DukeMedicine

Division of Cellular Therapy

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**DOCUMENT TITLE:**

Other Staff

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# ABMT-GEN-011
# SUPPORT STAFF

## 1 PURPOSE

1.1 To provide an outline of support staff and the services provided to the Adult Transplant and Cellular Therapy (ATCT) Program.

## 2 INTRODUCTION

2.1 Adult patients undergoing Hematopoietic Stem Cell Transplantation (HSCT) and/or receiving cellular therapy (CT) require coordinated care provided by an integrated team of all disciplines. Support staff provide essential services to the ongoing complex care of this patient population

## 3 SCOPE AND RESPONSIBILITIES

3.1 All support staff providing care to the PTCT patient are responsible to adhering to the contents of this document.

## 4 DEFINITIONS/ACRONYMS

| | | |
|---|---|---|
| 4.1 | AN | Adult Nutritionist |
| 4.2 | ATCT | Adult Transplant and Cellular |
| 4.3 | CIBMTR | Center for International Blood and Marrow Transplant Research |
| 4.4 | CT | Cellular Therapy |
| 4.5 | DOCR | Duke Office of Clinical Research |
| 4.6 | FSP | Family Support Program |
| 4.7 | HSCT | Hematopoietic Stem Cell Transplantation |
| 4.8 | IND | Investigational New Drug |
| 4.9 | IV | Intravenous |
| 4.10 | IS | Information System |
| 4.11 | IRB | Investigational Review Board |
| 4.12 | LCSW | Licensed Clinical Social Worker |
| 4.13 | OT | Occupational Therapy |
| 4.14 | PT | Physical Therapy |
| 4.15 | SOP | Standardized Operating Procedure |
| 4.16 | TED | Transplant Essential Data |

## 5 MATERIALS

5.1 N/A

## 6 EQUIPMENT

6.1 N/A

## 7 SAFETY

7.1 N/A

## 8 PROCEDURE

8.1 Dietary/Nutrition Staff

8.1.1 There is an Adult Nutritionist (AN) assigned to the program.

8.1.1.1 The AN:

8.1.1.1.1 Provides regular services to patients hospitalized on the Inpatient Unit.

8.1.1.1.2 Participates in rounds with the inpatient care team and also provides outpatient consultations on an as needed basis.

8.1.1.2 Additional services:

8.1.1.2.1 The inpatient unit contains a “galley”, which is stocked with age-appropriate snacks, formulas, high calorie drinks, popsicles, long shelf life food and frozen entrees for patients who prefer to eat outside of mealtimes.

8.1.1.2.2 A “galley” technician is assigned and provides individual food trays and assist with requested patient nourishments.

8.2 Social Services

8.2.1 There are dedicated Licensed Clinical Social Workers (LCSW) assigned in the program.

8.2.1.1 The LCSW:

8.2.1.1.1 Provides psychosocial assessments, diagnosis, treatment, input into discharge planning and consultation regarding patients and their families and caretakers.

8.2.1.1.2 Assist patients and families with coping with hospitalization, illness, diagnosis, treatment and/or life situation, including emotional, mental and substance abuse disorders in patients and parents/caretakers.

8.3 Clinical Research Team

8.3.1 The program has dedicated staff to assist with the Investigational Review Board (IRB) submissions, Investigational New Drugs (IND), protocol development, patient screening, patient education and

consenting, enrollment, protocol compliance, study related procedures, data management and research samples.

8.3.2 The team is comprised of a clinical trials manager, clinical research coordinators and clinical trials assistants.

8.3.2.1 Some of the clinical research coordinator staff are Registered Nurses.

8.3.3 The Clinical Research Team:

8.3.3.1 Ensure, in collaboration with all protocol study team members, protocols are carried out in accordance with institutional polices and applicable law.

8.3.3.2 Participates in a variety of independent activities involved in the collection, analysis, documentation, and interpretation of data related to many protocols.

8.3.3.3 Confer with Principal Investigators regarding data elements needed for protocols and assure all pertinent tests are performed and data is collected for all research studies.

8.3.3.4 Collaborate with the Duke Adult's clinical research unit (CRU) and the Duke Office of Clinical Research (DOCR) during study start up, throughout the course of the study and close out.

8.3.3.5 Collaborate with the CCRU and DOCR to create order sets for the electronic medical record for various studies and for patient related financial reconciliation.

8.4 Programmer

8.4.1 There is a full-time programmer assigned to the program.

8.4.2 The programmer:

8.4.2.1 Identifies and analyzes specific program-related information system (IS) and office automation requirements.

8.4.2.2 Develops, maintains, and modifies IS programs to meet program needs.

8.4.2.3 Responds to data requests and special projects for internal staff and external departments/organizations.

8.4.2.4 Investigates and evaluates new IS technologies to determine appropriateness and usability in the program.

8.5 Pharmacists

8.5.1 There are two dedicated full-time Clinical Pharmacist, one assigned to the inpatient unit and one assigned to the outpatient program.

