



# 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

## 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.

Patient Name	ID	Date	Day	Disease	Type	Time	Dose	Product	Location	Staff
James Joyner	137791	Fri	NHL	auto			960mcg	PBSC	RW	6/23/2014 2:58 PM Renee Welch
<b>Start of Week : 7/20/2014 (14)</b>										
<b>Treatment Date : 07/28/2014 - Mon (2)</b>										
NMDP	RID 199-706-6	Mon	NMDP Donor	NMDP	Lila "Katie" Byrd	BD7983	600mcg	PBSC	ALH	NMDP DID 1060-6478-5. 7/22/2014 11:45 AM Amy Harder
Hartsock, Jacob	D1306556	Mon	GVH	photo	@ 1 pm				PORT	7/22/2014 12:08 PM Marcene Davie
<b>Treatment Date : 07/29/2014 - Tue (6)</b>										
Benjamin Edwards	KP4428	Tue	AML	auto			780mcg	PBSC	KLW	Collecting off Cytarabine and VP16 7/9/2014 12:29 PM Carolyn McDonald
Hartsock, Jacob	D1306556	Tue	GVH	photo	@ 8 am				PORT	7/22/2014 12:09 PM Marcene Davie
Finley, Sarah	WX4158	Tue		photo	@ 12 noon				KLW	7/22/2014 12:11 PM Marcene Davie
John Taylor	H21489	Tue	Myeloma	auto			960	PBSC	ANA	7/23/2014 10:33 AM Allison Adler
NMDP	RID 199-706-6	Tue	NMDP Donor	NMDP	Lila "Katie" Byrd	BD7983	600mcg	PBSC	ALH	NMDP DID 1060-6478-5. 7/22/2014 11:45 AM Amy Harder
Alex Jankowski	YY1856	Tue	Healthy Donor	Allo	Josh Jankowski	FA8631		DLI	ALH	7/25/2014 2:34 PM Amy Harder
<b>Treatment Date : 07/30/2014 - Wed (4)</b>										
Benjamin Edwards	KP4428	Wed	AML	auto				PBSC	KLW	7/9/2014 12:27 PM Carolyn McDonald
Sarah Finley	WX4158	Wed	CTCL	photo	@ 10 am				Photo @ 10	7/22/2014 12:12 PM Marcene Davie
Anthony Thomas	RB2614	Wed	T cell lymphoma	photo					Photo @ 2	7/17/2014 4:52 PM Mary Christen
John Taylor	H21489	Wed	Myeloma	auto			960	PBSC	ANA	7/21/2014 10:34 AM Allison Adler
<b>Treatment Date : 07/31/2014 - Thu (2)</b>										
Anthony Thomas	RB2614	Thu	T cell lymphoma	photo					Photo @ 2	7/17/2014 4:52 PM Mary Christen
John Taylor	H21489	Thu	Myeloma	auto			960	PBSC	ANA	7/21/2014 10:35 AM Allison Adler
<b>Start of Week : 8/4/2014 (19)</b>										

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

The screenshot shows the 'PBMT Conference' window with the 'Section' set to 'Pheresis'. The 'Patient/Donor Lists' on the left include 'All PBMT Patients' and 'PBMT Donors'. The main list displays a schedule of apheresis procedures, including dates, patient names, donor names, and protocols. The status bar at the bottom indicates 'Pheresis Record: 1450/1475 Record Unlocked'.

