DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Donor Selection, Evaluation and Management

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APBMT-COMM-001
DONOR SELECTION, EVALUATION, AND MANAGEMENT

1 PURPOSE

1.1 To define the steps for donor selection, evaluation, and management for the donation of allogeneic and autologous cellular products in the adult and pediatric blood and marrow transplant (BMT), which includes cellular therapy (CT) programs. Donations may consist of any of the following:

1.1.1 Mobilized or non-mobilized peripheral blood

1.1.2 Directed and unrelated donor umbilical cord blood

1.1.3 Directed and unrelated bone marrow

2 INTRODUCTION

2.1 The multidisciplinary care team, led by the recipient's primary physician, will make the final determination of the treatment protocol and source of donor cells. Once determined, all donors, both allogeneic and autologous, must be cleared by trained medical personnel.

2.2 Many diagnoses affect adult and pediatric patients undergoing hematopoietic stem cell transplant (HSCT). Autologous and allogeneic transplants are performed in both adult and pediatric populations. Cells are obtained from bone marrow (BM), umbilical cord blood (UCB), or by peripheral blood donations of stem cells (PBSC). These donations help to facilitate marrow rescue after high-dose chemotherapy in patients with certain high-risk hematologic malignancies or recurrent solid tumors.

2.3 Allogeneic peripheral donations of mononuclear cells (PBMC) that may include granulocytes, lymphocytes, and natural killer (NK) cells may be utilized in the peri-transplant period to enhance protection against opportunistic pathogens or graft versus tumor effects.

2.4 Autologous PBMC donations may be utilized in either research studies or in the manufacturing of Chimeric antigen receptor T-cell (CAR-T) therapy treatments.

2.4.1 CAR-T treatments are utilized in the treatment of some types of cancer in which a patient's T-cells are genetically engineered in a laboratory to target and attack cancer cells in the patient's peripheral blood.

2.5 Cellular products from related donors and unrelated donors are used as indicated by medical practice under 21 CFR 1271 and Public Health Service Act Section 361.

2.6 Unrelated donor products are obtained through the NMDP, formally National Marrow Donor Program More than minimally manipulated cells from unrelated donors, such as donor lymphocyte infusions (DLIs), aldehyde dehydrogenase bright cells (ALDHbr), or CD-34 Select donations, may be used under IND per FDA 21 CFR 1271, 361.

3 SCOPE AND RESPONSIBILITIES

3.1 Physicians, Coordinators, Register Nurses (RN), Advanced Practice Providers (APPs), and Medical Technologist/Clinical Laboratory staff are required to follow these guidelines.

4 DEFINITIONS/ACRONYMS

4.1 *Eligible:* An allogeneic cellular therapy product donor for whom all the donor screening and testing have been completed in accordance with Applicable Law and who has been determined to be free of risk factor(s) for relevant communicable disease.

4.2 *Suitable:* Donor or recipient suitability refers to issues that relate to the general health or medical fitness of the donor or recipient to undergo the collection procedure or therapy.

4.3 *Urgent Medical Need:* A situation in which no comparable cellular therapy product is available, and the recipient is likely to suffer death or serious morbidity without the cellular product.

4.4 *Coordinator*: A nurse clinician who works with donors and/or legally authorized representative(s) to provide care across the continuum from pre-donation and if applicable during and post-transplant by providing coordination, support, and education.

4.4.1 Throughout this document, the coordinator, including nurse coordinator/clinician, donor coordinator, and transplant coordinator, will be called coordinator for better readability.

4.5 *Designee*: An individual with appropriate education, experience, or expertise who is given the authority to assume a specific responsibility. The person appointing the designee retains ultimate responsibility.

4.5.1 Throughout this document, the APPs, including physician assistants and nurse practitioner, will be called a designee.

4.6 ABMT Adult Blood and Marrow Transplant

4.7 ABO Blood Type

4.8 ALDHbr Aldehyde dehydrogenase bright cells

4.9 APBMT Adult and Pediatric Blood and Marrow Transplant

4.10 APP Advanced Practice Providers

4.11 ASHI American Society of Histocompatibility Immunogenetics

4.12 BCC Blood Cancer Center

4.13 BM Bone Marrow

4.14 BMT Blood and Marrow Transplant

4.15 CAP College of American Pathologist

4.16 CAR-T Chimeric Antigen Receptor T-cell

4.17	CBC/diff	Complete Blood Count with Differential
4.18	CD34	CD-34 antigen on white blood cells
4.19	CFR	Code of Federal Regulation
4.20	CLIA	Clinical Laboratory Improvement Amendments
4.21	CMP	Complete Metabolic Profile
4.22	CT	Cellular Therapy
4.23	CVC	Central Venous Catheter
4.24	DLI	Donor Lymphocyte Infusions
4.25	DUMN	Document of Urgent Medical Need
4.26	EMR	Electronic Medical Record
4.27	FACT	Foundation for the Accreditation of Cellular Therapy
4.28	FDA	Food and Drug Administration
4.29	G-CSF	Granulocyte-Colony-Stimulating Factor
4.30	H&P	History and Physical
4.31	HCG	Human Chorionic Gonadotropin
4.32	HLA	Human leukocyte antigen
4.33	HSCT	Hematopoietic Stem Cell Transplant
4.34	IND	Investigational New Drug
4.35	IR	Interventional Radiology
4.36	PIV	Peripheral Intravenous
4.37	Mg	Magnesium
4.38	NK	Natural Killer Cells
4.39	NIH	National Institute of Health
4.40	NMDP	National Marrow Donor Program
4.41	PBMC	Peripheral Blood Mononuclear Cells
4.42	PBMT	Pediatric Blood and Marrow Transplant
4.43	PBSC	Peripheral Blood Stem Cell
4.44	PRA	Panel Reactive Antibodies
4.45	RBC	Red Blood Cell
4.46	Rh	Rhesus factor
4.47	RN	Registered Nurse
4.48	SC	Subcutaneous Injection
4.49	STCL	Stem Cell Laboratory
4.50	UCB	Umbilical Cord Blood

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Donor Selection

8.1.1 Donors are evaluated to determine whether they are candidates for autologous or allogeneic transplantation, and, within each category, which type of cellular graft is their best option. Alternative donation methods will be discussed.

