



DukeMedicine
Division of Cellular Therapy



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

DOCUMENT NUMBER: APBMT-GEN-003

DOCUMENT TITLE:

Overview of the Collection Facilities

DOCUMENT NOTES:

Document Information

Revision: 10

Vault: APBMT-General-rel

Status: Release

Document Type: APBMT

Date Information

Creation Date: 16 Jan 2024

Release Date: 26 Jan 2024

Effective Date: 26 Jan 2024

Expiration Date:

Control Information

Author: MC363

Owner: MOORE171

Previous Number: APBMT-GEN-003 Rev 09

Change Number: APBMT-CCR-251

APBMT-GEN-003

OVERVIEW OF THE COLLECTION FACILITIES

1. PURPOSE

- 1.1. This document serves as an overview of the Adult and Pediatric Blood and Marrow Transplant (APBMT) clinical program's collection facilities for cellular therapies.

2. INTRODUCTION

- 2.1. The APBMT clinical program is comprised of integrated multidisciplinary facilities. For the full program composition and scope, refer to APBMT-COMM-008 *Overview of the Adult and Pediatric Blood and Marrow Transplant Program*.
 - 2.1.1. APBMT inpatient and outpatient facilities for the clinical care of pediatric and adult patients, which includes the adult Blood Cancer Center (BCC)
 - 2.1.2. A stem cell laboratory (STCL) processing facility
 - 2.1.3. A public cord blood bank facility- Carolinas Cord Blood Bank (CCBB)
 - 2.1.4. APBMT collection facilities
- 2.2. Located in distinct care areas, the APBMT collection facilities performs both autologous and allogeneic, related and unrelated, collections that include bone marrow, mobilized and non-mobilized peripheral blood, and umbilical cord blood.
- 2.3. There are dedicated personnel who care for patients and are responsible for maintaining and supporting the characteristics of each collection facility staff the APBMT collection facilities. Refer to APBMT-COMM-002 *Overview of the Collection Facility Personnel*.
- 2.4. All activities related to cellular therapy collections and within each respective facility is conducted in a manner designed to minimize risks to the health and safety of employees, donors, visitors, and volunteers.
 - 2.4.1. Duke Occupational and Environmental Online Safety Training Modules located at www.safety.duke.edu detail the standard operating procedures (SOPs), training, and compliance with Biologic, Chemical, Radiation, and Fire Safety. Monitoring systems for training and compliance are established and are set by hospital leadership.
 - 2.4.2. In the event the APBMT collection facilities' operations are interrupted, refer to the BCC Emergency Plan. At minimum the safety of the donor must be evaluated, required controlled documents shall be readily available using the "Down Time Computer", and the cellular products will be placed in secured transplant containers and promptly delivered to the STCL to ensure the integrity of the cellular product is not compromised.
 - 2.4.2.1. Transport containers are never left unattended or with unauthorized personnel.

- 2.5. The APBMT collection facilities, including the STCL, abides by all applicable governmental laws and regulation and maintain licenses, registrations, and accreditations as required by:
 - 2.5.1. The Food and Drug Administration (FDA) for the collection and processing of cellular products.
 - 2.5.2. The Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee ISCT-Europe (JACIE) standards.
- 2.6. The STCL is College of American Pathologist (CAP) accredited, as well as Clinical Laboratory Improvement Amendments (CLIA) certified.
- 2.7. The APBMT collection facilities are supported by the American Society for Histocompatibility and Immunogenetics (ASHI) accredited Human Leukocyte Antigen (HLA) Laboratory and the American Association of Blood Banks (AABB) accredited Transfusion Services at Duke University Hospital.

3. SCOPE AND RESPONSIBILITIES

- 3.1. Multidisciplinary: All members of the APBMT collection facilities and STCL are responsible for adhering to the contents of this overview document.

4. DEFINITIONS/ACRONYMS

- 4.1. Cellular Therapy: Somatic cell-based products (e.g., mobilized hematopoietic cells (HPC), mononuclear cells (MNC), cord blood cells, mesenchymal stromal cells, T cells, natural killer cells) that is procured from a donor and intended for processing and administration, to include immune effector cells (IECs), gene-modified cells, and other cellular therapies.
- 4.2. Cellular Therapy Collections and Products: Includes both apheresis and bone marrow harvest.
- 4.3. APBMT Adult and Pediatric Blood and Marrow Transplant Program
- 4.4. ABMT Adult Blood and Marrow Transplant
- 4.5. AED Automatic External Defibrillator
- 4.6. APP Advance Practice Provider
- 4.7. ARC American Red Cross
- 4.8. ASC Ambulatory Surgery Center
- 4.9. ASHI American Society for Histocompatibility and Immunogenetics
- 4.10. BCC Blood Cancer Center
- 4.11. BMT Bone Marrow Transplant
- 4.12. CAP College of American Pathologist
- 4.13. CCBB Carolinas Cord Blood Bank
- 4.14. CHC Children's Health Center
- 4.15. CLIA Clinical Laboratory Improvement Amendments

