DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM QUALITY MANAGEMENT PLAN

1 PURPOSE

1.1 The purpose of this procedure is to describe the process by which the Adult and Pediatric Blood and Marrow Transplant (APBMT) Clinical Programs, Adult and Pediatric Immune Effector Cell Therapy Programs, Adult and Pediatric Collection Programs, and Stem Cell Laboratory (STCL) ensure that they can consistently provide the highest quality patient care, products and services that meet and/or exceed customer satisfaction, accreditation and regulatory requirements, and operate with efficiency to maximize quality.

2 INTRODUCTION

2.1 The overall goal of the Quality Management System (QMS), under the direction of the Quality Systems Unit (QSU) is to ensure that the highest quality products, services and procedures are consistently available and practiced to guarantee the highest quality of care to patients and donors**.** The QSU is distinct and separate from manufacturing and other technical operations. The QSU reports independently to the Vice Dean for Clinical Research and the Dean of the School of Medicine. On an annual basis, at a minimum, the QSU Director provides summary reports to Executive Management and applicable Program/Medical Directors reflecting the performance and the effectiveness of the overall Quality Management Plan (QMP). The annual report and documentation of the review findings shall be made available to key personnel, the Immune Effector Cell Program Directors, the Collection Facility Directors, and the STCL Directors as well.

2.2 Continuous quality improvement is part of the daily activities of the programs. The QMS utilizes Quality System Essentials (QSE) that are internationally recognized as a potent methodology for creating and maintaining high quality standards. The Stem Cell Laboratory (STCL) is integral to the clinical programs since it provides products for administration; thus, it is included here but also has a dedicated QMP to cover STCL specific issues (see SOP: *STCL-QA-006 Stem Cell Laboratory Quality Management Plan*).

2.3 The Adult and Pediatric Clinical, Immune Effector Cell, and Collection Programs and the Stem Cell Laboratory are committed to maintaining a program that:

2.3.1 Meets regulatory and accreditation requirements.

2.3.2 Meets the needs of patients and families by providing the latest approaches to treating life threatening illnesses while delivering high quality care.

2.3.3 Supports growth, development and continuing education of staff.

2.3.4 Supports continued program growth and improvement.

2.4 The quality objectives of the program are:

2.4.1 Incorporation of key performance data, as listed below, from clinical, collection and processing facility quality management:

2.4.1.1 Prevention and detection of errors.

2.4.1.2 Identification and investigation of near misses.

2.4.1.3 Optimization of effectiveness and efficiencies.

2.4.1.4 Advancement of the science of blood and marrow transplantation while providing expert care to patients.

2.4.1.5 Compliance with all relevant regulations and accreditation standards including FACT, JCAHO, CLIA, CAP, AABB, NMDP, NIH, FDA, HRSA and all other applicable regulations.

3 SCOPE AND RESPONSIBILITIES

3.1 The Division Chiefs, who also serve as "Medical Directors" for FACT Accreditation Processes, or their designees will have authority and responsibility for ensuring that the Quality Management Program is effectively established and maintained.

3.2 All APBMT Clinical Programs, Immune Effector Cell Programs, Adult and Pediatric Collection Programs, Stem Cell Laboratory, and Quality Systems Unit employees engaged in activities that could affect the safety, quality, identity, purity, and potency (SQIPP) of a product and/or deliver care to a transplant patient are responsible for understanding and following the principles of this Standard Operating Procedure (SOP).

3.3 A separate Quality Systems Unit reporting to the Vice Dean for Clinical Research and the Dean of the School of Medicine has oversight of the quality systems within the programs. The QSU coordinates, monitors and facilitates defined Quality Assurance (QA) activities for the programs and ensures that the quality of products and services meet applicable regulatory and accreditation requirements.

3.4 The Division Chiefs, who also serve as "Medical Directors" for FACT Accreditation Processes, or their designees will not have oversight of his/her own work if they also perform tasks in the clinical program.

3.5 The Quality Systems Unit will report on the performance of the Quality Management Plan, at a minimum, quarterly to the Division Chiefs and the Adult and Pediatric Blood and Marrow Transplantation (APBMT) and Cellular Therapy Quality Assurance Review Committee.

4 DEFINITIONS/ACRONYMS

4.1 AABB American Associations of Blood Bank

4.2 ABMT Adult Blood and Marrow Transplant

4.3 APBMT Adult and Pediatric Blood and Marrow Transplant

4.4 APP Advanced Practice Provider

4.5 CAP College of American Pathologists

4.6	CAPA	Corrective and Preventive Action
4.7	CLIA	Clinical Laboratory Improvement Amendments
4.8	CME	Continuing Medical Education
4.9	DLI	Donor Leukocytes Infusion
4.10	FACT	Foundation for the Accreditation of Cellular Therapy
4.11	FDA	Food and Drug Administration
4.12	GMP	Good Manufacturing Practices
4.13	GVHD	Graft versus Host Disease
4.14	HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
4.15	HIPAA	Health Insurance Portability and Accountability Act
4.16	HPC	Hematopoietic Progenitor Cell
4.17	HRSA	Health Resources and Services Administration
4.18	IEC	Immune Effector Cell
4.19	IRB	Institutional Review Board
4.20	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
4.21	MNC	Mononuclear Cells
4.22	NIH	National Institute of Health
4.23	NMDP	National Marrow Donor Program
4.24	PBMT	Pediatric Blood and Marrow Transplant
4.25	PBPC	Peripheral Blood Progenitor Cell
4.26	QA	Quality Assurance
4.27	QMP	Quality Management Plan
4.28	QMS	Quality Management System
4.29	QSE	Quality System Essentials
4.30	QSU	Quality Systems Unit
4.31	SOP	Standard Operating Procedure
4.32	SQIPP	Safety, Quality, Identity, Purity and Potency
4.33	SRS	Safety Reporting System
4.34	STCL	Stem Cell Laboratory

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Organization

8.1.1 Together, the pediatric and adult programs are generically referred to as The Adult and Pediatric Blood and Marrow Transplant (APBMT) Program, so as to provide a joint nomenclature for ease of reference. However, each program is individually named as outlined below and includes each Program's Immune Effector Cell Program and all cellular therapy administered within each program. Full details of The APBMT Program structure and scope are outlined in APBMT-COMM-008 *Overview of the Adult and Pediatric Blood and Marrow Transplant Program*.

8.1.1.1 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*.

8.1.1.2 Adult Program: The Adult Blood and Marrow Transplant (ABMT) Program at Duke University Medical Center was established in 1984. In 2014, it formally became known as The Hematologic Malignancies and Cellular Therapy Division. For a full view of the program's timeline, see related document ABMT-GEN-004 *Personnel Overview.*

8.1.2 Each division has a Division Chief who provides general oversight of and are responsible for all aspects the APBMT Program, which includes all HSCT transplant processes and when applicable, the collection, processing and administration of cellular therapy, including immune effector cells.