Date	Patient Name	Donor Name	Protocol
03/29/2004	Brown, Sandra (donor)	Gran Donor for Terrence Brown	
04/01/2004	Brown, Sandra (donor)	Gran Donor for Terrence Brown	
04/05/2004	Brown, Sandra (donor)	Gran Donor for Terrence Brown	
04/05/2004	Houston, Jerry Thomas; 12 yr old, NB, A3973 Protocol, PURGE April 5-8?		
04/06/2004	Houston, Jerry Thomas; 12 yr old, NB, A3973 Protocol, PURGE April 5-8?		
04/07/2004	Houston, Jerry Thomas; 12 yr old, NB, A3973 Protocol, PURGE April 5-8?		
04/08/2004	Houston, Jerry Thomas; 12 yr old, NB, A3973 Protocol, PURGE April 5-8?		
03/28/2004	Joiner, Joe (donor)	Gran Donor for Trevor Joiner	
03/29/2004	Joiner, Joe (donor)	Gran Donor for Trevor Joiner	
04/01/2004	Joiner, Joe (donor)	Gran Donor for Trevor Joiner	
03/28/2004	Joseph, Edith (donor)	Gran donor for James Alex Joseph	
03/30/2004	Joseph, Edith (donor)	Gran donor for James Alex Joseph	
04/02/2004	Joseph, Edith (donor)	Gran donor for James Alex Joseph	
03/30/2004	Saleh, Fahad (donor)	Donor for Abdulaziz Saleh (Boost), CD34 selection	
03/31/2004	Saleh, Fahad (donor)		

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

The screenshot shows the 'Intranet Site Managers' window displaying a table of bone marrow harvests. The table includes columns for Date, Recipient Name, MRN, Diagnosis, Transplant Type, Donor Name, Donor MRN, Coordinator, Collection Type, Notes, Modified, and Modified By. The data is organized by date, showing various harvests for different recipients and donors.

Date	Recipient Name	MRN	Diagnosis	Transplant Type	Donor Name	Donor MRN	Coordinator	Collection Type	Notes	Modified	Modified By
6/23/2014	NMDP	RID 230-584-0	NMDP Donor	Allo-BM	Reuben Proctor	D1468911	ALH	Bone marrow	NMDP DID 1271-2969-0. 7:15am start. Drs Horwitz/Lopez.	6/3/2014 11:19 AM	Amy Harder
6/12/2014	Thomas Singleton	VX9777	myeloma	auto			ana	Harvest	7:15 case Dr. Long and Tanya	6/4/2014 8:54 AM	Allison Adler
5/7/2014	Cassandra Williams	EV6161	Healthy Donor	Allo	Roy Williams	GG2914	ALH	Bone Marrow Harvest	Dr Chao/Dr Long 9:00 am	5/1/2014 8:58 AM	Amy Harder
4/21/2014	Jay McIntosh	D1317511		Auto			TAH	Bone Marrow Harvest	7:15 am start, Dr Long/Tanya	4/16/2014 1:46 PM	Anita Harris
4/9/2014	NMDP recipient 220-705-1		Healthy Donor	NMDP	Kandace Wilson	PN8008	ALH	Bone Marrow Harvest	NMDP DID 1260-1451-3. 9am case, Drs Chao/Lopez.	3/19/2014 9:44 AM	Anita Harris
3/13/2014	NMDP Recipient # 205-725-8		Healthy Donor	NMDP	Russell Silverstein	D1410424	ALH	Bone Marrow Harvest	NMDP DID 0940-2127-6. Drs.Horwitz/Long; Harvest time 7:15 am. Courier leaves RDU at 2:25pm	3/19/2014 9:44 AM	Anita Harris
1/24/2014	NMDP		NMDP Donor	NMDP	Unavailable Yet		ALH	Bone Marrow Harvest	NMDP DID 0556-2663-4	1/17/2014 2:49 PM	Anita Harris
1/15/2014	NMDP	RID 201-091-9	Healthy Donor	NMDP	Bertilda Villafane	JA1778	ALH	Bone Marrow Harvest	NMDP DID 0812-7383-1. Requested 253x10^8. ACD ratio 10:1. 9am start. Drs Long/Lopez. Courier time pending	1/17/2014 2:49 PM	Anita Harris
12/3/2013	Christine Hamill	XR3609		Auto			KM	Bone Marrow Harvest	Dr Chao, 7:15 start	1/17/2014 2:49 PM	Anita Harris
10/15/2013	Sandra Covington	JS2264	T cell lymphoma	Allo	Sonya Staples (daughter)	D1333823	CSM	Bone Marrow Harvest	9am case; DOT: 10/16/2013 per Carolyn, Dr Rizzieri/T Hennig,PA; need 3-5 mls of BM for Johanna Jensen per BMT CTN 1101 protocol per Dorothy Mazzilli. Product must be rbc/plasma reduced before infusion (SePAK2); bwp	1/17/2014 2:49 PM	Anita Harris
10/10/2013	NMDP	RID 206-022-9	NMDP Donor	NMDP	Suzanne Keller-Dannelly	D1356558	ALH	Bone Marrow Harvest	NMDP DID 0523-5997-3, Dr Horwitz/Dr Long, 7:15am case. Additional ACD-A ratio 1:10. Courier pick up 3-5pm confirmed.	1/17/2014 2:49 PM	Anita Harris
9/13/2013	Allen Sandler	PD4965		Allo	Jay Sandler	D1303646	TAH	Bone Marrow Harvest	7:15AM time confirmed; both recipient and donor are A+. Direct infusion (QC only); bwp	1/17/2014 2:49 PM	Anita Harris
8/23/2013	NMDP	RID 202-420-9		NMDP	Richard A Hanner	D1317476	ALH	Bone Marrow Harvest	NMDP DID 1043-7219-8, 7:15am: Drs Chao/Horwitz	1/17/2014 2:49 PM	Anita Harris
8/13/2013	NMDP	103-950-5		NMDP	Alexis Johnson	D1301092	ALH	Bone Marrow Harvest	NMDP DID: 0652-0454-7, Dr Chao/Dr Horwitz, 7:15am. Courier pick up at 11am. SPECIAL INSTRUCTIONS regarding addition of ACD (in addition to heparin) to marrow; Dr. Horwitz aware and will add ACD (provided by the STCL) to the product in the OR.	1/17/2014 2:49 PM	Anita Harris
7/1/2013	Robert Landtiser	DHS402	MDS	Allo	Richard Landtiser	KD2627	KLW	Bone Marrow Harvest	Direct infusion; no processing required before product	1/17/2014 2:49 PM	Anita Harris