4.16.EMR	Electronic Medical Record
4.17.FACT	Foundation for the Accreditation of Cellular Therapy
4.18.HEPA	High Efficiency Particulate Air
4.19.HLA	Human Leukocyte Antigen
4.20.HPC	Hematopoietic Cells
4.21.IEC	Immune Effector Cells
4.22.ISCT	International Society Cell & Gene Therapy
4.23.JACIE	Joint Accreditation Committee ISCT-Europe
4.24.MNC	Mononuclear Cells
4.25.PBMT	Pediatric Blood and Marrow Transplant
4.26.RN	Registered Nurses
4.27.SC	Subcutaneous
4.28. STCL	Stem Cell Laboratory

5. MATERIALS

5.1. NA

6. EQUIPMENT

6.1. NA

7. SAFETY

7.1. NA

8. PROCEDURE

8.1. The APBMT Collection Facilities

8.1.1. The APBMT collection facilities include:

- 8.1.1.1. The adult blood and marrow transplant (ABMT) apheresis collection facility
- 8.1.1.2. The pediatric blood and marrow transplant (PBMT) apheresis collection facility
- 8.1.1.3. The pediatric and adult bone marrow harvest facility

8.1.2. Environmental, equipment, supplies, and cleaning of the APBMT collection facilities consists of:

- 8.1.2.1. Duke Hospital Facilities Management Department who manages the physical environments
- 8.1.2.2. Duke Clinical Engineering and Operations who manages quality control and repair of clinical equipment

- 8.1.2.3. Duke Materials Management who manages the critical supplies
- 8.1.2.4. Dedicated staff of the Duke Environment Services manage the cleaning
- 8.1.3. Critical facility parameters, which could affect product viability, integrity, contamination, sterility, and cross-contamination during collection, are accessed using APBMT-GEN-003 JA1 *Assessment of Apheresis Collection Facility Parameters*.
- 8.1.4. The APBMT collection facilities, including the STCL and supply area, are secure and control accessed designated suites, with adequate space and designed to minimize the risk of airborne microbial contamination.
- 8.1.5. The APBMT collection facilities have designated areas for appropriate preparation and storage of the reagents and equipment needed for the performance of the collection procedure.
- 8.1.6. There is adequate lighting, ventilation, toilets, and sinks throughout the collection facilities with readily available access to restroom amenities for staff and patients alike.
- 8.1.7. APBMT bone marrow harvest collections are performed in designated areas that are adequately spaced and separated to prevent mix-up, contamination, or cross-contamination of cellular therapy products.
- 8.1.8. APBMT apheresis collections are performed in designated treatment areas, in either chairs or beds adequately spaced and separated to prevent mix-up, contamination, or cross-contamination of cellular therapy products. Private rooms are available if patients are designated for Isolation Precautions.
- 8.1.9. APBMT cellular therapy products are processed by the STCL, except for research studies that state differently in its protocol or procedure manual.
- 8.2. ABMT Apheresis Collection Facility
 - 8.2.1. Facility, Location, and Hours of Operation
 - 8.2.1.1. The ABMT apheresis collection facility is located in the ABMT outpatient facility on the 1st floor of the North Pavilion, Suite 1100.
 - 8.2.1.2. Hour of operation are Monday through Friday 0800-1800; Saturdays, Sundays, and Holidays 0800-1600.
 - 8.2.1.3. While the ABMT outpatient facility is open on the weekends and some holidays, ABMT apheresis collections are not routinely performed on weekend days or holidays. Apheresis personnel will be available should the need arise for an apheresis collection to occur outside of routine weekdays.

8.3. PBMT Apheresis Collection Facility

8.3.1. Location and Hours of Operation:

APBMT-GEN-003 Overview of the Collection Facilities
 APBMT, DUMC
 Durham, NC

- 8.3.1.1. The Pediatric Apheresis Collection Facility is located on the 4th floor of the Children's Health Center (CHC), which is immediately adjacent to Duke North Hospital.
- 8.3.1.2. Hour of operation are Monday through Friday 0800-1930; Saturdays, and Sundays 0800-1830; Holidays 0800-1830. The collection facility is closed on Thanksgiving Day, Christmas Day, and New Year's Day.
- 8.3.1.3. While open on the weekends and some holidays, apheresis collections are not routinely performed on weekend days and holidays. Apheresis personnel will be available should the need arise for a collection to occur outside of routine weekdays.

8.4. APBMT Bone Marrow Harvest Collection Facility

8.4.1. Facility, Location, and Logistics

- 8.4.1.1. The APBMT bone marrow harvest collection facility is shared between the Duke University Hospital Operating Suites and the Ambulatory Surgery Center (ASC).
 - 8.4.1.1.1. Separate waiting, pre-op, and recovery rooms available.
 - 8.4.1.1.2. PBMT bone marrow harvest collections are primarily performed at the Duke University Hospital Operating Suites (Duke North).
 - 8.4.1.1.3. ABMT bone marrow harvest collections are primarily performed in the ASC located in the North Pavilion building on the 2nd floor.
 - 8.4.1.1.4. While the Duke North and the ASC are open 24-hours a day, bone marrow harvest collection are performed Monday through Friday between the hours of 0600-1700 and are not performed on weekend days or holidays.