8.1.3 Dr. Stefanie Sarantopoulos is the Adult Program Director and the Division Chief of the Division of Hematologic Malignancies, Transplant, and Cellular Therapies in the Department of Medicine. Dr. Kris Mahadeo is the Pediatric Program Director and the Division Chief of the Division of Pediatric Transplant and Cellular Therapies in the Department of Pediatrics. As of January 2024, each of these individuals assumed the role of Co-Program Directors for FACT. As such, they have oversight of any and all accreditation processes for each of the respective programs and the collective APBMT program. For purposes of FACT accreditation terminology and processes, each Division Chief also serves as the designated program specific "Medical Director".

8.1.4 In collaboration with each Division Chief, the related program facilities have the following leadership in place for focused management and oversight of each area and may serve as designees for facility specific documentation and needs:

8.1.5 The Adult and Pediatric Marrow Collection Facilities are under the co-direction of Drs. Stefanie Sarantopoulos and Kris Mahadeo respectively.

8.1.5.1 The Adult Marrow Collection facility is under the direction of Stefanie Sarantopoulos, MD. Dr. Sarantopoulos is responsible for the oversight of:

8.1.5.1.1 Pre-collection evaluation of the prospective donor at the time of donation.

8.1.5.1.2 Performance of the collection procedure.

8.1.5.1.3 Supervision of the staff for the procedure.

8.1.5.1.4 Management of any patient developing complications resulting from the collection procedure.

8.1.5.2 The Pediatric Marrow Collection facility is under the direction of Kris Mahadeo, MD. Dr. Mahadeo is responsible for the oversight of:

8.1.5.2.1 Pre-collection evaluation of the prospective donor at the time of donation.

8.1.5.2.2 Performance of the collection procedure.

8.1.5.2.3 Supervision of the staff for the procedure.

8.1.5.2.4 Management of any patient developing complications resulting from the collection procedure.

8.1.6 The Adult and pediatric Apheresis Collection Facilities are under the co-direction of Drs. Gwynn Long and Kris Mahadeo respectively.

8.1.6.1 The Adult Apheresis Collection facility is under the direction of Gwynn Long, MD. Dr. Long is responsible for the oversight of:

8.1.6.1.1 Pre-collection evaluation of the prospective donor at the time of donation.

8.1.6.1.2 Performance of the collection procedure.

8.1.6.1.3 Supervision of the staff for the procedure.

8.1.6.1.4 Management of any patient developing complications resulting from the collection procedure.

8.1.6.2 The Pediatric Apheresis Collection facility is under the direction of Kris Mahadeo, MD. Dr. Mahadeo is responsible for the oversight of:

8.1.6.2.1 Pre-collection evaluation of the prospective donor at the time of donation.

8.1.6.2.2 Performance of the collection procedure.

8.1.6.2.3 Supervision of the staff for the procedure.

8.1.6.2.4 Management of any patient developing complications resulting from the collection procedure.

8.1.7 The Adult and pediatric Immune Effector Cell (IEC) Programs are under the co-direction of Drs. Yubin Kang and Kris Mahadeo respectively.

8.1.7.1 The Adult IEC Program is under the direction of Yubin Kang, MD. Dr. Kang is responsible for the oversight of:

8.1.7.1.1 Evaluation of the prospective recipient in preparation for product receipt.

8.1.7.1.2 Administration of the IEC product.

8.1.7.1.3 Supervision of the staff involved in IEC processes.

8.1.7.1.4 Management of any complications resulting from IEC administration.

8.1.7.2 The Pediatric IEC Program is under the direction of Kris Mahadeo, MD. Dr. Mahadeo is responsible for the oversight of:

8.1.7.2.1 Evaluation of the prospective recipient in preparation for product receipt.

8.1.7.2.2 Administration of the IEC product.

8.1.7.2.3 Supervision of the staff involved in IEC processes.

8.1.7.2.4 Management of any complications resulting from IEC administration.

8.1.8 The Processing Facility (STCL) is under the co-direction of Drs. Joanne Kurtzberg and Beth Shaz. The STCL follows quality management plans as outlined in their laboratory policy. Joanne Kurtzberg (or designees) and Beth Shaz (or designees) jointly oversee all cellular products for the ABMT and PBMT Program. However, APBMT Facility Directors also have integral roles. Facility Directors work closely with STCL leadership to facilitate clinical workflow. For example, Dr. Gwynn Long, the Director of the Adult Apheresis Collection Facility

orchestrates orders for cell processing, cryopreservation, and administration for products related to ABMT patients. Likewise, APBMT Division Chiefs and Processing Facility Leadership together ensure close communication and collaboration between their teams. (see associated polices: STCL-SOP-032 Responsibility of Facility Directors; STCL-QA-006 Stem Cell Laboratory Quality Management Plan)

8.1.8.1 As Directors of the Processing Facility, Drs. Kurtzberg and Shaz are responsible for the oversight of:

8.1.8.1.1 Written or electronic orders outlining the procedures used to harvest and process all cellular products.

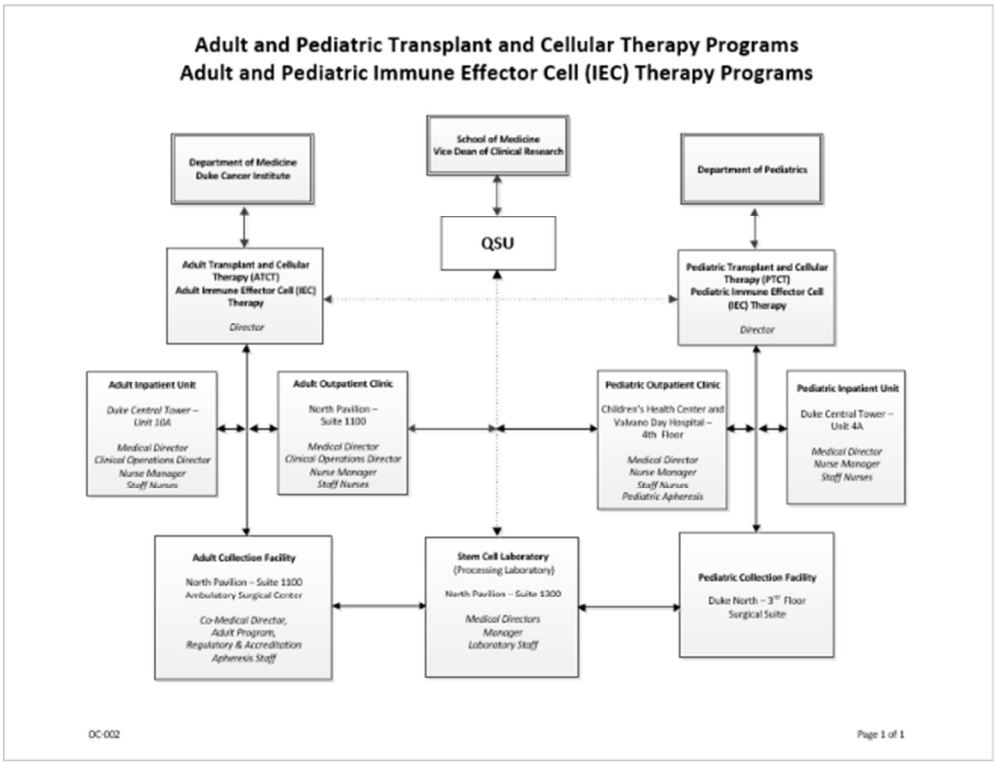
8.1.8.1.2 Written or electronic orders outlining the procedures used to thaw all cellular products.

