PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Pediatric Apheresis Supply Management

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PBMT-EQUIP-003
PEDIATRIC APHERESIS SUPPLY MANAGEMENT

1 PURPOSE

1.1 This Standard Operating Procedure (SOP) describes the steps used by trained personnel to receive, inspect, document and store supplies for pediatric apheresis.

2 INTRODUCTION

2.1 Pediatric apheresis supplies are stored in the Adult Blood and Marrow Transplant (ABMT) Clinic supply room. All pediatric apheresis supplies are stored on separate carts, to prevent mix-ups.

2.2 As part of a Quality Program for the production of cellular products, the Apheresis Coordinator must ensure that all apheresis supplies and services used consistently meet specified requirements. This is accomplished by initial qualification and regular evaluation of suppliers, and by continuous monitoring of critical supplies received in the ABMT Clinic supply room. This SOP defines the process for assuring and monitoring the quality of critical supplies, from receipt to use.

2.3 The Apheresis Coordinator/designee will document receipt of all supplies in the Pediatric Apheresis Supply Notebook, which is located on the designated cart. This record will include stock identification, lot numbers, quantity received, expiration dates and, if applicable, a package insert and a Certificate of Analysis(COA) or Certificate of Conformance(COC).

2.4 The Apheresis Coordinator/designee is responsible for reviewing the manufacturer's package insert for changes. If there are changes that require revisions to the procedure, appropriate revisions will be made to the procedures and staff training will occur.

2.5 The Apheresis Coordinator/designee is responsible for ensuring that the supplies are used in a first in, first out order.

3 SCOPE AND RESPONSIBILITIES

3.1 Apheresis Coordinator/designee, Clinical Quality Program (CQP) quality assurance (QA) personnel, Duke Hospital Material Management personnel.

3.2 The Apheresis Coordinator/designee is responsible for:

3.2.1 The accurate inspection, documentation, and storage of supplies received for apheresis.

3.2.2 Maintaining current copies of package inserts, Certificates of Analysis (COA), and retaining outdated copies of same.

3.2.3 The CQP QA personnel are responsible for inspecting and releasing the supplies for use.

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4 DEFINITIONS/ACRONYMS

4.1 ABMT: Adult Blood and Marrow Transplant

4.2 ACD-A: Acid citrate dextrose formula A

4.3 COA: Certificate of Analysis

4.4 COC: Certificate of Conformance

4.5 CQP: Clinical Quality Program

4.6 NS: Normal Saline

4.7 PDF: Portable Document File

4.8 QA: Quality Assurance

4.9 SOP: Standard Operating Procedure

5 MATERIALS

5.1 Pediatric Apheresis Supply Notebook

5.2 Red Sign for Quarantine (do not use)

5.3 Green Sign for Release (OK to Use)

5.4 Green Stickers for release (OK to Use)

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Materials management personnel will deliver apheresis supplies to the ABMT Clinic supply room. Supplies shipped directly from the supplier will be delivered directly to the ABMT Clinic.

8.2 Materials management personnel will place the newly delivered apheresis supplies in a designated area. They will place a red “Quarantine” sign, which is found with the Pediatric Apheresis Supply Notebook, to identify the new supplies delivered.

8.3 Materials management personnel will place the apheresis kits in designated area. The Apheresis Coordinator/designee will unbox and inspect the kits. They will place a red “Quarantine” sign on them.

8.4 The Apheresis coordinator/designee will inspect all delivered supplies for damage, contamination, leakage, abnormal color, cloudiness.

8.5 If there are any unacceptable supplies (see Section 8.4 above), the PBMT-EQUIP-003 FRM3 *Unacceptable Supply and Corrective Action Log* will be completed.

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8.6 The Apheresis Coordinator/designee will record the following supply information on the PBMT-EQUIP-003 FRM1 *Material Acceptance Specification Quality Checklist* in the Pediatric Apheresis Supply Notebook:

8.6.1 Initials of staff signing in supply

8.6.2 Date of receipt

8.6.3 Lot number(s)

8.6.4 Expiration date, if applicable

8.6.5 Quantity received

8.6.6 Matches packing slip, if applicable

8.6.7 Passes visual inspection

8.6.8 Product insert included, if applicable

8.6.8.1 If a product insert is delivered, document on the PBMT-EQUIP-003 FRM2 *Package Insert Review Log.* Verify that the revision date of the new package insert is the same as the package insert on file, under the appropriate product. Discard the product insert if it is.

8.6.8.2 If the product insert is a new version, record new version on the PBMT-EQUIP-003 FRM2 *Package Insert Review Log*.

8.6.8.2.1 Review the insert for changes. If changes are identified, notify Apheresis Coordinator for upcoming document revisions and training.

8.6.8.2.2 Place the new version in front of the old one in the Pediatric Apheresis Supply Notebook. The supply cannot be used until the Apheresis Coordinator has been contacted and procedure changes are implemented, and staff is trained.

NOTE: If package insert for apheresis kit is lost, contact Terumo BCT service desk and request copy.

8.6.9 Certificate of Analysis (COA), if applicable:

8.6.9.1 To obtain the COA for Normal Saline and Acid Citrate Dextrose Formula A (ACD-A):

Go to website Fenwal.com.

http://certificates.freseniuskabius.com/pages/CHome.aspx

Scroll to the bottom of page. Select Certificates. Select COA. Enter lot #. Print PDF file of the COA and place in Pediatric Apheresis Supply Notebook, COA section.

NOTE: Some COAs are not found on this website due to production flows and services available. Contact Apheresis Coordinator if unable to locate COA.

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8.7 Clinical Quality Program (CQP) QA personnel will inspect and verify that the supplies are acceptable, and that all applicable documentation is completed. After inspection and sign-off, the CQP QA personnel will place an "OK to Use" sign on the supplies.

8.8 The Apheresis coordinator/designee will rotate the new stock to ensure "first in first out rotation" of supplies.

8.9 Storage and Disposal

8.9.1 Pediatric apheresis supplies must be stored at appropriate temperature and humidity ranges in a safe, sanitary and orderly manner.

8.9.2 The ABMT Clinic supply room is the area where the pediatric apheresis supplies are stored. The temperature and humidity will be recorded each day in this area by the Apheresis Coordinator/designee.

8.9.3 Outdated supplies will be appropriately disposed according to Duke Hospital policy.

9 RELATED DOCUMENTS/FORMS

9.1 PBMT-EQUIP-003 FRM1 Materials Acceptance Specification Quality Checklist

9.2 PBMT-EQUIP-003 FRM2 Package Insert Review Log

9.3 PBMT-EQUIP-003 FRM3 Unacceptable Supply and Corrective Action Log

10 REFERENCES

10.1 AABB Standards for Hematopoietic Progenitor Cell Services, current edition

10.2 FDA Code of Federal Regulations, Title 21

10.3 FACT-JACIE Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	M. Ritt	Removed reference to Quality Systems Unit (QSU) throughout the document and replaced with Clinical Quality Program (CQP)

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Signature Manifest

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