

STEM CELL LABORATORY (STCL)



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STCL-SOP-039 SCHEDULING COLLECTION, INFUSION, AND PROCESSING PROCEDURES AND OBTAINING ORDERS

1 PURPOSE

1.1 The purpose of this procedure is to outline the process by which apheresis procedures, bone marrow harvests, and infusion procedures are scheduled and the process by which the orders for collection, processing, and infusions are obtained.

2 INTRODUCTION

2.1 This procedure describes the systems currently in place to communicate how apheresis procedures, bone marrow harvest procedures, and infusion procedures are scheduled and communicated to the medical staff, collection staff, and processing staff to ensure that there is adequate staffing and supplies available to accommodate such procedures. Written collection, processing, and infusion orders must be obtained before any cellular product can be collected, processed, or infused by the appropriate staff.

3 SCOPE AND RESPONSIBILITIES

3.1 The Adult and Pediatric Stem Cell Program Medical Directors, Stem Cell Laboratory Manager, Collection and Processing Staff, and Quality Systems Unit are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 BMT Bone Marrow Transplant
- 4.2 DOB date of birth
- 4.3 ISBT International Society of Blood Transfusion
- 4.4 MNCs mononuclear cells
- 4.5 N/A Not Applicable
- 4.6 PBMT Pediatric Bone Marrow Transplant
- 4.7 RBCs Red blood cells

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

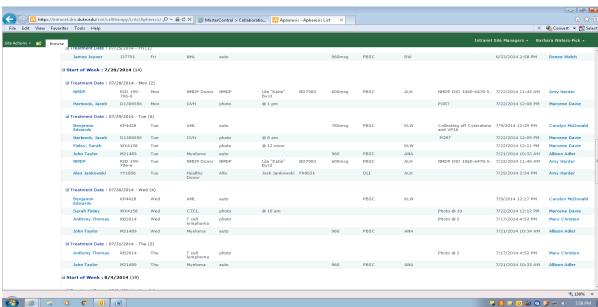
7.1 N/A

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8 PROCEDURE

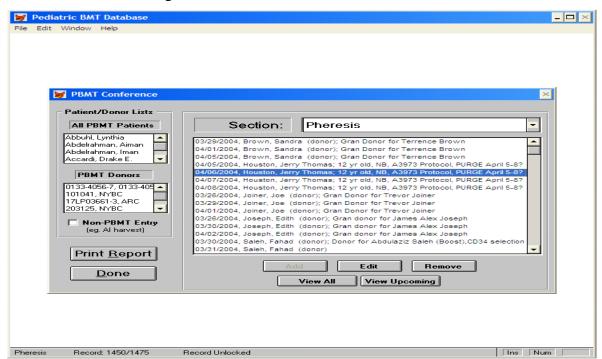
8.1 SCHEDULING COLLECTION PROCEDURES AND OBTAINING ORDERS

- 8.1.1 Lines of communication should be established before any product or service is provided, and such lines of communication should be established to provide easy bi-directional access to all necessary personnel.
- 8.1.2 Personnel involved in the scheduling process may include, but is not limited to collection staff, lab staff, Duke medical staff, donors, recipients' physicians, and transplant coordinators.
- 8.1.3 Initial scheduling may be done using a computer system; however a signed physician's order is needed prior to starting any collection procedure. Apheresis schedules are available and accessible to all designated staff via Sharepoint Cellular Therapy Treatment Program and PBMT Conference section of the Pediatric BMT Database. Bone marrow harvest schedules are also available and accessible to all designated staff via Sharepoint Cellular Therapy Treatment Program and PBMT Conference section of the Pediatric BMT Database. Schedules are continually updated as changes are made so they should be reviewed frequently in order keep up with the changes.
- 8.1.4 Schedules are closely monitored to ensure that adequate staffing is available to accommodate the scheduled procedures and to ensure that cellular products are collected in a timely manner based on each patient's transplant schedule.
- 8.1.5 Changes in the collection schedules are communicated in weekly staff meetings held by the Adult and Pediatric Transplant Programs to ensure that all appropriate updates are made to the respective schedules in a timely manner.
- 8.1.6 Apheresis schedule used by the Adult Blood and Marrow Transplant Program.

