



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Overview of the Collection Facility Personnel

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APBMT-GEN-002

OVERVIEW OF THE COLLECTION FACILITY PERSONNEL

1. PURPOSE

- 1.1. This document serves as an overview of the personnel required for everyday functioning for both the Adult and Pediatric Blood and Marrow Transplant (APBMT) collection facilities.

2. INTRODUCTION

- 2.1. The APBMT clinical program's collection facilities, including the Stem Cell Laboratory (STCL) processing facility, is comprised of integrated medical and nursing teams housed in close proximity to Duke University Medical Center in Durham, NC. The program employs staff training programs, protocols, and quality management systems.
- 2.2. The APBMT apheresis collection facility consists of a combined adult and pediatric program with designated areas for outpatient apheresis collections of cellular therapy products. Refer to APBMT-GEN-003 *Overview of the Collection Facilities*.
 - 2.2.1. The Adult Blood and Marrow Transplant (ABMT) apheresis suite is located on the first floor in the North Pavilion building.
 - 2.2.2. The Pediatric Blood and Marrow Transplant (PBMT) apheresis treatment room is located on the 4th floor of the Children's Health Center (CHC).
- 2.3. The APBMT bone marrow harvest collection facility is shared between the Duke University Hospital Operating Suites and the Ambulatory Surgery Center (ASC).
 - 2.3.1. PBMT bone marrow harvest collections are performed at the Duke University Hospital Operating Suites (Duke North).
 - 2.3.2. ABMT bone marrow harvest collections are performed in the ASC located in the North Pavilion building on the 2nd floor.

3. SCOPE AND RESPONSIBILITIES

- 3.1. Multidisciplinary: The dedicated pediatric and adult collection facilities are staffed by Registered Nurses (RNs), attending physicians, Advanced Practice Providers (APPs), Transplant Coordinators (TC), and additional allied staff, who care for the collection facilities patients and are responsible for maintaining and supporting the characteristics of each collection facility.

4. DEFINITIONS/ACRONYMS

- 4.1. APBMT: Adult and Pediatric Blood and Marrow Transplant
- 4.2. ABMT: Adult Blood and Marrow Transplant
- 4.3. APP: Advanced Practice Provider
- 4.4. CHC: Children's Health Center

- 4.5. CRF Code of Federal Register
- 4.6. ECP: Extracorporeal Photopheresis
- 4.7. FACT Foundation for the Accreditation of Cellular Therapy
- 4.8. PBMT: Pediatric Blood and Marrow Transplant
- 4.9. PBPC: Peripheral Blood Progenitor Cell
- 4.10. QM: Quality Manager
- 4.11. RN: Registered Nurse
- 4.12. SOP: Standard Operating Procedure
- 4.13. TC: Transplant Coordinator

5. MATERIALS

- 5.1. NA

6. EQUIPMENT

- 6.1. NA

7. SAFETY

- 7.1. NA

8. PROCEDURE

8.1. APBMT Directors

8.1.1. The collection and processing program directors for APBMT, including the STCL, are Drs. Joanne Kurtzberg and Nelson Chao. Refer to Standard Operating Procedures (SOPs): APBMT-COMM-027 *Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan* and STCL-SOP-032 *Responsibility of Facility Directors* for full list of responsibilities. These individuals also serve as the Medical Directors of the APBMT clinical programs. Both licensed physicians:

- 8.1.1.1. Have completed post-doctoral training in apheresis and bone marrow harvest collections.
- 8.1.1.2. Are responsible to oversee the APBMT SOPs for the program's operations and technical procedures.
- 8.1.1.3. Are responsible for the supervision of staff, administrative operations, and the Quality Management program.
- 8.1.1.4. Participate in annual education activities related to the collection of cellular therapy products.
- 8.1.1.5. Oversee written or electronic orders outlining the procedures used to harvest, process, and thaw all cellular products, including how to handle "Non-Conforming" products and testing after procurement, post-processing, and pre-infusion.

- 8.1.1.6. Assure compliance with the Foundation for the Accreditation of Cellular Therapy (FACT) collection standards, quality management plan, and applicable laws, including 21 Code of Federal Register (CFR) 1271 regulations.
- 8.1.2. The adult collection facility is under the direction of Dr. Gwynn Long and the pediatric collection facility is under the direction of Dr. Joanne Kurtzberg. Refer to SOPs: APBMT-COMM-027 *Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan* and STCL-SOP-032 *Responsibility of Facility Directors*. Both licensed physicians participate in annual education activities related to the collection of cellular therapy products and are responsible for the oversight/supervision of:
 - 8.1.2.1. Staff, administrative operations, and the Quality Management program.
 - 8.1.2.2. Pre-collection evaluation of the prospective donor at the time of donation.
 - 8.1.2.3. Performance of the collection procedure, related to marrow, peripheral blood progenitor cells (PBPC) and other cellular collections for both autologous and allogeneic use.
 - 8.1.2.4. Management of any patient developing complications resulting from the apheresis collection procedure.
 - 8.1.2.5. Assure compliance with the Foundation for the Accreditation of Cellular Therapy (FACT) collection standards, quality management plan, and applicable laws, including 21 Code of Federal Register (CFR) 1271 regulations.
- 8.2. Collection Facility Quality Manager
 - 8.2.1. The APBMT Program Collection Facilities for apheresis and bone marrow harvest collections quality manager is Patrick Killela, Ph.D.
 - 8.2.1.1. The Quality Manager is responsible for the establishment and maintenance system to review, modify, and approve all policies and SOPs related to compliance.
 - 8.2.1.2. The Quality Manager has an independent reporting structure and completes educational activities annually related to cellular therapy and quality management. Refer to APBMT-COMM-027 *Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan*.
- 8.3. APBMT Apheresis Collection Facility Support Staff
 - 8.3.1. The APBMT Collection Facility employs physicians, fellows, and APPs that are responsible for the care of the APBMT Collection Facility's donor throughout the collection procedure.