8.1.2 If an allogeneic transplant is determined to be the best option, a donor search is performed using related donors or through NMDP for unrelated donors. For more information regarding the NMDP, refer to ABMT-COLL-004 *NMDP Stem Cell Donation Procedure* and APBMT-COMM-041*Processing Facility Notification for Cellular Product Request*.

8.1.2.1 Information regarding the donation process will be provided to the potential allogeneic donor prior to human leukocyte antigen (HLA) typing. Refer to Section Titled “HLA Typing (Allogeneic donors, both related and unrelated)” for more information regarding the need for HLA typing.

8.1.2.2 Both related and unrelated donor options are evaluated for donor suitability.

8.1.2.2.1 The best available donor choice and cellular therapy type will be based on the recipient’s diagnosis, disease state, and co-morbidities.

8.1.2.3 When using peripheral or BM donations from related or unrelated donors, the clinical team should determine the number of cellular therapy donations permitted by the individual donor.

8.1.2.3.1 At a minimum, the allogeneic donor’s medical comorbidities and peripheral blood counts will be considered in the decision-making process for multiple donations.

8.1.2.4 If there are two or more suitable donors, the attending physician will determine which donor will be selected considering all aspects of the donor’s availability, HLA type match, and donor workup findings.

8.1.2.5 If a matched related or unrelated donor is not available, a mismatched related (haploidentical), mismatched unrelated, or UCB donors are evaluated for use.

8.1.2.5.1 In certain patient populations (e.g. sickle cell disease, thalassemia) a related haplo donor may preferentially be considered the choice donor as supported by scientific literature for any given disease state. Donor selection will be determined utilizing a combination of current scientific literature, available donor source, and clinical status for the recipient patient.

8.1.2.5.2 If an UCB is utilized, the units under consideration for selection will be HLA typed utilizing an attached segment to the cryopreservation bag in which the unit was banked. If a segment is not available, the unit will not be selected for the patient.

8.1.3 Donor age-specific and size-specific considerations will be applied.

8.1.3.1 Age-appropriate considerations will be applied to minor donors (less than (<) 18 years of age) and older (greater than (>) 60 years of age) donors.

8.1.3.2 Depending on the type of donation and/or the recipient, the donation will occur within either the adult or pediatric program utilizing the standard of care for screening, collection, and if indicated, line placement with or without sedation or general anesthesia.

8.1.3.2.1 Each will be performed by an age-specific trained specialist in those fields.

8.1.3.3 Autologous donations performed by a minor (less than (<) 18 years of age) will occur within the Children's Health Clinic (CHC).

8.1.3.4 Autologous donations performed by an older donor (donors greater than or equal to (≥) 18 years of age may occur within the ABMT apheresis area or the CHC depending on the provider group covering.

8.1.3.5 Allogeneic donation performed by an older donor (donors greater than or equal to (≥) 18 years of age) donating for an adult patient or to a pediatric patient will occur within the ABMT apheresis area.

8.1.3.5.1 If the recipient is a pediatric patient, the pediatric clinical team will consult with colleagues in the adult program as needed. **NOTE:** The pediatric clinical team will

determine if additional consultations are needed for line placement, transfusion, iron therapy, and/or Vitamin K therapy. Follow-up will be assessed and coordinated by the primary team.

8.1.3.6 The adult and/or pediatric donor's size determines if the apheresis machine will require a blood prime. Refer to APBMT-COLL-001 *Optia Blood Prime Procedure.*

8.2 Donor Advocates

8.2.1 According to Donor Registries for Bone Marrow Transplant, Technology Assessment (NIH Office of Medical Applications of Research, 1985) the role of the advocate is to:

8.2.1.1 Help ensure that the donor consent is made without time pressure and with full information.

8.2.1.2 Enhance the personal attention given to the donor during procedures.

8.2.1.3 Help prevent unnecessary inefficiencies and discomfort.

8.2.1.4 Mobilize official expressions of gratitude after the donation.

8.2.1.5 Aid in the resolution of subsequent problems.

8.2.2 Donors who are minors or mentally incapacitated may be assigned a donor advocate whose primary obligation is to help the donor understand the risks and benefits of donation and promote the donor's interest, well-being, and safety.

8.2.2.1 The donor advocate will be either a social worker, coordinator, or another provider not involved in the recipient's care.

8.2.2.2 The donor advocacy role will be documented.

8.2.3 Additionally, donors who are mentally incapacitated or not capable of full consent, including minors, will have their best interest represented by a parent/legally authorized representative or another authorized medical decision-maker.

8.2.3.1 A donor advocate will be utilized to appropriately counsel the donor and protect them from unsafe or futile donation procedures.

8.2.3.2 A donor advocate will be available if concerns are raised regarding whether the best interests of the donor are being adequately protected.

8.3 Donor Consent

8.3.1 Donor informed consent for the cellular therapy product donation shall be obtained and documented by a physician or designee knowledgeable

in the donation procedure and copies are provided to the collection facility prior to donation.

8.3.1.1 Unrelated donors are consented by their respective donor center or the NMDP team.

8.3.2 Before signing the written consent, the donors will undergo an educational session with a physician or designee and follow-up review with the coordinator, trained to transmit information appropriately and clearly.

