



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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APBMT-COMM-008

OVERVIEW OF THE ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

1 PURPOSE

- 1.1 To outline provide an overview of the Adult and Pediatric Blood and Marrow Transplant (APBMT) program which also includes the Immune Effector Cell Programs and other aspects of cellular therapy.

2 INTRODUCTION

- 2.1 Together, the pediatric and adult programs are generically referred to as The Adult and Pediatric Blood and Marrow Transplant (APBMT) Program. APBMT is comprised of integrated multidisciplinary teams housed in proximate space at Duke University Medical Center in Durham, NC.
 - 2.1.1 Pediatric Program: The Pediatric Blood and Marrow Transplant (PBMT) Program at Duke University Medical Center was established in 1990. In 2020, it formally became known as The Pediatric Transplant and Cellular Therapy Division (PTCT). For a full view of the program's timeline, see related document *PBMT-GEN-002 Overview of Duke University Pediatric Blood and Marrow Transplant Program Personnel*.
 - 2.1.2 Adult Program: The Adult Blood and Marrow Transplant (ABMT) Program at Duke University Medical Center was established in 1984. In 2021, it formally became known as The Hematologic Malignancies and Cellular Therapy Division. Before colocation, the Hematological Malignancies Clinic had resided in the Cancer Center. The ABMT Clinic and Hematological Malignancies Clinic are now located in the Blood and Cancer Center (BCC) at North Pavilion. All accreditations and certifications under the prior names apply at the BCC. For a full view of the program's timeline, see related document *ABMT-GEN-004 Personnel Overview*.
- 2.2 The program uses common staff training programs, standard operating procedures (SOPs), protocols, laboratories, and a separate quality systems unit. The Quality Systems Unit (QSU) is under the direction of the School of Medicine and has oversight of the quality management systems.
- 2.3 The APBMT clinical program abides by all applicable Federal and State laws and regulations and utilizes the in and outpatient units accredited by the Joint Commission on Accreditation of Healthcare Organizations.
- 2.4 Hematopoietic cell collection and processing facilities are an integral part of the program.
- 2.5 Both the collection and laboratory facilities abide by all applicable governmental law and regulations and are registered with the Food & Drug Administration (FDA) for the collection and processing of HCT/Ps and meet all of the

Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee ISCT-Europe (JACIE) standards.

- 2.6 The Stem Cell Transplant Laboratory (STCL) is both College of American Pathologist (CAP) and FACT accredited, as well as Clinical Laboratory Improvement Amendments (CLIA) certified.
- 2.7 The program is supported by an American Society for Histocompatibility and Immunogenetics (ASHI)-accredited HLA (human leukocyte antigen) Laboratory and the AABB accredited Transfusion Service at Duke Hospital.

3 SCOPE AND RESPONSIBILITIES

- 3.1 Leadership within the APBMT Program are responsible for having knowledge of the contents of this overview document.

4 DEFINITIONS/ACRONYMS

- 4.1 ABMT Adult Blood and Marrow Transplant
- 4.2 APBMT Adult and Pediatric Blood and Marrow Transplant
- 4.3 ASBMT American Society of Blood and Marrow Transplant
- 4.4 ASHI American Society for Histocompatibility and Immunogenetics
- 4.5 BCC Blood Cancer Center
- 4.6 CALGB Cancer and Leukemia Group B
- 4.7 CAP College of American Pathologist
- 4.8 CCBB Carolinas Cord Blood Bank
- 4.9 CLIA Clinical Laboratory Improvement Amendments
- 4.10 COG Children's Oncology Group
- 4.11 CTN Clinical Trials Network
- 4.12 FACT Foundation for the Accreditation of Cellular Therapy
- 4.13 HLA Human Leukocyte Antigen
- 4.14 ISCT International Society Cell & Gene Therapy
- 4.15 JACIE Joint Accreditation Committee ISCT-Europe
- 4.16 MC3 Marcus Center for Cellular Cures
- 4.17 NMDP National Marrow Donor Program
- 4.18 QSU Quality Systems Unit
- 4.19 STCL Stem Cell Laboratory
- 4.20 SOP Standard Operating Procedure

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Program – Composition

8.2 The program is comprised of:

8.2.1 Hospital inpatient and outpatient facilities for the clinical care of adult and pediatric patients

8.2.2 A clinical stem cell laboratory (STCL)

8.2.3 Integrated stem and progenitor cell collection facilities for both adult and pediatric patients

8.2.4 For more information about component of the Program Facilities, see related policies:

8.2.4.1 APBMT-COMM-018 *Overview of Clinical Units*

8.2.4.2 APBMT-GEN-003 *Overview of Collection Facilities*

8.3 Program - Scope

8.3.1 Both allogeneic, related and unrelated, and autologous transplants are performed.

8.3.2 Stem cell sources utilized include bone marrow, mobilized peripheral blood, and umbilical cord blood.

8.3.3 Ablative, reduce intensity and non-myeloablative conditioning is utilized.

8.3.4 Cellular therapy, including the Immune Effector Cell Programs for each Program's patient populations.

8.3.4.1 The Programs' Cellular Therapy Organizational and Reporting Structure is synonymous with that of the APBMT organizational structure.