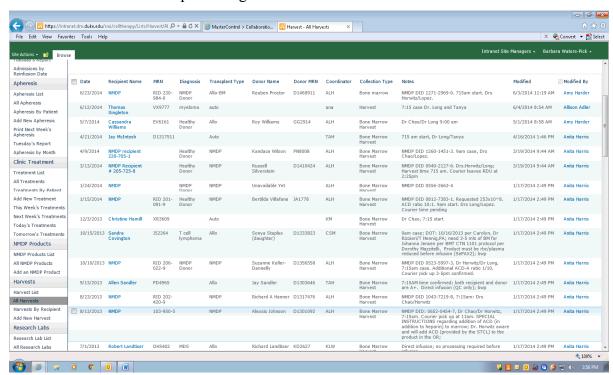


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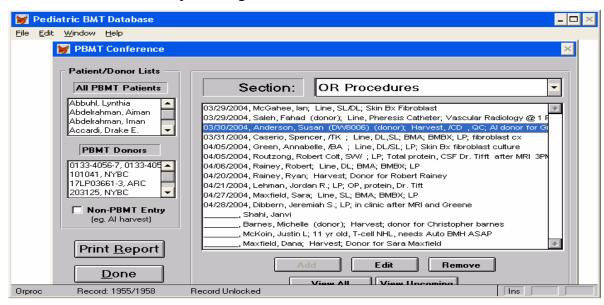
8.1.7 Apheresis schedule used by the Pediatric Blood and Marrow Transplant Program



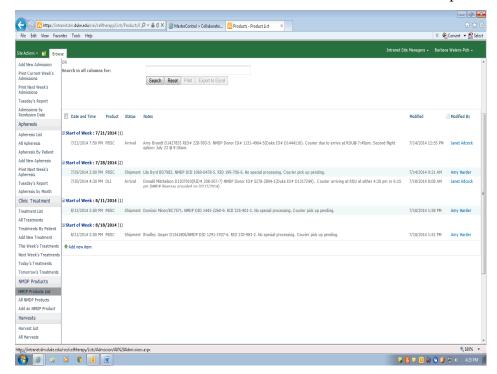
8.1.8 Bone Marrow Harvest schedule used by the Adult Blood and Marrow Transplant Program



8.1.9 Bone Marrow Harvest schedule used by the Pediatric Stem Cell Transplant Program



8.1.10 NMDP Products List for Adult Blood and Marrow Transplant Program



8.1.11 Before collection of a cellular therapy product, there must be a written physician's order on file within the program. If there are any questions regarding the collection of a cellular product, the ordering physician should be available for consultation. Acceptable endpoints (volume for each individual procedure and targeted CD34 yields for multiple procedures) and/or ranges are included on the physician's orders completed for each cellular product collected.