### 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

Date and Time	Product	Status	Notes	Modified	Modified By
7/22/2014 7:50 PM	PBSC	Arrival	Any Brandt D1427833 RID# 228-993-5, NMDP Donor ID# 1131-4964-5(Duke ID# D1444116), Courier due to arrive at RDU@ 7:45pm. Second flight option: July 23 @ 9:36am.	7/14/2014 12:55 PM	Janet Adcock
7/29/2014 2:00 PM	PBSC	Shipment	Lila Byrd B07983, NMDP DID 1060-6478-5, RID 199-706-6. No special processing. Courier pick up pending.	7/14/2014 9:21 AM	Amy Harder
7/30/2014 4:30 PM	DLI	Arrival	Donald Mitchellson D1307910(RID# 208-507-7) NMDP Donor ID# 5278-2894-1(Duke ID# D1317249), Courier arriving at RDU at either 4:30 pm or 6:15 pm (NMDP itinerary provided on 07/17/2014).	7/18/2014 8:08 AM	Janet Adcock
8/12/2014 2:00 PM	PBSC	Shipment	Dominic Minor/BCT571, NMDP DID 1443-2260-9, RID 225-901-1. No special processing. Courier pick up pending.	7/18/2014 1:58 PM	Amy Harder
8/21/2014 2:00 PM	PBSC	Shipment	Bradley Jasper D1341806/NMDP DID 1291-1937-6, RID 220-983-2. No special processing. Courier pick up pending.	7/18/2014 1:52 PM	Amy Harder

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.

