# InfoCard

## STEM CELL LABORATORY (STCL)

### DOCUMENT NUMBER: STCL-SOP-033

### DOCUMENT TITLE:
Stem Cell Laboratory Personnel

### DOCUMENT NOTES:

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**Document Information**

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- Document Type: SOPs

**Date Information**

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- Author: WATE02
- Owner: WATE02
- Previous Number: STCL-SOP-033 Rev 06
- Change Number: STCL-CCR-435

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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. Dr. Long, Chao, and Kurtzberg participate in regular CME activities and national and international scientific meetings, serve on study sections; grant review committees, and scientific advisory boards.

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 to 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 Administarte Assistant I (FTE)
8.7.7 1 Administarte 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

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<tr>
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<th>Author</th>
<th>Description of Change(s)</th>
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<tr>
<td>07</td>
<td>B. Waters-Pick</td>
<td>Section 8.5 – Changed to reflect STCL’s financial support of 1 FTE in Quality Service Unit (QSU)</td>
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<td>Section 8.7 – Modified section to reflect current information</td>
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<td>Section 8.9 – Removed STCL organizational chart from this document and provided reference to OC-007 STCL Organizational Chart</td>
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<td>Section 9.1 – Added reference to OC-007 Organizational Chart.</td>
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## Signature Manifest

### STCL-SOP-033 Stem Cell Laboratory Personnel

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### Management

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