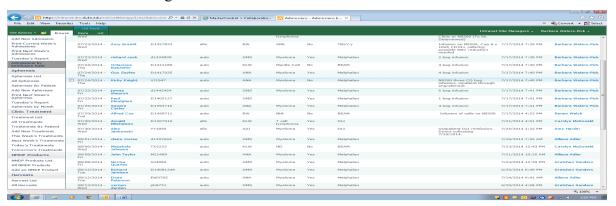
- 8.1.12 Collection orders are prepared using the following forms:
 - 8.1.12.1 PBMT-COLL-016 FRM2 Pediatric Apheresis Order Using Optia
 - 8.1.12.2 STCL-FORM-041 Doctor's Orders Adult Stem Cell Transplant Program
 - 8.1.12.3 STCL-FORM-062 Stem Cell Laboratory Processing Order Form
- 8.1.13 Collection orders shall be prepared and signed by the appropriate medical staff and shall contain at least the following information:
 - 8.1.13.1 Patient's Name
 - 8.1.13.2 Patient's Duke History #
 - 8.1.13.3 Patient's ABO/Rh
 - 8.1.13.4 Patient's DOB
 - 8.1.13.5 Patient's weight (if available)
 - 8.1.13.6 ISBT 128 barcode # assigned
 - 8.1.13.7 Donor's Name (*if applicable*)
 - 8.1.13.8 Donor's Duke History # (*if applicable*)
 - 8.1.13.9 Donor's ABO/Rh (*if applicable*)
 - 8.1.13.10 Donor's DOB (if applicable)
 - 8.1.13.11 Donor's weight (if applicable)
 - 8.1.13.12 Anticipated date of first collection procedure
 - 8.1.13.13 Blood volume to process daily or length of apheresis procedure (in hours)
 - 8.1.13.14 Collection goal (#MNC/kg or CD34+/kg)
 - 8.1.13.15 Ordering physicians signature
- 8.1.14 It is the responsibility of the collection staff to ensure that appropriate lab tests have been collected, to ensure that the equipment and supplies are available to accommodate the collection procedures, and to ensure that there is adequate staffing to ensure the safety of all patients and /or donors.

8.2 SCHEDULING INFUSION PROCEDURES AND OBTAINING ORDERS

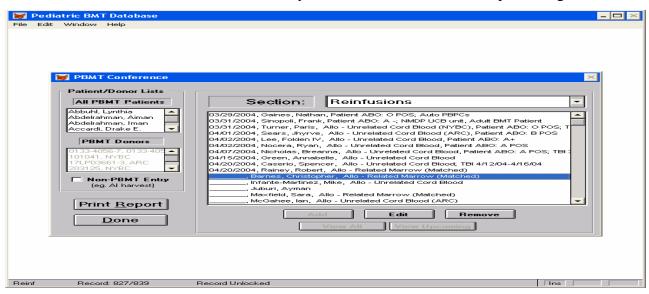
- 8.2.1 Lines of communication should be established before any product or service is provided, and such lines of communication should be established to provide easy bi-directional access to all necessary medical, nursing, and laboratory personnel.
- 8.2.2 Personnel involved in the scheduling of infusion procedures may include, but is not limited to nursing staff, laboratory staff, and Duke medical staff.

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- 8.2.3 Infusion dates are scheduled in advance. Infusion procedures are available and accessible to all designated staff via computer system. Schedules are continually updated as changes are made in the event that a patient's transplant regiment has been altered or delayed.
- 8.2.4 Schedules are closely monitored to ensure that adequate staffing is available to accommodate the scheduled procedures and to ensure that cellular products are processed in a timely manner based on each patient's transplant schedule.
- 8.2.5 Infusion schedule used by the Adult Blood and Marrow Transplant Program



8.2.6 Infusion schedule used by the Pediatric Stem Cell Transplant Program



- 8.2.7 Changes in infusion schedules are communicated in weekly staff meetings held by the Adult and Pediatric Transplant Programs to ensure that all appropriate updates are made to the respective schedules in a timely manner.
- 8.2.8 Because schedules are subject to change, they should be reviewed frequently.
- 8.2.9 The timing of infusion procedures is strategically coordinated between the laboratory and nursing staff to ensure that cellular products are not