- |   |            |      |                 |            |            |            |            |            |            |
|---|------------|------|-----------------|------------|------------|------------|------------|------------|------------|
| <a href="#">File</a> <a href="#">Edit</a> <a href="#">View</a> <a href="#">Favorites</a> <a href="#">Tools</a> <a href="#">Help</a> |            |      |                 |            |            |            |            |            |            |
| <a href="#">Site Actions</a> <a href="#">Add</a> <a href="#">Browse</a>   |            |      |                 |            |            |            |            |            |            |
| Site  | Time       | Week | List            | Site       | Time       | Week       | List       | Site       | Time       |
| <a href="#">Intranet Site Managers</a> <a href="#">Barbara Waters-Pick</a>  |            |      |                 |            |            |            |            |            |            |
| Add New Admission   |            |      |                 |            |            |            |            |            |            |
| Print Current Week's Admissions   | 07/23/2014 | Wend | Any Brandt      | D1427853   | allo       | KW         | AML        | No         | TBI/CV     |
| Print Next Week's Admissions  | 07/27/2014 | Wed  | richard cook    | d1434899   | auto       | GMS        | Myeloma    | Yes        | Helphalan  |
| Tuesday's Report  | 07/22/2014 | Wed  | 07/23/2014      | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 |
| Reported by Random Date   | 07/23/2014 | Thu  | 07/23/2014      | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 |
| Apheresis List  | 07/23/2014 | Thu  | Guy Sayles      | D1431200   | auto       | KWS        | Myeloma    | Yes        | Helphalan  |
| All Apheresis   | 07/23/2014 | Thu  | Kirby Knight    | D1431200   | auto       | ANA        | Myeloma    | Yes        | Helphalan  |
| Apheresis by Patient  | 07/23/2014 | Thu  | 07/23/2014      | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 | 07/23/2014 |
| Add New Apheresis   | 07/25/2014 | Fri  | James Shearon   | d1443454   | auto       | GMS        | Myeloma    | Yes        | Helphalan  |
| Print Next Week's Apheresis   | 07/25/2014 | Fri  | Paul Raughen    | D1405127   | auto       | GMS        | Myeloma    | Yes        | Helphalan  |
| Tuesday's Report  | 07/25/2014 | Fri  | Sandra Ruffe    | D1393716   | auto       | ANA        | Myeloma    | Yes        | Helphalan  |
| Apheresis by Month  | 07/25/2014 | Fri  | 07/25/2014      | 07/25/2014 | 07/25/2014 | 07/25/2014 | 07/25/2014 | 07/25/2014 | 07/25/2014 |
| Clinic Treatment  | 07/25/2014 | Fri  | Alfred Cox      | D1458711   | auto       | BW         | NBL        | No         | BEAM       |
| Treatment List  | 07/30/2014 | Wed  | donald McElchen | D1307910   | auto       | KJW        | T cell     | Yes        | DLI        |
| All Treatments  | 07/30/2014 | Wed  | Alex Jankowski  | VY1886     | allo       | AAJ        | Myeloma    | Yes        | DLI        |
| Treatment by Patient  | 08/01/2014 | Wed  | 08/01/2014      | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 |
| Add New Treatment   | 08/01/2014 | Wed  | 08/01/2014      | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 |
| This Week's Treatments  | 08/01/2014 | Wed  | 08/01/2014      | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 | 08/01/2014 |
| Next Week's Treatments  | 08/05/2014 | Wed  | 08/05/2014      | 08/05/2014 | 08/05/2014 | 08/05/2014 | 08/05/2014 | 08/05/2014 | 08/05/2014 |
| Today's Treatments  | 08/06/2014 | Wed  | 08/06/2014      | 08/06/2014 | 08/06/2014 | 08/06/2014 | 08/06/2014 | 08/06/2014 | 08/06/2014 |
| Tomorrow's Treatments   | 08/07/2014 | Wed  | 08/07/2014      | 08/07/2014 | 08/07/2014 | 08/07/2014 | 08/07/2014 | 08/07/2014 | 08/07/2014 |
| NPDR Products   | 08/08/2014 | Wed  | John Taylor     | H21489     | auto       | ANA        | Myeloma    | Yes        | Helphalan  |
| AB NPDR Products  | 08/08/2014 | Wed  | Norme Quarles   | G140409    | auto       | GMS        | Myeloma    | Yes        | Helphalan  |
| AB NPDR Product   | 08/12/2014 | Wed  | Richard Jamison | D14081348  | auto       | GMS        | Myeloma    | Yes        | Helphalan  |
| Harvests  | 08/12/2014 | Wed  | Dean Johnson    | EW9765     | auto       | ANA        | Myeloma    | Yes        | Helphalan  |
| Harvest List  | 08/12/2014 | Wed  | 08/12/2014      | 08/12/2014 | 08/12/2014 | 08/12/2014 | 08/12/2014 | 08/12/2014 | 08/12/2014 |
| All Harvests  | 08/13/2014 | Wed  | vernon Berlin   | ph8731     | auto       | GMS        | Myeloma    | Yes        | Helphalan  |