8.3.2.1 These educational sessions are explained in terms the donor can understand, in their native language, and opportunities will be given to ask questions if needed.

8.3.2.2 Topics will include, as applicable for each donor:

8.3.2.2.1 Details and intent of the planned procedure

8.3.2.2.2 Test and procedures performed for safety

8.3.2.2.3 Possible need for a central venous catheter (CVC) line access

8.3.2.2.4 Mobilization administration

8.3.2.2.5 Potential risks and benefits of the procedure

8.3.2.3 For more information regarding the donor consenting process, please refer to the following procedures for the adult and pediatric programs respectively: ABMT-GEN-024 *Autologous and Allogeneic Donor Consenting* and PBMT-GEN-059 *Autologous and Allogeneic Donor Consenting Procedure*.

8.4 Donor Evaluation

8.4.1 The Adult and Pediatric Blood and Marrow Transplant (APBMT) programs can evaluate autologous and related/unrelated allogeneic donor's where the donation is performed at Duke Hospital. The evaluation is done to protect the health of the donor and the recipient and to prove eligibility per FDA donor regulations (21 CFR Part 1271. The coordinator, as it is program-specific, will coordinate one or more clinic visits for donor evaluation.

8.4.1.1 For allogeneic donors, the coordinator will arrange the donor workup to be concomitant with the recipient's pre-transplant workup.

8.4.2 Unrelated allogeneic donors not collected at Duke are evaluated by the registry that facilitates the donation for transplantation, such as NMDP donations.

8.4.3 Donor evaluation information will be documented on the Duke Electronic Medical Record (EMR) utilizing the history and physical (H&P) form or related document.

8.4.3.1 APBMT notes located in the EMR are utilized for subsequent documentation not captured in the H&P during any outpatient visit.

8.4.3.2 Documentation is maintained in the EMR as per internal policy.

8.4.4 All donor evaluations and physical examinations are performed in a private room where all information may be confidentially maintained.

8.4.4.1 Autologous donors' exams will be performed by the primary physician or designee for autologous donors.

8.4.4.2 Related allogeneic donors' exams will be performed by a physician or designee that is not the primary transplant team overseeing the care of the recipient.

8.4.5 All donors will undergo the following during these visits:

8.4.5.1 Review of current medications and a medical review assessing for signs of IV drug abuse, heart disease, coagulation problems, and/or hypertension.

8.4.5.2 Donor screening labs and age-appropriate related testing, performed during evaluation. Refer to APBMT-COMM-001 JA2 *Collection of Donor Blood Samples for Infectious Disease Testing* for more information regarding donor infectious disease testing and other potential labs for eligibility.

8.4.5.2.1 For allogeneic donors testing is done to rule-out issues that may result in disease transmission from the donated cellular therapy product to the recipient per FDA donor regulations (21 CFR Part 1271).

8.4.5.3 Donor screening questionnaires, such as the APBMT-COMM-001 FRM3 *Donor Health History Questionnaire,* will review vaccination, travel, and blood transfusion histories.

8.4.6 Donor Questionnaire: APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* will be completed at a minimum on all allogenic donors greater than (>) 18 years of age.

8.4.6.1 The completed questionnaire will be signed and scanned in the EMR and the original will be sent to Stem Cell Laboratory (STCL) to file in laboratory file.

8.4.6.2 For the pediatric program the donor, or the parent or legally authorized representative in the case of a minor (less than (<) 18 years of age), will be provided with the questionnaire.

8.4.6.3 For the adult program only, allogeneic donors will be provided with the questionnaire.

8.4.6.4 The donor or the parent/legally authorized representative can complete the questionnaire independently and return it for review. Assistance in completing the questionnaire will be provided if needed.

8.4.6.5 Donors will be required to complete sections that apply to them individually. In the case of a minor (less than (<) 18 years of age), the parent or legally authorized representative will complete sections that apply to the minor donor.

8.4.6.6 The coordinator will use the APBMT-COMM-001 JA1 *Medical History Exclusion Criteria* as needed to assist the donor and/or parent/legally authorized representative in completing the questionnaire.

8.4.6.7 The coordinator assisting will review the completed questionnaire and applicable supplements and addendums.

8.4.6.8 After obtaining this information, if any exceptions and/or answered questions indicating an increased risk of infectious disease transmission to the recipient, the physician will assess the risks and benefits of the donation.

8.4.6.8.1 If the physician deems that the donation should occur despite the exception, he/she will document this on the questionnaire.

8.4.6.8.2 If the physician deems that the donation should not occur, the donation will be canceled, and the donor will be informed of this decision.

8.4.7 Supplement to the questionnaire, such as education material titled "Important Information You Must Know for Donations to Stem Cell Transplant Patients" is attached to the questionnaire.

8.4.7.1 This will be provided, at a minimum, to all allogeneic donors greater than or equal to (≥) 16 years of age.

8.4.7.1.1 This material may also be provided to other donors at the clinician's discretion.

8.4.8 An additional supplement to the questionnaire, referred to as COMM-QA-081 *Utilization of a Donor Medical History Addendum* will be provided to donors when required, as applicable.

8.4.8.1 Those administering the donor questionnaire should check to see if any addendums are active/required at the time of questionnaire administration. Addendums will be designated as a form (COMM-QA-081 FRM XX).

8.4.9 Donation Timeline:

8.4.9.1 The questionnaire will cover the entire donation period of 30-days for peripheral blood donations (PBSC and select

PBMC, such as granulocytes) and BM donations and for 7-days for specific PBMCs, such as for a DLI and/or NK Cell donations unless there is a change in donor status.