8.1.8.1.3 Written or electronic orders outlining how to handle “Non-Conforming” cellular products.

8.1.8.1.4 Testing of all cellular products after procurement, post processing, and pre-infusion.

8.1.9 The Quality Systems Unit (QSU), which reports through an independent structure to the Dean of the School of Medicine, facilitates the development, implementation, and maintenance of an effective Quality Management System and reports to the Adult and Pediatric Blood and Marrow Transplantation (APBMT) and Cellular Therapy Quality Assurance Review Committee on program performance and regulatory compliance (see SOP: *OC-006 QSU Organizational Chart*). The QSU monitors specific clinical outcomes, deviations, adverse experiences and non-confirming products. The QSU coordinates, monitors, and facilitates defined quality assurance activities related to the collection, processing, cryopreservation, storage and distribution of cellular therapy products from autologous and allogeneic donors and ensures that the quality of manufactured products meet applicable regulatory and accreditation requirements.

OC-002 APBMT Organizational Chart



8.1.10 The Adult and Pediatric Blood and Marrow Transplantation (APBMT) and Cellular Therapy Quality Assurance Review Committee is a multidisciplinary, charter driven committee consisting of designated division chiefs, medical directors, physician leadership, nursing leadership, and other relevant staff in key positions in all elements of the APBMT program.

8.1.10.1 This committee's scope is to ensure that the highest quality cellular therapies, products, services and procedures are consistently available and practiced guaranteeing the highest quality of care to patients and donors. To ensure this is met, the committee has oversight and review of quality management activities of the APBMT and Cellular Therapy programs, including but not limited to program performance, outcomes data, mortality reviews, regulatory/accreditation compliance, product efficacy and safety. IEC data is included as is that of the program's collection and processing facilities, Collection Facility data reviewed includes, but is not limited to, collection type, number of collections, target yields, positive culture results, and collection efficiency. Processing Facility data reviewed includes, but is not limited, to processing numbers, and resulting infusions, and positive culture results to name a few. Specifics for each of the above can be found in Committee Meeting Minutes. The committee is co-chaired by physician leaders, in the APBMT program, one from

adults and one from pediatrics. The chairs are responsible for oversight of committee activities and committee review of applicable APBMT program data, such as clinical quality indicators outlined in this document, and outcome reports. Chairs may formally sign committee related documents, which may be further distributed to program leadership as applicable.

8.1.10.2 The committee is set to meet quarterly to complete committee activities and may have ad hoc meetings on an as needed basis. Criteria for cellular therapy product safety, product efficacy, and the clinical outcomes are determined, as applicable, and reviewed at regular time intervals.

8.2 Resources

8.2.1 Clinical Personnel Training

8.2.1.1 Duke University Medical Center credentialing office maintains the credentials, licenses, Continuing Medical Education (CME), and clinical privileges for each of the adult and pediatric Division Chiefs, attending physicians, and advanced practice providers (APPs), each of which are re-evaluated yearly to confirm that they continue to have appropriate practice skills.

(See SOPs: *APBMT-COMM-022 Adult and Pediatric Blood and Marrow Transplant Programs' Training for Physicians*, *APBMT-COMM-023 Physician Training for Transplant Program Director and Attending Physicians Checklist*; and *APBMT-COMM-024 Nurse Practitioner Physician's Assistant Training Checklist*)

8.2.1.2 Job descriptions list relevant educational/training requirements and/or experience needed for each staff position within the program. All personnel must have appropriate certification(s) and training to enable them to perform their assigned function(s).

8.2.1.3 Advanced Practice Providers, and nursing staff go through an initial orientation and training program pertinent to their assigned job functions (See SOPs: *APBMT-COMM-020 Monitoring System for Training, Competency and Record Keeping; PBMT-GEN-006 Pediatric RNs Orientation and Training for the Inpatient Unit; PBMT-GEN-005 Training of RNs Employed in the McGovern-Davison Children's Health Center-Level 4; APBMT-COLL-002 Apheresis Nurse Training*).

8.2.1.4 A comprehensive orientation for new nursing employees, (Core Day I/II) is offered for all new clinical nursing employees and includes initial qualifications and case studies. Nursing staff have a mandatory comprehensive

preceptor workshop prior to becoming preceptors. Support is provided through the BMT program for staff to attend CME courses to meet credentialing requirements.

8.2.1.5 Competency evaluations for existing staff occurs on an annual basis through their respective disciplines and specifically through BMT, and includes assessment of competency for each critical function performed. Initial training and retraining, when appropriate, occurs for all procedures performed. Ongoing continuing education and re-credentialing programs are in place for each discipline.

8.2.1.6 Personnel are expected to participate in continuing education activities as required for accreditation and licensure.

8.2.1.7 Personnel are expected to confirm data and identification as they perform procedures and computer data entries.

8.2.1.8 Personnel are expected to record data/test results concurrent with the reading of result's determination.

8.2.1.9 Personnel are expected to maintain confidentiality according to program, institutional and Federal guidelines. All Duke Staff must sign the Duke Confidentiality Agreement annually. A copy of this form should be retained in the staff member's department file.

8.2.2 Apheresis Collection Training

8.2.2.1 Nursing staff performing apheresis go through an initial orientation and training program pertinent to their assigned job functions (see SOP: *APBMT-COLL-002 Apheresis Nurse Training*).

8.2.2.2 Proficiency skills for apheresis for Attending Physicians and Advanced Practice Providers are signed off yearly (see SOPs: *APBMT-COMM-023 Physician Training for Transplant Program Director* and *Attending Physicians Checklist* and *APBMT-COMM-024 Nurse Practitioner Physician's Assistant Training Checklist*).

8.2.3 Bone Marrow Collection Training

8.2.3.1 Attending Physicians and Advanced Practice Providers perform bone marrow harvest procedures following SOPs: *PBMT-COLL-008 Bone Marrow Harvest Procedure; ABMT-COLL-017 Bone Marrow Harvest Procedure.*

8.2.3.2 Proficiency skills for bone marrow harvest procedures for Attending Physicians and Advance Practice Providers are signed off yearly (see SOPs: *APBMT-COMM-023 Physician Training for Transplant Program Director and Attending Physicians Checklist, APBMT-COMM-024 Nurse Practitioner Physician's Assistant Training Checklist*).

