STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-SOP-032

DOCUMENT TITLE:

Responsibility of Facility Directors

DOCUMENT NOTES:

Document Information

Revision: 05	**Vault:** STCL-Processing-rel
Status: Release	**Document Type:** SOPs

Date Information

Creation Date: 10 Apr 2013	**Release Date:** 02 May 2013
Effective Date: 02 May 2013	**Expiration Date:**

Control Information

Author: WATE02	**Owner:** WATE02
Previous Number: STCL-SOP-032 Rev 04	**Change Number:** QSU-CCR-090

STCL-SOP-032
RESPONSIBILITY OF FACILITY DIRECTORS

1 PURPOSE

1.1 To define the responsibilities of the Medical Directors of the Adult Blood and Marrow Transplant Program and the Pediatric Blood and Marrow Transplant Program and their involvement with the Stem Cell Collection and Processing Facility at Duke University Medical Center.

2 INTRODUCTION

2.1 The Adult and Pediatric Collection and Processing Facility Directors are responsible for the quality management and supervision of the Stem Cell Collection Facility and Stem Cell Laboratory.

3 SCOPE AND RESPONSIBILITIES

3.1 The Collection and Processing Facility Directors are responsible for all technical procedures and administrative operations of the Collection Facility and processing operations in the Stem Cell Laboratory at Duke University Medical Center.

4 DEFINITIONS/ACRONYMS

4.1	FACT	Foundation for the Accreditation of Cellular Therapy
4.2	CRF	Code of Federal Register
4.3	SOP	Standard Operating Procedure
4.4	QM	Quality Management
4.5	CLIA	Clinical Laboratory Improvement Amendments of 1988
4.6	CAP	College of American Pathologists
4.7	HHS	Health and Human Services
4.8	N/A	Not Applicable

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Responsibilities – Adult Blood & Marrow Transplant Program Collection and Processing Director

8.1.1 **COLLECTION**: The Adult Blood and Marrow Transplant Director or designee is responsible for all adult patients/donors

8.1.1.1 Pre-collection evaluation of the prospective donor at the time of donation

8.1.1.2 Performance of the collection procedure

8.1.1.3 Supervision of the staff for the procedure

8.1.1.4 Care of any complications resulting from the collection procedure

8.1.1.5 Participates regularly in educational activities related to cellular therapy products collection and /or transplantation

8.1.1.6 Assuring compliance with FACT collection standards, quality management plan and applicable laws and 21 CFR 1271 regulations

8.1.1.7 The Collection Facility Director is responsible for all administrative and technical aspects of the Collection Facility. This includes development and implementation of all SOPs, training of personnel, design and execution of validation studies and audits, development of and compliance with the QM Program, maintenance of all equipment, data analysis, reporting, and compliance of the Collection Facility with these Standards and applicable law.

8.1.2 **PROCESSING**: The Adult Blood and Marrow Transplant Director or designee is responsible for all cellular products

8.1.2.1 Written orders outlining the procedures used to process all cellular products

8.1.2.2 Written orders outlining the procedures used to thaw all cellular products

8.1.2.3 Evaluation of all cellular products post processing and pre-infusion

8.1.2.4 Written orders outlining how to handle "Non-Conforming" cellular products

8.1.2.5 Assuring compliance with FACT collection standards, quality management plan and applicable laws and 21 CFR 1271 regulations

8.1.3 **GENERAL LABORATORY**: The Adult Blood and Marrow Transplant Director or designee is responsible for all aspects of the clinical laboratory. Some of these responsibilities have been assigned to

the Laboratory Manager including CLIA 493.1445 (493.1455(e)(3), 493-1445(e)(4), 493-1445(e)(5), 493-1445(e)(6), 493.1445(e)(7), 493.1445(e)(12), 493.1445(3)(13), 493.1445(e)(14)), 493.1451, and 493.1463.

8.1.3.1 Ensuring that the laboratory is enrolled in an HHS-approved proficiency testing program

8.1.3.2 Ensuring that quality control and quality assurance program are established and maintained to assure the quality of laboratory services provided to identify failures in quality, as they occur

8.1.3.3 Ensuring that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly

8.1.3.4 Ensuring that all laboratory personnel have the appropriate education, experience, training, and competency assessments to perform test procedures

8.1.3.5 Ensuring that all approved procedure manuals are available to all personnel responsible for any aspects of the testing process

8.1.3.6 Assuring compliance with all College of American Pathologists (CAP) laboratory standards

8.1.3.7 The Adult Collection and Processing Facility Director is responsible for the Quality Management Plan for the Adult Collection Unit and Processing Laboratory. The Adult Collection and Processing Facility Director or designee chairs the monthly Quality Review Committee and reviews and reports adult collection and processing audit results. The Adult Collection and Processing Facility Director reviews and revises Adult Collection and Processing Laboratory policies and procedures on a regular basis. The Adult Stem Cell Transplant Collection and Processing Director is responsible for ensuring quality control and following FACT standards for stem cell collection and laboratory processing. Deviations for Standard Operating Procedures are reviewed, documented, and approved, if indicated, by the Adult Collection and Processing Facility Director or designee.