8.4.9.2 If a donor is donating multiple times and the questionnaire elapsed from the initial donor qualification and the day of the actual donation, the coordinator will re-administer the questionnaire. The same procedure for reviewing and noting exceptions applies to each administration of the questionnaire.

8.4.10 Donor Test Requirements

NOTE: If any testing results are out of the normal range, the donor's physician will review the result and appropriate therapy will be prescribed, if indicated.

8.4.11 Routine labs - All donors will have routine labs performed at minimum once to maintain clinical monitoring. This may include:

8.4.11.1 Chemistry panels (CMP)

8.4.11.2 Magnesium

8.4.11.3 Coagulation factors

8.4.11.4 Human chorionic gonadotropin (HCG)

8.4.12 Additional testing:

8.4.12.1 Blood count with differential (CBC/diff) – which will be tested within 24 hours of the first apheresis donation or more often if clinically indicated and reviewed by the physician or designee.

8.4.12.2 The donor will be evaluated for the risk of hemoglobinopathy and if indicated hemoglobin electrophoresis will be performed prior to the administration of the mobilization agents.

8.4.12.3 A pregnancy test using serologic or urinalysis is performed on females of childbearing age within seven (7) days prior of the donor donating either non-mobilized or mobilized cells and, as applicable, within seven (7) days prior to of initiation of G-CSF administration, anesthesia administration, and the recipient's conditioning regimen.

8.4.12.3.1 Exempt from the pregnancy testing are females: who have had a hysterectomy, are over the age of 55, who are age 50 or greater with 12 months since last menses, who are age 45 or greater with 18 months since last menses. The pregnancy assessment (if testing is not indicated) will be addressed in the physician note.

8.4.12.3.2 Documentation of a negative pregnancy test and/or pregnancy assessment must be obtained.

8.4.13 HLA Typing (Allogeneic donors, both related and unrelated):

8.4.13.1 HLA typing from the prospective donor and the recipient is tested by an American Society of Histocompatibility Immunogenetics (ASHI) certified laboratory and/or an accredited College of American Pathologists (CAP) organization.

8.4.13.2 Typing includes at a minimum HLA-A, B, and DRB1 type for all allogeneic donors and HLA-C type for unrelated allogeneic donors and allogeneic donors other than siblings.

8.4.13.3 DNA High-resolution HLA-typing is initially performed and utilized for final donor selection. Verification and/or confirmatory HLA typing is performed for all donors and recipients using independently collected samples so that each pair is typed twice and a minimum of one of the types is at high resolution.

8.4.13.4 If the recipient has a history of alloimmunization, an anti-HLA antibody screen (PRA) will be obtained. If anti-HLA antibodies are present, every effort will be made to select an allogeneic donor who is negative for these antigens/alleles. If this is not possible, a desensitization program will be considered prior to or as part of cytoreduction. Additional anti-HLA antibody testing may be performed at intervals consistent with established clinical transplant protocols and following sensitizing events.

8.4.13.5 Verification and/or confirmation results shall be confirmed prior to administration of the preparative regimen, mobilization, or cellular therapy product donation, whichever is earliest.

8.4.13.5.1 In the event verification and/or confirmation typing is PENDING and/or unavailable due to unforeseen circumstances, such as testing machine malfunction, prior to donation the attending provider teams will do the following:

- Document the reason for the **Urgent Medical Need**, such as the selected donor's failure to mobilize after recipient started prep, in the EMR.
- Obtain APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of*

Emergency Cellular Products consent from donor and recipient.

- Complete the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing* and obtain the appropriate signatures in Section D: Urgent Medical Need.

8.4.14 ABO group and Rh type/Type and Screen:

8.4.14.1 Autologous and Allogeneic donors and recipients will be tested for ABO group and Rh type/Type and Screen (which includes red cell antibody) using two independently collected samples prior to donation.

8.4.14.2 Autologous donors: Two independently collected ABO/Rh or Type and Screen samples are obtained prior to chemotherapy regimen and the issue of cellular therapy products.

8.4.14.3 If discrepancies are noted, another ABO group and Rh type/Type and Screen will be drawn from the donor/recipient. Discrepancies will be resolved and documented in the donor/recipient's EMR before the issue of the cellular therapy product.

8.4.15 Infectious Disease Testing Requirements and Documentation:

8.4.15.1 Refer to APBMT-COMM-001 JA2 *Collection of Donor Blood Samples for Infectious Disease Testing* for all required testing and common eligibility labs collected by Duke.

8.4.15.2 Testing for infectious disease is documented on the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing* and performed per the Foundation for the Accreditation of Cellular Therapy (FACT) requirements by a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory for donor screening using the Food and Drug Administration (FDA) approved or cleared donor-screening kits.

8.4.15.3 Donation Timeline:

8.4.15.3.1 For donors undergoing donation for peripheral donations (PBSC, PBMC, and PBPC), CAR-T, BM, and dedicated granulocyte donors, infectious disease testing will be completed within 30 days of the donation, unless outlined specifically by a study. Donors donating over the 30 days will have these tests repeated.

8.4.15.3.2 For all donors undergoing donation for NK or DLI donations, infectious disease testing will be completed within 7 days of the donations. Donors donating over the 7 days will have these tests repeated.

8.4.16 Unrelated UCB donors are tested by the cord blood bank at the time of procurement of the cord blood donation. This information is provided to the transplant center through the NMDP data systems.

8.4.17 Donor Testing Documentation and Storage:

8.4.17.1 The results of FDA and eligibility required testing will be documented on APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing*. The original APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing* form will be scanned into the EMR and accompany each collected product to the STCL.

8.4.18 The clinical program is responsible for informing the collection facility and processing facility, as applicable, of donor test results or if any testing which was not performed.