8.2.4 Processing Training

8.2.4.1 See SOPs: *STCL-QA-006 Stem Cell Laboratory Quality Management Plan* and *STCL-TRN-001 Training in the Stem Cell Laboratory.*

8.2.5 Quality Personnel

8.2.5.1 Job descriptions list relevant educational/training requirements and or experience needed for each staff position within the QSU program. All personnel must have appropriate certification(s) and/or training to enable them to perform their assigned function(s).

8.2.5.2 Personnel are expected to participate in continuing education activities as required to maintain certification(s).

8.2.5.2.1 The Quality Manager shall participate in a minimum of ten (10) hours of educational hours related to cellular therapy and quality management annually. Continuing education shall include but is not limited to, activities related to the field of Hematopoietic Progenitor Cell (HPC) transplant.

8.2.5.3 Personnel within the QSU are charged with reporting audit results, deviations, non-conformances, complications, errors, product contamination, etc. Transplant outcomes, such as mortality, survival, graft versus host disease (GVHD) and engraftment, are analyzed using statistical software developed by the program staff. This information is reported during the multidisciplinary Adult and Pediatric Blood and Marrow Transplantation (APBMT) and Cellular Therapy Quality Assurance Review Committee.

8.3 Current Good Manufacturing Practices (GMP) Training

8.3.1 Physicians, collection and processing staff, and other applicable staff, will train annually, at a minimum, on Current Good Manufacturing Practices appropriate to the processes performed and in accordance with applicable law (See SOPs: *APBMT-COMM-022 Adult and Pediatric Blood and Marrow Transplant Programs' Training for Physicians; PBMT-GEN-010 Support staff,* and *STCL-TRN-001 Training in the Stem Cell Laboratory*).

8.4 Equipment and Software

8.4.1 The APBMT Programs, Adult and Pediatric Collection Programs, and Stem Cell Laboratory qualify critical equipment to ensure it performs as expected and maintains the operation of this equipment by adhering to necessary maintenance, calibration and certification schedules.

8.4.2 Equipment is used as procedures and manufacturer's directions dictate and shall conform to applicable laws and regulations. There will be adequate equipment and materials available in any area where procedures are performed.

8.4.3 Before a piece of equipment is placed into service, it will be entered into inventory and validated in-house for its intended use (see SOPs: *COMM-QA-044 Approaches to Validation* and *COMM-QA-044 FRM1 Instrument Equipment Validation Protocol FRM1*).

8.4.4 Quality control and preventative maintenance are performed on all pieces of equipment as specified in procedures and/or checklists. These steps meet regulatory requirements and manufacturer's recommendations (see SOPs*: ABMT-EQUIP-001 Quality Control of Equipment, PBMT-EQUIP-001 Quality Control of Apheresis Instruments* and *STCL-GEN-018 Quality Control Systems for the STCL*).

8.4.5 The Stem Cell Laboratory monitors equipment temperature, if applicable, using the Rees Scientific Environmental Monitoring system (see SOP: *STCL-EQUIP-013 Alarm System* and *Instructions in the Event of Equipment Malfunction, Failure, or Repair*).

8.4.6 The APBMT Programs, Adult and Pediatric Collection Programs, and Stem Cell Laboratory qualify critical equipment software and the electronic record systems to ensure it performs as expected and maintains the accuracy, integrity, identity, and confidentiality of each (see SOPs: *COMM-QA-044 Approaches to Validation, COMM-QA-044 FRM1 Instrument Equipment Validation Protocol FRM1* and *COMM-PAS-008 Electronic Record Systems for Clinical Programs*).

8.5 Supplies and Reagent

8.5.1 Reagents and supplies used for collecting, testing, processing, cryopreserving and thawing must be in-date and must meet appropriate criteria, including sterility measures and appropriate grade (see SOPs: *ABMT-GEN-019 Adult Apheresis/Photopheresis Supply Management, PBMT-EQUIP-003 Pediatric Apheresis Supply Management* and *STCL-GEN-002 STCL Supply Management Procedure*).

8.5.2 Reagents/supplies will be visually examined prior to use and any that appear to be contaminated will not be used for testing or processing.

8.5.3 Reagents/supplies are used as prescribed by the manufacturer.

8.5.4 Lot numbers and expiration dates of critical reagents and supplies coming into contact with transplant products are tracked and recorded in the patient's laboratory record.

8.5.5 Any component of a reagent "kit" is used only within that kit lot unless otherwise specified by the manufacturer.

8.6 Supplier Qualification

8.6.1 Critical supplies/services are identified and criteria for the quarantine, acceptance or rejection of supplies are established. Supplier qualification is performed on suppliers of critical supplies/services to ensure that quality standards are maintained. Suppliers are selected based on their ability to provide equipment/supplies that meet the needs and performance standards of the programs. Selection considerations might include equipment design, validation of intended use, training and service support, licenser, and the company's commitment to quality (see SOP: *COMM-QA-002 Supplier Qualifications*). QSU, as a designee of the Clinical Program Director, will review and approve Supplier Qualification plans routinely.

8.6.2 Contracts

8.6.2.1 The establishment and maintenance of written contractual agreements with third parties whose services impact the clinical care of the patient, donor, or cellular therapy product are obtained per Duke Health policies and procedures and are dated, reviewed, and renewed on a regular basis in alignment with Duke Health. This does not apply to agreements established between clinical programs and external sponsors, as those requirements would be determined at time of creation. (Also see SOPs: COMM-PAS-001 Third Party Agreement and COMM-QA-002 Supplier Qualifications).

8.6.2.2 Agreements that impact APBMT patients specifically are reviewed by the APBMT Program directly whenever possible within guidelines/requirements set forth by the institution and/or state/local/federal requirements. For agreements deemed under the sole purview of the institution (as determined by the institution after discussion with APBMT), we defer to the institution. In those instances, the APBMT Program will formally review APBMT specific obligations under the agreement and expected deliverables to the program prior to initiation and periodically as either required by the agreement but at a minimum of every two years.

8.6.2.3 Agreements under the sole purview of the APBMT Program will be formally reviewed by the program at a minimum of every two years.

8.7 Customer Feedback

8.7.1 To meet and/or exceed customer requirements, it is imperative that customer feedback is captured and process improvement plans are implemented as warranted. The adult program participates in Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The pediatric program participates in the Peds-CAHPS survey. Both surveys are conducted by the Duke University Health System Office of Performance Services. The collection facility, processing facility and the APBMT program have the opportunity to provide feedback to each other in real time using common schedules/databases and during weekly Clinical Program Patient Coordination meetings. Staff may utilize email and/or phone conversations to communicate feedback, including time-sensitive feedback that may be needed before the next scheduled Clinical Program Patient Coordination meeting. Feedback, including complaints and compliments regarding donor, recipient and any other patient related care is obtained on a regular basis through patient experience surveys which are distributed to patients following each patient experience. Responses requiring intervention or follow-up are reviewed by area specific leadership and corresponding quality driven committees. Additional information specific to Donor Collection follow-up can be found in APBMT-COMM-001 *Donor Selection, Evaluation, and Management* in the Section titled “Post Apheresis/Marrow Procedure Donor Management".

