



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Overview of Duke University Pediatric Blood and Marrow Transplant Program Personnel

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OVERVIEW OF DUKE UNIVERSITY PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM PERSONNEL

1 PURPOSE

- 1.1 To provide an overview of the personnel structure for the pediatric program for hematopoietic cell transplant and cellular therapy.

2 INTRODUCTION

2.1 Background/Timeline:

- 2.1.1 **1990:** The Pediatric Blood and Marrow Transplant (PBMT) Program, now formally known as The Pediatric Transplant and Cellular Therapy Division, at Duke University Medical Center is established with the support of Hardees Food Systems and the North Carolina Credit Union League.
 - 2.1.1.1 At that time, the program consists of the following:
 - 2.1.1.1.1 A 7 bed inpatient unit
 - 2.1.1.1.2 An outpatient clinic – open 5 days a week
 - 2.1.1.1.3 A treatment room on the inpatient unit for acute outpatient visits during the “off hours”
 - 2.1.1.1.4 A clinical processing laboratory – The Stem Cell Laboratory (STCL)
 - 2.1.1.1.5 The administrative staff required to support the program.
- 2.1.2 **1992:** The program becomes a certified member of the National Marrow Donor Program (NMDP).
- 2.1.3 **1996:** The program is awarded a contract from the National Heart Lung and Blood Institute to establish the Carolinas Cord Blood Bank (CCBB) at Duke, a public cord blood banking facility.
- 2.1.4 **1997:** The inpatient unit relocates within the Duke North bed Tower:
 - 2.1.4.1 The unit expands to a 16-bed unit.
 - 2.1.4.2 The unit includes a dedicated Bone Marrow Outpatient Procedure (BOPP) room for patients to be seen when the outpatient clinic is closed.
- 2.1.5 **2000:** The administrative support space and Stem Cell Laboratory (STCL) moves into a new, enlarged facility.
- 2.1.6 **2001:** The outpatient facilities relocate to a new space in the Children’s Health Center (CHC) containing:
 - 2.1.6.1 Standard outpatient examination rooms

- 2.1.6.2 An outpatient treatment facility, the Valvano Day Hospital (VDH), which is open 7 days a week. Here, outpatient infusion therapy is administered to patients recently discharged from the inpatient setting.
- 2.1.6.3 Dedicated on-site laboratory and pharmacy support.
- 2.1.6.4 Coordinated outpatient care with local home infusion companies as determined by the patient's third party payer.
- 2.1.7 **2004:** The PBMT program becomes a separate Division within the Department of Pediatrics.
- 2.1.8 **2010:** The Robertson Clinical and Translational Cell Therapy Program (CT2) is established to provide administrative and laboratory-based infrastructure to conduct early trials of cellular therapy products in the adult and pediatric populations. The CT program includes:
 - 2.1.8.1 Cell Therapy Clinical Trials program for studies in both traditional as well as in brain injuries, cerebral palsy, and autism.
 - 2.1.8.2 A Good Manufacturing Practice (GMP) Laboratory was established in 2011 for processing advanced cell and tissue based therapeutic products for pediatric and adult patients.
 - 2.1.8.3 A Quality Systems Unit (QSU) to ensure compliance with federal regulations and accreditation agencies.
 - 2.1.8.4 The Carolinas Cord Blood Bank (CCBB), one of the largest public cord blood banks in the world, with an extensive inventory of racially diverse cord blood units (CBU).
 - 2.1.8.4.1 Cord blood units banked at CCBB are listed through the National Marrow Donor Program.
 - 2.1.8.4.2 Donations may also be for directed donations for a family member who has a disease that may be treated with a cord blood transplant or by infusion through one of the clinical trials.
 - 2.1.8.5 The GMP Laboratory, QSU, CCBB are located in the North Pavilion Building, about 3 city blocks from the hospital inpatient units and outpatient clinics.
- 2.1.9 **2012:** The U.S. Food and Drug Administration (FDA) approves a Biologics License Application (BLA) for DUCORD.
 - 2.1.9.1 This product is given as an adjunctive procedure to patients with inborn errors of metabolism who are undergoing standard treatment with unrelated umbilical cord blood transplantation who have evidence of early demyelinating disease in the central nervous system.
- 2.1.10 **2018:** The Marcus Center for Cellular Cures (MC3) is established to further focus on developing cellular and biological therapies for autism,

cerebral palsy, stroke and related brain disorders. At this time, the name “Robertson Clinical and Translational Cell Therapy Program (CT2)” was retired.