8.5 Donor Ineligibility

8.5.1 Donor ineligibility at the time of donation is based on information found on either the APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* or the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing,* which is reviewed and signed. Positive findings for autologous donors do not deem the donor ineligible to donate.

8.5.1.1 Abnormal findings on the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing* and/or the APBMT-COMM-001 FRM3 *Donor Health History Questionnaire* will be discussed with the donor and possible recommendation for follow-up may be given, if applicable.

8.5.2 If the allogeneic donor is deemed ineligibile due to pending infectious disease testing or by the questionnaire and addendum, refer to the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing*, for specific instructions.

8.5.2.1 Donation from a donor who does not meet donation safety suitability and/or eligibility criteria shall require documentation of rationale why the donor was selected by the attending physician/designee.

8.5.2.2 Donation from a donor from the NMDP does not meet donation suitability and/or eligibility criteria shall require a completed Document of Urgent Medical Need (DUMN) provided by the NMDP to be scanned into the donors EMR.

8.5.3 The decision to use an "Urgent Medical Need" product will be discussed with the recipient PRIOR to donation and informed consent of both the donor and recipient must be documented. Refer to the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing* form for "Urgent Medical Need" documentation and the consent APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Products* for more information.

8.5.3.1 In limited scenarios and at the discretion of the attending physician, there may be situations where the physician deems donor ineligibility notification to the donor and/or the recipient is not necessary or in which consent may not be obtained as determined either by medical significance or otherwise. At such a time, this will be documented accordingly.

8.5.3.2 For unrelated donors collected at Duke for NMDP, results of positive donor screening tests will be provided to the NMDP who will inform the donor and prospective recipient as indicated.

8.5.4 The use of the APBMT-COMM-001 FRM1 *Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Products* consent will follow the donation timeline set forth by the APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing* form.

8.5.4.1 Completed forms will be:

8.5.4.1.1 Signed by the physician

8.5.4.1.2 Scanned into the EMR

8.5.4.1.3 Original copy will be delivered to STCL

8.6 Donor Clearance

8.6.1 Donor eligibility shall be confirmed and documented by the physician after a review of the donor's health history, exam, medical record, and testing results.

8.6.1.1 In the case of an allogeneic donor, eligibility will be documented in the recipient's medical records before the recipient's preparative regimen is initiated and before the allogeneic donor begins mobilization regimen when mobilization is required.

8.6.1.1.1 Records required for donor selection and eligibility determination will be in English or translated into English when crossing international borders.

8.6.1.2 All donors must be cleared and donor eligibility confirmed before donation for the following as applicable to each donor:

8.6.1.2.1 Apheresis procedure(s)

8.6.1.2.2 BM procedure(s)

8.6.1.2.3 Not currently pregnant

8.6.1.2.4 Anesthesia administration for BM procedures

8.6.1.2.5 Adequate peripheral venous access or CVC placement

8.6.1.2.6 Growth factor administration

8.6.1.3 The donor and the recipient, if applicable must demonstrate that he/she can:

8.6.1.3.1 Be compliant with the medications prescribed by their physician.

8.6.1.3.2 Manage a CVC, or report to care sites within the health system for this care.

8.6.1.3.3 Be compliant with appointments, generally twice per week.

8.6.1.3.4 Be able to avoid contact sports or contact activities during work or other daily responsibilities.

8.6.2 In addition, allogeneic donors must be evaluated and cleared for the following:

8.6.2.1 Infectious diseases

8.6.2.1.1 Testing must be negative or, if positive, cleared by the donor's physician

8.6.2.2 General anesthesia for marrow donation, if applicable

8.7 Donor Thresholds

8.7.1 Adult autologous donors must have adequate levels of the following prior to each donation:

8.7.1.1 Hemoglobin ($\geq$ 8 g/dL)*

8.7.1.2 Platelet count ($\geq$ 10,000/μL)

NOTE: The autologous donor may donate with hemoglobin between 7 and 7.9 g/dL if the autologous donor is receiving a blood transfusion at the end of the donation procedure.

8.7.2 Adult-related allogeneic peripheral blood donors must have adequate levels of the following before each donation:

8.7.2.1 Hemoglobin ($\geq$ 9 g/dL)

8.7.2.2 Platelet count (≥ 50,000/μL)

8.7.3 Adult unrelated allogeneic (NMDP) peripheral blood donors must have adequate levels of the following before donation.

8.7.3.1 Hemoglobin (≥ 9 g/dL)

8.7.3.2 Platelet count (≥ 120,000/μL) *Day 1

8.7.3.3 Platelet count (≥ 80,000/μL) *Day 2

8.7.4 Granulocyte donors must have the following before each donation:

8.7.4.1 Hemoglobin (≥ 10 g/dL)

8.7.4.2 If hemoglobin is < 10.5 g/dL, check the hemoglobin the day before the next planned donation.

8.7.4.2.1 If the hemoglobin is ≥ 10 g/dL, proceed with the procedure the next day without waiting for labs that are drawn at the time of the procedure.

8.7.4.2.2 If the hemoglobin is less than < 10 g/dL, skip the procedure and recheck the day before the next planned procedure.

8.7.5 Pediatric donors must have adequate levels of the following prior to each donation:

8.7.5.1 Hemoglobin

8.7.5.1.1 Pediatric donors weighing less than 50 kg, for which the cell separator is primed with packed red cells, the pre-apheresis parameters are hemoglobin > 9 g/dL.

8.7.5.1.2 Pediatric patients weighing more than 50 kg, for which the cell separator is NOT primed with packed red cells, the pre-apheresis parameters are a hemoglobin > 10 g/dL.