8.8 Emergency Management

8.8.1 Emergency policies in the event of interruption to the clinical program’s operations may be found through the Duke Health Intranet for emergency resources quick links (https://intranet.dh.duke.edu/SitePages/Quick%20Links.aspx), Duke University Emergency Homepage (https://emergency.duke.edu), and MasterControl related documents (see SOPs: *STCL-GEN-012 Safety* and *STCL-GEN-008 Stem Cell Laboratory Disaster Plan).*

8.8.2 In the event of an emergency within the Blood Cancer Center (BCC), including actions to take to secure and protect a cellular product in the event of operational interruption of the pediatric and adult Apheresis Collection Facilities, refer to the BCC Emergency Management Plan.

8.8.3 Each employee will participate in safety training programs as defined by the duties performed by that employee.

8.8.4 The environmental conditions in the Adult and Pediatric inpatient transplant and cellular therapy units, shall provide a safe and adequate place to work while fulfilling all pertinent regulatory requirements.

8.8.5 The environmental conditions in the outpatient transplant and cellular therapy clinics, operating rooms, and apheresis supply room(s) shall provide a safe and adequate place to work while fulfilling all pertinent regulatory requirements.

8.8.5.1 Temperature and humidity for the operating and procedure rooms, where marrow collection often occur, are monitored per hospital policy (See related DUH policy: *Relative Humidity (RH) and Temperature Monitoring and Response Policy*).

8.8.5.2 Temperature and humidity of the apheresis supply room, where adult and pediatric apheresis supplies are stored, is monitored daily (see SOP: *ABMT-GEN-021 Monitoring Temperature and Humidity*).

8.9 Process Control

8.9.1 Steps in operating processes must be defined and monitored to ensure consistency in performance. This is inherent in all procedures utilized by the APBMT Programs, Adult and Pediatric Collection Programs and Stem Cell Laboratory. Changes to a process with the potential to affect the potency, viability, or purity, of the cellular therapy product shall include an evaluation of risk to determine if the change might create an adverse impact anywhere in the operation and shall be validated or verified as appropriate (see SOPs: *COMM-PAS-004 Change Control; COMM-QA-044 Approaches to Validation*).

8.9.2 Handling of positive microbial results

8.9.2.1 Clinical specimens identified as having a "positive culture" are reported to the clinical programs per procedures entitled *STCL-EQUIP-011 Sterility Culture Using BacT-Alert Microbiology System* and *STCL-QA-007 Non-Conforming Products - Receipt, Processing, Distribution, and Disposition* then investigated and documented (see SOP: *STCL-EQUIP-011 FRM2 OOS-Product Sterility FRM2*).

8.9.2.2 The Clinical Program is responsible for notification and following up of the donor and/or the recipient of the contaminated products and will provide recommendations for care, if necessary (see SOPs: *APBMT-COMM-001 Donor Selection, Evaluation, and Management; STCL-QA-007 Non-Conforming Products –Receipt, Processing, Distribution, and Disposition).*

8.9.3 Tracking cellular products

8.9.3.1 The cellular therapy products are tracked from the donor to the recipient or final disposition and tracked from the recipient or final disposition to the donor using ISBT 128 barcode labels and chain of custody forms (see SOP: *STCL-SOP-030 Label Release, COMM-PAS-003 Labeling Cellular Therapy Products* and *STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form*).

8.9.4 Consenting

8.9.4.1 The allogeneic donor authorizes in advance to release their health information to the transplant physician and/or the recipient as appropriate (see *consents utilized by the clinical programs*).

8.9.5 Donations

8.9.5.1 Autologous and allogeneic, related and unrelated, directed and public donors are evaluated and treated in various clinical situations. Donor workups are conducted by a physician or health care professional who is not the primary transplant provider. The patients and donors are managed in both the inpatient and outpatient setting by the attending physicians, fellows, and Advanced Practice Providers (APP). (See related SOP for more detailed information: *APBMT-COMM-001 Donor Selection, Evaluation and Management*).

8.9.5.2 Autologous and allogeneic HPCs, derived from mobilized peripheral blood and bone marrow, are collected from donors in the ambulatory clinic or operating rooms, depending on the donor location and type of donation. The products collected include bone marrow, mobilized peripheral blood progenitor cells (PBPC), donor leukocytes (DLI/MNC) and granulocytes. Bone marrow harvests are performed under general anesthesia in an operating room at Duke Hospital or North Pavilion by an attending physician along with a second physician or APP. PBPC, granulocyte, and DLI collections are performed via leukapheresis in the outpatient clinic by trained medical technologists or nurses under the supervision of the respective Medical Directors.

8.9.6 Bone Marrow Collection

8.9.6.1 Marrow collection procedures are validated prior to use. The validation plan, results, and conclusions are reviewed and approved by the Division Chiefs and/or marrow collection facility director or designee and Quality Manager or designee (see SOPs: *COMM-QA-044 Approaches to Validation*, *PBMT-COLL-008 Bone Marrow Harvest Procedure* and *ABMT-COLL-017 Bone Marrow Harvest Procedure*).

8.10 Documents and Records

8.10.1 Procedures are developed for tracking of products from donor to recipient, deviations, complaints, and adverse reactions (see SOPs: *COMM-PAS-003 Labeling Cellular Therapy Products, COMM-QA-042 Deviations and Investigations, APBMT-COMM-030 Recording and Reporting of Adverse Events*).

8.10.2 All controlled documents, including but not limited to SOPs, job aids, forms, etc., are maintained in a web base password protected document management system called MasterControl (see SOPs: *DCO-SOP-004 Document Control Procedures for MasterControl*, *COMM-QA-060 MasterControl User Procedures-Documents* and *COMM-PAS-004 Change Control*).

8.10.3 MasterControl (MC) is a validated, CFR 21 Part 11 compliant, document management software product that is used as the main document control system for the automation and control of document approval, change control and distribution processes. MC manages critical information throughout the entire document lifecycle (see SOPs: *COMM-QA-016 Procedure Management* and *DCO-SOP-003 Configuration of Numbering Series Patterns in MasterControl*).

8.10.4 Documents are created, approved, released, version controlled, and archived in accordance with procedure (see SOPs: *DCO-SOP-004 Document Control Procedures for MasterControl*; *COMM-QA-016 Procedure Management* and *COMM-QA-057 Procedure Development*).

8.10.5 Each SOP is placed in an InfoCard and assigned a unique number using an automatic document number assignment (see SOP: *DCO-SOP-003 Configuration of Numbering Series Patterns in MasterControl*).