2.1.11 **2020:** The PBMT Division name is officially changed to the “Pediatric Transplant and Cellular Therapy” Division to reflect its broadened scope of cellular therapies.

2.1.12 **2021:** The inpatient unit relocates to the new patient bed tower: Duke Central Tower (DCT) – Unit 4A- officially named the Pediatric Transplant and Cellular Therapy & Oncology Unit.

2.1.12.1 The unit contains 17 beds

2.1.12.1.1 16 dedicated inpatient beds

2.1.12.1.2 1 flex bed which may be designated as an inpatient space or an outpatient procedure room depending on current need.

3 SCOPE AND RESPONSIBILITIES

3.1 All program leadership are responsible for having knowledge of the contents of this procedure.

4 DEFINITIONS/ACRONYMS

4.1	BLA	Biologics License Application
4.2	BOPP	Bone Marrow Outpatient Procedure
4.3	CBU	Cord Blood Units
4.4	CCBB	Carolinas Cord Blood Bank
4.5	CHC	Children’s Health Center
4.6	CT2	Robertson Clinical and Translational Cell Therapy Program
4.7	DCT	Duke Central Tower
4.8	FDA	Food and Drug Administration
4.9	GMP	Good Manufacturing Practice
4.10	MC3	Marcus Center for Cellular Cures
4.11	PBMT	Pediatric Blood and Marrow Transplant
4.12	PTCT	Pediatric Transplant and Cellular Therapy
4.13	QSU	Quality Systems Unit
4.14	STCL	Stem Cell Laboratory
4.15	VDH	Valvano Day Hospital

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 OVERVIEW/PROCEDURE

8.1 Originally, the program was staffed with:

8.1.1 Two dedicated pediatric BMT physicians with backup coverage from the Pediatric Hematology/Oncology staff.

8.2 After 1995, staffing was modified to include dedicated:

8.2.1 Pediatric BMT Physicians

8.2.2 Advanced Practice Providers

8.2.3 Nursing Staff

8.3 In 2021, the program is supported with:

8.3.1 5 full time Attending Physicians

8.3.2 1 program-specific Fellow

8.3.3 A dedicated team of clinicians for nighttime coverage

8.3.4 10 Pediatric Advanced Practice Providers

8.3.5 4 Nurse Coordinators

8.3.6 2 Financial Analysts

8.3.7 2 Social Workers

8.3.8 1 dedicated Pharmacist (Inpatient setting)

8.3.9 A team of Pharmacists (Outpatient setting)

8.3.10 1 Dietician

8.3.11 2 Child-life Therapists (Inpatient and Outpatient setting)

8.3.12 A team of Physical Therapists, Occupational Therapists, and Speech Therapists

8.3.13 A team of Child Psychiatrists and Psychologists

8.3.14 1 Music Therapist (Inpatient and Outpatient setting)

8.3.15 1 Quality Systems Unit

8.3.16 1 Computer Programmer

8.3.17 1 Clinical Trials Manager

8.3.18 4-8 Clinical Research Coordinators

8.3.19 3 Members of the Family Support Program

8.3.20 1 Discharge Planner

8.3.21 1 Search Coordinator

8.3.22 1 Chaplain

8.3.23 > 65 Registered Nurses (RNs) caring for PBMT patients in the inpatient and outpatient settings

9 RELATED DOCUMENTS/FORMS

9.1 N/A

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	Sally McCollum	<ul style="list-style-type: none"> - Section 2.1: 2021 change in location information added. - DCT added to acronyms - Section 8.3 updated for current staffing

Signature Manifest

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