8.7.5.2 Platelet count (≥ 75,000/μL)

8.7.6 Returning Donors:

8.7.6.1 Adult allogenic donors returning for peripheral blood donation or BM donation within 6 months of original donation must have the items listed below reviewed by their primary BMT clinical team and be cleared for repeat donation. A progress note must be documented to support approved clearance.

8.7.6.1.1 Previous medical records, tests, and labs.

8.7.6.2 Adult allogenic donors returning for peripheral blood donation or BM donation greater than 6 months of original donation must have:

8.7.6.2.1 A full repeat donor selection evaluation.

8.7.6.3 Any original adult allogeneic peripheral blood donor returning for DLI donation must have the items listed below reviewed by their primary BMT clinical team and be cleared for repeat donation. A progress note must be documented to support approved clearance:

8.7.6.3.1 Previous medical records, tests, and labs.

8.7.7 Multiple donations:

8.7.7.1 For donors donating multiple times consecutively, additional parameters should be considered. These donors are more likely to become iron deficient, hypokalemic, or hypoproteinemia over longer donation times. As such, these donors require more careful monitoring and follow-up.

8.7.8 Allogeneic donors may be pretreated with therapeutic iron and/or vitamin K.

8.8 Donor Collections

8.8.1 A written order from a physician specifying, at minimum, anticipated date and goals of donation and processing shall be documented. Refer to STCL-FORM-041 *Doctors Orders Adult Stem Cell Transplant Program* and PBMT-COLL-016 *Pediatric Apheresis Order Using Optia.*

8.8.2 There shall be written documentation of any donor health or safety issues pertaining to the donation procedure in writing to the Apheresis Collection Facility. Collection staff shall document a review of these issues prior to the donation.

8.8.3 Donor apheresis consent must be reviewed prior to the donation.

8.8.4 Peripheral Blood Access:

8.8.4.1 The appropriate and safe positioning and function of a CVC or peripheral intravenous catheter (PIV) is critical to the performance of the cellular therapy product donation by apheresis.

8.8.4.2 Adult allogeneic donors will have a peripheral vein assessment by a collection facility RN in consultation with the coordinator and the donor's primary team. A plan for CVC placement will be made if needed on donation day. Adult allogeneic donors require a CVC only if peripheral vein access is inadequate or unsuccessful.

8.8.4.2.1 Allogeneic donors of granulocytes will have a CVC placed before their donations to avoid consecutive PIV sticks.

8.8.4.3 Autologous donors for peripheral blood may have a CVC or a PIV placed prior to donation.

8.8.4.3.1 Adult donors that will go directly to transplant will have a CVC placed.

8.8.4.4 A licensed, trained, and qualified physician qualified to perform the procedure, which may include pediatric surgeons, general surgeons, or vascular radiologists, places CVCs.

8.8.4.5 The correct placement of the CVC placed in Interventional Radiology (IR) is performed using ultrasound guidance and confirmed by radiograph. If CVC was placed in general surgery, a radiograph confirms placement. The adequacy of the CVC placement is verified and documented in the donor's EMR.

8.8.4.6 Before the donation and use of a CVC, the collection facility RN staff must review the documentation of the CVC placement and appropriateness for use. The rationale for placement shall be documented in the donor's EMR. If the CVC is placed at a referring hospital, a copy of the CVC confirmatory report is obtained and placed in the donor's EMR.

8.8.5 Mobilization Administration:

8.8.5.1 Appropriate mobilization should be used for the diagnosis/disease being treated and for the donor being collected.

8.8.5.2 Mobilization requires an evaluation of any medical condition that would expose the donor to the risk of thrombotic events. This evaluation must be documented, including the pre-donation and donation period specific to growth factor administration. For adult BMT, refer to ABMT-GEN-034 *Colony Stimulating Factor Guidelines.*

8.8.5.3 The donor will be evaluated for the risk of hemoglobinopathy and if indicated hemoglobin electrophoresis or hemoglobin S will be performed prior to the administration of the mobilization agents.

8.8.5.4 Granulocyte Colony-Stimulating Growth Factors (G-CSF) are administered under the supervision of a licensed physician or designee experienced in the management of persons receiving these agents.

8.8.5.4.1 Specific orders for each donor are generated and filled by Duke's inpatient/outpatient pharmacy, local licensed pharmacies, or home health pharmacies depending on the patient's arrangement with their third-party payer.

8.8.5.5 For pediatric donors:

8.8.5.5.1 The first dose of G-CSF is administered usually by subcutaneous (SC) route in the clinic or on the inpatient unit.

8.8.5.5.2 If the first dose is tolerated, subsequent doses are administered either by nursing staff in the clinic or inpatient unit, or their parent or legal guardian outpatient after training has been completed.

8.8.5.6 For adult donors:

8.8.5.6.1 G-CSF is administered SC by nursing staff in the clinic or inpatient unit, or at home by their caregiver or self-injection after training has been completed a minimum of one hour to a maximum of 12-18 hours before the next planned procedure.

8.8.5.7 Donors may be mobilized with G-CSF depending on the type of donation requested.

8.8.5.7.1 Mobilization for autologous PBSC donations includes G-CSF +/- chemotherapy and if indicated, Plerixafor (Mozobil) or Motixafortide (Aphexda) may be used.

8.8.5.7.2 Mobilization for allogeneic (PBSC, granulocyte) donations may include G-CSF and if indicated, Plerixafor (Mozobil).

8.8.5.8 The readiness parameter for PBSC apheresis is determined by quantitation of the CD-34+ cells per microliter in the peripheral blood.

8.8.5.8.1 This parameter is not used for granulocyte, CAR-T, DLI, or NK cell donors.

8.8.5.9 Quantitative targets and endpoints for PBSC donations are expressed as required CD-34+ cells per kilogram of the recipient’s body weight.