8.10.5.1 SOP numbering will be assigned as alpha-alpha-###, where:

8.10.5.1.1 alpha – indicates the department/section InfoCard type; i.e., ABMT, APBMT, PBMT STCL, FLOW

8.10.5.1.2 alpha – indicates the specific category

8.10.5.1.3 ### – indicates the document number which is assigned sequentially for each document starting with 001

Example: APBMT-GEN-001, ABMT-GEN-038, PBMT-GEN-001, STCL-SOP-045

8.10.6 ABMT, PBMT and STCL procedures are developed using a standard format (see SOP: *COMM-QA-057 Procedure Development*). PDF versions of approved documents in MasterControl will be printed, scanned, and sent to EMMES for upload to STCL's database by QSU as documents become effective (see SOP: *COMM-QA-016 Procedure Management*). Personnel who do not have access to MasterControl can access their procedures in EMMES from any computer at https://web.emmes.com/study/duke/SOP/TableOfContents.htm.

8.10.7 As an internal control and safety measure, MasterControl PDF documents saved to a personal computer or alternate storage device expire and become unusable and inaccessible after 48 hours (see SOP: *COMM-QA-016 Procedure Management*).

8.10.8 Changes to controlled documents are managed through a Change Control process within MasterControl (see SOP: *COMM-PAS-004 Change Control*). Before new or revised procedures are implemented the staff must be trained (see SOPs: *APBMT-COMM-020 Monitoring System for Training, Competency and Record Keeping; APBMT-COLL-002 Apheresis Nursing Training* and *COMM-QA-060 MasterControl User Procedures-Documents*).

8.10.9 Procedures are reviewed biennially within MasterControl to identify recurring problems, potential points of failure, and need for process improvement by the Division Chiefs who are designated as Medical Directors for procedure and document signoff, document owners/authors and QSU (see SOP: *COMM-QA-066 Review of Documents in MasterControl*).

8.10.10 MasterControl retains all entered versions of controlled documents. Procedures retired from use are assigned an Expiration Date, archived and retained indefinitely within the MasterControl system (see SOPs: *COMM-QA-016 Procedure Management* and *DCO-SOP-004 Document Control Procedures for MasterControl*).

8.10.11 All donor and patient records are considered confidential and will be protected per Health Insurance Portability and Accountability Act (HIPAA) regulations and policies of Duke University Medical Center.

8.10.12 All records carry facility identification and comply with regulatory standards. Records should have a title that designates intended use, observed test results and interpretations, test date, and personnel identities. These must be legible and corrections must be clearly identified.

8.10.13 Test results and donor and patient records must be reviewed for completeness and accuracy in a timely manner.

8.10.14 Procedures and record systems are set up so that, whenever possible, current results can be compared to previous results. This allows staff to monitor accuracy of donor and patient identification and to detect significant changes during task performance.

8.10.15 Records are stored and retained as per the policies of Duke University Health Care System, the APBMT Programs and the Stem Cell Laboratory. Records should be retrievable within a reasonable amount of time (see SOPs: *COMM-PAS-002 Records Retention Schedule, APBMT-COMM-033 Records Management* and *STCL-GEN-015 Records Management*).

8.11 Event Management

8.11.1 Unexpected events are detected through a variety of mechanisms including but not limited to: audits, record review, tracking and trending, and procedure reviews. Should an event occur, it is investigated, documented, reported, and corrected through the appropriate process, depending on the nature of the event.

8.11.2 Deviations, Risk Assessment, and Corrective and Preventive Actions (CAPA):

8.11.2.1 The APBMT clinical programs, including collections facilities, and STCL programs are committed to capturing all deviation events and analyzing the information to detect systematic problems, determine root causes and implement suitable short term/long term corrective actions and report to regulatory/accrediting agencies as necessary.

8.11.2.2 Unplanned deviations to policies, processes, and procedures should immediately be called to a supervisor's attention then documented and investigated (see SOP: *COMM-QA-042 Deviations and Investigations*).

8.11.2.3 Planned deviations to policies, process, and procedures requires prior approval, prior to plan implementation, from a Division Chief, as the FACT Program Medical Director, or designees and the QSU as outlined in *COMM-QA-042 Deviations and Investigations.*

8.11.2.4 If a CAPA is required, follow-up of effectiveness of a CAPA will be performed in an appropriate timeframe (see SOP: *COMM-QA-076 Corrective and Preventive Actions).*

8.11.2.5 In exceptional circumstances a planned deviation from a policy, process or procedure, may be required. In these events a planned deviation may be requested in accordance with *COMM-QA-042 Deviations and Investigations*. The planned deviation is not considered approved until final approval is given by QA.

8.11.2.6 In the event that it is unclear if an event has occurred, *COMM-QA-042 Deviations and Investigations* should be utilized to determine the nature of, and, investigate the associated event. The user should proceed using the appropriate associated forms (*COMM-QA-042 FRM4 Deviation and Investigation Report, COMM-QA-076 Corrective and Preventive Actions*), as necessary.

8.11.3 Errors, Accidents, and Adverse Events

8.11.3.1 Adverse events that occur will be investigated, documented, and reported internally and/or externally as appropriate (see SOP: *APBMT-COMM-030 Recording and Reporting of Adverse Events*).

8.11.3.2 Documentation of adverse events can be accomplished by using the Duke Hospital safety reporting system (SRS), and/or *STCL-SOP-050 Infusion Form*, and/or *APBMT-COMM-030 FRM1 Adverse Event Form.*

8.11.3.3 Point of care errors and near-misses are also considered adverse events and are reported through SRS. Follow up is done by the managers in the area involved with the error.

8.11.3.4 Serious adverse events or accidents are reported to hospital Risk Management and/or Program Director(s) and follow-up actions are determined based on the severity of the problem.

8.11.3.5 When it is determined that a cellular therapy products was responsible for an adverse reaction, the reaction and results of the investigation will be reported to the donor's and recipient's physician, as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, governmental agencies, grant agencies, accrediting agencies, and Institutional Review Boards (IRBs) or Ethics Committee, as applicable and as required by applicable laws and regulations.

8.11.3.6 Examples of adverse events that must be reported to external regulatory/accrediting agencies include, but are not limited to:

8.11.3.6.1 Events involving the transmission of communicable disease (Infections related to the product).

8.11.3.6.2 Infused/released products that were contaminated during the manufacturing of the product (Product contamination).

8.11.3.6.3 Reactions that are fatal, life threatening, result in permanent impairment of a body function or permanent damage to body structure, or necessitate medical or surgical intervention.

8.11.3.7 Examples of adverse events that will be reported in the annual quality report include, but are not limited to (see SOP: *APBMT-COMM-030 Recording and Reporting of Adverse Events*):

8.11.3.7.1 Deaths

8.11.3.7.2 Product contamination

8.11.3.7.3 Infections related to the product

8.11.4 Complaints

8.11.4.1 Upon the receipt of a complaint, the complaint will be documented and reviewed according to *COMM-PAS-006 Product Complaint Management*.

8.11.4.2 Should it be determined that the complaint also includes one of the above other types of events, an appropriate event will be initiated.

8.12 Assessments

8.12.1 Audits will be used to recognize problems, detect trends, identify improvement opportunities, and verify the effectiveness of corrective and preventive actions, when appropriate, and follow-up on the effectiveness of these actions in a timely manner.

8.12.2 Audits shall be conducted by an individual with sufficient expertise and competence to identify problems, but who is not solely responsible for the process being audited.

