Reactive	☐ Pending
6.	HIV-1/HIV-2 Ab, HIV-1 Ag✹	☐ Positive	☐ Negative	☐ Pending
7.	HIV/HCV/HBV NAT ✹	☐ Reactive	☐ Non-Reactive	☐ Pending
8.	HTLV I/II Antibodies (HTLV I/II) ✹	☐ Positive	☐ Negative	☐ Pending
9.	West Nile Virus NAT✹	☐ Reactive	☐ Non-Reactive	☐ Pending
10.	Trypanosoma cruzi (Chagas) Antibody	☐ Positive	☐ Negative	☐ Pending

	Type and Screen Documentation:	**Results:**	
Instructions: Write the Group and Rh of the sample, then check whether the Antibody Screen is Positive or Negative.			
11.	ABO RH TYPE		
12.	RBC Antibody Screen	☐ Positive	☐ Negative

	Additional Testing Verification:	**Completed:**		
Instructions: Check YES whether the tests below have been completed, PENDING if results are pending, , or N/A if not applicable for collection.				
13.	HLA Confirmation/Verification Testing	☐ Yes	☐ Pending	☐ N/A
14.	Risk of Hemoglobinopathy (HEP/HbS)	☐ Yes	☐ No	☐ N/A
15.	Risk of Pregnancy (HCG)	☐ Yes	☐ No	☐ N/A

Table Footnotes: A CLIA-certified laboratory performs all testing.
✹FDA required testing for Allogeneic Donors.
The name of the establishment determining the eligibility of HCT/P is captured in APBMT-COMM-001 FRM2. It is located at 2400 Pratt Street, Durham, NC 27705.

Section B: Donor Clearance Review for Donation:

Instructions: Write the dates the questionnaire, addendum(s), and/or the infectious testing was collected and when it will expire. Then check YES if they are cleared for donation, NO if they are not cleared for donation, and Pending if Autologous testing has not resulted at time of donation.

APBMT-COMM-001 FRM2 (Patient Label)

Summary of Donor Eligibility & Infectious Testing

1.	Donor Health History Questionnaire[1]: (APBMT-COMM-001 FRM3)	Collected: ____/_____/_____ Expires: ___/_____/_____		
		☐ Yes	☐ No	☐ N/A
2.	Donor History Addendum(s)[1]:	COMM-QA-081 FRM _____		
		☐ Yes	☐ No	☐ N/A
3.	Infectious Disease Testing[1]:	Collected: ____/_____/_____ Expires:___/_____/_____		
		☐ Yes	☐ No	☐ Pending

[1] Required FDA Allogeneic Infectious Disease testing and risk factor screening for PBSC (Stem Cell), Bone Marrow, and Granulocyte Donations must be drawn within 30 days of donation, where DLI, NK Cell Donations must be drawn within 7 days.

Product Donation Date: _____ **DIN:_____**

Section C: Donor Clearance Met at Time of Donation:

Instructions:

- Check **YES** if the donor is eligible for donation or *AUTOLOGOUS*, then have the daily attending physician print, sign, and date.
- Check "**NO**" if the *Unrelated (NMDP) ALLOGENEIC* donor is deemed ineligible, and verify that a completed Document of Urgent Medical Need (DUMN) has been obtained and scanned into the electronic medical record (EMR). Then have the daily attending physician print, sign, and date.
- Check **NO** for any *Related ALLOGENEIC* donor who has pending verification or infectious disease testing and/or noted "**NO**" on any risk evaluation questions. Then go to Section D: Emergency Release for Cellular Products.

☐ **Yes**

I certify that I:

- ☐ Am aware of the autologous donor's pending infectious disease testing results and comfortable moving forward with the donation.
- ☐ Have reviewed the autologous donor's infectious disease testing results and the donor is deemed eligible for donation.
- ☐ Have reviewed all the allogenic donor's clearance results and the donor is deemed eligible for donation.

_____ _____ _____/_____/_____

Print Physician's Name *Physician's Signature* *Date*

☐ **No**

- ☐ Unrelated Allogeneic NMDP donor; see Document of Urgent Medical Need (DUMN)

I certify that the NMDP DUMN has been obtained and scanned into the electronic medical record (EMR).

_____ _____ _____/_____/_____

Print Physician's Name *Physician's Signature* *Date*

- ☐ **Related Allogeneic** donors with ANY **pending verfication results or pending infectious disease testing** and/or noted "**NO**" on any of the risk evaluation questions at the time of product donation.

Section D: Emergency Release for Cellular Products:

Instructions: The physician and Quality Manager/designee will review; then print, sign, and date as directed.