8.8.5.10 All quantitative cellular targets and endpoints are based on the type of apheresis procedure, apheresis volume, total cell counts, and protocols/treatment requirements.

8.8.6 Anesthesia Administration

8.8.6.1 A board-certified adult or pediatric anesthesiologist per internal hospital guidelines administers anesthesia.

8.8.6.1.1 Duke Hospital Certification Program approves physicians administering conscious sedation for bone marrow harvest donors.

8.8.7 Assessment of the Donor Before Each Procedure:

8.8.7.1 The APBMT donor will have a minimum of a CBC/diff drawn before each procedure. An ABO/Rh or Type and Screen, which includes the red cell antibody, will be drawn on the first day of apheresis.

8.8.7.2 Donor safety suitability criteria are based on the APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire.* In addition, vital signs and laboratory tests are reviewed to ensure that the donor has met minimal blood count criteria and is within acceptable donor thresholds to proceed with the procedure.

8.8.7.2.1 For apheresis procedures, the donor safety suitability is performed and documented by the collection facility RN immediately prior to each collection procedure. If the donor is healthy and well, with no new issues, the apheresis RN will proceed with the apheresis procedure. If the donor has any medical issues, the apheresis RN will notify the daily attending for evaluation.

8.8.7.2.2 For bone marrow harvest procedures, the donor safety suitability is performed by the attending/designee and/or coordinator. Donor suitability is verified by the harvest attending/designee immediately prior to the procedure.

8.8.8 Bone Marrow Procedure:

8.8.8.1 BM donors will be screened the same as any peripheral blood donors

8.8.8.2 Refer to APBMT-GEN-003 *Overview of the Collection Facilities* specific APBMT Bone Marrow Harvest Collection Facility information.

8.8.8.3 Physicians and/or designees perform adult BM procedures in the Ambulatory Surgery Center under sterile conditions.

8.8.8.4 Physicians and/or designees perform pediatric BM procedures in the Duke Hospital Operating Room under sterile conditions.

8.8.8.5 Refer to ABMT-COLL-017 *Bone Marrow Harvest Procedure* or the PBMT-COLL-008 *Bone Marrow Harvest Procedure* for more information regarding BM harvesting.

8.8.9 Apheresis Procedure:

8.8.9.1 Cellular therapy products from all donors are collected on an automated cell separator. Refer to ABMT-COLL-019 *Optia*

Continuous Mononuclear Cell (CMNC) Collection or PBMT-COLL-016 *Optia Apheresis System Continuous Mononuclear Cell-CMNC Collection Procedure*.

8.9 Donor Management

8.9.1 Management of Blood Loss:

8.9.1.1 If for any reason the blood contained in the apheresis machine cannot be returned to the patient, the volume of blood loss will be recorded on the ABMT-COLL-19 FRM *Optia CMNC Run Sheet* or PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*. The BMT physician or designee will be notified.

8.9.1.1.1 Hematocrit may be drawn and transfusion arranged if necessary. Extracorporeal volumes can be recalculated based on the new hematocrit. A donor who has lost the equivalent volume of a whole blood donation will be advised that he/she be deferred from donation for 8 weeks. The donor may donate in less than eight weeks if they meet the criterion for hemoglobin naturally or via transfusion and are approved by the medical director.

8.9.2 Management of Thrombocytopenia:

8.9.2.1 Apheresis donors may develop thrombocytopenia, especially after repeated, frequent donations.

8.9.2.2 For autologous donors in the Pediatric program, the donor requires minimum lab values as stated in Section Titled "Donor Thresholds". At the completion of the apheresis procedure, a post-blood count may be obtained to verify the donor is still within the required platelet value of greater than (≥) 75,000/μL.

8.9.2.3 For autologous donors in the Adult program, the apheresis procedure generally cuts the original platelet count in half in a 6-hour procedure. A platelet infusion may be required if the suspected platelet count after a 6-hours donation is less than (<) 25,000/μL. The patient may be discharged after the apheresis procedure if the platelet count is greater than (≥) 25,000/μL.

8.9.2.4 For allogeneic donors in the APBMT program, the apheresis procedure is discontinued if the donor's platelet count is < 50,000/μL. A prescription may be given to the donor for a CBC to be drawn at an outside blood lab, with results faxed to the coordinator and/or BMT team.

8.9.2.5 For the NMDP donors, the apheresis procedure is discontinued if the donor's platelet count is < 80,000 /μL.

8.9.3 Management of Hypocalcemia:

8.9.3.1 Many donors develop hypocalcemia during the apheresis procedure. In anticipation of this potential complication:

8.9.3.1.1 All pediatric and adult donors are placed on a calcium infusion preemptively to the apheresis procedure.

8.9.3.1.2 If an adult donor experiences citrate toxicity related to apheresis, the APBMT-COLL-014 *Heparin Protocol* can also be instituted.

8.9.4 Management of Emergencies, Disasters, and Interruptions

8.9.4.1 Emergency policies in the event of interruption to the apheresis facilities' operations may be found in the Blood Cancer Center (BCC) Emergency Plan.

8.9.4.1.1 In the event of an emergency, steps and actions will be taken to provide safety to the donor, plus to secure and protect the cellular product will be initiated.

8.10 Post Apheresis/Marrow Procedure Donor Management:

8.10.1 APBMT autologous and allogeneic donors are given printed educational information describing the apheresis or BM donation processes. The contact phone numbers are listed for each clinic and aftercare.

8.10.2 APBMT team will manage the donor for apheresis or BM related events that require follow-up. Follow-up care will be coordinated by the coordinator for donors who live out of the Duke Hospital vicinity.