- 8.3.1.1. Refer to APBMT-COMM-022 *Adult and Pediatric Blood and Marrow Transplant Programs' Training for Physician*, APBMT-COMM-023 *Physician Training for Transplant Program Director and Attending Physician Checklist*, and APBMT-COMM-024 *Nurse Practitioner Physician's Assistant Training Checklist*.
- 8.3.2. The APBMT Collection Facility employs population specific TCs that are used as a primary resource and liaison for the patient's care and the APBMT team. The APBMT TC may also be used as the donor advocate.
 - 8.3.2.1. Refer to the APBMT-COMM-025 *Adult and Pediatric Blood and Marrow Transplant Coordinator Nurse Clinician Competencies for the APBMT Collection Facility training*.
- 8.3.3. The APBMT Apheresis Collection Facility employs RNs who are licensed and fully trained in donor screening, the operation of the Terumo BCT Spectra Optia and/or the Therakos Cellex Photopheresis System, blood transfusion practices, and in general care of donors.
 - 8.3.3.1. The APBMT apheresis collection RN performs the collection procedure under the guidance of the APBMT attending physician.
 - 8.3.3.2. Refer to APBMT-COLL-002 *Apheresis Nurse Training* for the standard requirements of the apheresis collection facility RN staff training.
 - 8.3.3.3. For pediatric collections, CHC staff assist in carrying out the supportive care and treatment responsibilities, while the apheresis collection RN performs the collection procedure.
- 8.4. APBMT Bone Marrow Harvest Collection Support Staff
 - 8.4.1. Bone Marrow Harvest collection are performed by an APBMT attending physician, who may be assisted by an additional attending physician, an APP, or fellow.
 - 8.4.1.1. Refer to APBMT-COMM-022 *Adult and Pediatric Blood and Marrow Transplant Programs' Training for Physician*, APBMT-COMM-023 *Physician Training for Transplant Program Director and Attending Physician Checklist*, and APBMT-COMM-024 *Nurse Practitioner Physician's Assistant Training Checklist*.
- 8.5. Current Good Manufacturing Practices (GMP) Training
 - 8.5.1. Physicians, collection and processing staff, and other applicable staff, will train annually, at minimum, on the Current Good Manufacturing Practices appropriate to the processes performed and in accordance with applicable law.

- 8.5.1.1. Refer to COMM-QA-068 *Good Manufacturing Practices - GMP- Referred to as Current Good Manufacturing Practices – cGMP*

9. RELATED DOCUMENTS/FORMS

- 9.1.1. APBMT-COLL-002 Apheresis Nurse Training
- 9.1.2. APBMT-COMM-022 Adult and Pediatric Blood and Marrow Transplant Program's Training for Physician
- 9.1.3. APBMT-COMM-023 Physician Training for Transplant Program Director and Attending Checklist
- 9.1.4. APBMT-COMM-024 Nurse Practitioner Physician's Assistant Training Checklist
- 9.1.5. APBMT-COMM-025 Adult and Pediatric Blood and Marrow Transplant Coordinator Nurse Clinician Competencies
- 9.1.6. APBMT-GEN-003 Overview of the Collection Facilities
- 9.1.7. STCL-SOP-032 Responsibility of Facility Directors
- 9.1.8. COMM-QA-068 Good Manufacturing Practices - GMP- Referred to as Current Good Manufacturing Practices – cGMP
- 9.1.9. APBMT-COMM-027 Adult and Pediatric Blood and Marrow Transplant Program Quality Management Plan

10. REFERENCES

- 10.1. NA

11. REVISION HISTORY

Revision No.	Author	Description of Change(s)
09	M. Christen	<ul style="list-style-type: none"> • Updated related SOPs to current versions • Updated definition/acronyms throughout the document • Corrected grammar • Better defined training and competencies • Verified all other information is correct with current standards, practices, and names • Focused entire SOP to the Collection Facility Personnel and removed all non-personnel related material • Added related SOP that better relate to the personnel in the collection facilities

Signature Manifest

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