I certify that I have reviewed the donor's results and:

- Determined this cellular product to be an "**Urgent Medical Need**", urgent medical need, which means that no comparable HCT/P product (Human Cell, Tissue, or Cellular or Tissue-Based Product) is available and the recipient is likely to suffer death or serious morbidity without the transfusion of this cellular product.
- Verified the donor and recipient has signed the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Products* **PRIOR** to the donation.

_____ _____ _____/_____/_____

APBMT-COMM-001 FRM2 **(Patient Label)**

Summary of Donor Eligibility & Infectious Testing

Print Physician's Name	*Physician's Signature*	*Date*
		_____/_____/_____
Print Quality Manager's Name	*Quality Manger's Signature*	*Date*

Instructions for Completing the Summary of Donor Eligibility Form

Field	Requirements
Donation Instructions	
Patient Label	Apply donor's label.
Product Donation Date	Write the date the product is donated.
Unit ID#	Apply DIN (barcode) label
Product Donation Type	Check whether the product is an Autologous or Allogenic
Program	Check whether the donor is either an ABMT or PBMT donor.
Donor Testing Performed	Check whether the testing was performed at LabCorp Viromed, Duke Labs, and/or write the testing site.
Section A: Donor Testing: **Infectious Disease Testing** FDA requirements for infectious disease testing varies depending on type of product collection. 1. Autologous cell DO NOT require infectious disease testing, however, is a Duke APBMT Program best practice recommendation. 2. Allogenic cells require **ALL** FDA required testing.	Using the Donor Referral Panel-Viromed located in the donor's electronic medical record (EMR): 1. For Autologous Donors: a **REACTIVE** (Positive) and/or **PENDING** result for an infectious disease test under the Infectious Disease Testing header will NOT deem the donor ineligible to donate. 2. For Allogenic Donors: a **REACTIVE** (Positive) and/or **PENDING** result for an infectious disease test under the Infectious Disease Testing header will render the product and donor ineligible except for CMV and Treponema Pallidum (Syphilis) Antibody (confirmatory test is required). 3. Documentation of confirmatory test results of Treponema Pallidum (Syphilis) will be in donor's EMR, per FDA Per 21 CFR Part 1271.80(d)(1).
Section A: Donor Testing: **Type and Screen**	Write the **ABO** and **Rh** of donor sample.
Section A: Donor Testing: **RBC Antibody Screen**	Check whether the result is **Positive** or **Negative**
Section A: Donor Testing: **Additional Testing Verification** 1. Autologous cells may NOT require all listed testing. **2.** Allogenic cells require **ALL** verification testing. HCG testing if applicable.	1. HLA (Human Leukocyte Antigen): 1.1. Allogeneic donors and recipients shall be tested for HLA alleles. Typing shall include at a minimum HLA-A, B, and DRB1 type for all allogeneic donors and also HLA-C type for unrelated allogeneic donors and related allogeneic donors other than siblings. 1.2. Must have High-Resolution results at least once for confirmation (i.e.: High Resolution and High Resolution or High resolution and Low Resolution.) 1.2.1 In the event that confirmatory testing is pending at the time of donation, check "PENDING "and complete Section D

Instructions for Completing the Summary of Donor Eligibility Form

	2. Hemoglobinopathy assessment is required for all donors prior to mobilization for those at increased risk due to Sickle Cell Disease or Sickle-Beta-Thalassemia. 2.1. Testing can be performed using HEP or HbS results. 2.2. It is also reviewed on the APBMT-COMM-001 FRM3 Donor Health History Questionnaire. 3. Pregnancy during mobilization, chemotherapy regimen administration, or collection/harvest can be detrimental for a fetus. Therefore, a pregnancy test (HCG) shall be performed (blood or urine) on females of childbearing potential: 3.1. Within seven (7) days prior to starting the donor mobilization regimen or undergoing anesthesia 3.2. Within seven (7) days prior to the initiation of the recipient's preparative regimen 3.3. For collections without mobilization, a pregnancy test shall be performed within seven (7) days prior to cellular therapy collection
Field	**Requirements**
Section B: **Donor Clearance Review for Donation**	1. Write the date the Donor Health History Questionnaire was completed and the date it expires. 1.1. Check **YES** if the donor is clear for donation and **NO** if not clear 1.2. Check **N/A** if the donor is an ABMT Autologous patient 2. For the Donor History Addendum Form 1 & 3; for additional added addendums, write form(s) number, if applicable. 2.1. Check **YES** if the donor is clear for donation and **NO** if not clear 2.2. Check **N/A** if the donor is an ABMT Autologous patient 3. Write the dates the Infectious Disease Testing sample was collected and the date it expires 3.1. Check **YES** if the donor is clear for donation, **NO** if not clear, and **PENDING** for *Autologous* awaiting final infectious disease testing results. Refer to the Instructions for performing a PENDING form below. **Instructions for performing a PENDING form (Autologous ONLY):** ***NOTE:*** A PENDING result for an Autologous does NOT deem the donor ineligible. 1. Applying the donor's label 2. Write the date of donation and apply the DIN label 3. Check the appropriate type of donation and program 4. Complete the Type and Screen and RBC Antibody Screen 5. Complete the Additional Testing Verification 6. Under Section B: 6.1. Complete the Donor History Questionnaire and Donor History Addendum(s) 6.2. SKIP question #3 7. Under Section C: 7.1. Check YES 7.2. Check the appropriate box indicating the physician is aware of the autologous donor's pending infectious disease testing results.