8.12.3 Participation in audits ensures that the quality systems are meeting the stated requirements. Audits on the quality systems will be conducted regularly per *COMM-QA-039 JA3 QSU Audit Schedule Transplant Programs-STCL*.

8.12.4 Leadership for hospital quality will monitor the following areas on a routine basis where applicable:

8.12.4.1 Monthly and/or Quarterly nursing care documentation audits are performed on the inpatient unit and the outpatient clinic. The nursing staff has a Performance Improvement Committee that reviews findings and makes recommendations to staff for improvement.

8.12.4.2 Inpatient

8.12.4.2.1 Patient ID/Arm Band

8.12.4.2.2 Pain management

8.12.4.2.3 Skin

8.12.4.2.4 Restraints

8.12.4.2.5 CLABSI/CAUTI

8.12.4.2.6 FALLS/SPHM

8.12.4.3 Outpatient

8.12.4.3.1 Patient ID/Arm Band

8.12.4.3.2 Pain management

8.12.4.3.3 Time out/Procedural Sedation

8.12.5 The Clinical Program should meet accuracy criteria established by FACT, JACIE, and CIBMTR or EBMT, as applicable.

8.12.6 The Clinical Program will, at a minimum, yearly audit:

8.12.6.1 Accuracy of data contained in the Transplant Essential Data Forms.

8.12.6.2 Donor screening and testing including:

- Interim assessment of donor suitability prior to the start of the collection procedure

- Donor eligibility determination prior to the start of the collection procedure

8.12.6.3 Management of cellular therapy products with positive microbial culture results

8.12.6.4 Safety endpoints and immune effector cellular therapy toxicity management (see SOP: *COMM-QA-039 JA9 APBMT Immune Effector Cellular Therapy Safety Endpoints and Toxicity Management Audit*).

8.12.6.5 Chemotherapy protocols will be audited against the written order, at a minimum, yearly (see SOP: *COMM-QA-039 JA7 APBMT Chemotherapy and Treatment Plan Audit*).

8.13 Clinical Quality Indicators

8.13.1 Each clinical program will review pre-determined Clinical Quality Indicators, as shown in Table 1, for autologous, allogeneic, and alternative donor (non-matched sibling) transplants. Frequency of analysis can be seen in the corresponding table for each indicator category.

8.13.2 Each clinical program has established benchmarks for non-relapse mortality (treatment-related mortality) at 100 days following the administration of cellular therapy, as shown in Table 2 for ABMT and Table 3 for PBMT.

8.13.2.1 Transplant-related mortality will be estimated using the cumulative incidence method with relapse as a competing risk with respect to the benchmarks outlined in Table 2 and 3 using standards method for group sequential analysis [10.5, 10.6]. Analysis will occur quarterly and will include 3 years of data for all identified categories except the PBMT Autologous Tandem Category for which analysis will occur annually.

8.13.2.2 In the event any given benchmark is not achieved for any transplant category identified in Tables 2 and 3, an investigation will be performed and formally documented in the MasterControl System. Additional analysis may be necessary to examine the reasons for specification was not achieved. This will likely involve in-depth examination of patient populations, patient demographics, transplant types, preparative regimens, Graft versus Host Disease (GVHD) prophylaxis regimens and patient diagnoses and comorbidities. Following this investigation, any corrective actions will be clearly outlined, documented, and tracked.

8.13.3 Each clinical program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.

8.13.3.1 If expected one-year survival outcome is not met, the clinical program shall implement a corrective plan that formally documented in the MasterControl System.

8.13.4 Allogeneic transplants with more than one allogeneic transplant are excluded from the above clinical quality indicators and benchmark analyses. These transplants will be listed as a separate group and 1-year survival will be reported to the committee for this patient group.

8.13.5 Each clinical program will review pre-determined Clinical Endpoints, as shown in Table 4 and Table 5, for immune effector cell (IEC) therapy, including donor lymphocyte infusion (DLI). Reporting timeline can be seen in the corresponding table for each endpoint category.

8.13.6 All clinical quality indicators and endpoints above will be presented to the QA committee for review.

Table 1. ABMT and PBMT Clinical Quality Indicators

Quality Indicator	Reporting Frequency
Time to Engraftment*	Quarterly, Yearly
Catheter infections (fungal and bacterial)	Quarterly, Yearly
Acute and Chronic Graft versus Host Disease (GVHD)	Yearly
30 day Mortality	Quarterly, Yearly
100 day Mortality	Quarterly, Yearly
1 year Mortality	Yearly
1 year Overall Survival	Yearly
30 day Treatment Related, Non-Relapse, Mortality	Quarterly, Yearly
100 day Treatment Related, Non-Relapse, Mortality	Quarterly, Yearly
1 year Treatment Related, Non-Relapse, Mortality	Quarterly, Yearly

*analyzed by ANC and platelets

Table 2. ABMT Benchmarks for Treatment Related, Non-Relapse Mortality (TRM) at 100 days after Cellular Therapy Product Administration

Population	Benchmark	Rationale (Source)
Autologous Transplant (Single Agent Melphalan)	2%	Costa LJ, et al. Trends in utilization and outcomes of autologous transplantation as early therapy for multiple myeloma. Biol Blood Marrow Transplant 2013; 19: 1615-1624.

Table 2. ABMT Benchmarks for Treatment Related, Non-Relapse Mortality (TRM) at 100 days after Cellular Therapy Product Administration		
Population	**Benchmark**	**Rationale (Source)**
Autologous Transplant (Other Regimens)	5%	Chen YB, et al. Impact of conditioning Regimen on outcomes for patients with lymphoma undergoing high-dose therapy with autologous hematopoietic cell transplantation. Biol Blood Marrow Transplant 2015; 21: 1046-1053.
Allogeneic Ablative Transplant	20%	ElSawy M, et al. Multi-center validation of the prognostic value of the hematopoietic cell transplantation-specific comorbidity index among recipients of allogeneic haematopoietic cell transplantation. Brit J Haematology 2015; 170: 574-583.
Allogeneic Non-Ablative Transplant	15%	ElSawy M, et al. Multi-center validation of the prognostic value of the hematopoietic cell transplantation-specific comorbidity index among recipients of allogeneic haematopoietic cell transplantation. Brit J Haematology 2015; 170: 574-583.