8.10.2.1 All allogeneic donors will be called or seen in the clinic within 24 to 72 hours post donation. Even if there are no issues reported, the coordinator will call within four to six weeks post donation to inquire about the donor condition. If there are issues or concerns, will call weekly until all issues have been resolved. All documentation will be recorded in the EMR.

8.10.2.2 Additionally, all patients receive a patient experience survey following any patient experience within Duke Health. These surveys allow for patient feedback to measure, manage, and improve the patient experience within Duke Health. Survey results are shared with area-specific leadership for follow-up opportunities.

8.10.3 Staff from the Stem Cell Laboratory (STCL) will report positive cultures for any cellular product to the patient's Attending Physician. (See related STCL procedures: STCL-QA-007 *Non-Conforming*

Products- Receipt, Processing, Distribution, and Disposition; STCL-EQUIP-011 *Sterility Culture Using BacT-Alert Microbiology System*.)

8.10.3.1 The physician will assess confirmed positive sterility results for medical significance and a determination will be made regarding whether the donor and/or recipient should be notified and/or treated. If warranted, a treatment plan will be initiated. If indicated, the treatment plan will be based on the organism detected and may include blood cultures, antibiotic therapy, possible central line removal, and re-collection of cells if the product must be discarded.

8.10.4 All apheresis adverse events must be documented on APBMT-COMM-030 FRM1 *Adverse Event Form* per procedure APBMT-COMM-030 *Recording and Reporting of Adverse Events*. All serious or high-grade adverse events will be documented in the physician's note and reported to the Duke Hospital Safety Reporting System (SRS).

8.10.5 In the event there is a collection-related complication, the collection facility will notify the clinical program for the ongoing management of the specific complication(s).

8.10.6 If the collection-related event occurs with a donor from a registry, the clinical program will notify that registry of the complication and management.

8.11 Confirmation of Cellular Therapy Products:

8.11.1 The APBMT physician will confirm the availability and suitability of a donor or cellular therapy product before initiating the recipient's preparative regimen.

8.11.2 The clinical program will notify the processing facility (STCL) before requesting a cellular therapy product from a cord blood bank, registry, or another facility.

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-COLL-014 Heparin Protocol

9.2 ABMT-GEN-034 Colony Stimulating Factor Guidelines

9.3 ABMT-COLL-19 FRM Optia CMNC Run Sheet

9.4 ABMT-COLL-019 Optia Continuous Mononuclear Cell (CMNC) Collection

9.5 ABMT-GEN-024 Autologous and Allogeneic Donor Consenting

9.6 PBMT-GEN-059 Autologous and Allogeneic Donor Consenting Procedure

9.7 PBMT-COLL-016 Optia Apheresis System Continuous Mononuclear Cell-CMNC Collection Procedure.

9.8 PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet

9.9 APBMT-COMM-001 FRM1 Request and Authorization Form for the Donation and/or Infusion of Emergency Cellular Products

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

9.11 APBMT-COMM-001 FRM3 Donor Health History Questionnaire

9.12 APBMT-COMM-001 FRM4 Interim Donor History Questionnaire

9.13 APBMT-COMM-001 JA1 Medical History Exclusion Criteria

9.14 APBMT-COMM-001 JA2 Collection of Donor Blood Samples for Infectious Disease Testing

9.15 APBMT-COMM-030 Recording and Reporting of Adverse Events

9.16 APBMT-COMM-030 FRM1 Adverse Event Form

9.17 APBMT-COMM-041 Processing Facility Notification for Cellular Product Request

9.18 APBMT-COLL-001 Optia Blood Prime Procedure

9.19 APBMT-GEN-003 Overview of the Collection Facilities

9.20 COMM-QA-081 Utilization of a Donor Medical History Addendum

9.21 STCL-QA-007 Non-Conforming Products- Receipt, Processing, Distribution, and Disposition;

9.22 STCL-EQUIP-011 Sterility Culture Using BacT-Alert Microbiology System

10 REFERENCES

10.1 American Association of Blood Banks (AABB). Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.

10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation. Current edition.

10.3 Food and Drug Administration (FDA). 21 CFR 1271, Human Cellular and Tissue-Based Products.

10.4 Public Health Service Act Section 361

10.5 Anurathapan U, Hongeng S, Pakakasama S, Songdej D, Sirachainan N, Pongphitcha P, Chuansumrit A, Charoenkwan P, Jetsrisuparb A, Sanpakit K, Rujkijyanont P, Meekaewkunchorn A, Lektrakul Y, Iamsirirak P, Surapolchai P, Sirireung S, Sruamsiri R, Wahidiyat PA, Andersson BS. Hematopoietic Stem Cell Transplantation for Severe Thalassemia Patients from Haploidentical Donors Using a Novel Conditioning Regimen. Biol Blood Marrow Transplant. 2020 Jun;26(6):1106-1112. doi: 10.1016/j.bbmt.2020.01.002. Epub 2020 Jan 11. PMID: 31931116.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)

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26	K. Beale, M. Christen, K. Lynch	• Added Definitions regarding eligibility, suitability, and urgent medical need. • Correct grammar throughout the document. • Added DUMN acronym. • Clarified the donor's age-appropriate donation sites. • Clarified HLA DNA high-resolution typing is performed initially, and verification/confirmatory typing is done separately. • Added step-by-step procedure regarding HLA pending results, consenting, and completion of urgent medical need performed on APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing. • Added clarification between requirements for ineligible Related Allogenic Donors and ineligible NMDP Donors • Provided reason for the required Document of Urgent Medical Need • Added NMDP peripheral blood donor levels prior to donation. • Added information regarding Motixafortide mobilization.

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