Instructions for Completing the Summary of Donor Eligibility Form

	7.3 Have the daily physician/designee print, sign, and date the form. 8. Make a copy of the form 9. On the copy of the form, under Section A, mark pending under all Infectious Disease Testing Results and #3 Infectious Disease testing in Section B. The copied form with the "Pending" results will be sent to the STCL with the cellular product. 10. Place the original form in the PENDING folder located in the ABMT Apheresis Area. 11. Once, the results are available, the original form will be completed, scanned into the EMR, and sent to the STCL for documentation. ***NOTE:*** Original form for all PBMT autologous donor infectious disease testing may be maintained by the pediatric nurse coordinator until final results are obtained.
Section C: **Donor Clearance Met at Time of Donation**	If the donor is cleared at the time of donation or an AUTOLOGOUS collection: 1. Check YES 2. Check the box indicating review of autologous donor's infectious disease testing results and is deemed eligible for donation 3. Then have the daily attending physician print, sign, and date. If ALLOGENEIC donor is not clear at the time of donation: 1. Check "NO" 2. If NMDP DONOR: Check Unrelated Allogeneic NMDP donor and confirm DUMN is located in the EMR. a. The daily attending physician will print, sign, and date. If RELATED ALLOGENIC DONOR is not Clear at the time of Donation: Check **Related Allogeneic donor** with ANY **results pending** and/or noted **"NO" on any of the risk evaluations, then proceed to Section D.** ***NOTE:*** If the related donor is or will be considered not cleared or ineligible by the time of donation, an APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* consent will need to be signed by recipient and donor **PRIOR** to donation. Refer to Instructions for obtaining an APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* consent below. **Instructions for obtaining an APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* consent:** 1. The donor coordinator will notify the attending physician/designee and/or coordinator of clearance status and the need for the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* consent.

Instructions for Completing the Summary of Donor Eligibility Form

	2. The attending physician/designee will perform notification to the recipient of the product and be responsible for obtaining the consent. ***NOTE:*** The recipient has the right to refuse and the donation will not take place. Notification to the collection and processing facility should take place promptly. 3. If the recipient agrees to potentially receive a product that is not cleared or deemed ineligible at the time of donation, the attending physician/designee will obtain consent using the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* and ensure it is scanned into the EMR for the verification by the collection facility prior to donation. 4. The collection facility staff will verify the consent has been obtained via the EMR and ensure the STCL has a copy. 5. Prior to donation day or at minimum on the day of donation, the donor coordinator must obtain consent using the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* from the donor. ***NOTE:*** If the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* consent has **NOT** been obtained on both donor and recipient prior to donation, the donation will **not** be performed until confirmation of consent has been reviewed and documented.
Section D: **Emergency Release for Cellular Product**	The attending physician is responsible for reviewing any exception, verifying the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Product* consent has been completed, and determine if the product is acceptable as an "Urgent Medical Need". After the physician determines the cellular product is deemed an urgent medical need and accepted, the physician and quality manager/ designee will print, sign, and date form.

Revision History

05	K Beale M Christen K Lynch	Section A Updates: • Updated verbiage to Section A: Donor Testing under Instructions for Completing the Summary of Donor Eligibility Form • Removed Zika Virus requirements, no longer FDA-required • Updated the Additional Testing Verification, which includes, adding Confirmation/Verification to the HLA Testing, updating the risk of hemoglobinopathy testing, and adding the test name for pregnancy. Section C Updates: • Updated title and clarified instructions regarding completion. • Clarified "Yes" certification and provided appropriate checkboxes. • Added "No" instructions and post-actions regarding NMDP DUMN. • Added "No" instructions and post-actions regarding related allogeneic donors with either pending results or positive for risk factors based on risk evaluation. Instruction Updates: • Clarified Section A instructions regarding Autologous donors with reactive/pending results "will NOT deem the donor ineligible to donate". • Clarified HLA testing requirements. • Updated pregnancy test name (HCG) • Clarified the Autologous Donor Pending Result procedure. • Updated Section C and D requirement using step-by-step instructions.

Signature Manifest

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

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