8.3.5 For more information about Program Scope, see related policies:

8.3.5.1 ABMT-GEN-002 *ABMT Scope of Practice*

8.3.5.2 PBMT-GEN-001 *Scope of Care*

8.4 Program – Establishment

8.4.1 1984: Dr. William Peters established the adult program as an autologous transplant program.

8.4.2 1990: Dr. Joanne Kurtzberg established the pediatric program in 1990 as a combined autologous and allogeneic program.

- 8.4.3 1996: Dr. Nelson Chao was recruited to Duke to establish an adult allogeneic program and direct the overall adult program.
- 8.4.4 2020: The clinical programs combined have transplanted more than 8200 patients since their establishment. Approximately 70 pediatric and 250 adult patients are currently transplanted each year.
- 8.4.5 For more information about Program History and Personnel, see related policies:
 - 8.4.5.1 ABMT-GEN-004 *Personnel Overview*
 - 8.4.5.2 PBMT-GEN-002 *Overview of Duke University Pediatric Blood and Marrow Transplant Personnel*
- 8.5 Program - Divisional Structure
 - 8.5.1 The Adult Program is a separate division in the Department of Medicine, Division of Duke Hematological Malignancies and Cellular Therapy of Duke Hospital.
 - 8.5.2 The Pediatric Program is a separate division in the Department of Pediatrics, Division of Pediatric Blood and Marrow Transplantation and Children's Services in Duke Hospital.
 - 8.5.3 The Stem Cell Transplant Laboratory is a laboratory of Duke University Hospital.
 - 8.5.4 The combined program also works closely with the Marcus Center for Cellular Cures (MC3), which focuses on cellular therapy clinical trials and supports the Robertson GMP Laboratory and the Carolinas Cord Blood Bank (CCBB), an FDA licenses public cord blood bank.
 - 8.5.5 For more information about Program structure see related policies:
 - 8.5.5.1 ABMT-GEN-006 *Adult Transplant Leadership Team*
 - 8.5.5.2 PBMT-GEN-003 *Duke University Medical Center Pediatric Blood and Marrow Transplant Program Clinical Leadership*
- 8.6 Program – Specialty Support:
 - 8.6.1 The program is supported by a full complement of board certified, licensed adult medical and pediatric sub-specialists at Duke Medical Center including, but not limited to, experts in radiation therapy, infectious diseases, surgery, intensive care, anesthesiology, gastroenterology, pulmonology, cardiology, dermatology, neurology, nephrology, oncology, radiation oncology, hematology, pathology, obstetrics and gynecology, transfusion medicine, immunology, hepatology, interventional, radiology, diagnostic radiology, otolaryngology, ophthalmology, orthopedics, urology, psychiatry, emergency medicine, psychology, palliative/end of life care, rehabilitation services (physical therapy, occupational therapy, speech therapy), nutrition, and pharmacy medicine. All personnel performing collections follow the policies and procedures as related to their discipline and role.

- 8.6.2 For more information about additional staffing roles in support of the program, see related policies:
 - 8.6.2.1 ABMT-GEN-005 *Adult Transplant Team*
 - 8.6.2.2 ABMT-GEN-011 *Other Staff*
 - 8.6.2.3 PBMT-GEN-010 *Support Staff*
- 8.7 Program – Membership, Compliance, and Accreditation
 - 8.7.1 The Adult Collection Program also serves as a National Marrow Donor Program (NMDP) donor center.
 - 8.7.2 The Carolinas Cord Blood Bank, a FACT accredited, FDA licensed unrelated donor cord blood bank provides donor cord blood units to the program as well as to other international transplant centers.
 - 8.7.3 The Program:
 - 8.7.3.1 Has been a member of the National Marrow Donor Program since 1992.
 - 8.7.3.2 Is a certified transplantation site for the Cancer and Leukemia Group B (CALGB) and Children’s Oncology Group (COG), and transplant center and a full member of the Blood and Marrow Clinical Trials Network (CTN).
 - 8.7.3.3 Reports consecutive transplants to the Center for International Blood and Marrow Transplant Research (CIBMTR) and is a member of the American Society for Blood and Marrow Transplant (ASBMT) and the International Society Cell & Gene Therapy (ISCT).
 - 8.7.3.4 Achieved initial FACT accreditation on 05/14/04 and was reaccredited 05/16/07, 06/23/2010, 06/23/2013, 6/23/2016 and 6/23/2019.

9 RELATED DOCUMENTS/FORMS

- 9.1 ABMT-GEN-002 ABMT Scope of Practice
- 9.2 ABMT-GEN-004 Personnel Overview
- 9.3 ABMT-GEN-005 Adult Transplant Team
- 9.4 ABMT-GEN-011 Other Staff
- 9.5 APBMT-COMM-018 Overview of Clinical Units
- 9.6 APBMT-GEN-003 Overview of Collection Facilities
- 9.7 PBMT-GEN-001 Scope of Care
- 9.8 PBMT-GEN-002 Overview of Duke University Pediatric Blood and Marrow Transplant Personnel
- 9.9 PBMT-GEN-010 Support Staff

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

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11	Jennifer Frith	<ul style="list-style-type: none">Section 1.1 and 8.3 updated to include Immune Effector Cell Therapy as part of program scope and explanation of organizational structure.

Signature Manifest

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