8.5. Facilities that Support the APBMT Collection Facilities

8.5.1. STCL Processing Facility Support

- 8.5.1.1. The STCL processing facility serves, collaborates, and supports the APBMT clinical program and works closely with the APBMT collection facilities, as well as Duke University Hospital research program protocols and other transplant facilities through National Marrow Donor Program (NMDP). Refer to STCL-GEN-017 *Stem Cell Laboratory Overview*.

- 8.5.1.2. Services include, but not limited to testing, processing, cryopreservation, collection, thawing, and/or distribution of cellular therapy products.
- 8.5.1.3. Facility, Location, and Hours of Operation:
 - 8.5.1.3.1. The STCL processing facility is located on the 1st floor of the North Pavilion, Suite 1300.
 - 8.5.1.3.2. Hours of operation are Monday through Friday from 0830-2000 divided into 1st and 2nd shifts and closed on holidays.
 - 8.5.1.3.3. While apheresis collections are not routinely performed on weekends and holidays, limited staff is available on-call when needed to cover the processing and cryopreservation of apheresis products on weekends and/or holidays.
- 8.5.1.4. There are dedicated personnel responsible for maintaining and supporting the characteristics of the STCL processing facility. Refer to STCL-SOP-033 *Stem Cell Laboratory Personnel*.
- 8.5.2. APBMT Inpatient and Outpatient Facility Support
 - 8.5.2.1. The APBMT inpatient and outpatient facilities and clinical units support the APBMT collection facilities in the care of the pre- and post-transplant or reinfusion patient populations.
 - 8.5.2.2. There are dedicated personnel responsible for maintaining and supporting the characteristics of the APBMT inpatient and outpatient facilities. Refer to APBMT-COMM-018 *Overview of Clinical Units*.
- 8.5.3. Transfusion Services Support
 - 8.5.3.1. The Duke Hospital Transfusion Service provides 24-hour blood product support and is located on the 1st floor of Duke University Hospital.
 - 8.5.3.2. Blood product support includes irradiated, leukocyte depleted, and CMV negative blood products, which obtains products from the American Red Cross (ARC).
 - 8.5.3.3. The ARC has local collection facilities in Durham, as well as a regional center and National Testing Laboratory in Charlotte, NC.
- 8.5.4. Emergency Care Support
 - 8.5.4.1. Emergency medical care is available for the donor should the need arise.

- 8.5.4.1.1. In the Pediatric Apheresis Collection Facility, a pediatric code team is on call and available 24-hours a day.
- 8.5.4.1.2. In the Adult Apheresis Collection Facility, the care team calls 911 and the local emergency medical technicians (EMT) responses.
- 8.5.4.2. Code carts, oxygen, suction, and an automatic external defibrillator (AED) are available.
- 8.5.5. Intensive Care Support
 - 8.5.5.1. A dedicated Pediatric Intensive Care Unit that is adequately spaced, which is staffed with clinicians with age-specific competencies.
 - 8.5.5.1.1. This unit has availability of High Efficiency Particulate Air (HEPA) filtered isolation rooms for immuno-compromised patients.
 - 8.5.5.2. An Adult Medical Intensive Care Unit and Surgical Intensive Care Unit that is adequately spaced, which is staffed with clinicians with age-specific competencies.

9. RELATED DOCUMENTS/FORMS

- 9.1. APBMT-COMM-008 Overview of the Adult and Pediatric Blood and Marrow Transplant Program
- 9.2. APBMT-COMM-018 Overview of Clinical Units
- 9.3. APBMT-GEN-003 JA1 Assessment of Apheresis Collection Facility Parameters
- 9.4. APBMT-COMM-002 Overview of the Collection Facility Personnel
- 9.5. STCL-GEN-017 Stem Cell Laboratory Overview
- 9.6. STCL-SOP-033 Stem Cell Laboratory Personnel

10. REFERENCES

- 10.1. Buchsel, PC and PM Kapustay, Eds. Stem Cell Transplantation: A Clinical Textbook. Oncology Nursing Press, Pittsburgh PA. 2000.
- 10.2. American Association of Blood Banks (AABB). Standards for Hematopoietic Progenitor Cell and Cellular Product. 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)
10	Mary Christen	<ul style="list-style-type: none">• Added information regarding actions to take if APBMT collection facilities' have interruptions, which included a brief summary of minimum actions to take and the reference to the BCC Emergency Plan. (FACT C4.12)• Updated Reference listed in Section 10.

Signature Manifest

Document Number: APBMT-GEN-003

Revision: 10

Title: Overview of the Collection Facilities

Effective Date: 26 Jan 2024

All dates and times are in Eastern Time.

APBMT-GEN-003 Overview of the Collection Facilities

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Jan 2024, 01:38:47 PM	Approved