



## STEM CELL LABORATORY (STCL)



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Stem Cell Laboratory Personnel

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**Author:** WATE02

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## **STCL-SOP-033**

### **STEM CELL LABORATORY PERSONNEL**

#### **1 PURPOSE**

- 1.1 The purpose of this procedure is to list and describe the personnel responsible for the medical oversight, quality oversight, and the technical oversight provided to and by the Stem Cell Laboratory.

#### **2 INTRODUCTION**

- 2.1 N/A

#### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 N/A

#### **4 DEFINITIONS/ACROYNMS**

- |      |      |   |
|------|------|---|
| 4.1  | FDA  | Food and Drug Administration  |
| 4.2  | FACT | Foundation for the Accreditation of Cellular Therapy  |
| 4.3  | CME  | Continuing Medical Education  |
| 4.4  | ABMT | Adult Bone Marrow Transplant  |
| 4.5  | PBMT | Pediatric Bone Marrow Transplant  |
| 4.6  | STCL | Stem Cell Laboratory  |
| 4.7  | CAP  | College of American Pathologists  |
| 4.8  | QSU  | Quality Service Unit  |
| 4.9  | N/A  | Not Applicable  |
| 4.10 | FTE  | Full Time Employee  |
| 4.11 | PRN  | Employee paid on an "as needed basis" at an hourly rate, not eligible for benefits, or accrual of paid time off. PRN status is reserved for mission-critical contingency staffing for positions that are categorized as high demand/low supply. |

#### **5 MATERIALS**

- 5.1 N/A

#### **6 EQUIPMENT**

- 6.1 N/A

#### **7 SAFETY**

- 7.1 N/A

#### **8 STEM CELL LABORATORY PERSONNEL**

- 8.1 Dr. Joanne Kurtzberg, MD serves as Stem Cell Laboratory's Medical Director and the Medical Director of the Pediatric Blood and Marrow Transplant Program (PBMT Program). Dr. Kurtzberg, in collaboration with Dr. Nelson Chao, MD, the Medical Director of the Adult Blood and Marrow Transplant

Program (ABMT Program), along with one of their attending physicians, Dr. Gwynn Long, MD, make decisions on behalf of the patients and donors followed by the ABMT Program.

- 8.2 Dr. Kurtzberg and Dr. Chao both have a MD degree and are board certified in their respective disciplines and subspecialties. Dr. Kurtzberg assumes responsibility for the laboratory activities related to pediatric patients.
- 8.3 Dr. Chao and Dr. Long assume responsibility for the activities related to the adult patients, in consultation with Dr. Kurtzberg when deemed necessary.
- 8.4 Dr. Kurtzberg assumes the responsibility for the overall general laboratory activities including compliance with federal and state regulations, clinical research studies, and FDA, CAP, and FACT regulations. Drs. Kurtzberg, Chao, and Long participate in regular CME activities and national and international scientific meetings, serve on study sections; grant review committees, and scientific advisory boards.
- 8.5 The Stem Cell Laboratory (STCL) financially supports of one full-time employee in Quality Service Unit (QSU) which establishes, maintains, modifies, and reviews all systems and procedures to help ensure that the laboratory meets and is in compliance with FACT, CAP, and all other state and federal regulatory requirements, as deemed appropriate.
- 8.6 The STCL also contributes in the financial support of the document management system, MasterControl, also under the jurisdiction of the QSU. MasterControl provides a mechanism to create, route, and control all document control tasks in accordance with FDA 21 CFR Part 11 regulations.
- 8.7 The STCL currently employs the following employees; collectively, this staff is responsible for performing the technical and clerical workload in the laboratory. All of these individuals are properly trained, maintain task-specific competencies, and participate in annual continuing educational activities (based on the number of hours they work). Training, competencies, certifications, educational backgrounds, etc, are filed in the employee's respective training and personnel folders.
  - 8.7.1 1 Laboratory Manager (FTE)
  - 8.7.2 1 Medical Laboratory Scientist, Specialist (FTE)
  - 8.7.3 4 Medical Laboratory Scientist, Advanced (3 FTE, 1 vacancy)
  - 8.7.4 7 Medical Laboratory Scientist (6 FTE, 1 PRN)
  - 8.7.5 1 Lab Research Analyst II (FTE)
  - 8.7.6 1 Administrative Assistant I (FTE)
  - 8.7.7 1 Administrative Clerk (*vacant*)
- 8.8 The QSU Director establishes and maintains the QMP and ensures that the quality objectives are clearly defined and achieved. The QSU coordinates, facilitates, and monitors defined QA activities for the STCL and ensures that the quality of products and services meet applicable regulatory and accreditation requirements. QA functions provided by the QSU are distinct and separate from manufacturing and other technical operations. The Quality Systems Unit (QSU) has ultimate responsibility for maintaining the quality of the program by providing oversight related to the processing, cryopreservation, storage, and distribution of the products prepared in the

STCL. The QSU reports directly to DTRI Executive Management. The QSU Director provides summary reports to the Program/Medical Directors reflecting the performance of the QMP on a quarterly basis and annually to Adult and Pediatric Blood and Marrow Transplant QA committees.

- 8.9 The current organizational chart, outlining the responsibilities of the STCL employees, can be found in *OC-007 STCL Organizational Chart*. In order to stay current with any staffing changes, the organizational chart is reviewed at least 3 – 4 times per year so it can be updated as needed.

## 9 RELATED DOCUMENTS / FORMS

- 9.1 OC-007 STCL Organizational Chart

## 10 REFERENCES

- 10.1 N/A

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	B. Waters-Pick	Section 8.5 – Changed to reflect STCL’s financial support of 1 FTE in Quality Service Unit (QSU) Section 8.7 – Modified section to reflect current information Section 8.9 – Removed STCL organizational chart from this document and provided reference to OC-007 STCL Organizational Chart Section 9.1 – Added reference to OC-007 Organizational Chart.

**Signature Manifest****Document Number:** STCL-SOP-033**Revision:** 07**Title:** Stem Cell Laboratory Personnel

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**STCL-SOP-033 Stem Cell Laboratory Personnel****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		15 Feb 2019, 07:50:54 PM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		15 Feb 2019, 07:51:09 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		18 Feb 2019, 09:54:32 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)			
Lisa Eddinger (LE42)			
Taylor Orr (TSO4)			
Richard Bryant (RB232)		19 Feb 2019, 07:24:20 AM	Approved

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Sandy Mulligan (MULLI026)		12 Apr 2019, 03:43:58 PM	Approved