8.1.4 Responsibilities – Pediatric Blood & Marrow Transplant Program Collection and Processing Director

8.1.5 **COLLECTION:** The Pediatric Blood and Marrow Transplant Director or designee is responsible for all pediatric patients/donors

8.1.5.1 Pre-collection evaluation of the prospective donor at the time of donation

8.1.5.2 Performance of the collection procedure

8.1.5.3 Supervision of the assistants for the procedure

8.1.5.4 Care of any complications resulting from the collection procedure

8.1.5.5 Assuring compliance with FACT collection standards, quality management plan and applicable laws and 21 CFR 1271 regulations

8.1.6 **PROCESSING** The Pediatric Blood and Marrow Transplant Director or designee is responsible for all cellular products

8.1.6.1 Written orders outlining the procedures used to process all cellular products

8.1.6.2 Written orders outlining the procedures used to thaw all cellular products

8.1.6.3 Evaluation of all cellular products post processing and pre-infusion

8.1.6.4 Written orders outlining how to handle "Non-Conforming" cellular products

8.1.6.5 Assuring compliance with FACT collection standards and applicable laws and 21 CFR 1271 regulations

8.1.7 **GENERAL LABORATORY** The Pediatric Blood and Marrow Transplant Director or designee is responsible for all aspects of the clinical laboratory. Some of these responsibilities have been assigned to the Laboratory Manager including CLIA 493.1445 (493.1455(e)(3), 493-1445(e)(4), 493-1445(e)(5), 493-1445(e)(6), 493.1445(e)(7), 493.1445(e)(12), 493.1445(3)(13), 493.1445(e)(14)), 493.1451, and 493.1463.

8.1.7.1 Ensuring that the laboratory is enrolled in an HHS-approved proficiency testing program

8.1.7.2 Ensuring that quality control and quality assurance program are established and maintained to assure the quality of laboratory services provided to identify failures in quality, as they occur

8.1.7.3 Ensuring that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly

8.1.7.4 Ensuring that all laboratory personnel have the appropriate education, experience, training, and competency assessments to perform test procedures

8.1.7.5 Ensuring that all approved procedure manuals are available to all personnel responsible for any aspects of the testing process

8.1.7.6 Assuring compliance with all College of American Pathologists (CAP) laboratory standards

8.1.7.7 The Pediatric Collection and Processing Facility Director are responsible for the Quality Management Plan for the Pediatric Collection Unit and processing laboratory. The Pediatric Collection and Processing Facility Director sends pediatric collection and processing data to the monthly Quality Review Committee and reviews and reports pediatric collection and processing audit results. The Pediatric Collection and Processing Facility Director reviews and revises Pediatric Collection and Processing Laboratory policies and procedures on a regular basis. The Pediatric Stem Cell Transplant Collection and Processing Director is responsible for ensuring quality control and following FACT standards for stem cell collection and laboratory processing. Deviations from Standard Operating Procedures are reviewed, documented and approved if indicated by the Pediatric Collection Facility Director or designee.

8.1.8 **Coverage:** The Adult & Pediatric Blood and Marrow Transplant Program Collection Facility and Processing directors cover for each other when they are absent from the collection or processing sites.

9 RELATED DOCUMENTS/FORMS

9.1 NA

10 REFERENCES

10.1 Foundation for Accreditation of Cellular Therapy Standards – Current Edition. Memo from Salvatore V. Pizzo MD PhD Director, Clinical Laboratories, Chairman, Department of Pathology Dated June 17, 2002

10.3 Memo from Dr. Joanne Kurtzberg, MD, Assignment of Technical Supervisor / Manager Responsibilities (CLIA 493.1445, 493.1451, and 493.1463) by the Director of the STCL dated 12/16/2010.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
05	B. Waters-Pick	Section 11 added.

Signature Manifest

Document Number: STCL-SOP-032 **Revision:** 05
Title: Responsibility of Facility Directors

All dates and times are in Eastern Time.

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Author Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		24 Apr 2013, 10:49:04 AM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		24 Apr 2013, 10:49:32 AM	Approved

Medical Director Approval

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Joanne Kurtzberg (KURTZ001)		24 Apr 2013, 07:23:00 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		25 Apr 2013, 08:09:47 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		29 Apr 2013, 12:27:08 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Sharon Hartis (SH259)		29 Apr 2013, 12:27:09 PM	Email Sent

Review: STCL-SOP-032 05

Review

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		02 Mar 2015, 07:12:57 PM	Reviewed
Betsy Jordan (BJ42)		03 Mar 2015, 08:29:00 AM	Reviewed
Joanne Kurtzberg (KURTZ001)		03 Mar 2015, 02:24:42 PM	Reviewed
Sharon Hartis (SH259)		04 Mar 2015, 09:09:13 AM	Reviewed
John Carpenter (JPC27)		15 Apr 2015, 09:53:29 AM	Reviewed