Table 3. PBMT Benchmarks for Treatment Related, Non-Relapse Mortality (TRM) at 100 days after Cellular Therapy Product Administration		
Population	**Benchmark**	**Rationale (Source)**
Autologous Single Peripheral Blood Stem Cell (PBSC) Transplant	10%	Busulfan and melphalan versus carboplatin, etoposide, and melphalan as high-dose chemotherapy for high-risk neuroblastoma (HR-NBL1/SIOPEN): an international, randomized, multi-arm, open-label, phase 3 trial. Lancet Oncol 2017; 18: 500-514.
Autologous Tandem Transplant	10%	Busulfan and melphalan versus carboplatin, etoposide, and melphalan as high-dose chemotherapy for high-risk neuroblastoma (HR-NBL1 / SIOPEN): an international, randomized, multi-arm, open-label, phase 3 trial. Lancet Oncol 2017; 18: 500-514.
Allogeneic Matched-Related Bone Marrow Transplant	10%	Practice of Medicine

Table 3. PBMT Benchmarks for Treatment Related, Non-Relapse Mortality (TRM) at 100 days after Cellular Therapy Product Administration		
Population	**Benchmark**	**Rationale (Source)**
Allogeneic Alternative Donor Transplant	30%	Wagner JE, Eapen M, Carter S, et al. One-Unit Versus Two Unit Cord-Blood Transplantation for Hematologic Cancers. N Engl J Med 2014; 371; 1685-94.

Table 4. APBMT Endpoints of Clinical Function for Immune Effector Cells (IEC) Administration		
Clinical Endpoint	**Reporting Timeline**	**Reporting Categories**
Treatment Related, Non-Relapse, Mortality (TRM)	• 30 days • 100 days • 1 year	• By disease • By product (separates research from commercial)
Incidence of Cytokine Release Syndrome (CRS)	• 30 days • 100 days	• By disease • By product (separates research from commercial)
Incidence of Neurotoxicity	• 30 days • 100 days	• By disease • By product (separates research from commercial)
Overall survival (OS)	• 30 days • 100 days • 1 year	• By disease
Event Free Survival (EFS)	• 30 days • 100 days • 1 year	• By disease

Table 5. APBMT Endpoints of Clinical Function for Donor Lymphocyte Infusion (DLI)	
Clinical Endpoint	**Reporting Timeline**
Overall survival (OS)	• 30 days • 100 days • 1 year
Treatment Related, Non-Relapse, Mortality (TRM)	• 30 days • 100 days • 1 year
Graft versus Host Disease (GVHD)	• 30 days • 100 days • 1 year

9 RELATED DOCUMENTS AND FORMS

9.1 ABMT-COLL-017 Bone Marrow Harvest Procedure

9.2 ABMT-EQUIP-001 Quality Control of Equipment

9.3 ABMT-GEN-004 Personnel Overview

9.4 ABMT-GEN-019 Adult Apheresis/Photopheresis Supply Management

9.5 ABMT-GEN-021 Monitoring Temperature and Humidity

9.6 APBMT-COLL-002 Apheresis Nurse Training

9.7 APBMT-COMM-001 Donor Selection, Evaluation and Management

9.8 APBMT-COMM-020 Monitoring System for Training, Competency and Record Keeping

9.9 APBMT-COMM-022 Adult and Pediatric Blood and Marrow Transplant Programs' Training for Physicians

9.10 APBMT-COMM-023 Physician Training for Transplant Program Director and Attending Physicians Checklist

9.11 APBMT-COMM-024 Nurse Practitioner Physician's Assistant Training Checklist

9.12 APBMT-COMM-030 Recording and Reporting of Adverse Events

9.13 APBMT-COMM-030 FRM1 Adverse Event Form

9.14 APBMT-COMM-033 Records Management

9.15 APBMT-GEN-003 Overview of Collection Facilities

9.16 COMM-PAS-001 Third Party Agreement

9.17 COMM-PAS-002 Records Retention Schedule

9.18 COMM-PAS-003 Labeling Cellular Therapy Products

9.19 COMM-PAS-004 Change Control

9.20 COMM-PAS-006 Product Complaint Management

9.21 COMM-PAS-008 Electronic Record Systems for Clinical Programs

9.22 COMM-QA-002 Supplier Qualifications

9.23 COMM-QA-016 Procedure Management

9.24 COMM-QA-039 JA3 QSU Audit Schedule Transplant Programs - STCL

9.25 COMM-QA-039 JA7 APBMT Chemotherapy and Treatment Plan Audit

9.26 COMM-QA-039 JA9 APBMT Immune Effector Cellular Therapy Safety Endpoints and Toxicity Management Audit

9.27 COMM-QA-042 Deviations and Investigations

9.28 COMM-QA-042 FRM4 Deviation and Investigation Report FRM4

9.29 COMM-QA-044 Approaches to Validation

9.30 COMM-QA-044 FRM1 Instrument Equipment Validation Protocol FRM1

9.31 COMM-QA-057 Procedure Development

9.32 COMM-QA-060 MasterControl User Procedures-Documents

9.33 COMM-QA-066 Review of Documents in MasterControl

9.34 COMM-QA-076 Corrective and Preventive Actions

9.35 DCO-SOP-003 Configuration of Numbering Series Patterns in MasterControl

9.36 DCO-SOP-004 Document Control Procedures for MasterControl

9.37 OC-002 APBMT Organizational Chart

9.38 OC-006 QSU Organizational Chart

9.39 PBMT-COLL-008 Bone Marrow Harvest Procedure

9.40 PBMT-EQUIP-001 Quality Control of Apheresis Instruments

9.41 PBMT-EQUIP-003 Pediatric Apheresis Supply Management

9.42 PBMT-GEN-002 Overview of Duke University Pediatric Blood and Marrow Transplant Program Personnel

9.43 PBMT-GEN-005 Training of RNs Employed in the McGovern-Davison Children's Health Center Level 4

9.44 PBMT-GEN-006 Pediatric RNs Orientation and Training for the Inpatient Unit

9.45 PBMT-GEN-010 Support Staff

9.46 STCL-EQUIP-011 Sterility Culture Using BacT-Alert Microbiology System

9.47 STCL-EQUIP-011 FRM2 OOS-Product Sterility FRM2

9.48 STCL-EQUIP-013 Alarm System and Instructions in the Event of Equipment Malfunction, Failure, or Repair

9.49 STCL-GEN-002 STCL Supply Management Procedure

9.50 STCL-GEN-008 Stem Cell Laboratory Disaster Plan

9.51 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form

9.52 STCL-GEN-012 Safety

9.53 STCL-GEN-015 Records Management

9.54 STCL-GEN-018 Quality Control Systems for the STCL

9.55 STCL-QA-006 Stem Cell Laboratory Quality Management Plan

9.56 STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition

9.57 STCL-SOP-030 Label Release

9.58 STCL-SOP-032 Responsibility of Facility Directors

9.59 STCL-SOP-050 Infusion Form

9.60 STCL-TRN-001 Training in the Stem Cell Laboratory

10 REFERENCES

10.1 JCAHO: Accreditation Manual for Hospitals

10.2 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Current Edition

10.3 Duke University Health System Policies

10.4 Duke University IRB Policies

10.5 Pintilie M. Competing Risks: A Practical Perspective. West Sussex, England: John Wiley and Sons, Ltd; 2006.

10.6 Logan BR, Zhang MJ. The use of group sequential designs with common competing risks tests. Stat Med. 2013. 32(6):899-913.

11 REVISION HISTORY

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23	S. McCollum	- Section 8.6.2 Updated to include review timelines for Contracted Agreements.

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