- 
- The screenshot shows the "Pediatric BMT Database" application window. A "PBMT Conference" dialog box is open, displaying patient lists and a section of reinfusions.
- Patient/Donor Lists**
- All PBMT Patients:**
    - Abduhl, Lynthis
    - Abdelrahman, Aiman
    - Abdelrahman, Iman
    - Accardi, Drake E.
  - PBMT Donors:**
    - 0133-4056-7; 0133-4056-8
    - 101041, NYBC
    - 17LP03661-3, ARC
    - 203125, NYBC
- ☐ Non-PBMT Entry (eg. AI harvest)
- Print Report**
- Done**
- Section:** Reinfusions
- |             |                         |  |  |
|-------------|-------------------------|--|--|
| 03/29/2004, | Gaines, Nathan,         | Patient ABO: O POS;                              | Auto PBPCs                               |
| 03/31/2004, | Sinopoli, Frank,        | Patient ABO: A -;                                | NMOP UCB unit , Adult BMT Patient        |
| 03/31/2004, | Turner, Paris,          | Allo - Unrelated Cord Blood (NYBC),              | Patient ABO: O POS; TBI 4/1/2004-4/15/04 |
| 04/01/2004, | Sears, Jhyrve,          | Allo - Unrelated Cord Blood (ARC),               | Patient ABO: B POS                       |
| 04/02/2004, | Lee, Folden IV,         | Allo - Unrelated Cord Blood, Patient ABO: A+     |  |
| 04/02/2004, | Nocera, Ryan,           | Allo - Unrelated Cord Blood, Patient ABO: A POS  |  |
| 04/07/2004, | Nicholas, Breanna,      | Allo - Unrelated Cord Blood, Patient ABO: A POS; | TBI 4/1/2004-4/15/04                     |
| 04/15/2004, | Green, Annabelle,       | Allo - Unrelated Cord Blood                      |  |
| 04/20/2004, | Caserio, Spencer,       | Allo - Unrelated Cord Blood;                     | TBI 4/1/2004-4/15/04                     |
| 04/20/2004, | Rainey, Robert,         | Allo - Related Marrow (Matched)                  |  |
| 04/20/2004, | Jarvis, Christopher,    | Allo - Related Marrow (Matched)                  |  |
| 04/20/2004, | Intente-Martinez, Mike, | Allo - Unrelated Cord Blood                      |  |
| 04/20/2004, | Juburi, Ayman           |  |  |
| 04/20/2004, | Maxfield, Sara,         | Allo - Related Marrow (Matched)                  |  |
| 04/20/2004, | McGahee, Ian,           | Allo - Unrelated Cord Blood (ARC)                |  |
- Add Edit Remove**
- View All View Upcoming**

- STCL-SOP-039 Scheduling Collection, Infusion, and Processing Procedures and Obtaining Orders  
Stem Cell Laboratory, DUMC  
Durham, NC

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

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*)

- 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 than 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	<ul style="list-style-type: none"><li>Section 8.1.3 – Replaced “via computer” with Sharepoint Cellular Therapy Treatment Program and PBMT Conference section of Pediatric BMT Database</li><li>Section 8.1.11 – Added “therapy” and removed “is initiated”</li><li>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.</li><li>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.</li><li>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</li><li>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.</li></ul>

## Signature Manifest

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#### Author

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		12 Jun 2020, 11:27:22 AM	Approved

#### Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		12 Jun 2020, 11:27:43 AM	Approved

#### Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		12 Jun 2020, 05:10:10 PM	Approved

#### Quality

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch (IMS19)		15 Jun 2020, 09:47:51 AM	Approved

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