8.5.2 The Clinical Pharmacist is responsible for:

8.5.2.1 Providing specialized pharmaceutical services to improve drug usage and therapeutic outcomes including, but not

limited to, advising physicians on issues concerning drug therapy, the inherent toxicity of drugs and their side effects, as well as assisting in the prescription of appropriate doses.

8.5.2.2 Mentoring pharmacists in training including, but not limited to, Duke Pharmacy Practice Residents, University of North Carolina, and Campbell University students; activities should include both practical and didactic experiences.

8.5.2.3 Maintaining liaison relationships with medical and nursing staff; provide timely information pertaining to pharmaceutical supplies, drug usage and compatibility, state and federal regulations regarding drug controls, and Joint Commission Standards.

8.5.2.4 Conducting, reconciling, and evaluating medication histories, assessing compliance, and suggesting modifications so as to achieve desired outcomes; instruct patients in the proper use of prescribed drugs and make Patient Care Rounds with physicians to evaluate patient progress.

8.5.2.5 Individualizing medication regimens using sound principles, accounting for pharmacodynamic and pharmacokinetic variations in drug absorption, distribution, metabolism, and elimination with responsibility for establishing and continually improving the delivery of Pharmaceutical Care to patients within areas of direct responsibility and assisting others in the department with the same.

8.5.2.6 Conducting and participating in research including, but not limited to, performing as the primary investigator or co-investigator for research programs which will impact on the delivery of quality care or examine the pharmaco-economic impact of providing care to the patients in the Duke Health System.

8.5.2.7 Participating in development and implementation of guidelines or Standardized Operating Procedures (SOP) related in the pharmaceutical management of transplant recipients

8.6 Education/Training

8.6.1 Requires a Doctor of Pharmacy degree and a North Carolina Pharmacist's License.

8.6.2 Licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure.

8.6.3 Training shall include:

8.6.3.1 An overview of hematology/oncology patient care, including the cellular therapy process.

8.6.3.2 Adverse events including, but not limited to, cytokine release syndrome and neurological toxicities.

8.6.3.3 Therapeutic drug monitoring, including but not limited to, anti-infective agents, immunosuppressive therapy, anti-seizure medications, and anticoagulation.

8.6.3.4 Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.

8.6.3.5 Recognition of medications that require adjustment for organ dysfunction.

8.6.4 Participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.

8.6.5 Continuing education shall include, but is not limited to, activities related to the field of HSCT.

8.7 Physical/Occupation Therapy

8.7.1 There is a Physical and Occupational Therapist available both inpatient and outpatient to evaluate patients and develop exercise and rehabilitation treatment plans.

8.7.2 All allogeneic patients are seen and evaluated by physical therapy and occupational therapy on admission to the inpatient unit.

8.7.3 On the inpatient unit, there is a dedicated patient gym the Physical Therapist may use to assist in these activities.

8.7.4 There is a dedicated space in the outpatient ABMT Clinic where physical therapy and occupational therapy services are performed which include initial consults, follow up therapy and evaluation throughout continuum of care.

8.8 Data Management Staff

8.8.1 Designated data management staff will collect and maintain all necessary data to complete Transplant Essential Data (TED) Forms of the Center for International Blood and Marrow Transplant Research (CIBMTR) or the Minimal Essential DAT-A forms of the EBMT.

8.8.1.1 Data for both allogeneic and autologous transplants will be submitted to a national or international database. For example, the Stem Cell Therapeutics Outcome Database for allogeneic data.

8.8.1.2 Data will be collected for all patients for at least one (1) year following administration of a cellular therapy product

8.8.2 Designated data management staff will collect and submit all data elements included in the appropriate Cellular Immunotherapy Data Resource (CIDR) form(s) of the CIBMTR or the Cellular Therapy Med-A forms of the EBMT. This includes data for non-transplant cellular therapy, such as CAR-T cell products.

8.8.3 Designated data management staff will participate in continuing education annually.

## 9 RELATED DOCUMENTS/FORMS

9.1 N/A

## 10 REFERENCES

10.1 N/A

## 11 REVISION HISTORY

| Revision No. | Author | Description of Change(s) |
|---|---|---|
| 08 | Jennifer Frith | • Title update to remove old scope and reflect support staff<br>• Recently added cellular therapy scope included throughout<br>• Minor wording and formatting updates throughout to improve document flow<br>• Section 1, 2, 3 – scope updated to include cellular therapy<br>• Section 4 – acronyms updated for SOP requirement compliance<br>• Section 8.1 – formatting updated for ease in reading; current scope updated for additional services<br>• Section 8.3.3 regarding conduction of protocols - added to reflect alignment with FACT standards:<br>• Section 8.8 additional data management scope - added to reflect alignment with current FACT standards. |

## Signature Manifest

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