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- processed and/or issued to the transplant facility until such time that the patient and nursing staff are prepared to accept and administer those products.
- 8.2.10 Before any fresh or frozen cellular product is prepared for infusion, written orders must be completed and signed by the ordering (*or designated*) physician. Acceptable endpoints and/or ranges are included on the physician's orders completed for each cellular product prepared for infusion.
- 8.2.11 Infusion orders are prepared using the STCL-FORM-056 Cellular Therapy Infusion Request Form.
- 8.2.12 Infusion orders shall be prepared and signed by the appropriate medical staff and shall contain at least the following information:
 - 8.2.12.1 Patient's Name
 - 8.2.12.2 Patient's Duke History #
 - 8.2.12.3 Patient's ABO/Rh
 - 8.2.12.4 Patient's DOB
 - 8.2.12.5 Patient's weight (*if available*)
 - 8.2.12.6 ISBT 128 barcode # assigned
 - 8.2.12.7 Donor's Name (*if applicable*)
 - 8.2.12.8 Donor's Duke History # (*if applicable*)
 - 8.2.12.9 Donor's ABO/Rh (*if applicable*)
 - 8.2.12.10 Donor's DOB (if applicable)
 - 8.2.12.11 Hematopoietic Product (selection)
 - 8.2.12.12 Description of the product
 - 8.2.12.13 Collection Date(s)
 - 8.2.12.14 Total Nucleated Cell Count (TNCC)
 - 8.2.12.15 Total Cell Dose (per kg)
 - 8.2.12.16 Total CD34+ dose (*pre-freeze*)
 - 8.2.12.17 Thawing and Infusion Protocol
 - 8.2.12.18 Requesting physician's signature
 - 8.2.12.19 Special Instructions
 - 8.2.12.20 Signature, date, and time of personnel delivering and accepting cellular product for infusion

8.3 OBTAINING PROCESSING ORDERS FOR ALL CELLULAR PRODUCTS

8.3.1 Lines of communication should be established before any product or service is provided, and such lines of communication should be

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- established to provide easy bi-directional access to all necessary laboratory personnel.
- 8.3.2 Personnel in the STCL are involved in the processing of cellular products for the adult and pediatric transplant programs. Changes in processing schedules are communicated in weekly staff meetings held by the Adult and Pediatric Blood and Marrow Transplant Programs to ensure that updates are made to the respective schedules in a timely manner.
- 8.3.3 Schedules are reviewed frequently in the laboratory and the processing procedures are discussed internally to ensure that all designated staff is proactively informed of upcoming laboratory procedures.
- 8.3.4 Proactive communication is essential to ensure that adequate staff is available in the laboratory to process cellular products, as they are scheduled, and to ensure that the necessary reagents and supplies are available for upcoming procedures.
- 8.3.5 Before processing any cellular product, there must be a written physician's order on file within the laboratory. If there are questions associated with how a cellular product is to be processed, the physician (*or designee*) who signed the orders should be available for consultation. Acceptable endpoints and/or ranges are noted on the processing orders for each cellular product collected when appropriate.
- 8.3.6 If the physician provides a verbal order or written order via e-mail, that order will be reflected on the signed order.
 - **NOTE:** (*Example*: The physician is contacted at 9 pm to find out whether a product needs to be RBC reduced or not. If the product does NOT require RBC reduction, a note on the signed order will be added to reflect "RBC reduction not required per Dr. Smith").
- 8.3.7 Processing orders are obtained by using the following forms, as applicable: STCL-FORM-041 Doctor's Orders Adult Stem Cell Transplant Program, STCL-FORM-056 Cellular Therapy Infusion Request Form, or STCL-FORM-062 Stem Cell Laboratory Processing Order Form.
- 8.3.8 Processing orders shall be prepared and signed by the appropriate medical staff and shall contain at least the following information:
 - 8.3.8.1 Patient's Name
 - 8.3.8.2 Patient's Duke History #
 - 8.3.8.3 Patient's ABO/Rh
 - 8.3.8.4 Patient's DOB
 - 8.3.8.5 Patient's weight (*if available*)
 - 8.3.8.6 Donor's Name (*if applicable*)
 - 8.3.8.7 Donor's Duke History # (*if applicable*)

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8.3.8.8 Donor's ABO/Rh (if applicable) 8.3.8.9 Donor's DOB (if applicable) 8.3.8.10 Donor's weight (if applicable) 8.3.8.11 Anticipated date of first collection/processing procedure 8.3.8.12 Collection goal (#MNC/kg or CD34+/kg) 8.3.8.13 Ordering physician's signature 8.3.8.14 It is the responsibility of the processing staff to ensure that physician orders have been prepared and signed before manipulating any cellular product. It is also the responsibility of the processing staff to ensure that appropriate staffing levels, equipment, supplies, and reagents are available to accommodate the processing of all cellular products. 8.3.8.15 All orders are maintained in the laboratory in the patient's/donor's permanent laboratory file. 8.3.8.16 **Endpoints** 8.3.8.16.1 For individual apheresis procedures, volumes and endpoints, usually five blood volume exchanges or more, are specified on the physician order form. 8.3.8.16.2 For multiple apheresis procedures, a CD34+ cells/kg target is reflected on the physician order form. 8.3.8.16.3 If there is more CD34+ cells/kg collected then desired for infusion, the orders may provide instructions to cryopreserve the excess cells in the STCL for future use. 8.3.8.16.4 If a product may require RBC reduction, due to the blood types of the recipient and the donor, the physician will be contacted with the total volume of incompatible RBCs in the entire product and make a determination regarding whether or not the product requires RBC reduction or not.

NOTE: "Two (2) mL of incompatible RBCs per kg of recipient's weight" is generally considered acceptable but the final determination needs to be made by one of the physicians.

9 RELATED DOCUMENTS/FORMS

- 9.1 PBMT-COLL-016 Spectra Optia Apheresis System Continuous Mononuclear (CMNC) Collection Procedure
- 9.2 PBMT-COLL-016 FRM2 Pediatric Apheresis Order Using Optia
- 9.3 PBMT-COLL-017 Spectra Optia Apheresis System Granulocyte (PMN)
 Collection Procedure
- 9.4 STCL-FORM-041 Doctor's Orders Adult Stem Cell Transplant Program
- 9.5 STCL-FORM-056 Cellular Therapy Infusion Request Form
- 9.6 STCL-FORM-062 Stem Cell Laboratory Processing Order Form

10 REFERENCES

- 10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product (current edition).
- 10.2 American Association of Blood Banks. Standards for Blood Banks and Transfusion Services (current edition).
- 10.3 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation (current edition).

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)		
06	B. Waters- Pick	 Section 8.1.3 – Replaced "via computer" with Sharepoint Cellular Therapy Treatment Program and PBMT Conference section of Pediatric BMT Database Section 8.1.11 – Added "therapy" and removed "is initiated" Section 8.1.12 – Added PBMT-COLL-106 FRM2 Pediatric Apheresis Order Using Optia and STCL-FORM-062 Stem Cell Laboratory Processing Order Form; Removed "STCL-FORM-052 Doctor's Orders for Pediatric Apheresis Using the Cobe Spectra, STCL-FORM-052 DUMC Orders for Granulocyte Apheresis Procedures Using the Cobe Spectra. Section 8.3.7 – Removed STCL-COLL-003 Stem Cell Laboratory Processing Order Form and added STCL-FORM-062 Stem Cell Laboratory Processing Order Form. Section 9 – Added PBMT-COLL-016 Spectra Optia Apheresis System Continuous Mononuclear (CMNC) Collection Procedure, PBMT-COLL-016 FRM2 Pediatric Apheresis Order Using Optia, PBMT-COLL-017 Spectra Optia Apheresis System Granulocyte (PMNC) Collection Procedure, and STCL-FORM-062 Stem Cell Laboratory Processing Order Form Section 9 – Removed STCL-052 Doctor's Orders for Pediatric Apheresis Using the Cobe Spectra, STCL-FORM-053 DUMC Orders for Granulocyte Apheresis Using the Cobe Spectra, STCL-FORM-053 DUMC Orders for Granulocyte Apheresis Procedures Using Cobe Spectra, and STCL-COLL-003 Stem Cell Laboratory Processing Order Form. 		

Signature Manifest

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